Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tisagenlecleucel (Kymriah®)

Novartis Pharma GmbH

Modul 4 A - Separater Anhang 4-H.1 (Teil 2)

Refraktäre oder rezidivierte pädiatrische akute lymphatische B-Zell-Leukämie

Studie CCTL019B2202 (ELIANA)

Stand: 31.08.2023

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Table 221a

Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age

Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (32.4)	0	11 (32.4)
Blood and lymphatic system disorders			
-Total	3 (8.8)	3 (8.8)	0
Anaemia	3 (8.8)	3 (8.8)	0
Investigations			
-Total	11 (32.4)	0	11 (32.4)
White blood cell count decreased	6 (17.6)	1 (2.9)	5 (14.7)
Lymphocyte count decreased	5 (14.7)	0	5 (14.7)
Platelet count decreased	5 (14.7)	1 (2.9)	4 (11.8)
Neutrophil count decreased	4 (11.8)	1 (2.9)	3 (8.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221a
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (25.8)	3 (9.7)	5 (16.1)
Blood and lymphatic system disorders			
-Total	3 (9.7)	3 (9.7)	0
Anaemia	3 (9.7)	3 (9.7)	0
Febrile neutropenia	2 (6.5)	2 (6.5)	0
Investigations			
-Total	5 (16.1)	1 (3.2)	4 (12.9)
White blood cell count decreased	4 (12.9)	1 (3.2)	3 (9.7)
Neutrophil count decreased	2 (6.5)	0	2 (6.5)
Lymphocyte count decreased	1 (3.2)	0	1 (3.2)
Platelet count decreased	1 (3.2)	0	1 (3.2)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	3 (9.7)	2 (6.5)	1 (3.2)
Hypokalaemia	3 (9.7)	2 (6.5)	1 (3.2)

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Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (23.1)	2 (15.4)	1 (7.7)
Blood and lymphatic system disorders			
-Total	2 (15.4)	2 (15.4)	0
Febrile neutropenia	2 (15.4)	2 (15.4)	0
Infections and infestations			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Bacteraemia	1 (7.7)	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	1 (7.7)
Oral herpes	1 (7.7)	1 (7.7)	0
Staphylococcal bacteraemia	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			

Age: >=18

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (7.7)	1 (7.7)	0
Hypocalcaemia	1 (7.7)	1 (7.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.7)	1 (7.7)	0
Pain in jaw	1 (7.7)	1 (7.7)	0

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Table 221b
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (21.7)	1 (2.2)	9 (19.6)
Blood and lymphatic system disorders			
-Total	5 (10.9)	5 (10.9)	0
Anaemia	5 (10.9)	5 (10.9)	0
Febrile neutropenia	1 (2.2)	1 (2.2)	0
Investigations			
-Total	9 (19.6)	0	9 (19.6)
White blood cell count decreased	5 (10.9)	1 (2.2)	4 (8.7)
Lymphocyte count decreased	4 (8.7)	0	4 (8.7)
Platelet count decreased	4 (8.7)	1 (2.2)	3 (6.5)
Neutrophil count decreased	3 (6.5)	0	3 (6.5)

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Table 221b
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (28.1)	3 (9.4)	6 (18.8)
Blood and lymphatic system disorders			
-Total	3 (9.4)	3 (9.4)	0
Febrile neutropenia	3 (9.4)	3 (9.4)	0
Anaemia	1 (3.1)	1 (3.1)	0
Investigations			
-Total	7 (21.9)	1 (3.1)	6 (18.8)
White blood cell count decreased	5 (15.6)	1 (3.1)	4 (12.5)
Neutrophil count decreased	3 (9.4)	1 (3.1)	2 (6.3)
Lymphocyte count decreased	2 (6.3)	0	2 (6.3)
Platelet count decreased	2 (6.3)	0	2 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
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Table 221c
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (28.1)	4 (7.0)	12 (21.1)
Blood and lymphatic system disorders			
-Total	6 (10.5)	6 (10.5)	0
Anaemia	5 (8.8)	5 (8.8)	0
Febrile neutropenia	2 (3.5)	2 (3.5)	0
Investigations			
-Total	12 (21.1)	1 (1.8)	11 (19.3)
White blood cell count decreased	8 (14.0)	2 (3.5)	6 (10.5)
Neutrophil count decreased	5 (8.8)	1 (1.8)	4 (7.0)
Lymphocyte count decreased	4 (7.0)	0	4 (7.0)
Platelet count decreased	4 (7.0)	1 (1.8)	3 (5.3)

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Hypokalaemia	2 (3.5)	1 (1.8)	1 (1.8)

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Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0
Investigations			
-Total	1 (10.0)	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	1 (10.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders			
-Total	2 (18.2)	2 (18.2)	0
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Anaemia	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	1 (9.1)	1 (9.1)	0
Generalised oedema	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	3 (27.3)	1 (9.1)	2 (18.2)

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (9.1)	0	1 (9.1)
Fungaemia	1 (9.1)	0	1 (9.1)
Oral herpes	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Lymphocyte count decreased	2 (18.2)	0	2 (18.2)
Platelet count decreased	2 (18.2)	0	2 (18.2)
White blood cell count decreased	2 (18.2)	0	2 (18.2)
Neutrophil count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	2 (18.2)	2 (18.2)	0
Hypocalcaemia	1 (9.1)	1 (9.1)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	1 (9.1)	0

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in jaw	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Epistaxis	1 (9.1)	1 (9.1)	0
Pulmonary haemorrhage	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 221d
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	3 (21.4)	5 (35.7)
Blood and lymphatic system disorders			
-Total	3 (21.4)	3 (21.4)	0
Anaemia	2 (14.3)	2 (14.3)	0
Febrile neutropenia	2 (14.3)	2 (14.3)	0
Infections and infestations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Escherichia bacteraemia	1 (7.1)	0	1 (7.1)
Oral herpes	1 (7.1)	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	1 (7.1)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (35.7)	1 (7.1)	4 (28.6)
White blood cell count decreased	3 (21.4)	1 (7.1)	2 (14.3)
Neutrophil count decreased	2 (14.3)	0	2 (14.3)
Platelet count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Lymphocyte count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	2 (14.3)	2 (14.3)	0
Hypocalcaemia	1 (7.1)	1 (7.1)	0
Hypokalaemia	1 (7.1)	1 (7.1)	0
Hypophosphataemia	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Pain in jaw	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	1 (7.1)	1 (7.1)	0
Hypotension	1 (7.1)	1 (7.1)	0

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Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (23.4)	3 (4.7)	12 (18.8)
Blood and lymphatic system disorders			
-Total	5 (7.8)	5 (7.8)	0
Anaemia	4 (6.3)	4 (6.3)	0
Febrile neutropenia	2 (3.1)	2 (3.1)	0
Investigations			
-Total	11 (17.2)	0	11 (17.2)
White blood cell count decreased	7 (10.9)	1 (1.6)	6 (9.4)
Lymphocyte count decreased	5 (7.8)	0	5 (7.8)
Neutrophil count decreased	4 (6.3)	1 (1.6)	3 (4.7)
Platelet count decreased	4 (6.3)	0	4 (6.3)

Ethnicity: Other

Group term Preferred term	All patients N=64 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	2 (3.1)	1 (1.6)	1 (1.6)
Hypokalaemia	2 (3.1)	1 (1.6)	1 (1.6)

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Table 221e
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (33.3)	2 (33.3)	0
Infections and infestations			
-Total	1 (16.7)	1 (16.7)	0
Vulval cellulitis	1 (16.7)	1 (16.7)	0
Investigations			
-Total	1 (16.7)	1 (16.7)	0
White blood cell count decreased	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	1 (16.7)	1 (16.7)	0
Irritability	1 (16.7)	1 (16.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (25.0)	3 (4.2)	15 (20.8)
Blood and lymphatic system disorders			
-Total	8 (11.1)	8 (11.1)	0
Anaemia	6 (8.3)	6 (8.3)	0
Febrile neutropenia	4 (5.6)	4 (5.6)	0
Investigations			
-Total	15 (20.8)	0	15 (20.8)
White blood cell count decreased	9 (12.5)	1 (1.4)	8 (11.1)
Lymphocyte count decreased	6 (8.3)	0	6 (8.3)
Neutrophil count decreased	6 (8.3)	1 (1.4)	5 (6.9)
Platelet count decreased	6 (8.3)	1 (1.4)	5 (6.9)

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Table 221f

Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	1 (100)	0
Hypogammaglobulinaemia	1 (100)	1 (100)	0

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Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (24.7)	4 (5.2)	15 (19.5)
Blood and lymphatic system disorders			
-Total	8 (10.4)	8 (10.4)	0
Anaemia	6 (7.8)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	4 (5.2)	0
Investigations			
-Total	16 (20.8)	1 (1.3)	15 (19.5)
White blood cell count decreased	10 (13.0)	2 (2.6)	8 (10.4)
Lymphocyte count decreased	6 (7.8)	0	6 (7.8)
Neutrophil count decreased	6 (7.8)	1 (1.3)	5 (6.5)
Platelet count decreased	6 (7.8)	1 (1.3)	5 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221g
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (24.7)	4 (5.2)	15 (19.5)
Blood and lymphatic system disorders			
-Total	8 (10.4)	8 (10.4)	0
Anaemia	6 (7.8)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	4 (5.2)	0
Investigations			
-Total	16 (20.8)	1 (1.3)	15 (19.5)
White blood cell count decreased	10 (13.0)	2 (2.6)	8 (10.4)
Lymphocyte count decreased	6 (7.8)	0	6 (7.8)
Neutrophil count decreased	6 (7.8)	1 (1.3)	5 (6.5)
Platelet count decreased	6 (7.8)	1 (1.3)	5 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 221h
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Lymphocyte count decreased	1 (100)	0	1 (100)
Neutrophil count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221h
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (23.4)	4 (5.2)	14 (18.2)
Blood and lymphatic system disorders			
-Total	8 (10.4)	8 (10.4)	0
Anaemia	6 (7.8)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	4 (5.2)	0
Investigations			
-Total	15 (19.5)	1 (1.3)	14 (18.2)
White blood cell count decreased	9 (11.7)	2 (2.6)	7 (9.1)
Platelet count decreased	6 (7.8)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	5 (6.5)	0	5 (6.5)
Neutrophil count decreased	5 (6.5)	0	5 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221i
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (24.7)	4 (5.2)	15 (19.5)
Blood and lymphatic system disorders			
-Total	8 (10.4)	8 (10.4)	0
Anaemia	6 (7.8)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	4 (5.2)	0
Investigations			
-Total	16 (20.8)	1 (1.3)	15 (19.5)
White blood cell count decreased	10 (13.0)	2 (2.6)	8 (10.4)
Lymphocyte count decreased	6 (7.8)	0	6 (7.8)
Neutrophil count decreased	6 (7.8)	1 (1.3)	5 (6.5)
Platelet count decreased	6 (7.8)	1 (1.3)	5 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221j
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (11.1)	2 (7.4)	1 (3.7)
Blood and lymphatic system disorders			
-Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Anaemia	1 (3.7)	1 (3.7)	0
Investigations			
-Total	1 (3.7)	0	1 (3.7)
Neutrophil count decreased	1 (3.7)	0	1 (3.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221j
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (31.4)	2 (3.9)	14 (27.5)
Blood and lymphatic system disorders			
-Total	6 (11.8)	6 (11.8)	0
Anaemia	5 (9.8)	5 (9.8)	0
Febrile neutropenia	2 (3.9)	2 (3.9)	0
Investigations			
-Total	15 (29.4)	1 (2.0)	14 (27.5)
White blood cell count decreased	10 (19.6)	2 (3.9)	8 (15.7)
Lymphocyte count decreased	6 (11.8)	0	6 (11.8)
Platelet count decreased	6 (11.8)	1 (2.0)	5 (9.8)
Neutrophil count decreased	5 (9.8)	1 (2.0)	4 (7.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221k
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (40.7)	3 (11.1)	8 (29.6)
Blood and lymphatic system disorders			
-Total	4 (14.8)	4 (14.8)	0
Anaemia	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Investigations			
-Total	7 (25.9)	0	7 (25.9)
Lymphocyte count decreased	5 (18.5)	0	5 (18.5)
White blood cell count decreased	4 (14.8)	1 (3.7)	3 (11.1)
Neutrophil count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Platelet count decreased	2 (7.4)	0	2 (7.4)

Region: Europe

Group term Preferred term	All patients N=27 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Hypokalaemia	2 (7.4)	1 (3.7)	1 (3.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221k
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (22.7)	2 (4.5)	8 (18.2)
Blood and lymphatic system disorders			
-Total	4 (9.1)	4 (9.1)	0
Anaemia	4 (9.1)	4 (9.1)	0
Febrile neutropenia	2 (4.5)	2 (4.5)	0
Investigations			
-Total	9 (20.5)	1 (2.3)	8 (18.2)
White blood cell count decreased	6 (13.6)	1 (2.3)	5 (11.4)
Neutrophil count decreased	4 (9.1)	0	4 (9.1)
Platelet count decreased	4 (9.1)	1 (2.3)	3 (6.8)
Lymphocyte count decreased	1 (2.3)	0	1 (2.3)

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	1 (2.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221l
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (26.1)	2 (4.3)	10 (21.7)
Blood and lymphatic system disorders			
-Total	5 (10.9)	5 (10.9)	0
Anaemia	3 (6.5)	3 (6.5)	0
Febrile neutropenia	2 (4.3)	2 (4.3)	0
Investigations			
-Total	10 (21.7)	0	10 (21.7)
White blood cell count decreased	8 (17.4)	1 (2.2)	7 (15.2)
Neutrophil count decreased	5 (10.9)	1 (2.2)	4 (8.7)
Lymphocyte count decreased	4 (8.7)	0	4 (8.7)
Platelet count decreased	4 (8.7)	1 (2.2)	3 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221l
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (21.9)	2 (6.3)	5 (15.6)
Blood and lymphatic system disorders			
-Total	3 (9.4)	3 (9.4)	0
Anaemia	3 (9.4)	3 (9.4)	0
Febrile neutropenia	2 (6.3)	2 (6.3)	0
Investigations			
-Total	6 (18.8)	1 (3.1)	5 (15.6)
Lymphocyte count decreased	2 (6.3)	0	2 (6.3)
Platelet count decreased	2 (6.3)	0	2 (6.3)
White blood cell count decreased	2 (6.3)	1 (3.1)	1 (3.1)
Neutrophil count decreased	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221m
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (29.2)	4 (6.2)	15 (23.1)
Blood and lymphatic system disorders			
-Total	8 (12.3)	8 (12.3)	0
Anaemia	6 (9.2)	6 (9.2)	0
Febrile neutropenia	4 (6.2)	4 (6.2)	0
Investigations			
-Total	16 (24.6)	1 (1.5)	15 (23.1)
White blood cell count decreased	10 (15.4)	2 (3.1)	8 (12.3)
Lymphocyte count decreased	6 (9.2)	0	6 (9.2)
Neutrophil count decreased	6 (9.2)	1 (1.5)	5 (7.7)
Platelet count decreased	6 (9.2)	1 (1.5)	5 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221n
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (24.0)	1 (4.0)	5 (20.0)
Blood and lymphatic system disorders			
-Total	3 (12.0)	3 (12.0)	0
Anaemia	3 (12.0)	3 (12.0)	0
Febrile neutropenia	2 (8.0)	2 (8.0)	0
Investigations			
-Total	5 (20.0)	0	5 (20.0)
Lymphocyte count decreased	2 (8.0)	0	2 (8.0)
Neutrophil count decreased	2 (8.0)	0	2 (8.0)
Platelet count decreased	2 (8.0)	1 (4.0)	1 (4.0)
White blood cell count decreased	2 (8.0)	0	2 (8.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221n
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (24.5)	3 (5.7)	10 (18.9)
Blood and lymphatic system disorders			
-Total	5 (9.4)	5 (9.4)	0
Anaemia	3 (5.7)	3 (5.7)	0
Febrile neutropenia	2 (3.8)	2 (3.8)	0
Investigations			
-Total	11 (20.8)	1 (1.9)	10 (18.9)
White blood cell count decreased	8 (15.1)	2 (3.8)	6 (11.3)
Lymphocyte count decreased	4 (7.5)	0	4 (7.5)
Neutrophil count decreased	4 (7.5)	1 (1.9)	3 (5.7)
Platelet count decreased	4 (7.5)	0	4 (7.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221o
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	1 (9.1)	2 (18.2)
Blood and lymphatic system disorders			
-Total	1 (9.1)	0	1 (9.1)
Leukopenia	1 (9.1)	0	1 (9.1)
Immune system disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypogammaglobulinaemia	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221o
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (26.9)	4 (6.0)	14 (20.9)
Blood and lymphatic system disorders			
-Total	8 (11.9)	8 (11.9)	0
Anaemia	6 (9.0)	6 (9.0)	0
Febrile neutropenia	4 (6.0)	4 (6.0)	0
Investigations			
-Total	15 (22.4)	1 (1.5)	14 (20.9)
White blood cell count decreased	9 (13.4)	2 (3.0)	7 (10.4)
Lymphocyte count decreased	6 (9.0)	0	6 (9.0)
Neutrophil count decreased	6 (9.0)	1 (1.5)	5 (7.5)
Platelet count decreased	6 (9.0)	1 (1.5)	5 (7.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221p
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	0	3 (50.0)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0
Investigations			
-Total	3 (50.0)	0	3 (50.0)
Platelet count decreased	2 (33.3)	0	2 (33.3)
Lymphocyte count decreased	1 (16.7)	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221p
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (22.2)	4 (5.6)	12 (16.7)
Blood and lymphatic system disorders			
-Total	7 (9.7)	7 (9.7)	0
Anaemia	5 (6.9)	5 (6.9)	0
Febrile neutropenia	4 (5.6)	4 (5.6)	0
Investigations			
-Total	13 (18.1)	1 (1.4)	12 (16.7)
White blood cell count decreased	9 (12.5)	2 (2.8)	7 (9.7)
Lymphocyte count decreased	5 (6.9)	0	5 (6.9)
Neutrophil count decreased	5 (6.9)	1 (1.4)	4 (5.6)
Platelet count decreased	4 (5.6)	1 (1.4)	3 (4.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221q

Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (36.8)	3 (7.9)	11 (28.9)
Blood and lymphatic system disorders			
-Total	5 (13.2)	5 (13.2)	0
Anaemia	3 (7.9)	3 (7.9)	0
Febrile neutropenia	2 (5.3)	2 (5.3)	0
Investigations			
-Total	11 (28.9)	1 (2.6)	10 (26.3)
White blood cell count decreased	8 (21.1)	2 (5.3)	6 (15.8)
Lymphocyte count decreased	5 (13.2)	0	5 (13.2)
Platelet count decreased	4 (10.5)	0	4 (10.5)
Neutrophil count decreased	3 (7.9)	1 (2.6)	2 (5.3)
Metabolism and nutrition disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.6)	0	1 (2.6)
Hypokalaemia	1 (2.6)	0	1 (2.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221q
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (17.9)	2 (5.1)	5 (12.8)
Blood and lymphatic system disorders			
-Total	3 (7.7)	3 (7.7)	0
Anaemia	3 (7.7)	3 (7.7)	0
Febrile neutropenia	2 (5.1)	2 (5.1)	0
Investigations			
-Total	5 (12.8)	0	5 (12.8)
Neutrophil count decreased	3 (7.7)	0	3 (7.7)
Platelet count decreased	2 (5.1)	1 (2.6)	1 (2.6)
White blood cell count decreased	2 (5.1)	0	2 (5.1)
Lymphocyte count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=39 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	2 (5.1)	2 (5.1)	0
Hypokalaemia	2 (5.1)	2 (5.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221q
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Generalised oedema	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Fungaemia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Pulmonary haemorrhage	1 (100)	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (33.3)	2 (33.3)	0
Infections and infestations			
-Total	1 (16.7)	1 (16.7)	0
Vulval cellulitis	1 (16.7)	1 (16.7)	0
Investigations			
-Total	1 (16.7)	1 (16.7)	0
White blood cell count decreased	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	1 (16.7)	1 (16.7)	0
Irritability	1 (16.7)	1 (16.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (31.8)	1 (4.5)	6 (27.3)
Blood and lymphatic system disorders			
-Total	3 (13.6)	3 (13.6)	0
Anaemia	3 (13.6)	3 (13.6)	0
Febrile neutropenia	2 (9.1)	2 (9.1)	0
Investigations			
-Total	6 (27.3)	0	6 (27.3)
Lymphocyte count decreased	3 (13.6)	0	3 (13.6)
Neutrophil count decreased	2 (9.1)	1 (4.5)	1 (4.5)
Platelet count decreased	2 (9.1)	0	2 (9.1)
White blood cell count decreased	2 (9.1)	0	2 (9.1)

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Hypokalaemia	1 (4.5)	1 (4.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (13.3)	1 (6.7)	1 (6.7)
Blood and lymphatic system disorders			
-Total	1 (6.7)	1 (6.7)	0
Anaemia	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	1 (6.7)	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0
Investigations			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Blood fibrinogen decreased	1 (6.7)	1 (6.7)	0

Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Platelet count decreased	1 (6.7)	1 (6.7)	0
White blood cell count decreased	1 (6.7)	0	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 221r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (34.3)	3 (8.6)	9 (25.7)
Blood and lymphatic system disorders			
-Total	4 (11.4)	4 (11.4)	0
Anaemia	2 (5.7)	2 (5.7)	0
Febrile neutropenia	2 (5.7)	2 (5.7)	0
Investigations			
-Total	8 (22.9)	0	8 (22.9)
White blood cell count decreased	6 (17.1)	1 (2.9)	5 (14.3)
Lymphocyte count decreased	3 (8.6)	0	3 (8.6)
Neutrophil count decreased	3 (8.6)	0	3 (8.6)

Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	3 (8.6)	0	3 (8.6)
Metabolism and nutrition disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Hypokalaemia	2 (5.7)	1 (2.9)	1 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	2 (25.0)	6 (75.0)
Blood and lymphatic system disorders			
-Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Anaemia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Endocrine disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	3 (37.5)	3 (37.5)	0

Age: <10 years

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (12.5)	1 (12.5)	0
Diarrhoea	1 (12.5)	1 (12.5)	0
Duodenal perforation	1 (12.5)	1 (12.5)	0
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	3 (37.5)	3 (37.5)	0
Generalised oedema	1 (12.5)	1 (12.5)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	3 (37.5)	3 (37.5)
Acute sinusitis	1 (12.5)	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	1 (12.5)
Device related infection	1 (12.5)	1 (12.5)	0

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Peritonitis	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
C-reactive protein increased	1 (12.5)	1 (12.5)	0
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Tumour lysis syndrome	2 (25.0)	1 (12.5)	1 (12.5)
Nervous system disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Encephalopathy	1 (12.5)	1 (12.5)	0
Haemorrhage intracranial	1 (12.5)	0	1 (12.5)
Psychiatric disorders			

Age: <10 years

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (12.5)	1 (12.5)	0
Mental status changes	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Pulmonary haemorrhage	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	2 (28.6)	4 (57.1)
Blood and lymphatic system disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Anaemia	2 (28.6)	2 (28.6)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	3 (42.9)	3 (42.9)	0
Tachycardia	2 (28.6)	2 (28.6)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	1 (14.3)
Colitis	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Haemoperitoneum	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	1 (14.3)	1 (14.3)	0
Graft versus host disease	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (14.3)	0	1 (14.3)
Klebsiella bacteraemia	1 (14.3)	1 (14.3)	0
Oral herpes	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Serratia sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0
Investigations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Alanine aminotransferase increased	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood potassium decreased	1 (14.3)	1 (14.3)	0
Serum ferritin increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	3 (42.9)	3 (42.9)	0

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	2 (28.6)	2 (28.6)	0
Hyperammonaemia	1 (14.3)	1 (14.3)	0
Hyperkalaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Cognitive disorder	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Respiratory failure	2 (28.6)	0	2 (28.6)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Hypotension	4 (57.1)	3 (42.9)	1 (14.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	3 (100)	1 (33.3)	2 (66.7)
Pancytopenia	2 (66.7)	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Cardiac failure	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)

Age: >=18

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	1 (33.3)	0	1 (33.3)
Device related sepsis	1 (33.3)	1 (33.3)	0
Fungal sepsis	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	1 (33.3)	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hyperglycaemia	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute respiratory distress syndrome	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	2 (22.2)	7 (77.8)
Blood and lymphatic system disorders			
-Total	4 (44.4)	4 (44.4)	0
Anaemia	2 (22.2)	2 (22.2)	0
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Hyperleukocytosis	1 (11.1)	1 (11.1)	0
Cardiac disorders			
-Total	3 (33.3)	3 (33.3)	0
Tachycardia	2 (22.2)	2 (22.2)	0
Left ventricular dysfunction	1 (11.1)	1 (11.1)	0
Endocrine disorders			

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	0	1 (11.1)
Hypercalcaemia of malignancy	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Abdominal compartment syndrome	1 (11.1)	0	1 (11.1)
Abdominal pain	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	1 (11.1)	0
Duodenal perforation	1 (11.1)	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Haemoperitoneum	1 (11.1)	0	1 (11.1)
Stomatitis	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	4 (44.4)	4 (44.4)	0
Pyrexia	2 (22.2)	2 (22.2)	0
Generalised oedema	1 (11.1)	1 (11.1)	0
Pain	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	2 (22.2)	0
Hyperbilirubinaemia	2 (22.2)	2 (22.2)	0
Infections and infestations			
-Total	7 (77.8)	3 (33.3)	4 (44.4)
Device related infection	1 (11.1)	1 (11.1)	0
Disseminated trichosporonosis	1 (11.1)	0	1 (11.1)
Fungaemia	1 (11.1)	0	1 (11.1)
Klebsiella bacteraemia	1 (11.1)	1 (11.1)	0
Oral herpes	1 (11.1)	1 (11.1)	0
Peritonitis	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Serratia sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			
-Total	1 (11.1)	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0
Investigations			

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Aspartate aminotransferase increased	1 (11.1)	0	1 (11.1)
C-reactive protein increased	1 (11.1)	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Metabolic acidosis	2 (22.2)	2 (22.2)	0
Tumour lysis syndrome	2 (22.2)	1 (11.1)	1 (11.1)
Hyperammonaemia	1 (11.1)	1 (11.1)	0
Hyperkalaemia	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Cognitive disorder	1 (11.1)	1 (11.1)	0
Encephalopathy	1 (11.1)	1 (11.1)	0
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)
Psychiatric disorders			

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Respiratory failure	3 (33.3)	0	3 (33.3)
Pulmonary haemorrhage	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	4 (44.4)	3 (33.3)	1 (11.1)
Hypotension	4 (44.4)	3 (33.3)	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	3 (33.3)	5 (55.6)
Blood and lymphatic system disorders			
-Total	5 (55.6)	2 (22.2)	3 (33.3)
Febrile neutropenia	2 (22.2)	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	1 (11.1)	1 (11.1)
Anaemia	1 (11.1)	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	1 (11.1)	0
Cardiac failure	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	1 (11.1)	0
Colitis	1 (11.1)	1 (11.1)	0
Immune system disorders			
-Total	1 (11.1)	1 (11.1)	0
Graft versus host disease	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	7 (77.8)	3 (33.3)	4 (44.4)
Acute sinusitis	1 (11.1)	1 (11.1)	0
Aspergillus infection	1 (11.1)	0	1 (11.1)
Bacteraemia	1 (11.1)	1 (11.1)	0
Bacterial sepsis	1 (11.1)	0	1 (11.1)
Device related sepsis	1 (11.1)	1 (11.1)	0
Fungal sepsis	1 (11.1)	0	1 (11.1)
Fungal skin infection	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)
Systemic mycosis	1 (11.1)	1 (11.1)	0
Investigations			

Gender: Female

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (22.2)	2 (22.2)	0
Alanine aminotransferase increased	1 (11.1)	1 (11.1)	0
Blood potassium decreased	1 (11.1)	1 (11.1)	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0
Serum ferritin increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Hyperglycaemia	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (11.1)	0	1 (11.1)
Acute respiratory distress syndrome	1 (11.1)	0	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	4 (36.4)	7 (63.6)
Blood and lymphatic system disorders			
-Total	6 (54.5)	5 (45.5)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Pancytopenia	2 (18.2)	1 (9.1)	1 (9.1)
Anaemia	1 (9.1)	1 (9.1)	0
Hyperleukocytosis	1 (9.1)	1 (9.1)	0
Cardiac disorders			
-Total	3 (27.3)	3 (27.3)	0
Tachycardia	2 (18.2)	2 (18.2)	0
Cardiac failure	1 (9.1)	1 (9.1)	0

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Endocrine disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypercalcaemia of malignancy	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Abdominal compartment syndrome	1 (9.1)	0	1 (9.1)
Abdominal pain	1 (9.1)	1 (9.1)	0
Colitis	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haemoperitoneum	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	3 (27.3)	3 (27.3)	0
Pyrexia	2 (18.2)	2 (18.2)	0
Pain	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hyperbilirubinaemia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	1 (9.1)	1 (9.1)	0
Graft versus host disease	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	9 (81.8)	4 (36.4)	5 (45.5)
Acute sinusitis	1 (9.1)	1 (9.1)	0
Aspergillus infection	1 (9.1)	0	1 (9.1)
Bacteraemia	1 (9.1)	1 (9.1)	0
Bacterial sepsis	1 (9.1)	0	1 (9.1)
Device related infection	1 (9.1)	1 (9.1)	0
Device related sepsis	1 (9.1)	1 (9.1)	0
Disseminated trichosporonosis	1 (9.1)	0	1 (9.1)
Fungal sepsis	1 (9.1)	0	1 (9.1)
Fungal skin infection	1 (9.1)	1 (9.1)	0
Oral herpes	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Serratia sepsis	1 (9.1)	0	1 (9.1)

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Systemic mycosis	1 (9.1)	1 (9.1)	0
Investigations			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
C-reactive protein increased	2 (18.2)	2 (18.2)	0
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	6 (54.5)	4 (36.4)	2 (18.2)
Metabolic acidosis	2 (18.2)	2 (18.2)	0
Tumour lysis syndrome	2 (18.2)	1 (9.1)	1 (9.1)
Hyperammonaemia	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	2 (18.2)	2 (18.2)	0
Cognitive disorder	1 (9.1)	1 (9.1)	0
Encephalopathy	1 (9.1)	1 (9.1)	0

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Mental status changes	2 (18.2)	2 (18.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Respiratory failure	2 (18.2)	0	2 (18.2)
Acute respiratory distress syndrome	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Hypotension	3 (27.3)	2 (18.2)	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Anaemia	1 (20.0)	1 (20.0)	0
Thrombocytopenia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	1 (20.0)	1 (20.0)	0
Left ventricular dysfunction	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Duodenal perforation	1 (20.0)	1 (20.0)	0

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Klebsiella bacteraemia	1 (20.0)	1 (20.0)	0
Peritonitis	1 (20.0)	1 (20.0)	0
Pneumonia fungal	1 (20.0)	0	1 (20.0)
Injury, poisoning and procedural complications			
-Total	1 (20.0)	1 (20.0)	0
Post procedural haemorrhage	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Alanine aminotransferase increased	1 (20.0)	1 (20.0)	0
Blood potassium decreased	1 (20.0)	1 (20.0)	0
Serum ferritin increased	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	1 (20.0)	0	1 (20.0)
Haemorrhage intracranial	1 (20.0)	0	1 (20.0)
Vascular disorders			

Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (20.0)	1 (20.0)	0
Hypotension	1 (20.0)	1 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Febrile neutropenia	2 (100)	1 (50.0)	1 (50.0)
Anaemia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Stomatitis	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	1 (50.0)	1 (50.0)	0
Hepatobiliary disorders			
-Total	1 (50.0)	1 (50.0)	0
Hyperbilirubinaemia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	0	2 (100)
Fungaemia	1 (50.0)	0	1 (50.0)
Pneumonia	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
Platelet count decreased	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pulmonary haemorrhage	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	1 (33.3)	0
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Colitis	1 (33.3)	1 (33.3)	0

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	1 (33.3)	0
Immune system disorders			
-Total	1 (33.3)	1 (33.3)	0
Graft versus host disease	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Bacteraemia	1 (33.3)	1 (33.3)	0
Disseminated trichosporonosis	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperkalaemia	1 (33.3)	1 (33.3)	0
Metabolic acidosis	1 (33.3)	1 (33.3)	0
Psychiatric disorders			
-Total	1 (33.3)	1 (33.3)	0

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypotension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (93.3)	4 (26.7)	10 (66.7)
Blood and lymphatic system disorders			
-Total	8 (53.3)	5 (33.3)	3 (20.0)
Anaemia	3 (20.0)	3 (20.0)	0
Febrile neutropenia	3 (20.0)	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Thrombocytopenia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	3 (20.0)	3 (20.0)	0
Cardiac failure	1 (6.7)	1 (6.7)	0

Ethnicity: Other

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Tachycardia	1 (6.7)	1 (6.7)	0
Endocrine disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypercalcaemia of malignancy	1 (6.7)	0	1 (6.7)
Gastrointestinal disorders			
-Total	5 (33.3)	4 (26.7)	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Abdominal pain	1 (6.7)	1 (6.7)	0
Diarrhoea	1 (6.7)	1 (6.7)	0
Duodenal perforation	1 (6.7)	1 (6.7)	0
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
Haemoperitoneum	1 (6.7)	0	1 (6.7)
Stomatitis	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	3 (20.0)	3 (20.0)	0
Generalised oedema	1 (6.7)	1 (6.7)	0

Ethnicity: Other

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Hepatobiliary disorders			
-Total	2 (13.3)	2 (13.3)	0
Hyperbilirubinaemia	2 (13.3)	2 (13.3)	0
Infections and infestations			
-Total	11 (73.3)	5 (33.3)	6 (40.0)
Acute sinusitis	1 (6.7)	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Fungaemia	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Oral herpes	1 (6.7)	1 (6.7)	0
Peritonitis	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)
Serratia sepsis	1 (6.7)	0	1 (6.7)
Staphylococcal infection	1 (6.7)	0	1 (6.7)
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
-Total	5 (33.3)	3 (20.0)	2 (13.3)
C-reactive protein increased	2 (13.3)	2 (13.3)	0
Alanine aminotransferase increased	1 (6.7)	1 (6.7)	0
Aspartate aminotransferase increased	1 (6.7)	0	1 (6.7)
Blood potassium decreased	1 (6.7)	1 (6.7)	0
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	1 (6.7)
Serum ferritin increased	1 (6.7)	1 (6.7)	0

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	5 (33.3)	3 (20.0)	2 (13.3)
Tumour lysis syndrome	2 (13.3)	1 (6.7)	1 (6.7)
Hyperammonaemia	1 (6.7)	1 (6.7)	0
Hyperglycaemia	1 (6.7)	0	1 (6.7)
Metabolic acidosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Cognitive disorder	1 (6.7)	1 (6.7)	0
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
-Total	1 (6.7)	1 (6.7)	0
Mental status changes	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Respiratory failure	2 (13.3)	0	2 (13.3)

Ethnicity: Other

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Pulmonary haemorrhage	1 (6.7)	0	1 (6.7)
Pulmonary oedema	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	2 (13.3)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Anaemia	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Cardiac disorders			
-Total	2 (100)	2 (100)	0
Tachycardia	2 (100)	2 (100)	0
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)

Response status at study entry: Primary refractory

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	2 (100)	2 (100)	0
Metabolic acidosis	2 (100)	2 (100)	0
Hyperkalaemia	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	1 (50.0)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Cognitive disorder	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	2 (100)	2 (100)	0
Hypotension	2 (100)	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (93.8)	5 (31.3)	10 (62.5)
Blood and lymphatic system disorders			
-Total	7 (43.8)	4 (25.0)	3 (18.8)
Febrile neutropenia	3 (18.8)	2 (12.5)	1 (6.3)
Anaemia	2 (12.5)	2 (12.5)	0
Pancytopenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Thrombocytopenia	1 (6.3)	0	1 (6.3)
Cardiac disorders			
-Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders			
-Total	1 (6.3)	0	1 (6.3)
Hypercalcaemia of malignancy	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	5 (31.3)	5 (31.3)	0
Abdominal pain	1 (6.3)	1 (6.3)	0
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	1 (6.3)	0
Duodenal perforation	1 (6.3)	1 (6.3)	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
Stomatitis	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	3 (18.8)	3 (18.8)	0
Generalised oedema	1 (6.3)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Hepatobiliary disorders			
-Total	2 (12.5)	2 (12.5)	0

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	2 (12.5)	2 (12.5)	0
Immune system disorders			
-Total	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	12 (75.0)	6 (37.5)	6 (37.5)
Acute sinusitis	1 (6.3)	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0
Oral herpes	1 (6.3)	1 (6.3)	0
Peritonitis	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
C-reactive protein increased	2 (12.5)	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0
Blood potassium decreased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Platelet count decreased	1 (6.3)	0	1 (6.3)
Serum ferritin increased	1 (6.3)	1 (6.3)	0
Metabolism and nutrition disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
Tumour lysis syndrome	2 (12.5)	1 (6.3)	1 (6.3)
Hyperammonaemia	1 (6.3)	1 (6.3)	0

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (6.3)	0	1 (6.3)
Nervous system disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Respiratory failure	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders			
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	3 (16.7)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Endocrine disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypercalcaemia of malignancy	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	6 (33.3)	5 (27.8)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	4 (22.2)	4 (22.2)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Generalised oedema	1 (5.6)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	2 (11.1)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	14 (77.8)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
C-reactive protein increased	2 (11.1)	2 (11.1)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Hyperammonaemia	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222g
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders			
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	3 (16.7)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Endocrine disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypercalcaemia of malignancy	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	6 (33.3)	5 (27.8)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	4 (22.2)	4 (22.2)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Generalised oedema	1 (5.6)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	2 (11.1)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	14 (77.8)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
C-reactive protein increased	2 (11.1)	2 (11.1)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Hyperammonaemia	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Anaemia	1 (50.0)	1 (50.0)	0
Cardiac disorders			
-Total	2 (100)	2 (100)	0
Left ventricular dysfunction	1 (50.0)	1 (50.0)	0
Tachycardia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)

Hypodiploidy: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Klebsiella bacteraemia	1 (50.0)	1 (50.0)	0
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	1 (50.0)	0
Post procedural haemorrhage	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Metabolic acidosis	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	1 (50.0)	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	2 (100)	2 (100)	0
Hypotension	2 (100)	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (93.8)	4 (25.0)	11 (68.8)
Blood and lymphatic system disorders			
-Total	8 (50.0)	5 (31.3)	3 (18.8)
Febrile neutropenia	4 (25.0)	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	2 (12.5)	0
Pancytopenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Thrombocytopenia	1 (6.3)	0	1 (6.3)
Cardiac disorders			
-Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (6.3)	1 (6.3)	0
Endocrine disorders			
-Total	1 (6.3)	0	1 (6.3)
Hypercalcaemia of malignancy	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	5 (31.3)	5 (31.3)	0
Abdominal pain	1 (6.3)	1 (6.3)	0
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	1 (6.3)	0
Duodenal perforation	1 (6.3)	1 (6.3)	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
Stomatitis	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	4 (25.0)	4 (25.0)	0
Pyrexia	2 (12.5)	2 (12.5)	0
Generalised oedema	1 (6.3)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	2 (12.5)	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	2 (12.5)	0
Immune system disorders			
-Total	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	12 (75.0)	5 (31.3)	7 (43.8)
Acute sinusitis	1 (6.3)	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (6.3)	1 (6.3)	0
Peritonitis	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Investigations			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
C-reactive protein increased	2 (12.5)	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0
Blood potassium decreased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Platelet count decreased	1 (6.3)	0	1 (6.3)
Serum ferritin increased	1 (6.3)	1 (6.3)	0
Metabolism and nutrition disorders			
-Total	5 (31.3)	3 (18.8)	2 (12.5)
Tumour lysis syndrome	2 (12.5)	1 (6.3)	1 (6.3)
Hyperammonaemia	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (6.3)	0	1 (6.3)
Hyperkalaemia	1 (6.3)	1 (6.3)	0
Metabolic acidosis	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (25.0)	1 (6.3)	3 (18.8)
Respiratory failure	2 (12.5)	0	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			

Hypodiploidy: No

Group term Preferred term	All patients N=16 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Acute sinusitis	1 (100)	1 (100)	0
Fungal skin infection	1 (100)	1 (100)	0
Systemic mycosis	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	4 (23.5)	12 (70.6)
Blood and lymphatic system disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Anaemia	3 (17.6)	3 (17.6)	0
Febrile neutropenia	3 (17.6)	2 (11.8)	1 (5.9)
Pancytopenia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	1 (5.9)
Cardiac disorders			
-Total	4 (23.5)	4 (23.5)	0
Tachycardia	2 (11.8)	2 (11.8)	0

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Endocrine disorders			
-Total	1 (5.9)	0	1 (5.9)
Hypercalcaemia of malignancy	1 (5.9)	0	1 (5.9)
Gastrointestinal disorders			
-Total	6 (35.3)	5 (29.4)	1 (5.9)
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)
Abdominal pain	1 (5.9)	1 (5.9)	0
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	1 (5.9)	0
Duodenal perforation	1 (5.9)	1 (5.9)	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
Stomatitis	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	4 (23.5)	4 (23.5)	0

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (11.8)	2 (11.8)	0
Generalised oedema	1 (5.9)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			
-Total	2 (11.8)	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	2 (11.8)	0
Immune system disorders			
-Total	1 (5.9)	1 (5.9)	0
Graft versus host disease	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	13 (76.5)	5 (29.4)	8 (47.1)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)
Fungaemia	1 (5.9)	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.9)	0	1 (5.9)
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0
Oral herpes	1 (5.9)	1 (5.9)	0
Peritonitis	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
C-reactive protein increased	2 (11.8)	2 (11.8)	0
Alanine aminotransferase increased	1 (5.9)	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Platelet count decreased	1 (5.9)	0	1 (5.9)
Serum ferritin increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	6 (35.3)	4 (23.5)	2 (11.8)
Metabolic acidosis	2 (11.8)	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	1 (5.9)	1 (5.9)
Hyperammonaemia	1 (5.9)	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	1 (5.9)
Hyperkalaemia	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Cognitive disorder	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	2 (11.8)	2 (11.8)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (11.8)	2 (11.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	3 (17.6)	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Blood and lymphatic system disorders			
-Total	2 (66.7)	2 (66.7)	0
Anaemia	2 (66.7)	2 (66.7)	0
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	1 (33.3)

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	1 (33.3)	1 (33.3)	0
Generalised oedema	1 (33.3)	1 (33.3)	0
Hepatobiliary disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	3 (100)	0	3 (100)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Fungaemia	1 (33.3)	0	1 (33.3)
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Investigations			
-Total	2 (66.7)	0	2 (66.7)
Aspartate aminotransferase increased	1 (33.3)	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	1 (33.3)

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0
Metabolic acidosis	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Cognitive disorder	1 (33.3)	1 (33.3)	0
Psychiatric disorders			
-Total	1 (33.3)	1 (33.3)	0
Mental status changes	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Respiratory failure	2 (66.7)	0	2 (66.7)
Pulmonary haemorrhage	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypotension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (93.3)	5 (33.3)	9 (60.0)
Blood and lymphatic system disorders			
-Total	7 (46.7)	4 (26.7)	3 (20.0)
Febrile neutropenia	3 (20.0)	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	1 (6.7)	1 (6.7)
Anaemia	1 (6.7)	1 (6.7)	0
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Thrombocytopenia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	3 (20.0)	3 (20.0)	0
Cardiac failure	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (6.7)	1 (6.7)	0
Endocrine disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypercalcaemia of malignancy	1 (6.7)	0	1 (6.7)
Gastrointestinal disorders			
-Total	4 (26.7)	4 (26.7)	0
Abdominal pain	1 (6.7)	1 (6.7)	0
Colitis	1 (6.7)	1 (6.7)	0
Diarrhoea	1 (6.7)	1 (6.7)	0
Duodenal perforation	1 (6.7)	1 (6.7)	0
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	3 (20.0)	3 (20.0)	0
Pyrexia	2 (13.3)	2 (13.3)	0
Pain	1 (6.7)	1 (6.7)	0
Hepatobiliary disorders			
-Total	1 (6.7)	1 (6.7)	0
Hyperbilirubinaemia	1 (6.7)	1 (6.7)	0

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (6.7)	1 (6.7)	0
Graft versus host disease	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	11 (73.3)	6 (40.0)	5 (33.3)
Acute sinusitis	1 (6.7)	1 (6.7)	0
Bacteraemia	1 (6.7)	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Disseminated trichosporonosis	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Oral herpes	1 (6.7)	1 (6.7)	0
Peritonitis	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
-Total	3 (20.0)	3 (20.0)	0
C-reactive protein increased	2 (13.3)	2 (13.3)	0
Alanine aminotransferase increased	1 (6.7)	1 (6.7)	0
Blood potassium decreased	1 (6.7)	1 (6.7)	0
Serum ferritin increased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	5 (33.3)	3 (20.0)	2 (13.3)
Tumour lysis syndrome	2 (13.3)	1 (6.7)	1 (6.7)
Hyperammonaemia	1 (6.7)	1 (6.7)	0
Hyperglycaemia	1 (6.7)	0	1 (6.7)
Hyperkalaemia	1 (6.7)	1 (6.7)	0
Metabolic acidosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
-Total	1 (6.7)	1 (6.7)	0
Mental status changes	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	2 (13.3)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	2 (50.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)
Pancytopenia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Diarrhoea	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			

Region: Europe

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (50.0)	2 (50.0)	0
Pain	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Device related infection	1 (25.0)	1 (25.0)	0
Device related sepsis	1 (25.0)	1 (25.0)	0
Pneumonia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	2 (50.0)	0
C-reactive protein increased	2 (50.0)	2 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Tumour lysis syndrome	2 (50.0)	1 (25.0)	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Encephalopathy	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (100)	3 (25.0)	9 (75.0)
Blood and lymphatic system disorders			
-Total	7 (58.3)	5 (41.7)	2 (16.7)
Anaemia	3 (25.0)	3 (25.0)	0
Febrile neutropenia	3 (25.0)	3 (25.0)	0
Hyperleukocytosis	1 (8.3)	1 (8.3)	0
Pancytopenia	1 (8.3)	0	1 (8.3)
Thrombocytopenia	1 (8.3)	0	1 (8.3)
Cardiac disorders			
-Total	4 (33.3)	4 (33.3)	0
Tachycardia	2 (16.7)	2 (16.7)	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Cardiac failure	1 (8.3)	1 (8.3)	0
Left ventricular dysfunction	1 (8.3)	1 (8.3)	0
Endocrine disorders			
-Total	1 (8.3)	0	1 (8.3)
Hypercalcaemia of malignancy	1 (8.3)	0	1 (8.3)
Gastrointestinal disorders			
-Total	4 (33.3)	3 (25.0)	1 (8.3)
Abdominal compartment syndrome	1 (8.3)	0	1 (8.3)
Colitis	1 (8.3)	1 (8.3)	0
Gastrointestinal haemorrhage	1 (8.3)	1 (8.3)	0
Haemoperitoneum	1 (8.3)	0	1 (8.3)
Stomatitis	1 (8.3)	1 (8.3)	0
General disorders and administration site conditions			
-Total	2 (16.7)	2 (16.7)	0
Generalised oedema	1 (8.3)	1 (8.3)	0
Pyrexia	1 (8.3)	1 (8.3)	0
Hepatobiliary disorders			

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	2 (16.7)	2 (16.7)	0
Hyperbilirubinaemia	2 (16.7)	2 (16.7)	0
Immune system disorders			
-Total	1 (8.3)	1 (8.3)	0
Graft versus host disease	1 (8.3)	1 (8.3)	0
Infections and infestations			
-Total	10 (83.3)	3 (25.0)	7 (58.3)
Acute sinusitis	1 (8.3)	1 (8.3)	0
Aspergillus infection	1 (8.3)	0	1 (8.3)
Bacteraemia	1 (8.3)	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	1 (8.3)
Disseminated trichosporonosis	1 (8.3)	0	1 (8.3)
Fungaemia	1 (8.3)	0	1 (8.3)
Fungal sepsis	1 (8.3)	0	1 (8.3)
Fungal skin infection	1 (8.3)	1 (8.3)	0
Klebsiella bacteraemia	1 (8.3)	1 (8.3)	0
Oral herpes	1 (8.3)	1 (8.3)	0
Pneumonia fungal	1 (8.3)	0	1 (8.3)

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Sepsis	1 (8.3)	0	1 (8.3)
Serratia sepsis	1 (8.3)	0	1 (8.3)
Staphylococcal infection	1 (8.3)	0	1 (8.3)
Systemic mycosis	1 (8.3)	1 (8.3)	0
Injury, poisoning and procedural complications			
-Total	1 (8.3)	1 (8.3)	0
Post procedural haemorrhage	1 (8.3)	1 (8.3)	0
Investigations			
-Total	3 (25.0)	1 (8.3)	2 (16.7)
Alanine aminotransferase increased	1 (8.3)	1 (8.3)	0
Aspartate aminotransferase increased	1 (8.3)	0	1 (8.3)
Blood potassium decreased	1 (8.3)	1 (8.3)	0
Neutrophil count decreased	1 (8.3)	0	1 (8.3)
Platelet count decreased	1 (8.3)	0	1 (8.3)
Serum ferritin increased	1 (8.3)	1 (8.3)	0
Metabolism and nutrition disorders			
-Total	4 (33.3)	3 (25.0)	1 (8.3)

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Metabolic acidosis	2 (16.7)	2 (16.7)	0
Hyperammonaemia	1 (8.3)	1 (8.3)	0
Hyperglycaemia	1 (8.3)	0	1 (8.3)
Hyperkalaemia	1 (8.3)	1 (8.3)	0
Nervous system disorders			
-Total	1 (8.3)	1 (8.3)	0
Cognitive disorder	1 (8.3)	1 (8.3)	0
Psychiatric disorders			
-Total	2 (16.7)	2 (16.7)	0
Mental status changes	2 (16.7)	2 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (41.7)	1 (8.3)	4 (33.3)
Respiratory failure	3 (25.0)	0	3 (25.0)
Acute respiratory distress syndrome	1 (8.3)	0	1 (8.3)
Pulmonary haemorrhage	1 (8.3)	0	1 (8.3)
Pulmonary oedema	1 (8.3)	0	1 (8.3)
Tachypnoea	1 (8.3)	1 (8.3)	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	4 (33.3)	3 (25.0)	1 (8.3)
Hypotension	4 (33.3)	3 (25.0)	1 (8.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Duodenal perforation	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Peritonitis	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Haemorrhage intracranial	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	4 (40.0)	5 (50.0)
Blood and lymphatic system disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Febrile neutropenia	2 (20.0)	1 (10.0)	1 (10.0)
Pancytopenia	2 (20.0)	1 (10.0)	1 (10.0)
Anaemia	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	2 (20.0)	2 (20.0)	0
Cardiac failure	1 (10.0)	1 (10.0)	0
Left ventricular dysfunction	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (40.0)	4 (40.0)	0
Abdominal pain	1 (10.0)	1 (10.0)	0
Colitis	1 (10.0)	1 (10.0)	0
Diarrhoea	1 (10.0)	1 (10.0)	0
Duodenal perforation	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	3 (30.0)	3 (30.0)	0
Generalised oedema	1 (10.0)	1 (10.0)	0
Pain	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Hepatobiliary disorders			
-Total	1 (10.0)	1 (10.0)	0
Hyperbilirubinaemia	1 (10.0)	1 (10.0)	0
Immune system disorders			
-Total	1 (10.0)	1 (10.0)	0
Graft versus host disease	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	8 (80.0)	5 (50.0)	3 (30.0)
Bacteraemia	1 (10.0)	1 (10.0)	0
Bacterial sepsis	1 (10.0)	0	1 (10.0)
Device related infection	1 (10.0)	1 (10.0)	0
Device related sepsis	1 (10.0)	1 (10.0)	0
Fungaemia	1 (10.0)	0	1 (10.0)
Fungal sepsis	1 (10.0)	0	1 (10.0)
Klebsiella bacteraemia	1 (10.0)	1 (10.0)	0
Peritonitis	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			
-Total	1 (10.0)	1 (10.0)	0
Post procedural haemorrhage	1 (10.0)	1 (10.0)	0
Investigations			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
C-reactive protein increased	2 (20.0)	2 (20.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (10.0)	0	1 (10.0)
Platelet count decreased	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Tumour lysis syndrome	2 (20.0)	1 (10.0)	1 (10.0)
Hyperglycaemia	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Encephalopathy	1 (10.0)	1 (10.0)	0
Haemorrhage intracranial	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Acute respiratory distress syndrome	1 (10.0)	0	1 (10.0)
Pulmonary haemorrhage	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (10.0)	1 (10.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders			
-Total	5 (62.5)	4 (50.0)	1 (12.5)
Anaemia	2 (25.0)	2 (25.0)	0
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Tachycardia	2 (25.0)	2 (25.0)	0
Endocrine disorders			

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
Haemoperitoneum	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Acute sinusitis	1 (12.5)	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	1 (12.5)

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Blood potassium decreased	1 (12.5)	1 (12.5)	0
Serum ferritin increased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	3 (37.5)	3 (37.5)	0
Metabolic acidosis	2 (25.0)	2 (25.0)	0

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperammonaemia	1 (12.5)	1 (12.5)	0
Hyperkalaemia	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	2 (25.0)	2 (25.0)	0
Mental status changes	2 (25.0)	2 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	2 (25.0)	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Duodenal perforation	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Acute sinusitis	1 (25.0)	1 (25.0)	0
Aspergillus infection	1 (25.0)	0	1 (25.0)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (25.0)	1 (25.0)	0
Peritonitis	1 (25.0)	1 (25.0)	0
Systemic mycosis	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Haemorrhage intracranial	1 (25.0)	0	1 (25.0)
Psychiatric disorders			
-Total	1 (25.0)	1 (25.0)	0
Mental status changes	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	4 (28.6)	10 (71.4)
Blood and lymphatic system disorders			
-Total	8 (57.1)	5 (35.7)	3 (21.4)
Anaemia	3 (21.4)	3 (21.4)	0
Febrile neutropenia	3 (21.4)	2 (14.3)	1 (7.1)
Pancytopenia	2 (14.3)	1 (7.1)	1 (7.1)
Hyperleukocytosis	1 (7.1)	1 (7.1)	0
Thrombocytopenia	1 (7.1)	0	1 (7.1)
Cardiac disorders			
-Total	4 (28.6)	4 (28.6)	0
Tachycardia	2 (14.3)	2 (14.3)	0

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (7.1)	1 (7.1)	0
Left ventricular dysfunction	1 (7.1)	1 (7.1)	0
Endocrine disorders			
-Total	1 (7.1)	0	1 (7.1)
Hypercalcaemia of malignancy	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	5 (35.7)	4 (28.6)	1 (7.1)
Abdominal compartment syndrome	1 (7.1)	0	1 (7.1)
Abdominal pain	1 (7.1)	1 (7.1)	0
Colitis	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0
Gastrointestinal haemorrhage	1 (7.1)	1 (7.1)	0
Haemoperitoneum	1 (7.1)	0	1 (7.1)
Stomatitis	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	4 (28.6)	4 (28.6)	0
Pyrexia	2 (14.3)	2 (14.3)	0

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	1 (7.1)	1 (7.1)	0
Pain	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	2 (14.3)	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	2 (14.3)	0
Immune system disorders			
-Total	1 (7.1)	1 (7.1)	0
Graft versus host disease	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	11 (78.6)	4 (28.6)	7 (50.0)
Bacteraemia	1 (7.1)	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	1 (7.1)
Device related infection	1 (7.1)	1 (7.1)	0
Device related sepsis	1 (7.1)	1 (7.1)	0
Disseminated trichosporonosis	1 (7.1)	0	1 (7.1)
Fungaemia	1 (7.1)	0	1 (7.1)
Fungal sepsis	1 (7.1)	0	1 (7.1)
Klebsiella bacteraemia	1 (7.1)	1 (7.1)	0

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	1 (7.1)
Sepsis	1 (7.1)	0	1 (7.1)
Serratia sepsis	1 (7.1)	0	1 (7.1)
Staphylococcal infection	1 (7.1)	0	1 (7.1)
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Post procedural haemorrhage	1 (7.1)	1 (7.1)	0
Investigations			
-Total	5 (35.7)	3 (21.4)	2 (14.3)
C-reactive protein increased	2 (14.3)	2 (14.3)	0
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)
Blood potassium decreased	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	1 (7.1)

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Metabolic acidosis	2 (14.3)	2 (14.3)	0
Tumour lysis syndrome	2 (14.3)	1 (7.1)	1 (7.1)
Hyperammonaemia	1 (7.1)	1 (7.1)	0
Hyperglycaemia	1 (7.1)	0	1 (7.1)
Hyperkalaemia	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	2 (14.3)	2 (14.3)	0
Cognitive disorder	1 (7.1)	1 (7.1)	0
Encephalopathy	1 (7.1)	1 (7.1)	0
Psychiatric disorders			
-Total	1 (7.1)	1 (7.1)	0
Mental status changes	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (35.7)	1 (7.1)	4 (28.6)

Eligibility for SCT: No

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (21.4)	0	3 (21.4)
Acute respiratory distress syndrome	1 (7.1)	0	1 (7.1)
Pulmonary haemorrhage	1 (7.1)	0	1 (7.1)
Pulmonary oedema	1 (7.1)	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Hypotension	4 (28.6)	3 (21.4)	1 (7.1)

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	1 (50.0)	0
Thrombocytopenia	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood potassium decreased	1 (50.0)	1 (50.0)	0
Serum ferritin increased	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	5 (31.3)	11 (68.8)
Blood and lymphatic system disorders			
-Total	8 (50.0)	6 (37.5)	2 (12.5)
Febrile neutropenia	4 (25.0)	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	2 (12.5)	0
Pancytopenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Cardiac disorders			
-Total	4 (25.0)	4 (25.0)	0
Tachycardia	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders			
-Total	1 (6.3)	0	1 (6.3)
Hypercalcaemia of malignancy	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	6 (37.5)	5 (31.3)	1 (6.3)
Abdominal compartment syndrome	1 (6.3)	0	1 (6.3)
Abdominal pain	1 (6.3)	1 (6.3)	0
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	1 (6.3)	0
Duodenal perforation	1 (6.3)	1 (6.3)	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
Haemoperitoneum	1 (6.3)	0	1 (6.3)
Stomatitis	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	4 (25.0)	4 (25.0)	0
Pyrexia	2 (12.5)	2 (12.5)	0
Generalised oedema	1 (6.3)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	2 (12.5)	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	2 (12.5)	0
Immune system disorders			
-Total	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	14 (87.5)	6 (37.5)	8 (50.0)
Acute sinusitis	1 (6.3)	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (6.3)	1 (6.3)	0
Peritonitis	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Serratia sepsis	1 (6.3)	0	1 (6.3)
Staphylococcal infection	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
C-reactive protein increased	2 (12.5)	2 (12.5)	0
Aspartate aminotransferase increased	1 (6.3)	0	1 (6.3)
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Platelet count decreased	1 (6.3)	0	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	6 (37.5)	4 (25.0)	2 (12.5)
Metabolic acidosis	2 (12.5)	2 (12.5)	0
Tumour lysis syndrome	2 (12.5)	1 (6.3)	1 (6.3)
Hyperammonaemia	1 (6.3)	1 (6.3)	0
Hyperglycaemia	1 (6.3)	0	1 (6.3)
Hyperkalaemia	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	3 (18.8)	2 (12.5)	1 (6.3)
Cognitive disorder	1 (6.3)	1 (6.3)	0
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (31.3)	1 (6.3)	4 (25.0)
Respiratory failure	3 (18.8)	0	3 (18.8)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Pulmonary oedema	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Hypotension	4 (25.0)	3 (18.8)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders			
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	3 (16.7)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Endocrine disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypercalcaemia of malignancy	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	6 (33.3)	5 (27.8)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	4 (22.2)	4 (22.2)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Generalised oedema	1 (5.6)	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	2 (11.1)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	14 (77.8)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
C-reactive protein increased	2 (11.1)	2 (11.1)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Hyperammonaemia	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Duodenal perforation	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Peritonitis	1 (100)	1 (100)	0
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Haemorrhage intracranial	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	5 (29.4)	11 (64.7)
Blood and lymphatic system disorders			
-Total	9 (52.9)	6 (35.3)	3 (17.6)
Febrile neutropenia	4 (23.5)	3 (17.6)	1 (5.9)
Anaemia	3 (17.6)	3 (17.6)	0
Pancytopenia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	1 (5.9)
Cardiac disorders			
-Total	4 (23.5)	4 (23.5)	0
Tachycardia	2 (11.8)	2 (11.8)	0

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Endocrine disorders			
-Total	1 (5.9)	0	1 (5.9)
Hypercalcaemia of malignancy	1 (5.9)	0	1 (5.9)
Gastrointestinal disorders			
-Total	5 (29.4)	4 (23.5)	1 (5.9)
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)
Abdominal pain	1 (5.9)	1 (5.9)	0
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	1 (5.9)	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
Stomatitis	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	4 (23.5)	4 (23.5)	0
Pyrexia	2 (11.8)	2 (11.8)	0

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	1 (5.9)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			
-Total	2 (11.8)	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	2 (11.8)	0
Immune system disorders			
-Total	1 (5.9)	1 (5.9)	0
Graft versus host disease	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	13 (76.5)	5 (29.4)	8 (47.1)
Acute sinusitis	1 (5.9)	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)
Fungaemia	1 (5.9)	0	1 (5.9)

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.9)	0	1 (5.9)
Fungal skin infection	1 (5.9)	1 (5.9)	0
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0
Oral herpes	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Systemic mycosis	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
C-reactive protein increased	2 (11.8)	2 (11.8)	0
Alanine aminotransferase increased	1 (5.9)	1 (5.9)	0

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (5.9)	0	1 (5.9)
Blood potassium decreased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Platelet count decreased	1 (5.9)	0	1 (5.9)
Serum ferritin increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	6 (35.3)	4 (23.5)	2 (11.8)
Metabolic acidosis	2 (11.8)	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	1 (5.9)	1 (5.9)
Hyperammonaemia	1 (5.9)	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	1 (5.9)
Hyperkalaemia	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	2 (11.8)	2 (11.8)	0
Cognitive disorder	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Psychiatric disorders			

Down syndrome: No

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (11.8)	2 (11.8)	0
Mental status changes	2 (11.8)	2 (11.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	3 (17.6)	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders			
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	3 (16.7)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Endocrine disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypercalcaemia of malignancy	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	6 (33.3)	5 (27.8)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	4 (22.2)	4 (22.2)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Generalised oedema	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	2 (11.1)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	14 (77.8)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
C-reactive protein increased	2 (11.1)	2 (11.1)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Hyperammonaemia	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Anaemia	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Cardiac disorders			
-Total	2 (100)	2 (100)	0
Tachycardia	2 (100)	2 (100)	0
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	2 (100)	2 (100)	0
Metabolic acidosis	2 (100)	2 (100)	0
Hyperkalaemia	1 (50.0)	1 (50.0)	0
Nervous system disorders			

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0
Cognitive disorder	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	2 (100)	2 (100)	0
Hypotension	2 (100)	2 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	4 (50.0)	4 (50.0)
Blood and lymphatic system disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Anaemia	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Pancytopenia	1 (12.5)	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Left ventricular dysfunction	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Diarrhoea	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Acute sinusitis	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (12.5)	1 (12.5)	0
Device related sepsis	1 (12.5)	1 (12.5)	0
Fungal skin infection	1 (12.5)	1 (12.5)	0
Klebsiella bacteraemia	1 (12.5)	1 (12.5)	0
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Post procedural haemorrhage	1 (12.5)	1 (12.5)	0
Investigations			
-Total	3 (37.5)	3 (37.5)	0
C-reactive protein increased	2 (25.0)	2 (25.0)	0
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Blood potassium decreased	1 (12.5)	1 (12.5)	0
Serum ferritin increased	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (25.0)	2 (25.0)	0
Hyperammonaemia	1 (12.5)	1 (12.5)	0
Tumour lysis syndrome	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Mental status changes	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

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-Only AEs occured to non-infused patients are summarized.
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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Aspergillus infection	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Mental status changes	1 (100)	1 (100)	0

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-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 222r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Febrile neutropenia	2 (28.6)	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	1 (14.3)	0
Pancytopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Cardiac failure	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (42.9)	3 (42.9)	0
Colitis	1 (14.3)	1 (14.3)	0
Duodenal perforation	1 (14.3)	1 (14.3)	0
Stomatitis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	2 (28.6)	2 (28.6)	0
Generalised oedema	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	1 (14.3)	1 (14.3)	0
Graft versus host disease	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (14.3)	0	1 (14.3)
Fungaemia	1 (14.3)	0	1 (14.3)
Fungal sepsis	1 (14.3)	0	1 (14.3)
Peritonitis	1 (14.3)	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)
Investigations			
-Total	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Platelet count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	2 (28.6)	0	2 (28.6)
Hyperglycaemia	1 (14.3)	0	1 (14.3)
Tumour lysis syndrome	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Encephalopathy	1 (14.3)	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)

Number of previous relapses: >=3

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Acute respiratory distress syndrome	1 (14.3)	0	1 (14.3)
Pulmonary haemorrhage	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (82.9)	7 (17.1)	27 (65.9)
Blood and lymphatic system disorders			
-Total	23 (56.1)	18 (43.9)	5 (12.2)
Febrile neutropenia	17 (41.5)	17 (41.5)	0
Anaemia	12 (29.3)	12 (29.3)	0
Thrombocytopenia	7 (17.1)	2 (4.9)	5 (12.2)
Neutropenia	4 (9.8)	1 (2.4)	3 (7.3)
Leukopenia	3 (7.3)	1 (2.4)	2 (4.9)
Disseminated intravascular coagulation	1 (2.4)	1 (2.4)	0
Pancytopenia	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	5 (12.2)	3 (7.3)	2 (4.9)
Left ventricular dysfunction	2 (4.9)	2 (4.9)	0
Tachycardia	2 (4.9)	1 (2.4)	1 (2.4)
Cardiac arrest	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders			
-Total	4 (9.8)	4 (9.8)	0
Stomatitis	3 (7.3)	3 (7.3)	0
Mouth haemorrhage	1 (2.4)	1 (2.4)	0
Nausea	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions			
-Total	6 (14.6)	3 (7.3)	3 (7.3)
Pyrexia	4 (9.8)	3 (7.3)	1 (2.4)
Multiple organ dysfunction syndrome	2 (4.9)	0	2 (4.9)
Hepatobiliary disorders			
-Total	2 (4.9)	2 (4.9)	0
Hepatic function abnormal	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (2.4)	1 (2.4)	0
Immune system disorders			
-Total	16 (39.0)	7 (17.1)	9 (22.0)
Cytokine release syndrome	11 (26.8)	3 (7.3)	8 (19.5)
Haemophagocytic lymphohistiocytosis	2 (4.9)	0	2 (4.9)
Hypogammaglobulinaemia	2 (4.9)	2 (4.9)	0
Immunodeficiency	2 (4.9)	2 (4.9)	0
Graft versus host disease	1 (2.4)	1 (2.4)	0
Infections and infestations			
-Total	10 (24.4)	6 (14.6)	4 (9.8)
Parainfluenzae virus infection	3 (7.3)	2 (4.9)	1 (2.4)
Pneumonia	3 (7.3)	1 (2.4)	2 (4.9)
Escherichia bacteraemia	2 (4.9)	2 (4.9)	0
Staphylococcal bacteraemia	2 (4.9)	2 (4.9)	0
Clostridium difficile infection	1 (2.4)	1 (2.4)	0
Gastroenteritis	1 (2.4)	1 (2.4)	0
Human herpesvirus 6 infection	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (2.4)	1 (2.4)	0
Rhinovirus infection	1 (2.4)	1 (2.4)	0
Sepsis	1 (2.4)	0	1 (2.4)
Sinusitis	1 (2.4)	1 (2.4)	0
Staphylococcal infection	1 (2.4)	1 (2.4)	0
Investigations			
-Total	27 (65.9)	7 (17.1)	20 (48.8)
Neutrophil count decreased	17 (41.5)	2 (4.9)	15 (36.6)
White blood cell count decreased	17 (41.5)	1 (2.4)	16 (39.0)
Lymphocyte count decreased	14 (34.1)	6 (14.6)	8 (19.5)
Platelet count decreased	11 (26.8)	4 (9.8)	7 (17.1)
Aspartate aminotransferase increased	5 (12.2)	3 (7.3)	2 (4.9)
Alanine aminotransferase increased	4 (9.8)	4 (9.8)	0
Blood bilirubin increased	4 (9.8)	4 (9.8)	0
C-reactive protein increased	2 (4.9)	2 (4.9)	0
Blood creatinine increased	1 (2.4)	1 (2.4)	0
Metabolism and nutrition disorders			

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (29.3)	6 (14.6)	6 (14.6)
Decreased appetite	5 (12.2)	4 (9.8)	1 (2.4)
Hypokalaemia	5 (12.2)	3 (7.3)	2 (4.9)
Hyperglycaemia	4 (9.8)	4 (9.8)	0
Hypophosphataemia	4 (9.8)	3 (7.3)	1 (2.4)
Hypocalcaemia	2 (4.9)	2 (4.9)	0
Hyperkalaemia	1 (2.4)	1 (2.4)	0
Malnutrition	1 (2.4)	1 (2.4)	0
Metabolic acidosis	1 (2.4)	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	1 (2.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (7.3)	3 (7.3)	0
Back pain	2 (4.9)	2 (4.9)	0
Pain in extremity	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	4 (9.8)	4 (9.8)	0
Encephalopathy	3 (7.3)	3 (7.3)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (2.4)	1 (2.4)	0
Renal and urinary disorders			
-Total	2 (4.9)	0	2 (4.9)
Acute kidney injury	2 (4.9)	0	2 (4.9)
Renal tubular necrosis	1 (2.4)	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (31.7)	6 (14.6)	7 (17.1)
Hypoxia	6 (14.6)	4 (9.8)	2 (4.9)
Dyspnoea	3 (7.3)	1 (2.4)	2 (4.9)
Pulmonary oedema	3 (7.3)	3 (7.3)	0
Respiratory failure	3 (7.3)	0	3 (7.3)
Tachypnoea	3 (7.3)	2 (4.9)	1 (2.4)
Epistaxis	2 (4.9)	2 (4.9)	0
Acute respiratory distress syndrome	1 (2.4)	0	1 (2.4)
Pleural effusion	1 (2.4)	1 (2.4)	0
Vascular disorders			
-Total	9 (22.0)	6 (14.6)	3 (7.3)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	7 (17.1)	4 (9.8)	3 (7.3)
Hypertension	3 (7.3)	3 (7.3)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (90.0)	8 (20.0)	28 (70.0)
Blood and lymphatic system disorders			
-Total	24 (60.0)	12 (30.0)	12 (30.0)
Febrile neutropenia	15 (37.5)	13 (32.5)	2 (5.0)
Anaemia	7 (17.5)	6 (15.0)	1 (2.5)
Neutropenia	7 (17.5)	1 (2.5)	6 (15.0)
Thrombocytopenia	3 (7.5)	1 (2.5)	2 (5.0)
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Leukopenia	2 (5.0)	0	2 (5.0)
Pancytopenia	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	8 (20.0)	5 (12.5)	3 (7.5)
Tachycardia	3 (7.5)	3 (7.5)	0
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)
Left ventricular dysfunction	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	4 (10.0)	4 (10.0)	0
Nausea	2 (5.0)	2 (5.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
Vomiting	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	7 (17.5)	6 (15.0)	1 (2.5)
Pyrexia	7 (17.5)	6 (15.0)	1 (2.5)
Hepatobiliary disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hepatic function abnormal	2 (5.0)	1 (2.5)	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	22 (55.0)	13 (32.5)	9 (22.5)
Cytokine release syndrome	19 (47.5)	10 (25.0)	9 (22.5)
Hypogammaglobulinaemia	6 (15.0)	6 (15.0)	0
Graft versus host disease	2 (5.0)	2 (5.0)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	1 (2.5)	0
Immunodeficiency	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	18 (45.0)	12 (30.0)	6 (15.0)
Sepsis	3 (7.5)	1 (2.5)	2 (5.0)
Staphylococcal bacteraemia	3 (7.5)	3 (7.5)	0
Bacteraemia	2 (5.0)	2 (5.0)	0
Pneumonia	2 (5.0)	2 (5.0)	0
Septic shock	2 (5.0)	0	2 (5.0)
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Adenovirus infection	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (2.5)	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	1 (2.5)	0
Encephalitis viral	1 (2.5)	0	1 (2.5)
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0
Investigations			
-Total	22 (55.0)	9 (22.5)	13 (32.5)
Neutrophil count decreased	7 (17.5)	1 (2.5)	6 (15.0)
White blood cell count decreased	7 (17.5)	0	7 (17.5)
Lymphocyte count decreased	6 (15.0)	3 (7.5)	3 (7.5)
Aspartate aminotransferase increased	5 (12.5)	3 (7.5)	2 (5.0)
Platelet count decreased	5 (12.5)	1 (2.5)	4 (10.0)
Alanine aminotransferase increased	4 (10.0)	4 (10.0)	0
Blood bilirubin increased	4 (10.0)	4 (10.0)	0
Serum ferritin increased	3 (7.5)	3 (7.5)	0
Blood creatinine increased	2 (5.0)	1 (2.5)	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0
C-reactive protein increased	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	1 (2.5)	1 (2.5)
Weight decreased	2 (5.0)	2 (5.0)	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	20 (50.0)	15 (37.5)	5 (12.5)
Hypokalaemia	9 (22.5)	8 (20.0)	1 (2.5)
Decreased appetite	6 (15.0)	5 (12.5)	1 (2.5)
Hypophosphataemia	4 (10.0)	4 (10.0)	0
Metabolic acidosis	4 (10.0)	2 (5.0)	2 (5.0)
Tumour lysis syndrome	4 (10.0)	3 (7.5)	1 (2.5)
Hypervolaemia	3 (7.5)	3 (7.5)	0
Hyperkalaemia	2 (5.0)	1 (2.5)	1 (2.5)
Acidosis	1 (2.5)	1 (2.5)	0
Hyperglycaemia	1 (2.5)	1 (2.5)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (7.5)	3 (7.5)	0
Pain in extremity	2 (5.0)	2 (5.0)	0
Back pain	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	4 (10.0)	4 (10.0)	0
Seizure	2 (5.0)	2 (5.0)	0
Cognitive disorder	1 (2.5)	1 (2.5)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Somnolence	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	4 (10.0)	4 (10.0)	0
Anxiety	3 (7.5)	3 (7.5)	0
Delirium	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Acute kidney injury	5 (12.5)	2 (5.0)	3 (7.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	15 (37.5)	4 (10.0)	11 (27.5)
Hypoxia	7 (17.5)	3 (7.5)	4 (10.0)
Respiratory failure	5 (12.5)	0	5 (12.5)
Acute respiratory distress syndrome	2 (5.0)	0	2 (5.0)
Pleural effusion	2 (5.0)	1 (2.5)	1 (2.5)
Pulmonary oedema	2 (5.0)	1 (2.5)	1 (2.5)
Tachypnoea	2 (5.0)	2 (5.0)	0
Dyspnoea	1 (2.5)	1 (2.5)	0
Respiratory distress	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	12 (30.0)	7 (17.5)	5 (12.5)
Hypotension	11 (27.5)	6 (15.0)	5 (12.5)
Hypertension	1 (2.5)	1 (2.5)	0
Venoocclusive disease	1 (2.5)	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	4 (23.5)	13 (76.5)
Blood and lymphatic system disorders			
-Total	10 (58.8)	7 (41.2)	3 (17.6)
Febrile neutropenia	7 (41.2)	6 (35.3)	1 (5.9)
Anaemia	3 (17.6)	3 (17.6)	0
Neutropenia	2 (11.8)	1 (5.9)	1 (5.9)
Pancytopenia	2 (11.8)	1 (5.9)	1 (5.9)
Thrombocytopenia	2 (11.8)	2 (11.8)	0
Cardiac disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	2 (11.8)	1 (5.9)	1 (5.9)
Tachycardia	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Gingivitis ulcerative	1 (5.9)	1 (5.9)	0
Mouth haemorrhage	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Pyrexia	2 (11.8)	2 (11.8)	0
Catheter site pain	1 (5.9)	1 (5.9)	0
Multiple organ dysfunction syndrome	1 (5.9)	0	1 (5.9)
Hepatobiliary disorders			
-Total	2 (11.8)	2 (11.8)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Hyperbilirubinaemia	1 (5.9)	1 (5.9)	0
Immune system disorders			
-Total	9 (52.9)	5 (29.4)	4 (23.5)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytokine release syndrome	8 (47.1)	4 (23.5)	4 (23.5)
Allergy to immunoglobulin therapy	1 (5.9)	1 (5.9)	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	1 (5.9)	0
Immunodeficiency	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	11 (64.7)	8 (47.1)	3 (17.6)
Bacteraemia	2 (11.8)	1 (5.9)	1 (5.9)
Parainfluenzae virus infection	2 (11.8)	2 (11.8)	0
Pneumonia	2 (11.8)	1 (5.9)	1 (5.9)
Staphylococcal bacteraemia	2 (11.8)	2 (11.8)	0
Adenovirus infection	1 (5.9)	1 (5.9)	0
Candida infection	1 (5.9)	0	1 (5.9)
Catheter site infection	1 (5.9)	1 (5.9)	0
Clostridium difficile infection	1 (5.9)	1 (5.9)	0
Encephalitis viral	1 (5.9)	1 (5.9)	0
Escherichia bacteraemia	1 (5.9)	0	1 (5.9)
Gastroenteritis	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Granulicatella infection	1 (5.9)	1 (5.9)	0
Herpes simplex	1 (5.9)	1 (5.9)	0
Human herpesvirus 6 infection	1 (5.9)	1 (5.9)	0
Oral herpes	1 (5.9)	1 (5.9)	0
Pharyngitis streptococcal	1 (5.9)	1 (5.9)	0
Pneumonia fungal	1 (5.9)	1 (5.9)	0
Respiratory syncytial virus infection	1 (5.9)	1 (5.9)	0
Respiratory tract infection	1 (5.9)	1 (5.9)	0
Rhinovirus infection	1 (5.9)	1 (5.9)	0
Septic shock	1 (5.9)	0	1 (5.9)
Sinusitis	1 (5.9)	1 (5.9)	0
Staphylococcal abscess	1 (5.9)	1 (5.9)	0
Staphylococcal infection	1 (5.9)	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	1 (5.9)
Systemic candida	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Viral upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Transfusion reaction	1 (5.9)	1 (5.9)	0
Transplant failure	1 (5.9)	0	1 (5.9)
Investigations			
-Total	10 (58.8)	4 (23.5)	6 (35.3)
Aspartate aminotransferase increased	4 (23.5)	4 (23.5)	0
Platelet count decreased	4 (23.5)	1 (5.9)	3 (17.6)
Blood bilirubin increased	2 (11.8)	2 (11.8)	0
C-reactive protein increased	2 (11.8)	1 (5.9)	1 (5.9)
Neutrophil count decreased	2 (11.8)	0	2 (11.8)
White blood cell count decreased	2 (11.8)	0	2 (11.8)
Alanine aminotransferase increased	1 (5.9)	1 (5.9)	0
Blood creatinine increased	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood glucose increased	1 (5.9)	0	1 (5.9)
Blood lactate dehydrogenase increased	1 (5.9)	1 (5.9)	0
Blood phosphorus decreased	1 (5.9)	1 (5.9)	0
Blood potassium decreased	1 (5.9)	0	1 (5.9)
Fibrin d dimer increased	1 (5.9)	0	1 (5.9)
Lymphocyte count decreased	1 (5.9)	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	6 (35.3)	5 (29.4)	1 (5.9)
Decreased appetite	3 (17.6)	3 (17.6)	0
Hypervolaemia	3 (17.6)	3 (17.6)	0
Hypocalcaemia	3 (17.6)	3 (17.6)	0
Hypokalaemia	2 (11.8)	2 (11.8)	0
Hypophosphataemia	2 (11.8)	2 (11.8)	0
Acidosis	1 (5.9)	0	1 (5.9)
Hypoalbuminaemia	1 (5.9)	1 (5.9)	0
Malnutrition	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Polydipsia	1 (5.9)	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (17.6)	3 (17.6)	0
Pain in jaw	2 (11.8)	2 (11.8)	0
Back pain	1 (5.9)	1 (5.9)	0
Joint effusion	1 (5.9)	1 (5.9)	0
Myopathy	1 (5.9)	1 (5.9)	0
Spinal pain	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Cognitive disorder	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Neurological decompensation	1 (5.9)	0	1 (5.9)
Neuropathy peripheral	1 (5.9)	1 (5.9)	0
Somnolence	1 (5.9)	1 (5.9)	0
Psychiatric disorders			

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.8)	2 (11.8)	0
Delirium	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Acute kidney injury	1 (5.9)	1 (5.9)	0
Renal failure	1 (5.9)	0	1 (5.9)
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			
-Total	1 (5.9)	1 (5.9)	0
Endometriosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (41.2)	3 (17.6)	4 (23.5)
Hypoxia	3 (17.6)	3 (17.6)	0
Pulmonary oedema	3 (17.6)	2 (11.8)	1 (5.9)
Respiratory failure	2 (11.8)	0	2 (11.8)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Dyspnoea	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	1 (5.9)	1 (5.9)	0
Laryngeal oedema	1 (5.9)	0	1 (5.9)
Respiratory distress	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			
-Total	1 (5.9)	1 (5.9)	0
Decubitus ulcer	1 (5.9)	1 (5.9)	0
Surgical and medical procedures			
-Total	1 (5.9)	1 (5.9)	0
Thrombolysis	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	5 (29.4)	2 (11.8)	3 (17.6)
Hypotension	4 (23.5)	2 (11.8)	2 (11.8)
Hypertension	1 (5.9)	1 (5.9)	0
Venoocclusive disease	1 (5.9)	0	1 (5.9)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (89.1)	11 (20.0)	38 (69.1)
Blood and lymphatic system disorders			
-Total	28 (50.9)	17 (30.9)	11 (20.0)
Febrile neutropenia	17 (30.9)	17 (30.9)	0
Anaemia	14 (25.5)	13 (23.6)	1 (1.8)
Thrombocytopenia	8 (14.5)	2 (3.6)	6 (10.9)
Neutropenia	7 (12.7)	1 (1.8)	6 (10.9)
Leukopenia	4 (7.3)	0	4 (7.3)
Pancytopenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	8 (14.5)	8 (14.5)	0

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	4 (7.3)	4 (7.3)	0
Left ventricular dysfunction	3 (5.5)	3 (5.5)	0
Cardiac failure	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	3 (5.5)	3 (5.5)	0
Stomatitis	3 (5.5)	3 (5.5)	0
General disorders and administration site conditions			
-Total	8 (14.5)	6 (10.9)	2 (3.6)
Pyrexia	8 (14.5)	6 (10.9)	2 (3.6)
Immune system disorders			
-Total	24 (43.6)	12 (21.8)	12 (21.8)
Cytokine release syndrome	19 (34.5)	8 (14.5)	11 (20.0)
Hypogammaglobulinaemia	4 (7.3)	4 (7.3)	0
Haemophagocytic lymphohistiocytosis	3 (5.5)	2 (3.6)	1 (1.8)
Immunodeficiency	3 (5.5)	3 (5.5)	0
Infections and infestations			
-Total	14 (25.5)	9 (16.4)	5 (9.1)

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	5 (9.1)	3 (5.5)	2 (3.6)
Staphylococcal bacteraemia	4 (7.3)	4 (7.3)	0
Metapneumovirus infection	3 (5.5)	3 (5.5)	0
Parainfluenzae virus infection	3 (5.5)	2 (3.6)	1 (1.8)
Sepsis	3 (5.5)	1 (1.8)	2 (3.6)
Investigations			
-Total	30 (54.5)	10 (18.2)	20 (36.4)
Neutrophil count decreased	14 (25.5)	2 (3.6)	12 (21.8)
White blood cell count decreased	14 (25.5)	1 (1.8)	13 (23.6)
Lymphocyte count decreased	11 (20.0)	4 (7.3)	7 (12.7)
Platelet count decreased	11 (20.0)	4 (7.3)	7 (12.7)
Aspartate aminotransferase increased	9 (16.4)	6 (10.9)	3 (5.5)
Blood bilirubin increased	8 (14.5)	8 (14.5)	0
Alanine aminotransferase increased	6 (10.9)	6 (10.9)	0
Blood creatinine increased	3 (5.5)	3 (5.5)	0
C-reactive protein increased	2 (3.6)	2 (3.6)	0
Serum ferritin increased	1 (1.8)	1 (1.8)	0

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	21 (38.2)	14 (25.5)	7 (12.7)
Hypokalaemia	9 (16.4)	7 (12.7)	2 (3.6)
Decreased appetite	7 (12.7)	5 (9.1)	2 (3.6)
Hyperglycaemia	4 (7.3)	4 (7.3)	0
Tumour lysis syndrome	4 (7.3)	3 (5.5)	1 (1.8)
Hypocalcaemia	3 (5.5)	3 (5.5)	0
Hypophosphataemia	3 (5.5)	2 (3.6)	1 (1.8)
Metabolic acidosis	3 (5.5)	2 (3.6)	1 (1.8)
Hypervolaemia	2 (3.6)	2 (3.6)	0
Nervous system disorders			
-Total	5 (9.1)	5 (9.1)	0
Headache	3 (5.5)	3 (5.5)	0
Encephalopathy	2 (3.6)	2 (3.6)	0
Renal and urinary disorders			
-Total	2 (3.6)	0	2 (3.6)
Acute kidney injury	2 (3.6)	0	2 (3.6)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (29.1)	3 (5.5)	13 (23.6)
Hypoxia	8 (14.5)	4 (7.3)	4 (7.3)
Respiratory failure	7 (12.7)	0	7 (12.7)
Pulmonary oedema	4 (7.3)	2 (3.6)	2 (3.6)
Pleural effusion	3 (5.5)	2 (3.6)	1 (1.8)
Dyspnoea	2 (3.6)	1 (1.8)	1 (1.8)
Tachypnoea	2 (3.6)	1 (1.8)	1 (1.8)
Vascular disorders			
-Total	14 (25.5)	11 (20.0)	3 (5.5)
Hypotension	11 (20.0)	8 (14.5)	3 (5.5)
Hypertension	3 (5.5)	3 (5.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (88.4)	10 (23.3)	28 (65.1)
Blood and lymphatic system disorders			
-Total	29 (67.4)	20 (46.5)	9 (20.9)
Febrile neutropenia	22 (51.2)	19 (44.2)	3 (7.0)
Anaemia	8 (18.6)	8 (18.6)	0
Neutropenia	6 (14.0)	2 (4.7)	4 (9.3)
Thrombocytopenia	4 (9.3)	3 (7.0)	1 (2.3)
Pancytopenia	3 (7.0)	2 (4.7)	1 (2.3)
Leukopenia	1 (2.3)	1 (2.3)	0
Cardiac disorders			
-Total	6 (14.0)	3 (7.0)	3 (7.0)

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	3 (7.0)	1 (2.3)	2 (4.7)
Tachycardia	2 (4.7)	1 (2.3)	1 (2.3)
Left ventricular dysfunction	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	2 (4.7)	2 (4.7)	0
Stomatitis	2 (4.7)	2 (4.7)	0
General disorders and administration site conditions			
-Total	5 (11.6)	5 (11.6)	0
Pyrexia	5 (11.6)	5 (11.6)	0
Immune system disorders			
-Total	21 (48.8)	11 (25.6)	10 (23.3)
Cytokine release syndrome	19 (44.2)	9 (20.9)	10 (23.3)
Hypogammaglobulinaemia	4 (9.3)	4 (9.3)	0
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)
Immunodeficiency	1 (2.3)	1 (2.3)	0
Infections and infestations			
-Total	13 (30.2)	7 (16.3)	6 (14.0)

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	4 (9.3)	3 (7.0)	1 (2.3)
Septic shock	3 (7.0)	0	3 (7.0)
Staphylococcal bacteraemia	3 (7.0)	3 (7.0)	0
Parainfluenzae virus infection	2 (4.7)	2 (4.7)	0
Pneumonia	2 (4.7)	1 (2.3)	1 (2.3)
Sepsis	1 (2.3)	0	1 (2.3)
Investigations			
-Total	26 (60.5)	8 (18.6)	18 (41.9)
Neutrophil count decreased	12 (27.9)	1 (2.3)	11 (25.6)
White blood cell count decreased	12 (27.9)	0	12 (27.9)
Lymphocyte count decreased	10 (23.3)	5 (11.6)	5 (11.6)
Platelet count decreased	9 (20.9)	2 (4.7)	7 (16.3)
Aspartate aminotransferase increased	5 (11.6)	4 (9.3)	1 (2.3)
C-reactive protein increased	4 (9.3)	3 (7.0)	1 (2.3)
Alanine aminotransferase increased	3 (7.0)	3 (7.0)	0
Blood lactate dehydrogenase increased	3 (7.0)	3 (7.0)	0
Serum ferritin increased	3 (7.0)	2 (4.7)	1 (2.3)

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	2 (4.7)	2 (4.7)	0
Blood creatinine increased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	16 (37.2)	12 (27.9)	4 (9.3)
Decreased appetite	7 (16.3)	7 (16.3)	0
Hypokalaemia	7 (16.3)	6 (14.0)	1 (2.3)
Hypophosphataemia	7 (16.3)	7 (16.3)	0
Hypervolaemia	4 (9.3)	4 (9.3)	0
Hypocalcaemia	3 (7.0)	3 (7.0)	0
Metabolic acidosis	2 (4.7)	0	2 (4.7)
Tumour lysis syndrome	2 (4.7)	1 (2.3)	1 (2.3)
Hyperglycaemia	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.0)	3 (7.0)	0
Pain in extremity	3 (7.0)	3 (7.0)	0
Nervous system disorders			
-Total	3 (7.0)	3 (7.0)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	3 (7.0)	3 (7.0)	0
Psychiatric disorders			
-Total	6 (14.0)	6 (14.0)	0
Anxiety	3 (7.0)	3 (7.0)	0
Mental status changes	3 (7.0)	3 (7.0)	0
Renal and urinary disorders			
-Total	6 (14.0)	3 (7.0)	3 (7.0)
Acute kidney injury	6 (14.0)	3 (7.0)	3 (7.0)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (39.5)	9 (20.9)	8 (18.6)
Hypoxia	8 (18.6)	6 (14.0)	2 (4.7)
Acute respiratory distress syndrome	4 (9.3)	0	4 (9.3)
Pulmonary oedema	4 (9.3)	4 (9.3)	0
Dyspnoea	3 (7.0)	2 (4.7)	1 (2.3)
Respiratory failure	3 (7.0)	0	3 (7.0)
Tachypnoea	3 (7.0)	3 (7.0)	0
Vascular disorders			

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (25.6)	4 (9.3)	7 (16.3)
Hypotension	11 (25.6)	4 (9.3)	7 (16.3)
Hypertension	2 (4.7)	2 (4.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (91.4)	17 (24.3)	47 (67.1)
Blood and lymphatic system disorders			
-Total	40 (57.1)	27 (38.6)	13 (18.6)
Febrile neutropenia	25 (35.7)	24 (34.3)	1 (1.4)
Anaemia	15 (21.4)	14 (20.0)	1 (1.4)
Neutropenia	9 (12.9)	3 (4.3)	6 (8.6)
Thrombocytopenia	8 (11.4)	3 (4.3)	5 (7.1)
Pancytopenia	4 (5.7)	3 (4.3)	1 (1.4)
Leukopenia	3 (4.3)	1 (1.4)	2 (2.9)
Disseminated intravascular coagulation	2 (2.9)	2 (2.9)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	11 (15.7)	8 (11.4)	3 (4.3)
Tachycardia	6 (8.6)	5 (7.1)	1 (1.4)
Cardiac failure	3 (4.3)	2 (2.9)	1 (1.4)
Left ventricular dysfunction	2 (2.9)	2 (2.9)	0
Cardiac arrest	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	5 (7.1)	5 (7.1)	0
Stomatitis	3 (4.3)	3 (4.3)	0
Nausea	2 (2.9)	2 (2.9)	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	10 (14.3)	7 (10.0)	3 (4.3)
Pyrexia	9 (12.9)	7 (10.0)	2 (2.9)
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	31 (44.3)	19 (27.1)	12 (17.1)
Cytokine release syndrome	26 (37.1)	14 (20.0)	12 (17.1)
Hypogammaglobulinaemia	8 (11.4)	8 (11.4)	0
Haemophagocytic lymphohistiocytosis	3 (4.3)	2 (2.9)	1 (1.4)
Immunodeficiency	3 (4.3)	3 (4.3)	0
Infections and infestations			
-Total	23 (32.9)	16 (22.9)	7 (10.0)
Parainfluenzae virus infection	4 (5.7)	3 (4.3)	1 (1.4)
Pneumonia	4 (5.7)	3 (4.3)	1 (1.4)
Sepsis	4 (5.7)	1 (1.4)	3 (4.3)
Staphylococcal bacteraemia	4 (5.7)	4 (5.7)	0
Staphylococcal infection	4 (5.7)	3 (4.3)	1 (1.4)
Bacteraemia	2 (2.9)	2 (2.9)	0
Bronchopulmonary aspergillosis	2 (2.9)	1 (1.4)	1 (1.4)
Adenovirus infection	1 (1.4)	1 (1.4)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	40 (57.1)	15 (21.4)	25 (35.7)
Neutrophil count decreased	18 (25.7)	3 (4.3)	15 (21.4)
Lymphocyte count decreased	17 (24.3)	8 (11.4)	9 (12.9)
White blood cell count decreased	16 (22.9)	1 (1.4)	15 (21.4)
Platelet count decreased	14 (20.0)	4 (5.7)	10 (14.3)
Aspartate aminotransferase increased	9 (12.9)	7 (10.0)	2 (2.9)
Blood bilirubin increased	7 (10.0)	7 (10.0)	0
Alanine aminotransferase increased	5 (7.1)	5 (7.1)	0
C-reactive protein increased	4 (5.7)	4 (5.7)	0
Blood creatinine increased	3 (4.3)	2 (2.9)	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatine phosphokinase increased	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Gamma-glutamyltransferase increased	1 (1.4)	1 (1.4)	0
Serum ferritin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	26 (37.1)	18 (25.7)	8 (11.4)
Hypokalaemia	11 (15.7)	8 (11.4)	3 (4.3)
Decreased appetite	9 (12.9)	7 (10.0)	2 (2.9)
Hypophosphataemia	6 (8.6)	6 (8.6)	0
Hypervolaemia	4 (5.7)	4 (5.7)	0
Hyperglycaemia	3 (4.3)	3 (4.3)	0
Hypocalcaemia	3 (4.3)	3 (4.3)	0
Metabolic acidosis	3 (4.3)	2 (2.9)	1 (1.4)
Tumour lysis syndrome	3 (4.3)	1 (1.4)	2 (2.9)
Hyperkalaemia	2 (2.9)	2 (2.9)	0
Acidosis	1 (1.4)	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (5.7)	4 (5.7)	0
Back pain	3 (4.3)	3 (4.3)	0
Pain in extremity	1 (1.4)	1 (1.4)	0
Pain in jaw	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	6 (8.6)	6 (8.6)	0
Encephalopathy	5 (7.1)	5 (7.1)	0
Cognitive disorder	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	3 (4.3)	3 (4.3)	0
Mental status changes	2 (2.9)	2 (2.9)	0
Anxiety	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	6 (8.6)	3 (4.3)	3 (4.3)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	6 (8.6)	3 (4.3)	3 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	23 (32.9)	10 (14.3)	13 (18.6)
Hypoxia	10 (14.3)	8 (11.4)	2 (2.9)
Respiratory failure	8 (11.4)	0	8 (11.4)
Pulmonary oedema	6 (8.6)	4 (5.7)	2 (2.9)
Tachypnoea	4 (5.7)	4 (5.7)	0
Acute respiratory distress syndrome	3 (4.3)	0	3 (4.3)
Dyspnoea	3 (4.3)	2 (2.9)	1 (1.4)
Epistaxis	2 (2.9)	2 (2.9)	0
Pleural effusion	2 (2.9)	2 (2.9)	0
Vascular disorders			
-Total	18 (25.7)	11 (15.7)	7 (10.0)
Hypotension	18 (25.7)	11 (15.7)	7 (10.0)
Hypertension	1 (1.4)	1 (1.4)	0
Venoocclusive disease	1 (1.4)	1 (1.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (73.3)	3 (20.0)	8 (53.3)
Blood and lymphatic system disorders			
-Total	7 (46.7)	2 (13.3)	5 (33.3)
Febrile neutropenia	4 (26.7)	4 (26.7)	0
Neutropenia	4 (26.7)	0	4 (26.7)
Leukopenia	2 (13.3)	0	2 (13.3)
Thrombocytopenia	2 (13.3)	0	2 (13.3)
Anaemia	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	1 (6.7)	0
Lymphopenia	1 (6.7)	0	1 (6.7)

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Cardiac disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Cardiac arrest	1 (6.7)	0	1 (6.7)
Cardiac failure	1 (6.7)	0	1 (6.7)
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	3 (20.0)	3 (20.0)	0
Anal inflammation	1 (6.7)	1 (6.7)	0
Duodenal perforation	1 (6.7)	1 (6.7)	0
Oral pain	1 (6.7)	1 (6.7)	0
Stomatitis	1 (6.7)	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Hepatobiliary disorders			
-Total	4 (26.7)	2 (13.3)	2 (13.3)

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic function abnormal	3 (20.0)	2 (13.3)	1 (6.7)
Hepatomegaly	1 (6.7)	0	1 (6.7)
Immune system disorders			
-Total	5 (33.3)	2 (13.3)	3 (20.0)
Cytokine release syndrome	5 (33.3)	2 (13.3)	3 (20.0)
Infections and infestations			
-Total	7 (46.7)	6 (40.0)	1 (6.7)
Bacteraemia	1 (6.7)	1 (6.7)	0
Bronchopulmonary aspergillosis	1 (6.7)	1 (6.7)	0
Cytomegalovirus infection reactivation	1 (6.7)	1 (6.7)	0
Encephalitis viral	1 (6.7)	0	1 (6.7)
Escherichia bacteraemia	1 (6.7)	1 (6.7)	0
Human herpesvirus 6 infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Meningitis bacterial	1 (6.7)	1 (6.7)	0
Oral herpes	1 (6.7)	1 (6.7)	0
Peritonitis	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	1 (6.7)	0

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Viral infection	1 (6.7)	1 (6.7)	0
Investigations			
-Total	6 (40.0)	2 (13.3)	4 (26.7)
White blood cell count decreased	4 (26.7)	0	4 (26.7)
Neutrophil count decreased	2 (13.3)	0	2 (13.3)
Alanine aminotransferase increased	1 (6.7)	1 (6.7)	0
Aspartate aminotransferase increased	1 (6.7)	1 (6.7)	0
Blood bilirubin increased	1 (6.7)	1 (6.7)	0
Blood creatine phosphokinase increased	1 (6.7)	1 (6.7)	0
Blood fibrinogen decreased	1 (6.7)	1 (6.7)	0
Blood lactate dehydrogenase increased	1 (6.7)	1 (6.7)	0
Gamma-glutamyltransferase increased	1 (6.7)	1 (6.7)	0
Platelet count decreased	1 (6.7)	1 (6.7)	0

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Metabolic acidosis	2 (13.3)	0	2 (13.3)
Tumour lysis syndrome	2 (13.3)	2 (13.3)	0
Hypercalcaemia	1 (6.7)	0	1 (6.7)
Hyperkalaemia	1 (6.7)	0	1 (6.7)
Hyperphosphataemia	1 (6.7)	0	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (13.3)	2 (13.3)	0
Back pain	1 (6.7)	1 (6.7)	0
Muscular weakness	1 (6.7)	1 (6.7)	0
Pain in extremity	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	1 (6.7)	0	1 (6.7)
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	1 (6.7)	0
Anxiety	1 (6.7)	1 (6.7)	0
Renal and urinary disorders			
-Total	2 (13.3)	0	2 (13.3)
Acute kidney injury	2 (13.3)	0	2 (13.3)
Reproductive system and breast disorders			
-Total	1 (6.7)	1 (6.7)	0
Endometriosis	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (26.7)	0	4 (26.7)
Hypoxia	4 (26.7)	0	4 (26.7)
Dyspnoea	1 (6.7)	1 (6.7)	0
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)

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Table 223c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	13 (100)
Blood and lymphatic system disorders			
-Total	10 (76.9)	8 (61.5)	2 (15.4)
Febrile neutropenia	10 (76.9)	8 (61.5)	2 (15.4)
Anaemia	6 (46.2)	6 (46.2)	0
Thrombocytopenia	2 (15.4)	2 (15.4)	0
Cardiac disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Cardiac arrest	1 (7.7)	0	1 (7.7)
Left ventricular dysfunction	1 (7.7)	1 (7.7)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinus bradycardia	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	4 (30.8)	4 (30.8)	0
Mouth haemorrhage	1 (7.7)	1 (7.7)	0
Nausea	1 (7.7)	1 (7.7)	0
Pancreatitis	1 (7.7)	1 (7.7)	0
Stomatitis	1 (7.7)	1 (7.7)	0
Vomiting	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			
-Total	6 (46.2)	4 (30.8)	2 (15.4)
Pyrexia	3 (23.1)	3 (23.1)	0
Multiple organ dysfunction syndrome	2 (15.4)	0	2 (15.4)
Generalised oedema	1 (7.7)	1 (7.7)	0
Pain	1 (7.7)	1 (7.7)	0
Hepatobiliary disorders			
-Total	2 (15.4)	2 (15.4)	0
Hyperbilirubinaemia	2 (15.4)	2 (15.4)	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	9 (69.2)	2 (15.4)	7 (53.8)
Cytokine release syndrome	7 (53.8)	1 (7.7)	6 (46.2)
Allergy to immunoglobulin therapy	1 (7.7)	1 (7.7)	0
Chronic graft versus host disease	1 (7.7)	1 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	1 (7.7)
Immunodeficiency	1 (7.7)	1 (7.7)	0
Infections and infestations			
-Total	8 (61.5)	4 (30.8)	4 (30.8)
Pneumonia	2 (15.4)	0	2 (15.4)
Staphylococcal bacteraemia	2 (15.4)	2 (15.4)	0
Adenovirus infection	1 (7.7)	1 (7.7)	0
Bacteraemia	1 (7.7)	0	1 (7.7)
Covid-19 pneumonia	1 (7.7)	0	1 (7.7)
Encephalitis viral	1 (7.7)	1 (7.7)	0
Enterobacter infection	1 (7.7)	1 (7.7)	0
Enterovirus infection	1 (7.7)	1 (7.7)	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (7.7)	0	1 (7.7)
Fungaemia	1 (7.7)	0	1 (7.7)
Herpes zoster	1 (7.7)	1 (7.7)	0
Influenza	1 (7.7)	0	1 (7.7)
Klebsiella infection	1 (7.7)	1 (7.7)	0
Mastoiditis	1 (7.7)	1 (7.7)	0
Oral herpes	1 (7.7)	1 (7.7)	0
Otitis externa	1 (7.7)	1 (7.7)	0
Otitis media	1 (7.7)	1 (7.7)	0
Parainfluenzae virus infection	1 (7.7)	1 (7.7)	0
Pharyngitis streptococcal	1 (7.7)	1 (7.7)	0
Respiratory syncytial virus infection	1 (7.7)	1 (7.7)	0
Respiratory tract infection	1 (7.7)	1 (7.7)	0
Rhinovirus infection	1 (7.7)	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	1 (7.7)	0
Urinary tract infection	1 (7.7)	1 (7.7)	0
Viral upper respiratory tract infection	1 (7.7)	1 (7.7)	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (7.7)	1 (7.7)	0
Transfusion reaction	1 (7.7)	1 (7.7)	0
Investigations			
-Total	10 (76.9)	1 (7.7)	9 (69.2)
Neutrophil count decreased	6 (46.2)	0	6 (46.2)
White blood cell count decreased	6 (46.2)	0	6 (46.2)
Platelet count decreased	5 (38.5)	1 (7.7)	4 (30.8)
Aspartate aminotransferase increased	4 (30.8)	2 (15.4)	2 (15.4)
Lymphocyte count decreased	4 (30.8)	1 (7.7)	3 (23.1)
Alanine aminotransferase increased	3 (23.1)	3 (23.1)	0
Blood bilirubin increased	2 (15.4)	2 (15.4)	0
Blood lactate dehydrogenase increased	2 (15.4)	2 (15.4)	0
C-reactive protein increased	2 (15.4)	1 (7.7)	1 (7.7)
Fibrin d dimer increased	2 (15.4)	1 (7.7)	1 (7.7)
Serum ferritin increased	2 (15.4)	1 (7.7)	1 (7.7)

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (7.7)	1 (7.7)	0
Blood creatinine increased	1 (7.7)	1 (7.7)	0
Blood fibrinogen decreased	1 (7.7)	0	1 (7.7)
Blood uric acid increased	1 (7.7)	1 (7.7)	0
Electrocardiogram qt prolonged	1 (7.7)	0	1 (7.7)
Oxygen saturation decreased	1 (7.7)	1 (7.7)	0
Troponin increased	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	9 (69.2)	7 (53.8)	2 (15.4)
Decreased appetite	5 (38.5)	5 (38.5)	0
Hypokalaemia	5 (38.5)	5 (38.5)	0
Hypophosphataemia	4 (30.8)	3 (23.1)	1 (7.7)
Hypocalcaemia	3 (23.1)	3 (23.1)	0
Hyperglycaemia	2 (15.4)	2 (15.4)	0
Hypervolaemia	2 (15.4)	2 (15.4)	0
Acidosis	1 (7.7)	0	1 (7.7)
Hypoalbuminaemia	1 (7.7)	1 (7.7)	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (7.7)	1 (7.7)	0
Obesity	1 (7.7)	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	1 (7.7)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (30.8)	4 (30.8)	0
Arthralgia	1 (7.7)	1 (7.7)	0
Haemarthrosis	1 (7.7)	1 (7.7)	0
Myopathy	1 (7.7)	1 (7.7)	0
Pain in extremity	1 (7.7)	1 (7.7)	0
Pain in jaw	1 (7.7)	1 (7.7)	0
Nervous system disorders			
-Total	2 (15.4)	2 (15.4)	0
Cognitive disorder	1 (7.7)	1 (7.7)	0
Neuropathy peripheral	1 (7.7)	1 (7.7)	0
Psychiatric disorders			
-Total	2 (15.4)	2 (15.4)	0
Anxiety	1 (7.7)	1 (7.7)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (7.7)	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (53.8)	3 (23.1)	4 (30.8)
Hypoxia	2 (15.4)	2 (15.4)	0
Pulmonary oedema	2 (15.4)	2 (15.4)	0
Acute respiratory distress syndrome	1 (7.7)	0	1 (7.7)
Dyspnoea	1 (7.7)	0	1 (7.7)
Epistaxis	1 (7.7)	1 (7.7)	0
Pleural effusion	1 (7.7)	0	1 (7.7)
Pulmonary haemorrhage	1 (7.7)	0	1 (7.7)
Respiratory failure	1 (7.7)	0	1 (7.7)
Tachypnoea	1 (7.7)	0	1 (7.7)
Skin and subcutaneous tissue disorders			
-Total	2 (15.4)	2 (15.4)	0
Decubitus ulcer	1 (7.7)	1 (7.7)	0
Rash maculo-papular	1 (7.7)	1 (7.7)	0
Surgical and medical procedures			

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (7.7)	1 (7.7)	0
Thrombolysis	1 (7.7)	1 (7.7)	0
Vascular disorders			
-Total	7 (53.8)	4 (30.8)	3 (23.1)
Hypertension	4 (30.8)	4 (30.8)	0
Hypotension	2 (15.4)	0	2 (15.4)
Capillary leak syndrome	1 (7.7)	1 (7.7)	0
Venoocclusive disease	1 (7.7)	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	2 (11.1)	16 (88.9)
Blood and lymphatic system disorders			
-Total	11 (61.1)	8 (44.4)	3 (16.7)
Febrile neutropenia	10 (55.6)	8 (44.4)	2 (11.1)
Anaemia	6 (33.3)	5 (27.8)	1 (5.6)
Thrombocytopenia	3 (16.7)	3 (16.7)	0
Coagulopathy	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cardiac arrest	1 (5.6)	0	1 (5.6)
Cardiac failure	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Sinus bradycardia	1 (5.6)	1 (5.6)	0
Tachycardia	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Mouth haemorrhage	1 (5.6)	1 (5.6)	0
Vomiting	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	5 (27.8)	4 (22.2)	1 (5.6)
Pyrexia	4 (22.2)	4 (22.2)	0
Multiple organ dysfunction syndrome	1 (5.6)	0	1 (5.6)
Hepatobiliary disorders			
-Total	1 (5.6)	1 (5.6)	0
Hyperbilirubinaemia	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	10 (55.6)	2 (11.1)	8 (44.4)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	9 (50.0)	1 (5.6)	8 (44.4)
Allergy to immunoglobulin therapy	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Haemophagocytic lymphohistiocytosis	1 (5.6)	1 (5.6)	0
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	11 (61.1)	7 (38.9)	4 (22.2)
Adenovirus infection	2 (11.1)	2 (11.1)	0
Bacteraemia	2 (11.1)	1 (5.6)	1 (5.6)
Escherichia bacteraemia	2 (11.1)	1 (5.6)	1 (5.6)
Staphylococcal bacteraemia	2 (11.1)	2 (11.1)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bk virus infection	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Encephalitis viral	1 (5.6)	1 (5.6)	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0
Metapneumovirus infection	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pharyngitis streptococcal	1 (5.6)	1 (5.6)	0
Pneumocystis jirovecii pneumonia	1 (5.6)	1 (5.6)	0
Pneumonia fungal	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Septic shock	1 (5.6)	0	1 (5.6)
Sinusitis	1 (5.6)	1 (5.6)	0
Sinusitis fungal	1 (5.6)	1 (5.6)	0
Upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	2 (11.1)	2 (11.1)	0
Procedural pain	1 (5.6)	1 (5.6)	0
Transfusion reaction	1 (5.6)	1 (5.6)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (61.1)	2 (11.1)	9 (50.0)
Aspartate aminotransferase increased	6 (33.3)	4 (22.2)	2 (11.1)
Alanine aminotransferase increased	4 (22.2)	4 (22.2)	0
Blood bilirubin increased	4 (22.2)	4 (22.2)	0
Neutrophil count decreased	4 (22.2)	0	4 (22.2)
Platelet count decreased	4 (22.2)	0	4 (22.2)
White blood cell count decreased	4 (22.2)	0	4 (22.2)
Blood creatinine increased	2 (11.1)	2 (11.1)	0
Blood lactate dehydrogenase increased	2 (11.1)	2 (11.1)	0
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)
Fibrin d dimer increased	2 (11.1)	1 (5.6)	1 (5.6)
Serum ferritin increased	2 (11.1)	1 (5.6)	1 (5.6)
Activated partial thromboplastin time prolonged	1 (5.6)	1 (5.6)	0
Blood uric acid increased	1 (5.6)	0	1 (5.6)
Electrocardiogram qt prolonged	1 (5.6)	0	1 (5.6)
Lymphocyte count decreased	1 (5.6)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Troponin increased	1 (5.6)	1 (5.6)	0
Urine output decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	11 (61.1)	7 (38.9)	4 (22.2)
Decreased appetite	6 (33.3)	6 (33.3)	0
Hypocalcaemia	4 (22.2)	4 (22.2)	0
Hypokalaemia	4 (22.2)	3 (16.7)	1 (5.6)
Hypophosphataemia	4 (22.2)	4 (22.2)	0
Hypervolaemia	3 (16.7)	3 (16.7)	0
Tumour lysis syndrome	3 (16.7)	2 (11.1)	1 (5.6)
Acidosis	2 (11.1)	1 (5.6)	1 (5.6)
Hyperglycaemia	2 (11.1)	2 (11.1)	0
Hyperkalaemia	2 (11.1)	2 (11.1)	0
Malnutrition	2 (11.1)	2 (11.1)	0
Metabolic acidosis	2 (11.1)	1 (5.6)	1 (5.6)
Hypercalcaemia	1 (5.6)	1 (5.6)	0
Hyperuricaemia	1 (5.6)	1 (5.6)	0
Hypoalbuminaemia	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Obesity	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (27.8)	5 (27.8)	0
Arthralgia	1 (5.6)	1 (5.6)	0
Back pain	1 (5.6)	1 (5.6)	0
Haemarthrosis	1 (5.6)	1 (5.6)	0
Myopathy	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	1 (5.6)	0
Pain in jaw	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	4 (22.2)	2 (11.1)	2 (11.1)
Cerebral haemorrhage	1 (5.6)	0	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Neurological decompensation	1 (5.6)	0	1 (5.6)
Neuropathy peripheral	1 (5.6)	1 (5.6)	0
Somnolence	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	3 (16.7)	3 (16.7)	0
Anxiety	1 (5.6)	1 (5.6)	0
Delirium	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	5 (27.8)	2 (11.1)	3 (16.7)
Acute kidney injury	3 (16.7)	1 (5.6)	2 (11.1)
Haematuria	1 (5.6)	1 (5.6)	0
Renal failure	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (50.0)	3 (16.7)	6 (33.3)
Hypoxia	3 (16.7)	2 (11.1)	1 (5.6)
Pulmonary oedema	3 (16.7)	2 (11.1)	1 (5.6)
Acute respiratory distress syndrome	2 (11.1)	0	2 (11.1)
Pleural effusion	2 (11.1)	1 (5.6)	1 (5.6)
Respiratory failure	2 (11.1)	0	2 (11.1)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (5.6)	1 (5.6)	0
Epistaxis	1 (5.6)	1 (5.6)	0
Respiratory distress	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.6)	1 (5.6)	0
Decubitus ulcer	1 (5.6)	1 (5.6)	0
Surgical and medical procedures			
-Total	1 (5.6)	1 (5.6)	0
Thrombolysis	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	10 (55.6)	7 (38.9)	3 (16.7)
Hypotension	8 (44.4)	5 (27.8)	3 (16.7)
Hypertension	2 (11.1)	2 (11.1)	0
Capillary leak syndrome	1 (5.6)	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (87.5)	19 (23.8)	51 (63.8)
Blood and lymphatic system disorders			
-Total	46 (57.5)	29 (36.3)	17 (21.3)
Febrile neutropenia	29 (36.3)	28 (35.0)	1 (1.3)
Anaemia	16 (20.0)	16 (20.0)	0
Neutropenia	13 (16.3)	3 (3.8)	10 (12.5)
Thrombocytopenia	9 (11.3)	2 (2.5)	7 (8.8)
Leukopenia	5 (6.3)	1 (1.3)	4 (5.0)
Pancytopenia	4 (5.0)	3 (3.8)	1 (1.3)
Coagulopathy	1 (1.3)	1 (1.3)	0
Cardiac disorders			

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (16.3)	8 (10.0)	5 (6.3)
Tachycardia	5 (6.3)	4 (5.0)	1 (1.3)
Cardiac failure	3 (3.8)	1 (1.3)	2 (2.5)
Left ventricular dysfunction	3 (3.8)	3 (3.8)	0
Cardiac arrest	2 (2.5)	0	2 (2.5)
Gastrointestinal disorders			
-Total	7 (8.8)	6 (7.5)	1 (1.3)
Stomatitis	5 (6.3)	5 (6.3)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Mouth haemorrhage	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	11 (13.8)	7 (8.8)	4 (5.0)
Pyrexia	9 (11.3)	7 (8.8)	2 (2.5)
Multiple organ dysfunction syndrome	2 (2.5)	0	2 (2.5)
Hepatobiliary disorders			
-Total	1 (1.3)	1 (1.3)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (1.3)	1 (1.3)	0
Immune system disorders			
-Total	37 (46.3)	23 (28.8)	14 (17.5)
Cytokine release syndrome	29 (36.3)	16 (20.0)	13 (16.3)
Hypogammaglobulinaemia	7 (8.8)	7 (8.8)	0
Immunodeficiency	4 (5.0)	4 (5.0)	0
Haemophagocytic lymphohistiocytosis	3 (3.8)	1 (1.3)	2 (2.5)
Graft versus host disease	2 (2.5)	2 (2.5)	0
Infections and infestations			
-Total	29 (36.3)	18 (22.5)	11 (13.8)
Pneumonia	7 (8.8)	4 (5.0)	3 (3.8)
Parainfluenzae virus infection	5 (6.3)	4 (5.0)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	5 (6.3)	0
Sepsis	4 (5.0)	1 (1.3)	3 (3.8)
Staphylococcal infection	4 (5.0)	3 (3.8)	1 (1.3)
Bacteraemia	2 (2.5)	2 (2.5)	0
Metapneumovirus infection	2 (2.5)	2 (2.5)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	2 (2.5)	0	2 (2.5)
Sinusitis	2 (2.5)	2 (2.5)	0
Upper respiratory tract infection	2 (2.5)	2 (2.5)	0
Encephalitis viral	1 (1.3)	0	1 (1.3)
Escherichia bacteraemia	1 (1.3)	1 (1.3)	0
Oral herpes	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	1 (1.3)	0
Investigations			
-Total	45 (56.3)	16 (20.0)	29 (36.3)
Neutrophil count decreased	22 (27.5)	3 (3.8)	19 (23.8)
White blood cell count decreased	22 (27.5)	1 (1.3)	21 (26.3)
Lymphocyte count decreased	20 (25.0)	9 (11.3)	11 (13.8)
Platelet count decreased	16 (20.0)	6 (7.5)	10 (12.5)
Aspartate aminotransferase increased	8 (10.0)	6 (7.5)	2 (2.5)
Blood bilirubin increased	6 (7.5)	6 (7.5)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	5 (6.3)	5 (6.3)	0
C-reactive protein increased	4 (5.0)	4 (5.0)	0
Blood creatinine increased	2 (2.5)	1 (1.3)	1 (1.3)
Serum ferritin increased	2 (2.5)	2 (2.5)	0
Blood lactate dehydrogenase increased	1 (1.3)	1 (1.3)	0
Blood uric acid increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	1 (1.3)	0
Urine output decreased	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	27 (33.8)	19 (23.8)	8 (10.0)
Hypokalaemia	12 (15.0)	10 (12.5)	2 (2.5)
Decreased appetite	8 (10.0)	6 (7.5)	2 (2.5)
Hypophosphataemia	6 (7.5)	5 (6.3)	1 (1.3)
Hyperglycaemia	3 (3.8)	3 (3.8)	0
Hypervolaemia	3 (3.8)	3 (3.8)	0
Metabolic acidosis	3 (3.8)	1 (1.3)	2 (2.5)
Tumour lysis syndrome	3 (3.8)	2 (2.5)	1 (1.3)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (2.5)	2 (2.5)	0
Hypercalcaemia	1 (1.3)	0	1 (1.3)
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.3)	5 (6.3)	0
Back pain	3 (3.8)	3 (3.8)	0
Pain in extremity	2 (2.5)	2 (2.5)	0
Pain in jaw	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	6 (7.5)	5 (6.3)	1 (1.3)
Encephalopathy	4 (5.0)	4 (5.0)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	1 (1.3)	0
Somnolence	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	6 (7.5)	6 (7.5)	0
Anxiety	2 (2.5)	2 (2.5)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	2 (2.5)	2 (2.5)	0
Mental status changes	2 (2.5)	2 (2.5)	0
Renal and urinary disorders			
-Total	5 (6.3)	2 (2.5)	3 (3.8)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	25 (31.3)	10 (12.5)	15 (18.8)
Hypoxia	13 (16.3)	8 (10.0)	5 (6.3)
Respiratory failure	8 (10.0)	0	8 (10.0)
Dyspnoea	5 (6.3)	3 (3.8)	2 (2.5)
Pulmonary oedema	5 (6.3)	4 (5.0)	1 (1.3)
Tachypnoea	4 (5.0)	3 (3.8)	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	2 (2.5)
Epistaxis	2 (2.5)	2 (2.5)	0
Pleural effusion	1 (1.3)	1 (1.3)	0
Respiratory distress	1 (1.3)	0	1 (1.3)
Vascular disorders			

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	16 (20.0)	9 (11.3)	7 (8.8)
Hypotension	14 (17.5)	7 (8.8)	7 (8.8)
Hypertension	3 (3.8)	3 (3.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Febrile neutropenia	3 (37.5)	2 (25.0)	1 (12.5)
Anaemia	1 (12.5)	1 (12.5)	0
Coagulopathy	1 (12.5)	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Tachycardia	3 (37.5)	2 (25.0)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)
Melaena	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Pyrexia	2 (25.0)	2 (25.0)	0
Multiple organ dysfunction syndrome	1 (12.5)	0	1 (12.5)
Systemic inflammatory response syndrome	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cholestasis	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	2 (25.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Encephalitis	1 (12.5)	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Vulval cellulitis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)
Vasoplegia syndrome	1 (12.5)	0	1 (12.5)
Wound	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	1 (12.5)	2 (25.0)
Aspartate aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	1 (12.5)
Lipase increased	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	5 (62.5)	4 (50.0)	1 (12.5)
Hypophosphataemia	2 (25.0)	2 (25.0)	0
Metabolic acidosis	2 (25.0)	2 (25.0)	0
Acidosis	1 (12.5)	1 (12.5)	0
Hyperkalaemia	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (12.5)	0	1 (12.5)
Hyperuricaemia	1 (12.5)	1 (12.5)	0
Hypocalcaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Rhabdomyolysis	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	2 (25.0)	2 (25.0)	0
Cognitive disorder	1 (12.5)	1 (12.5)	0
Encephalopathy	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Irritability	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (12.5)	0	1 (12.5)
Reproductive system and breast disorders			
-Total	1 (12.5)	1 (12.5)	0
Vaginal ulceration	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Respiratory failure	2 (25.0)	0	2 (25.0)
Tachypnoea	2 (25.0)	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	1 (12.5)
Acute respiratory failure	1 (12.5)	1 (12.5)	0
Atelectasis	1 (12.5)	1 (12.5)	0
Dyspnoea	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory acidosis	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Petechiae	1 (12.5)	1 (12.5)	0
Skin necrosis	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	3 (37.5)	1 (12.5)
Hypertension	1 (12.5)	1 (12.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (86.7)	18 (20.0)	60 (66.7)
Blood and lymphatic system disorders			
-Total	50 (55.6)	33 (36.7)	17 (18.9)
Febrile neutropenia	36 (40.0)	34 (37.8)	2 (2.2)
Anaemia	21 (23.3)	20 (22.2)	1 (1.1)
Neutropenia	13 (14.4)	3 (3.3)	10 (11.1)
Thrombocytopenia	11 (12.2)	5 (5.6)	6 (6.7)
Leukopenia	5 (5.6)	1 (1.1)	4 (4.4)
Disseminated intravascular coagulation	2 (2.2)	2 (2.2)	0
Coagulopathy	1 (1.1)	1 (1.1)	0
Cardiac disorders			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (3.3)	3 (3.3)	0
Tachycardia	3 (3.3)	3 (3.3)	0
Gastrointestinal disorders			
-Total	6 (6.7)	5 (5.6)	1 (1.1)
Stomatitis	5 (5.6)	5 (5.6)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
General disorders and administration site conditions			
-Total	13 (14.4)	9 (10.0)	4 (4.4)
Pyrexia	11 (12.2)	9 (10.0)	2 (2.2)
Multiple organ dysfunction syndrome	2 (2.2)	0	2 (2.2)
Immune system disorders			
-Total	41 (45.6)	21 (23.3)	20 (22.2)
Cytokine release syndrome	36 (40.0)	17 (18.9)	19 (21.1)
Hypogammaglobulinaemia	7 (7.8)	7 (7.8)	0
Haemophagocytic lymphohistiocytosis	3 (3.3)	2 (2.2)	1 (1.1)
Infections and infestations			
-Total	17 (18.9)	12 (13.3)	5 (5.6)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	6 (6.7)	3 (3.3)	3 (3.3)
Staphylococcal bacteraemia	6 (6.7)	6 (6.7)	0
Parainfluenzae virus infection	5 (5.6)	4 (4.4)	1 (1.1)
Staphylococcal infection	3 (3.3)	3 (3.3)	0
Encephalitis	1 (1.1)	0	1 (1.1)
Investigations			
-Total	51 (56.7)	17 (18.9)	34 (37.8)
White blood cell count decreased	25 (27.8)	1 (1.1)	24 (26.7)
Neutrophil count decreased	23 (25.6)	2 (2.2)	21 (23.3)
Lymphocyte count decreased	20 (22.2)	8 (8.9)	12 (13.3)
Platelet count decreased	19 (21.1)	6 (6.7)	13 (14.4)
Aspartate aminotransferase increased	12 (13.3)	9 (10.0)	3 (3.3)
Blood bilirubin increased	9 (10.0)	9 (10.0)	0
Alanine aminotransferase increased	8 (8.9)	8 (8.9)	0
C-reactive protein increased	6 (6.7)	5 (5.6)	1 (1.1)
Blood creatine phosphokinase increased	1 (1.1)	1 (1.1)	0
Metabolism and nutrition disorders			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (35.6)	21 (23.3)	11 (12.2)
Hypokalaemia	15 (16.7)	13 (14.4)	2 (2.2)
Decreased appetite	14 (15.6)	12 (13.3)	2 (2.2)
Hypophosphataemia	8 (8.9)	7 (7.8)	1 (1.1)
Hypervolaemia	6 (6.7)	6 (6.7)	0
Tumour lysis syndrome	6 (6.7)	4 (4.4)	2 (2.2)
Hyperglycaemia	5 (5.6)	5 (5.6)	0
Hypocalcaemia	5 (5.6)	5 (5.6)	0
Metabolic acidosis	3 (3.3)	0	3 (3.3)
Hyperkalaemia	2 (2.2)	1 (1.1)	1 (1.1)
Acidosis	1 (1.1)	0	1 (1.1)
Hypernatraemia	1 (1.1)	1 (1.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.2)	2 (2.2)	0
Pain in extremity	2 (2.2)	2 (2.2)	0
Nervous system disorders			
-Total	5 (5.6)	5 (5.6)	0
Encephalopathy	4 (4.4)	4 (4.4)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	7 (7.8)	3 (3.3)	4 (4.4)
Acute kidney injury	6 (6.7)	2 (2.2)	4 (4.4)
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	28 (31.1)	11 (12.2)	17 (18.9)
Hypoxia	15 (16.7)	9 (10.0)	6 (6.7)
Respiratory failure	8 (8.9)	0	8 (8.9)
Pulmonary oedema	7 (7.8)	6 (6.7)	1 (1.1)
Dyspnoea	4 (4.4)	3 (3.3)	1 (1.1)
Acute respiratory distress syndrome	3 (3.3)	0	3 (3.3)
Tachypnoea	3 (3.3)	2 (2.2)	1 (1.1)
Atelectasis	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	21 (23.3)	12 (13.3)	9 (10.0)
Hypotension	18 (20.0)	9 (10.0)	9 (10.0)
Hypertension	4 (4.4)	4 (4.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Pancytopenia	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)
Hypogammaglobulinaemia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0
Investigations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Weight decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)
Haemochromatosis	1 (50.0)	1 (50.0)	0
Hypocalcaemia	1 (50.0)	1 (50.0)	0
Hypokalaemia	1 (50.0)	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	1 (50.0)
Seizure	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0
Renal tubular disorder	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (50.0)	0	1 (50.0)
Pleural effusion	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	1 (50.0)	0

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Table 223f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	83 (86.5)	19 (19.8)	64 (66.7)
Blood and lymphatic system disorders			
-Total	55 (57.3)	36 (37.5)	19 (19.8)
Febrile neutropenia	38 (39.6)	35 (36.5)	3 (3.1)
Anaemia	22 (22.9)	21 (21.9)	1 (1.0)
Neutropenia	12 (12.5)	3 (3.1)	9 (9.4)
Thrombocytopenia	12 (12.5)	5 (5.2)	7 (7.3)
Leukopenia	5 (5.2)	1 (1.0)	4 (4.2)
Pancytopenia	3 (3.1)	2 (2.1)	1 (1.0)
Disseminated intravascular coagulation	2 (2.1)	2 (2.1)	0
Cardiac disorders			

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (6.3)	5 (5.2)	1 (1.0)
Tachycardia	6 (6.3)	5 (5.2)	1 (1.0)
Gastrointestinal disorders			
-Total	5 (5.2)	5 (5.2)	0
Stomatitis	5 (5.2)	5 (5.2)	0
General disorders and administration site conditions			
-Total	12 (12.5)	10 (10.4)	2 (2.1)
Pyrexia	12 (12.5)	10 (10.4)	2 (2.1)
Immune system disorders			
-Total	40 (41.7)	20 (20.8)	20 (20.8)
Cytokine release syndrome	36 (37.5)	16 (16.7)	20 (20.8)
Hypogammaglobulinaemia	7 (7.3)	7 (7.3)	0
Infections and infestations			
-Total	21 (21.9)	13 (13.5)	8 (8.3)
Pneumonia	7 (7.3)	4 (4.2)	3 (3.1)
Staphylococcal bacteraemia	7 (7.3)	7 (7.3)	0
Parainfluenzae virus infection	5 (5.2)	4 (4.2)	1 (1.0)
Sepsis	3 (3.1)	0	3 (3.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (2.1)	2 (2.1)	0
Encephalitis	1 (1.0)	0	1 (1.0)
Respiratory syncytial virus infection	1 (1.0)	1 (1.0)	0
Investigations			
-Total	56 (58.3)	19 (19.8)	37 (38.5)
Neutrophil count decreased	26 (27.1)	3 (3.1)	23 (24.0)
White blood cell count decreased	26 (27.1)	1 (1.0)	25 (26.0)
Lymphocyte count decreased	21 (21.9)	9 (9.4)	12 (12.5)
Platelet count decreased	20 (20.8)	6 (6.3)	14 (14.6)
Aspartate aminotransferase increased	13 (13.5)	10 (10.4)	3 (3.1)
Blood bilirubin increased	9 (9.4)	9 (9.4)	0
Alanine aminotransferase increased	8 (8.3)	8 (8.3)	0
C-reactive protein increased	6 (6.3)	5 (5.2)	1 (1.0)
Blood creatinine increased	3 (3.1)	2 (2.1)	1 (1.0)
Weight decreased	1 (1.0)	1 (1.0)	0
Metabolism and nutrition disorders			
-Total	35 (36.5)	25 (26.0)	10 (10.4)
Hypokalaemia	15 (15.6)	12 (12.5)	3 (3.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	13 (13.5)	12 (12.5)	1 (1.0)
Hypophosphataemia	10 (10.4)	9 (9.4)	1 (1.0)
Hypervolaemia	6 (6.3)	6 (6.3)	0
Hyperglycaemia	5 (5.2)	5 (5.2)	0
Hypocalcaemia	5 (5.2)	5 (5.2)	0
Metabolic acidosis	5 (5.2)	2 (2.1)	3 (3.1)
Tumour lysis syndrome	5 (5.2)	3 (3.1)	2 (2.1)
Nervous system disorders			
-Total	8 (8.3)	7 (7.3)	1 (1.0)
Encephalopathy	5 (5.2)	5 (5.2)	0
Seizure	2 (2.1)	2 (2.1)	0
Cerebral haemorrhage	1 (1.0)	0	1 (1.0)
Renal and urinary disorders			
-Total	8 (8.3)	3 (3.1)	5 (5.2)
Acute kidney injury	8 (8.3)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (30.2)	12 (12.5)	17 (17.7)
Hypoxia	16 (16.7)	10 (10.4)	6 (6.3)

Philadelphia chromosome/BCR-ABL: Non-Positive

Group term Preferred term	All patients N=96 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	10 (10.4)	0	10 (10.4)
Pulmonary oedema	8 (8.3)	6 (6.3)	2 (2.1)
Dyspnoea	5 (5.2)	3 (3.1)	2 (2.1)
Tachypnoea	5 (5.2)	4 (4.2)	1 (1.0)
Pleural effusion	2 (2.1)	2 (2.1)	0
Vascular disorders			
-Total	25 (26.0)	15 (15.6)	10 (10.4)
Hypotension	22 (22.9)	12 (12.5)	10 (10.4)
Hypertension	5 (5.2)	5 (5.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223g
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	84 (86.6)	20 (20.6)	64 (66.0)
Blood and lymphatic system disorders			
-Total	55 (56.7)	36 (37.1)	19 (19.6)
Febrile neutropenia	39 (40.2)	36 (37.1)	3 (3.1)
Anaemia	22 (22.7)	21 (21.6)	1 (1.0)
Neutropenia	13 (13.4)	3 (3.1)	10 (10.3)
Thrombocytopenia	12 (12.4)	5 (5.2)	7 (7.2)
Leukopenia	5 (5.2)	1 (1.0)	4 (4.1)
Cardiac disorders			
-Total	6 (6.2)	5 (5.2)	1 (1.0)
Tachycardia	6 (6.2)	5 (5.2)	1 (1.0)
Gastrointestinal disorders			

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (5.2)	5 (5.2)	0
Stomatitis	5 (5.2)	5 (5.2)	0
General disorders and administration site conditions			
-Total	13 (13.4)	11 (11.3)	2 (2.1)
Pyrexia	13 (13.4)	11 (11.3)	2 (2.1)
Immune system disorders			
-Total	42 (43.3)	21 (21.6)	21 (21.6)
Cytokine release syndrome	38 (39.2)	17 (17.5)	21 (21.6)
Hypogammaglobulinaemia	8 (8.2)	8 (8.2)	0
Infections and infestations			
-Total	16 (16.5)	12 (12.4)	4 (4.1)
Pneumonia	7 (7.2)	4 (4.1)	3 (3.1)
Staphylococcal bacteraemia	7 (7.2)	7 (7.2)	0
Parainfluenzae virus infection	5 (5.2)	4 (4.1)	1 (1.0)
Investigations			
-Total	55 (56.7)	18 (18.6)	37 (38.1)
Neutrophil count decreased	26 (26.8)	3 (3.1)	23 (23.7)
White blood cell count decreased	26 (26.8)	1 (1.0)	25 (25.8)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	21 (21.6)	9 (9.3)	12 (12.4)
Platelet count decreased	20 (20.6)	6 (6.2)	14 (14.4)
Aspartate aminotransferase increased	14 (14.4)	10 (10.3)	4 (4.1)
Blood bilirubin increased	10 (10.3)	10 (10.3)	0
Alanine aminotransferase increased	9 (9.3)	9 (9.3)	0
C-reactive protein increased	6 (6.2)	5 (5.2)	1 (1.0)
Metabolism and nutrition disorders			
-Total	37 (38.1)	26 (26.8)	11 (11.3)
Hypokalaemia	16 (16.5)	13 (13.4)	3 (3.1)
Decreased appetite	14 (14.4)	12 (12.4)	2 (2.1)
Hypophosphataemia	10 (10.3)	9 (9.3)	1 (1.0)
Hypervolaemia	6 (6.2)	6 (6.2)	0
Hypocalcaemia	6 (6.2)	6 (6.2)	0
Tumour lysis syndrome	6 (6.2)	4 (4.1)	2 (2.1)
Hyperglycaemia	5 (5.2)	5 (5.2)	0
Metabolic acidosis	5 (5.2)	2 (2.1)	3 (3.1)
Nervous system disorders			
-Total	5 (5.2)	5 (5.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	5 (5.2)	5 (5.2)	0
Renal and urinary disorders			
-Total	8 (8.2)	3 (3.1)	5 (5.2)
Acute kidney injury	8 (8.2)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (29.9)	12 (12.4)	17 (17.5)
Hypoxia	16 (16.5)	10 (10.3)	6 (6.2)
Respiratory failure	10 (10.3)	0	10 (10.3)
Pulmonary oedema	8 (8.2)	6 (6.2)	2 (2.1)
Dyspnoea	5 (5.2)	3 (3.1)	2 (2.1)
Tachypnoea	5 (5.2)	4 (4.1)	1 (1.0)
Vascular disorders			
-Total	25 (25.8)	15 (15.5)	10 (10.3)
Hypotension	22 (22.7)	12 (12.4)	10 (10.3)
Hypertension	5 (5.2)	5 (5.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	1 (33.3)	0
Anaemia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
-Total	2 (66.7)	2 (66.7)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Investigations			
-Total	2 (66.7)	0	2 (66.7)
Aspartate aminotransferase increased	1 (33.3)	0	1 (33.3)
Lymphocyte count decreased	1 (33.3)	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	1 (33.3)
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0
Metabolic acidosis	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	2 (66.7)	0
Hypotension	2 (66.7)	2 (66.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	81 (85.3)	19 (20.0)	62 (65.3)
Blood and lymphatic system disorders			
-Total	54 (56.8)	35 (36.8)	19 (20.0)
Febrile neutropenia	39 (41.1)	36 (37.9)	3 (3.2)
Anaemia	21 (22.1)	20 (21.1)	1 (1.1)
Neutropenia	13 (13.7)	3 (3.2)	10 (10.5)
Thrombocytopenia	12 (12.6)	5 (5.3)	7 (7.4)
Leukopenia	5 (5.3)	1 (1.1)	4 (4.2)
Cardiac disorders			
-Total	8 (8.4)	7 (7.4)	1 (1.1)
Tachycardia	5 (5.3)	4 (4.2)	1 (1.1)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	3 (3.2)	3 (3.2)	0
Gastrointestinal disorders			
-Total	6 (6.3)	5 (5.3)	1 (1.1)
Stomatitis	5 (5.3)	5 (5.3)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
General disorders and administration site conditions			
-Total	13 (13.7)	11 (11.6)	2 (2.1)
Pyrexia	13 (13.7)	11 (11.6)	2 (2.1)
Immune system disorders			
-Total	42 (44.2)	21 (22.1)	21 (22.1)
Cytokine release syndrome	38 (40.0)	17 (17.9)	21 (22.1)
Hypogammaglobulinaemia	8 (8.4)	8 (8.4)	0
Infections and infestations			
-Total	18 (18.9)	14 (14.7)	4 (4.2)
Pneumonia	7 (7.4)	4 (4.2)	3 (3.2)
Staphylococcal bacteraemia	7 (7.4)	7 (7.4)	0
Parainfluenzae virus infection	5 (5.3)	4 (4.2)	1 (1.1)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	3 (3.2)	3 (3.2)	0
Investigations			
-Total	53 (55.8)	18 (18.9)	35 (36.8)
Neutrophil count decreased	25 (26.3)	3 (3.2)	22 (23.2)
White blood cell count decreased	25 (26.3)	1 (1.1)	24 (25.3)
Lymphocyte count decreased	20 (21.1)	9 (9.5)	11 (11.6)
Platelet count decreased	20 (21.1)	6 (6.3)	14 (14.7)
Aspartate aminotransferase increased	13 (13.7)	10 (10.5)	3 (3.2)
Blood bilirubin increased	10 (10.5)	10 (10.5)	0
Alanine aminotransferase increased	9 (9.5)	9 (9.5)	0
C-reactive protein increased	6 (6.3)	5 (5.3)	1 (1.1)
Metabolism and nutrition disorders			
-Total	36 (37.9)	25 (26.3)	11 (11.6)
Hypokalaemia	16 (16.8)	13 (13.7)	3 (3.2)
Decreased appetite	14 (14.7)	12 (12.6)	2 (2.1)
Hypophosphataemia	10 (10.5)	9 (9.5)	1 (1.1)
Hypervolaemia	6 (6.3)	6 (6.3)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	6 (6.3)	6 (6.3)	0
Tumour lysis syndrome	6 (6.3)	4 (4.2)	2 (2.1)
Hyperglycaemia	5 (5.3)	5 (5.3)	0
Metabolic acidosis	4 (4.2)	1 (1.1)	3 (3.2)
Nervous system disorders			
-Total	6 (6.3)	6 (6.3)	0
Encephalopathy	5 (5.3)	5 (5.3)	0
Cognitive disorder	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	8 (8.4)	3 (3.2)	5 (5.3)
Acute kidney injury	8 (8.4)	3 (3.2)	5 (5.3)
Respiratory, thoracic and mediastinal disorders			
-Total	28 (29.5)	12 (12.6)	16 (16.8)
Hypoxia	16 (16.8)	10 (10.5)	6 (6.3)
Respiratory failure	9 (9.5)	0	9 (9.5)
Pulmonary oedema	7 (7.4)	6 (6.3)	1 (1.1)
Dyspnoea	5 (5.3)	3 (3.2)	2 (2.1)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	5 (5.3)	4 (4.2)	1 (1.1)
Vascular disorders			
-Total	23 (24.2)	13 (13.7)	10 (10.5)
Hypotension	20 (21.1)	10 (10.5)	10 (10.5)
Hypertension	5 (5.3)	5 (5.3)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Acute sinusitis	1 (50.0)	1 (50.0)	0
Fungal skin infection	1 (50.0)	1 (50.0)	0
Systemic mycosis	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Gamma-glutamyltransferase increased	1 (50.0)	1 (50.0)	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	82 (85.4)	19 (19.8)	63 (65.6)
Blood and lymphatic system disorders			
-Total	54 (56.3)	35 (36.5)	19 (19.8)
Febrile neutropenia	38 (39.6)	35 (36.5)	3 (3.1)
Anaemia	22 (22.9)	21 (21.9)	1 (1.0)
Neutropenia	13 (13.5)	3 (3.1)	10 (10.4)
Thrombocytopenia	12 (12.5)	5 (5.2)	7 (7.3)
Leukopenia	5 (5.2)	1 (1.0)	4 (4.2)
Cardiac disorders			
-Total	6 (6.3)	5 (5.2)	1 (1.0)
Tachycardia	6 (6.3)	5 (5.2)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (5.2)	5 (5.2)	0
Stomatitis	5 (5.2)	5 (5.2)	0
General disorders and administration site conditions			
-Total	13 (13.5)	11 (11.5)	2 (2.1)
Pyrexia	13 (13.5)	11 (11.5)	2 (2.1)
Immune system disorders			
-Total	42 (43.8)	21 (21.9)	21 (21.9)
Cytokine release syndrome	38 (39.6)	17 (17.7)	21 (21.9)
Hypogammaglobulinaemia	8 (8.3)	8 (8.3)	0
Infections and infestations			
-Total	16 (16.7)	12 (12.5)	4 (4.2)
Pneumonia	7 (7.3)	4 (4.2)	3 (3.1)
Staphylococcal bacteraemia	7 (7.3)	7 (7.3)	0
Parainfluenzae virus infection	5 (5.2)	4 (4.2)	1 (1.0)
Investigations			
-Total	54 (56.3)	18 (18.8)	36 (37.5)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	26 (27.1)	3 (3.1)	23 (24.0)
White blood cell count decreased	25 (26.0)	1 (1.0)	24 (25.0)
Lymphocyte count decreased	21 (21.9)	9 (9.4)	12 (12.5)
Platelet count decreased	20 (20.8)	6 (6.3)	14 (14.6)
Aspartate aminotransferase increased	14 (14.6)	10 (10.4)	4 (4.2)
Blood bilirubin increased	10 (10.4)	10 (10.4)	0
Alanine aminotransferase increased	9 (9.4)	9 (9.4)	0
C-reactive protein increased	6 (6.3)	5 (5.2)	1 (1.0)
Gamma-glutamyltransferase increased	1 (1.0)	1 (1.0)	0
Metabolism and nutrition disorders			
-Total	37 (38.5)	26 (27.1)	11 (11.5)
Hypokalaemia	16 (16.7)	13 (13.5)	3 (3.1)
Decreased appetite	14 (14.6)	12 (12.5)	2 (2.1)
Hypophosphataemia	10 (10.4)	9 (9.4)	1 (1.0)
Hypervolaemia	6 (6.3)	6 (6.3)	0
Hypocalcaemia	6 (6.3)	6 (6.3)	0
Tumour lysis syndrome	6 (6.3)	4 (4.2)	2 (2.1)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	5 (5.2)	5 (5.2)	0
Metabolic acidosis	5 (5.2)	2 (2.1)	3 (3.1)
Nervous system disorders			
-Total	5 (5.2)	5 (5.2)	0
Encephalopathy	5 (5.2)	5 (5.2)	0
Renal and urinary disorders			
-Total	8 (8.3)	3 (3.1)	5 (5.2)
Acute kidney injury	8 (8.3)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (30.2)	12 (12.5)	17 (17.7)
Hypoxia	16 (16.7)	10 (10.4)	6 (6.3)
Respiratory failure	10 (10.4)	0	10 (10.4)
Pulmonary oedema	8 (8.3)	6 (6.3)	2 (2.1)
Dyspnoea	5 (5.2)	3 (3.1)	2 (2.1)
Tachypnoea	5 (5.2)	4 (4.2)	1 (1.0)
Vascular disorders			
-Total	25 (26.0)	15 (15.6)	10 (10.4)

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	22 (22.9)	12 (12.5)	10 (10.4)
Hypertension	5 (5.2)	5 (5.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (90.0)	6 (20.0)	21 (70.0)
Blood and lymphatic system disorders			
-Total	15 (50.0)	9 (30.0)	6 (20.0)
Febrile neutropenia	9 (30.0)	9 (30.0)	0
Anaemia	5 (16.7)	5 (16.7)	0
Neutropenia	5 (16.7)	1 (3.3)	4 (13.3)
Thrombocytopenia	4 (13.3)	1 (3.3)	3 (10.0)
Leukopenia	1 (3.3)	0	1 (3.3)
Cardiac disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Tachycardia	3 (10.0)	2 (6.7)	1 (3.3)
Gastrointestinal disorders			

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (16.7)	5 (16.7)	0
Diarrhoea	2 (6.7)	2 (6.7)	0
Pancreatitis	2 (6.7)	2 (6.7)	0
Stomatitis	2 (6.7)	2 (6.7)	0
General disorders and administration site conditions			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Pyrexia	3 (10.0)	2 (6.7)	1 (3.3)
Hepatobiliary disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Hepatic function abnormal	3 (10.0)	2 (6.7)	1 (3.3)
Immune system disorders			
-Total	19 (63.3)	10 (33.3)	9 (30.0)
Cytokine release syndrome	17 (56.7)	8 (26.7)	9 (30.0)
Hypogammaglobulinaemia	3 (10.0)	3 (10.0)	0
Haemophagocytic lymphohistiocytosis	2 (6.7)	1 (3.3)	1 (3.3)
Immunodeficiency	2 (6.7)	2 (6.7)	0
Infections and infestations			

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (43.3)	10 (33.3)	3 (10.0)
Bacteraemia	3 (10.0)	3 (10.0)	0
Pneumonia	3 (10.0)	3 (10.0)	0
Staphylococcal infection	3 (10.0)	2 (6.7)	1 (3.3)
Bronchiolitis	2 (6.7)	2 (6.7)	0
Sepsis	2 (6.7)	0	2 (6.7)
Parainfluenzae virus infection	1 (3.3)	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Investigations			
-Total	19 (63.3)	6 (20.0)	13 (43.3)
Neutrophil count decreased	9 (30.0)	0	9 (30.0)
Platelet count decreased	7 (23.3)	2 (6.7)	5 (16.7)
White blood cell count decreased	7 (23.3)	1 (3.3)	6 (20.0)
Lymphocyte count decreased	6 (20.0)	3 (10.0)	3 (10.0)
Alanine aminotransferase increased	3 (10.0)	3 (10.0)	0
Aspartate aminotransferase increased	2 (6.7)	1 (3.3)	1 (3.3)
Blood bilirubin increased	2 (6.7)	2 (6.7)	0

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (6.7)	1 (3.3)	1 (3.3)
Blood uric acid increased	2 (6.7)	1 (3.3)	1 (3.3)
C-reactive protein increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	14 (46.7)	10 (33.3)	4 (13.3)
Hypokalaemia	9 (30.0)	8 (26.7)	1 (3.3)
Decreased appetite	4 (13.3)	4 (13.3)	0
Hypophosphataemia	3 (10.0)	2 (6.7)	1 (3.3)
Tumour lysis syndrome	3 (10.0)	2 (6.7)	1 (3.3)
Hypocalcaemia	2 (6.7)	2 (6.7)	0
Metabolic acidosis	2 (6.7)	1 (3.3)	1 (3.3)
Hypervolaemia	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	2 (6.7)	2 (6.7)	0
Encephalopathy	2 (6.7)	2 (6.7)	0
Psychiatric disorders			
-Total	2 (6.7)	2 (6.7)	0
Mental status changes	2 (6.7)	2 (6.7)	0

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	5 (16.7)	1 (3.3)	4 (13.3)
Acute kidney injury	5 (16.7)	1 (3.3)	4 (13.3)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (40.0)	3 (10.0)	9 (30.0)
Hypoxia	8 (26.7)	4 (13.3)	4 (13.3)
Respiratory failure	3 (10.0)	0	3 (10.0)
Acute respiratory distress syndrome	2 (6.7)	0	2 (6.7)
Atelectasis	2 (6.7)	2 (6.7)	0
Pulmonary oedema	2 (6.7)	1 (3.3)	1 (3.3)
Tachypnoea	2 (6.7)	2 (6.7)	0
Dyspnoea	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	9 (30.0)	3 (10.0)	6 (20.0)
Hypotension	7 (23.3)	2 (6.7)	5 (16.7)
Hypertension	2 (6.7)	2 (6.7)	0
Venoocclusive disease	2 (6.7)	1 (3.3)	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (88.2)	14 (20.6)	46 (67.6)
Blood and lymphatic system disorders			
-Total	42 (61.8)	28 (41.2)	14 (20.6)
Febrile neutropenia	30 (44.1)	27 (39.7)	3 (4.4)
Anaemia	17 (25.0)	16 (23.5)	1 (1.5)
Neutropenia	8 (11.8)	2 (2.9)	6 (8.8)
Thrombocytopenia	8 (11.8)	4 (5.9)	4 (5.9)
Leukopenia	4 (5.9)	1 (1.5)	3 (4.4)
Pancytopenia	4 (5.9)	3 (4.4)	1 (1.5)
Cardiac disorders			
-Total	7 (10.3)	7 (10.3)	0
Left ventricular dysfunction	4 (5.9)	4 (5.9)	0

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (4.4)	3 (4.4)	0
Gastrointestinal disorders			
-Total	3 (4.4)	3 (4.4)	0
Stomatitis	3 (4.4)	3 (4.4)	0
General disorders and administration site conditions			
-Total	10 (14.7)	9 (13.2)	1 (1.5)
Pyrexia	10 (14.7)	9 (13.2)	1 (1.5)
Immune system disorders			
-Total	26 (38.2)	13 (19.1)	13 (19.1)
Cytokine release syndrome	21 (30.9)	9 (13.2)	12 (17.6)
Hypogammaglobulinaemia	5 (7.4)	5 (7.4)	0
Haemophagocytic lymphohistiocytosis	2 (2.9)	1 (1.5)	1 (1.5)
Immunodeficiency	2 (2.9)	2 (2.9)	0
Infections and infestations			
-Total	15 (22.1)	9 (13.2)	6 (8.8)
Staphylococcal bacteraemia	6 (8.8)	6 (8.8)	0
Parainfluenzae virus infection	4 (5.9)	3 (4.4)	1 (1.5)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (5.9)	1 (1.5)	3 (4.4)
Sepsis	2 (2.9)	1 (1.5)	1 (1.5)
Bacteraemia	1 (1.5)	0	1 (1.5)
Staphylococcal infection	1 (1.5)	1 (1.5)	0
Investigations			
-Total	36 (52.9)	12 (17.6)	24 (35.3)
White blood cell count decreased	19 (27.9)	0	19 (27.9)
Neutrophil count decreased	17 (25.0)	3 (4.4)	14 (20.6)
Lymphocyte count decreased	15 (22.1)	6 (8.8)	9 (13.2)
Platelet count decreased	13 (19.1)	4 (5.9)	9 (13.2)
Aspartate aminotransferase increased	12 (17.6)	9 (13.2)	3 (4.4)
Blood bilirubin increased	8 (11.8)	8 (11.8)	0
Alanine aminotransferase increased	6 (8.8)	6 (8.8)	0
C-reactive protein increased	5 (7.4)	4 (5.9)	1 (1.5)
Serum ferritin increased	4 (5.9)	3 (4.4)	1 (1.5)
Metabolism and nutrition disorders			
-Total	23 (33.8)	16 (23.5)	7 (10.3)
Decreased appetite	10 (14.7)	8 (11.8)	2 (2.9)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	7 (10.3)	5 (7.4)	2 (2.9)
Hypophosphataemia	7 (10.3)	7 (10.3)	0
Hyperglycaemia	5 (7.4)	5 (7.4)	0
Hypervolaemia	5 (7.4)	5 (7.4)	0
Hypocalcaemia	4 (5.9)	4 (5.9)	0
Metabolic acidosis	3 (4.4)	1 (1.5)	2 (2.9)
Tumour lysis syndrome	3 (4.4)	2 (2.9)	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	4 (5.9)	4 (5.9)	0
Back pain	4 (5.9)	4 (5.9)	0
Nervous system disorders			
-Total	3 (4.4)	3 (4.4)	0
Encephalopathy	3 (4.4)	3 (4.4)	0
Psychiatric disorders			
-Total	1 (1.5)	1 (1.5)	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	3 (4.4)	2 (2.9)	1 (1.5)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (4.4)	2 (2.9)	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (29.4)	9 (13.2)	11 (16.2)
Hypoxia	8 (11.8)	6 (8.8)	2 (2.9)
Respiratory failure	7 (10.3)	0	7 (10.3)
Pulmonary oedema	6 (8.8)	5 (7.4)	1 (1.5)
Dyspnoea	4 (5.9)	3 (4.4)	1 (1.5)
Tachypnoea	3 (4.4)	2 (2.9)	1 (1.5)
Acute respiratory distress syndrome	2 (2.9)	0	2 (2.9)
Vascular disorders			
-Total	17 (25.0)	12 (17.6)	5 (7.4)
Hypotension	15 (22.1)	10 (14.7)	5 (7.4)
Hypertension	3 (4.4)	3 (4.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (93.8)	8 (25.0)	22 (68.8)
Blood and lymphatic system disorders			
-Total	20 (62.5)	14 (43.8)	6 (18.8)
Febrile neutropenia	11 (34.4)	10 (31.3)	1 (3.1)
Anaemia	9 (28.1)	9 (28.1)	0
Neutropenia	6 (18.8)	2 (6.3)	4 (12.5)
Thrombocytopenia	4 (12.5)	2 (6.3)	2 (6.3)
Pancytopenia	3 (9.4)	3 (9.4)	0
Leukopenia	2 (6.3)	1 (3.1)	1 (3.1)
Gastrointestinal disorders			
-Total	1 (3.1)	1 (3.1)	0

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	2 (6.3)	2 (6.3)	0
Pyrexia	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	18 (56.3)	9 (28.1)	9 (28.1)
Cytokine release syndrome	13 (40.6)	5 (15.6)	8 (25.0)
Hypogammaglobulinaemia	5 (15.6)	5 (15.6)	0
Immunodeficiency	4 (12.5)	4 (12.5)	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)
Infections and infestations			
-Total	13 (40.6)	6 (18.8)	7 (21.9)
Pneumonia	5 (15.6)	2 (6.3)	3 (9.4)
Sepsis	3 (9.4)	1 (3.1)	2 (6.3)
Bacteraemia	2 (6.3)	1 (3.1)	1 (3.1)
Bronchopulmonary aspergillosis	2 (6.3)	1 (3.1)	1 (3.1)
Device related infection	2 (6.3)	2 (6.3)	0

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (6.3)	2 (6.3)	0
Herpes zoster	2 (6.3)	2 (6.3)	0
Parainfluenzae virus infection	2 (6.3)	2 (6.3)	0
Encephalitis viral	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	18 (56.3)	7 (21.9)	11 (34.4)
Lymphocyte count decreased	10 (31.3)	1 (3.1)	9 (28.1)
White blood cell count decreased	10 (31.3)	0	10 (31.3)
Neutrophil count decreased	8 (25.0)	0	8 (25.0)
Platelet count decreased	6 (18.8)	1 (3.1)	5 (15.6)
C-reactive protein increased	3 (9.4)	3 (9.4)	0
Alanine aminotransferase increased	2 (6.3)	2 (6.3)	0
Weight decreased	2 (6.3)	2 (6.3)	0
Aspartate aminotransferase increased	1 (3.1)	1 (3.1)	0

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	10 (31.3)	6 (18.8)	4 (12.5)
Hypokalaemia	6 (18.8)	5 (15.6)	1 (3.1)
Hypophosphataemia	3 (9.4)	2 (6.3)	1 (3.1)
Decreased appetite	2 (6.3)	1 (3.1)	1 (3.1)
Hyperglycaemia	2 (6.3)	2 (6.3)	0
Hypocalcaemia	2 (6.3)	2 (6.3)	0
Tumour lysis syndrome	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Back pain	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	4 (12.5)	4 (12.5)	0
Encephalopathy	2 (6.3)	2 (6.3)	0
Seizure	2 (6.3)	2 (6.3)	0
Respiratory, thoracic and mediastinal disorders			

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (15.6)	3 (9.4)	2 (6.3)
Pulmonary oedema	3 (9.4)	3 (9.4)	0
Dyspnoea	1 (3.1)	0	1 (3.1)
Respiratory failure	1 (3.1)	0	1 (3.1)
Tachypnoea	1 (3.1)	0	1 (3.1)
Vascular disorders			
-Total	3 (9.4)	3 (9.4)	0
Hypertension	2 (6.3)	2 (6.3)	0
Hypotension	1 (3.1)	1 (3.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (87.7)	12 (21.1)	38 (66.7)
Blood and lymphatic system disorders			
-Total	33 (57.9)	23 (40.4)	10 (17.5)
Febrile neutropenia	27 (47.4)	25 (43.9)	2 (3.5)
Anaemia	13 (22.8)	12 (21.1)	1 (1.8)
Thrombocytopenia	7 (12.3)	3 (5.3)	4 (7.0)
Neutropenia	4 (7.0)	1 (1.8)	3 (5.3)
Leukopenia	2 (3.5)	0	2 (3.5)
Pancytopenia	1 (1.8)	0	1 (1.8)
Cardiac disorders			
-Total	15 (26.3)	10 (17.5)	5 (8.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	6 (10.5)	5 (8.8)	1 (1.8)
Left ventricular dysfunction	4 (7.0)	4 (7.0)	0
Cardiac arrest	3 (5.3)	0	3 (5.3)
Cardiac failure	3 (5.3)	2 (3.5)	1 (1.8)
Gastrointestinal disorders			
-Total	4 (7.0)	4 (7.0)	0
Stomatitis	4 (7.0)	4 (7.0)	0
General disorders and administration site conditions			
-Total	11 (19.3)	9 (15.8)	2 (3.5)
Pyrexia	11 (19.3)	9 (15.8)	2 (3.5)
Immune system disorders			
-Total	22 (38.6)	12 (21.1)	10 (17.5)
Cytokine release syndrome	20 (35.1)	10 (17.5)	10 (17.5)
Haemophagocytic lymphohistiocytosis	3 (5.3)	2 (3.5)	1 (1.8)
Hypogammaglobulinaemia	3 (5.3)	3 (5.3)	0
Infections and infestations			
-Total	19 (33.3)	13 (22.8)	6 (10.5)

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	6 (10.5)	6 (10.5)	0
Clostridium difficile infection	3 (5.3)	3 (5.3)	0
Metapneumovirus infection	3 (5.3)	3 (5.3)	0
Septic shock	3 (5.3)	0	3 (5.3)
Staphylococcal infection	3 (5.3)	2 (3.5)	1 (1.8)
Parainfluenzae virus infection	2 (3.5)	1 (1.8)	1 (1.8)
Bacteraemia	1 (1.8)	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	1 (1.8)	0
Pneumonia	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Sepsis	1 (1.8)	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	35 (61.4)	13 (22.8)	22 (38.6)
Neutrophil count decreased	15 (26.3)	3 (5.3)	12 (21.1)
Aspartate aminotransferase increased	13 (22.8)	9 (15.8)	4 (7.0)
Platelet count decreased	12 (21.1)	4 (7.0)	8 (14.0)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	12 (21.1)	1 (1.8)	11 (19.3)
Lymphocyte count decreased	11 (19.3)	8 (14.0)	3 (5.3)
Blood bilirubin increased	9 (15.8)	9 (15.8)	0
Alanine aminotransferase increased	7 (12.3)	7 (12.3)	0
Blood creatinine increased	4 (7.0)	3 (5.3)	1 (1.8)
Serum ferritin increased	4 (7.0)	3 (5.3)	1 (1.8)
Blood lactate dehydrogenase increased	3 (5.3)	3 (5.3)	0
C-reactive protein increased	3 (5.3)	2 (3.5)	1 (1.8)
Blood creatine phosphokinase increased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	25 (43.9)	19 (33.3)	6 (10.5)
Decreased appetite	12 (21.1)	11 (19.3)	1 (1.8)
Hypokalaemia	10 (17.5)	8 (14.0)	2 (3.5)
Hypophosphataemia	7 (12.3)	7 (12.3)	0
Hypervolaemia	6 (10.5)	6 (10.5)	0
Hypocalcaemia	4 (7.0)	4 (7.0)	0
Metabolic acidosis	4 (7.0)	2 (3.5)	2 (3.5)

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (5.3)	3 (5.3)	0
Hyperkalaemia	3 (5.3)	2 (3.5)	1 (1.8)
Tumour lysis syndrome	3 (5.3)	2 (3.5)	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	6 (10.5)	6 (10.5)	0
Back pain	3 (5.3)	3 (5.3)	0
Pain in extremity	3 (5.3)	3 (5.3)	0
Nervous system disorders			
-Total	4 (7.0)	4 (7.0)	0
Encephalopathy	3 (5.3)	3 (5.3)	0
Seizure	1 (1.8)	1 (1.8)	0
Psychiatric disorders			
-Total	6 (10.5)	6 (10.5)	0
Delirium	3 (5.3)	3 (5.3)	0
Mental status changes	3 (5.3)	3 (5.3)	0
Renal and urinary disorders			
-Total	6 (10.5)	3 (5.3)	3 (5.3)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	6 (10.5)	3 (5.3)	3 (5.3)
Respiratory, thoracic and mediastinal disorders			
-Total	26 (45.6)	10 (17.5)	16 (28.1)
Hypoxia	13 (22.8)	10 (17.5)	3 (5.3)
Respiratory failure	9 (15.8)	0	9 (15.8)
Pulmonary oedema	5 (8.8)	3 (5.3)	2 (3.5)
Acute respiratory distress syndrome	4 (7.0)	0	4 (7.0)
Dyspnoea	4 (7.0)	3 (5.3)	1 (1.8)
Tachypnoea	4 (7.0)	4 (7.0)	0
Epistaxis	3 (5.3)	3 (5.3)	0
Pleural effusion	3 (5.3)	2 (3.5)	1 (1.8)
Vascular disorders			
-Total	21 (36.8)	12 (21.1)	9 (15.8)
Hypotension	20 (35.1)	11 (19.3)	9 (15.8)
Hypertension	3 (5.3)	3 (5.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	1 (11.1)	7 (77.8)
Blood and lymphatic system disorders			
-Total	4 (44.4)	0	4 (44.4)
Neutropenia	3 (33.3)	0	3 (33.3)
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Leukopenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiac failure	1 (11.1)	0	1 (11.1)

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders			
-Total	1 (11.1)	1 (11.1)	0
Duodenal perforation	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Hepatic function abnormal	3 (33.3)	2 (22.2)	1 (11.1)
Immune system disorders			
-Total	5 (55.6)	2 (22.2)	3 (33.3)
Cytokine release syndrome	5 (55.6)	2 (22.2)	3 (33.3)
Infections and infestations			
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Upper respiratory tract infection	2 (22.2)	2 (22.2)	0
Bacteraemia	1 (11.1)	1 (11.1)	0
Encephalitis viral	1 (11.1)	0	1 (11.1)
Meningitis bacterial	1 (11.1)	1 (11.1)	0
Parainfluenzae virus infection	1 (11.1)	1 (11.1)	0
Peritonitis	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	1 (11.1)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (11.1)	1 (11.1)	0
Rhinovirus infection	1 (11.1)	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	1 (11.1)	0
Investigations			
-Total	5 (55.6)	0	5 (55.6)
White blood cell count decreased	4 (44.4)	0	4 (44.4)
Neutrophil count decreased	3 (33.3)	0	3 (33.3)
Platelet count decreased	2 (22.2)	1 (11.1)	1 (11.1)
Blood creatine phosphokinase increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Tumour lysis syndrome	2 (22.2)	2 (22.2)	0
Metabolic acidosis	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	1 (11.1)	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (22.2)	0	2 (22.2)
Acute kidney injury	2 (22.2)	0	2 (22.2)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (33.3)	0	3 (33.3)
Hypoxia	3 (33.3)	0	3 (33.3)
Vascular disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypotension	1 (11.1)	0	1 (11.1)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (91.4)	14 (24.1)	39 (67.2)
Blood and lymphatic system disorders			
-Total	35 (60.3)	24 (41.4)	11 (19.0)
Febrile neutropenia	22 (37.9)	21 (36.2)	1 (1.7)
Anaemia	15 (25.9)	15 (25.9)	0
Neutropenia	9 (15.5)	2 (3.4)	7 (12.1)
Thrombocytopenia	7 (12.1)	3 (5.2)	4 (6.9)
Leukopenia	5 (8.6)	1 (1.7)	4 (6.9)
Pancytopenia	4 (6.9)	3 (5.2)	1 (1.7)
Disseminated intravascular coagulation	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	7 (12.1)	6 (10.3)	1 (1.7)
Left ventricular dysfunction	3 (5.2)	3 (5.2)	0
Tachycardia	2 (3.4)	2 (3.4)	0
Cardiac arrest	1 (1.7)	0	1 (1.7)
Cardiac failure	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	4 (6.9)	4 (6.9)	0
Stomatitis	3 (5.2)	3 (5.2)	0
Nausea	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	7 (12.1)	6 (10.3)	1 (1.7)
Pyrexia	7 (12.1)	6 (10.3)	1 (1.7)
Immune system disorders			
-Total	29 (50.0)	18 (31.0)	11 (19.0)
Cytokine release syndrome	23 (39.7)	12 (20.7)	11 (19.0)
Hypogammaglobulinaemia	6 (10.3)	6 (10.3)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	3 (5.2)	3 (5.2)	0
Immunodeficiency	2 (3.4)	2 (3.4)	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	23 (39.7)	14 (24.1)	9 (15.5)
Parainfluenzae virus infection	4 (6.9)	3 (5.2)	1 (1.7)
Pneumonia	4 (6.9)	3 (5.2)	1 (1.7)
Bacteraemia	3 (5.2)	2 (3.4)	1 (1.7)
Bronchopulmonary aspergillosis	3 (5.2)	2 (3.4)	1 (1.7)
Metapneumovirus infection	3 (5.2)	3 (5.2)	0
Sepsis	3 (5.2)	1 (1.7)	2 (3.4)
Septic shock	3 (5.2)	0	3 (5.2)
Sinusitis	3 (5.2)	3 (5.2)	0
Upper respiratory tract infection	3 (5.2)	3 (5.2)	0
Staphylococcal bacteraemia	2 (3.4)	2 (3.4)	0
Staphylococcal infection	2 (3.4)	2 (3.4)	0
Clostridium difficile infection	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	32 (55.2)	11 (19.0)	21 (36.2)
Neutrophil count decreased	18 (31.0)	1 (1.7)	17 (29.3)
White blood cell count decreased	16 (27.6)	0	16 (27.6)
Lymphocyte count decreased	14 (24.1)	4 (6.9)	10 (17.2)
Platelet count decreased	14 (24.1)	5 (8.6)	9 (15.5)
Alanine aminotransferase increased	7 (12.1)	7 (12.1)	0
Aspartate aminotransferase increased	6 (10.3)	4 (6.9)	2 (3.4)
Blood bilirubin increased	5 (8.6)	5 (8.6)	0
C-reactive protein increased	4 (6.9)	4 (6.9)	0
Blood creatinine increased	2 (3.4)	2 (3.4)	0
Serum ferritin increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	21 (36.2)	14 (24.1)	7 (12.1)
Hypokalaemia	11 (19.0)	9 (15.5)	2 (3.4)
Decreased appetite	8 (13.8)	6 (10.3)	2 (3.4)
Hypophosphataemia	5 (8.6)	4 (6.9)	1 (1.7)

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	4 (6.9)	2 (3.4)	2 (3.4)
Hypocalcaemia	3 (5.2)	3 (5.2)	0
Hyperglycaemia	2 (3.4)	2 (3.4)	0
Hypervolaemia	2 (3.4)	2 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (6.9)	4 (6.9)	0
Back pain	3 (5.2)	3 (5.2)	0
Pain in extremity	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	8 (13.8)	8 (13.8)	0
Headache	3 (5.2)	3 (5.2)	0
Seizure	3 (5.2)	3 (5.2)	0
Encephalopathy	2 (3.4)	2 (3.4)	0
Psychiatric disorders			
-Total	2 (3.4)	2 (3.4)	0
Anxiety	1 (1.7)	1 (1.7)	0
Mental status changes	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (3.4)	0	2 (3.4)
Acute kidney injury	2 (3.4)	0	2 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (27.6)	7 (12.1)	9 (15.5)
Hypoxia	7 (12.1)	4 (6.9)	3 (5.2)
Pulmonary oedema	4 (6.9)	4 (6.9)	0
Respiratory failure	3 (5.2)	0	3 (5.2)
Acute respiratory distress syndrome	2 (3.4)	0	2 (3.4)
Dyspnoea	2 (3.4)	2 (3.4)	0
Pleural effusion	1 (1.7)	0	1 (1.7)
Tachypnoea	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	9 (15.5)	5 (8.6)	4 (6.9)
Hypotension	8 (13.8)	4 (6.9)	4 (6.9)
Hypertension	1 (1.7)	1 (1.7)	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	8 (20.0)	27 (67.5)
Blood and lymphatic system disorders			
-Total	22 (55.0)	13 (32.5)	9 (22.5)
Febrile neutropenia	17 (42.5)	15 (37.5)	2 (5.0)
Anaemia	7 (17.5)	6 (15.0)	1 (2.5)
Thrombocytopenia	5 (12.5)	2 (5.0)	3 (7.5)
Neutropenia	4 (10.0)	1 (2.5)	3 (7.5)
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Cardiac disorders			
-Total	9 (22.5)	4 (10.0)	5 (12.5)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	4 (10.0)	3 (7.5)	1 (2.5)
Cardiac failure	3 (7.5)	1 (2.5)	2 (5.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	6 (15.0)	4 (10.0)	2 (5.0)
Abdominal compartment syndrome	2 (5.0)	0	2 (5.0)
Nausea	2 (5.0)	2 (5.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
Vomiting	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	9 (22.5)	5 (12.5)	4 (10.0)
Pyrexia	6 (15.0)	5 (12.5)	1 (2.5)
Multiple organ dysfunction syndrome	3 (7.5)	0	3 (7.5)
Immune system disorders			
-Total	18 (45.0)	7 (17.5)	11 (27.5)
Cytokine release syndrome	15 (37.5)	5 (12.5)	10 (25.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	3 (7.5)	1 (2.5)	2 (5.0)
Hypogammaglobulinaemia	2 (5.0)	2 (5.0)	0
Immunodeficiency	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	12 (30.0)	8 (20.0)	4 (10.0)
Staphylococcal bacteraemia	5 (12.5)	5 (12.5)	0
Pneumonia	3 (7.5)	1 (2.5)	2 (5.0)
Clostridium difficile infection	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Bacteraemia	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0
Sepsis	1 (2.5)	0	1 (2.5)
Investigations			
-Total	24 (60.0)	7 (17.5)	17 (42.5)
White blood cell count decreased	10 (25.0)	1 (2.5)	9 (22.5)
Aspartate aminotransferase increased	8 (20.0)	6 (15.0)	2 (5.0)
Neutrophil count decreased	8 (20.0)	2 (5.0)	6 (15.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (17.5)	5 (12.5)	2 (5.0)
Platelet count decreased	6 (15.0)	1 (2.5)	5 (12.5)
Blood bilirubin increased	5 (12.5)	5 (12.5)	0
Blood lactate dehydrogenase increased	3 (7.5)	3 (7.5)	0
Serum ferritin increased	3 (7.5)	2 (5.0)	1 (2.5)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood creatinine increased	2 (5.0)	1 (2.5)	1 (2.5)
C-reactive protein increased	2 (5.0)	1 (2.5)	1 (2.5)
Fibrin d dimer increased	2 (5.0)	1 (2.5)	1 (2.5)
Urine output decreased	2 (5.0)	1 (2.5)	1 (2.5)
Metabolism and nutrition disorders			
-Total	16 (40.0)	11 (27.5)	5 (12.5)
Decreased appetite	6 (15.0)	6 (15.0)	0
Hypokalaemia	5 (12.5)	4 (10.0)	1 (2.5)
Hypophosphataemia	5 (12.5)	5 (12.5)	0
Metabolic acidosis	5 (12.5)	2 (5.0)	3 (7.5)
Hypervolaemia	4 (10.0)	4 (10.0)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (7.5)	3 (7.5)	0
Hyperkalaemia	3 (7.5)	2 (5.0)	1 (2.5)
Hypocalcaemia	3 (7.5)	3 (7.5)	0
Acidosis	2 (5.0)	1 (2.5)	1 (2.5)
Hypercalcaemia	2 (5.0)	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.5)	3 (7.5)	0
Pain in extremity	2 (5.0)	2 (5.0)	0
Back pain	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	5 (12.5)	5 (12.5)	0
Encephalopathy	3 (7.5)	3 (7.5)	0
Cognitive disorder	2 (5.0)	2 (5.0)	0
Somnolence	2 (5.0)	2 (5.0)	0
Psychiatric disorders			
-Total	7 (17.5)	7 (17.5)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	3 (7.5)	3 (7.5)	0
Anxiety	2 (5.0)	2 (5.0)	0
Mental status changes	2 (5.0)	2 (5.0)	0
Renal and urinary disorders			
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Acute kidney injury	6 (15.0)	3 (7.5)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (42.5)	5 (12.5)	12 (30.0)
Hypoxia	9 (22.5)	6 (15.0)	3 (7.5)
Respiratory failure	7 (17.5)	0	7 (17.5)
Pulmonary oedema	4 (10.0)	2 (5.0)	2 (5.0)
Tachypnoea	4 (10.0)	3 (7.5)	1 (2.5)
Dyspnoea	3 (7.5)	1 (2.5)	2 (5.0)
Acute respiratory distress syndrome	2 (5.0)	0	2 (5.0)
Pleural effusion	2 (5.0)	2 (5.0)	0
Vascular disorders			
-Total	16 (40.0)	10 (25.0)	6 (15.0)

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	14 (35.0)	8 (20.0)	6 (15.0)
Hypertension	4 (10.0)	4 (10.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (88.2)	5 (29.4)	10 (58.8)
Blood and lymphatic system disorders			
-Total	10 (58.8)	8 (47.1)	2 (11.8)
Febrile neutropenia	9 (52.9)	9 (52.9)	0
Neutropenia	2 (11.8)	0	2 (11.8)
Leukopenia	1 (5.9)	0	1 (5.9)
Cardiac disorders			
-Total	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	3 (17.6)	3 (17.6)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (5.9)	1 (5.9)	0
Anal fistula	1 (5.9)	1 (5.9)	0
Duodenal perforation	1 (5.9)	1 (5.9)	0
Neutropenic colitis	1 (5.9)	1 (5.9)	0
Proctalgia	1 (5.9)	1 (5.9)	0
Stomatitis	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Hepatic function abnormal	1 (5.9)	0	1 (5.9)
Immune system disorders			
-Total	6 (35.3)	5 (29.4)	1 (5.9)
Cytokine release syndrome	6 (35.3)	5 (29.4)	1 (5.9)
Infections and infestations			
-Total	8 (47.1)	7 (41.2)	1 (5.9)
Catheter site infection	2 (11.8)	2 (11.8)	0
Acute sinusitis	1 (5.9)	1 (5.9)	0
Anal abscess	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (5.9)	0	1 (5.9)
Ear infection	1 (5.9)	1 (5.9)	0
Fungal pharyngitis	1 (5.9)	1 (5.9)	0
Fungal skin infection	1 (5.9)	1 (5.9)	0
Peritonitis	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	1 (5.9)	0
Staphylococcal abscess	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Staphylococcal infection	1 (5.9)	1 (5.9)	0
Systemic mycosis	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Varicella zoster virus infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Investigations			
-Total	10 (58.8)	4 (23.5)	6 (35.3)
Lymphocyte count decreased	6 (35.3)	4 (23.5)	2 (11.8)
Neutrophil count decreased	6 (35.3)	1 (5.9)	5 (29.4)
White blood cell count decreased	5 (29.4)	0	5 (29.4)

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	4 (23.5)	4 (23.5)	0
Platelet count decreased	4 (23.5)	4 (23.5)	0
Blood bilirubin increased	3 (17.6)	3 (17.6)	0
Alanine aminotransferase increased	2 (11.8)	2 (11.8)	0
Blood creatine phosphokinase increased	1 (5.9)	1 (5.9)	0
Blood creatinine increased	1 (5.9)	1 (5.9)	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0
Haemoglobin decreased	1 (5.9)	1 (5.9)	0
Weight increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	6 (35.3)	6 (35.3)	0
Hypokalaemia	3 (17.6)	3 (17.6)	0
Decreased appetite	2 (11.8)	2 (11.8)	0
Hypophosphataemia	2 (11.8)	2 (11.8)	0
Hypertriglyceridaemia	1 (5.9)	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Acute kidney injury	1 (5.9)	0	1 (5.9)
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			
-Total	1 (5.9)	1 (5.9)	0
Prostatitis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (23.5)	2 (11.8)	2 (11.8)
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Epistaxis	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Laryngeal oedema	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			
-Total	1 (5.9)	1 (5.9)	0
Eczema	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (87.7)	14 (17.3)	57 (70.4)
Blood and lymphatic system disorders			
-Total	45 (55.6)	28 (34.6)	17 (21.0)
Febrile neutropenia	30 (37.0)	27 (33.3)	3 (3.7)
Anaemia	22 (27.2)	21 (25.9)	1 (1.2)
Thrombocytopenia	12 (14.8)	5 (6.2)	7 (8.6)
Neutropenia	11 (13.6)	3 (3.7)	8 (9.9)
Leukopenia	4 (4.9)	1 (1.2)	3 (3.7)
Cardiac disorders			
-Total	9 (11.1)	8 (9.9)	1 (1.2)
Tachycardia	6 (7.4)	5 (6.2)	1 (1.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	3 (3.7)	3 (3.7)	0
Gastrointestinal disorders			
-Total	5 (6.2)	5 (6.2)	0
Stomatitis	4 (4.9)	4 (4.9)	0
Abdominal pain	1 (1.2)	1 (1.2)	0
General disorders and administration site conditions			
-Total	13 (16.0)	11 (13.6)	2 (2.5)
Pyrexia	13 (16.0)	11 (13.6)	2 (2.5)
Hepatobiliary disorders			
-Total	2 (2.5)	2 (2.5)	0
Hepatic function abnormal	2 (2.5)	2 (2.5)	0
Immune system disorders			
-Total	36 (44.4)	16 (19.8)	20 (24.7)
Cytokine release syndrome	32 (39.5)	12 (14.8)	20 (24.7)
Hypogammaglobulinaemia	8 (9.9)	8 (9.9)	0
Infections and infestations			
-Total	17 (21.0)	12 (14.8)	5 (6.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	6 (7.4)	3 (3.7)	3 (3.7)
Staphylococcal bacteraemia	6 (7.4)	6 (7.4)	0
Parainfluenzae virus infection	5 (6.2)	4 (4.9)	1 (1.2)
Staphylococcal infection	3 (3.7)	2 (2.5)	1 (1.2)
Upper respiratory tract infection	2 (2.5)	2 (2.5)	0
Investigations			
-Total	46 (56.8)	14 (17.3)	32 (39.5)
White blood cell count decreased	21 (25.9)	1 (1.2)	20 (24.7)
Neutrophil count decreased	20 (24.7)	2 (2.5)	18 (22.2)
Platelet count decreased	16 (19.8)	2 (2.5)	14 (17.3)
Lymphocyte count decreased	15 (18.5)	5 (6.2)	10 (12.3)
Aspartate aminotransferase increased	10 (12.3)	6 (7.4)	4 (4.9)
Alanine aminotransferase increased	7 (8.6)	7 (8.6)	0
Blood bilirubin increased	7 (8.6)	7 (8.6)	0
C-reactive protein increased	6 (7.4)	5 (6.2)	1 (1.2)
Blood creatinine increased	3 (3.7)	2 (2.5)	1 (1.2)
Blood creatine phosphokinase increased	1 (1.2)	0	1 (1.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.2)	1 (1.2)	0
Weight increased	1 (1.2)	1 (1.2)	0
Metabolism and nutrition disorders			
-Total	31 (38.3)	19 (23.5)	12 (14.8)
Hypokalaemia	13 (16.0)	10 (12.3)	3 (3.7)
Decreased appetite	12 (14.8)	10 (12.3)	2 (2.5)
Hypophosphataemia	8 (9.9)	7 (8.6)	1 (1.2)
Hypervolaemia	6 (7.4)	6 (7.4)	0
Hypocalcaemia	6 (7.4)	6 (7.4)	0
Hyperglycaemia	5 (6.2)	5 (6.2)	0
Metabolic acidosis	5 (6.2)	2 (2.5)	3 (3.7)
Tumour lysis syndrome	5 (6.2)	3 (3.7)	2 (2.5)
Hypertriglyceridaemia	1 (1.2)	0	1 (1.2)
Nervous system disorders			
-Total	5 (6.2)	5 (6.2)	0
Encephalopathy	5 (6.2)	5 (6.2)	0
Psychiatric disorders			
-Total	2 (2.5)	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (2.5)	2 (2.5)	0
Renal and urinary disorders			
-Total	7 (8.6)	3 (3.7)	4 (4.9)
Acute kidney injury	7 (8.6)	3 (3.7)	4 (4.9)
Renal tubular necrosis	1 (1.2)	0	1 (1.2)
Respiratory, thoracic and mediastinal disorders			
-Total	27 (33.3)	11 (13.6)	16 (19.8)
Hypoxia	14 (17.3)	9 (11.1)	5 (6.2)
Respiratory failure	10 (12.3)	0	10 (12.3)
Pulmonary oedema	8 (9.9)	6 (7.4)	2 (2.5)
Dyspnoea	5 (6.2)	3 (3.7)	2 (2.5)
Tachypnoea	5 (6.2)	4 (4.9)	1 (1.2)
Epistaxis	2 (2.5)	2 (2.5)	0
Vascular disorders			
-Total	23 (28.4)	14 (17.3)	9 (11.1)
Hypotension	20 (24.7)	11 (13.6)	9 (11.1)
Hypertension	5 (6.2)	5 (6.2)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (85.7)	10 (35.7)	14 (50.0)
Blood and lymphatic system disorders			
-Total	16 (57.1)	9 (32.1)	7 (25.0)
Febrile neutropenia	11 (39.3)	10 (35.7)	1 (3.6)
Anaemia	6 (21.4)	6 (21.4)	0
Thrombocytopenia	5 (17.9)	3 (10.7)	2 (7.1)
Neutropenia	4 (14.3)	1 (3.6)	3 (10.7)
Leukopenia	3 (10.7)	1 (3.6)	2 (7.1)
Disseminated intravascular coagulation	2 (7.1)	2 (7.1)	0
Pancytopenia	2 (7.1)	2 (7.1)	0
Cardiac disorders			

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Tachycardia	2 (7.1)	1 (3.6)	1 (3.6)
Gastrointestinal disorders			
-Total	3 (10.7)	3 (10.7)	0
Nausea	2 (7.1)	2 (7.1)	0
Stomatitis	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions			
-Total	4 (14.3)	1 (3.6)	3 (10.7)
Multiple organ dysfunction syndrome	2 (7.1)	0	2 (7.1)
Pyrexia	2 (7.1)	1 (3.6)	1 (3.6)
Immune system disorders			
-Total	11 (39.3)	6 (21.4)	5 (17.9)
Cytokine release syndrome	7 (25.0)	3 (10.7)	4 (14.3)
Hypogammaglobulinaemia	3 (10.7)	3 (10.7)	0
Haemophagocytic lymphohistiocytosis	2 (7.1)	0	2 (7.1)
Immunodeficiency	2 (7.1)	2 (7.1)	0
Infections and infestations			

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (32.1)	6 (21.4)	3 (10.7)
Staphylococcal bacteraemia	4 (14.3)	4 (14.3)	0
Encephalitis	2 (7.1)	0	2 (7.1)
Parainfluenzae virus infection	2 (7.1)	2 (7.1)	0
Pneumonia	2 (7.1)	1 (3.6)	1 (3.6)
Respiratory syncytial virus infection	2 (7.1)	2 (7.1)	0
Rhinovirus infection	2 (7.1)	2 (7.1)	0
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0
Investigations			
-Total	15 (53.6)	6 (21.4)	9 (32.1)
Neutrophil count decreased	8 (28.6)	2 (7.1)	6 (21.4)
Lymphocyte count decreased	7 (25.0)	5 (17.9)	2 (7.1)
White blood cell count decreased	6 (21.4)	1 (3.6)	5 (17.9)
Platelet count decreased	4 (14.3)	0	4 (14.3)
C-reactive protein increased	3 (10.7)	3 (10.7)	0
Alanine aminotransferase increased	2 (7.1)	2 (7.1)	0
Aspartate aminotransferase increased	2 (7.1)	1 (3.6)	1 (3.6)
Blood bilirubin increased	2 (7.1)	2 (7.1)	0

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	2 (7.1)	2 (7.1)	0
Metabolism and nutrition disorders			
-Total	8 (28.6)	5 (17.9)	3 (10.7)
Hypokalaemia	5 (17.9)	3 (10.7)	2 (7.1)
Decreased appetite	3 (10.7)	2 (7.1)	1 (3.6)
Hypophosphataemia	3 (10.7)	3 (10.7)	0
Hyperglycaemia	2 (7.1)	2 (7.1)	0
Hypocalcaemia	2 (7.1)	2 (7.1)	0
Hypervolaemia	1 (3.6)	1 (3.6)	0
Tumour lysis syndrome	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	4 (14.3)	4 (14.3)	0
Encephalopathy	2 (7.1)	2 (7.1)	0
Seizure	2 (7.1)	2 (7.1)	0
Renal and urinary disorders			
-Total	1 (3.6)	0	1 (3.6)
Acute kidney injury	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	6 (21.4)	2 (7.1)	4 (14.3)
Acute respiratory distress syndrome	2 (7.1)	0	2 (7.1)
Dyspnoea	2 (7.1)	0	2 (7.1)
Hypoxia	2 (7.1)	2 (7.1)	0
Pleural effusion	2 (7.1)	1 (3.6)	1 (3.6)
Pulmonary oedema	2 (7.1)	2 (7.1)	0
Tachypnoea	2 (7.1)	1 (3.6)	1 (3.6)
Vascular disorders			
-Total	5 (17.9)	4 (14.3)	1 (3.6)
Hypotension	4 (14.3)	3 (10.7)	1 (3.6)
Hypertension	2 (7.1)	2 (7.1)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (88.6)	11 (15.7)	51 (72.9)
Blood and lymphatic system disorders			
-Total	41 (58.6)	28 (40.0)	13 (18.6)
Febrile neutropenia	28 (40.0)	26 (37.1)	2 (2.9)
Anaemia	16 (22.9)	15 (21.4)	1 (1.4)
Neutropenia	9 (12.9)	2 (2.9)	7 (10.0)
Thrombocytopenia	7 (10.0)	2 (2.9)	5 (7.1)
Leukopenia	2 (2.9)	0	2 (2.9)
Pancytopenia	2 (2.9)	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (11.4)	6 (8.6)	2 (2.9)
Cardiac failure	4 (5.7)	2 (2.9)	2 (2.9)
Tachycardia	4 (5.7)	4 (5.7)	0
Gastrointestinal disorders			
-Total	4 (5.7)	4 (5.7)	0
Stomatitis	3 (4.3)	3 (4.3)	0
Nausea	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	12 (17.1)	10 (14.3)	2 (2.9)
Pyrexia	11 (15.7)	10 (14.3)	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	34 (48.6)	17 (24.3)	17 (24.3)
Cytokine release syndrome	31 (44.3)	14 (20.0)	17 (24.3)
Hypogammaglobulinaemia	5 (7.1)	5 (7.1)	0
Haemophagocytic lymphohistiocytosis	2 (2.9)	2 (2.9)	0
Immunodeficiency	2 (2.9)	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	18 (25.7)	13 (18.6)	5 (7.1)
Pneumonia	5 (7.1)	3 (4.3)	2 (2.9)
Bacteraemia	4 (5.7)	3 (4.3)	1 (1.4)
Staphylococcal infection	4 (5.7)	3 (4.3)	1 (1.4)
Parainfluenzae virus infection	3 (4.3)	2 (2.9)	1 (1.4)
Staphylococcal bacteraemia	3 (4.3)	3 (4.3)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	40 (57.1)	12 (17.1)	28 (40.0)
White blood cell count decreased	20 (28.6)	0	20 (28.6)
Neutrophil count decreased	18 (25.7)	1 (1.4)	17 (24.3)
Platelet count decreased	16 (22.9)	6 (8.6)	10 (14.3)
Lymphocyte count decreased	14 (20.0)	4 (5.7)	10 (14.3)
Aspartate aminotransferase increased	12 (17.1)	9 (12.9)	3 (4.3)
Blood bilirubin increased	8 (11.4)	8 (11.4)	0
Alanine aminotransferase increased	7 (10.0)	7 (10.0)	0
C-reactive protein increased	3 (4.3)	2 (2.9)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	2 (2.9)	1 (1.4)	1 (1.4)
Metabolism and nutrition disorders			
-Total	29 (41.4)	21 (30.0)	8 (11.4)
Decreased appetite	11 (15.7)	10 (14.3)	1 (1.4)
Hypokalaemia	11 (15.7)	10 (14.3)	1 (1.4)
Hypophosphataemia	7 (10.0)	6 (8.6)	1 (1.4)
Hypervolaemia	5 (7.1)	5 (7.1)	0
Metabolic acidosis	5 (7.1)	2 (2.9)	3 (4.3)
Tumour lysis syndrome	5 (7.1)	3 (4.3)	2 (2.9)
Hypocalcaemia	4 (5.7)	4 (5.7)	0
Hyperglycaemia	3 (4.3)	3 (4.3)	0
Nervous system disorders			
-Total	4 (5.7)	4 (5.7)	0
Encephalopathy	3 (4.3)	3 (4.3)	0
Seizure	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (10.0)	3 (4.3)	4 (5.7)
Acute kidney injury	7 (10.0)	3 (4.3)	4 (5.7)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	27 (38.6)	10 (14.3)	17 (24.3)
Hypoxia	14 (20.0)	8 (11.4)	6 (8.6)
Respiratory failure	10 (14.3)	0	10 (14.3)
Pulmonary oedema	6 (8.6)	4 (5.7)	2 (2.9)
Dyspnoea	3 (4.3)	3 (4.3)	0
Tachypnoea	3 (4.3)	3 (4.3)	0
Acute respiratory distress syndrome	2 (2.9)	0	2 (2.9)
Pleural effusion	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	20 (28.6)	11 (15.7)	9 (12.9)
Hypotension	18 (25.7)	9 (12.9)	9 (12.9)
Hypertension	3 (4.3)	3 (4.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	3 (27.3)	7 (63.6)
Blood and lymphatic system disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Neutropenia	2 (18.2)	0	2 (18.2)
Anaemia	1 (9.1)	1 (9.1)	0
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Leukopenia	1 (9.1)	0	1 (9.1)
Pancytopenia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Hypogammaglobulinaemia	3 (27.3)	3 (27.3)	0
Cytokine release syndrome	2 (18.2)	1 (9.1)	1 (9.1)
Infections and infestations			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Device related infection	1 (9.1)	1 (9.1)	0
Encephalitis	1 (9.1)	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Paronychia	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	1 (9.1)	0
Staphylococcal skin infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0
Investigations			
-Total	7 (63.6)	2 (18.2)	5 (45.5)
Platelet count decreased	4 (36.4)	0	4 (36.4)
White blood cell count decreased	3 (27.3)	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0
Blood bilirubin increased	1 (9.1)	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	1 (9.1)
Blood uric acid increased	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
Weight decreased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	0	1 (9.1)

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemochromatosis	1 (9.1)	1 (9.1)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Autonomic neuropathy	1 (9.1)	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	1 (9.1)	0
Renal tubular disorder	1 (9.1)	1 (9.1)	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypertension	1 (9.1)	1 (9.1)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	76 (87.4)	17 (19.5)	59 (67.8)
Blood and lymphatic system disorders			
-Total	53 (60.9)	36 (41.4)	17 (19.5)
Febrile neutropenia	38 (43.7)	35 (40.2)	3 (3.4)
Anaemia	21 (24.1)	20 (23.0)	1 (1.1)
Thrombocytopenia	12 (13.8)	5 (5.7)	7 (8.0)
Neutropenia	11 (12.6)	3 (3.4)	8 (9.2)
Leukopenia	4 (4.6)	1 (1.1)	3 (3.4)
Pancytopenia	3 (3.4)	2 (2.3)	1 (1.1)
Disseminated intravascular coagulation	2 (2.3)	2 (2.3)	0
Cardiac disorders			

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (6.9)	5 (5.7)	1 (1.1)
Tachycardia	6 (6.9)	5 (5.7)	1 (1.1)
Gastrointestinal disorders			
-Total	5 (5.7)	5 (5.7)	0
Stomatitis	5 (5.7)	5 (5.7)	0
Pancreatitis	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	13 (14.9)	11 (12.6)	2 (2.3)
Pyrexia	13 (14.9)	11 (12.6)	2 (2.3)
Immune system disorders			
-Total	38 (43.7)	18 (20.7)	20 (23.0)
Cytokine release syndrome	36 (41.4)	16 (18.4)	20 (23.0)
Hypogammaglobulinaemia	5 (5.7)	5 (5.7)	0
Infections and infestations			
-Total	21 (24.1)	13 (14.9)	8 (9.2)
Pneumonia	7 (8.0)	4 (4.6)	3 (3.4)
Staphylococcal bacteraemia	7 (8.0)	7 (8.0)	0
Parainfluenzae virus infection	4 (4.6)	3 (3.4)	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	3 (3.4)	0	3 (3.4)
Upper respiratory tract infection	2 (2.3)	2 (2.3)	0
Device related infection	1 (1.1)	1 (1.1)	0
Encephalitis	1 (1.1)	0	1 (1.1)
Respiratory syncytial virus infection	1 (1.1)	1 (1.1)	0
Rhinovirus infection	1 (1.1)	1 (1.1)	0
Investigations			
-Total	50 (57.5)	18 (20.7)	32 (36.8)
Neutrophil count decreased	24 (27.6)	3 (3.4)	21 (24.1)
White blood cell count decreased	23 (26.4)	1 (1.1)	22 (25.3)
Lymphocyte count decreased	19 (21.8)	9 (10.3)	10 (11.5)
Platelet count decreased	16 (18.4)	6 (6.9)	10 (11.5)
Aspartate aminotransferase increased	14 (16.1)	10 (11.5)	4 (4.6)
Blood bilirubin increased	9 (10.3)	9 (10.3)	0
Alanine aminotransferase increased	8 (9.2)	8 (9.2)	0
C-reactive protein increased	5 (5.7)	4 (4.6)	1 (1.1)
Serum ferritin increased	3 (3.4)	2 (2.3)	1 (1.1)
Blood fibrinogen decreased	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.1)	0	1 (1.1)
Gamma-glutamyltransferase increased	1 (1.1)	1 (1.1)	0
Weight decreased	1 (1.1)	1 (1.1)	0
Metabolism and nutrition disorders			
-Total	35 (40.2)	26 (29.9)	9 (10.3)
Hypokalaemia	15 (17.2)	12 (13.8)	3 (3.4)
Decreased appetite	13 (14.9)	12 (13.8)	1 (1.1)
Hypophosphataemia	9 (10.3)	9 (10.3)	0
Hypervolaemia	6 (6.9)	6 (6.9)	0
Hypocalcaemia	6 (6.9)	6 (6.9)	0
Tumour lysis syndrome	6 (6.9)	4 (4.6)	2 (2.3)
Hyperglycaemia	5 (5.7)	5 (5.7)	0
Metabolic acidosis	5 (5.7)	2 (2.3)	3 (3.4)
Nervous system disorders			
-Total	10 (11.5)	9 (10.3)	1 (1.1)
Encephalopathy	5 (5.7)	5 (5.7)	0
Headache	2 (2.3)	2 (2.3)	0
Seizure	2 (2.3)	2 (2.3)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cerebral haemorrhage	1 (1.1)	0	1 (1.1)
Renal and urinary disorders			
-Total	8 (9.2)	3 (3.4)	5 (5.7)
Acute kidney injury	8 (9.2)	3 (3.4)	5 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (33.3)	12 (13.8)	17 (19.5)
Hypoxia	16 (18.4)	10 (11.5)	6 (6.9)
Respiratory failure	10 (11.5)	0	10 (11.5)
Pulmonary oedema	8 (9.2)	6 (6.9)	2 (2.3)
Dyspnoea	5 (5.7)	3 (3.4)	2 (2.3)
Tachypnoea	5 (5.7)	4 (4.6)	1 (1.1)
Vascular disorders			
-Total	24 (27.6)	14 (16.1)	10 (11.5)
Hypotension	22 (25.3)	12 (13.8)	10 (11.5)
Hypertension	4 (4.6)	4 (4.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	4 (57.1)	4 (57.1)	0
Febrile neutropenia	3 (42.9)	3 (42.9)	0
Anaemia	2 (28.6)	2 (28.6)	0
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Duodenal perforation	1 (14.3)	1 (14.3)	0
Dysphagia	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatic function abnormal	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Cytokine release syndrome	3 (42.9)	0	3 (42.9)
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	5 (71.4)	5 (71.4)	0
Bronchiolitis	1 (14.3)	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Metapneumovirus infection	1 (14.3)	1 (14.3)	0
Peritonitis	1 (14.3)	1 (14.3)	0
Pneumonia respiratory syncytial viral	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Investigations			

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (85.7)	0	6 (85.7)
Neutrophil count decreased	4 (57.1)	1 (14.3)	3 (42.9)
White blood cell count decreased	4 (57.1)	0	4 (57.1)
Lymphocyte count decreased	3 (42.9)	2 (28.6)	1 (14.3)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)
Platelet count decreased	2 (28.6)	0	2 (28.6)
Urine output decreased	2 (28.6)	1 (14.3)	1 (14.3)
Alanine aminotransferase increased	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	1 (14.3)	0
Blood creatine phosphokinase increased	1 (14.3)	1 (14.3)	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0
Weight increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Decreased appetite	2 (28.6)	2 (28.6)	0
Hypercalcaemia	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (14.3)	1 (14.3)	0
Hyperkalaemia	1 (14.3)	1 (14.3)	0
Hypokalaemia	1 (14.3)	1 (14.3)	0
Metabolic acidosis	1 (14.3)	0	1 (14.3)
Obesity	1 (14.3)	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Cerebral haemorrhage	1 (14.3)	0	1 (14.3)
Encephalopathy	1 (14.3)	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)
Somnolence	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Acute kidney injury	3 (42.9)	1 (14.3)	2 (28.6)

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Hypoxia	4 (57.1)	2 (28.6)	2 (28.6)
Pleural effusion	1 (14.3)	1 (14.3)	0
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Hypotension	3 (42.9)	1 (14.3)	2 (28.6)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (86.8)	21 (23.1)	58 (63.7)
Blood and lymphatic system disorders			
-Total	51 (56.0)	32 (35.2)	19 (20.9)
Febrile neutropenia	36 (39.6)	33 (36.3)	3 (3.3)
Anaemia	20 (22.0)	19 (20.9)	1 (1.1)
Neutropenia	13 (14.3)	3 (3.3)	10 (11.0)
Thrombocytopenia	12 (13.2)	5 (5.5)	7 (7.7)
Leukopenia	5 (5.5)	1 (1.1)	4 (4.4)
Cardiac disorders			
-Total	5 (5.5)	4 (4.4)	1 (1.1)
Tachycardia	5 (5.5)	4 (4.4)	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	6 (6.6)	5 (5.5)	1 (1.1)
Stomatitis	5 (5.5)	5 (5.5)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
General disorders and administration site conditions			
-Total	13 (14.3)	11 (12.1)	2 (2.2)
Pyrexia	13 (14.3)	11 (12.1)	2 (2.2)
Hepatobiliary disorders			
-Total	2 (2.2)	2 (2.2)	0
Hepatic function abnormal	2 (2.2)	2 (2.2)	0
Immune system disorders			
-Total	38 (41.8)	20 (22.0)	18 (19.8)
Cytokine release syndrome	35 (38.5)	17 (18.7)	18 (19.8)
Hypogammaglobulinaemia	7 (7.7)	7 (7.7)	0
Infections and infestations			
-Total	20 (22.0)	15 (16.5)	5 (5.5)
Pneumonia	7 (7.7)	4 (4.4)	3 (3.3)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	7 (7.7)	7 (7.7)	0
Parainfluenzae virus infection	5 (5.5)	4 (4.4)	1 (1.1)
Escherichia bacteraemia	2 (2.2)	1 (1.1)	1 (1.1)
Metapneumovirus infection	2 (2.2)	2 (2.2)	0
Upper respiratory tract infection	2 (2.2)	2 (2.2)	0
Bronchiolitis	1 (1.1)	1 (1.1)	0
Investigations			
-Total	50 (54.9)	18 (19.8)	32 (35.2)
Neutrophil count decreased	22 (24.2)	2 (2.2)	20 (22.0)
White blood cell count decreased	22 (24.2)	1 (1.1)	21 (23.1)
Lymphocyte count decreased	18 (19.8)	7 (7.7)	11 (12.1)
Platelet count decreased	18 (19.8)	6 (6.6)	12 (13.2)
Aspartate aminotransferase increased	13 (14.3)	10 (11.0)	3 (3.3)
Blood bilirubin increased	9 (9.9)	9 (9.9)	0
Alanine aminotransferase increased	8 (8.8)	8 (8.8)	0
C-reactive protein increased	6 (6.6)	5 (5.5)	1 (1.1)
Blood creatinine increased	2 (2.2)	2 (2.2)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (1.1)	0	1 (1.1)
Blood immunoglobulin m decreased	1 (1.1)	1 (1.1)	0
Weight increased	1 (1.1)	1 (1.1)	0
Metabolism and nutrition disorders			
-Total	34 (37.4)	24 (26.4)	10 (11.0)
Hypokalaemia	15 (16.5)	12 (13.2)	3 (3.3)
Decreased appetite	12 (13.2)	10 (11.0)	2 (2.2)
Hypophosphataemia	10 (11.0)	9 (9.9)	1 (1.1)
Hypervolaemia	6 (6.6)	6 (6.6)	0
Hypocalcaemia	6 (6.6)	6 (6.6)	0
Tumour lysis syndrome	5 (5.5)	3 (3.3)	2 (2.2)
Hyperglycaemia	4 (4.4)	4 (4.4)	0
Metabolic acidosis	4 (4.4)	2 (2.2)	2 (2.2)
Hyperkalaemia	2 (2.2)	1 (1.1)	1 (1.1)
Hypercalcaemia	1 (1.1)	0	1 (1.1)
Nervous system disorders			
-Total	5 (5.5)	4 (4.4)	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	4 (4.4)	4 (4.4)	0
Cerebral haemorrhage	1 (1.1)	0	1 (1.1)
Somnolence	1 (1.1)	1 (1.1)	0
Psychiatric disorders			
-Total	2 (2.2)	2 (2.2)	0
Mental status changes	2 (2.2)	2 (2.2)	0
Renal and urinary disorders			
-Total	5 (5.5)	2 (2.2)	3 (3.3)
Acute kidney injury	5 (5.5)	2 (2.2)	3 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	26 (28.6)	10 (11.0)	16 (17.6)
Hypoxia	12 (13.2)	8 (8.8)	4 (4.4)
Respiratory failure	10 (11.0)	0	10 (11.0)
Pulmonary oedema	8 (8.8)	6 (6.6)	2 (2.2)
Dyspnoea	5 (5.5)	3 (3.3)	2 (2.2)
Tachypnoea	4 (4.4)	3 (3.3)	1 (1.1)
Pleural effusion	2 (2.2)	1 (1.1)	1 (1.1)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	22 (24.2)	14 (15.4)	8 (8.8)
Hypotension	19 (20.9)	11 (12.1)	8 (8.8)
Hypertension	5 (5.5)	5 (5.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	7 (17.5)	31 (77.5)
Blood and lymphatic system disorders			
-Total	28 (70.0)	16 (40.0)	12 (30.0)
Febrile neutropenia	16 (40.0)	15 (37.5)	1 (2.5)
Anaemia	13 (32.5)	13 (32.5)	0
Neutropenia	11 (27.5)	2 (5.0)	9 (22.5)
Thrombocytopenia	6 (15.0)	1 (2.5)	5 (12.5)
Leukopenia	4 (10.0)	1 (2.5)	3 (7.5)
Coagulopathy	2 (5.0)	2 (5.0)	0
Lymphopenia	2 (5.0)	0	2 (5.0)
Pancytopenia	2 (5.0)	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Cardiac arrest	1 (2.5)	0	1 (2.5)
Cardiac failure	1 (2.5)	0	1 (2.5)
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	3 (7.5)	3 (7.5)	0
Nausea	2 (5.0)	2 (5.0)	0
Stomatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	5 (12.5)	3 (7.5)	2 (5.0)
Pyrexia	4 (10.0)	3 (7.5)	1 (2.5)
Pain	2 (5.0)	2 (5.0)	0
Multiple organ dysfunction syndrome	1 (2.5)	0	1 (2.5)
Hepatobiliary disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	3 (7.5)	2 (5.0)	1 (2.5)
Immune system disorders			
-Total	27 (67.5)	16 (40.0)	11 (27.5)
Cytokine release syndrome	20 (50.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	7 (17.5)	7 (17.5)	0
Immunodeficiency	4 (10.0)	4 (10.0)	0
Graft versus host disease	1 (2.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	19 (47.5)	11 (27.5)	8 (20.0)
Parainfluenzae virus infection	4 (10.0)	3 (7.5)	1 (2.5)
Pneumonia	4 (10.0)	2 (5.0)	2 (5.0)
Bacteraemia	3 (7.5)	2 (5.0)	1 (2.5)
Bronchopulmonary aspergillosis	3 (7.5)	2 (5.0)	1 (2.5)
Catheter site infection	2 (5.0)	2 (5.0)	0
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Escherichia bacteraemia	2 (5.0)	1 (2.5)	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Gastroenteritis	2 (5.0)	2 (5.0)	0
Herpes zoster	2 (5.0)	2 (5.0)	0
Human herpesvirus 6 infection	2 (5.0)	2 (5.0)	0
Oral herpes	2 (5.0)	2 (5.0)	0
Rhinovirus infection	2 (5.0)	2 (5.0)	0
Sepsis	2 (5.0)	1 (2.5)	1 (2.5)
Sinusitis	2 (5.0)	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	2 (5.0)	0
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Clostridium difficile infection	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Investigations			
-Total	27 (67.5)	7 (17.5)	20 (50.0)
White blood cell count decreased	17 (42.5)	0	17 (42.5)
Neutrophil count decreased	14 (35.0)	1 (2.5)	13 (32.5)
Lymphocyte count decreased	11 (27.5)	2 (5.0)	9 (22.5)
Platelet count decreased	11 (27.5)	3 (7.5)	8 (20.0)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (12.5)	5 (12.5)	0
Aspartate aminotransferase increased	5 (12.5)	4 (10.0)	1 (2.5)
Blood bilirubin increased	2 (5.0)	2 (5.0)	0
Gamma-glutamyltransferase increased	2 (5.0)	2 (5.0)	0
Weight decreased	2 (5.0)	2 (5.0)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0
C-reactive protein increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	14 (35.0)	10 (25.0)	4 (10.0)
Hypokalaemia	7 (17.5)	6 (15.0)	1 (2.5)
Decreased appetite	4 (10.0)	2 (5.0)	2 (5.0)
Hyperglycaemia	3 (7.5)	3 (7.5)	0
Hypophosphataemia	3 (7.5)	3 (7.5)	0
Hypocalcaemia	2 (5.0)	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	5 (12.5)	0
Back pain	3 (7.5)	3 (7.5)	0
Pain in extremity	2 (5.0)	2 (5.0)	0
Nervous system disorders			
-Total	4 (10.0)	4 (10.0)	0
Seizure	2 (5.0)	2 (5.0)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Headache	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	2 (5.0)	2 (5.0)	0
Anxiety	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	8 (20.0)	5 (12.5)
Hypoxia	7 (17.5)	4 (10.0)	3 (7.5)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pulmonary oedema	4 (10.0)	4 (10.0)	0
Dyspnoea	3 (7.5)	2 (5.0)	1 (2.5)
Tachypnoea	3 (7.5)	2 (5.0)	1 (2.5)
Epistaxis	1 (2.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	6 (15.0)	4 (10.0)	2 (5.0)
Hypotension	5 (12.5)	3 (7.5)	2 (5.0)
Hypertension	1 (2.5)	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (92.5)	9 (22.5)	28 (70.0)
Blood and lymphatic system disorders			
-Total	23 (57.5)	17 (42.5)	6 (15.0)
Febrile neutropenia	20 (50.0)	19 (47.5)	1 (2.5)
Anaemia	7 (17.5)	6 (15.0)	1 (2.5)
Thrombocytopenia	6 (15.0)	4 (10.0)	2 (5.0)
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Neutropenia	2 (5.0)	1 (2.5)	1 (2.5)
Leukopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	8 (20.0)	4 (10.0)	4 (10.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (7.5)	2 (5.0)	1 (2.5)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)
Left ventricular dysfunction	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	8 (20.0)	7 (17.5)	1 (2.5)
Stomatitis	3 (7.5)	3 (7.5)	0
Diarrhoea	2 (5.0)	2 (5.0)	0
Pancreatitis	2 (5.0)	2 (5.0)	0
Vomiting	2 (5.0)	2 (5.0)	0
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Nausea	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Pyrexia	7 (17.5)	6 (15.0)	1 (2.5)
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Hepatobiliary disorders			
-Total	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (2.5)	1 (2.5)	0
Immune system disorders			
-Total	19 (47.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	18 (45.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	3 (7.5)	2 (5.0)	1 (2.5)
Graft versus host disease	1 (2.5)	1 (2.5)	0
Hypogammaglobulinaemia	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	16 (40.0)	13 (32.5)	3 (7.5)
Staphylococcal bacteraemia	5 (12.5)	5 (12.5)	0
Bronchiolitis	2 (5.0)	2 (5.0)	0
Clostridium difficile infection	2 (5.0)	2 (5.0)	0
Metapneumovirus infection	2 (5.0)	2 (5.0)	0
Pneumocystis jirovecii pneumonia	2 (5.0)	1 (2.5)	1 (2.5)
Pneumonia	2 (5.0)	2 (5.0)	0
Septic shock	2 (5.0)	0	2 (5.0)
Bacteraemia	1 (2.5)	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0
Sepsis	1 (2.5)	0	1 (2.5)
Sinusitis	1 (2.5)	1 (2.5)	0
Staphylococcal infection	1 (2.5)	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	28 (70.0)	12 (30.0)	16 (40.0)
Neutrophil count decreased	11 (27.5)	2 (5.0)	9 (22.5)
Lymphocyte count decreased	10 (25.0)	7 (17.5)	3 (7.5)
White blood cell count decreased	9 (22.5)	1 (2.5)	8 (20.0)
Aspartate aminotransferase increased	8 (20.0)	6 (15.0)	2 (5.0)
Blood bilirubin increased	8 (20.0)	8 (20.0)	0
Platelet count decreased	8 (20.0)	3 (7.5)	5 (12.5)
Alanine aminotransferase increased	4 (10.0)	4 (10.0)	0
C-reactive protein increased	4 (10.0)	3 (7.5)	1 (2.5)
Serum ferritin increased	4 (10.0)	3 (7.5)	1 (2.5)
Blood creatinine increased	3 (7.5)	2 (5.0)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	3 (7.5)	3 (7.5)	0
Blood fibrinogen decreased	2 (5.0)	1 (2.5)	1 (2.5)
Blood uric acid increased	2 (5.0)	1 (2.5)	1 (2.5)
Electrocardiogram qt prolonged	2 (5.0)	1 (2.5)	1 (2.5)
Fibrin d dimer increased	2 (5.0)	1 (2.5)	1 (2.5)
Urine output decreased	2 (5.0)	1 (2.5)	1 (2.5)
Weight increased	2 (5.0)	2 (5.0)	0
Metabolism and nutrition disorders			
-Total	20 (50.0)	13 (32.5)	7 (17.5)
Decreased appetite	10 (25.0)	10 (25.0)	0
Hypokalaemia	9 (22.5)	7 (17.5)	2 (5.0)
Hypophosphataemia	7 (17.5)	6 (15.0)	1 (2.5)
Hypervolaemia	6 (15.0)	6 (15.0)	0
Hypocalcaemia	4 (10.0)	4 (10.0)	0
Tumour lysis syndrome	3 (7.5)	2 (5.0)	1 (2.5)
Hypercalcaemia	2 (5.0)	1 (2.5)	1 (2.5)
Hyperglycaemia	2 (5.0)	2 (5.0)	0
Hyperkalaemia	2 (5.0)	1 (2.5)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	2 (5.0)	1 (2.5)	1 (2.5)
Metabolic acidosis	2 (5.0)	0	2 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0
Back pain	1 (2.5)	1 (2.5)	0
Pain in extremity	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	7 (17.5)	7 (17.5)	0
Encephalopathy	3 (7.5)	3 (7.5)	0
Headache	2 (5.0)	2 (5.0)	0
Somnolence	2 (5.0)	2 (5.0)	0
Cognitive disorder	1 (2.5)	1 (2.5)	0
Seizure	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	6 (15.0)	6 (15.0)	0
Delirium	3 (7.5)	3 (7.5)	0
Anxiety	2 (5.0)	2 (5.0)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Acute kidney injury	5 (12.5)	2 (5.0)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (42.5)	5 (12.5)	12 (30.0)
Hypoxia	9 (22.5)	6 (15.0)	3 (7.5)
Respiratory failure	6 (15.0)	0	6 (15.0)
Acute respiratory distress syndrome	3 (7.5)	0	3 (7.5)
Pleural effusion	3 (7.5)	2 (5.0)	1 (2.5)
Pulmonary oedema	3 (7.5)	2 (5.0)	1 (2.5)
Atelectasis	2 (5.0)	2 (5.0)	0
Dyspnoea	2 (5.0)	1 (2.5)	1 (2.5)
Epistaxis	2 (5.0)	2 (5.0)	0
Respiratory distress	2 (5.0)	0	2 (5.0)
Tachypnoea	2 (5.0)	2 (5.0)	0
Vascular disorders			
-Total	15 (37.5)	8 (20.0)	7 (17.5)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	13 (32.5)	6 (15.0)	7 (17.5)
Hypertension	4 (10.0)	4 (10.0)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	5 (27.8)	9 (50.0)
Blood and lymphatic system disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Febrile neutropenia	3 (16.7)	2 (11.1)	1 (5.6)
Anaemia	2 (11.1)	2 (11.1)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	3 (16.7)	3 (16.7)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Generalised oedema	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	1 (5.6)	1 (5.6)	0
Hyperbilirubinaemia	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (50.0)	3 (16.7)	6 (33.3)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Investigations			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (22.2)	0	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Febrile neutropenia	3 (37.5)	2 (25.0)	1 (12.5)
Anaemia	1 (12.5)	1 (12.5)	0
Coagulopathy	1 (12.5)	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (37.5)	2 (25.0)	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)
Melaena	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Pyrexia	2 (25.0)	2 (25.0)	0
Multiple organ dysfunction syndrome	1 (12.5)	0	1 (12.5)
Systemic inflammatory response syndrome	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cholestasis	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	2 (25.0)	0	2 (25.0)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	1 (12.5)
Hypogammaglobulinaemia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Encephalitis	1 (12.5)	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Vulval cellulitis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (12.5)	0	1 (12.5)
Wound	1 (12.5)	1 (12.5)	0
Investigations			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	1 (12.5)	2 (25.0)
Aspartate aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	1 (12.5)
Lipase increased	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	5 (62.5)	4 (50.0)	1 (12.5)
Hypophosphataemia	2 (25.0)	2 (25.0)	0
Metabolic acidosis	2 (25.0)	2 (25.0)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	1 (12.5)	1 (12.5)	0
Hyperkalaemia	1 (12.5)	1 (12.5)	0
Hypernatraemia	1 (12.5)	0	1 (12.5)
Hyperuricaemia	1 (12.5)	1 (12.5)	0
Hypocalcaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Rhabdomyolysis	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	2 (25.0)	2 (25.0)	0
Cognitive disorder	1 (12.5)	1 (12.5)	0
Encephalopathy	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Irritability	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)
Renal tubular necrosis	1 (12.5)	0	1 (12.5)
Reproductive system and breast disorders			
-Total	1 (12.5)	1 (12.5)	0
Vaginal ulceration	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Respiratory failure	2 (25.0)	0	2 (25.0)
Tachypnoea	2 (25.0)	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	1 (12.5)
Acute respiratory failure	1 (12.5)	1 (12.5)	0
Atelectasis	1 (12.5)	1 (12.5)	0
Dyspnoea	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory acidosis	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Petechiae	1 (12.5)	1 (12.5)	0
Skin necrosis	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	3 (37.5)	1 (12.5)
Hypertension	1 (12.5)	1 (12.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (83.3)	7 (23.3)	18 (60.0)
Blood and lymphatic system disorders			
-Total	13 (43.3)	7 (23.3)	6 (20.0)
Febrile neutropenia	9 (30.0)	8 (26.7)	1 (3.3)
Anaemia	5 (16.7)	5 (16.7)	0
Neutropenia	4 (13.3)	1 (3.3)	3 (10.0)
Thrombocytopenia	4 (13.3)	2 (6.7)	2 (6.7)
Leukopenia	1 (3.3)	0	1 (3.3)
Pancytopenia	1 (3.3)	1 (3.3)	0
Cardiac disorders			
-Total	7 (23.3)	5 (16.7)	2 (6.7)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	3 (10.0)	3 (10.0)	0
Cardiac failure	2 (6.7)	0	2 (6.7)
Tachycardia	2 (6.7)	2 (6.7)	0
Gastrointestinal disorders			
-Total	5 (16.7)	4 (13.3)	1 (3.3)
Nausea	2 (6.7)	2 (6.7)	0
Stomatitis	2 (6.7)	2 (6.7)	0
Abdominal compartment syndrome	1 (3.3)	0	1 (3.3)
Pancreatitis	1 (3.3)	1 (3.3)	0
Vomiting	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Pyrexia	4 (13.3)	3 (10.0)	1 (3.3)
Multiple organ dysfunction syndrome	2 (6.7)	0	2 (6.7)
Immune system disorders			
-Total	12 (40.0)	5 (16.7)	7 (23.3)
Cytokine release syndrome	10 (33.3)	4 (13.3)	6 (20.0)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	3 (10.0)	2 (6.7)	1 (3.3)
Hypogammaglobulinaemia	1 (3.3)	1 (3.3)	0
Immunodeficiency	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	9 (30.0)	6 (20.0)	3 (10.0)
Staphylococcal bacteraemia	3 (10.0)	3 (10.0)	0
Clostridium difficile infection	2 (6.7)	2 (6.7)	0
Pneumonia	2 (6.7)	0	2 (6.7)
Bacteraemia	1 (3.3)	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	1 (3.3)	0
Sepsis	1 (3.3)	0	1 (3.3)
Investigations			
-Total	17 (56.7)	6 (20.0)	11 (36.7)
White blood cell count decreased	8 (26.7)	1 (3.3)	7 (23.3)
Lymphocyte count decreased	7 (23.3)	3 (10.0)	4 (13.3)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	6 (20.0)	5 (16.7)	1 (3.3)
Neutrophil count decreased	6 (20.0)	1 (3.3)	5 (16.7)
Blood bilirubin increased	5 (16.7)	5 (16.7)	0
Platelet count decreased	4 (13.3)	1 (3.3)	3 (10.0)
C-reactive protein increased	3 (10.0)	2 (6.7)	1 (3.3)
Blood lactate dehydrogenase increased	2 (6.7)	2 (6.7)	0
Electrocardiogram qt prolonged	2 (6.7)	1 (3.3)	1 (3.3)
Fibrin d dimer increased	2 (6.7)	1 (3.3)	1 (3.3)
Serum ferritin increased	2 (6.7)	1 (3.3)	1 (3.3)
Blood creatinine increased	1 (3.3)	1 (3.3)	0
Urine output decreased	1 (3.3)	1 (3.3)	0
Weight increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	10 (33.3)	6 (20.0)	4 (13.3)
Decreased appetite	7 (23.3)	7 (23.3)	0
Hypervolaemia	5 (16.7)	5 (16.7)	0
Hyperglycaemia	3 (10.0)	3 (10.0)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	2 (6.7)	1 (3.3)	1 (3.3)
Hypocalcaemia	2 (6.7)	2 (6.7)	0
Hypokalaemia	2 (6.7)	2 (6.7)	0
Hypophosphataemia	2 (6.7)	2 (6.7)	0
Metabolic acidosis	2 (6.7)	0	2 (6.7)
Tumour lysis syndrome	2 (6.7)	2 (6.7)	0
Acidosis	1 (3.3)	0	1 (3.3)
Hypercalcaemia	1 (3.3)	1 (3.3)	0
Hyperkalaemia	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	2 (6.7)	2 (6.7)	0
Cognitive disorder	1 (3.3)	1 (3.3)	0
Encephalopathy	1 (3.3)	1 (3.3)	0
Somnolence	1 (3.3)	1 (3.3)	0
Psychiatric disorders			
-Total	4 (13.3)	4 (13.3)	0
Delirium	3 (10.0)	3 (10.0)	0
Anxiety	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Acute kidney injury	3 (10.0)	1 (3.3)	2 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (40.0)	3 (10.0)	9 (30.0)
Hypoxia	6 (20.0)	3 (10.0)	3 (10.0)
Respiratory failure	4 (13.3)	0	4 (13.3)
Pulmonary oedema	3 (10.0)	2 (6.7)	1 (3.3)
Epistaxis	2 (6.7)	2 (6.7)	0
Pleural effusion	2 (6.7)	2 (6.7)	0
Respiratory distress	2 (6.7)	0	2 (6.7)
Acute respiratory distress syndrome	1 (3.3)	0	1 (3.3)
Atelectasis	1 (3.3)	1 (3.3)	0
Dyspnoea	1 (3.3)	0	1 (3.3)
Tachypnoea	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	11 (36.7)	6 (20.0)	5 (16.7)

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	10 (33.3)	5 (16.7)	5 (16.7)
Hypertension	2 (6.7)	2 (6.7)	0
Venoocclusive disease	1 (3.3)	1 (3.3)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 223r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	2 (11.1)	15 (83.3)
Blood and lymphatic system disorders			
-Total	11 (61.1)	8 (44.4)	3 (16.7)
Febrile neutropenia	10 (55.6)	10 (55.6)	0
Anaemia	3 (16.7)	2 (11.1)	1 (5.6)
Neutropenia	2 (11.1)	0	2 (11.1)
Thrombocytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Disseminated intravascular coagulation	1 (5.6)	1 (5.6)	0
Leukopenia	1 (5.6)	0	1 (5.6)
Lymphopenia	1 (5.6)	0	1 (5.6)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Cardiac arrest	2 (11.1)	0	2 (11.1)
Cardiac failure	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	4 (22.2)	4 (22.2)	0
Anal inflammation	1 (5.6)	1 (5.6)	0
Dysphagia	1 (5.6)	1 (5.6)	0
Oral pain	1 (5.6)	1 (5.6)	0
Pancreatitis	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	1 (5.6)	0
Vomiting	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	3 (16.7)	3 (16.7)	0
Pyrexia	3 (16.7)	3 (16.7)	0
Hepatobiliary disorders			
-Total	1 (5.6)	0	1 (5.6)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (5.6)	0	1 (5.6)
Immune system disorders			
-Total	9 (50.0)	5 (27.8)	4 (22.2)
Cytokine release syndrome	8 (44.4)	4 (22.2)	4 (22.2)
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0
Immunodeficiency	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	10 (55.6)	9 (50.0)	1 (5.6)
Bronchopulmonary aspergillosis	2 (11.1)	2 (11.1)	0
Staphylococcal bacteraemia	2 (11.1)	2 (11.1)	0
Adenovirus infection	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bk virus infection	1 (5.6)	1 (5.6)	0
Bronchiolitis	1 (5.6)	1 (5.6)	0
Cytomegalovirus infection reactivation	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Escherichia bacteraemia	1 (5.6)	1 (5.6)	0
Human herpesvirus 6 infection	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pneumocystis jirovecii pneumonia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	1 (5.6)	0
Pneumonia respiratory syncytial viral	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Sinusitis fungal	1 (5.6)	1 (5.6)	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0
Upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Viral infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	12 (66.7)	3 (16.7)	9 (50.0)
White blood cell count decreased	6 (33.3)	0	6 (33.3)
Platelet count decreased	5 (27.8)	2 (11.1)	3 (16.7)
Alanine aminotransferase increased	4 (22.2)	4 (22.2)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (22.2)	0	4 (22.2)
Blood bilirubin increased	3 (16.7)	3 (16.7)	0
Lymphocyte count decreased	3 (16.7)	2 (11.1)	1 (5.6)
Aspartate aminotransferase increased	2 (11.1)	1 (5.6)	1 (5.6)
Blood creatinine increased	2 (11.1)	1 (5.6)	1 (5.6)
Blood fibrinogen decreased	2 (11.1)	1 (5.6)	1 (5.6)
Gamma-glutamyltransferase increased	2 (11.1)	2 (11.1)	0
Activated partial thromboplastin time prolonged	1 (5.6)	1 (5.6)	0
Blood lactate dehydrogenase increased	1 (5.6)	1 (5.6)	0
Blood uric acid increased	1 (5.6)	1 (5.6)	0
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Urine output decreased	1 (5.6)	0	1 (5.6)
Weight decreased	1 (5.6)	1 (5.6)	0
Weight increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (44.4)	5 (27.8)	3 (16.7)
Hypokalaemia	6 (33.3)	5 (27.8)	1 (5.6)
Hypophosphataemia	4 (22.2)	3 (16.7)	1 (5.6)
Decreased appetite	2 (11.1)	2 (11.1)	0
Hypercalcaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	1 (5.6)
Hyperphosphataemia	1 (5.6)	0	1 (5.6)
Hypocalcaemia	1 (5.6)	1 (5.6)	0
Malnutrition	1 (5.6)	1 (5.6)	0
Metabolic acidosis	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (16.7)	3 (16.7)	0
Back pain	2 (11.1)	2 (11.1)	0
Muscular weakness	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	1 (5.6)	0
Nervous system disorders			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Somnolence	1 (5.6)	1 (5.6)	0
Psychiatric disorders			
-Total	3 (16.7)	3 (16.7)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Anxiety	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	2 (11.1)	2 (11.1)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0
Haematuria	1 (5.6)	1 (5.6)	0
Reproductive system and breast disorders			
-Total	1 (5.6)	1 (5.6)	0
Endometriosis	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (22.2)	2 (11.1)	2 (11.1)
Hypoxia	3 (16.7)	2 (11.1)	1 (5.6)

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspnoea	1 (5.6)	1 (5.6)	0
Pleural effusion	1 (5.6)	0	1 (5.6)
Respiratory failure	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	8 (44.4)	5 (27.8)	3 (16.7)
Hypotension	4 (22.2)	2 (11.1)	2 (11.1)
Hypertension	2 (11.1)	2 (11.1)	0
Capillary leak syndrome	1 (5.6)	1 (5.6)	0
Venoocclusive disease	1 (5.6)	0	1 (5.6)

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Table 223r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (90.5)	8 (19.0)	30 (71.4)
Blood and lymphatic system disorders			
-Total	28 (66.7)	19 (45.2)	9 (21.4)
Febrile neutropenia	17 (40.5)	16 (38.1)	1 (2.4)
Anaemia	13 (31.0)	13 (31.0)	0
Neutropenia	7 (16.7)	2 (4.8)	5 (11.9)
Thrombocytopenia	5 (11.9)	2 (4.8)	3 (7.1)
Leukopenia	3 (7.1)	1 (2.4)	2 (4.8)
Pancytopenia	3 (7.1)	2 (4.8)	1 (2.4)
Coagulopathy	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated intravascular coagulation	1 (2.4)	1 (2.4)	0
Lymphopenia	1 (2.4)	0	1 (2.4)
Cardiac disorders			
-Total	4 (9.5)	3 (7.1)	1 (2.4)
Cardiac arrest	1 (2.4)	0	1 (2.4)
Cardiac failure	1 (2.4)	1 (2.4)	0
Left ventricular dysfunction	1 (2.4)	1 (2.4)	0
Tachycardia	1 (2.4)	1 (2.4)	0
Gastrointestinal disorders			
-Total	3 (7.1)	3 (7.1)	0
Stomatitis	2 (4.8)	2 (4.8)	0
Nausea	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions			
-Total	4 (9.5)	3 (7.1)	1 (2.4)
Pyrexia	4 (9.5)	3 (7.1)	1 (2.4)
Immune system disorders			
-Total	22 (52.4)	13 (31.0)	9 (21.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	18 (42.9)	9 (21.4)	9 (21.4)
Hypogammaglobulinaemia	5 (11.9)	5 (11.9)	0
Immunodeficiency	2 (4.8)	2 (4.8)	0
Infections and infestations			
-Total	18 (42.9)	8 (19.0)	10 (23.8)
Parainfluenzae virus infection	4 (9.5)	3 (7.1)	1 (2.4)
Bacteraemia	3 (7.1)	2 (4.8)	1 (2.4)
Pneumonia	3 (7.1)	2 (4.8)	1 (2.4)
Sepsis	3 (7.1)	1 (2.4)	2 (4.8)
Septic shock	3 (7.1)	0	3 (7.1)
Sinusitis	2 (4.8)	2 (4.8)	0
Staphylococcal infection	2 (4.8)	2 (4.8)	0
Upper respiratory tract infection	2 (4.8)	2 (4.8)	0
Adenovirus infection	1 (2.4)	1 (2.4)	0
Bronchiolitis	1 (2.4)	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	1 (2.4)
Clostridium difficile infection	1 (2.4)	1 (2.4)	0
Encephalitis	1 (2.4)	0	1 (2.4)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (2.4)	0	1 (2.4)
Human herpesvirus 6 infection	1 (2.4)	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	1 (2.4)	0
Oral herpes	1 (2.4)	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	1 (2.4)
Respiratory syncytial virus infection	1 (2.4)	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Investigations			
-Total	25 (59.5)	10 (23.8)	15 (35.7)
Neutrophil count decreased	13 (31.0)	1 (2.4)	12 (28.6)
White blood cell count decreased	11 (26.2)	0	11 (26.2)
Lymphocyte count decreased	10 (23.8)	3 (7.1)	7 (16.7)
Platelet count decreased	10 (23.8)	3 (7.1)	7 (16.7)
Alanine aminotransferase increased	4 (9.5)	4 (9.5)	0
Aspartate aminotransferase increased	4 (9.5)	3 (7.1)	1 (2.4)
C-reactive protein increased	3 (7.1)	3 (7.1)	0
Blood bilirubin increased	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (2.4)	1 (2.4)	0
Blood creatinine increased	1 (2.4)	1 (2.4)	0
Blood uric acid increased	1 (2.4)	0	1 (2.4)
Serum ferritin increased	1 (2.4)	1 (2.4)	0
Weight decreased	1 (2.4)	1 (2.4)	0
Metabolism and nutrition disorders			
-Total	14 (33.3)	9 (21.4)	5 (11.9)
Hypokalaemia	7 (16.7)	6 (14.3)	1 (2.4)
Decreased appetite	5 (11.9)	3 (7.1)	2 (4.8)
Tumour lysis syndrome	3 (7.1)	1 (2.4)	2 (4.8)
Hyperglycaemia	2 (4.8)	2 (4.8)	0
Hypocalcaemia	2 (4.8)	2 (4.8)	0
Hypophosphataemia	2 (4.8)	2 (4.8)	0
Hypernatraemia	1 (2.4)	1 (2.4)	0
Hypervolaemia	1 (2.4)	1 (2.4)	0
Malnutrition	1 (2.4)	1 (2.4)	0
Musculoskeletal and connective tissue disorders			

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.1)	3 (7.1)	0
Back pain	2 (4.8)	2 (4.8)	0
Pain in extremity	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	8 (19.0)	8 (19.0)	0
Headache	3 (7.1)	3 (7.1)	0
Seizure	3 (7.1)	3 (7.1)	0
Encephalopathy	2 (4.8)	2 (4.8)	0
Psychiatric disorders			
-Total	2 (4.8)	2 (4.8)	0
Anxiety	1 (2.4)	1 (2.4)	0
Mental status changes	1 (2.4)	1 (2.4)	0
Renal and urinary disorders			
-Total	3 (7.1)	1 (2.4)	2 (4.8)
Acute kidney injury	2 (4.8)	0	2 (4.8)
Renal tubular necrosis	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (33.3)	7 (16.7)	7 (16.7)
Hypoxia	6 (14.3)	4 (9.5)	2 (4.8)
Pulmonary oedema	4 (9.5)	4 (9.5)	0
Respiratory failure	3 (7.1)	0	3 (7.1)
Acute respiratory distress syndrome	2 (4.8)	0	2 (4.8)
Dyspnoea	2 (4.8)	2 (4.8)	0
Epistaxis	1 (2.4)	1 (2.4)	0
Tachypnoea	1 (2.4)	1 (2.4)	0
Vascular disorders			
-Total	4 (9.5)	2 (4.8)	2 (4.8)
Hypotension	4 (9.5)	2 (4.8)	2 (4.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (54.5)	6 (18.2)	9 (27.3)
Blood and lymphatic system disorders			
- Total	6 (18.2)	6 (18.2)	0
Febrile neutropenia	6 (18.2)	6 (18.2)	0
General disorders and administration site conditions			
- Total	2 (6.1)	0	0
Pyrexia	2 (6.1)	0	0
Immune system disorders			
- Total	18 (54.5)	3 (9.1)	8 (24.2)
Cytokine release syndrome	18 (54.5)	3 (9.1)	8 (24.2)
Renal and urinary disorders			
- Total	2 (6.1)	0	2 (6.1)
Acute kidney injury	2 (6.1)	0	2 (6.1)

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.0)	0	1 (3.0)
Hypoxia	1 (3.0)	0	1 (3.0)
Vascular disorders			
- Total	3 (9.1)	0	3 (9.1)
Hypotension	3 (9.1)	0	3 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (75.8)	10 (30.3)	13 (39.4)
Blood and lymphatic system disorders			
- Total	6 (18.2)	5 (15.2)	1 (3.0)
Febrile neutropenia	6 (18.2)	5 (15.2)	1 (3.0)
General disorders and administration site conditions			
- Total	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	0
Immune system disorders			
- Total	23 (69.7)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	10 (30.3)	9 (27.3)
Renal and urinary disorders			
- Total	2 (6.1)	2 (6.1)	0
Acute kidney injury	2 (6.1)	2 (6.1)	0

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (9.1)	1 (3.0)	2 (6.1)
Hypoxia	2 (6.1)	1 (3.0)	1 (3.0)
Respiratory failure	2 (6.1)	0	2 (6.1)
Vascular disorders			
- Total	4 (12.1)	2 (6.1)	2 (6.1)
Hypotension	4 (12.1)	2 (6.1)	2 (6.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (64.3)	4 (28.6)	4 (28.6)
Blood and lymphatic system disorders			
- Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Immune system disorders			
- Total	9 (64.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	3 (21.4)	4 (28.6)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (7.1)	0	1 (7.1)
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
- Total	1 (7.1)	0	1 (7.1)

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (20.0)	4 (13.3)	1 (3.3)
Blood and lymphatic system disorders			
- Total	3 (10.0)	3 (10.0)	0
Febrile neutropenia	3 (10.0)	3 (10.0)	0
General disorders and administration site conditions			
- Total	3 (10.0)	0	0
Pyrexia	3 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypoxia	1 (3.3)	1 (3.3)	0
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (9.7)	2 (6.5)	1 (3.2)
General disorders and administration site conditions			
- Total	1 (3.2)	1 (3.2)	0
Pyrexia	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
- Total	1 (3.2)	0	1 (3.2)
Acute kidney injury	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.2)	1 (3.2)	0
Hypoxia	1 (3.2)	1 (3.2)	0
Vascular disorders			
- Total	1 (3.2)	0	1 (3.2)

Group term Preferred term	All patients N=31 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (3.2)	0	1 (3.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=14		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=20		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (9.1)	0	1 (4.5)
General disorders and administration site conditions			
- Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.5)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (12.5)	0	0
General disorders and administration site conditions			
- Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (63.6)	9 (27.3)	10 (30.3)
Blood and lymphatic system disorders			
- Total	8 (24.2)	8 (24.2)	0
Febrile neutropenia	8 (24.2)	8 (24.2)	0
General disorders and administration site conditions			
- Total	4 (12.1)	0	0
Pyrexia	4 (12.1)	0	0
Immune system disorders			
- Total	18 (54.5)	3 (9.1)	8 (24.2)
Cytokine release syndrome	18 (54.5)	3 (9.1)	8 (24.2)
Renal and urinary disorders			
- Total	2 (6.1)	0	2 (6.1)

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (6.1)	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (9.1)	1 (3.0)	2 (6.1)
Hypoxia	2 (6.1)	1 (3.0)	1 (3.0)
Respiratory failure	1 (3.0)	0	1 (3.0)
Vascular disorders			
- Total	3 (9.1)	0	3 (9.1)
Hypotension	3 (9.1)	0	3 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (75.8)	8 (24.2)	15 (45.5)
Blood and lymphatic system disorders			
- Total	6 (18.2)	5 (15.2)	1 (3.0)
Febrile neutropenia	6 (18.2)	5 (15.2)	1 (3.0)
General disorders and administration site conditions			
- Total	2 (6.1)	1 (3.0)	0
Pyrexia	2 (6.1)	1 (3.0)	0
Immune system disorders			
- Total	23 (69.7)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	10 (30.3)	9 (27.3)
Renal and urinary disorders			
- Total	3 (9.1)	2 (6.1)	1 (3.0)

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	3 (9.1)	2 (6.1)	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (15.2)	2 (6.1)	3 (9.1)
Hypoxia	3 (9.1)	2 (6.1)	1 (3.0)
Respiratory failure	3 (9.1)	0	3 (9.1)
Vascular disorders			
- Total	4 (12.1)	1 (3.0)	3 (9.1)
Hypotension	4 (12.1)	1 (3.0)	3 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224a
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (71.4)	4 (28.6)	4 (28.6)
Blood and lymphatic system disorders			
- Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
- Total	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	0
Immune system disorders			
- Total	9 (64.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	3 (21.4)	4 (28.6)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (7.1)	0	1 (7.1)

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
- Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (52.2)	8 (17.4)	13 (28.3)
Blood and lymphatic system disorders			
- Total	6 (13.0)	6 (13.0)	0
Febrile neutropenia	6 (13.0)	6 (13.0)	0
General disorders and administration site conditions			
- Total	2 (4.3)	0	0
Pyrexia	2 (4.3)	0	0
Immune system disorders			
- Total	23 (50.0)	7 (15.2)	11 (23.9)
Cytokine release syndrome	23 (50.0)	7 (15.2)	11 (23.9)
Renal and urinary disorders			
- Total	1 (2.2)	0	1 (2.2)
Acute kidney injury	1 (2.2)	0	1 (2.2)

Group term Preferred term	All patients N=46 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (6.5)	0	3 (6.5)
Respiratory failure	2 (4.3)	0	2 (4.3)
Hypoxia	1 (2.2)	0	1 (2.2)
Vascular disorders			
- Total	2 (4.3)	0	2 (4.3)
Hypotension	2 (4.3)	0	2 (4.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (82.4)	12 (35.3)	13 (38.2)
Blood and lymphatic system disorders			
- Total	7 (20.6)	6 (17.6)	1 (2.9)
Febrile neutropenia	7 (20.6)	6 (17.6)	1 (2.9)
General disorders and administration site conditions			
- Total	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	0
Immune system disorders			
- Total	27 (79.4)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	9 (26.5)	10 (29.4)
Renal and urinary disorders			
- Total	3 (8.8)	2 (5.9)	1 (2.9)
Acute kidney injury	3 (8.8)	2 (5.9)	1 (2.9)

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.9)	1 (2.9)	1 (2.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Vascular disorders			
- Total	6 (17.6)	2 (5.9)	4 (11.8)
Hypotension	6 (17.6)	2 (5.9)	4 (11.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (16.3)	5 (11.6)	1 (2.3)
Blood and lymphatic system disorders			
- Total	3 (7.0)	3 (7.0)	0
Febrile neutropenia	3 (7.0)	3 (7.0)	0
General disorders and administration site conditions			
- Total	3 (7.0)	1 (2.3)	0
Pyrexia	3 (7.0)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.7)	1 (2.3)	1 (2.3)
Hypoxia	1 (2.3)	1 (2.3)	0
Respiratory failure	1 (2.3)	0	1 (2.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.3)	1 (3.1)	1 (3.1)
General disorders and administration site conditions			
- Total	1 (3.1)	0	0
Pyrexia	1 (3.1)	0	0
Renal and urinary disorders			
- Total	1 (3.1)	0	1 (3.1)
Acute kidney injury	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.1)	1 (3.1)	0
Hypoxia	1 (3.1)	1 (3.1)	0
Vascular disorders			
- Total	1 (3.1)	0	1 (3.1)

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (3.1)	0	1 (3.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (3.4)	0	0
General disorders and administration site conditions			
- Total	1 (3.4)	0	0
Pyrexia	1 (3.4)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (9.5)	0	1 (4.8)
General disorders and administration site conditions			
- Total	1 (4.8)	0	0
Pyrexia	1 (4.8)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.8)	0	1 (4.8)
Respiratory failure	1 (4.8)	0	1 (4.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (58.7)	10 (21.7)	14 (30.4)
Blood and lymphatic system disorders			
- Total	8 (17.4)	8 (17.4)	0
Febrile neutropenia	8 (17.4)	8 (17.4)	0
General disorders and administration site conditions			
- Total	5 (10.9)	1 (2.2)	0
Pyrexia	5 (10.9)	1 (2.2)	0
Immune system disorders			
- Total	23 (50.0)	7 (15.2)	11 (23.9)
Cytokine release syndrome	23 (50.0)	7 (15.2)	11 (23.9)
Renal and urinary disorders			
- Total	1 (2.2)	0	1 (2.2)

Group term Preferred term	All patients N=46 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (10.9)	1 (2.2)	4 (8.7)
Respiratory failure	3 (6.5)	0	3 (6.5)
Hypoxia	2 (4.3)	1 (2.2)	1 (2.2)
Vascular disorders			
- Total	2 (4.3)	0	2 (4.3)
Hypotension	2 (4.3)	0	2 (4.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224b
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (85.3)	11 (32.4)	15 (44.1)
Blood and lymphatic system disorders			
- Total	7 (20.6)	6 (17.6)	1 (2.9)
Febrile neutropenia	7 (20.6)	6 (17.6)	1 (2.9)
General disorders and administration site conditions			
- Total	2 (5.9)	0	0
Pyrexia	2 (5.9)	0	0
Immune system disorders			
- Total	27 (79.4)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	9 (26.5)	10 (29.4)
Renal and urinary disorders			
- Total	4 (11.8)	2 (5.9)	2 (5.9)

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	4 (11.8)	2 (5.9)	2 (5.9)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (11.8)	2 (5.9)	2 (5.9)
Hypoxia	3 (8.8)	2 (5.9)	1 (2.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Vascular disorders			
- Total	6 (17.6)	1 (2.9)	5 (14.7)
Hypotension	6 (17.6)	1 (2.9)	5 (14.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	38 (64.4)	18 (30.5)	15 (25.4)
Blood and lymphatic system disorders			
- Total	10 (16.9)	9 (15.3)	1 (1.7)
Febrile neutropenia	10 (16.9)	9 (15.3)	1 (1.7)
General disorders and administration site conditions			
- Total	2 (3.4)	0	0
Pyrexia	2 (3.4)	0	0
Immune system disorders			
- Total	37 (62.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	14 (23.7)	12 (20.3)
Renal and urinary disorders			
- Total	4 (6.8)	2 (3.4)	2 (3.4)
Acute kidney injury	4 (6.8)	2 (3.4)	2 (3.4)

Group term Preferred term	All patients N=59 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.8)	1 (1.7)	3 (5.1)
Hypoxia	2 (3.4)	1 (1.7)	1 (1.7)
Respiratory failure	2 (3.4)	0	2 (3.4)
Vascular disorders			
- Total	6 (10.2)	2 (3.4)	4 (6.8)
Hypotension	6 (10.2)	2 (3.4)	4 (6.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (50.0)	1 (10.0)	4 (40.0)
Immune system disorders			
- Total	4 (40.0)	1 (10.0)	3 (30.0)
Cytokine release syndrome	4 (40.0)	1 (10.0)	3 (30.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (10.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (81.8)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
- Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
General disorders and administration site conditions			
- Total	1 (9.1)	0	0
Pyrexia	1 (9.1)	0	0
Immune system disorders			
- Total	9 (81.8)	1 (9.1)	6 (54.5)
Cytokine release syndrome	9 (81.8)	1 (9.1)	6 (54.5)
Vascular disorders			
- Total	2 (18.2)	0	2 (18.2)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (18.2)	0	2 (18.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (10.9)	3 (5.5)	2 (3.6)
Blood and lymphatic system disorders			
- Total	2 (3.6)	2 (3.6)	0
Febrile neutropenia	2 (3.6)	2 (3.6)	0
General disorders and administration site conditions			
- Total	1 (1.8)	0	0
Pyrexia	1 (1.8)	0	0
Renal and urinary disorders			
- Total	1 (1.8)	0	1 (1.8)
Acute kidney injury	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (3.6)	1 (1.8)	1 (1.8)

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (1.8)	1 (1.8)	0
Respiratory failure	1 (1.8)	0	1 (1.8)
Vascular disorders			
- Total	1 (1.8)	0	1 (1.8)
Hypotension	1 (1.8)	0	1 (1.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (11.1)	1 (11.1)	0
Blood and lymphatic system disorders			
- Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
- Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (18.2)	2 (18.2)	0
General disorders and administration site conditions			
- Total	2 (18.2)	1 (9.1)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (9.1)	1 (9.1)	0
Hypoxia	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (7.7)	0	1 (2.6)
General disorders and administration site conditions			
- Total	2 (5.1)	0	0
Pyrexia	2 (5.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.6)	0	1 (2.6)
Respiratory failure	1 (2.6)	0	1 (2.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=6		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=5		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (69.5)	17 (28.8)	18 (30.5)
Blood and lymphatic system disorders			
- Total	11 (18.6)	10 (16.9)	1 (1.7)
Febrile neutropenia	11 (18.6)	10 (16.9)	1 (1.7)
General disorders and administration site conditions			
- Total	4 (6.8)	0	0
Pyrexia	4 (6.8)	0	0
Immune system disorders			
- Total	37 (62.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	14 (23.7)	12 (20.3)
Renal and urinary disorders			
- Total	5 (8.5)	2 (3.4)	3 (5.1)

Group term Preferred term	All patients N=59 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (8.5)	2 (3.4)	3 (5.1)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (11.9)	2 (3.4)	5 (8.5)
Respiratory failure	4 (6.8)	0	4 (6.8)
Hypoxia	3 (5.1)	2 (3.4)	1 (1.7)
Vascular disorders			
- Total	6 (10.2)	1 (1.7)	5 (8.5)
Hypotension	6 (10.2)	1 (1.7)	5 (8.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (60.0)	2 (20.0)	4 (40.0)
Blood and lymphatic system disorders			
- Total	1 (10.0)	1 (10.0)	0
Febrile neutropenia	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
- Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Immune system disorders			
- Total	4 (40.0)	1 (10.0)	3 (30.0)
Cytokine release syndrome	4 (40.0)	1 (10.0)	3 (30.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (10.0)	0	1 (10.0)

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224c
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (81.8)	2 (18.2)	7 (63.6)
Blood and lymphatic system disorders			
- Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
General disorders and administration site conditions			
- Total	2 (18.2)	1 (9.1)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Immune system disorders			
- Total	9 (81.8)	1 (9.1)	6 (54.5)
Cytokine release syndrome	9 (81.8)	1 (9.1)	6 (54.5)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (9.1)	1 (9.1)	0

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (9.1)	1 (9.1)	0
Vascular disorders			
- Total	2 (18.2)	0	2 (18.2)
Hypotension	2 (18.2)	0	2 (18.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	3 (20.0)	9 (60.0)
Blood and lymphatic system disorders			
- Total	5 (33.3)	4 (26.7)	1 (6.7)
Febrile neutropenia	5 (33.3)	4 (26.7)	1 (6.7)
Immune system disorders			
- Total	13 (86.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	1 (6.7)	8 (53.3)
Renal and urinary disorders			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
Acute kidney injury	2 (13.3)	1 (6.7)	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (13.3)	0	2 (13.3)
Hypoxia	1 (6.7)	0	1 (6.7)

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
- Total	3 (20.0)	1 (6.7)	2 (13.3)
Hypotension	3 (20.0)	1 (6.7)	2 (13.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	39 (60.0)	17 (26.2)	17 (26.2)
Blood and lymphatic system disorders			
- Total	8 (12.3)	8 (12.3)	0
Febrile neutropenia	8 (12.3)	8 (12.3)	0
General disorders and administration site conditions			
- Total	3 (4.6)	0	0
Pyrexia	3 (4.6)	0	0
Immune system disorders			
- Total	37 (56.9)	15 (23.1)	13 (20.0)
Cytokine release syndrome	37 (56.9)	15 (23.1)	13 (20.0)
Renal and urinary disorders			
- Total	2 (3.1)	1 (1.5)	1 (1.5)
Acute kidney injury	2 (3.1)	1 (1.5)	1 (1.5)

Group term Preferred term	All patients N=65 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.6)	1 (1.5)	2 (3.1)
Hypoxia	2 (3.1)	1 (1.5)	1 (1.5)
Respiratory failure	2 (3.1)	0	2 (3.1)
Vascular disorders			
- Total	5 (7.7)	1 (1.5)	4 (6.2)
Hypotension	5 (7.7)	1 (1.5)	4 (6.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (21.4)	2 (14.3)	1 (7.1)
Blood and lymphatic system disorders			
- Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
- Total	1 (7.1)	1 (7.1)	0
Pyrexia	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
- Total	1 (7.1)	0	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Vascular disorders			
- Total	1 (7.1)	0	1 (7.1)

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (9.8)	4 (6.6)	1 (1.6)
Blood and lymphatic system disorders			
- Total	2 (3.3)	2 (3.3)	0
Febrile neutropenia	2 (3.3)	2 (3.3)	0
General disorders and administration site conditions			
- Total	3 (4.9)	0	0
Pyrexia	3 (4.9)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.9)	2 (3.3)	1 (1.6)
Hypoxia	2 (3.3)	2 (3.3)	0
Respiratory failure	1 (1.6)	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=7		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (7.0)	0	1 (2.3)
General disorders and administration site conditions			
- Total	2 (4.7)	0	0
Pyrexia	2 (4.7)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.3)	0	1 (2.3)
Respiratory failure	1 (2.3)	0	1 (2.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	2 (13.3)	10 (66.7)
Blood and lymphatic system disorders			
- Total	5 (33.3)	4 (26.7)	1 (6.7)
Febrile neutropenia	5 (33.3)	4 (26.7)	1 (6.7)
General disorders and administration site conditions			
- Total	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Immune system disorders			
- Total	13 (86.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	1 (6.7)	8 (53.3)
Renal and urinary disorders			
- Total	3 (20.0)	1 (6.7)	2 (13.3)

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	3 (20.0)	1 (6.7)	2 (13.3)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (13.3)	0	2 (13.3)
Hypoxia	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
- Total	3 (20.0)	0	3 (20.0)
Hypotension	3 (20.0)	0	3 (20.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224d
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (66.2)	19 (29.2)	19 (29.2)
Blood and lymphatic system disorders			
- Total	10 (15.4)	10 (15.4)	0
Febrile neutropenia	10 (15.4)	10 (15.4)	0
General disorders and administration site conditions			
- Total	6 (9.2)	0	0
Pyrexia	6 (9.2)	0	0
Immune system disorders			
- Total	37 (56.9)	15 (23.1)	13 (20.0)
Cytokine release syndrome	37 (56.9)	15 (23.1)	13 (20.0)
Renal and urinary disorders			
- Total	2 (3.1)	1 (1.5)	1 (1.5)

Group term Preferred term	All patients N=65 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (3.1)	1 (1.5)	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (10.8)	3 (4.6)	4 (6.2)
Hypoxia	4 (6.2)	3 (4.6)	1 (1.5)
Respiratory failure	4 (6.2)	0	4 (6.2)
Vascular disorders			
- Total	5 (7.7)	1 (1.5)	4 (6.2)
Hypotension	5 (7.7)	1 (1.5)	4 (6.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Immune system disorders			
- Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (63.5)	19 (25.7)	23 (31.1)
Blood and lymphatic system disorders			
- Total	11 (14.9)	11 (14.9)	0
Febrile neutropenia	11 (14.9)	11 (14.9)	0
General disorders and administration site conditions			
- Total	2 (2.7)	0	0
Pyrexia	2 (2.7)	0	0
Immune system disorders			
- Total	46 (62.2)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	16 (21.6)	19 (25.7)
Renal and urinary disorders			
- Total	2 (2.7)	1 (1.4)	1 (1.4)
Acute kidney injury	2 (2.7)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.8)	1 (1.4)	4 (5.4)
Hypoxia	3 (4.1)	1 (1.4)	2 (2.7)
Respiratory failure	3 (4.1)	0	3 (4.1)
Vascular disorders			
- Total	7 (9.5)	2 (2.7)	5 (6.8)
Hypotension	7 (9.5)	2 (2.7)	5 (6.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=5		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (12.9)	6 (8.6)	2 (2.9)
Blood and lymphatic system disorders			
- Total	3 (4.3)	3 (4.3)	0
Febrile neutropenia	3 (4.3)	3 (4.3)	0
General disorders and administration site conditions			
- Total	4 (5.7)	1 (1.4)	0
Pyrexia	4 (5.7)	1 (1.4)	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.3)	2 (2.9)	1 (1.4)

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.9)	2 (2.9)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	0
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (4.3)	0	1 (2.1)
General disorders and administration site conditions			
- Total	1 (2.1)	0	0
Pyrexia	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.1)	0	1 (2.1)
Respiratory failure	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Immune system disorders			
- Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Vascular disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	51 (68.9)	20 (27.0)	26 (35.1)
Blood and lymphatic system disorders			
- Total	13 (17.6)	13 (17.6)	0
Febrile neutropenia	13 (17.6)	13 (17.6)	0
General disorders and administration site conditions			
- Total	6 (8.1)	1 (1.4)	0
Pyrexia	6 (8.1)	1 (1.4)	0
Immune system disorders			
- Total	46 (62.2)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	16 (21.6)	19 (25.7)
Renal and urinary disorders			
- Total	3 (4.1)	1 (1.4)	2 (2.7)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (12.2)	3 (4.1)	6 (8.1)
Hypoxia	5 (6.8)	3 (4.1)	2 (2.7)
Respiratory failure	5 (6.8)	0	5 (6.8)
Vascular disorders			
- Total	7 (9.5)	1 (1.4)	6 (8.1)
Hypotension	7 (9.5)	1 (1.4)	6 (8.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224e
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	1 (50.0)	1 (50.0)
Immune system disorders			
- Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	50 (64.1)	19 (24.4)	25 (32.1)
Blood and lymphatic system disorders			
- Total	13 (16.7)	12 (15.4)	1 (1.3)
Febrile neutropenia	13 (16.7)	12 (15.4)	1 (1.3)
General disorders and administration site conditions			
- Total	3 (3.8)	0	0
Pyrexia	3 (3.8)	0	0
Immune system disorders			
- Total	48 (61.5)	15 (19.2)	20 (25.6)
Cytokine release syndrome	48 (61.5)	15 (19.2)	20 (25.6)
Renal and urinary disorders			
- Total	4 (5.1)	2 (2.6)	2 (2.6)
Acute kidney injury	4 (5.1)	2 (2.6)	2 (2.6)

Group term Preferred term	All patients N=78 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.4)	1 (1.3)	4 (5.1)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.6)
Respiratory failure	3 (3.8)	0	3 (3.8)
Vascular disorders			
- Total	8 (10.3)	2 (2.6)	6 (7.7)
Hypotension	8 (10.3)	2 (2.6)	6 (7.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
- Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (11.0)	5 (6.8)	2 (2.7)
Blood and lymphatic system disorders			
- Total	3 (4.1)	3 (4.1)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
General disorders and administration site conditions			
- Total	3 (4.1)	0	0
Pyrexia	3 (4.1)	0	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.1)	2 (2.7)	1 (1.4)

Group term Preferred term	All patients N=73 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.7)	2 (2.7)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=2		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (6.3)	0	1 (2.1)
General disorders and administration site conditions			
- Total	2 (4.2)	0	0
Pyrexia	2 (4.2)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.1)	0	1 (2.1)
Respiratory failure	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	1 (50.0)	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Immune system disorders			
- Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	54 (69.2)	20 (25.6)	28 (35.9)
Blood and lymphatic system disorders			
- Total	15 (19.2)	14 (17.9)	1 (1.3)
Febrile neutropenia	15 (19.2)	14 (17.9)	1 (1.3)
General disorders and administration site conditions			
- Total	6 (7.7)	0	0
Pyrexia	6 (7.7)	0	0
Immune system disorders			
- Total	48 (61.5)	15 (19.2)	20 (25.6)
Cytokine release syndrome	48 (61.5)	15 (19.2)	20 (25.6)
Renal and urinary disorders			
- Total	5 (6.4)	2 (2.6)	3 (3.8)

Group term Preferred term	All patients N=78 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (6.4)	2 (2.6)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (11.5)	3 (3.8)	6 (7.7)
Hypoxia	5 (6.4)	3 (3.8)	2 (2.6)
Respiratory failure	5 (6.4)	0	5 (6.4)
Vascular disorders			
- Total	8 (10.3)	1 (1.3)	7 (9.0)
Hypotension	8 (10.3)	1 (1.3)	7 (9.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224f
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (65.8)	20 (25.3)	26 (32.9)
Blood and lymphatic system disorders			
- Total	13 (16.5)	12 (15.2)	1 (1.3)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
General disorders and administration site conditions			
- Total	3 (3.8)	0	0
Pyrexia	3 (3.8)	0	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	4 (5.1)	2 (2.5)	2 (2.5)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.3)	1 (1.3)	4 (5.1)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Vascular disorders			
- Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (12.2)	6 (8.1)	2 (2.7)
Blood and lymphatic system disorders			
- Total	3 (4.1)	3 (4.1)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
General disorders and administration site conditions			
- Total	4 (5.4)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.1)	2 (2.7)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.7)	2 (2.7)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (6.0)	0	1 (2.0)
General disorders and administration site conditions			
- Total	2 (4.0)	0	0
Pyrexia	2 (4.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (70.9)	21 (26.6)	29 (36.7)
Blood and lymphatic system disorders			
- Total	15 (19.0)	14 (17.7)	1 (1.3)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
General disorders and administration site conditions			
- Total	7 (8.9)	1 (1.3)	0
Pyrexia	7 (8.9)	1 (1.3)	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	5 (6.3)	2 (2.5)	3 (3.8)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (11.4)	3 (3.8)	6 (7.6)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Vascular disorders			
- Total	8 (10.1)	1 (1.3)	7 (8.9)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224g
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (65.8)	20 (25.3)	26 (32.9)
Blood and lymphatic system disorders			
- Total	13 (16.5)	12 (15.2)	1 (1.3)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
General disorders and administration site conditions			
- Total	3 (3.8)	0	0
Pyrexia	3 (3.8)	0	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	4 (5.1)	2 (2.5)	2 (2.5)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.3)	1 (1.3)	4 (5.1)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Vascular disorders			
- Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (12.2)	6 (8.1)	2 (2.7)
Blood and lymphatic system disorders			
- Total	3 (4.1)	3 (4.1)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
General disorders and administration site conditions			
- Total	4 (5.4)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.1)	2 (2.7)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.7)	2 (2.7)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (6.1)	0	1 (2.0)
General disorders and administration site conditions			
- Total	2 (4.1)	0	0
Pyrexia	2 (4.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (70.9)	21 (26.6)	29 (36.7)
Blood and lymphatic system disorders			
- Total	15 (19.0)	14 (17.7)	1 (1.3)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
General disorders and administration site conditions			
- Total	7 (8.9)	1 (1.3)	0
Pyrexia	7 (8.9)	1 (1.3)	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	5 (6.3)	2 (2.5)	3 (3.8)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (11.4)	3 (3.8)	6 (7.6)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Vascular disorders			
- Total	8 (10.1)	1 (1.3)	7 (8.9)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224h
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (65.8)	20 (25.3)	26 (32.9)
Blood and lymphatic system disorders			
- Total	13 (16.5)	12 (15.2)	1 (1.3)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
General disorders and administration site conditions			
- Total	3 (3.8)	0	0
Pyrexia	3 (3.8)	0	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	4 (5.1)	2 (2.5)	2 (2.5)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (6.3)	1 (1.3)	4 (5.1)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Vascular disorders			
- Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (12.2)	6 (8.1)	2 (2.7)
Blood and lymphatic system disorders			
- Total	3 (4.1)	3 (4.1)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
General disorders and administration site conditions			
- Total	4 (5.4)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.1)	2 (2.7)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.7)	2 (2.7)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (6.1)	0	1 (2.0)
General disorders and administration site conditions			
- Total	2 (4.1)	0	0
Pyrexia	2 (4.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (70.9)	21 (26.6)	29 (36.7)
Blood and lymphatic system disorders			
- Total	15 (19.0)	14 (17.7)	1 (1.3)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
General disorders and administration site conditions			
- Total	7 (8.9)	1 (1.3)	0
Pyrexia	7 (8.9)	1 (1.3)	0
Immune system disorders			
- Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Renal and urinary disorders			
- Total	5 (6.3)	2 (2.5)	3 (3.8)

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (11.4)	3 (3.8)	6 (7.6)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Vascular disorders			
- Total	8 (10.1)	1 (1.3)	7 (8.9)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224i
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (70.4)	7 (25.9)	10 (37.0)
Blood and lymphatic system disorders			
- Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Immune system disorders			
- Total	19 (70.4)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	7 (25.9)	9 (33.3)
Renal and urinary disorders			
- Total	2 (7.4)	1 (3.7)	1 (3.7)
Acute kidney injury	2 (7.4)	1 (3.7)	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.7)	1 (3.7)	0
Hypoxia	1 (3.7)	1 (3.7)	0

Group term Preferred term	All patients N=27 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	5 (18.5)	2 (7.4)	3 (11.1)
Hypotension	5 (18.5)	2 (7.4)	3 (11.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	33 (62.3)	13 (24.5)	16 (30.2)
Blood and lymphatic system disorders			
- Total	11 (20.8)	10 (18.9)	1 (1.9)
Febrile neutropenia	11 (20.8)	10 (18.9)	1 (1.9)
General disorders and administration site conditions			
- Total	3 (5.7)	0	0
Pyrexia	3 (5.7)	0	0
Immune system disorders			
- Total	31 (58.5)	9 (17.0)	12 (22.6)
Cytokine release syndrome	31 (58.5)	9 (17.0)	12 (22.6)
Renal and urinary disorders			
- Total	2 (3.8)	1 (1.9)	1 (1.9)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)

Group term Preferred term	All patients N=53 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (7.5)	0	4 (7.5)
Respiratory failure	3 (5.7)	0	3 (5.7)
Hypoxia	2 (3.8)	0	2 (3.8)
Vascular disorders			
- Total	3 (5.7)	0	3 (5.7)
Hypotension	3 (5.7)	0	3 (5.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (12.0)	2 (8.0)	1 (4.0)
Blood and lymphatic system disorders			
- Total	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
- Total	1 (4.0)	0	1 (4.0)
Acute kidney injury	1 (4.0)	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.0)	1 (4.0)	0
Hypoxia	1 (4.0)	1 (4.0)	0
Vascular disorders			
- Total	1 (4.0)	0	1 (4.0)

Group term Preferred term	All patients N=25 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (4.0)	0	1 (4.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (12.0)	4 (8.0)	1 (2.0)
Blood and lymphatic system disorders			
- Total	2 (4.0)	2 (4.0)	0
Febrile neutropenia	2 (4.0)	2 (4.0)	0
General disorders and administration site conditions			
- Total	4 (8.0)	1 (2.0)	0
Pyrexia	4 (8.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.0)	1 (2.0)	1 (2.0)
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=16		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (8.8)	0	1 (2.9)
General disorders and administration site conditions			
- Total	2 (5.9)	0	0
Pyrexia	2 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (70.4)	7 (25.9)	11 (40.7)
Blood and lymphatic system disorders			
- Total	3 (11.1)	3 (11.1)	0
Febrile neutropenia	3 (11.1)	3 (11.1)	0
Immune system disorders			
- Total	19 (70.4)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	7 (25.9)	9 (33.3)
Renal and urinary disorders			
- Total	3 (11.1)	1 (3.7)	2 (7.4)
Acute kidney injury	3 (11.1)	1 (3.7)	2 (7.4)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (7.4)	2 (7.4)	0

Group term Preferred term	All patients N=27 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (7.4)	2 (7.4)	0
Vascular disorders			
- Total	5 (18.5)	1 (3.7)	4 (14.8)
Hypotension	5 (18.5)	1 (3.7)	4 (14.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (69.8)	14 (26.4)	18 (34.0)
Blood and lymphatic system disorders			
- Total	12 (22.6)	11 (20.8)	1 (1.9)
Febrile neutropenia	12 (22.6)	11 (20.8)	1 (1.9)
General disorders and administration site conditions			
- Total	7 (13.2)	1 (1.9)	0
Pyrexia	7 (13.2)	1 (1.9)	0
Immune system disorders			
- Total	31 (58.5)	9 (17.0)	12 (22.6)
Cytokine release syndrome	31 (58.5)	9 (17.0)	12 (22.6)
Renal and urinary disorders			
- Total	2 (3.8)	1 (1.9)	1 (1.9)

Group term Preferred term	All patients N=53 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (13.2)	1 (1.9)	6 (11.3)
Respiratory failure	5 (9.4)	0	5 (9.4)
Hypoxia	3 (5.7)	1 (1.9)	2 (3.8)
Vascular disorders			
- Total	3 (5.7)	0	3 (5.7)
Hypotension	3 (5.7)	0	3 (5.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224j
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (53.6)	5 (17.9)	8 (28.6)
Immune system disorders			
- Total	15 (53.6)	5 (17.9)	8 (28.6)
Cytokine release syndrome	15 (53.6)	5 (17.9)	8 (28.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	33 (73.3)	14 (31.1)	15 (33.3)
Blood and lymphatic system disorders			
- Total	13 (28.9)	12 (26.7)	1 (2.2)
Febrile neutropenia	13 (28.9)	12 (26.7)	1 (2.2)
General disorders and administration site conditions			
- Total	3 (6.7)	0	0
Pyrexia	3 (6.7)	0	0
Immune system disorders			
- Total	31 (68.9)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	10 (22.2)	10 (22.2)
Renal and urinary disorders			
- Total	4 (8.9)	2 (4.4)	2 (4.4)
Acute kidney injury	4 (8.9)	2 (4.4)	2 (4.4)

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (11.1)	1 (2.2)	4 (8.9)
Hypoxia	3 (6.7)	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	3 (6.7)
Vascular disorders			
- Total	8 (17.8)	2 (4.4)	6 (13.3)
Hypotension	8 (17.8)	2 (4.4)	6 (13.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (57.1)	1 (14.3)	3 (42.9)
Immune system disorders			
- Total	4 (57.1)	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	1 (14.3)	3 (42.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (7.1)	1 (3.6)	1 (3.6)
Blood and lymphatic system disorders			
- Total	1 (3.6)	1 (3.6)	0
Febrile neutropenia	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.6)	0	1 (3.6)
Respiratory failure	1 (3.6)	0	1 (3.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (17.5)	5 (12.5)	1 (2.5)
Blood and lymphatic system disorders			
- Total	2 (5.0)	2 (5.0)	0
Febrile neutropenia	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
- Total	4 (10.0)	1 (2.5)	0
Pyrexia	4 (10.0)	1 (2.5)	0
Renal and urinary disorders			
- Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.0)	2 (5.0)	0

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (5.0)	2 (5.0)	0
Vascular disorders			
- Total	1 (2.5)	0	1 (2.5)
Hypotension	1 (2.5)	0	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=7		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=22		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (8.7)	0	1 (4.3)
General disorders and administration site conditions			
- Total	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.3)	0	1 (4.3)
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0
General disorders and administration site conditions			
- Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (57.1)	6 (21.4)	9 (32.1)
Blood and lymphatic system disorders			
- Total	1 (3.6)	1 (3.6)	0
Febrile neutropenia	1 (3.6)	1 (3.6)	0
Immune system disorders			
- Total	15 (53.6)	5 (17.9)	8 (28.6)
Cytokine release syndrome	15 (53.6)	5 (17.9)	8 (28.6)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.6)	0	1 (3.6)
Respiratory failure	1 (3.6)	0	1 (3.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	35 (77.8)	14 (31.1)	17 (37.8)
Blood and lymphatic system disorders			
- Total	14 (31.1)	13 (28.9)	1 (2.2)
Febrile neutropenia	14 (31.1)	13 (28.9)	1 (2.2)
General disorders and administration site conditions			
- Total	6 (13.3)	1 (2.2)	0
Pyrexia	6 (13.3)	1 (2.2)	0
Immune system disorders			
- Total	31 (68.9)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	10 (22.2)	10 (22.2)
Renal and urinary disorders			
- Total	5 (11.1)	2 (4.4)	3 (6.7)

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (11.1)	2 (4.4)	3 (6.7)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (17.8)	3 (6.7)	5 (11.1)
Hypoxia	5 (11.1)	3 (6.7)	2 (4.4)
Respiratory failure	4 (8.9)	0	4 (8.9)
Vascular disorders			
- Total	8 (17.8)	1 (2.2)	7 (15.6)
Hypotension	8 (17.8)	1 (2.2)	7 (15.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224k
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	1 (14.3)	3 (42.9)
General disorders and administration site conditions			
- Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			
- Total	4 (57.1)	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	1 (14.3)	3 (42.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (60.4)	13 (27.1)	13 (27.1)
Blood and lymphatic system disorders			
- Total	5 (10.4)	5 (10.4)	0
Febrile neutropenia	5 (10.4)	5 (10.4)	0
General disorders and administration site conditions			
- Total	1 (2.1)	0	0
Pyrexia	1 (2.1)	0	0
Immune system disorders			
- Total	29 (60.4)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	11 (22.9)	11 (22.9)
Vascular disorders			
- Total	3 (6.3)	1 (2.1)	2 (4.2)
Hypotension	3 (6.3)	1 (2.1)	2 (4.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (71.9)	7 (21.9)	13 (40.6)
Blood and lymphatic system disorders			
- Total	8 (25.0)	7 (21.9)	1 (3.1)
Febrile neutropenia	8 (25.0)	7 (21.9)	1 (3.1)
General disorders and administration site conditions			
- Total	2 (6.3)	0	0
Pyrexia	2 (6.3)	0	0
Immune system disorders			
- Total	21 (65.6)	5 (15.6)	10 (31.3)
Cytokine release syndrome	21 (65.6)	5 (15.6)	10 (31.3)
Renal and urinary disorders			
- Total	4 (12.5)	2 (6.3)	2 (6.3)
Acute kidney injury	4 (12.5)	2 (6.3)	2 (6.3)

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (15.6)	1 (3.1)	4 (12.5)
Hypoxia	3 (9.4)	1 (3.1)	2 (6.3)
Respiratory failure	3 (9.4)	0	3 (9.4)
Vascular disorders			
- Total	5 (15.6)	1 (3.1)	4 (12.5)
Hypotension	5 (15.6)	1 (3.1)	4 (12.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (14.6)	5 (10.4)	1 (2.1)
Blood and lymphatic system disorders			
- Total	3 (6.3)	3 (6.3)	0
Febrile neutropenia	3 (6.3)	3 (6.3)	0
General disorders and administration site conditions			
- Total	4 (8.3)	1 (2.1)	0
Pyrexia	4 (8.3)	1 (2.1)	0
Renal and urinary disorders			
- Total	1 (2.1)	0	1 (2.1)
Acute kidney injury	1 (2.1)	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.1)	1 (2.1)	0

Group term Preferred term	All patients N=48 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (2.1)	1 (2.1)	0
Vascular disorders			
- Total	1 (2.1)	0	1 (2.1)
Hypotension	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (7.4)	1 (3.7)	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (7.4)	1 (3.7)	1 (3.7)
Hypoxia	1 (3.7)	1 (3.7)	0
Respiratory failure	1 (3.7)	0	1 (3.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (6.1)	0	1 (3.0)
General disorders and administration site conditions			
- Total	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.0)	0	1 (3.0)
Respiratory failure	1 (3.0)	0	1 (3.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (5.9)	0	0
General disorders and administration site conditions			
- Total	1 (5.9)	0	0
Pyrexia	1 (5.9)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (66.7)	14 (29.2)	15 (31.3)
Blood and lymphatic system disorders			
- Total	7 (14.6)	7 (14.6)	0
Febrile neutropenia	7 (14.6)	7 (14.6)	0
General disorders and administration site conditions			
- Total	5 (10.4)	1 (2.1)	0
Pyrexia	5 (10.4)	1 (2.1)	0
Immune system disorders			
- Total	29 (60.4)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	11 (22.9)	11 (22.9)
Renal and urinary disorders			
- Total	1 (2.1)	0	1 (2.1)

Group term Preferred term	All patients N=48 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (2.1)	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.2)	1 (2.1)	1 (2.1)
Hypoxia	1 (2.1)	1 (2.1)	0
Respiratory failure	1 (2.1)	0	1 (2.1)
Vascular disorders			
- Total	3 (6.3)	0	3 (6.3)
Hypotension	3 (6.3)	0	3 (6.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (75.0)	7 (21.9)	14 (43.8)
Blood and lymphatic system disorders			
- Total	8 (25.0)	7 (21.9)	1 (3.1)
Febrile neutropenia	8 (25.0)	7 (21.9)	1 (3.1)
General disorders and administration site conditions			
- Total	2 (6.3)	0	0
Pyrexia	2 (6.3)	0	0
Immune system disorders			
- Total	21 (65.6)	5 (15.6)	10 (31.3)
Cytokine release syndrome	21 (65.6)	5 (15.6)	10 (31.3)
Renal and urinary disorders			
- Total	4 (12.5)	2 (6.3)	2 (6.3)

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (21.9)	2 (6.3)	5 (15.6)
Hypoxia	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory failure	4 (12.5)	0	4 (12.5)
Vascular disorders			
- Total	5 (15.6)	1 (3.1)	4 (12.5)
Hypotension	5 (15.6)	1 (3.1)	4 (12.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224l
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (76.9)	7 (53.8)	2 (15.4)
Blood and lymphatic system disorders			
- Total	6 (46.2)	6 (46.2)	0
Febrile neutropenia	6 (46.2)	6 (46.2)	0
General disorders and administration site conditions			
- Total	1 (7.7)	0	0
Pyrexia	1 (7.7)	0	0
Immune system disorders			
- Total	10 (76.9)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	4 (30.8)	1 (7.7)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (7.7)	1 (7.7)	0
Hypoxia	1 (7.7)	1 (7.7)	0

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (62.7)	13 (19.4)	24 (35.8)
Blood and lymphatic system disorders			
- Total	7 (10.4)	6 (9.0)	1 (1.5)
Febrile neutropenia	7 (10.4)	6 (9.0)	1 (1.5)
General disorders and administration site conditions			
- Total	2 (3.0)	0	0
Pyrexia	2 (3.0)	0	0
Immune system disorders			
- Total	40 (59.7)	12 (17.9)	20 (29.9)
Cytokine release syndrome	40 (59.7)	12 (17.9)	20 (29.9)
Renal and urinary disorders			
- Total	4 (6.0)	2 (3.0)	2 (3.0)
Acute kidney injury	4 (6.0)	2 (3.0)	2 (3.0)

Group term Preferred term	All patients N=67 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.0)	0	4 (6.0)
Respiratory failure	3 (4.5)	0	3 (4.5)
Hypoxia	2 (3.0)	0	2 (3.0)
Vascular disorders			
- Total	6 (9.0)	1 (1.5)	5 (7.5)
Hypotension	6 (9.0)	1 (1.5)	5 (7.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=13		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (14.5)	6 (9.7)	2 (3.2)
Blood and lymphatic system disorders			
- Total	3 (4.8)	3 (4.8)	0
Febrile neutropenia	3 (4.8)	3 (4.8)	0
General disorders and administration site conditions			
- Total	4 (6.5)	1 (1.6)	0
Pyrexia	4 (6.5)	1 (1.6)	0
Renal and urinary disorders			
- Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.8)	2 (3.2)	1 (1.6)

Group term Preferred term	All patients N=62 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (3.2)	2 (3.2)	0
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
- Total	1 (1.6)	0	1 (1.6)
Hypotension	1 (1.6)	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=8		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (7.1)	0	1 (2.4)
General disorders and administration site conditions			
- Total	2 (4.8)	0	0
Pyrexia	2 (4.8)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.4)	0	1 (2.4)
Respiratory failure	1 (2.4)	0	1 (2.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (76.9)	7 (53.8)	2 (15.4)
Blood and lymphatic system disorders			
- Total	6 (46.2)	6 (46.2)	0
Febrile neutropenia	6 (46.2)	6 (46.2)	0
General disorders and administration site conditions			
- Total	1 (7.7)	0	0
Pyrexia	1 (7.7)	0	0
Immune system disorders			
- Total	10 (76.9)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	4 (30.8)	1 (7.7)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (7.7)	1 (7.7)	0

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (7.7)	1 (7.7)	0
Vascular disorders			
- Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (68.7)	14 (20.9)	27 (40.3)
Blood and lymphatic system disorders			
- Total	9 (13.4)	8 (11.9)	1 (1.5)
Febrile neutropenia	9 (13.4)	8 (11.9)	1 (1.5)
General disorders and administration site conditions			
- Total	6 (9.0)	1 (1.5)	0
Pyrexia	6 (9.0)	1 (1.5)	0
Immune system disorders			
- Total	40 (59.7)	12 (17.9)	20 (29.9)
Cytokine release syndrome	40 (59.7)	12 (17.9)	20 (29.9)
Renal and urinary disorders			
- Total	5 (7.5)	2 (3.0)	3 (4.5)

Group term Preferred term	All patients N=67 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (7.5)	2 (3.0)	3 (4.5)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (11.9)	2 (3.0)	6 (9.0)
Respiratory failure	5 (7.5)	0	5 (7.5)
Hypoxia	4 (6.0)	2 (3.0)	2 (3.0)
Vascular disorders			
- Total	6 (9.0)	0	6 (9.0)
Hypotension	6 (9.0)	0	6 (9.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224m
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (50.0)	7 (26.9)	4 (15.4)
Blood and lymphatic system disorders			
- Total	4 (15.4)	4 (15.4)	0
Febrile neutropenia	4 (15.4)	4 (15.4)	0
General disorders and administration site conditions			
- Total	2 (7.7)	0	0
Pyrexia	2 (7.7)	0	0
Immune system disorders			
- Total	12 (46.2)	3 (11.5)	4 (15.4)
Cytokine release syndrome	12 (46.2)	3 (11.5)	4 (15.4)
Renal and urinary disorders			
- Total	1 (3.8)	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	1 (3.8)

Group term Preferred term	All patients N=26 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	1 (3.8)	0	1 (3.8)
Hypotension	1 (3.8)	0	1 (3.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	39 (72.2)	13 (24.1)	22 (40.7)
Blood and lymphatic system disorders			
- Total	9 (16.7)	8 (14.8)	1 (1.9)
Febrile neutropenia	9 (16.7)	8 (14.8)	1 (1.9)
General disorders and administration site conditions			
- Total	1 (1.9)	0	0
Pyrexia	1 (1.9)	0	0
Immune system disorders			
- Total	38 (70.4)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	13 (24.1)	17 (31.5)
Renal and urinary disorders			
- Total	3 (5.6)	2 (3.7)	1 (1.9)
Acute kidney injury	3 (5.6)	2 (3.7)	1 (1.9)

Group term Preferred term	All patients N=54 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (9.3)	1 (1.9)	4 (7.4)
Hypoxia	3 (5.6)	1 (1.9)	2 (3.7)
Respiratory failure	3 (5.6)	0	3 (5.6)
Vascular disorders			
- Total	7 (13.0)	2 (3.7)	5 (9.3)
Hypotension	7 (13.0)	2 (3.7)	5 (9.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (12.0)	3 (12.0)	0
Blood and lymphatic system disorders			
- Total	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
- Total	1 (4.0)	1 (4.0)	0
Pyrexia	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.0)	1 (4.0)	0
Hypoxia	1 (4.0)	1 (4.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (12.0)	3 (6.0)	2 (4.0)
Blood and lymphatic system disorders			
- Total	2 (4.0)	2 (4.0)	0
Febrile neutropenia	2 (4.0)	2 (4.0)	0
General disorders and administration site conditions			
- Total	3 (6.0)	0	0
Pyrexia	3 (6.0)	0	0
Renal and urinary disorders			
- Total	1 (2.0)	0	1 (2.0)
Acute kidney injury	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (4.0)	1 (2.0)	1 (2.0)

Group term Preferred term	All patients N=50 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)
Vascular disorders			
- Total	1 (2.0)	0	1 (2.0)
Hypotension	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (10.0)	0	0
General disorders and administration site conditions			
- Total	2 (10.0)	0	0
Pyrexia	2 (10.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (3.3)	0	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.3)	0	1 (3.3)
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (53.8)	7 (26.9)	4 (15.4)
Blood and lymphatic system disorders			
- Total	4 (15.4)	4 (15.4)	0
Febrile neutropenia	4 (15.4)	4 (15.4)	0
General disorders and administration site conditions			
- Total	4 (15.4)	1 (3.8)	0
Pyrexia	4 (15.4)	1 (3.8)	0
Immune system disorders			
- Total	12 (46.2)	3 (11.5)	4 (15.4)
Cytokine release syndrome	12 (46.2)	3 (11.5)	4 (15.4)
Renal and urinary disorders			
- Total	1 (3.8)	0	1 (3.8)

Group term Preferred term	All patients N=26 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (3.8)	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.8)	1 (3.8)	0
Hypoxia	1 (3.8)	1 (3.8)	0
Vascular disorders			
- Total	1 (3.8)	0	1 (3.8)
Hypotension	1 (3.8)	0	1 (3.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (77.8)	14 (25.9)	25 (46.3)
Blood and lymphatic system disorders			
- Total	11 (20.4)	10 (18.5)	1 (1.9)
Febrile neutropenia	11 (20.4)	10 (18.5)	1 (1.9)
General disorders and administration site conditions			
- Total	3 (5.6)	0	0
Pyrexia	3 (5.6)	0	0
Immune system disorders			
- Total	38 (70.4)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	13 (24.1)	17 (31.5)
Renal and urinary disorders			
- Total	4 (7.4)	2 (3.7)	2 (3.7)

Group term Preferred term	All patients N=54 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	4 (7.4)	2 (3.7)	2 (3.7)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (14.8)	2 (3.7)	6 (11.1)
Respiratory failure	5 (9.3)	0	5 (9.3)
Hypoxia	4 (7.4)	2 (3.7)	2 (3.7)
Vascular disorders			
- Total	7 (13.0)	1 (1.9)	6 (11.1)
Hypotension	7 (13.0)	1 (1.9)	6 (11.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224n
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (36.4)	1 (9.1)	1 (9.1)
Immune system disorders			
- Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (69.6)	19 (27.5)	25 (36.2)
Blood and lymphatic system disorders			
- Total	13 (18.8)	12 (17.4)	1 (1.4)
Febrile neutropenia	13 (18.8)	12 (17.4)	1 (1.4)
General disorders and administration site conditions			
- Total	3 (4.3)	0	0
Pyrexia	3 (4.3)	0	0
Immune system disorders			
- Total	46 (66.7)	15 (21.7)	20 (29.0)
Cytokine release syndrome	46 (66.7)	15 (21.7)	20 (29.0)
Renal and urinary disorders			
- Total	4 (5.8)	2 (2.9)	2 (2.9)
Acute kidney injury	4 (5.8)	2 (2.9)	2 (2.9)

Group term Preferred term	All patients N=69 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (7.2)	1 (1.4)	4 (5.8)
Hypoxia	3 (4.3)	1 (1.4)	2 (2.9)
Respiratory failure	3 (4.3)	0	3 (4.3)
Vascular disorders			
- Total	8 (11.6)	2 (2.9)	6 (8.7)
Hypotension	8 (11.6)	2 (2.9)	6 (8.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=11		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (14.1)	6 (9.4)	2 (3.1)
Blood and lymphatic system disorders			
- Total	3 (4.7)	3 (4.7)	0
Febrile neutropenia	3 (4.7)	3 (4.7)	0
General disorders and administration site conditions			
- Total	4 (6.3)	1 (1.6)	0
Pyrexia	4 (6.3)	1 (1.6)	0
Renal and urinary disorders			
- Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.7)	2 (3.1)	1 (1.6)

Group term Preferred term	All patients N=64 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (3.1)	2 (3.1)	0
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
- Total	1 (1.6)	0	1 (1.6)
Hypotension	1 (1.6)	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (11.1)	0	0
General disorders and administration site conditions			
- Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (4.9)	0	1 (2.4)
General disorders and administration site conditions			
- Total	1 (2.4)	0	0
Pyrexia	1 (2.4)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.4)	0	1 (2.4)
Respiratory failure	1 (2.4)	0	1 (2.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (45.5)	1 (9.1)	1 (9.1)
General disorders and administration site conditions			
- Total	1 (9.1)	0	0
Pyrexia	1 (9.1)	0	0
Immune system disorders			
- Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	51 (73.9)	20 (29.0)	28 (40.6)
Blood and lymphatic system disorders			
- Total	15 (21.7)	14 (20.3)	1 (1.4)
Febrile neutropenia	15 (21.7)	14 (20.3)	1 (1.4)
General disorders and administration site conditions			
- Total	6 (8.7)	1 (1.4)	0
Pyrexia	6 (8.7)	1 (1.4)	0
Immune system disorders			
- Total	46 (66.7)	15 (21.7)	20 (29.0)
Cytokine release syndrome	46 (66.7)	15 (21.7)	20 (29.0)
Renal and urinary disorders			
- Total	5 (7.2)	2 (2.9)	3 (4.3)

Group term Preferred term	All patients N=69 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	5 (7.2)	2 (2.9)	3 (4.3)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (13.0)	3 (4.3)	6 (8.7)
Hypoxia	5 (7.2)	3 (4.3)	2 (2.9)
Respiratory failure	5 (7.2)	0	5 (7.2)
Vascular disorders			
- Total	8 (11.6)	1 (1.4)	7 (10.1)
Hypotension	8 (11.6)	1 (1.4)	7 (10.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224o
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	2 (33.3)	0
Febrile neutropenia	2 (33.3)	2 (33.3)	0
Immune system disorders			
- Total	4 (66.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	3 (50.0)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	0	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	2 (33.3)	0	2 (33.3)
Hypotension	2 (33.3)	0	2 (33.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (64.9)	19 (25.7)	23 (31.1)
Blood and lymphatic system disorders			
- Total	11 (14.9)	10 (13.5)	1 (1.4)
Febrile neutropenia	11 (14.9)	10 (13.5)	1 (1.4)
General disorders and administration site conditions			
- Total	3 (4.1)	0	0
Pyrexia	3 (4.1)	0	0
Immune system disorders			
- Total	46 (62.2)	16 (21.6)	18 (24.3)
Cytokine release syndrome	46 (62.2)	16 (21.6)	18 (24.3)
Renal and urinary disorders			
- Total	2 (2.7)	1 (1.4)	1 (1.4)
Acute kidney injury	2 (2.7)	1 (1.4)	1 (1.4)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (5.4)	1 (1.4)	3 (4.1)
Respiratory failure	3 (4.1)	0	3 (4.1)
Hypoxia	2 (2.7)	1 (1.4)	1 (1.4)
Vascular disorders			
- Total	6 (8.1)	2 (2.7)	4 (5.4)
Hypotension	6 (8.1)	2 (2.7)	4 (5.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0
General disorders and administration site conditions			
- Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (11.4)	6 (8.6)	2 (2.9)
Blood and lymphatic system disorders			
- Total	3 (4.3)	3 (4.3)	0
Febrile neutropenia	3 (4.3)	3 (4.3)	0
General disorders and administration site conditions			
- Total	3 (4.3)	1 (1.4)	0
Pyrexia	3 (4.3)	1 (1.4)	0
Renal and urinary disorders			
- Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (4.3)	2 (2.9)	1 (1.4)

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (2.9)	2 (2.9)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
- Total	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=4		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (6.5)	0	1 (2.2)
General disorders and administration site conditions			
- Total	2 (4.3)	0	0
Pyrexia	2 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.2)	0	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	2 (33.3)	0
Febrile neutropenia	2 (33.3)	2 (33.3)	0
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Immune system disorders			
- Total	4 (66.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	3 (50.0)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	0	1 (16.7)
Vascular disorders			
- Total	2 (33.3)	0	2 (33.3)
Hypotension	2 (33.3)	0	2 (33.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	51 (68.9)	20 (27.0)	26 (35.1)
Blood and lymphatic system disorders			
- Total	13 (17.6)	12 (16.2)	1 (1.4)
Febrile neutropenia	13 (17.6)	12 (16.2)	1 (1.4)
General disorders and administration site conditions			
- Total	6 (8.1)	1 (1.4)	0
Pyrexia	6 (8.1)	1 (1.4)	0
Immune system disorders			
- Total	46 (62.2)	16 (21.6)	18 (24.3)
Cytokine release syndrome	46 (62.2)	16 (21.6)	18 (24.3)
Renal and urinary disorders			
- Total	3 (4.1)	1 (1.4)	2 (2.7)

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (10.8)	3 (4.1)	5 (6.8)
Respiratory failure	5 (6.8)	0	5 (6.8)
Hypoxia	4 (5.4)	3 (4.1)	1 (1.4)
Vascular disorders			
- Total	6 (8.1)	1 (1.4)	5 (6.8)
Hypotension	6 (8.1)	1 (1.4)	5 (6.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224p
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (57.5)	10 (25.0)	11 (27.5)
Blood and lymphatic system disorders			
- Total	2 (5.0)	1 (2.5)	1 (2.5)
Febrile neutropenia	2 (5.0)	1 (2.5)	1 (2.5)
General disorders and administration site conditions			
- Total	1 (2.5)	0	0
Pyrexia	1 (2.5)	0	0
Immune system disorders			
- Total	23 (57.5)	9 (22.5)	10 (25.0)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)
Renal and urinary disorders			
- Total	1 (2.5)	1 (2.5)	0
Acute kidney injury	1 (2.5)	1 (2.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (72.5)	10 (25.0)	15 (37.5)
Blood and lymphatic system disorders			
- Total	11 (27.5)	11 (27.5)	0
Febrile neutropenia	11 (27.5)	11 (27.5)	0
General disorders and administration site conditions			
- Total	2 (5.0)	0	0
Pyrexia	2 (5.0)	0	0
Immune system disorders			
- Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Renal and urinary disorders			
- Total	3 (7.5)	1 (2.5)	2 (5.0)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (12.5)	1 (2.5)	4 (10.0)
Hypoxia	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory failure	3 (7.5)	0	3 (7.5)
Vascular disorders			
- Total	8 (20.0)	2 (5.0)	6 (15.0)
Hypotension	8 (20.0)	2 (5.0)	6 (15.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (10.0)	2 (5.0)	1 (2.5)
Blood and lymphatic system disorders			
- Total	1 (2.5)	1 (2.5)	0
Febrile neutropenia	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
- Total	3 (7.5)	0	0
Pyrexia	3 (7.5)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.0)	1 (2.5)	1 (2.5)
Hypoxia	1 (2.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (14.3)	4 (11.4)	1 (2.9)
Blood and lymphatic system disorders			
- Total	2 (5.7)	2 (5.7)	0
Febrile neutropenia	2 (5.7)	2 (5.7)	0
General disorders and administration site conditions			
- Total	1 (2.9)	1 (2.9)	0
Pyrexia	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
- Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.9)	1 (2.9)	0

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (2.9)	1 (2.9)	0
Vascular disorders			
- Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (3.3)	0	0
General disorders and administration site conditions			
- Total	1 (3.3)	0	0
Pyrexia	1 (3.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (10.0)	0	1 (5.0)
General disorders and administration site conditions			
- Total	1 (5.0)	0	0
Pyrexia	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (67.5)	12 (30.0)	12 (30.0)
Blood and lymphatic system disorders			
- Total	3 (7.5)	2 (5.0)	1 (2.5)
Febrile neutropenia	3 (7.5)	2 (5.0)	1 (2.5)
General disorders and administration site conditions			
- Total	4 (10.0)	0	0
Pyrexia	4 (10.0)	0	0
Immune system disorders			
- Total	23 (57.5)	9 (22.5)	10 (25.0)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)
Renal and urinary disorders			
- Total	1 (2.5)	1 (2.5)	0

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.0)	1 (2.5)	1 (2.5)
Hypoxia	1 (2.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (72.5)	9 (22.5)	17 (42.5)
Blood and lymphatic system disorders			
- Total	12 (30.0)	12 (30.0)	0
Febrile neutropenia	12 (30.0)	12 (30.0)	0
General disorders and administration site conditions			
- Total	3 (7.5)	1 (2.5)	0
Pyrexia	3 (7.5)	1 (2.5)	0
Immune system disorders			
- Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Renal and urinary disorders			
- Total	4 (10.0)	1 (2.5)	3 (7.5)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	4 (10.0)	1 (2.5)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (17.5)	2 (5.0)	5 (12.5)
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Respiratory failure	4 (10.0)	0	4 (10.0)
Vascular disorders			
- Total	8 (20.0)	1 (2.5)	7 (17.5)
Hypotension	8 (20.0)	1 (2.5)	7 (17.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224q
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Immune system disorders			
- Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r

Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Safety Set

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (59.1)	4 (18.2)	8 (36.4)
Blood and lymphatic system disorders			
- Total	4 (18.2)	4 (18.2)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
General disorders and administration site conditions			
- Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Immune system disorders			
- Total	13 (59.1)	4 (18.2)	6 (27.3)
Cytokine release syndrome	13 (59.1)	4 (18.2)	6 (27.3)
Renal and urinary disorders			
- Total	1 (4.5)	0	1 (4.5)
Acute kidney injury	1 (4.5)	0	1 (4.5)

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (13.6)	0	3 (13.6)
Respiratory failure	2 (9.1)	0	2 (9.1)
Hypoxia	1 (4.5)	0	1 (4.5)
Vascular disorders			
- Total	3 (13.6)	0	3 (13.6)
Hypotension	3 (13.6)	0	3 (13.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (64.7)	4 (23.5)	6 (35.3)
Blood and lymphatic system disorders			
- Total	4 (23.5)	4 (23.5)	0
Febrile neutropenia	4 (23.5)	4 (23.5)	0
Immune system disorders			
- Total	10 (58.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	4 (23.5)	4 (23.5)
Renal and urinary disorders			
- Total	1 (5.9)	1 (5.9)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (11.8)	1 (5.9)	1 (5.9)

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
- Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypotension	3 (17.6)	1 (5.9)	2 (11.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (65.7)	11 (31.4)	9 (25.7)
Blood and lymphatic system disorders			
- Total	3 (8.6)	3 (8.6)	0
Febrile neutropenia	3 (8.6)	3 (8.6)	0
General disorders and administration site conditions			
- Total	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	0
Immune system disorders			
- Total	23 (65.7)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	8 (22.9)	9 (25.7)
Vascular disorders			
- Total	1 (2.9)	1 (2.9)	0

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (2.9)	1 (2.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=5		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (10.0)	1 (5.0)	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0
Respiratory failure	1 (5.0)	0	1 (5.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (20.0)	3 (20.0)	0
Blood and lymphatic system disorders			
- Total	2 (13.3)	2 (13.3)	0
Febrile neutropenia	2 (13.3)	2 (13.3)	0
General disorders and administration site conditions			
- Total	2 (13.3)	1 (6.7)	0
Pyrexia	2 (13.3)	1 (6.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (11.4)	2 (5.7)	1 (2.9)
Blood and lymphatic system disorders			
- Total	1 (2.9)	1 (2.9)	0
Febrile neutropenia	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
- Total	2 (5.7)	0	0
Pyrexia	2 (5.7)	0	0
Renal and urinary disorders			
- Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (2.9)	1 (2.9)	0

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (2.9)	1 (2.9)	0
Vascular disorders			
- Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	0
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=13		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=11		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (8.7)	0	1 (4.3)
General disorders and administration site conditions			
- Total	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (4.3)	0	1 (4.3)
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
General disorders and administration site conditions			
- Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Immune system disorders			
- Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Renal and urinary disorders			
- Total	2 (33.3)	1 (16.7)	1 (16.7)

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Vascular disorders			
- Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (63.6)	4 (18.2)	9 (40.9)
Blood and lymphatic system disorders			
- Total	4 (18.2)	4 (18.2)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
General disorders and administration site conditions			
- Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Immune system disorders			
- Total	13 (59.1)	4 (18.2)	6 (27.3)
Cytokine release syndrome	13 (59.1)	4 (18.2)	6 (27.3)
Renal and urinary disorders			
- Total	1 (4.5)	0	1 (4.5)

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (22.7)	1 (4.5)	4 (18.2)
Respiratory failure	3 (13.6)	0	3 (13.6)
Hypoxia	2 (9.1)	1 (4.5)	1 (4.5)
Vascular disorders			
- Total	3 (13.6)	0	3 (13.6)
Hypotension	3 (13.6)	0	3 (13.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (70.6)	5 (29.4)	6 (35.3)
Blood and lymphatic system disorders			
- Total	5 (29.4)	5 (29.4)	0
Febrile neutropenia	5 (29.4)	5 (29.4)	0
General disorders and administration site conditions			
- Total	2 (11.8)	1 (5.9)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Immune system disorders			
- Total	10 (58.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	4 (23.5)	4 (23.5)
Renal and urinary disorders			
- Total	1 (5.9)	1 (5.9)	0

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
- Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypotension	3 (17.6)	1 (5.9)	2 (11.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (71.4)	11 (31.4)	11 (31.4)
Blood and lymphatic system disorders			
- Total	4 (11.4)	4 (11.4)	0
Febrile neutropenia	4 (11.4)	4 (11.4)	0
General disorders and administration site conditions			
- Total	3 (8.6)	0	0
Pyrexia	3 (8.6)	0	0
Immune system disorders			
- Total	23 (65.7)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	8 (22.9)	9 (25.7)
Renal and urinary disorders			
- Total	1 (2.9)	0	1 (2.9)

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.7)	1 (2.9)	1 (2.9)
Hypoxia	1 (2.9)	1 (2.9)	0
Respiratory failure	1 (2.9)	0	1 (2.9)
Vascular disorders			
- Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 224r
Serious adverse events (SAE) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (26.8)	11 (26.8)	0
Blood and lymphatic system disorders			
- Total	10 (24.4)	10 (24.4)	0
Febrile neutropenia	10 (24.4)	10 (24.4)	0
General disorders and administration site conditions			
- Total	2 (4.9)	1 (2.4)	0
Pyrexia	2 (4.9)	1 (2.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (7.5)	2 (5.0)	0
Blood and lymphatic system disorders			
- Total	2 (5.0)	2 (5.0)	0
Febrile neutropenia	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
- Total	1 (2.5)	0	0
Pyrexia	1 (2.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225a
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (35.3)	3 (17.6)	1 (5.9)
Blood and lymphatic system disorders			
- Total	4 (23.5)	3 (17.6)	1 (5.9)
Febrile neutropenia	4 (23.5)	3 (17.6)	1 (5.9)
General disorders and administration site conditions			
- Total	2 (11.8)	0	0
Pyrexia	2 (11.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (16.4)	7 (12.7)	0
Blood and lymphatic system disorders			
- Total	6 (10.9)	6 (10.9)	0
Febrile neutropenia	6 (10.9)	6 (10.9)	0
General disorders and administration site conditions			
- Total	4 (7.3)	1 (1.8)	0
Pyrexia	4 (7.3)	1 (1.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225b
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (25.6)	9 (20.9)	1 (2.3)
Blood and lymphatic system disorders			
- Total	10 (23.3)	9 (20.9)	1 (2.3)
Febrile neutropenia	10 (23.3)	9 (20.9)	1 (2.3)
General disorders and administration site conditions			
- Total	1 (2.3)	0	0
Pyrexia	1 (2.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (22.9)	13 (18.6)	0
Blood and lymphatic system disorders			
- Total	12 (17.1)	12 (17.1)	0
Febrile neutropenia	12 (17.1)	12 (17.1)	0
General disorders and administration site conditions			
- Total	5 (7.1)	1 (1.4)	0
Pyrexia	5 (7.1)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (6.7)	1 (6.7)	0
Blood and lymphatic system disorders			
- Total	1 (6.7)	1 (6.7)	0
Febrile neutropenia	1 (6.7)	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225c
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (23.1)	2 (15.4)	1 (7.7)
Blood and lymphatic system disorders			
- Total	3 (23.1)	2 (15.4)	1 (7.7)
Febrile neutropenia	3 (23.1)	2 (15.4)	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (11.1)	0	0
General disorders and administration site conditions			
- Total	2 (11.1)	0	0
Pyrexia	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225d
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (22.5)	16 (20.0)	1 (1.3)
Blood and lymphatic system disorders			
- Total	16 (20.0)	15 (18.8)	1 (1.3)
Febrile neutropenia	16 (20.0)	15 (18.8)	1 (1.3)
General disorders and administration site conditions			
- Total	3 (3.8)	1 (1.3)	0
Pyrexia	3 (3.8)	1 (1.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225e

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	1 (12.5)	0
Blood and lymphatic system disorders			
- Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225e

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (20.0)	15 (16.7)	1 (1.1)
Blood and lymphatic system disorders			
- Total	15 (16.7)	14 (15.6)	1 (1.1)
Febrile neutropenia	15 (16.7)	14 (15.6)	1 (1.1)
General disorders and administration site conditions			
- Total	4 (4.4)	1 (1.1)	0
Pyrexia	4 (4.4)	1 (1.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225e

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (20.8)	16 (16.7)	1 (1.0)
Blood and lymphatic system disorders			
- Total	16 (16.7)	15 (15.6)	1 (1.0)
Febrile neutropenia	16 (16.7)	15 (15.6)	1 (1.0)
General disorders and administration site conditions			
- Total	5 (5.2)	1 (1.0)	0
Pyrexia	5 (5.2)	1 (1.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225f

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (20.6)	16 (16.5)	1 (1.0)
Blood and lymphatic system disorders			
- Total	16 (16.5)	15 (15.5)	1 (1.0)
Febrile neutropenia	16 (16.5)	15 (15.5)	1 (1.0)
General disorders and administration site conditions			
- Total	5 (5.2)	1 (1.0)	0
Pyrexia	5 (5.2)	1 (1.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225g

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	0
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (20.0)	16 (16.8)	1 (1.1)
Blood and lymphatic system disorders			
- Total	16 (16.8)	15 (15.8)	1 (1.1)
Febrile neutropenia	16 (16.8)	15 (15.8)	1 (1.1)
General disorders and administration site conditions			
- Total	4 (4.2)	1 (1.1)	0
Pyrexia	4 (4.2)	1 (1.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225h
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	2 (100)	0
Blood and lymphatic system disorders			
- Total	2 (100)	2 (100)	0
Febrile neutropenia	2 (100)	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (18.8)	14 (14.6)	1 (1.0)
Blood and lymphatic system disorders			
- Total	14 (14.6)	13 (13.5)	1 (1.0)
Febrile neutropenia	14 (14.6)	13 (13.5)	1 (1.0)
General disorders and administration site conditions			
- Total	5 (5.2)	1 (1.0)	0
Pyrexia	5 (5.2)	1 (1.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225i
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (16.7)	3 (10.0)	0
Blood and lymphatic system disorders			
- Total	3 (10.0)	3 (10.0)	0
Febrile neutropenia	3 (10.0)	3 (10.0)	0
General disorders and administration site conditions			
- Total	2 (6.7)	0	0
Pyrexia	2 (6.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (22.1)	13 (19.1)	1 (1.5)
Blood and lymphatic system disorders			
- Total	13 (19.1)	12 (17.6)	1 (1.5)
Febrile neutropenia	13 (19.1)	12 (17.6)	1 (1.5)
General disorders and administration site conditions			
- Total	3 (4.4)	1 (1.5)	0
Pyrexia	3 (4.4)	1 (1.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225j

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

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

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (25.0)	7 (21.9)	1 (3.1)
Blood and lymphatic system disorders			
- Total	7 (21.9)	6 (18.8)	1 (3.1)
Febrile neutropenia	7 (21.9)	6 (18.8)	1 (3.1)
General disorders and administration site conditions			
- Total	2 (6.3)	1 (3.1)	0
Pyrexia	2 (6.3)	1 (3.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (19.3)	8 (14.0)	0
Blood and lymphatic system disorders			
- Total	8 (14.0)	8 (14.0)	0
Febrile neutropenia	8 (14.0)	8 (14.0)	0
General disorders and administration site conditions			
- Total	3 (5.3)	0	0
Pyrexia	3 (5.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225k
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (11.1)	1 (11.1)	0
Blood and lymphatic system disorders			
- Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (20.7)	11 (19.0)	1 (1.7)
Blood and lymphatic system disorders			
- Total	11 (19.0)	10 (17.2)	1 (1.7)
Febrile neutropenia	11 (19.0)	10 (17.2)	1 (1.7)
General disorders and administration site conditions			
- Total	2 (3.4)	1 (1.7)	0
Pyrexia	2 (3.4)	1 (1.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (20.0)	5 (12.5)	0
Blood and lymphatic system disorders			
- Total	5 (12.5)	5 (12.5)	0
Febrile neutropenia	5 (12.5)	5 (12.5)	0
General disorders and administration site conditions			
- Total	3 (7.5)	0	0
Pyrexia	3 (7.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225l
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (35.3)	6 (35.3)	0
Blood and lymphatic system disorders			
- Total	6 (35.3)	6 (35.3)	0
Febrile neutropenia	6 (35.3)	6 (35.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (17.3)	10 (12.3)	1 (1.2)
Blood and lymphatic system disorders			
- Total	10 (12.3)	9 (11.1)	1 (1.2)
Febrile neutropenia	10 (12.3)	9 (11.1)	1 (1.2)
General disorders and administration site conditions			
- Total	5 (6.2)	1 (1.2)	0
Pyrexia	5 (6.2)	1 (1.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225m
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (14.3)	4 (14.3)	0
Blood and lymphatic system disorders			
- Total	4 (14.3)	4 (14.3)	0
Febrile neutropenia	4 (14.3)	4 (14.3)	0
General disorders and administration site conditions			
- Total	1 (3.6)	0	0
Pyrexia	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (22.9)	12 (17.1)	1 (1.4)
Blood and lymphatic system disorders			
- Total	12 (17.1)	11 (15.7)	1 (1.4)
Febrile neutropenia	12 (17.1)	11 (15.7)	1 (1.4)
General disorders and administration site conditions			
- Total	4 (5.7)	1 (1.4)	0
Pyrexia	4 (5.7)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225n

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (36.4)	3 (27.3)	0
Blood and lymphatic system disorders			
- Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
General disorders and administration site conditions			
- Total	2 (18.2)	0	0
Pyrexia	2 (18.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (18.4)	13 (14.9)	1 (1.1)
Blood and lymphatic system disorders			
- Total	13 (14.9)	12 (13.8)	1 (1.1)
Febrile neutropenia	13 (14.9)	12 (13.8)	1 (1.1)
General disorders and administration site conditions			
- Total	3 (3.4)	1 (1.1)	0
Pyrexia	3 (3.4)	1 (1.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225o

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Baseline extramedullary disease presence: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (22.0)	16 (17.6)	1 (1.1)
Blood and lymphatic system disorders			
- Total	16 (17.6)	15 (16.5)	1 (1.1)
Febrile neutropenia	16 (17.6)	15 (16.5)	1 (1.1)
General disorders and administration site conditions			
- Total	5 (5.5)	1 (1.1)	0
Pyrexia	5 (5.5)	1 (1.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225p
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (20.0)	8 (20.0)	0
Blood and lymphatic system disorders			
- Total	8 (20.0)	8 (20.0)	0
Febrile neutropenia	8 (20.0)	8 (20.0)	0
General disorders and administration site conditions			
- Total	1 (2.5)	0	0
Pyrexia	1 (2.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (20.0)	6 (15.0)	0
Blood and lymphatic system disorders			
- Total	6 (15.0)	6 (15.0)	0
Febrile neutropenia	6 (15.0)	6 (15.0)	0
General disorders and administration site conditions			
- Total	2 (5.0)	0	0
Pyrexia	2 (5.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225q

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (22.2)	2 (11.1)	1 (5.6)
Blood and lymphatic system disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
General disorders and administration site conditions			
- Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	1 (12.5)	0
Blood and lymphatic system disorders			
- Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (13.3)	3 (10.0)	0
Blood and lymphatic system disorders			
- Total	2 (6.7)	2 (6.7)	0
Febrile neutropenia	2 (6.7)	2 (6.7)	0
General disorders and administration site conditions			
- Total	3 (10.0)	1 (3.3)	0
Pyrexia	3 (10.0)	1 (3.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r
Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (33.3)	5 (27.8)	0
Blood and lymphatic system disorders			
- Total	5 (27.8)	5 (27.8)	0
Febrile neutropenia	5 (27.8)	5 (27.8)	0
General disorders and administration site conditions			
- Total	1 (5.6)	0	0
Pyrexia	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (19.0)	7 (16.7)	1 (2.4)
Blood and lymphatic system disorders			
- Total	8 (19.0)	7 (16.7)	1 (2.4)
Febrile neutropenia	8 (19.0)	7 (16.7)	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 225r

Serious adverse events (SAE) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226a

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age

Age: <10 years

	All patients N=34		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226a

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226a

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=18

	All patients N=13		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226b

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Male

	All patients N=46		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226b

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Female

	All patients N=32		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226c

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race

Race: White

	All patients N=57		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226c

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race

Race: Asian

	All patients N=10		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226c

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race

Race: Other

	All patients N=11		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226d

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226d

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Other

	All patients N=64		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226e

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226e

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226e

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Response status at study entry: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226f

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226f

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226f

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Philadelphia chromosome/BCR-ABL: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226g

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226g

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: No

	All patients N=77		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226g

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Mixed-lineage leukemia rearrangement: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226h

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226h

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: No

	All patients N=77		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226h

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226i

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226i

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: No

	All patients N=77		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226i

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226j

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

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

	All patients N=27		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226j

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

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

	All patients N=51		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226j

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

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

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226k

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region

Region: Europe

	All patients N=27		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226k

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region

Region: US

	All patients N=44		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226k

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region

Region: Rest of World

	All patients N=7		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226l

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Yes

	All patients N=46		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226l

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226l

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226m

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226m

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: No

	All patients N=65		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226m

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226n

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226n

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226n

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Baseline bone marrow tumor burden: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226o

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226o

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Baseline extramedullary disease presence: No

	All patients N=67		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226o

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Baseline extramedullary disease presence: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226p

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Yes

	All patients N=6		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226p

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: No

	All patients N=72		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226p

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226q

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: > Median

	All patients N=38		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226q

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226q

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226r

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226r

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226r

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226r

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 226r

Serious adverse events (SAE) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (100)	3 (37.5)	5 (62.5)
Blood and lymphatic system disorders			
- Total	2 (25.0)	2 (25.0)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
- Total	2 (25.0)	2 (25.0)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
- Total	5 (62.5)	2 (25.0)	3 (37.5)
Aspergillus infection	1 (12.5)	0	1 (12.5)
Device related infection	1 (12.5)	1 (12.5)	0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Investigations			
- Total	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
- Total	1 (12.5)	0	1 (12.5)
Tumour lysis syndrome	1 (12.5)	0	1 (12.5)
Nervous system disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Encephalopathy	1 (12.5)	1 (12.5)	0
Haemorrhage intracranial	1 (12.5)	0	1 (12.5)
Psychiatric disorders			
- Total	1 (12.5)	1 (12.5)	0
Mental status changes	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
- Total	1 (12.5)	0	0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (12.5)	0	1 (12.5)
Pulmonary haemorrhage	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	2 (28.6)	3 (42.9)
Cardiac disorders			
- Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
- Total	3 (42.9)	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	1 (14.3)
Colitis	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Haemoperitoneum	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
- Total	1 (14.3)	0	0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (14.3)	0	0
Infections and infestations			
- Total	5 (71.4)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0
Disseminated trichosporonosis	1 (14.3)	0	1 (14.3)
Klebsiella bacteraemia	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Serratia sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
- Total	1 (14.3)	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
- Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (42.9)	1 (14.3)	2 (28.6)
Respiratory failure	2 (28.6)	0	2 (28.6)
Pulmonary oedema	1 (14.3)	0	1 (14.3)

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
- Total	3 (42.9)	1 (14.3)	1 (14.3)
Hypotension	2 (28.6)	1 (14.3)	1 (14.3)
Hypertension	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
- Total	2 (66.7)	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Pancytopenia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
- Total	1 (33.3)	1 (33.3)	0
Cardiac failure	1 (33.3)	1 (33.3)	0
Infections and infestations			
- Total	3 (100)	1 (33.3)	2 (66.7)
Bacterial sepsis	1 (33.3)	0	1 (33.3)
Device related sepsis	1 (33.3)	1 (33.3)	0

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Investigations			
- Total	1 (33.3)	1 (33.3)	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Acute respiratory distress syndrome	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (100)	3 (33.3)	6 (66.7)
Blood and lymphatic system disorders			
- Total	1 (11.1)	1 (11.1)	0
Hyperleukocytosis	1 (11.1)	1 (11.1)	0
Cardiac disorders			
- Total	1 (11.1)	1 (11.1)	0
Left ventricular dysfunction	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
- Total	2 (22.2)	1 (11.1)	1 (11.1)
Abdominal compartment syndrome	1 (11.1)	0	1 (11.1)
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Haemoperitoneum	1 (11.1)	0	1 (11.1)
General disorders and administration site conditions			

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	3 (33.3)	2 (22.2)	0
Pyrexia	2 (22.2)	1 (11.1)	0
Pain	1 (11.1)	1 (11.1)	0
Infections and infestations			
- Total	6 (66.7)	2 (22.2)	4 (44.4)
Device related infection	1 (11.1)	1 (11.1)	0
Disseminated trichosporonosis	1 (11.1)	0	1 (11.1)
Fungaemia	1 (11.1)	0	1 (11.1)
Klebsiella bacteraemia	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Serratia sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			
- Total	1 (11.1)	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0
Investigations			
- Total	1 (11.1)	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	1 (11.1)	0	1 (11.1)
Tumour lysis syndrome	1 (11.1)	0	1 (11.1)
Nervous system disorders			
- Total	2 (22.2)	1 (11.1)	1 (11.1)
Encephalopathy	1 (11.1)	1 (11.1)	0
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
- Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
- Total	1 (11.1)	0	0
Acute kidney injury	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (44.4)	1 (11.1)	3 (33.3)
Respiratory failure	3 (33.3)	0	3 (33.3)
Pulmonary haemorrhage	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Vascular disorders			

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	2 (22.2)	1 (11.1)	1 (11.1)
Hypotension	2 (22.2)	1 (11.1)	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (77.8)	3 (33.3)	4 (44.4)
Blood and lymphatic system disorders			
- Total	3 (33.3)	2 (22.2)	1 (11.1)
Febrile neutropenia	2 (22.2)	1 (11.1)	1 (11.1)
Pancytopenia	1 (11.1)	1 (11.1)	0
Cardiac disorders			
- Total	1 (11.1)	1 (11.1)	0
Cardiac failure	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
- Total	1 (11.1)	1 (11.1)	0
Colitis	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	0	0
Infections and infestations			

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	7 (77.8)	3 (33.3)	4 (44.4)
Aspergillus infection	1 (11.1)	0	1 (11.1)
Bacteraemia	1 (11.1)	1 (11.1)	0
Bacterial sepsis	1 (11.1)	0	1 (11.1)
Device related sepsis	1 (11.1)	1 (11.1)	0
Fungal sepsis	1 (11.1)	0	1 (11.1)
Fungal skin infection	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)
Systemic mycosis	1 (11.1)	1 (11.1)	0
Investigations			
- Total	1 (11.1)	1 (11.1)	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0
Psychiatric disorders			
- Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (11.1)	0	1 (11.1)
Acute respiratory distress syndrome	1 (11.1)	0	1 (11.1)

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	1 (11.1)	0	0
Hypertension	1 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (100)	5 (45.5)	6 (54.5)
Blood and lymphatic system disorders			
- Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Hyperleukocytosis	1 (9.1)	1 (9.1)	0
Pancytopenia	1 (9.1)	1 (9.1)	0
Cardiac disorders			
- Total	1 (9.1)	1 (9.1)	0
Cardiac failure	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
- Total	3 (27.3)	2 (18.2)	1 (9.1)
Abdominal compartment syndrome	1 (9.1)	0	1 (9.1)
Colitis	1 (9.1)	1 (9.1)	0

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (9.1)	0	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haemoperitoneum	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
- Total	3 (27.3)	2 (18.2)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Infections and infestations			
- Total	9 (81.8)	4 (36.4)	5 (45.5)
Aspergillus infection	1 (9.1)	0	1 (9.1)
Bacteraemia	1 (9.1)	1 (9.1)	0
Bacterial sepsis	1 (9.1)	0	1 (9.1)
Device related infection	1 (9.1)	1 (9.1)	0
Device related sepsis	1 (9.1)	1 (9.1)	0
Disseminated trichosporonosis	1 (9.1)	0	1 (9.1)
Fungal sepsis	1 (9.1)	0	1 (9.1)
Fungal skin infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Serratia sepsis	1 (9.1)	0	1 (9.1)

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Systemic mycosis	1 (9.1)	1 (9.1)	0
Investigations			
- Total	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
- Total	1 (9.1)	0	1 (9.1)
Tumour lysis syndrome	1 (9.1)	0	1 (9.1)
Nervous system disorders			
- Total	1 (9.1)	1 (9.1)	0
Encephalopathy	1 (9.1)	1 (9.1)	0
Psychiatric disorders			
- Total	2 (18.2)	2 (18.2)	0
Mental status changes	2 (18.2)	2 (18.2)	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (36.4)	1 (9.1)	3 (27.3)
Respiratory failure	2 (18.2)	0	2 (18.2)
Acute respiratory distress syndrome	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
- Total	2 (18.2)	0	1 (9.1)
Hypertension	1 (9.1)	0	0
Hypotension	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (60.0)	1 (20.0)	2 (40.0)
Cardiac disorders			
- Total	1 (20.0)	1 (20.0)	0
Left ventricular dysfunction	1 (20.0)	1 (20.0)	0
Infections and infestations			
- Total	2 (40.0)	1 (20.0)	1 (20.0)
Klebsiella bacteraemia	1 (20.0)	1 (20.0)	0
Pneumonia fungal	1 (20.0)	0	1 (20.0)
Injury, poisoning and procedural complications			
- Total	1 (20.0)	1 (20.0)	0
Post procedural haemorrhage	1 (20.0)	1 (20.0)	0
Nervous system disorders			
- Total	1 (20.0)	0	1 (20.0)

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemorrhage intracranial	1 (20.0)	0	1 (20.0)
Vascular disorders			
- Total	1 (20.0)	1 (20.0)	0
Hypotension	1 (20.0)	1 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
- Total	1 (50.0)	0	1 (50.0)
Febrile neutropenia	1 (50.0)	0	1 (50.0)
Infections and infestations			
- Total	2 (100)	0	2 (100)
Fungaemia	1 (50.0)	0	1 (50.0)
Pneumonia	1 (50.0)	0	1 (50.0)
Investigations			
- Total	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
Renal and urinary disorders			

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (50.0)	0	0
Acute kidney injury	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Pulmonary haemorrhage	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (100)	1 (33.3)	2 (66.7)
Gastrointestinal disorders			
- Total	1 (33.3)	1 (33.3)	0
Colitis	1 (33.3)	1 (33.3)	0
Diarrhoea	1 (33.3)	0	0
Infections and infestations			
- Total	3 (100)	1 (33.3)	2 (66.7)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Bacteraemia	1 (33.3)	1 (33.3)	0
Disseminated trichosporonosis	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
- Total	1 (33.3)	1 (33.3)	0
Mental status changes	1 (33.3)	1 (33.3)	0

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
- Total	1 (33.3)	0	0
Hypertension	1 (33.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	5 (33.3)	8 (53.3)
Blood and lymphatic system disorders			
- Total	4 (26.7)	3 (20.0)	1 (6.7)
Febrile neutropenia	2 (13.3)	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Pancytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
- Total	2 (13.3)	2 (13.3)	0
Cardiac failure	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
Haemoperitoneum	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
- Total	3 (20.0)	2 (13.3)	0
Pyrexia	2 (13.3)	1 (6.7)	0
Pain	1 (6.7)	1 (6.7)	0
Infections and infestations			
- Total	10 (66.7)	4 (26.7)	6 (40.0)
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Fungaemia	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)
Serratia sepsis	1 (6.7)	0	1 (6.7)

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (6.7)	0	1 (6.7)
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
- Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
- Total	1 (6.7)	0	1 (6.7)
Tumour lysis syndrome	1 (6.7)	0	1 (6.7)
Nervous system disorders			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
- Total	1 (6.7)	1 (6.7)	0
Mental status changes	1 (6.7)	1 (6.7)	0

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
- Total	1 (6.7)	0	0
Acute kidney injury	1 (6.7)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	4 (26.7)	1 (6.7)	3 (20.0)
Respiratory failure	2 (13.3)	0	2 (13.3)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Pulmonary haemorrhage	1 (6.7)	0	1 (6.7)
Pulmonary oedema	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227e

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	2 (100)
Gastrointestinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
- Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227e

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (87.5)	6 (37.5)	8 (50.0)
Blood and lymphatic system disorders			
- Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
- Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
- Total	2 (12.5)	2 (12.5)	0
Colitis	1 (6.3)	1 (6.3)	0

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
- Total	2 (12.5)	2 (12.5)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Infections and infestations			
- Total	11 (68.8)	5 (31.3)	6 (37.5)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
- Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
- Total	1 (6.3)	0	1 (6.3)
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
- Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
- Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (18.8)	1 (6.3)	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Respiratory failure	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
- Total	3 (18.8)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	1 (6.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227e

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry

Enrolled set – non – infused patients

Response status at study entry: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227f

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227f

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
- Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
- Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
- Total	3 (16.7)	2 (11.1)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
- Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
- Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
- Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
- Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
- Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
- Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
- Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227f

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL

Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227g

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: Yes

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227g

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
- Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
- Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
- Total	3 (16.7)	2 (11.1)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
- Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
- Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
- Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
- Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
- Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
- Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
- Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227g

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement

Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	1 (50.0)	1 (50.0)
Cardiac disorders			
- Total	1 (50.0)	1 (50.0)	0
Left ventricular dysfunction	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
- Total	2 (100)	1 (50.0)	1 (50.0)

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (50.0)	1 (50.0)	0
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
- Total	1 (50.0)	1 (50.0)	0
Post procedural haemorrhage	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)
Vascular disorders			
- Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (87.5)	5 (31.3)	9 (56.3)
Blood and lymphatic system disorders			
- Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
- Total	1 (6.3)	1 (6.3)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
- Total	2 (12.5)	2 (12.5)	0
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	0	0

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
- Total	2 (12.5)	2 (12.5)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Infections and infestations			
- Total	11 (68.8)	4 (25.0)	7 (43.8)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (6.3)	1 (6.3)	0
Investigations			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
- Total	1 (6.3)	0	1 (6.3)
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
- Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Renal and urinary disorders			
- Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			

Group term Preferred term	All patients N=16 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	4 (25.0)	1 (6.3)	3 (18.8)
Respiratory failure	2 (12.5)	0	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
- Total	2 (12.5)	0	1 (6.3)
Hypertension	1 (6.3)	0	0
Hypotension	1 (6.3)	0	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
- Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Infections and infestations			
- Total	1 (100)	1 (100)	0
Fungal skin infection	1 (100)	1 (100)	0
Systemic mycosis	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (88.2)	5 (29.4)	10 (58.8)
Blood and lymphatic system disorders			
- Total	3 (17.6)	2 (11.8)	1 (5.9)
Febrile neutropenia	1 (5.9)	0	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Pancytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
- Total	2 (11.8)	2 (11.8)	0
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
- Total	3 (17.6)	2 (11.8)	1 (5.9)
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	0	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
General disorders and administration site conditions			
- Total	3 (17.6)	2 (11.8)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Infections and infestations			
- Total	12 (70.6)	4 (23.5)	8 (47.1)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)
Fungaemia	1 (5.9)	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	1 (5.9)
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Injury, poisoning and procedural complications			
- Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
- Total	2 (11.8)	1 (5.9)	1 (5.9)
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
- Total	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	0	1 (5.9)
Nervous system disorders			
- Total	2 (11.8)	1 (5.9)	1 (5.9)
Encephalopathy	1 (5.9)	1 (5.9)	0
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
- Total	2 (11.8)	2 (11.8)	0
Mental status changes	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
- Total	1 (5.9)	0	0
Acute kidney injury	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
- Total	3 (17.6)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted

by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227j

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

Enrolled set – non – infused patients

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (100)	0	3 (100)
Gastrointestinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0
Infections and infestations			
- Total	3 (100)	0	3 (100)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Fungaemia	1 (33.3)	0	1 (33.3)
Serratia sepsis	1 (33.3)	0	1 (33.3)

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Investigations			
- Total	1 (33.3)	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
- Total	1 (33.3)	1 (33.3)	0
Mental status changes	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
- Total	1 (33.3)	0	0
Acute kidney injury	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (66.7)	0	2 (66.7)
Respiratory failure	2 (66.7)	0	2 (66.7)
Pulmonary haemorrhage	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients
Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	6 (40.0)	7 (46.7)
Blood and lymphatic system disorders			
- Total	4 (26.7)	3 (20.0)	1 (6.7)
Febrile neutropenia	2 (13.3)	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Pancytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
- Total	2 (13.3)	2 (13.3)	0
Cardiac failure	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
- Total	2 (13.3)	2 (13.3)	0
Colitis	1 (6.7)	1 (6.7)	0

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (6.7)	0	0
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
- Total	2 (13.3)	2 (13.3)	0
Pain	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Infections and infestations			
- Total	10 (66.7)	5 (33.3)	5 (33.3)
Bacteraemia	1 (6.7)	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Disseminated trichosporonosis	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
- Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
- Total	1 (6.7)	1 (6.7)	0
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
- Total	1 (6.7)	0	1 (6.7)
Tumour lysis syndrome	1 (6.7)	0	1 (6.7)
Nervous system disorders			
- Total	2 (13.3)	1 (6.7)	1 (6.7)
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
- Total	1 (6.7)	1 (6.7)	0
Mental status changes	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (20.0)	1 (6.7)	2 (13.3)

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
- Total	3 (20.0)	1 (6.7)	1 (6.7)
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)
Hypertension	1 (6.7)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227j

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes

Enrolled set – non – infused patients

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

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (100)	2 (50.0)	2 (50.0)
Blood and lymphatic system disorders			
- Total	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)
Pancytopenia	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
- Total	2 (50.0)	2 (50.0)	0
Pain	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
- Total	3 (75.0)	2 (50.0)	1 (25.0)
Device related infection	1 (25.0)	1 (25.0)	0
Device related sepsis	1 (25.0)	1 (25.0)	0

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (25.0)	0	1 (25.0)
Investigations			
- Total	1 (25.0)	1 (25.0)	0
C-reactive protein increased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
- Total	1 (25.0)	0	1 (25.0)
Tumour lysis syndrome	1 (25.0)	0	1 (25.0)
Nervous system disorders			
- Total	1 (25.0)	1 (25.0)	0
Encephalopathy	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (91.7)	4 (33.3)	7 (58.3)
Blood and lymphatic system disorders			
- Total	2 (16.7)	2 (16.7)	0
Febrile neutropenia	1 (8.3)	1 (8.3)	0
Hyperleukocytosis	1 (8.3)	1 (8.3)	0
Cardiac disorders			
- Total	2 (16.7)	2 (16.7)	0
Cardiac failure	1 (8.3)	1 (8.3)	0
Left ventricular dysfunction	1 (8.3)	1 (8.3)	0
Gastrointestinal disorders			
- Total	3 (25.0)	2 (16.7)	1 (8.3)
Abdominal compartment syndrome	1 (8.3)	0	1 (8.3)
Colitis	1 (8.3)	1 (8.3)	0

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (8.3)	0	0
Gastrointestinal haemorrhage	1 (8.3)	1 (8.3)	0
Haemoperitoneum	1 (8.3)	0	1 (8.3)
General disorders and administration site conditions			
- Total	1 (8.3)	0	0
Pyrexia	1 (8.3)	0	0
Infections and infestations			
- Total	10 (83.3)	3 (25.0)	7 (58.3)
Aspergillus infection	1 (8.3)	0	1 (8.3)
Bacteraemia	1 (8.3)	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	1 (8.3)
Disseminated trichosporonosis	1 (8.3)	0	1 (8.3)
Fungaemia	1 (8.3)	0	1 (8.3)
Fungal sepsis	1 (8.3)	0	1 (8.3)
Fungal skin infection	1 (8.3)	1 (8.3)	0
Klebsiella bacteraemia	1 (8.3)	1 (8.3)	0
Pneumonia fungal	1 (8.3)	0	1 (8.3)
Sepsis	1 (8.3)	0	1 (8.3)
Serratia sepsis	1 (8.3)	0	1 (8.3)

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (8.3)	0	1 (8.3)
Systemic mycosis	1 (8.3)	1 (8.3)	0
Injury, poisoning and procedural complications			
- Total	1 (8.3)	1 (8.3)	0
Post procedural haemorrhage	1 (8.3)	1 (8.3)	0
Investigations			
- Total	1 (8.3)	0	1 (8.3)
Neutrophil count decreased	1 (8.3)	0	1 (8.3)
Psychiatric disorders			
- Total	2 (16.7)	2 (16.7)	0
Mental status changes	2 (16.7)	2 (16.7)	0
Renal and urinary disorders			
- Total	1 (8.3)	0	0
Acute kidney injury	1 (8.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (41.7)	1 (8.3)	4 (33.3)
Respiratory failure	3 (25.0)	0	3 (25.0)
Acute respiratory distress syndrome	1 (8.3)	0	1 (8.3)
Pulmonary haemorrhage	1 (8.3)	0	1 (8.3)

Group term Preferred term	All patients N=12 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (8.3)	0	1 (8.3)
Tachypnoea	1 (8.3)	1 (8.3)	0
Vascular disorders			
- Total	3 (25.0)	1 (8.3)	1 (8.3)
Hypotension	2 (16.7)	1 (8.3)	1 (8.3)
Hypertension	1 (8.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	1 (50.0)
Nervous system disorders			
- Total	1 (50.0)	0	1 (50.0)
Haemorrhage intracranial	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (90.0)	4 (40.0)	5 (50.0)
Blood and lymphatic system disorders			
- Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	1 (10.0)	0	1 (10.0)
Pancytopenia	1 (10.0)	1 (10.0)	0
Cardiac disorders			
- Total	2 (20.0)	2 (20.0)	0
Cardiac failure	1 (10.0)	1 (10.0)	0
Left ventricular dysfunction	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
- Total	1 (10.0)	1 (10.0)	0
Colitis	1 (10.0)	1 (10.0)	0
Diarrhoea	1 (10.0)	0	0

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
- Total	2 (20.0)	2 (20.0)	0
Pain	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Infections and infestations			
- Total	7 (70.0)	4 (40.0)	3 (30.0)
Bacteraemia	1 (10.0)	1 (10.0)	0
Bacterial sepsis	1 (10.0)	0	1 (10.0)
Device related infection	1 (10.0)	1 (10.0)	0
Device related sepsis	1 (10.0)	1 (10.0)	0
Fungaemia	1 (10.0)	0	1 (10.0)
Fungal sepsis	1 (10.0)	0	1 (10.0)
Klebsiella bacteraemia	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			
- Total	1 (10.0)	1 (10.0)	0
Post procedural haemorrhage	1 (10.0)	1 (10.0)	0
Investigations			
- Total	2 (20.0)	1 (10.0)	1 (10.0)

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (10.0)	1 (10.0)	0
Neutrophil count decreased	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
- Total	1 (10.0)	0	1 (10.0)
Tumour lysis syndrome	1 (10.0)	0	1 (10.0)
Nervous system disorders			
- Total	2 (20.0)	1 (10.0)	1 (10.0)
Encephalopathy	1 (10.0)	1 (10.0)	0
Haemorrhage intracranial	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
- Total	1 (10.0)	0	0
Acute kidney injury	1 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (20.0)	0	2 (20.0)
Acute respiratory distress syndrome	1 (10.0)	0	1 (10.0)
Pulmonary haemorrhage	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
- Total	2 (20.0)	1 (10.0)	0

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (10.0)	0	0
Hypotension	1 (10.0)	1 (10.0)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
- Total	2 (25.0)	2 (25.0)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
Haemoperitoneum	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
- Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
- Total	6 (75.0)	1 (12.5)	5 (62.5)
Aspergillus infection	1 (12.5)	0	1 (12.5)
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
- Total	2 (25.0)	2 (25.0)	0
Mental status changes	2 (25.0)	2 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (37.5)	1 (12.5)	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
- Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Infections and infestations			
- Total	2 (50.0)	1 (25.0)	1 (25.0)
Aspergillus infection	1 (25.0)	0	1 (25.0)
Fungal skin infection	1 (25.0)	1 (25.0)	0
Systemic mycosis	1 (25.0)	1 (25.0)	0
Nervous system disorders			
- Total	1 (25.0)	0	1 (25.0)
Haemorrhage intracranial	1 (25.0)	0	1 (25.0)
Psychiatric disorders			

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
- Total	1 (25.0)	1 (25.0)	0
Mental status changes	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (92.9)	5 (35.7)	8 (57.1)
Blood and lymphatic system disorders			
- Total	3 (21.4)	2 (14.3)	1 (7.1)
Febrile neutropenia	1 (7.1)	0	1 (7.1)
Hyperleukocytosis	1 (7.1)	1 (7.1)	0
Pancytopenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
- Total	2 (14.3)	2 (14.3)	0
Cardiac failure	1 (7.1)	1 (7.1)	0
Left ventricular dysfunction	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
- Total	3 (21.4)	2 (14.3)	1 (7.1)
Abdominal compartment syndrome	1 (7.1)	0	1 (7.1)

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	0	0
Gastrointestinal haemorrhage	1 (7.1)	1 (7.1)	0
Haemoperitoneum	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
- Total	3 (21.4)	2 (14.3)	0
Pyrexia	2 (14.3)	1 (7.1)	0
Pain	1 (7.1)	1 (7.1)	0
Infections and infestations			
- Total	11 (78.6)	4 (28.6)	7 (50.0)
Bacteraemia	1 (7.1)	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	1 (7.1)
Device related infection	1 (7.1)	1 (7.1)	0
Device related sepsis	1 (7.1)	1 (7.1)	0
Disseminated trichosporonosis	1 (7.1)	0	1 (7.1)
Fungaemia	1 (7.1)	0	1 (7.1)
Fungal sepsis	1 (7.1)	0	1 (7.1)
Klebsiella bacteraemia	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	1 (7.1)

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (7.1)	0	1 (7.1)
Sepsis	1 (7.1)	0	1 (7.1)
Serratia sepsis	1 (7.1)	0	1 (7.1)
Staphylococcal infection	1 (7.1)	0	1 (7.1)
Injury, poisoning and procedural complications			
- Total	1 (7.1)	1 (7.1)	0
Post procedural haemorrhage	1 (7.1)	1 (7.1)	0
Investigations			
- Total	2 (14.3)	1 (7.1)	1 (7.1)
C-reactive protein increased	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
- Total	1 (7.1)	0	1 (7.1)
Tumour lysis syndrome	1 (7.1)	0	1 (7.1)
Nervous system disorders			
- Total	1 (7.1)	1 (7.1)	0
Encephalopathy	1 (7.1)	1 (7.1)	0
Psychiatric disorders			
- Total	1 (7.1)	1 (7.1)	0

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
- Total	1 (7.1)	0	0
Acute kidney injury	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (35.7)	1 (7.1)	4 (28.6)
Respiratory failure	3 (21.4)	0	3 (21.4)
Acute respiratory distress syndrome	1 (7.1)	0	1 (7.1)
Pulmonary haemorrhage	1 (7.1)	0	1 (7.1)
Pulmonary oedema	1 (7.1)	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0
Vascular disorders			
- Total	3 (21.4)	1 (7.1)	1 (7.1)
Hypotension	2 (14.3)	1 (7.1)	1 (7.1)
Hypertension	1 (7.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227m

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Enrolled set – non – infused patients

Eligibility for SCT: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227n

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227n

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (100)	6 (37.5)	10 (62.5)
Blood and lymphatic system disorders			
- Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
- Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
- Total	3 (18.8)	2 (12.5)	1 (6.3)
Abdominal compartment syndrome	1 (6.3)	0	1 (6.3)

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
Haemoperitoneum	1 (6.3)	0	1 (6.3)
General disorders and administration site conditions			
- Total	3 (18.8)	2 (12.5)	0
Pyrexia	2 (12.5)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0
Infections and infestations			
- Total	13 (81.3)	5 (31.3)	8 (50.0)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Serratia sepsis	1 (6.3)	0	1 (6.3)
Staphylococcal infection	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
- Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
- Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
- Total	1 (6.3)	0	1 (6.3)
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
- Total	2 (12.5)	1 (6.3)	1 (6.3)

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
- Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Renal and urinary disorders			
- Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (31.3)	1 (6.3)	4 (25.0)
Respiratory failure	3 (18.8)	0	3 (18.8)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Pulmonary oedema	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
- Total	3 (18.8)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	1 (6.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227n

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden

Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227o

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Enrolled set – non – infused patients

Baseline extramedullary disease presence: Yes

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227o

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
- Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
- Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
- Total	3 (16.7)	2 (11.1)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
- Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
- Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
- Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
- Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
- Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
- Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
- Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227o

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence

Enrolled set – non – infused patients

Baseline extramedullary disease presence: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)
Nervous system disorders			
- Total	1 (100)	0	1 (100)
Haemorrhage intracranial	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (88.2)	6 (35.3)	9 (52.9)
Blood and lymphatic system disorders			
- Total	4 (23.5)	3 (17.6)	1 (5.9)
Febrile neutropenia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Pancytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
- Total	2 (11.8)	2 (11.8)	0
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
- Total	3 (17.6)	2 (11.8)	1 (5.9)
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	0	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
General disorders and administration site conditions			
- Total	3 (17.6)	2 (11.8)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Infections and infestations			
- Total	13 (76.5)	5 (29.4)	8 (47.1)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)
Fungaemia	1 (5.9)	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	1 (5.9)
Fungal skin infection	1 (5.9)	1 (5.9)	0

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Systemic mycosis	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
- Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
- Total	2 (11.8)	1 (5.9)	1 (5.9)
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
- Total	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	0	1 (5.9)
Nervous system disorders			
- Total	1 (5.9)	1 (5.9)	0

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (5.9)	1 (5.9)	0
Psychiatric disorders			
- Total	2 (11.8)	2 (11.8)	0
Mental status changes	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
- Total	1 (5.9)	0	0
Acute kidney injury	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
- Total	3 (17.6)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: > Median

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: <=Median

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227q

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion

Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
- Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
- Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
- Total	3 (16.7)	2 (11.1)	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
- Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
- Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
- Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
- Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
- Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
- Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
- Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	2 (100)
Gastrointestinal disorders			
- Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
- Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	5 (62.5)	2 (25.0)
Blood and lymphatic system disorders			
- Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Pancytopenia	1 (12.5)	1 (12.5)	0
Cardiac disorders			
- Total	1 (12.5)	1 (12.5)	0
Left ventricular dysfunction	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
- Total	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
- Total	6 (75.0)	4 (50.0)	2 (25.0)
Device related infection	1 (12.5)	1 (12.5)	0
Device related sepsis	1 (12.5)	1 (12.5)	0
Fungal skin infection	1 (12.5)	1 (12.5)	0
Klebsiella bacteraemia	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
- Total	1 (12.5)	1 (12.5)	0
Post procedural haemorrhage	1 (12.5)	1 (12.5)	0
Investigations			
- Total	1 (12.5)	1 (12.5)	0
C-reactive protein increased	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
- Total	1 (12.5)	1 (12.5)	0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (12.5)	1 (12.5)	0
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (100)	0	1 (100)
Infections and infestations			
- Total	1 (100)	0	1 (100)
Aspergillus infection	1 (100)	0	1 (100)
Psychiatric disorders			
- Total	1 (100)	1 (100)	0
Mental status changes	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (85.7)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders			
- Total	1 (14.3)	0	1 (14.3)
Febrile neutropenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
- Total	1 (14.3)	1 (14.3)	0
Cardiac failure	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
- Total	1 (14.3)	1 (14.3)	0
Colitis	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0
General disorders and administration site conditions			

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
- Total	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	1 (14.3)	0
Infections and infestations			
- Total	4 (57.1)	1 (14.3)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0
Bacterial sepsis	1 (14.3)	0	1 (14.3)
Fungaemia	1 (14.3)	0	1 (14.3)
Fungal sepsis	1 (14.3)	0	1 (14.3)
Pneumonia	1 (14.3)	0	1 (14.3)
Investigations			
- Total	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
- Total	1 (14.3)	0	1 (14.3)
Tumour lysis syndrome	1 (14.3)	0	1 (14.3)
Nervous system disorders			
- Total	2 (28.6)	1 (14.3)	1 (14.3)
Encephalopathy	1 (14.3)	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
- Total	1 (14.3)	0	0
Acute kidney injury	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (28.6)	0	2 (28.6)
Acute respiratory distress syndrome	1 (14.3)	0	1 (14.3)
Pulmonary haemorrhage	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
- Total	1 (14.3)	0	0
Hypertension	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 227r

Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Enrolled set – non – infused patients

Number of previous relapses: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (65.9)	12 (29.3)	12 (29.3)
Blood and lymphatic system disorders			
- Total	12 (29.3)	12 (29.3)	0
Febrile neutropenia	12 (29.3)	12 (29.3)	0
General disorders and administration site conditions			
- Total	8 (19.5)	1 (2.4)	0
Pyrexia	8 (19.5)	1 (2.4)	0
Immune system disorders			
- Total	18 (43.9)	3 (7.3)	8 (19.5)
Cytokine release syndrome	18 (43.9)	3 (7.3)	8 (19.5)
Renal and urinary disorders			
- Total	3 (7.3)	0	2 (4.9)
Acute kidney injury	3 (7.3)	0	2 (4.9)

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (12.2)	1 (2.4)	4 (9.8)
Respiratory failure	3 (7.3)	0	3 (7.3)
Hypoxia	2 (4.9)	1 (2.4)	1 (2.4)
Vascular disorders			
- Total	4 (9.8)	1 (2.4)	3 (7.3)
Hypotension	4 (9.8)	1 (2.4)	3 (7.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (72.5)	9 (22.5)	18 (45.0)
Blood and lymphatic system disorders			
- Total	7 (17.5)	6 (15.0)	1 (2.5)
Febrile neutropenia	7 (17.5)	6 (15.0)	1 (2.5)
General disorders and administration site conditions			
- Total	3 (7.5)	1 (2.5)	0
Pyrexia	3 (7.5)	1 (2.5)	0
Immune system disorders			
- Total	23 (57.5)	10 (25.0)	9 (22.5)
Cytokine release syndrome	23 (57.5)	10 (25.0)	9 (22.5)
Renal and urinary disorders			
- Total	3 (7.5)	2 (5.0)	1 (2.5)
Acute kidney injury	3 (7.5)	2 (5.0)	1 (2.5)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	7 (17.5)	2 (5.0)	5 (12.5)
Respiratory failure	5 (12.5)	0	5 (12.5)
Hypoxia	3 (7.5)	2 (5.0)	1 (2.5)
Vascular disorders			
- Total	6 (15.0)	2 (5.0)	4 (10.0)
Hypotension	6 (15.0)	2 (5.0)	4 (10.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228a
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (64.7)	4 (23.5)	5 (29.4)
Blood and lymphatic system disorders			
- Total	4 (23.5)	3 (17.6)	1 (5.9)
Febrile neutropenia	4 (23.5)	3 (17.6)	1 (5.9)
General disorders and administration site conditions			
- Total	2 (11.8)	0	0
Pyrexia	2 (11.8)	0	0
Immune system disorders			
- Total	9 (52.9)	3 (17.6)	4 (23.5)
Cytokine release syndrome	9 (52.9)	3 (17.6)	4 (23.5)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.9)	0	1 (5.9)

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
- Total	1 (5.9)	0	1 (5.9)
Hypotension	1 (5.9)	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	36 (65.5)	13 (23.6)	19 (34.5)
Blood and lymphatic system disorders			
- Total	11 (20.0)	11 (20.0)	0
Febrile neutropenia	11 (20.0)	11 (20.0)	0
General disorders and administration site conditions			
- Total	11 (20.0)	2 (3.6)	0
Pyrexia	11 (20.0)	2 (3.6)	0
Immune system disorders			
- Total	23 (41.8)	7 (12.7)	11 (20.0)
Cytokine release syndrome	23 (41.8)	7 (12.7)	11 (20.0)
Renal and urinary disorders			
- Total	2 (3.6)	0	1 (1.8)
Acute kidney injury	2 (3.6)	0	1 (1.8)

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (16.4)	1 (1.8)	8 (14.5)
Respiratory failure	7 (12.7)	0	7 (12.7)
Hypoxia	2 (3.6)	1 (1.8)	1 (1.8)
Vascular disorders			
- Total	5 (9.1)	2 (3.6)	3 (5.5)
Hypotension	5 (9.1)	2 (3.6)	3 (5.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228b
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	31 (72.1)	12 (27.9)	16 (37.2)
Blood and lymphatic system disorders			
- Total	12 (27.9)	10 (23.3)	2 (4.7)
Febrile neutropenia	12 (27.9)	10 (23.3)	2 (4.7)
General disorders and administration site conditions			
- Total	2 (4.7)	0	0
Pyrexia	2 (4.7)	0	0
Immune system disorders			
- Total	27 (62.8)	9 (20.9)	10 (23.3)
Cytokine release syndrome	27 (62.8)	9 (20.9)	10 (23.3)
Renal and urinary disorders			
- Total	4 (9.3)	2 (4.7)	2 (4.7)
Acute kidney injury	4 (9.3)	2 (4.7)	2 (4.7)

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (9.3)	2 (4.7)	2 (4.7)
Hypoxia	3 (7.0)	2 (4.7)	1 (2.3)
Respiratory failure	2 (4.7)	0	2 (4.7)
Vascular disorders			
- Total	6 (14.0)	1 (2.3)	5 (11.6)
Hypotension	6 (14.0)	1 (2.3)	5 (11.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	49 (70.0)	20 (28.6)	22 (31.4)
Blood and lymphatic system disorders			
- Total	17 (24.3)	16 (22.9)	1 (1.4)
Febrile neutropenia	17 (24.3)	16 (22.9)	1 (1.4)
General disorders and administration site conditions			
- Total	10 (14.3)	1 (1.4)	0
Pyrexia	10 (14.3)	1 (1.4)	0
Immune system disorders			
- Total	37 (52.9)	14 (20.0)	12 (17.1)
Cytokine release syndrome	37 (52.9)	14 (20.0)	12 (17.1)
Renal and urinary disorders			
- Total	5 (7.1)	2 (2.9)	3 (4.3)
Acute kidney injury	5 (7.1)	2 (2.9)	3 (4.3)

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (14.3)	2 (2.9)	8 (11.4)
Respiratory failure	7 (10.0)	0	7 (10.0)
Hypoxia	3 (4.3)	2 (2.9)	1 (1.4)
Vascular disorders			
- Total	8 (11.4)	2 (2.9)	6 (8.6)
Hypotension	8 (11.4)	2 (2.9)	6 (8.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (46.7)	3 (20.0)	4 (26.7)
Blood and lymphatic system disorders			
- Total	2 (13.3)	2 (13.3)	0
Febrile neutropenia	2 (13.3)	2 (13.3)	0
General disorders and administration site conditions			
- Total	1 (6.7)	0	0
Pyrexia	1 (6.7)	0	0
Immune system disorders			
- Total	4 (26.7)	1 (6.7)	3 (20.0)
Cytokine release syndrome	4 (26.7)	1 (6.7)	3 (20.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (6.7)	0	1 (6.7)
Hypoxia	1 (6.7)	0	1 (6.7)

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
- Total	1 (6.7)	1 (6.7)	0
Hypotension	1 (6.7)	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228c
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (84.6)	2 (15.4)	9 (69.2)
Blood and lymphatic system disorders			
- Total	4 (30.8)	3 (23.1)	1 (7.7)
Febrile neutropenia	4 (30.8)	3 (23.1)	1 (7.7)
General disorders and administration site conditions			
- Total	2 (15.4)	1 (7.7)	0
Pyrexia	2 (15.4)	1 (7.7)	0
Immune system disorders			
- Total	9 (69.2)	1 (7.7)	6 (46.2)
Cytokine release syndrome	9 (69.2)	1 (7.7)	6 (46.2)
Renal and urinary disorders			
- Total	1 (7.7)	0	0

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypoxia	1 (7.7)	1 (7.7)	0
Respiratory failure	1 (7.7)	0	1 (7.7)
Vascular disorders			
- Total	2 (15.4)	0	2 (15.4)
Hypotension	2 (15.4)	0	2 (15.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (83.3)	3 (16.7)	11 (61.1)
Blood and lymphatic system disorders			
- Total	5 (27.8)	4 (22.2)	1 (5.6)
Febrile neutropenia	5 (27.8)	4 (22.2)	1 (5.6)
General disorders and administration site conditions			
- Total	3 (16.7)	1 (5.6)	0
Pyrexia	3 (16.7)	1 (5.6)	0
Immune system disorders			
- Total	13 (72.2)	1 (5.6)	8 (44.4)
Cytokine release syndrome	13 (72.2)	1 (5.6)	8 (44.4)
Renal and urinary disorders			
- Total	3 (16.7)	1 (5.6)	2 (11.1)
Acute kidney injury	3 (16.7)	1 (5.6)	2 (11.1)

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	3 (16.7)	0	3 (16.7)
Respiratory failure	2 (11.1)	0	2 (11.1)
Hypoxia	1 (5.6)	0	1 (5.6)
Vascular disorders			
- Total	4 (22.2)	1 (5.6)	3 (16.7)
Hypotension	4 (22.2)	1 (5.6)	3 (16.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228d
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (65.0)	22 (27.5)	24 (30.0)
Blood and lymphatic system disorders			
- Total	18 (22.5)	17 (21.3)	1 (1.3)
Febrile neutropenia	18 (22.5)	17 (21.3)	1 (1.3)
General disorders and administration site conditions			
- Total	10 (12.5)	1 (1.3)	0
Pyrexia	10 (12.5)	1 (1.3)	0
Immune system disorders			
- Total	37 (46.3)	15 (18.8)	13 (16.3)
Cytokine release syndrome	37 (46.3)	15 (18.8)	13 (16.3)
Renal and urinary disorders			
- Total	3 (3.8)	1 (1.3)	1 (1.3)
Acute kidney injury	3 (3.8)	1 (1.3)	1 (1.3)

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	10 (12.5)	3 (3.8)	7 (8.8)
Respiratory failure	7 (8.8)	0	7 (8.8)
Hypoxia	4 (5.0)	3 (3.8)	1 (1.3)
Vascular disorders			
- Total	7 (8.8)	2 (2.5)	5 (6.3)
Hypotension	7 (8.8)	2 (2.5)	5 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	1 (12.5)	5 (62.5)
Blood and lymphatic system disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	1 (12.5)	1 (12.5)
General disorders and administration site conditions			
- Total	2 (25.0)	0	0
Pyrexia	2 (25.0)	0	0
Immune system disorders			
- Total	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)
Renal and urinary disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	0	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Vascular disorders			
- Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	60 (66.7)	24 (26.7)	30 (33.3)
Blood and lymphatic system disorders			
- Total	21 (23.3)	20 (22.2)	1 (1.1)
Febrile neutropenia	21 (23.3)	20 (22.2)	1 (1.1)
General disorders and administration site conditions			
- Total	11 (12.2)	2 (2.2)	0
Pyrexia	11 (12.2)	2 (2.2)	0
Immune system disorders			
- Total	46 (51.1)	16 (17.8)	19 (21.1)
Cytokine release syndrome	46 (51.1)	16 (17.8)	19 (21.1)
Renal and urinary disorders			
- Total	4 (4.4)	1 (1.1)	2 (2.2)
Acute kidney injury	4 (4.4)	1 (1.1)	2 (2.2)

Group term Preferred term	All patients N=90 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	11 (12.2)	3 (3.3)	8 (8.9)
Respiratory failure	7 (7.8)	0	7 (7.8)
Hypoxia	5 (5.6)	3 (3.3)	2 (2.2)
Vascular disorders			
- Total	10 (11.1)	3 (3.3)	7 (7.8)
Hypotension	10 (11.1)	3 (3.3)	7 (7.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228e
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Response status at study entry: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	1 (50.0)	1 (50.0)
General disorders and administration site conditions			
- Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Immune system disorders			
- Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	65 (67.7)	24 (25.0)	34 (35.4)
Blood and lymphatic system disorders			
- Total	23 (24.0)	21 (21.9)	2 (2.1)
Febrile neutropenia	23 (24.0)	21 (21.9)	2 (2.1)
General disorders and administration site conditions			
- Total	12 (12.5)	1 (1.0)	0
Pyrexia	12 (12.5)	1 (1.0)	0
Immune system disorders			
- Total	48 (50.0)	15 (15.6)	20 (20.8)
Cytokine release syndrome	48 (50.0)	15 (15.6)	20 (20.8)
Renal and urinary disorders			
- Total	6 (6.3)	2 (2.1)	3 (3.1)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.1)

Group term Preferred term	All patients N=96 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	13 (13.5)	3 (3.1)	10 (10.4)
Respiratory failure	9 (9.4)	0	9 (9.4)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Vascular disorders			
- Total	11 (11.5)	3 (3.1)	8 (8.3)
Hypotension	11 (11.5)	3 (3.1)	8 (8.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228f
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Philadelphia chromosome/BCR-ABL: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	67 (69.1)	25 (25.8)	35 (36.1)
Blood and lymphatic system disorders			
- Total	23 (23.7)	21 (21.6)	2 (2.1)
Febrile neutropenia	23 (23.7)	21 (21.6)	2 (2.1)
General disorders and administration site conditions			
- Total	13 (13.4)	2 (2.1)	0
Pyrexia	13 (13.4)	2 (2.1)	0
Immune system disorders			
- Total	50 (51.5)	16 (16.5)	21 (21.6)
Cytokine release syndrome	50 (51.5)	16 (16.5)	21 (21.6)
Renal and urinary disorders			
- Total	6 (6.2)	2 (2.1)	3 (3.1)
Acute kidney injury	6 (6.2)	2 (2.1)	3 (3.1)

Group term Preferred term	All patients N=97 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	13 (13.4)	3 (3.1)	10 (10.3)
Respiratory failure	9 (9.3)	0	9 (9.3)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Vascular disorders			
- Total	11 (11.3)	3 (3.1)	8 (8.2)
Hypotension	11 (11.3)	3 (3.1)	8 (8.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228g
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Mixed-lineage leukemia rearrangement: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (66.7)	1 (33.3)	1 (33.3)
General disorders and administration site conditions			
- Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
- Total	1 (33.3)	1 (33.3)	0
Hypotension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	65 (68.4)	24 (25.3)	34 (35.8)
Blood and lymphatic system disorders			
- Total	23 (24.2)	21 (22.1)	2 (2.1)
Febrile neutropenia	23 (24.2)	21 (22.1)	2 (2.1)
General disorders and administration site conditions			
- Total	12 (12.6)	2 (2.1)	0
Pyrexia	12 (12.6)	2 (2.1)	0
Immune system disorders			
- Total	50 (52.6)	16 (16.8)	21 (22.1)
Cytokine release syndrome	50 (52.6)	16 (16.8)	21 (22.1)
Renal and urinary disorders			
- Total	6 (6.3)	2 (2.1)	3 (3.2)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.2)

Group term Preferred term	All patients N=95 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	12 (12.6)	3 (3.2)	9 (9.5)
Respiratory failure	8 (8.4)	0	8 (8.4)
Hypoxia	5 (5.3)	3 (3.2)	2 (2.1)
Vascular disorders			
- Total	10 (10.5)	2 (2.1)	8 (8.4)
Hypotension	10 (10.5)	2 (2.1)	8 (8.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228h
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy

Hypodiploidy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	1 (50.0)	0
Blood and lymphatic system disorders			
- Total	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	66 (68.8)	24 (25.0)	35 (36.5)
Blood and lymphatic system disorders			
- Total	22 (22.9)	20 (20.8)	2 (2.1)
Febrile neutropenia	22 (22.9)	20 (20.8)	2 (2.1)
General disorders and administration site conditions			
- Total	13 (13.5)	2 (2.1)	0
Pyrexia	13 (13.5)	2 (2.1)	0
Immune system disorders			
- Total	50 (52.1)	16 (16.7)	21 (21.9)
Cytokine release syndrome	50 (52.1)	16 (16.7)	21 (21.9)
Renal and urinary disorders			
- Total	6 (6.3)	2 (2.1)	3 (3.1)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.1)

Group term Preferred term	All patients N=96 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	13 (13.5)	3 (3.1)	10 (10.4)
Respiratory failure	9 (9.4)	0	9 (9.4)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Vascular disorders			
- Total	11 (11.5)	3 (3.1)	8 (8.3)
Hypotension	11 (11.5)	3 (3.1)	8 (8.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228i
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like

BCR-ABL1-like: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (73.3)	7 (23.3)	14 (46.7)
Blood and lymphatic system disorders			
- Total	6 (20.0)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	6 (20.0)	0
General disorders and administration site conditions			
- Total	1 (3.3)	0	0
Pyrexia	1 (3.3)	0	0
Immune system disorders			
- Total	19 (63.3)	7 (23.3)	9 (30.0)
Cytokine release syndrome	19 (63.3)	7 (23.3)	9 (30.0)
Renal and urinary disorders			
- Total	4 (13.3)	1 (3.3)	2 (6.7)
Acute kidney injury	4 (13.3)	1 (3.3)	2 (6.7)

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (16.7)	2 (6.7)	3 (10.0)
Respiratory failure	3 (10.0)	0	3 (10.0)
Hypoxia	2 (6.7)	2 (6.7)	0
Vascular disorders			
- Total	5 (16.7)	1 (3.3)	4 (13.3)
Hypotension	5 (16.7)	1 (3.3)	4 (13.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	45 (66.2)	18 (26.5)	21 (30.9)
Blood and lymphatic system disorders			
- Total	17 (25.0)	15 (22.1)	2 (2.9)
Febrile neutropenia	17 (25.0)	15 (22.1)	2 (2.9)
General disorders and administration site conditions			
- Total	12 (17.6)	2 (2.9)	0
Pyrexia	12 (17.6)	2 (2.9)	0
Immune system disorders			
- Total	31 (45.6)	9 (13.2)	12 (17.6)
Cytokine release syndrome	31 (45.6)	9 (13.2)	12 (17.6)
Renal and urinary disorders			
- Total	2 (2.9)	1 (1.5)	1 (1.5)
Acute kidney injury	2 (2.9)	1 (1.5)	1 (1.5)

Group term Preferred term	All patients N=68 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (11.8)	1 (1.5)	7 (10.3)
Respiratory failure	6 (8.8)	0	6 (8.8)
Hypoxia	3 (4.4)	1 (1.5)	2 (2.9)
Vascular disorders			
- Total	6 (8.8)	2 (2.9)	4 (5.9)
Hypotension	6 (8.8)	2 (2.9)	4 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228j
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Complex karyotypes II (>=5 unrelated abnormalities) : Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (59.4)	7 (21.9)	10 (31.3)
Blood and lymphatic system disorders			
- Total	5 (15.6)	4 (12.5)	1 (3.1)
Febrile neutropenia	5 (15.6)	4 (12.5)	1 (3.1)
General disorders and administration site conditions			
- Total	3 (9.4)	1 (3.1)	0
Pyrexia	3 (9.4)	1 (3.1)	0
Immune system disorders			
- Total	15 (46.9)	5 (15.6)	8 (25.0)
Cytokine release syndrome	15 (46.9)	5 (15.6)	8 (25.0)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.1)	0	1 (3.1)
Respiratory failure	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (75.4)	17 (29.8)	22 (38.6)
Blood and lymphatic system disorders			
- Total	17 (29.8)	16 (28.1)	1 (1.8)
Febrile neutropenia	17 (29.8)	16 (28.1)	1 (1.8)
General disorders and administration site conditions			
- Total	9 (15.8)	1 (1.8)	0
Pyrexia	9 (15.8)	1 (1.8)	0
Immune system disorders			
- Total	31 (54.4)	10 (17.5)	10 (17.5)
Cytokine release syndrome	31 (54.4)	10 (17.5)	10 (17.5)
Renal and urinary disorders			
- Total	6 (10.5)	2 (3.5)	3 (5.3)
Acute kidney injury	6 (10.5)	2 (3.5)	3 (5.3)

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	12 (21.1)	3 (5.3)	9 (15.8)
Respiratory failure	8 (14.0)	0	8 (14.0)
Hypoxia	5 (8.8)	3 (5.3)	2 (3.5)
Vascular disorders			
- Total	11 (19.3)	3 (5.3)	8 (14.0)
Hypotension	11 (19.3)	3 (5.3)	8 (14.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228k
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (55.6)	1 (11.1)	3 (33.3)
Blood and lymphatic system disorders			
- Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
- Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0
Immune system disorders			
- Total	4 (44.4)	1 (11.1)	3 (33.3)
Cytokine release syndrome	4 (44.4)	1 (11.1)	3 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted

by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	39 (67.2)	17 (29.3)	18 (31.0)
Blood and lymphatic system disorders			
- Total	12 (20.7)	11 (19.0)	1 (1.7)
Febrile neutropenia	12 (20.7)	11 (19.0)	1 (1.7)
General disorders and administration site conditions			
- Total	8 (13.8)	2 (3.4)	0
Pyrexia	8 (13.8)	2 (3.4)	0
Immune system disorders			
- Total	29 (50.0)	11 (19.0)	11 (19.0)
Cytokine release syndrome	29 (50.0)	11 (19.0)	11 (19.0)
Renal and urinary disorders			
- Total	2 (3.4)	0	1 (1.7)
Acute kidney injury	2 (3.4)	0	1 (1.7)

Group term Preferred term	All patients N=58 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (6.9)	1 (1.7)	3 (5.2)
Respiratory failure	3 (5.2)	0	3 (5.2)
Hypoxia	1 (1.7)	1 (1.7)	0
Vascular disorders			
- Total	5 (8.6)	2 (3.4)	3 (5.2)
Hypotension	5 (8.6)	2 (3.4)	3 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (70.0)	8 (20.0)	17 (42.5)
Blood and lymphatic system disorders			
- Total	11 (27.5)	10 (25.0)	1 (2.5)
Febrile neutropenia	11 (27.5)	10 (25.0)	1 (2.5)
General disorders and administration site conditions			
- Total	5 (12.5)	0	0
Pyrexia	5 (12.5)	0	0
Immune system disorders			
- Total	21 (52.5)	5 (12.5)	10 (25.0)
Cytokine release syndrome	21 (52.5)	5 (12.5)	10 (25.0)
Renal and urinary disorders			
- Total	4 (10.0)	2 (5.0)	2 (5.0)
Acute kidney injury	4 (10.0)	2 (5.0)	2 (5.0)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	9 (22.5)	2 (5.0)	7 (17.5)
Respiratory failure	6 (15.0)	0	6 (15.0)
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Vascular disorders			
- Total	6 (15.0)	1 (2.5)	5 (12.5)
Hypotension	6 (15.0)	1 (2.5)	5 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228l
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy

Prior SCT therapy: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (64.7)	8 (47.1)	2 (11.8)
Blood and lymphatic system disorders			
- Total	8 (47.1)	8 (47.1)	0
Febrile neutropenia	8 (47.1)	8 (47.1)	0
General disorders and administration site conditions			
- Total	1 (5.9)	0	0
Pyrexia	1 (5.9)	0	0
Immune system disorders			
- Total	10 (58.8)	4 (23.5)	1 (5.9)
Cytokine release syndrome	10 (58.8)	4 (23.5)	1 (5.9)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (5.9)	1 (5.9)	0
Hypoxia	1 (5.9)	1 (5.9)	0

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
- Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	56 (69.1)	17 (21.0)	33 (40.7)
Blood and lymphatic system disorders			
- Total	15 (18.5)	13 (16.0)	2 (2.5)
Febrile neutropenia	15 (18.5)	13 (16.0)	2 (2.5)
General disorders and administration site conditions			
- Total	12 (14.8)	2 (2.5)	0
Pyrexia	12 (14.8)	2 (2.5)	0
Immune system disorders			
- Total	40 (49.4)	12 (14.8)	20 (24.7)
Cytokine release syndrome	40 (49.4)	12 (14.8)	20 (24.7)
Renal and urinary disorders			
- Total	6 (7.4)	2 (2.5)	3 (3.7)
Acute kidney injury	6 (7.4)	2 (2.5)	3 (3.7)

Group term Preferred term	All patients N=81 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	12 (14.8)	2 (2.5)	10 (12.3)
Respiratory failure	9 (11.1)	0	9 (11.1)
Hypoxia	4 (4.9)	2 (2.5)	2 (2.5)
Vascular disorders			
- Total	9 (11.1)	2 (2.5)	7 (8.6)
Hypotension	9 (11.1)	2 (2.5)	7 (8.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228m
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT

Eligibility for SCT: Missing

	All patients N=0		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (57.1)	8 (28.6)	4 (14.3)
Blood and lymphatic system disorders			
- Total	5 (17.9)	5 (17.9)	0
Febrile neutropenia	5 (17.9)	5 (17.9)	0
General disorders and administration site conditions			
- Total	6 (21.4)	1 (3.6)	0
Pyrexia	6 (21.4)	1 (3.6)	0
Immune system disorders			
- Total	12 (42.9)	3 (10.7)	4 (14.3)
Cytokine release syndrome	12 (42.9)	3 (10.7)	4 (14.3)
Renal and urinary disorders			
- Total	1 (3.6)	0	1 (3.6)
Acute kidney injury	1 (3.6)	0	1 (3.6)

Group term Preferred term	All patients N=28 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (3.6)	1 (3.6)	0
Hypoxia	1 (3.6)	1 (3.6)	0
Vascular disorders			
- Total	2 (7.1)	1 (3.6)	1 (3.6)
Hypotension	2 (7.1)	1 (3.6)	1 (3.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	51 (72.9)	17 (24.3)	31 (44.3)
Blood and lymphatic system disorders			
- Total	18 (25.7)	16 (22.9)	2 (2.9)
Febrile neutropenia	18 (25.7)	16 (22.9)	2 (2.9)
General disorders and administration site conditions			
- Total	7 (10.0)	1 (1.4)	0
Pyrexia	7 (10.0)	1 (1.4)	0
Immune system disorders			
- Total	38 (54.3)	13 (18.6)	17 (24.3)
Cytokine release syndrome	38 (54.3)	13 (18.6)	17 (24.3)
Renal and urinary disorders			
- Total	5 (7.1)	2 (2.9)	2 (2.9)
Acute kidney injury	5 (7.1)	2 (2.9)	2 (2.9)

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	12 (17.1)	2 (2.9)	10 (14.3)
Respiratory failure	9 (12.9)	0	9 (12.9)
Hypoxia	4 (5.7)	2 (2.9)	2 (2.9)
Vascular disorders			
- Total	9 (12.9)	2 (2.9)	7 (10.0)
Hypotension	9 (12.9)	2 (2.9)	7 (10.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228n
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Baseline bone marrow tumor burden: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (54.5)	1 (9.1)	1 (9.1)
General disorders and administration site conditions			
- Total	2 (18.2)	0	0
Pyrexia	2 (18.2)	0	0
Immune system disorders			
- Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	61 (70.1)	24 (27.6)	34 (39.1)
Blood and lymphatic system disorders			
- Total	23 (26.4)	21 (24.1)	2 (2.3)
Febrile neutropenia	23 (26.4)	21 (24.1)	2 (2.3)
General disorders and administration site conditions			
- Total	11 (12.6)	2 (2.3)	0
Pyrexia	11 (12.6)	2 (2.3)	0
Immune system disorders			
- Total	46 (52.9)	15 (17.2)	20 (23.0)
Cytokine release syndrome	46 (52.9)	15 (17.2)	20 (23.0)
Renal and urinary disorders			
- Total	6 (6.9)	2 (2.3)	3 (3.4)
Acute kidney injury	6 (6.9)	2 (2.3)	3 (3.4)

Group term Preferred term	All patients N=87 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	13 (14.9)	3 (3.4)	10 (11.5)
Respiratory failure	9 (10.3)	0	9 (10.3)
Hypoxia	5 (5.7)	3 (3.4)	2 (2.3)
Vascular disorders			
- Total	11 (12.6)	3 (3.4)	8 (9.2)
Hypotension	11 (12.6)	3 (3.4)	8 (9.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228o
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Baseline extramedullary disease presence: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders			
- Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
General disorders and administration site conditions			
- Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			
- Total	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	4 (57.1)	0	3 (42.9)
Renal and urinary disorders			
- Total	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	2 (28.6)	1 (14.3)	1 (14.3)

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	1 (14.3)	0	1 (14.3)
Hypoxia	1 (14.3)	0	1 (14.3)
Vascular disorders			
- Total	2 (28.6)	0	2 (28.6)
Hypotension	2 (28.6)	0	2 (28.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	62 (68.1)	24 (26.4)	32 (35.2)
Blood and lymphatic system disorders			
- Total	21 (23.1)	19 (20.9)	2 (2.2)
Febrile neutropenia	21 (23.1)	19 (20.9)	2 (2.2)
General disorders and administration site conditions			
- Total	12 (13.2)	2 (2.2)	0
Pyrexia	12 (13.2)	2 (2.2)	0
Immune system disorders			
- Total	46 (50.5)	16 (17.6)	18 (19.8)
Cytokine release syndrome	46 (50.5)	16 (17.6)	18 (19.8)
Renal and urinary disorders			
- Total	4 (4.4)	1 (1.1)	2 (2.2)
Acute kidney injury	4 (4.4)	1 (1.1)	2 (2.2)

Group term Preferred term	All patients N=91 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	12 (13.2)	3 (3.3)	9 (9.9)
Respiratory failure	9 (9.9)	0	9 (9.9)
Hypoxia	4 (4.4)	3 (3.3)	1 (1.1)
Vascular disorders			
- Total	9 (9.9)	3 (3.3)	6 (6.6)
Hypotension	9 (9.9)	3 (3.3)	6 (6.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228p
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome

Down syndrome: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (70.0)	12 (30.0)	12 (30.0)
Blood and lymphatic system disorders			
- Total	7 (17.5)	6 (15.0)	1 (2.5)
Febrile neutropenia	7 (17.5)	6 (15.0)	1 (2.5)
General disorders and administration site conditions			
- Total	6 (15.0)	0	0
Pyrexia	6 (15.0)	0	0
Immune system disorders			
- Total	23 (57.5)	9 (22.5)	10 (25.0)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)
Renal and urinary disorders			
- Total	1 (2.5)	1 (2.5)	0
Acute kidney injury	1 (2.5)	1 (2.5)	0

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (5.0)	1 (2.5)	1 (2.5)
Hypoxia	1 (2.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	31 (77.5)	10 (25.0)	18 (45.0)
Blood and lymphatic system disorders			
- Total	14 (35.0)	14 (35.0)	0
Febrile neutropenia	14 (35.0)	14 (35.0)	0
General disorders and administration site conditions			
- Total	5 (12.5)	1 (2.5)	0
Pyrexia	5 (12.5)	1 (2.5)	0
Immune system disorders			
- Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Renal and urinary disorders			
- Total	4 (10.0)	1 (2.5)	3 (7.5)
Acute kidney injury	4 (10.0)	1 (2.5)	3 (7.5)

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	8 (20.0)	2 (5.0)	6 (15.0)
Respiratory failure	5 (12.5)	0	5 (12.5)
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Vascular disorders			
- Total	9 (22.5)	2 (5.0)	7 (17.5)
Hypotension	9 (22.5)	2 (5.0)	7 (17.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228q
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (44.4)	3 (16.7)	5 (27.8)
Blood and lymphatic system disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
General disorders and administration site conditions			
- Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Renal and urinary disorders			
- Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
- Total	3 (16.7)	0	3 (16.7)

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (16.7)	0	3 (16.7)
Vascular disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (87.5)	1 (12.5)	5 (62.5)
Blood and lymphatic system disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	1 (12.5)	1 (12.5)
General disorders and administration site conditions			
- Total	2 (25.0)	0	0
Pyrexia	2 (25.0)	0	0
Immune system disorders			
- Total	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)
Renal and urinary disorders			
- Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	2 (25.0)	0	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Vascular disorders			
- Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (66.7)	8 (26.7)	10 (33.3)
Blood and lymphatic system disorders			
- Total	6 (20.0)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	6 (20.0)	0
General disorders and administration site conditions			
- Total	6 (20.0)	1 (3.3)	0
Pyrexia	6 (20.0)	1 (3.3)	0
Immune system disorders			
- Total	13 (43.3)	4 (13.3)	6 (20.0)
Cytokine release syndrome	13 (43.3)	4 (13.3)	6 (20.0)
Renal and urinary disorders			
- Total	1 (3.3)	0	1 (3.3)
Acute kidney injury	1 (3.3)	0	1 (3.3)

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
- Total	5 (16.7)	1 (3.3)	4 (13.3)
Respiratory failure	3 (10.0)	0	3 (10.0)
Hypoxia	2 (6.7)	1 (3.3)	1 (3.3)
Vascular disorders			
- Total	6 (20.0)	2 (6.7)	4 (13.3)
Hypotension	6 (20.0)	2 (6.7)	4 (13.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (66.7)	5 (27.8)	6 (33.3)
Blood and lymphatic system disorders			
- Total	6 (33.3)	6 (33.3)	0
Febrile neutropenia	6 (33.3)	6 (33.3)	0
General disorders and administration site conditions			
- Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Immune system disorders			
- Total	10 (55.6)	4 (22.2)	4 (22.2)
Cytokine release syndrome	10 (55.6)	4 (22.2)	4 (22.2)
Renal and urinary disorders			
- Total	1 (5.6)	1 (5.6)	0

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
- Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypoxia	2 (11.1)	1 (5.6)	1 (5.6)
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
- Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypotension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (66.7)	11 (26.2)	14 (33.3)
Blood and lymphatic system disorders			
- Total	9 (21.4)	8 (19.0)	1 (2.4)
Febrile neutropenia	9 (21.4)	8 (19.0)	1 (2.4)
General disorders and administration site conditions			
- Total	3 (7.1)	0	0
Pyrexia	3 (7.1)	0	0
Immune system disorders			
- Total	23 (54.8)	8 (19.0)	9 (21.4)
Cytokine release syndrome	23 (54.8)	8 (19.0)	9 (21.4)
Renal and urinary disorders			
- Total	2 (4.8)	0	1 (2.4)

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (4.8)	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders			
- Total	4 (9.5)	1 (2.4)	3 (7.1)
Respiratory failure	3 (7.1)	0	3 (7.1)
Hypoxia	1 (2.4)	1 (2.4)	0
Vascular disorders			
- Total	1 (2.4)	0	1 (2.4)
Hypotension	1 (2.4)	0	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 228r
Serious adverse events (SAE) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Number of previous relapses: Missing

	All patients N=0		
Group term Preferred term	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
No records met the criteria			

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (97.0)	2 (6.1)	5 (15.2)	5 (15.2)	20 (60.6)
Cytokine Release Syndrome					
-Total	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Hematological disorders including cytopenias					
-Total	25 (75.8)	1 (3.0)	1 (3.0)	7 (21.2)	16 (48.5)
White blood cell count decreased	16 (48.5)	2 (6.1)	1 (3.0)	2 (6.1)	11 (33.3)
Anaemia	13 (39.4)	3 (9.1)	3 (9.1)	7 (21.2)	0
Neutrophil count decreased	13 (39.4)	0	2 (6.1)	1 (3.0)	10 (30.3)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	12 (36.4)	0	0	12 (36.4)	0
Platelet count decreased	11 (33.3)	2 (6.1)	1 (3.0)	4 (12.1)	4 (12.1)
Lymphocyte count decreased	8 (24.2)	0	0	5 (15.2)	3 (9.1)
Thrombocytopenia	4 (12.1)	0	0	0	4 (12.1)
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Leukopenia	1 (3.0)	0	0	1 (3.0)	0
Lymphopenia	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	14 (42.4)	3 (9.1)	4 (12.1)	6 (18.2)	1 (3.0)
Conjunctivitis	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Clostridium difficile infection	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Oral infection	2 (6.1)	0	2 (6.1)	0	0
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Bk virus infection	1 (3.0)	1 (3.0)	0	0	0
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	1 (3.0)	1 (3.0)	0	0	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Oral herpes	1 (3.0)	0	0	1 (3.0)	0
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (57.6)	5 (15.2)	9 (27.3)	5 (15.2)	0
Hypogammaglobulinaemia	10 (30.3)	1 (3.0)	7 (21.2)	2 (6.1)	0
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood immunoglobulin a decreased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Blood immunoglobulin g decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Immunodeficiency	2 (6.1)	0	0	2 (6.1)	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	15 (45.5)	9 (27.3)	2 (6.1)	4 (12.1)	0
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Delirium	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hallucination	2 (6.1)	0	2 (6.1)	0	0
Irritability	2 (6.1)	2 (6.1)	0	0	0
Lethargy	2 (6.1)	2 (6.1)	0	0	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Agitation	1 (3.0)	1 (3.0)	0	0	0
Depressed level of consciousness	1 (3.0)	0	0	1 (3.0)	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0
Restlessness	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (93.9)	1 (3.0)	3 (9.1)	10 (30.3)	17 (51.5)
Cytokine Release Syndrome					
-Total	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hematological disorders including cytopenias					
-Total	21 (63.6)	0	1 (3.0)	8 (24.2)	12 (36.4)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	6 (18.2)	1 (3.0)	0	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)
Anaemia	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Neutropenia	4 (12.1)	0	0	0	4 (12.1)
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Leukopenia	2 (6.1)	0	1 (3.0)	0	1 (3.0)
Haemoglobin decreased	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	12 (36.4)	2 (6.1)	4 (12.1)	5 (15.2)	1 (3.0)
Anal abscess	1 (3.0)	0	0	1 (3.0)	0
Bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	1 (3.0)	0
Cholecystitis infective	1 (3.0)	0	1 (3.0)	0	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Gastroenteritis norovirus	1 (3.0)	1 (3.0)	0	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Otitis externa	1 (3.0)	0	1 (3.0)	0	0
Paronychia	1 (3.0)	0	1 (3.0)	0	0
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (39.4)	0	7 (21.2)	6 (18.2)	0
Hypogammaglobulinaemia	10 (30.3)	0	5 (15.2)	5 (15.2)	0
Immunodeficiency	1 (3.0)	0	0	1 (3.0)	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Selective igg subclass deficiency	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	11 (33.3)	4 (12.1)	4 (12.1)	3 (9.1)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Agitation	2 (6.1)	0	2 (6.1)	0	0
Cognitive disorder	2 (6.1)	0	2 (6.1)	0	0
Mental status changes	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dysarthria	1 (3.0)	0	0	1 (3.0)	0
Dysphagia	1 (3.0)	0	0	1 (3.0)	0
Generalised tonic-clonic seizure	1 (3.0)	0	1 (3.0)	0	0
Muscular weakness	1 (3.0)	0	0	1 (3.0)	0
Seizure	1 (3.0)	0	1 (3.0)	0	0
Tumour Lysis Syndrome					
-Total	3 (9.1)	0	0	3 (9.1)	0
Tumour lysis syndrome	3 (9.1)	0	0	3 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	1 (7.1)	5 (35.7)	7 (50.0)
Cytokine Release Syndrome					
-Total	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Haemophagocytic lymphohistiocytosis	1 (7.1)	0	0	1 (7.1)	0
Hematological disorders including cytopenias					
-Total	7 (50.0)	1 (7.1)	0	4 (28.6)	2 (14.3)
Anaemia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	9 (64.3)	1 (7.1)	2 (14.3)	5 (35.7)	1 (7.1)
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0
Atypical pneumonia	1 (7.1)	1 (7.1)	0	0	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Granulicatella infection	1 (7.1)	0	0	1 (7.1)	0
Herpes simplex	1 (7.1)	0	0	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (7.1)	0	1 (7.1)	0	0
Myringitis	1 (7.1)	1 (7.1)	0	0	0
Oral candidiasis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Sinusitis	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Stomatococcal infection	1 (7.1)	0	1 (7.1)	0	0
Systemic candida	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection viral	1 (7.1)	1 (7.1)	0	0	0
Varicella zoster virus infection	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Hypogammaglobulinaemia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Serious neurological adverse reactions					
-Total	5 (35.7)	0	2 (14.3)	3 (21.4)	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Delirium	2 (14.3)	0	0	2 (14.3)	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Affect lability	1 (7.1)	0	1 (7.1)	0	0
Amnesia	1 (7.1)	0	1 (7.1)	0	0
Aphasia	1 (7.1)	1 (7.1)	0	0	0
Cognitive disorder	1 (7.1)	0	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Hallucination	1 (7.1)	1 (7.1)	0	0	0
Hallucination, visual	1 (7.1)	0	1 (7.1)	0	0
Irritability	1 (7.1)	1 (7.1)	0	0	0
Lethargy	1 (7.1)	0	1 (7.1)	0	0

Timing: within 8 weeks post infusion, Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Sluggishness	1 (7.1)	0	1 (7.1)	0	0
Social avoidant behaviour	1 (7.1)	0	1 (7.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (73.3)	4 (13.3)	3 (10.0)	6 (20.0)	9 (30.0)
Hematological disorders including cytopenias					
-Total	13 (43.3)	3 (10.0)	1 (3.3)	5 (16.7)	4 (13.3)
Neutrophil count decreased	7 (23.3)	1 (3.3)	1 (3.3)	2 (6.7)	3 (10.0)
White blood cell count decreased	7 (23.3)	3 (10.0)	2 (6.7)	1 (3.3)	1 (3.3)
Platelet count decreased	5 (16.7)	3 (10.0)	0	1 (3.3)	1 (3.3)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Anaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Thrombocytopenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Myelodysplastic syndrome	1 (3.3)	0	0	1 (3.3)	0
Infections					
-Total	17 (56.7)	2 (6.7)	5 (16.7)	5 (16.7)	5 (16.7)
Upper respiratory tract infection	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Nasopharyngitis	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Otitis media	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Gastroenteritis	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Metapneumovirus infection	2 (6.7)	0	0	2 (6.7)	0
Pneumocystis jirovecii pneumonia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Pneumonia	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Rhinovirus infection	2 (6.7)	0	2 (6.7)	0	0
Viral infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Bronchopulmonary aspergillosis	1 (3.3)	0	0	0	1 (3.3)
Cellulitis	1 (3.3)	0	1 (3.3)	0	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Cystitis	1 (3.3)	0	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	1 (3.3)	0	0
Enterobacter infection	1 (3.3)	0	0	1 (3.3)	0
Gingivitis	1 (3.3)	1 (3.3)	0	0	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Human herpesvirus 6 infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella infection	1 (3.3)	0	0	1 (3.3)	0
Mastoiditis	1 (3.3)	0	0	1 (3.3)	0
Oral candidiasis	1 (3.3)	0	1 (3.3)	0	0
Oral herpes	1 (3.3)	0	1 (3.3)	0	0
Otitis externa	1 (3.3)	0	0	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	0	0	1 (3.3)
Respiratory syncytial virus infection	1 (3.3)	0	1 (3.3)	0	0
Respiratory tract infection viral	1 (3.3)	0	1 (3.3)	0	0
Rhinitis	1 (3.3)	0	1 (3.3)	0	0
Salmonellosis	1 (3.3)	0	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal sepsis	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal skin infection	1 (3.3)	0	1 (3.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Hypogammaglobulinaemia	3 (10.0)	0	3 (10.0)	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Serious neurological adverse reactions					
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Agitation	1 (3.3)	1 (3.3)	0	0	0
Delirium	1 (3.3)	0	1 (3.3)	0	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Mood altered	1 (3.3)	1 (3.3)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (77.4)	2 (6.5)	11 (35.5)	6 (19.4)	5 (16.1)
Hematological disorders including cytopenias					
-Total	9 (29.0)	2 (6.5)	2 (6.5)	2 (6.5)	3 (9.7)
Neutropenia	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Neutrophil count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Anaemia	1 (3.2)	1 (3.2)	0	0	0
Leukopenia	1 (3.2)	0	1 (3.2)	0	0
Lymphocyte count decreased	1 (3.2)	0	1 (3.2)	0	0
Infections					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (51.6)	2 (6.5)	8 (25.8)	4 (12.9)	2 (6.5)
Sinusitis	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Upper respiratory tract infection	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Gastroenteritis	2 (6.5)	2 (6.5)	0	0	0
Nasopharyngitis	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Respiratory tract infection	2 (6.5)	0	2 (6.5)	0	0
Skin papilloma	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Adenovirus infection	1 (3.2)	0	0	1 (3.2)	0
Bacteraemia	1 (3.2)	0	1 (3.2)	0	0
Bk virus infection	1 (3.2)	0	0	1 (3.2)	0
Coronavirus infection	1 (3.2)	0	0	1 (3.2)	0
Ear infection	1 (3.2)	0	1 (3.2)	0	0
Encephalitis	1 (3.2)	0	0	0	1 (3.2)
Gastroenteritis clostridial	1 (3.2)	0	1 (3.2)	0	0
Gastroenteritis viral	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal infection	1 (3.2)	1 (3.2)	0	0	0
Herpes simplex	1 (3.2)	0	1 (3.2)	0	0
Influenza	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (3.2)	0	0	1 (3.2)	0
Molluscum contagiosum	1 (3.2)	1 (3.2)	0	0	0
Otitis externa	1 (3.2)	0	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0	0	0
Paronychia	1 (3.2)	0	1 (3.2)	0	0
Pneumonia	1 (3.2)	0	1 (3.2)	0	0
Respiratory syncytial virus infection	1 (3.2)	0	0	1 (3.2)	0
Rhinitis	1 (3.2)	1 (3.2)	0	0	0
Rhinovirus infection	1 (3.2)	0	1 (3.2)	0	0
Septic shock	1 (3.2)	0	0	0	1 (3.2)
Sinusitis fungal	1 (3.2)	0	0	1 (3.2)	0
Tinea pedis	1 (3.2)	1 (3.2)	0	0	0
Viral haemorrhagic cystitis	1 (3.2)	0	0	1 (3.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (22.6)	0	6 (19.4)	1 (3.2)	0
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (3.2)	0	0	1 (3.2)	0
Blood immunoglobulin m decreased	1 (3.2)	0	0	1 (3.2)	0
Immunoglobulins decreased	1 (3.2)	0	1 (3.2)	0	0
Serious neurological adverse reactions					
-Total	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Memory impairment	1 (3.2)	0	1 (3.2)	0	0
Mental status changes	1 (3.2)	0	1 (3.2)	0	0
Seizure	1 (3.2)	0	0	1 (3.2)	0
Tumour Lysis Syndrome					
-Total	1 (3.2)	0	0	0	1 (3.2)
Tumour lysis syndrome	1 (3.2)	0	0	0	1 (3.2)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (64.3)	0	3 (21.4)	4 (28.6)	2 (14.3)
Hematological disorders including cytopenias					
-Total	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Anaemia	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Neutropenia	2 (14.3)	0	0	1 (7.1)	1 (7.1)
White blood cell count decreased	1 (7.1)	0	0	1 (7.1)	0
Infections					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute sinusitis	1 (7.1)	0	1 (7.1)	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Ear, nose and throat infection	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Nail infection	1 (7.1)	1 (7.1)	0	0	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (28.6)	0	3 (21.4)	1 (7.1)	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Immunodeficiency	1 (7.1)	0	0	1 (7.1)	0

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (50.0)	2 (10.0)	5 (25.0)	1 (5.0)	2 (10.0)
Cytokine Release Syndrome					
-Total	1 (5.0)	0	0	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)
Hematological disorders including cytopenias					
-Total	4 (20.0)	2 (10.0)	0	2 (10.0)	0
Agranulocytosis	1 (5.0)	0	0	1 (5.0)	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Infections					
-Total	8 (40.0)	1 (5.0)	4 (20.0)	1 (5.0)	2 (10.0)
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	1 (5.0)	0	0	0
Herpes virus infection	1 (5.0)	0	1 (5.0)	0	0
Influenza	1 (5.0)	0	0	0	1 (5.0)
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Rhinovirus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Streptococcal sepsis	1 (5.0)	0	1 (5.0)	0	0
Viral skin infection	1 (5.0)	1 (5.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	1 (4.5)	3 (13.6)	8 (36.4)	2 (9.1)
Hematological disorders including cytopenias					
-Total	1 (4.5)	0	0	0	1 (4.5)
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	12 (54.5)	1 (4.5)	1 (4.5)	8 (36.4)	2 (9.1)
Sinusitis	4 (18.2)	0	4 (18.2)	0	0
Conjunctivitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Covid-19	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Herpes zoster	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Otitis media	2 (9.1)	0	2 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (9.1)	0	2 (9.1)	0	0
Sepsis	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Skin infection	2 (9.1)	0	2 (9.1)	0	0
Upper respiratory tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Bronchiolitis	1 (4.5)	0	0	1 (4.5)	0
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Clostridium difficile colitis	1 (4.5)	0	0	1 (4.5)	0
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Ear infection	1 (4.5)	0	0	1 (4.5)	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis escherichia coli	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis salmonella	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis viral	1 (4.5)	0	1 (4.5)	0	0
Meningitis pneumococcal	1 (4.5)	0	0	1 (4.5)	0
Nail infection	1 (4.5)	0	1 (4.5)	0	0
Oral candidiasis	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (4.5)	0	0	1 (4.5)	0
Pneumonia respiratory syncytial viral	1 (4.5)	0	0	1 (4.5)	0
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Septic shock	1 (4.5)	0	0	0	1 (4.5)
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Syphilis	1 (4.5)	0	1 (4.5)	0	0
Urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Urinary tract infection pseudomonal	1 (4.5)	0	1 (4.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (13.6)	0	3 (13.6)	0	0
Hypogammaglobulinaemia	2 (9.1)	0	2 (9.1)	0	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Serious neurological adverse reactions					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Dysarthria	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (4.5)	0	0	1 (4.5)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Hematological disorders including cytopenias					
-Total	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Neutrophil count decreased	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					
-Total	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Sinusitis	2 (25.0)	0	2 (25.0)	0	0
Acute sinusitis	1 (12.5)	0	1 (12.5)	0	0
Fungal skin infection	1 (12.5)	0	1 (12.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (12.5)	0	1 (12.5)	0	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Urinary tract infection	1 (12.5)	0	1 (12.5)	0	0
Varicella zoster virus infection	1 (12.5)	0	1 (12.5)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	0	5 (15.2)	6 (18.2)	22 (66.7)
Cytokine Release Syndrome					
-Total	24 (72.7)	3 (9.1)	9 (27.3)	3 (9.1)	9 (27.3)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Hematological disorders including cytopenias					
-Total	27 (81.8)	1 (3.0)	1 (3.0)	9 (27.3)	16 (48.5)
White blood cell count decreased	17 (51.5)	2 (6.1)	2 (6.1)	2 (6.1)	11 (33.3)
Neutrophil count decreased	16 (48.5)	0	1 (3.0)	3 (9.1)	12 (36.4)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	14 (42.4)	3 (9.1)	4 (12.1)	7 (21.2)	0
Platelet count decreased	14 (42.4)	4 (12.1)	1 (3.0)	5 (15.2)	4 (12.1)
Febrile neutropenia	13 (39.4)	0	0	13 (39.4)	0
Lymphocyte count decreased	10 (30.3)	0	0	7 (21.2)	3 (9.1)
Thrombocytopenia	5 (15.2)	0	0	1 (3.0)	4 (12.1)
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Lymphopenia	2 (6.1)	0	0	2 (6.1)	0
Agranulocytosis	1 (3.0)	0	0	1 (3.0)	0
Leukopenia	1 (3.0)	0	0	1 (3.0)	0
Myelodysplastic syndrome	1 (3.0)	0	0	1 (3.0)	0
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	25 (75.8)	4 (12.1)	7 (21.2)	7 (21.2)	7 (21.2)
Upper respiratory tract infection	6 (18.2)	4 (12.1)	2 (6.1)	0	0
Conjunctivitis	5 (15.2)	1 (3.0)	4 (12.1)	0	0
Gastroenteritis	3 (9.1)	2 (6.1)	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Pneumonia	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Rhinovirus infection	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Candida infection	2 (6.1)	0	2 (6.1)	0	0
Clostridium difficile infection	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Metapneumovirus infection	2 (6.1)	0	0	2 (6.1)	0
Oral herpes	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Oral infection	2 (6.1)	0	2 (6.1)	0	0
Parainfluenzae virus infection	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Pneumocystis jirovecii pneumonia	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Staphylococcal bacteraemia	2 (6.1)	0	0	2 (6.1)	0
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Viral infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Bk virus infection	1 (3.0)	1 (3.0)	0	0	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (3.0)	0	1 (3.0)	0	0
Covid-19 pneumonia	1 (3.0)	0	0	0	1 (3.0)
Cystitis	1 (3.0)	0	1 (3.0)	0	0
Cytomegalovirus infection reactivation	1 (3.0)	0	0	1 (3.0)	0
Device related infection	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	1 (3.0)	0	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Enterobacter infection	1 (3.0)	0	0	1 (3.0)	0
Enterovirus infection	1 (3.0)	0	0	1 (3.0)	0
Fungal infection	1 (3.0)	0	1 (3.0)	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Herpes virus infection	1 (3.0)	0	1 (3.0)	0	0
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Human herpesvirus 6 infection	1 (3.0)	0	0	1 (3.0)	0
Influenza	1 (3.0)	0	0	0	1 (3.0)
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0
Localised infection	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (3.0)	0	0	1 (3.0)	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Otitis externa	1 (3.0)	0	0	1 (3.0)	0
Otitis media acute	1 (3.0)	0	1 (3.0)	0	0
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection viral	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	0	1 (3.0)	0	0
Salmonellosis	1 (3.0)	0	1 (3.0)	0	0
Sepsis	1 (3.0)	0	0	0	1 (3.0)
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal sepsis	1 (3.0)	0	0	0	1 (3.0)
Staphylococcal skin infection	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (3.0)	0	1 (3.0)	0	0
Viral skin infection	1 (3.0)	1 (3.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (60.6)	3 (9.1)	12 (36.4)	5 (15.2)	0
Hypogammaglobulinaemia	13 (39.4)	1 (3.0)	10 (30.3)	2 (6.1)	0
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood immunoglobulin a decreased	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Blood immunoglobulin g decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Immunodeficiency	2 (6.1)	0	0	2 (6.1)	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	16 (48.5)	8 (24.2)	3 (9.1)	5 (15.2)	0
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Agitation	2 (6.1)	2 (6.1)	0	0	0
Hallucination	2 (6.1)	0	2 (6.1)	0	0
Irritability	2 (6.1)	2 (6.1)	0	0	0
Lethargy	2 (6.1)	2 (6.1)	0	0	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Depressed level of consciousness	1 (3.0)	0	0	1 (3.0)	0
Mental status changes	1 (3.0)	0	0	1 (3.0)	0
Mood altered	1 (3.0)	1 (3.0)	0	0	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0
Restlessness	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	1 (3.0)	2 (6.1)	10 (30.3)	20 (60.6)
Cytokine Release Syndrome					
-Total	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hematological disorders including cytopenias					
-Total	21 (63.6)	0	1 (3.0)	7 (21.2)	13 (39.4)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Lymphocyte count decreased	6 (18.2)	0	1 (3.0)	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)
Neutropenia	5 (15.2)	0	0	0	5 (15.2)
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Leukopenia	2 (6.1)	0	1 (3.0)	0	1 (3.0)
Haemoglobin decreased	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Infections					
-Total	23 (69.7)	2 (6.1)	4 (12.1)	12 (36.4)	5 (15.2)
Upper respiratory tract infection	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Rhinovirus infection	4 (12.1)	0	4 (12.1)	0	0
Sinusitis	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Bacteraemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Conjunctivitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Covid-19	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Ear infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Gastroenteritis	2 (6.1)	2 (6.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Herpes zoster	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Nail infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Nasopharyngitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Otitis externa	2 (6.1)	0	2 (6.1)	0	0
Otitis media	2 (6.1)	0	2 (6.1)	0	0
Paronychia	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Respiratory tract infection	2 (6.1)	0	2 (6.1)	0	0
Rhinitis	2 (6.1)	2 (6.1)	0	0	0
Sepsis	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Septic shock	2 (6.1)	0	0	0	2 (6.1)
Skin infection	2 (6.1)	0	2 (6.1)	0	0
Skin papilloma	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Staphylococcal bacteraemia	2 (6.1)	0	0	2 (6.1)	0
Adenovirus infection	1 (3.0)	0	0	1 (3.0)	0
Anal abscess	1 (3.0)	0	0	1 (3.0)	0
Bk virus infection	1 (3.0)	0	0	1 (3.0)	0
Bronchiolitis	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	1 (3.0)	0
Cholecystitis infective	1 (3.0)	0	1 (3.0)	0	0
Clostridium difficile colitis	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Coronavirus infection	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Folliculitis	1 (3.0)	0	1 (3.0)	0	0
Fungal infection	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis clostridial	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis escherichia coli	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis norovirus	1 (3.0)	1 (3.0)	0	0	0
Gastroenteritis salmonella	1 (3.0)	0	0	1 (3.0)	0
Gastrointestinal infection	1 (3.0)	1 (3.0)	0	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Herpes simplex	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.0)	0	1 (3.0)	0	0
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Metapneumovirus infection	1 (3.0)	0	0	1 (3.0)	0
Molluscum contagiosum	1 (3.0)	1 (3.0)	0	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Oral herpes	1 (3.0)	1 (3.0)	0	0	0
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0	0	0
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0
Pneumonia respiratory syncytial viral	1 (3.0)	0	0	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	0	0	1 (3.0)	0
Sinusitis fungal	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0
Syphilis	1 (3.0)	0	1 (3.0)	0	0
Tinea pedis	1 (3.0)	1 (3.0)	0	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection pseudomonal	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (3.0)	0	0	1 (3.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (57.6)	0	12 (36.4)	7 (21.2)	0
Hypogammaglobulinaemia	15 (45.5)	0	10 (30.3)	5 (15.2)	0
Blood immunoglobulin a decreased	1 (3.0)	0	0	1 (3.0)	0
Blood immunoglobulin g decreased	1 (3.0)	0	1 (3.0)	0	0
Blood immunoglobulin m decreased	1 (3.0)	0	0	1 (3.0)	0
Immunodeficiency	1 (3.0)	0	0	1 (3.0)	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Selective igg subclass deficiency	1 (3.0)	0	1 (3.0)	0	0
Serious neurological adverse reactions					
-Total	14 (42.4)	4 (12.1)	5 (15.2)	5 (15.2)	0
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Mental status changes	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Seizure	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Agitation	2 (6.1)	0	2 (6.1)	0	0
Cognitive disorder	2 (6.1)	0	2 (6.1)	0	0
Dysarthria	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dysphagia	1 (3.0)	0	0	1 (3.0)	0
Generalised tonic-clonic seizure	1 (3.0)	0	1 (3.0)	0	0
Memory impairment	1 (3.0)	0	1 (3.0)	0	0
Muscular weakness	1 (3.0)	0	0	1 (3.0)	0
Tumour Lysis Syndrome					
-Total	4 (12.1)	0	0	3 (9.1)	1 (3.0)
Tumour lysis syndrome	4 (12.1)	0	0	3 (9.1)	1 (3.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229a
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	6 (42.9)	7 (50.0)
Cytokine Release Syndrome					
-Total	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Haemophagocytic lymphohistiocytosis	1 (7.1)	0	0	1 (7.1)	0
Hematological disorders including cytopenias					
-Total	8 (57.1)	0	0	6 (42.9)	2 (14.3)
Anaemia	5 (35.7)	1 (7.1)	2 (14.3)	2 (14.3)	0
Neutropenia	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	0	0	1 (7.1)
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	13 (92.9)	2 (14.3)	3 (21.4)	6 (42.9)	2 (14.3)
Sinusitis	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Acute sinusitis	2 (14.3)	0	2 (14.3)	0	0
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0
Atypical pneumonia	1 (7.1)	1 (7.1)	0	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Ear, nose and throat infection	1 (7.1)	0	1 (7.1)	0	0
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Fungal skin infection	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Granulicatella infection	1 (7.1)	0	0	1 (7.1)	0
Herpes simplex	1 (7.1)	0	0	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	0	0	1 (7.1)	0
Influenza	1 (7.1)	0	1 (7.1)	0	0
Klebsiella bacteraemia	1 (7.1)	0	1 (7.1)	0	0
Myringitis	1 (7.1)	1 (7.1)	0	0	0
Nail infection	1 (7.1)	1 (7.1)	0	0	0
Oral candidiasis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal abscess	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Stomatococcal infection	1 (7.1)	0	1 (7.1)	0	0
Systemic candida	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection viral	1 (7.1)	1 (7.1)	0	0	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (57.1)	2 (14.3)	5 (35.7)	1 (7.1)	0
Hypogammaglobulinaemia	5 (35.7)	1 (7.1)	4 (28.6)	0	0
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Immunodeficiency	1 (7.1)	0	0	1 (7.1)	0
Serious neurological adverse reactions					
-Total	5 (35.7)	0	2 (14.3)	3 (21.4)	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Delirium	2 (14.3)	0	0	2 (14.3)	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Affect lability	1 (7.1)	0	1 (7.1)	0	0
Amnesia	1 (7.1)	0	1 (7.1)	0	0
Aphasia	1 (7.1)	1 (7.1)	0	0	0
Cognitive disorder	1 (7.1)	0	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Hallucination	1 (7.1)	1 (7.1)	0	0	0
Hallucination, visual	1 (7.1)	0	1 (7.1)	0	0
Irritability	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	1 (7.1)	0	1 (7.1)	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Sluggishness	1 (7.1)	0	1 (7.1)	0	0
Social avoidant behaviour	1 (7.1)	0	1 (7.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (91.3)	2 (4.3)	8 (17.4)	9 (19.6)	23 (50.0)
Cytokine Release Syndrome					
-Total	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Haemophagocytic lymphohistiocytosis	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Hematological disorders including cytopenias					
-Total	27 (58.7)	0	2 (4.3)	9 (19.6)	16 (34.8)
White blood cell count decreased	12 (26.1)	2 (4.3)	1 (2.2)	1 (2.2)	8 (17.4)
Febrile neutropenia	11 (23.9)	0	0	11 (23.9)	0
Platelet count decreased	11 (23.9)	2 (4.3)	2 (4.3)	4 (8.7)	3 (6.5)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (17.4)	0	0	0	8 (17.4)
Anaemia	7 (15.2)	1 (2.2)	3 (6.5)	3 (6.5)	0
Lymphocyte count decreased	5 (10.9)	0	0	2 (4.3)	3 (6.5)
Thrombocytopenia	5 (10.9)	0	0	0	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Leukopenia	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	19 (41.3)	3 (6.5)	7 (15.2)	9 (19.6)	0
Clostridium difficile infection	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Conjunctivitis	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Staphylococcal infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Candida infection	2 (4.3)	0	2 (4.3)	0	0
Oral infection	2 (4.3)	0	2 (4.3)	0	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (2.2)	1 (2.2)	0	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Nail infection	1 (2.2)	1 (2.2)	0	0	0
Oral herpes	1 (2.2)	0	0	1 (2.2)	0
Otitis externa	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (43.5)	3 (6.5)	11 (23.9)	6 (13.0)	0
Hypogammaglobulinaemia	12 (26.1)	1 (2.2)	8 (17.4)	3 (6.5)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Blood immunoglobulin m decreased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Immunodeficiency	2 (4.3)	0	0	2 (4.3)	0
Immunoglobulins decreased	2 (4.3)	0	2 (4.3)	0	0
Blood immunoglobulin g decreased	1 (2.2)	1 (2.2)	0	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	13 (28.3)	8 (17.4)	2 (4.3)	3 (6.5)	0
Delirium	5 (10.9)	2 (4.3)	1 (2.2)	2 (4.3)	0
Confusional state	4 (8.7)	4 (8.7)	0	0	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Agitation	2 (4.3)	0	2 (4.3)	0	0
Somnolence	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0
Irritability	1 (2.2)	1 (2.2)	0	0	0
Lethargy	1 (2.2)	1 (2.2)	0	0	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Tumour Lysis Syndrome					
-Total	3 (6.5)	0	0	3 (6.5)	0
Tumour lysis syndrome	3 (6.5)	0	0	3 (6.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	1 (2.9)	11 (32.4)	21 (61.8)
Cytokine Release Syndrome					
-Total	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Haemophagocytic lymphohistiocytosis	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	26 (76.5)	2 (5.9)	0	10 (29.4)	14 (41.2)
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)
Anaemia	14 (41.2)	4 (11.8)	5 (14.7)	5 (14.7)	0
Neutrophil count decreased	12 (35.3)	0	3 (8.8)	2 (5.9)	7 (20.6)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	12 (35.3)	1 (2.9)	2 (5.9)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	10 (29.4)	2 (5.9)	0	6 (17.6)	2 (5.9)
Platelet count decreased	10 (29.4)	2 (5.9)	1 (2.9)	2 (5.9)	5 (14.7)
Neutropenia	5 (14.7)	0	1 (2.9)	1 (2.9)	3 (8.8)
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Leukopenia	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	16 (47.1)	3 (8.8)	3 (8.8)	7 (20.6)	3 (8.8)
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Rhinovirus infection	2 (5.9)	0	2 (5.9)	0	0
Staphylococcal bacteraemia	2 (5.9)	0	0	2 (5.9)	0
Staphylococcal infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Localised infection	1 (2.9)	1 (2.9)	0	0	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Nail infection	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection viral	1 (2.9)	1 (2.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (50.0)	4 (11.8)	8 (23.5)	5 (14.7)	0
Hypogammaglobulinaemia	11 (32.4)	1 (2.9)	6 (17.6)	4 (11.8)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	18 (52.9)	5 (14.7)	6 (17.6)	7 (20.6)	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Agitation	3 (8.8)	2 (5.9)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	3 (8.8)	3 (8.8)	0	0	0
Somnolence	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cognitive disorder	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Irritability	2 (5.9)	2 (5.9)	0	0	0
Lethargy	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Mental status changes	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	0	1 (2.9)	0
Generalised tonic-clonic seizure	1 (2.9)	0	1 (2.9)	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Muscular weakness	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (67.4)	4 (9.3)	6 (14.0)	10 (23.3)	9 (20.9)
Hematological disorders including cytopenias					
-Total	12 (27.9)	2 (4.7)	1 (2.3)	5 (11.6)	4 (9.3)
White blood cell count decreased	5 (11.6)	2 (4.7)	2 (4.7)	0	1 (2.3)
Neutrophil count decreased	4 (9.3)	0	0	2 (4.7)	2 (4.7)
Febrile neutropenia	3 (7.0)	0	0	3 (7.0)	0
Platelet count decreased	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Anaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Lymphocyte count decreased	2 (4.7)	0	0	2 (4.7)	0
Thrombocytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.3)	0	1 (2.3)	0	0
Lymphopenia	1 (2.3)	0	0	1 (2.3)	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	24 (55.8)	5 (11.6)	7 (16.3)	7 (16.3)	5 (11.6)
Upper respiratory tract infection	6 (14.0)	3 (7.0)	2 (4.7)	1 (2.3)	0
Nasopharyngitis	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Metapneumovirus infection	3 (7.0)	0	0	3 (7.0)	0
Pneumonia	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Gastroenteritis	2 (4.7)	2 (4.7)	0	0	0
Otitis media	2 (4.7)	0	2 (4.7)	0	0
Parainfluenzae virus infection	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Pneumocystis jirovecii pneumonia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Respiratory syncytial virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory tract infection	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Rhinovirus infection	2 (4.7)	0	2 (4.7)	0	0
Skin papilloma	2 (4.7)	1 (2.3)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Adenovirus infection	1 (2.3)	0	0	1 (2.3)	0
Bacteraemia	1 (2.3)	0	1 (2.3)	0	0
Bk virus infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis	1 (2.3)	0	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Coronavirus infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection reactivation	1 (2.3)	0	0	1 (2.3)	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0
Encephalitis	1 (2.3)	0	0	0	1 (2.3)
Gastroenteritis clostridial	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal infection	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Herpes simplex	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Human herpesvirus 6 infection	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (2.3)	0	1 (2.3)	0	0
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Nail infection	1 (2.3)	1 (2.3)	0	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Salmonellosis	1 (2.3)	0	1 (2.3)	0	0
Sinusitis	1 (2.3)	0	1 (2.3)	0	0
Sinusitis fungal	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal sepsis	1 (2.3)	0	0	0	1 (2.3)
Tinea pedis	1 (2.3)	1 (2.3)	0	0	0
Viral haemorrhagic cystitis	1 (2.3)	0	0	1 (2.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (20.9)	1 (2.3)	6 (14.0)	2 (4.7)	0
Hypogammaglobulinaemia	5 (11.6)	0	5 (11.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Blood immunoglobulin m decreased	1 (2.3)	0	0	1 (2.3)	0
Immunodeficiency	1 (2.3)	0	0	1 (2.3)	0
Immunoglobulins decreased	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Agitation	1 (2.3)	1 (2.3)	0	0	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Memory impairment	1 (2.3)	0	1 (2.3)	0	0
Mood altered	1 (2.3)	1 (2.3)	0	0	0
Seizure	1 (2.3)	0	0	1 (2.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	2 (6.3)	11 (34.4)	6 (18.8)	7 (21.9)
Hematological disorders including cytopenias					
-Total	14 (43.8)	4 (12.5)	2 (6.3)	4 (12.5)	4 (12.5)
Neutrophil count decreased	6 (18.8)	2 (6.3)	1 (3.1)	1 (3.1)	2 (6.3)
White blood cell count decreased	5 (15.6)	2 (6.3)	0	3 (9.4)	0
Anaemia	4 (12.5)	3 (9.4)	0	1 (3.1)	0
Neutropenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
Lymphocyte count decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Platelet count decreased	2 (6.3)	2 (6.3)	0	0	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	16 (50.0)	0	8 (25.0)	5 (15.6)	3 (9.4)
Gastroenteritis	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Rhinovirus infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Parainfluenzae virus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Sinusitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Bronchopulmonary aspergillosis	1 (3.1)	0	0	0	1 (3.1)
Cystitis	1 (3.1)	0	1 (3.1)	0	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Ear, nose and throat infection	1 (3.1)	0	1 (3.1)	0	0
Enterobacter infection	1 (3.1)	0	0	1 (3.1)	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Mastoiditis	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (3.1)	0	1 (3.1)	0	0
Otitis externa	1 (3.1)	0	0	1 (3.1)	0
Otitis media	1 (3.1)	0	0	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection viral	1 (3.1)	0	1 (3.1)	0	0
Rhinitis	1 (3.1)	0	1 (3.1)	0	0
Septic shock	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal skin infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	6 (18.8)	0	6 (18.8)	0	0
Hypogammaglobulinaemia	5 (15.6)	0	5 (15.6)	0	0
B-cell aplasia	1 (3.1)	0	1 (3.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Mental status changes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (48.3)	2 (6.9)	3 (10.3)	7 (24.1)	2 (6.9)
Cytokine Release Syndrome					
-Total	1 (3.4)	0	0	0	1 (3.4)
Haemophagocytic lymphohistiocytosis	1 (3.4)	0	0	0	1 (3.4)
Hematological disorders including cytopenias					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Agranulocytosis	1 (3.4)	0	0	1 (3.4)	0
Anaemia	1 (3.4)	0	1 (3.4)	0	0
Neutrophil count decreased	1 (3.4)	1 (3.4)	0	0	0
Platelet count decreased	1 (3.4)	1 (3.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Infections					
-Total	13 (44.8)	2 (6.9)	2 (6.9)	7 (24.1)	2 (6.9)
Conjunctivitis	4 (13.8)	2 (6.9)	2 (6.9)	0	0
Covid-19	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Influenza	2 (6.9)	0	1 (3.4)	0	1 (3.4)
Oral herpes	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Pneumonia	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Rhinovirus infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Sepsis	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Skin infection	2 (6.9)	0	2 (6.9)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Acute sinusitis	1 (3.4)	0	1 (3.4)	0	0
Candida infection	1 (3.4)	0	1 (3.4)	0	0
Clostridium difficile colitis	1 (3.4)	0	0	1 (3.4)	0
Covid-19 pneumonia	1 (3.4)	0	0	0	1 (3.4)

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (3.4)	0	0	1 (3.4)	0
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis escherichia coli	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis salmonella	1 (3.4)	0	0	1 (3.4)	0
Herpes virus infection	1 (3.4)	0	1 (3.4)	0	0
Herpes zoster	1 (3.4)	0	1 (3.4)	0	0
Ophthalmic herpes zoster	1 (3.4)	0	1 (3.4)	0	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	0	0	1 (3.4)	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Staphylococcal abscess	1 (3.4)	0	0	1 (3.4)	0
Staphylococcal bacteraemia	1 (3.4)	0	0	1 (3.4)	0
Streptococcal sepsis	1 (3.4)	0	1 (3.4)	0	0
Syphilis	1 (3.4)	0	1 (3.4)	0	0
Viral skin infection	1 (3.4)	1 (3.4)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (3.4)	0	1 (3.4)	0	0
Blood immunoglobulin g decreased	1 (3.4)	0	1 (3.4)	0	0
Serious neurological adverse reactions					
-Total	1 (3.4)	0	1 (3.4)	0	0
Dysarthria	1 (3.4)	0	1 (3.4)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (61.9)	1 (4.8)	6 (28.6)	3 (14.3)	3 (14.3)
Hematological disorders including cytopenias					
-Total	5 (23.8)	2 (9.5)	0	1 (4.8)	2 (9.5)
Neutrophil count decreased	2 (9.5)	1 (4.8)	0	0	1 (4.8)
Neutropenia	1 (4.8)	0	0	0	1 (4.8)
Neutropenic infection	1 (4.8)	0	0	1 (4.8)	0
Platelet count decreased	1 (4.8)	1 (4.8)	0	0	0
Infections					
-Total	10 (47.6)	0	5 (23.8)	3 (14.3)	2 (9.5)
Sinusitis	4 (19.0)	0	4 (19.0)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (14.3)	1 (4.8)	2 (9.5)	0	0
Bronchitis	2 (9.5)	0	2 (9.5)	0	0
Fungal infection	2 (9.5)	0	2 (9.5)	0	0
Rhinovirus infection	2 (9.5)	0	2 (9.5)	0	0
Urinary tract infection	2 (9.5)	0	2 (9.5)	0	0
Bronchiolitis	1 (4.8)	0	0	1 (4.8)	0
Device related sepsis	1 (4.8)	0	0	1 (4.8)	0
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Fungal skin infection	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Gastroenteritis viral	1 (4.8)	0	1 (4.8)	0	0
Herpes zoster	1 (4.8)	0	0	1 (4.8)	0
Meningitis pneumococcal	1 (4.8)	0	0	1 (4.8)	0
Nail infection	1 (4.8)	0	1 (4.8)	0	0
Neutropenic infection	1 (4.8)	0	0	1 (4.8)	0
Oral candidiasis	1 (4.8)	0	1 (4.8)	0	0
Otitis media	1 (4.8)	0	1 (4.8)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (4.8)	0	0	1 (4.8)	0
Sepsis	1 (4.8)	0	0	0	1 (4.8)
Septic shock	1 (4.8)	0	0	0	1 (4.8)
Skin infection	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection pseudomonal	1 (4.8)	0	1 (4.8)	0	0
Varicella zoster virus infection	1 (4.8)	0	1 (4.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (14.3)	0	3 (14.3)	0	0
Hypogammaglobulinaemia	3 (14.3)	0	3 (14.3)	0	0
Serious neurological adverse reactions					
-Total	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	0	1 (4.8)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (100)	1 (2.2)	6 (13.0)	13 (28.3)	26 (56.5)
Cytokine Release Syndrome					
-Total	31 (67.4)	3 (6.5)	8 (17.4)	8 (17.4)	12 (26.1)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Haemophagocytic lymphohistiocytosis	4 (8.7)	1 (2.2)	0	2 (4.3)	1 (2.2)
Hematological disorders including cytopenias					
-Total	29 (63.0)	0	2 (4.3)	11 (23.9)	16 (34.8)
Febrile neutropenia	12 (26.1)	0	0	12 (26.1)	0
Neutrophil count decreased	12 (26.1)	1 (2.2)	0	2 (4.3)	9 (19.6)
Platelet count decreased	12 (26.1)	2 (4.3)	2 (4.3)	5 (10.9)	3 (6.5)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	12 (26.1)	1 (2.2)	2 (4.3)	1 (2.2)	8 (17.4)
Anaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Lymphocyte count decreased	7 (15.2)	0	0	4 (8.7)	3 (6.5)
Thrombocytopenia	6 (13.0)	0	0	1 (2.2)	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Leukopenia	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Lymphopenia	2 (4.3)	0	0	2 (4.3)	0
Agranulocytosis	1 (2.2)	0	0	1 (2.2)	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	37 (80.4)	7 (15.2)	9 (19.6)	15 (32.6)	6 (13.0)
Upper respiratory tract infection	8 (17.4)	4 (8.7)	2 (4.3)	2 (4.3)	0
Conjunctivitis	6 (13.0)	2 (4.3)	4 (8.7)	0	0
Pneumonia	6 (13.0)	1 (2.2)	1 (2.2)	2 (4.3)	2 (4.3)
Nasopharyngitis	5 (10.9)	3 (6.5)	2 (4.3)	0	0
Rhinovirus infection	4 (8.7)	0	3 (6.5)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	3 (6.5)	0	3 (6.5)	0	0
Clostridium difficile infection	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Influenza	3 (6.5)	0	2 (4.3)	0	1 (2.2)
Metapneumovirus infection	3 (6.5)	0	0	3 (6.5)	0
Oral herpes	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Otitis media	3 (6.5)	0	3 (6.5)	0	0
Parainfluenzae virus infection	3 (6.5)	1 (2.2)	0	1 (2.2)	1 (2.2)
Staphylococcal bacteraemia	3 (6.5)	0	0	3 (6.5)	0
Staphylococcal infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Bk virus infection	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Covid-19	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Ear infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Gastroenteritis	2 (4.3)	2 (4.3)	0	0	0
Gingivitis	2 (4.3)	2 (4.3)	0	0	0
Herpes zoster	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Nail infection	2 (4.3)	2 (4.3)	0	0	0
Oral infection	2 (4.3)	0	2 (4.3)	0	0
Otitis externa	2 (4.3)	0	2 (4.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	2 (4.3)	0	2 (4.3)	0	0
Pneumocystis jirovecii pneumonia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Respiratory syncytial virus infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Respiratory tract infection	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Rhinitis	2 (4.3)	2 (4.3)	0	0	0
Sepsis	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Sinusitis	2 (4.3)	0	2 (4.3)	0	0
Skin infection	2 (4.3)	0	2 (4.3)	0	0
Skin papilloma	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Viral infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Adenovirus infection	1 (2.2)	0	0	1 (2.2)	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Cellulitis	1 (2.2)	0	1 (2.2)	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Coronavirus infection	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0
Device related infection	1 (2.2)	0	0	1 (2.2)	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis clostridial	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal infection	1 (2.2)	1 (2.2)	0	0	0
Herpes simplex	1 (2.2)	0	1 (2.2)	0	0
Herpes virus infection	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Molluscum contagiosum	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Salmonellosis	1 (2.2)	0	1 (2.2)	0	0
Sinusitis fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Streptococcal sepsis	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Viral haemorrhagic cystitis	1 (2.2)	0	0	1 (2.2)	0
Viral skin infection	1 (2.2)	1 (2.2)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (58.7)	3 (6.5)	16 (34.8)	8 (17.4)	0
Hypogammaglobulinaemia	17 (37.0)	1 (2.2)	13 (28.3)	3 (6.5)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	4 (8.7)	2 (4.3)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Immunodeficiency	3 (6.5)	0	0	3 (6.5)	0
Blood immunoglobulin g decreased	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Immunoglobulins decreased	2 (4.3)	0	2 (4.3)	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	15 (32.6)	8 (17.4)	3 (6.5)	4 (8.7)	0
Delirium	6 (13.0)	2 (4.3)	2 (4.3)	2 (4.3)	0
Confusional state	4 (8.7)	4 (8.7)	0	0	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Agitation	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Dysarthria	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Somnolence	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0
Irritability	1 (2.2)	1 (2.2)	0	0	0
Lethargy	1 (2.2)	1 (2.2)	0	0	0
Memory impairment	1 (2.2)	0	1 (2.2)	0	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Mood altered	1 (2.2)	1 (2.2)	0	0	0
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Tumour Lysis Syndrome					
-Total	3 (6.5)	0	0	3 (6.5)	0
Tumour lysis syndrome	3 (6.5)	0	0	3 (6.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229b
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	2 (5.9)	9 (26.5)	23 (67.6)
Cytokine Release Syndrome					
-Total	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Haemophagocytic lymphohistiocytosis	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	27 (79.4)	1 (2.9)	0	11 (32.4)	15 (44.1)
Anaemia	16 (47.1)	5 (14.7)	5 (14.7)	6 (17.6)	0
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	13 (38.2)	2 (5.9)	2 (5.9)	1 (2.9)	8 (23.5)
Neutrophil count decreased	12 (35.3)	0	2 (5.9)	2 (5.9)	8 (23.5)
Platelet count decreased	12 (35.3)	4 (11.8)	1 (2.9)	2 (5.9)	5 (14.7)
Lymphocyte count decreased	10 (29.4)	1 (2.9)	1 (2.9)	6 (17.6)	2 (5.9)
Neutropenia	7 (20.6)	0	1 (2.9)	2 (5.9)	4 (11.8)
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Leukopenia	1 (2.9)	0	0	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	24 (70.6)	1 (2.9)	5 (14.7)	10 (29.4)	8 (23.5)
Rhinovirus infection	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Sinusitis	5 (14.7)	0	3 (8.8)	2 (5.9)	0
Upper respiratory tract infection	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Gastroenteritis	4 (11.8)	2 (5.9)	0	2 (5.9)	0
Oral candidiasis	3 (8.8)	0	3 (8.8)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Bacteraemia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Bronchitis	2 (5.9)	0	2 (5.9)	0	0
Bronchopulmonary aspergillosis	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Fungal infection	2 (5.9)	0	2 (5.9)	0	0
Nail infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Nasopharyngitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Otitis media	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Septic shock	2 (5.9)	0	0	0	2 (5.9)
Staphylococcal bacteraemia	2 (5.9)	0	0	2 (5.9)	0
Staphylococcal infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bronchiolitis	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Cystitis	1 (2.9)	0	1 (2.9)	0	0
Device related sepsis	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	1 (2.9)	0	0
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis viral	1 (2.9)	0	1 (2.9)	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Localised infection	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia respiratory syncytial viral	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Rhinitis	1 (2.9)	0	1 (2.9)	0	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Urinary tract infection viral	1 (2.9)	1 (2.9)	0	0	0
Varicella zoster virus infection	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (58.8)	2 (5.9)	13 (38.2)	5 (14.7)	0
Hypogammaglobulinaemia	16 (47.1)	1 (2.9)	11 (32.4)	4 (11.8)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Blood immunoglobulin g decreased	2 (5.9)	0	2 (5.9)	0	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	20 (58.8)	4 (11.8)	7 (20.6)	9 (26.5)	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Mental status changes	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Agitation	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Confusional state	3 (8.8)	3 (8.8)	0	0	0
Seizure	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Somnolence	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cognitive disorder	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Irritability	2 (5.9)	2 (5.9)	0	0	0
Lethargy	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	0	1 (2.9)	0
Generalised tonic-clonic seizure	1 (2.9)	0	1 (2.9)	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Muscular weakness	1 (2.9)	0	0	1 (2.9)	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Tumour lysis syndrome	2 (5.9)	0	0	1 (2.9)	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (94.9)	3 (5.1)	8 (13.6)	17 (28.8)	28 (47.5)
Cytokine Release Syndrome					
-Total	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Haemophagocytic lymphohistiocytosis	5 (8.5)	1 (1.7)	1 (1.7)	2 (3.4)	1 (1.7)
Hematological disorders including cytopenias					
-Total	37 (62.7)	2 (3.4)	2 (3.4)	15 (25.4)	18 (30.5)
Febrile neutropenia	18 (30.5)	0	0	17 (28.8)	1 (1.7)
Anaemia	16 (27.1)	4 (6.8)	7 (11.9)	5 (8.5)	0
Platelet count decreased	15 (25.4)	3 (5.1)	3 (5.1)	4 (6.8)	5 (8.5)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	15 (25.4)	3 (5.1)	3 (5.1)	2 (3.4)	7 (11.9)
Neutrophil count decreased	13 (22.0)	0	3 (5.1)	1 (1.7)	9 (15.3)
Lymphocyte count decreased	12 (20.3)	2 (3.4)	0	6 (10.2)	4 (6.8)
Neutropenia	6 (10.2)	0	2 (3.4)	1 (1.7)	3 (5.1)
Thrombocytopenia	5 (8.5)	0	0	1 (1.7)	4 (6.8)
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pancytopenia	2 (3.4)	0	0	2 (3.4)	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	24 (40.7)	4 (6.8)	8 (13.6)	10 (16.9)	2 (3.4)
Staphylococcal infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Clostridium difficile infection	4 (6.8)	1 (1.7)	0	3 (5.1)	0
Conjunctivitis	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Candida infection	3 (5.1)	0	2 (3.4)	0	1 (1.7)
Nail infection	2 (3.4)	2 (3.4)	0	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (1.7)	0	0	1 (1.7)	0
Atypical pneumonia	1 (1.7)	1 (1.7)	0	0	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Herpes simplex	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Localised infection	1 (1.7)	1 (1.7)	0	0	0
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	0	1 (1.7)	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	1 (1.7)	0	0
Sinusitis	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Stomatococcal infection	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	31 (52.5)	5 (8.5)	15 (25.4)	11 (18.6)	0
Hypogammaglobulinaemia	18 (30.5)	1 (1.7)	10 (16.9)	7 (11.9)	0
Blood immunoglobulin m decreased	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin a decreased	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Immunodeficiency	3 (5.1)	0	0	3 (5.1)	0
Blood immunoglobulin g decreased	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Selective igg subclass deficiency	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	22 (37.3)	10 (16.9)	4 (6.8)	8 (13.6)	0
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Somnolence	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Tremor	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Agitation	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Hallucination	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Irritability	3 (5.1)	3 (5.1)	0	0	0
Mental status changes	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	0	0	1 (1.7)	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0
Generalised tonic-clonic seizure	1 (1.7)	0	1 (1.7)	0	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0
Seizure	1 (1.7)	0	0	1 (1.7)	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	3 (30.0)	6 (60.0)
Cytokine Release Syndrome					
-Total	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hematological disorders including cytopenias					
-Total	7 (70.0)	0	0	1 (10.0)	6 (60.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Leukopenia	1 (10.0)	0	0	0	1 (10.0)
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0
Infections					
-Total	7 (70.0)	2 (20.0)	1 (10.0)	3 (30.0)	1 (10.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (30.0)	0	3 (30.0)	0	0
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0

Timing: within 8 weeks post infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	1 (10.0)	0	0
Tumour Lysis Syndrome					
-Total	2 (20.0)	0	0	2 (20.0)	0
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	0	0	10 (90.9)
Cytokine Release Syndrome					
-Total	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Hematological disorders including cytopenias					
-Total	9 (81.8)	0	0	3 (27.3)	6 (54.5)
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Anaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Infections					
-Total	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Adenovirus infection	1 (9.1)	0	0	1 (9.1)	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hypogammaglobulinaemia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Serious neurological adverse reactions					
-Total	7 (63.6)	3 (27.3)	3 (27.3)	1 (9.1)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Agitation	1 (9.1)	1 (9.1)	0	0	0
Amnesia	1 (9.1)	0	1 (9.1)	0	0
Hallucination, visual	1 (9.1)	0	1 (9.1)	0	0
Lethargy	1 (9.1)	1 (9.1)	0	0	0
Tremor	1 (9.1)	1 (9.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (9.1)	0	0	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (74.5)	5 (9.1)	15 (27.3)	10 (18.2)	11 (20.0)
Hematological disorders including cytopenias					
-Total	18 (32.7)	4 (7.3)	3 (5.5)	7 (12.7)	4 (7.3)
Neutrophil count decreased	8 (14.5)	1 (1.8)	1 (1.8)	3 (5.5)	3 (5.5)
White blood cell count decreased	8 (14.5)	3 (5.5)	2 (3.6)	2 (3.6)	1 (1.8)
Anaemia	5 (9.1)	4 (7.3)	0	1 (1.8)	0
Lymphocyte count decreased	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Platelet count decreased	4 (7.3)	2 (3.6)	0	1 (1.8)	1 (1.8)
Febrile neutropenia	2 (3.6)	0	0	2 (3.6)	0
Neutropenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.8)	0	1 (1.8)	0	0
Myelodysplastic syndrome	1 (1.8)	0	0	1 (1.8)	0
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	32 (58.2)	3 (5.5)	15 (27.3)	7 (12.7)	7 (12.7)
Upper respiratory tract infection	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0
Gastroenteritis	5 (9.1)	3 (5.5)	0	2 (3.6)	0
Nasopharyngitis	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Metapneumovirus infection	3 (5.5)	0	0	3 (5.5)	0
Parainfluenzae virus infection	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Pneumonia	3 (5.5)	1 (1.8)	1 (1.8)	0	1 (1.8)
Sinusitis	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Pneumocystis jirovecii pneumonia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Respiratory syncytial virus infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Respiratory tract infection	2 (3.6)	0	2 (3.6)	0	0
Rhinitis	2 (3.6)	1 (1.8)	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Cystitis	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Ear infection	1 (1.8)	0	1 (1.8)	0	0
Ear, nose and throat infection	1 (1.8)	0	1 (1.8)	0	0
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (1.8)	0	1 (1.8)	0	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	0	1 (1.8)	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection viral	1 (1.8)	0	1 (1.8)	0	0
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Septic shock	1 (1.8)	0	0	0	1 (1.8)
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Staphylococcal skin infection	1 (1.8)	0	1 (1.8)	0	0
Tinea pedis	1 (1.8)	1 (1.8)	0	0	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	0	1 (1.8)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (16.4)	1 (1.8)	7 (12.7)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	6 (10.9)	0	6 (10.9)	0	0
Blood immunoglobulin a decreased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
B-cell aplasia	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin m decreased	1 (1.8)	0	0	1 (1.8)	0
Immunoglobulins decreased	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	3 (5.5)	1 (1.8)	1 (1.8)	1 (1.8)	0
Agitation	1 (1.8)	1 (1.8)	0	0	0
Memory impairment	1 (1.8)	0	1 (1.8)	0	0
Mental status changes	1 (1.8)	0	1 (1.8)	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Seizure	1 (1.8)	0	0	1 (1.8)	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	0	1 (1.8)
Tumour lysis syndrome	1 (1.8)	0	0	0	1 (1.8)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

			All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (66.7)	0	1 (11.1)	1 (11.1)	4 (44.4)
Hematological disorders including cytopenias					
-Total	5 (55.6)	0	0	1 (11.1)	4 (44.4)
Neutropenia	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Lymphopenia	1 (11.1)	0	0	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
White blood cell count decreased	1 (11.1)	0	0	1 (11.1)	0
Infections					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Cytomegalovirus infection reactivation	1 (11.1)	0	0	1 (11.1)	0
Human herpesvirus 6 infection	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Viral infection	1 (11.1)	0	0	1 (11.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (22.2)	0	2 (22.2)	0	0
Hypogammaglobulinaemia	2 (22.2)	0	2 (22.2)	0	0
Serious neurological adverse reactions					
-Total	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	1 (9.1)	5 (45.5)	1 (9.1)
Hematological disorders including cytopenias					
-Total	3 (27.3)	2 (18.2)	0	1 (9.1)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Platelet count decreased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0	0	0
Infections					
-Total	6 (54.5)	1 (9.1)	0	4 (36.4)	1 (9.1)
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Ear infection	1 (9.1)	0	1 (9.1)	0	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Nail infection	1 (9.1)	1 (9.1)	0	0	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Parainfluenzae virus infection	1 (9.1)	0	1 (9.1)	0	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Hypogammaglobulinaemia	2 (18.2)	0	2 (18.2)	0	0
Blood immunoglobulin g decreased	1 (9.1)	0	1 (9.1)	0	0
Immunodeficiency	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (53.8)	2 (5.1)	6 (15.4)	9 (23.1)	4 (10.3)
Hematological disorders including cytopenias					
-Total	6 (15.4)	2 (5.1)	0	2 (5.1)	2 (5.1)
Neutrophil count decreased	2 (5.1)	1 (2.6)	0	0	1 (2.6)
Platelet count decreased	2 (5.1)	2 (5.1)	0	0	0
Agranulocytosis	1 (2.6)	0	0	1 (2.6)	0
Anaemia	1 (2.6)	0	1 (2.6)	0	0
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Neutropenic infection	1 (2.6)	0	0	1 (2.6)	0
Thrombocytopenia	1 (2.6)	0	1 (2.6)	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	18 (46.2)	2 (5.1)	4 (10.3)	9 (23.1)	3 (7.7)
Sinusitis	5 (12.8)	0	5 (12.8)	0	0
Conjunctivitis	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Rhinovirus infection	3 (7.7)	0	3 (7.7)	0	0
Sepsis	3 (7.7)	0	0	1 (2.6)	2 (5.1)
Upper respiratory tract infection	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Bronchitis	2 (5.1)	0	2 (5.1)	0	0
Fungal infection	2 (5.1)	0	2 (5.1)	0	0
Herpes zoster	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Oral herpes	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Skin infection	2 (5.1)	0	2 (5.1)	0	0
Urinary tract infection	2 (5.1)	0	2 (5.1)	0	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Bronchiolitis	1 (2.6)	0	0	1 (2.6)	0
Candida infection	1 (2.6)	0	1 (2.6)	0	0
Clostridium difficile colitis	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (2.6)	0	0	1 (2.6)	0
Device related sepsis	1 (2.6)	0	0	1 (2.6)	0
Ear infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	1 (2.6)	0	0	0
Gastroenteritis escherichia coli	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis salmonella	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis viral	1 (2.6)	0	1 (2.6)	0	0
Herpes virus infection	1 (2.6)	0	1 (2.6)	0	0
Influenza	1 (2.6)	0	1 (2.6)	0	0
Meningitis pneumococcal	1 (2.6)	0	0	1 (2.6)	0
Nail infection	1 (2.6)	0	1 (2.6)	0	0
Neutropenic infection	1 (2.6)	0	0	1 (2.6)	0
Ophthalmic herpes zoster	1 (2.6)	0	1 (2.6)	0	0
Oral candidiasis	1 (2.6)	0	1 (2.6)	0	0
Otitis media	1 (2.6)	0	1 (2.6)	0	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Septic shock	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal abscess	1 (2.6)	0	0	1 (2.6)	0
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Streptococcal sepsis	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection pseudomonal	1 (2.6)	0	1 (2.6)	0	0
Viral skin infection	1 (2.6)	1 (2.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (10.3)	0	4 (10.3)	0	0
Hypogammaglobulinaemia	3 (7.7)	0	3 (7.7)	0	0
Blood immunoglobulin g decreased	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	2 (5.1)	0	1 (2.6)	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (2.6)	0	1 (2.6)	0	0
Seizure	1 (2.6)	0	0	1 (2.6)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Infections					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Fungal skin infection	1 (16.7)	0	1 (16.7)	0	0
Otitis media	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	0	1 (16.7)	0
Varicella zoster virus infection	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	0	1 (20.0)
Cytokine Release Syndrome					
-Total	1 (20.0)	0	0	0	1 (20.0)
Haemophagocytic lymphohistiocytosis	1 (20.0)	0	0	0	1 (20.0)
Hematological disorders including cytopenias					
-Total	1 (20.0)	1 (20.0)	0	0	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0	0	0
Infections					
-Total	3 (60.0)	0	2 (40.0)	0	1 (20.0)
Conjunctivitis	1 (20.0)	1 (20.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	1 (20.0)	1 (20.0)	0	0	0
Covid-19 pneumonia	1 (20.0)	0	0	0	1 (20.0)
Enterovirus infection	1 (20.0)	0	0	1 (20.0)	0
Influenza	1 (20.0)	0	0	0	1 (20.0)
Parainfluenzae virus infection	1 (20.0)	0	0	1 (20.0)	0
Pneumonia	1 (20.0)	0	0	0	1 (20.0)
Rhinovirus infection	1 (20.0)	0	0	1 (20.0)	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Syphilis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	1 (1.7)	7 (11.9)	18 (30.5)	33 (55.9)
Cytokine Release Syndrome					
-Total	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Haemophagocytic lymphohistiocytosis	5 (8.5)	1 (1.7)	1 (1.7)	2 (3.4)	1 (1.7)
Hematological disorders including cytopenias					
-Total	39 (66.1)	1 (1.7)	2 (3.4)	17 (28.8)	19 (32.2)
Anaemia	19 (32.2)	6 (10.2)	8 (13.6)	5 (8.5)	0
Febrile neutropenia	19 (32.2)	0	0	18 (30.5)	1 (1.7)
Platelet count decreased	18 (30.5)	5 (8.5)	3 (5.1)	5 (8.5)	5 (8.5)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	17 (28.8)	1 (1.7)	2 (3.4)	3 (5.1)	11 (18.6)
White blood cell count decreased	16 (27.1)	3 (5.1)	4 (6.8)	2 (3.4)	7 (11.9)
Lymphocyte count decreased	14 (23.7)	1 (1.7)	1 (1.7)	8 (13.6)	4 (6.8)
Neutropenia	8 (13.6)	0	2 (3.4)	2 (3.4)	4 (6.8)
Thrombocytopenia	6 (10.2)	0	0	2 (3.4)	4 (6.8)
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pancytopenia	2 (3.4)	0	0	2 (3.4)	0
Agranulocytosis	1 (1.7)	0	0	1 (1.7)	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	45 (76.3)	5 (8.5)	11 (18.6)	18 (30.5)	11 (18.6)
Upper respiratory tract infection	9 (15.3)	4 (6.8)	4 (6.8)	1 (1.7)	0
Conjunctivitis	7 (11.9)	2 (3.4)	5 (8.5)	0	0
Rhinovirus infection	7 (11.9)	0	6 (10.2)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	6 (10.2)	4 (6.8)	0	2 (3.4)	0
Sinusitis	6 (10.2)	0	4 (6.8)	2 (3.4)	0
Staphylococcal infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Candida infection	4 (6.8)	0	3 (5.1)	0	1 (1.7)
Clostridium difficile infection	4 (6.8)	1 (1.7)	0	3 (5.1)	0
Nasopharyngitis	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Pneumonia	4 (6.8)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Metapneumovirus infection	3 (5.1)	0	0	3 (5.1)	0
Nail infection	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Oral candidiasis	3 (5.1)	0	3 (5.1)	0	0
Oral herpes	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Parainfluenzae virus infection	3 (5.1)	1 (1.7)	0	1 (1.7)	1 (1.7)
Rhinitis	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Sepsis	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Acute sinusitis	2 (3.4)	0	2 (3.4)	0	0
Bronchitis	2 (3.4)	0	2 (3.4)	0	0
Bronchopulmonary aspergillosis	2 (3.4)	0	0	1 (1.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Encephalitis	2 (3.4)	0	0	0	2 (3.4)
Fungal infection	2 (3.4)	0	2 (3.4)	0	0
Gastroenteritis viral	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Gingivitis	2 (3.4)	2 (3.4)	0	0	0
Herpes simplex	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Herpes zoster	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Influenza	2 (3.4)	0	2 (3.4)	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0
Otitis media	2 (3.4)	0	2 (3.4)	0	0
Paronychia	2 (3.4)	0	2 (3.4)	0	0
Pneumocystis jirovecii pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Respiratory syncytial virus infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Respiratory tract infection	2 (3.4)	0	2 (3.4)	0	0
Septic shock	2 (3.4)	0	0	0	2 (3.4)
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Skin papilloma	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Urinary tract infection	2 (3.4)	0	2 (3.4)	0	0
Adenovirus infection	1 (1.7)	0	0	1 (1.7)	0
Anal abscess	1 (1.7)	0	0	1 (1.7)	0
Atypical pneumonia	1 (1.7)	1 (1.7)	0	0	0
Bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Bk virus infection	1 (1.7)	0	0	1 (1.7)	0
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	1 (1.7)	0	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile colitis	1 (1.7)	0	0	1 (1.7)	0
Coronavirus infection	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Cystitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0
Ear, nose and throat infection	1 (1.7)	0	1 (1.7)	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis escherichia coli	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis salmonella	1 (1.7)	0	0	1 (1.7)	0
Gastrointestinal infection	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Herpes virus infection	1 (1.7)	0	1 (1.7)	0	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Localised infection	1 (1.7)	1 (1.7)	0	0	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	1 (1.7)	0	0
Salmonellosis	1 (1.7)	0	1 (1.7)	0	0
Sinusitis fungal	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal sepsis	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal skin infection	1 (1.7)	0	1 (1.7)	0	0
Stomatococcal infection	1 (1.7)	0	1 (1.7)	0	0
Streptococcal sepsis	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Tinea pedis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection pseudomonal	1 (1.7)	0	1 (1.7)	0	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral skin infection	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	35 (59.3)	3 (5.1)	20 (33.9)	12 (20.3)	0
Hypogammaglobulinaemia	24 (40.7)	1 (1.7)	16 (27.1)	7 (11.9)	0
Blood immunoglobulin a decreased	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin m decreased	6 (10.2)	3 (5.1)	1 (1.7)	2 (3.4)	0
Blood immunoglobulin g decreased	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Immunodeficiency	3 (5.1)	0	0	3 (5.1)	0
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Selective igg subclass deficiency	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	25 (42.4)	10 (16.9)	5 (8.5)	10 (16.9)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0
Agitation	5 (8.5)	2 (3.4)	3 (5.1)	0	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Somnolence	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Tremor	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Mental status changes	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Hallucination	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Irritability	3 (5.1)	3 (5.1)	0	0	0
Seizure	3 (5.1)	0	0	3 (5.1)	0
Dysarthria	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised tonic-clonic seizure	1 (1.7)	0	1 (1.7)	0	0
Memory impairment	1 (1.7)	0	1 (1.7)	0	0
Mood altered	1 (1.7)	1 (1.7)	0	0	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Tumour lysis syndrome	2 (3.4)	0	0	1 (1.7)	1 (1.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	3 (30.0)	6 (60.0)
Cytokine Release Syndrome					
-Total	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hematological disorders including cytopenias					
-Total	7 (70.0)	0	0	1 (10.0)	6 (60.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Leukopenia	1 (10.0)	0	0	0	1 (10.0)
Lymphopenia	1 (10.0)	0	0	1 (10.0)	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0
Infections					
-Total	8 (80.0)	2 (20.0)	1 (10.0)	4 (40.0)	1 (10.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Cytomegalovirus infection reactivation	1 (10.0)	0	0	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Fungal skin infection	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	0	1 (10.0)	0
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Nasopharyngitis	1 (10.0)	1 (10.0)	0	0	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Otitis media	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Upper respiratory tract infection	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0
Varicella zoster virus infection	1 (10.0)	0	1 (10.0)	0	0
Viral infection	1 (10.0)	0	0	1 (10.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (50.0)	0	5 (50.0)	0	0
Hypogammaglobulinaemia	5 (50.0)	0	5 (50.0)	0	0
Serious neurological adverse reactions					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Delirium	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	2 (20.0)	0	0	2 (20.0)	0
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229c
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	0	1 (9.1)	10 (90.9)
Cytokine Release Syndrome					
-Total	10 (90.9)	1 (9.1)	1 (9.1)	1 (9.1)	7 (63.6)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Haemophagocytic lymphohistiocytosis	1 (9.1)	0	0	0	1 (9.1)
Hematological disorders including cytopenias					
-Total	10 (90.9)	0	0	4 (36.4)	6 (54.5)
Anaemia	6 (54.5)	1 (9.1)	1 (9.1)	4 (36.4)	0
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Infections					
-Total	8 (72.7)	1 (9.1)	2 (18.2)	3 (27.3)	2 (18.2)
Upper respiratory tract infection	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Parainfluenzae virus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Rhinovirus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	2 (18.2)	0	0	2 (18.2)	0
Adenovirus infection	1 (9.1)	0	0	1 (9.1)	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Covid-19	1 (9.1)	1 (9.1)	0	0	0
Covid-19 pneumonia	1 (9.1)	0	0	0	1 (9.1)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Enterovirus infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Influenza	1 (9.1)	0	0	0	1 (9.1)
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Nail infection	1 (9.1)	1 (9.1)	0	0	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Syphilis	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (63.6)	2 (18.2)	4 (36.4)	1 (9.1)	0
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0
Blood immunoglobulin g decreased	1 (9.1)	0	1 (9.1)	0	0
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Immunodeficiency	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	7 (63.6)	2 (18.2)	3 (27.3)	2 (18.2)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Agitation	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Amnesia	1 (9.1)	0	1 (9.1)	0	0
Hallucination, visual	1 (9.1)	0	1 (9.1)	0	0
Lethargy	1 (9.1)	1 (9.1)	0	0	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0
Tremor	1 (9.1)	1 (9.1)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (9.1)	0	0	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	3 (20.0)	1 (6.7)	11 (73.3)
Cytokine Release Syndrome					
-Total	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Haemophagocytic lymphohistiocytosis	1 (6.7)	0	0	1 (6.7)	0
Hematological disorders including cytopenias					
-Total	9 (60.0)	0	0	4 (26.7)	5 (33.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Infections					
-Total	5 (33.3)	1 (6.7)	1 (6.7)	3 (20.0)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Adenovirus infection	1 (6.7)	0	0	1 (6.7)	0
Atypical pneumonia	1 (6.7)	1 (6.7)	0	0	0
Candida infection	1 (6.7)	0	1 (6.7)	0	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Gastroenteritis norovirus	1 (6.7)	1 (6.7)	0	0	0
Klebsiella bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal infection	1 (6.7)	0	1 (6.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (33.3)	1 (6.7)	3 (20.0)	1 (6.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Selective igg subclass deficiency	1 (6.7)	0	1 (6.7)	0	0
Serious neurological adverse reactions					
-Total	6 (40.0)	0	4 (26.7)	2 (13.3)	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Agitation	1 (6.7)	0	1 (6.7)	0	0
Amnesia	1 (6.7)	0	1 (6.7)	0	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Hallucination, visual	1 (6.7)	0	1 (6.7)	0	0
Mental status changes	1 (6.7)	0	1 (6.7)	0	0
Tremor	1 (6.7)	1 (6.7)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (13.3)	0	0	2 (13.3)	0
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (93.8)	3 (4.6)	6 (9.2)	19 (29.2)	33 (50.8)
Cytokine Release Syndrome					
-Total	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Haemophagocytic lymphohistiocytosis	4 (6.2)	1 (1.5)	1 (1.5)	1 (1.5)	1 (1.5)
Hematological disorders including cytopenias					
-Total	44 (67.7)	2 (3.1)	2 (3.1)	15 (23.1)	25 (38.5)
White blood cell count decreased	21 (32.3)	3 (4.6)	3 (4.6)	2 (3.1)	13 (20.0)
Febrile neutropenia	18 (27.7)	0	0	18 (27.7)	0
Neutrophil count decreased	18 (27.7)	0	3 (4.6)	2 (3.1)	13 (20.0)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	18 (27.7)	4 (6.2)	3 (4.6)	6 (9.2)	5 (7.7)
Anaemia	17 (26.2)	5 (7.7)	7 (10.8)	5 (7.7)	0
Lymphocyte count decreased	15 (23.1)	2 (3.1)	0	8 (12.3)	5 (7.7)
Neutropenia	9 (13.8)	0	2 (3.1)	1 (1.5)	6 (9.2)
Thrombocytopenia	7 (10.8)	0	0	1 (1.5)	6 (9.2)
Leukopenia	3 (4.6)	0	1 (1.5)	1 (1.5)	1 (1.5)
Pancytopenia	2 (3.1)	0	0	2 (3.1)	0
Haemoglobin decreased	1 (1.5)	0	0	1 (1.5)	0
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	30 (46.2)	5 (7.7)	9 (13.8)	13 (20.0)	3 (4.6)
Clostridium difficile infection	4 (6.2)	1 (1.5)	0	3 (4.6)	0
Conjunctivitis	4 (6.2)	0	4 (6.2)	0	0
Staphylococcal infection	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Candida infection	2 (3.1)	0	1 (1.5)	0	1 (1.5)
Nail infection	2 (3.1)	2 (3.1)	0	0	0
Oral herpes	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Oral infection	2 (3.1)	0	2 (3.1)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Oral candidiasis	1 (1.5)	0	1 (1.5)	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.5)	0	1 (1.5)	0	0
Pneumonia	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Varicella zoster virus infection	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	32 (49.2)	6 (9.2)	16 (24.6)	10 (15.4)	0
Hypogammaglobulinaemia	19 (29.2)	1 (1.5)	12 (18.5)	6 (9.2)	0
Blood immunoglobulin m decreased	6 (9.2)	4 (6.2)	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Immunodeficiency	3 (4.6)	0	0	3 (4.6)	0
Blood immunoglobulin g decreased	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Immunoglobulins decreased	2 (3.1)	0	2 (3.1)	0	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	25 (38.5)	13 (20.0)	4 (6.2)	8 (12.3)	0
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Delirium	6 (9.2)	2 (3.1)	2 (3.1)	2 (3.1)	0
Tremor	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Agitation	4 (6.2)	2 (3.1)	2 (3.1)	0	0
Hallucination	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Irritability	3 (4.6)	3 (4.6)	0	0	0
Lethargy	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Muscular weakness	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Seizure	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.1)	0	0	2 (3.1)	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (64.3)	0	2 (14.3)	4 (28.6)	3 (21.4)
Hematological disorders including cytopenias					
-Total	3 (21.4)	0	0	2 (14.3)	1 (7.1)
Anaemia	2 (14.3)	0	0	2 (14.3)	0
Neutrophil count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
White blood cell count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					
-Total	7 (50.0)	0	1 (7.1)	4 (28.6)	2 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=14			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Bacteraemia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Respiratory syncytial virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0
Bk virus infection	1 (7.1)	0	0	1 (7.1)	0
Gastroenteritis	1 (7.1)	1 (7.1)	0	0	0
Gastroenteritis clostridial	1 (7.1)	0	1 (7.1)	0	0
Herpes simplex	1 (7.1)	0	1 (7.1)	0	0
Metapneumovirus infection	1 (7.1)	0	0	1 (7.1)	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Parainfluenzae virus infection	1 (7.1)	0	1 (7.1)	0	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Pneumocystis jirovecii pneumonia	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Septic shock	1 (7.1)	0	0	0	1 (7.1)
Sinusitis fungal	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (21.4)	0	3 (21.4)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Serious neurological adverse reactions					
-Total	1 (7.1)	0	1 (7.1)	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	0	1 (7.1)
Tumour lysis syndrome	1 (7.1)	0	0	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (75.4)	6 (9.8)	15 (24.6)	12 (19.7)	13 (21.3)
Hematological disorders including cytopenias					
-Total	23 (37.7)	6 (9.8)	3 (4.9)	7 (11.5)	7 (11.5)
Neutrophil count decreased	8 (13.1)	2 (3.3)	1 (1.6)	2 (3.3)	3 (4.9)
White blood cell count decreased	8 (13.1)	4 (6.6)	2 (3.3)	2 (3.3)	0
Neutropenia	5 (8.2)	0	0	2 (3.3)	3 (4.9)
Anaemia	4 (6.6)	4 (6.6)	0	0	0
Lymphocyte count decreased	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Platelet count decreased	4 (6.6)	3 (4.9)	0	1 (1.6)	0
Febrile neutropenia	2 (3.3)	0	0	2 (3.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (3.3)	0	0	1 (1.6)	1 (1.6)
Leukopenia	1 (1.6)	0	1 (1.6)	0	0
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	33 (54.1)	5 (8.2)	14 (23.0)	8 (13.1)	6 (9.8)
Nasopharyngitis	7 (11.5)	4 (6.6)	3 (4.9)	0	0
Upper respiratory tract infection	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Gastroenteritis	4 (6.6)	2 (3.3)	0	2 (3.3)	0
Rhinovirus infection	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Parainfluenzae virus infection	3 (4.9)	1 (1.6)	0	1 (1.6)	1 (1.6)
Pneumonia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Respiratory tract infection	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Sinusitis	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Ear infection	2 (3.3)	0	2 (3.3)	0	0
Metapneumovirus infection	2 (3.3)	0	0	2 (3.3)	0
Otitis externa	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Otitis media	2 (3.3)	0	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Skin papilloma	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Viral infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	0	1 (1.6)	0	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	0	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (19.7)	1 (1.6)	9 (14.8)	2 (3.3)	0
Hypogammaglobulinaemia	8 (13.1)	0	8 (13.1)	0	0
Blood immunoglobulin a decreased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
B-cell aplasia	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Agitation	1 (1.6)	1 (1.6)	0	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Memory impairment	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (1.6)	0	0	1 (1.6)	0
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Seizure	1 (1.6)	0	0	1 (1.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	0	3 (42.9)	0	0
Infections					
-Total	3 (42.9)	0	3 (42.9)	0	0
Covid-19	1 (14.3)	1 (14.3)	0	0	0
Otitis media acute	1 (14.3)	0	1 (14.3)	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Syphilis	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	0	1 (14.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (55.8)	3 (7.0)	6 (14.0)	10 (23.3)	5 (11.6)
Cytokine Release Syndrome					
-Total	1 (2.3)	0	0	0	1 (2.3)
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	0	0	1 (2.3)
Hematological disorders including cytopenias					
-Total	7 (16.3)	3 (7.0)	0	2 (4.7)	2 (4.7)
Neutrophil count decreased	3 (7.0)	2 (4.7)	0	0	1 (2.3)
Platelet count decreased	2 (4.7)	2 (4.7)	0	0	0
Agranulocytosis	1 (2.3)	0	0	1 (2.3)	0
Anaemia	1 (2.3)	0	1 (2.3)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0
Thrombocytopenia	1 (2.3)	0	1 (2.3)	0	0
Infections					
-Total	20 (46.5)	2 (4.7)	4 (9.3)	10 (23.3)	4 (9.3)
Sinusitis	6 (14.0)	0	6 (14.0)	0	0
Conjunctivitis	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Rhinovirus infection	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Upper respiratory tract infection	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Sepsis	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Bronchitis	2 (4.7)	0	2 (4.7)	0	0
Fungal infection	2 (4.7)	0	2 (4.7)	0	0
Herpes zoster	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Influenza	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Oral herpes	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Otitis media	2 (4.7)	0	2 (4.7)	0	0
Pneumonia	2 (4.7)	0	0	1 (2.3)	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (4.7)	0	2 (4.7)	0	0
Urinary tract infection	2 (4.7)	0	2 (4.7)	0	0
Acute sinusitis	1 (2.3)	0	1 (2.3)	0	0
Bronchiolitis	1 (2.3)	0	0	1 (2.3)	0
Candida infection	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	0	1 (2.3)	0
Covid-19	1 (2.3)	0	0	1 (2.3)	0
Covid-19 pneumonia	1 (2.3)	0	0	0	1 (2.3)
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	0	1 (2.3)	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Fungal skin infection	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis	1 (2.3)	1 (2.3)	0	0	0
Gastroenteritis escherichia coli	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis salmonella	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	1 (2.3)	0	0
Herpes virus infection	1 (2.3)	0	1 (2.3)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Nail infection	1 (2.3)	0	1 (2.3)	0	0
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0
Ophthalmic herpes zoster	1 (2.3)	0	1 (2.3)	0	0
Oral candidiasis	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Septic shock	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal abscess	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Streptococcal sepsis	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection pseudomonal	1 (2.3)	0	1 (2.3)	0	0
Varicella zoster virus infection	1 (2.3)	0	1 (2.3)	0	0
Viral skin infection	1 (2.3)	1 (2.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (9.3)	0	4 (9.3)	0	0
Hypogammaglobulinaemia	3 (7.0)	0	3 (7.0)	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Dysarthria	1 (2.3)	0	1 (2.3)	0	0
Seizure	1 (2.3)	0	0	1 (2.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	2 (13.3)	1 (6.7)	12 (80.0)
Cytokine Release Syndrome					
-Total	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Haemophagocytic lymphohistiocytosis	1 (6.7)	0	0	1 (6.7)	0
Hematological disorders including cytopenias					
-Total	10 (66.7)	0	0	5 (33.3)	5 (33.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	5 (33.3)	0	1 (6.7)	4 (26.7)	0
Neutrophil count decreased	3 (20.0)	0	0	0	3 (20.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Infections					
-Total	11 (73.3)	0	5 (33.3)	4 (26.7)	2 (13.3)
Upper respiratory tract infection	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Adenovirus infection	2 (13.3)	0	0	2 (13.3)	0
Bacteraemia	2 (13.3)	0	1 (6.7)	0	1 (6.7)
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Atypical pneumonia	1 (6.7)	1 (6.7)	0	0	0
Bk virus infection	1 (6.7)	0	0	1 (6.7)	0
Candida infection	1 (6.7)	0	1 (6.7)	0	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Covid-19	1 (6.7)	1 (6.7)	0	0	0
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Gastroenteritis	1 (6.7)	1 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (6.7)	0	1 (6.7)	0	0
Gastroenteritis norovirus	1 (6.7)	1 (6.7)	0	0	0
Herpes simplex	1 (6.7)	0	1 (6.7)	0	0
Klebsiella bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Metapneumovirus infection	1 (6.7)	0	0	1 (6.7)	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Otitis media acute	1 (6.7)	0	1 (6.7)	0	0
Parainfluenzae virus infection	1 (6.7)	0	1 (6.7)	0	0
Pharyngitis streptococcal	1 (6.7)	0	0	1 (6.7)	0
Pneumocystis jirovecii pneumonia	1 (6.7)	0	0	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Septic shock	1 (6.7)	0	0	0	1 (6.7)
Sinusitis fungal	1 (6.7)	0	0	1 (6.7)	0
Skin infection	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal infection	1 (6.7)	0	1 (6.7)	0	0
Syphilis	1 (6.7)	0	1 (6.7)	0	0
Urinary tract infection	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (53.3)	1 (6.7)	6 (40.0)	1 (6.7)	0
Hypogammaglobulinaemia	6 (40.0)	1 (6.7)	4 (26.7)	1 (6.7)	0
Blood immunoglobulin g decreased	1 (6.7)	0	1 (6.7)	0	0
Selective igg subclass deficiency	1 (6.7)	0	1 (6.7)	0	0
Serious neurological adverse reactions					
-Total	7 (46.7)	0	5 (33.3)	2 (13.3)	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Mental status changes	2 (13.3)	0	2 (13.3)	0	0
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Agitation	1 (6.7)	0	1 (6.7)	0	0
Amnesia	1 (6.7)	0	1 (6.7)	0	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (6.7)	0	1 (6.7)	0	0
Tremor	1 (6.7)	1 (6.7)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Tumour lysis syndrome	3 (20.0)	0	0	2 (13.3)	1 (6.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229d
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (100)	1 (1.5)	6 (9.2)	21 (32.3)	37 (56.9)
Cytokine Release Syndrome					
-Total	48 (73.8)	5 (7.7)	13 (20.0)	16 (24.6)	14 (21.5)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Haemophagocytic lymphohistiocytosis	5 (7.7)	1 (1.5)	1 (1.5)	1 (1.5)	2 (3.1)
Hematological disorders including cytopenias					
-Total	46 (70.8)	1 (1.5)	2 (3.1)	17 (26.2)	26 (40.0)
White blood cell count decreased	22 (33.8)	3 (4.6)	4 (6.2)	2 (3.1)	13 (20.0)
Neutrophil count decreased	21 (32.3)	1 (1.5)	2 (3.1)	4 (6.2)	14 (21.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (32.3)	6 (9.2)	3 (4.6)	7 (10.8)	5 (7.7)
Anaemia	20 (30.8)	7 (10.8)	8 (12.3)	5 (7.7)	0
Febrile neutropenia	19 (29.2)	0	0	19 (29.2)	0
Lymphocyte count decreased	17 (26.2)	1 (1.5)	1 (1.5)	10 (15.4)	5 (7.7)
Neutropenia	11 (16.9)	0	2 (3.1)	2 (3.1)	7 (10.8)
Thrombocytopenia	8 (12.3)	0	0	2 (3.1)	6 (9.2)
Leukopenia	3 (4.6)	0	1 (1.5)	1 (1.5)	1 (1.5)
Lymphopenia	2 (3.1)	0	0	2 (3.1)	0
Pancytopenia	2 (3.1)	0	0	2 (3.1)	0
Agranulocytosis	1 (1.5)	0	0	1 (1.5)	0
Haemoglobin decreased	1 (1.5)	0	0	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	50 (76.9)	8 (12.3)	9 (13.8)	21 (32.3)	12 (18.5)
Upper respiratory tract infection	9 (13.8)	5 (7.7)	2 (3.1)	2 (3.1)	0
Rhinovirus infection	8 (12.3)	0	6 (9.2)	2 (3.1)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	7 (10.8)	1 (1.5)	6 (9.2)	0	0
Nasopharyngitis	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Sinusitis	7 (10.8)	0	5 (7.7)	2 (3.1)	0
Pneumonia	6 (9.2)	1 (1.5)	1 (1.5)	2 (3.1)	2 (3.1)
Gastroenteritis	5 (7.7)	3 (4.6)	0	2 (3.1)	0
Clostridium difficile infection	4 (6.2)	1 (1.5)	0	3 (4.6)	0
Nail infection	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Oral herpes	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Otitis media	4 (6.2)	0	3 (4.6)	1 (1.5)	0
Parainfluenzae virus infection	4 (6.2)	1 (1.5)	0	2 (3.1)	1 (1.5)
Staphylococcal infection	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Candida infection	3 (4.6)	0	2 (3.1)	0	1 (1.5)
Ear infection	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Herpes zoster	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Influenza	3 (4.6)	0	2 (3.1)	0	1 (1.5)
Oral candidiasis	3 (4.6)	0	3 (4.6)	0	0
Otitis externa	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Respiratory tract infection	3 (4.6)	1 (1.5)	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Sepsis	3 (4.6)	0	0	1 (1.5)	2 (3.1)
Staphylococcal bacteraemia	3 (4.6)	0	0	3 (4.6)	0
Acute sinusitis	2 (3.1)	0	2 (3.1)	0	0
Bronchitis	2 (3.1)	0	2 (3.1)	0	0
Bronchopulmonary aspergillosis	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Encephalitis	2 (3.1)	0	0	0	2 (3.1)
Fungal infection	2 (3.1)	0	2 (3.1)	0	0
Gastroenteritis viral	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Gingivitis	2 (3.1)	2 (3.1)	0	0	0
Human herpesvirus 6 infection	2 (3.1)	0	0	2 (3.1)	0
Metapneumovirus infection	2 (3.1)	0	0	2 (3.1)	0
Oral infection	2 (3.1)	0	2 (3.1)	0	0
Paronychia	2 (3.1)	0	2 (3.1)	0	0
Skin infection	2 (3.1)	0	2 (3.1)	0	0
Skin papilloma	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Urinary tract infection	2 (3.1)	0	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Viral infection	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Anal abscess	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchiolitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Coronavirus infection	1 (1.5)	0	0	1 (1.5)	0
Covid-19	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Herpes virus infection	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	0	1 (1.5)
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Salmonellosis	1 (1.5)	0	1 (1.5)	0	0
Septic shock	1 (1.5)	0	0	0	1 (1.5)
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal skin infection	1 (1.5)	0	1 (1.5)	0	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Streptococcal sepsis	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	39 (60.0)	4 (6.2)	23 (35.4)	12 (18.5)	0
Hypogammaglobulinaemia	27 (41.5)	1 (1.5)	20 (30.8)	6 (9.2)	0
Blood immunoglobulin a decreased	7 (10.8)	5 (7.7)	1 (1.5)	1 (1.5)	0
Blood immunoglobulin m decreased	7 (10.8)	4 (6.2)	1 (1.5)	2 (3.1)	0
Immunodeficiency	4 (6.2)	0	0	4 (6.2)	0
Blood immunoglobulin g decreased	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Immunoglobulins decreased	2 (3.1)	0	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	28 (43.1)	12 (18.5)	5 (7.7)	11 (16.9)	0
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Delirium	7 (10.8)	2 (3.1)	3 (4.6)	2 (3.1)	0
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Agitation	5 (7.7)	3 (4.6)	2 (3.1)	0	0
Tremor	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Seizure	4 (6.2)	0	1 (1.5)	3 (4.6)	0
Hallucination	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Irritability	3 (4.6)	3 (4.6)	0	0	0
Lethargy	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Mental status changes	3 (4.6)	1 (1.5)	0	2 (3.1)	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Dysarthria	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Muscular weakness	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.1)	0	0	2 (3.1)	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	0	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine Release Syndrome					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (95.9)	3 (4.1)	8 (10.8)	19 (25.7)	41 (55.4)
Cytokine Release Syndrome					
-Total	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Hematological disorders including cytopenias					
-Total	49 (66.2)	2 (2.7)	2 (2.7)	18 (24.3)	27 (36.5)
Febrile neutropenia	23 (31.1)	0	0	22 (29.7)	1 (1.4)
White blood cell count decreased	22 (29.7)	3 (4.1)	2 (2.7)	2 (2.7)	15 (20.3)
Platelet count decreased	20 (27.0)	4 (5.4)	3 (4.1)	6 (8.1)	7 (9.5)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	19 (25.7)	4 (5.4)	7 (9.5)	8 (10.8)	0
Neutrophil count decreased	17 (23.0)	0	3 (4.1)	1 (1.4)	13 (17.6)
Lymphocyte count decreased	14 (18.9)	2 (2.7)	0	7 (9.5)	5 (6.8)
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	7 (9.5)	0	0	2 (2.7)	5 (6.8)
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	34 (45.9)	6 (8.1)	10 (13.5)	16 (21.6)	2 (2.7)
Staphylococcal infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Conjunctivitis	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Candida infection	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.1)	0	0	3 (4.1)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.7)	2 (2.7)	0	0	0
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	34 (45.9)	7 (9.5)	17 (23.0)	10 (13.5)	0
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Blood immunoglobulin a decreased	5 (6.8)	4 (5.4)	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	0	1 (1.4)	0
Immunodeficiency	3 (4.1)	0	0	3 (4.1)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	28 (37.8)	12 (16.2)	7 (9.5)	9 (12.2)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Agitation	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	3 (4.1)	3 (4.1)	0	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Mental status changes	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Seizure	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=74 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	4 (5.4)	0	0	4 (5.4)	0
Tumour lysis syndrome	4 (5.4)	0	0	4 (5.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Hematological disorders including cytopenias					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (72.9)	5 (7.1)	15 (21.4)	15 (21.4)	16 (22.9)
Hematological disorders including cytopenias					
-Total	24 (34.3)	5 (7.1)	3 (4.3)	8 (11.4)	8 (11.4)
White blood cell count decreased	9 (12.9)	4 (5.7)	2 (2.9)	2 (2.9)	1 (1.4)
Neutrophil count decreased	8 (11.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (5.7)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	38 (54.3)	5 (7.1)	13 (18.6)	12 (17.1)	8 (11.4)
Nasopharyngitis	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Upper respiratory tract infection	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Gastroenteritis	4 (5.7)	2 (2.9)	0	2 (2.9)	0
Parainfluenzae virus infection	4 (5.7)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Pneumonia	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Respiratory tract infection	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Sinusitis	3 (4.3)	0	2 (2.9)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (21.4)	1 (1.4)	12 (17.1)	2 (2.9)	0
Hypogammaglobulinaemia	10 (14.3)	0	10 (14.3)	0	0
Blood immunoglobulin a decreased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (55.3)	3 (6.4)	9 (19.1)	9 (19.1)	5 (10.6)
Cytokine Release Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Hematological disorders including cytopenias					
-Total	7 (14.9)	3 (6.4)	0	2 (4.3)	2 (4.3)
Neutrophil count decreased	3 (6.4)	2 (4.3)	0	0	1 (2.1)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
Anaemia	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Infections					
-Total	22 (46.8)	2 (4.3)	7 (14.9)	9 (19.1)	4 (8.5)
Sinusitis	5 (10.6)	0	5 (10.6)	0	0
Upper respiratory tract infection	5 (10.6)	2 (4.3)	2 (4.3)	1 (2.1)	0
Conjunctivitis	4 (8.5)	2 (4.3)	2 (4.3)	0	0
Rhinovirus infection	3 (6.4)	0	2 (4.3)	1 (2.1)	0
Sepsis	3 (6.4)	0	0	1 (2.1)	2 (4.3)
Skin infection	3 (6.4)	0	3 (6.4)	0	0
Bronchitis	2 (4.3)	0	2 (4.3)	0	0
Covid-19	2 (4.3)	1 (2.1)	0	1 (2.1)	0
Fungal infection	2 (4.3)	0	2 (4.3)	0	0
Herpes zoster	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Influenza	2 (4.3)	0	1 (2.1)	0	1 (2.1)
Oral herpes	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Otitis media	2 (4.3)	0	2 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (4.3)	0	2 (4.3)	0	0
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Bronchiolitis	1 (2.1)	0	0	1 (2.1)	0
Candida infection	1 (2.1)	0	1 (2.1)	0	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Enterovirus infection	1 (2.1)	0	0	1 (2.1)	0
Folliculitis	1 (2.1)	0	1 (2.1)	0	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis	1 (2.1)	1 (2.1)	0	0	0
Gastroenteritis viral	1 (2.1)	0	1 (2.1)	0	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Nail infection	1 (2.1)	0	1 (2.1)	0	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0
Pneumonia	1 (2.1)	0	0	0	1 (2.1)
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinitis	1 (2.1)	1 (2.1)	0	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Syphilis	1 (2.1)	0	1 (2.1)	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Varicella zoster virus infection	1 (2.1)	0	1 (2.1)	0	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (8.5)	0	4 (8.5)	0	0
Hypogammaglobulinaemia	3 (6.4)	0	3 (6.4)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)	0	0
Serious neurological adverse reactions					
-Total	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Dysarthria	1 (2.1)	0	1 (2.1)	0	0
Seizure	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229e
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	1 (1.4)	7 (9.5)	20 (27.0)	46 (62.2)
Cytokine Release Syndrome					
-Total	56 (75.7)	4 (5.4)	15 (20.3)	17 (23.0)	20 (27.0)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Hematological disorders including cytopenias					
-Total	52 (70.3)	1 (1.4)	2 (2.7)	21 (28.4)	28 (37.8)
Febrile neutropenia	24 (32.4)	0	0	23 (31.1)	1 (1.4)
Anaemia	23 (31.1)	6 (8.1)	8 (10.8)	9 (12.2)	0
Platelet count decreased	23 (31.1)	6 (8.1)	3 (4.1)	7 (9.5)	7 (9.5)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	23 (31.1)	3 (4.1)	3 (4.1)	2 (2.7)	15 (20.3)
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)
Lymphocyte count decreased	16 (21.6)	1 (1.4)	1 (1.4)	9 (12.2)	5 (6.8)
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	8 (10.8)	0	0	3 (4.1)	5 (6.8)
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Lymphopenia	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	58 (78.4)	8 (10.8)	13 (17.6)	24 (32.4)	13 (17.6)
Upper respiratory tract infection	12 (16.2)	5 (6.8)	4 (5.4)	3 (4.1)	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0
Conjunctivitis	7 (9.5)	2 (2.7)	5 (6.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Otitis media	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Pneumonia	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)
Staphylococcal bacteraemia	5 (6.8)	0	0	5 (6.8)	0
Staphylococcal infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Candida infection	4 (5.4)	0	3 (4.1)	0	1 (1.4)
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Nail infection	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Oral herpes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Bacteraemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Ear infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Herpes zoster	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Influenza	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Oral candidiasis	3 (4.1)	0	3 (4.1)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rhinitis	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Skin infection	3 (4.1)	0	3 (4.1)	0	0
Urinary tract infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Acute sinusitis	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	2 (2.7)	0	0	2 (2.7)	0
Bk virus infection	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Bronchitis	2 (2.7)	0	2 (2.7)	0	0
Bronchopulmonary aspergillosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Covid-19	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.7)	0	2 (2.7)	0	0
Gastroenteritis viral	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gingivitis	2 (2.7)	2 (2.7)	0	0	0
Herpes simplex	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	2 (2.7)	0	0	2 (2.7)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Paronychia	2 (2.7)	0	2 (2.7)	0	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Varicella zoster virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	44 (59.5)	5 (6.8)	27 (36.5)	12 (16.2)	0
Hypogammaglobulinaemia	31 (41.9)	2 (2.7)	23 (31.1)	6 (8.1)	0
Blood immunoglobulin a decreased	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Immunodeficiency	4 (5.4)	0	0	4 (5.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	32 (43.2)	11 (14.9)	9 (12.2)	12 (16.2)	0
Delirium	8 (10.8)	2 (2.7)	3 (4.1)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Agitation	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Mental status changes	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Seizure	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Irritability	3 (4.1)	3 (4.1)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.8)	0	0	4 (5.4)	1 (1.4)
Tumour lysis syndrome	5 (6.8)	0	0	4 (5.4)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Serious neurological adverse reactions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (94.9)	3 (3.8)	9 (11.5)	19 (24.4)	43 (55.1)
Cytokine Release Syndrome					
-Total	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Haemophagocytic lymphohistiocytosis	5 (6.4)	1 (1.3)	1 (1.3)	2 (2.6)	1 (1.3)
Hematological disorders including cytopenias					
-Total	51 (65.4)	2 (2.6)	2 (2.6)	17 (21.8)	30 (38.5)
Febrile neutropenia	25 (32.1)	0	0	23 (29.5)	2 (2.6)
White blood cell count decreased	24 (30.8)	3 (3.8)	3 (3.8)	2 (2.6)	16 (20.5)
Anaemia	21 (26.9)	5 (6.4)	8 (10.3)	8 (10.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (26.9)	4 (5.1)	3 (3.8)	6 (7.7)	8 (10.3)
Neutrophil count decreased	20 (25.6)	0	3 (3.8)	2 (2.6)	15 (19.2)
Lymphocyte count decreased	15 (19.2)	2 (2.6)	0	8 (10.3)	5 (6.4)
Neutropenia	9 (11.5)	0	2 (2.6)	1 (1.3)	6 (7.7)
Thrombocytopenia	8 (10.3)	0	0	2 (2.6)	6 (7.7)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	35 (44.9)	6 (7.7)	10 (12.8)	16 (20.5)	3 (3.8)
Conjunctivitis	5 (6.4)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.4)	0	3 (3.8)	2 (2.6)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.6)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.6)	2 (2.6)	0	0	0
Oral herpes	2 (2.6)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.6)	0	2 (2.6)	0	0
Rhinovirus infection	2 (2.6)	0	2 (2.6)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	37 (47.4)	7 (9.0)	19 (24.4)	11 (14.1)	0
Hypogammaglobulinaemia	23 (29.5)	2 (2.6)	14 (17.9)	7 (9.0)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (7.7)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	5 (6.4)	4 (5.1)	1 (1.3)	0	0
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Blood immunoglobulin g decreased	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Immunoglobulins decreased	2 (2.6)	0	2 (2.6)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	30 (38.5)	13 (16.7)	7 (9.0)	10 (12.8)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (9.0)	7 (9.0)	0	0	0
Delirium	7 (9.0)	2 (2.6)	2 (2.6)	3 (3.8)	0
Tremor	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Agitation	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Somnolence	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Seizure	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.8)	0	0	3 (3.8)	0
Tumour lysis syndrome	3 (3.8)	0	0	3 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
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Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Serious neurological adverse reactions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (72.6)	6 (8.2)	17 (23.3)	15 (20.5)	15 (20.5)
Hematological disorders including cytopenias					
-Total	26 (35.6)	6 (8.2)	3 (4.1)	9 (12.3)	8 (11.0)
Neutrophil count decreased	10 (13.7)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.5)
White blood cell count decreased	10 (13.7)	4 (5.5)	2 (2.7)	3 (4.1)	1 (1.4)
Anaemia	6 (8.2)	4 (5.5)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	38 (52.1)	5 (6.8)	15 (20.5)	11 (15.1)	7 (9.6)
Nasopharyngitis	7 (9.6)	4 (5.5)	3 (4.1)	0	0
Upper respiratory tract infection	7 (9.6)	3 (4.1)	3 (4.1)	1 (1.4)	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.5)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.5)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (19.2)	1 (1.4)	11 (15.1)	2 (2.7)	0
Hypogammaglobulinaemia	9 (12.3)	0	9 (12.3)	0	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	4 (5.5)	1 (1.4)	2 (2.7)	1 (1.4)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Serious neurological adverse reactions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=48			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (54.2)	3 (6.3)	9 (18.8)	9 (18.8)	5 (10.4)
Cytokine Release Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Hematological disorders including cytopenias					
-Total	7 (14.6)	3 (6.3)	0	2 (4.2)	2 (4.2)
Neutrophil count decreased	3 (6.3)	2 (4.2)	0	0	1 (2.1)
Platelet count decreased	2 (4.2)	2 (4.2)	0	0	0
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
Anaemia	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Infections					
-Total	22 (45.8)	2 (4.2)	7 (14.6)	9 (18.8)	4 (8.3)
Sinusitis	6 (12.5)	0	6 (12.5)	0	0
Upper respiratory tract infection	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0
Conjunctivitis	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Skin infection	3 (6.3)	0	3 (6.3)	0	0
Bronchitis	2 (4.2)	0	2 (4.2)	0	0
Covid-19	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Fungal infection	2 (4.2)	0	2 (4.2)	0	0
Herpes zoster	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Influenza	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Oral herpes	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Otitis media	2 (4.2)	0	2 (4.2)	0	0
Pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (4.2)	0	0	0	2 (4.2)
Urinary tract infection	2 (4.2)	0	2 (4.2)	0	0
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Bronchiolitis	1 (2.1)	0	0	1 (2.1)	0
Candida infection	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile colitis	1 (2.1)	0	0	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Enterovirus infection	1 (2.1)	0	0	1 (2.1)	0
Folliculitis	1 (2.1)	0	1 (2.1)	0	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis	1 (2.1)	1 (2.1)	0	0	0
Gastroenteritis escherichia coli	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis salmonella	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis viral	1 (2.1)	0	1 (2.1)	0	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Nail infection	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinitis	1 (2.1)	1 (2.1)	0	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Syphilis	1 (2.1)	0	1 (2.1)	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Varicella zoster virus infection	1 (2.1)	0	1 (2.1)	0	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.3)	0	4 (8.3)	0	0
Hypogammaglobulinaemia	3 (6.3)	0	3 (6.3)	0	0
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)	0	0
Serious neurological adverse reactions					
-Total	1 (2.1)	0	0	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Serious neurological adverse reactions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Tumour Lysis Syndrome					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229f
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (100)	1 (1.3)	8 (10.3)	22 (28.2)	47 (60.3)
Cytokine Release Syndrome					
-Total	59 (75.6)	5 (6.4)	17 (21.8)	16 (20.5)	21 (26.9)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Haemophagocytic lymphohistiocytosis	6 (7.7)	1 (1.3)	1 (1.3)	2 (2.6)	2 (2.6)
Hematological disorders including cytopenias					
-Total	54 (69.2)	1 (1.3)	2 (2.6)	20 (25.6)	31 (39.7)
Febrile neutropenia	26 (33.3)	0	0	24 (30.8)	2 (2.6)
Anaemia	25 (32.1)	7 (9.0)	9 (11.5)	9 (11.5)	0
White blood cell count decreased	25 (32.1)	3 (3.8)	4 (5.1)	2 (2.6)	16 (20.5)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	24 (30.8)	1 (1.3)	2 (2.6)	4 (5.1)	17 (21.8)
Platelet count decreased	24 (30.8)	6 (7.7)	3 (3.8)	7 (9.0)	8 (10.3)
Lymphocyte count decreased	17 (21.8)	1 (1.3)	1 (1.3)	10 (12.8)	5 (6.4)
Neutropenia	11 (14.1)	0	2 (2.6)	2 (2.6)	7 (9.0)
Thrombocytopenia	9 (11.5)	0	0	3 (3.8)	6 (7.7)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphopenia	2 (2.6)	0	0	2 (2.6)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	59 (75.6)	8 (10.3)	14 (17.9)	24 (30.8)	13 (16.7)
Upper respiratory tract infection	12 (15.4)	5 (6.4)	5 (6.4)	2 (2.6)	0
Rhinovirus infection	9 (11.5)	0	7 (9.0)	2 (2.6)	0
Conjunctivitis	8 (10.3)	2 (2.6)	6 (7.7)	0	0
Nasopharyngitis	7 (9.0)	4 (5.1)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Gastroenteritis	6 (7.7)	4 (5.1)	0	2 (2.6)	0
Pneumonia	6 (7.7)	1 (1.3)	1 (1.3)	2 (2.6)	2 (2.6)
Otitis media	5 (6.4)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.4)	1 (1.3)	1 (1.3)	2 (2.6)	1 (1.3)
Staphylococcal bacteraemia	5 (6.4)	0	0	5 (6.4)	0
Staphylococcal infection	5 (6.4)	0	3 (3.8)	2 (2.6)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.6)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Influenza	3 (3.8)	0	2 (2.6)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.6)	1 (1.3)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.6)	1 (1.3)	0
Acute sinusitis	2 (2.6)	0	2 (2.6)	0	0
Adenovirus infection	2 (2.6)	0	0	2 (2.6)	0
Bk virus infection	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.6)	0	2 (2.6)	0	0
Bronchopulmonary aspergillosis	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.6)	0	2 (2.6)	0	0
Gastroenteritis viral	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.6)	2 (2.6)	0	0	0
Herpes simplex	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.6)	0	0	2 (2.6)	0
Oral infection	2 (2.6)	0	2 (2.6)	0	0
Pneumocystis jirovecii pneumonia	2 (2.6)	0	0	1 (1.3)	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.6)	0	0	0	2 (2.6)
Septic shock	2 (2.6)	0	0	0	2 (2.6)
Skin papilloma	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Varicella zoster virus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	46 (59.0)	5 (6.4)	28 (35.9)	13 (16.7)	0
Hypogammaglobulinaemia	32 (41.0)	2 (2.6)	23 (29.5)	7 (9.0)	0
Blood immunoglobulin a decreased	7 (9.0)	5 (6.4)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (9.0)	4 (5.1)	1 (1.3)	2 (2.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Immunoglobulins decreased	2 (2.6)	0	2 (2.6)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	33 (42.3)	12 (15.4)	9 (11.5)	12 (15.4)	0
Delirium	8 (10.3)	2 (2.6)	3 (3.8)	3 (3.8)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (9.0)	7 (9.0)	0	0	0
Agitation	6 (7.7)	3 (3.8)	3 (3.8)	0	0
Tremor	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Mental status changes	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Somnolence	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.6)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.1)	0	0	3 (3.8)	1 (1.3)
Tumour lysis syndrome	4 (5.1)	0	0	3 (3.8)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Hematological disorders including cytopenias					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	1 (100)	0	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	75 (94.9)	2 (2.5)	9 (11.4)	20 (25.3)	44 (55.7)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Hematological disorders including cytopenias					
-Total	52 (65.8)	1 (1.3)	2 (2.5)	19 (24.1)	30 (38.0)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	20 (25.3)	4 (5.1)	8 (10.1)	8 (10.1)	0
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	35 (44.3)	6 (7.6)	10 (12.7)	16 (20.3)	3 (3.8)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	36 (45.6)	6 (7.6)	19 (24.1)	11 (13.9)	0
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	30 (38.0)	12 (15.2)	8 (10.1)	10 (12.7)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Irritability	2 (2.5)	2 (2.5)	0	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.1)	0	0	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Hematological disorders including cytopenias					
-Total	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (73.0)	6 (8.1)	16 (21.6)	16 (21.6)	16 (21.6)
Hematological disorders including cytopenias					
-Total	25 (33.8)	5 (6.8)	3 (4.1)	9 (12.2)	8 (10.8)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	9 (12.2)	3 (4.1)	2 (2.7)	3 (4.1)	1 (1.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	40 (54.1)	5 (6.8)	15 (20.3)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (18.9)	1 (1.4)	11 (14.9)	2 (2.7)	0
Hypogammaglobulinaemia	9 (12.2)	0	9 (12.2)	0	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (54.0)	3 (6.0)	9 (18.0)	10 (20.0)	5 (10.0)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Hematological disorders including cytopenias					
-Total	7 (14.0)	3 (6.0)	0	2 (4.0)	2 (4.0)
Neutrophil count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)
Platelet count decreased	2 (4.0)	2 (4.0)	0	0	0
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Infections					
-Total	23 (46.0)	2 (4.0)	7 (14.0)	10 (20.0)	4 (8.0)
Sinusitis	6 (12.0)	0	6 (12.0)	0	0
Upper respiratory tract infection	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Conjunctivitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Rhinovirus infection	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Sepsis	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Skin infection	3 (6.0)	0	3 (6.0)	0	0
Bronchitis	2 (4.0)	0	2 (4.0)	0	0
Covid-19	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.0)	0	2 (4.0)	0	0
Herpes zoster	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Otitis media	2 (4.0)	0	2 (4.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.0)	0	2 (4.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.0)	0	4 (8.0)	0	0
Hypogammaglobulinaemia	3 (6.0)	0	3 (6.0)	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	0	1 (2.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Hematological disorders including cytopenias					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	1 (100)	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Serious neurological adverse reactions					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229g
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	7 (8.9)	22 (27.8)	49 (62.0)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	17 (21.5)	17 (21.5)	22 (27.8)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Hematological disorders including cytopenias					
-Total	55 (69.6)	0	2 (2.5)	22 (27.8)	31 (39.2)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	24 (30.4)	6 (7.6)	9 (11.4)	9 (11.4)	0
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	24 (30.4)	2 (2.5)	4 (5.1)	2 (2.5)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	61 (77.2)	8 (10.1)	14 (17.7)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	7 (8.9)	4 (5.1)	3 (3.8)	0	0
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Gastroenteritis	6 (7.6)	4 (5.1)	0	2 (2.5)	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	46 (58.2)	5 (6.3)	28 (35.4)	13 (16.5)	0
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0
Blood immunoglobulin a decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (7.6)	3 (3.8)	1 (1.3)	2 (2.5)	0
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	34 (43.0)	11 (13.9)	10 (12.7)	13 (16.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Irritability	2 (2.5)	2 (2.5)	0	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematological disorders including cytopenias					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	75 (94.9)	3 (3.8)	9 (11.4)	20 (25.3)	43 (54.4)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Hematological disorders including cytopenias					
-Total	52 (65.8)	2 (2.5)	2 (2.5)	19 (24.1)	29 (36.7)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
White blood cell count decreased	23 (29.1)	3 (3.8)	3 (3.8)	1 (1.3)	16 (20.3)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	19 (24.1)	0	3 (3.8)	2 (2.5)	14 (17.7)
Lymphocyte count decreased	14 (17.7)	2 (2.5)	0	7 (8.9)	5 (6.3)
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	35 (44.3)	6 (7.6)	10 (12.7)	16 (20.3)	3 (3.8)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	36 (45.6)	7 (8.9)	18 (22.8)	11 (13.9)	0
Hypogammaglobulinaemia	22 (27.8)	2 (2.5)	13 (16.5)	7 (8.9)	0
Blood immunoglobulin m decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	5 (6.3)	4 (5.1)	1 (1.3)	0	0
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	31 (39.2)	13 (16.5)	8 (10.1)	10 (12.7)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.1)	0	0	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematological disorders including cytopenias					
-Total	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Cystitis	1 (100)	0	1 (100)	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (73.0)	6 (8.1)	17 (23.0)	16 (21.6)	15 (20.3)
Hematological disorders including cytopenias					
-Total	25 (33.8)	6 (8.1)	3 (4.1)	9 (12.2)	7 (9.5)
Neutrophil count decreased	9 (12.2)	2 (2.7)	1 (1.4)	3 (4.1)	3 (4.1)
White blood cell count decreased	9 (12.2)	4 (5.4)	2 (2.7)	2 (2.7)	1 (1.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	39 (52.7)	5 (6.8)	14 (18.9)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (20.3)	1 (1.4)	12 (16.2)	2 (2.7)	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Hematological disorders including cytopenias					
-Total	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (53.1)	3 (6.1)	8 (16.3)	10 (20.4)	5 (10.2)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Hematological disorders including cytopenias					
-Total	6 (12.2)	2 (4.1)	0	2 (4.1)	2 (4.1)
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Platelet count decreased	1 (2.0)	1 (2.0)	0	0	0
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Infections					
-Total	22 (44.9)	2 (4.1)	6 (12.2)	10 (20.4)	4 (8.2)
Sinusitis	6 (12.2)	0	6 (12.2)	0	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Skin infection	3 (6.1)	0	3 (6.1)	0	0
Covid-19	2 (4.1)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.1)	0	2 (4.1)	0	0
Herpes zoster	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Otitis media	2 (4.1)	0	2 (4.1)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.1)	0	2 (4.1)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	1 (2.0)	0	1 (2.0)	0	0
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (8.2)	0	4 (8.2)	0	0
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	0	1 (2.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematological disorders including cytopenias					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cystitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229h
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	8 (10.1)	22 (27.8)	48 (60.8)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	17 (21.5)	17 (21.5)	22 (27.8)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Hematological disorders including cytopenias					
-Total	55 (69.6)	1 (1.3)	2 (2.5)	22 (27.8)	30 (38.0)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	24 (30.4)	3 (3.8)	4 (5.1)	1 (1.3)	16 (20.3)
Neutrophil count decreased	23 (29.1)	1 (1.3)	2 (2.5)	4 (5.1)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)
Lymphocyte count decreased	16 (20.3)	1 (1.3)	1 (1.3)	9 (11.4)	5 (6.3)
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	60 (75.9)	8 (10.1)	13 (16.5)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Nasopharyngitis	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	2 (2.5)	2 (2.5)	0	0	0
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	46 (58.2)	5 (6.3)	28 (35.4)	13 (16.5)	0
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0
Blood immunoglobulin a decreased	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (8.9)	4 (5.1)	1 (1.3)	2 (2.5)	0
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	35 (44.3)	12 (15.2)	10 (12.7)	13 (16.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	75 (94.9)	3 (3.8)	8 (10.1)	20 (25.3)	44 (55.7)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Hematological disorders including cytopenias					
-Total	53 (67.1)	2 (2.5)	2 (2.5)	19 (24.1)	30 (38.0)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	34 (43.0)	6 (7.6)	9 (11.4)	16 (20.3)	3 (3.8)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	37 (46.8)	7 (8.9)	19 (24.1)	11 (13.9)	0
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	5 (6.3)	4 (5.1)	1 (1.3)	0	0
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	31 (39.2)	13 (16.5)	8 (10.1)	10 (12.7)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.1)	0	0	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (74.3)	6 (8.1)	17 (23.0)	16 (21.6)	16 (21.6)
Hematological disorders including cytopenias					
-Total	26 (35.1)	6 (8.1)	3 (4.1)	9 (12.2)	8 (10.8)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	10 (13.5)	4 (5.4)	2 (2.7)	3 (4.1)	1 (1.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	40 (54.1)	5 (6.8)	15 (20.3)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (20.3)	1 (1.4)	12 (16.2)	2 (2.7)	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (55.1)	3 (6.1)	9 (18.4)	10 (20.4)	5 (10.2)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Hematological disorders including cytopenias					
-Total	7 (14.3)	3 (6.1)	0	2 (4.1)	2 (4.1)
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)
Platelet count decreased	2 (4.1)	2 (4.1)	0	0	0
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Infections					
-Total	23 (46.9)	2 (4.1)	7 (14.3)	10 (20.4)	4 (8.2)
Sinusitis	6 (12.2)	0	6 (12.2)	0	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Skin infection	3 (6.1)	0	3 (6.1)	0	0
Bronchitis	2 (4.1)	0	2 (4.1)	0	0
Covid-19	2 (4.1)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.1)	0	2 (4.1)	0	0
Herpes zoster	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Otitis media	2 (4.1)	0	2 (4.1)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.1)	0	2 (4.1)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.2)	0	4 (8.2)	0	0
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	0	1 (2.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Infections					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229i
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	7 (8.9)	22 (27.8)	49 (62.0)
Cytokine Release Syndrome					
-Total	61 (77.2)	5 (6.3)	17 (21.5)	17 (21.5)	22 (27.8)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Hematological disorders including cytopenias					
-Total	56 (70.9)	1 (1.3)	2 (2.5)	22 (27.8)	31 (39.2)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0
White blood cell count decreased	25 (31.6)	3 (3.8)	4 (5.1)	2 (2.5)	16 (20.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)
Platelet count decreased	24 (30.4)	6 (7.6)	3 (3.8)	7 (8.9)	8 (10.1)
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	60 (75.9)	8 (10.1)	13 (16.5)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Nasopharyngitis	7 (8.9)	4 (5.1)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Gastroenteritis	6 (7.6)	4 (5.1)	0	2 (2.5)	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	47 (59.5)	5 (6.3)	29 (36.7)	13 (16.5)	0
Hypogammaglobulinaemia	33 (41.8)	2 (2.5)	24 (30.4)	7 (8.9)	0
Blood immunoglobulin a decreased	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	7 (8.9)	4 (5.1)	1 (1.3)	2 (2.5)	0
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	35 (44.3)	12 (15.2)	10 (12.7)	13 (16.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (88.9)	2 (7.4)	3 (11.1)	7 (25.9)	12 (44.4)
Cytokine Release Syndrome					
-Total	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Hematological disorders including cytopenias					
-Total	15 (55.6)	2 (7.4)	1 (3.7)	4 (14.8)	8 (29.6)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
White blood cell count decreased	7 (25.9)	0	1 (3.7)	1 (3.7)	5 (18.5)
Lymphocyte count decreased	6 (22.2)	2 (7.4)	0	2 (7.4)	2 (7.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (18.5)	1 (3.7)	1 (3.7)	1 (3.7)	2 (7.4)
Anaemia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Febrile neutropenia	3 (11.1)	0	0	3 (11.1)	0
Neutropenia	3 (11.1)	0	1 (3.7)	0	2 (7.4)
Thrombocytopenia	2 (7.4)	0	0	0	2 (7.4)
Haemoglobin decreased	1 (3.7)	0	0	1 (3.7)	0
Infections					
-Total	16 (59.3)	4 (14.8)	5 (18.5)	5 (18.5)	2 (7.4)
Clostridium difficile infection	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Conjunctivitis	2 (7.4)	0	2 (7.4)	0	0
Oral infection	2 (7.4)	0	2 (7.4)	0	0
Staphylococcal infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Anal abscess	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Bk virus infection	1 (3.7)	1 (3.7)	0	0	0
Bronchopulmonary aspergillosis	1 (3.7)	0	0	1 (3.7)	0
Cholecystitis infective	1 (3.7)	0	1 (3.7)	0	0
Encephalitis	1 (3.7)	0	0	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Gastroenteritis norovirus	1 (3.7)	1 (3.7)	0	0	0
Localised infection	1 (3.7)	1 (3.7)	0	0	0
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Myringitis	1 (3.7)	1 (3.7)	0	0	0
Nail infection	1 (3.7)	1 (3.7)	0	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Paronychia	1 (3.7)	0	1 (3.7)	0	0
Pneumonia	1 (3.7)	0	0	1 (3.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	11 (40.7)	2 (7.4)	5 (18.5)	4 (14.8)	0
Hypogammaglobulinaemia	7 (25.9)	1 (3.7)	3 (11.1)	3 (11.1)	0
Blood immunoglobulin m decreased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blood immunoglobulin a decreased	1 (3.7)	1 (3.7)	0	0	0
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (3.7)	0	0	1 (3.7)	0
Immunoglobulins decreased	1 (3.7)	0	1 (3.7)	0	0
Serious neurological adverse reactions					
-Total	8 (29.6)	5 (18.5)	1 (3.7)	2 (7.4)	0
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Confusional state	2 (7.4)	2 (7.4)	0	0	0
Mental status changes	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Agitation	1 (3.7)	0	1 (3.7)	0	0
Dysphagia	1 (3.7)	0	0	1 (3.7)	0
Generalised tonic-clonic seizure	1 (3.7)	0	1 (3.7)	0	0
Irritability	1 (3.7)	1 (3.7)	0	0	0
Seizure	1 (3.7)	0	1 (3.7)	0	0
Somnolence	1 (3.7)	0	0	1 (3.7)	0
Tumour Lysis Syndrome					
-Total	2 (7.4)	0	0	2 (7.4)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (7.4)	0	0	2 (7.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (98.1)	1 (1.9)	6 (11.3)	13 (24.5)	32 (60.4)
Cytokine Release Syndrome					
-Total	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	0	1 (1.9)	0
Hematological disorders including cytopenias					
-Total	38 (71.7)	0	1 (1.9)	15 (28.3)	22 (41.5)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	17 (32.1)	3 (5.7)	6 (11.3)	8 (15.1)	0
White blood cell count decreased	17 (32.1)	3 (5.7)	2 (3.8)	1 (1.9)	11 (20.8)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	16 (30.2)	3 (5.7)	2 (3.8)	5 (9.4)	6 (11.3)
Neutrophil count decreased	13 (24.5)	0	2 (3.8)	2 (3.8)	9 (17.0)
Lymphocyte count decreased	9 (17.0)	0	0	6 (11.3)	3 (5.7)
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Leukopenia	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)
Pancytopenia	2 (3.8)	0	0	2 (3.8)	0
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	19 (35.8)	2 (3.8)	5 (9.4)	11 (20.8)	1 (1.9)
Candida infection	3 (5.7)	0	2 (3.8)	0	1 (1.9)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Staphylococcal bacteraemia	3 (5.7)	0	0	3 (5.7)	0
Staphylococcal infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Clostridium difficile infection	2 (3.8)	0	0	2 (3.8)	0
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Rhinovirus infection	2 (3.8)	0	2 (3.8)	0	0
Adenovirus infection	1 (1.9)	0	0	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Gingivitis	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes simplex	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	0	1 (1.9)	0	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	26 (49.1)	5 (9.4)	14 (26.4)	7 (13.2)	0
Hypogammaglobulinaemia	16 (30.2)	1 (1.9)	11 (20.8)	4 (7.5)	0
Blood immunoglobulin a decreased	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Immunodeficiency	2 (3.8)	0	0	2 (3.8)	0
B-cell aplasia	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin g decreased	1 (1.9)	1 (1.9)	0	0	0
Immunoglobulins decreased	1 (1.9)	0	1 (1.9)	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	23 (43.4)	8 (15.1)	7 (13.2)	8 (15.1)	0
Confusional state	5 (9.4)	5 (9.4)	0	0	0
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Delirium	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Somnolence	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Cognitive disorder	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Hallucination	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Lethargy	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Mental status changes	1 (1.9)	0	1 (1.9)	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (1.9)	0	0	1 (1.9)	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.8)	0	0	2 (3.8)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=25			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (60.0)	0	4 (16.0)	6 (24.0)	5 (20.0)
Hematological disorders including cytopenias					
-Total	8 (32.0)	1 (4.0)	1 (4.0)	4 (16.0)	2 (8.0)
Neutropenia	3 (12.0)	0	0	2 (8.0)	1 (4.0)
Platelet count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Anaemia	1 (4.0)	1 (4.0)	0	0	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	0	1 (4.0)	0	0
Neutrophil count decreased	1 (4.0)	0	0	0	1 (4.0)
Thrombocytopenia	1 (4.0)	0	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (4.0)	1 (4.0)	0	0	0
Infections					
-Total	12 (48.0)	2 (8.0)	4 (16.0)	3 (12.0)	3 (12.0)
Nasopharyngitis	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Sinusitis	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Gastroenteritis	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rhinovirus infection	2 (8.0)	0	2 (8.0)	0	0
Coronavirus infection	1 (4.0)	0	0	1 (4.0)	0
Device related infection	1 (4.0)	0	0	1 (4.0)	0
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Gastroenteritis viral	1 (4.0)	1 (4.0)	0	0	0
Influenza	1 (4.0)	0	1 (4.0)	0	0
Metapneumovirus infection	1 (4.0)	0	0	1 (4.0)	0
Nail infection	1 (4.0)	1 (4.0)	0	0	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	0	0	1 (4.0)
Pneumonia	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (4.0)	0	1 (4.0)	0	0
Septic shock	1 (4.0)	0	0	0	1 (4.0)
Staphylococcal sepsis	1 (4.0)	0	0	0	1 (4.0)
Tinea pedis	1 (4.0)	1 (4.0)	0	0	0
Viral infection	1 (4.0)	0	1 (4.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (20.0)	0	3 (12.0)	2 (8.0)	0
Hypogammaglobulinaemia	3 (12.0)	0	3 (12.0)	0	0
Blood immunoglobulin a decreased	1 (4.0)	0	0	1 (4.0)	0
Blood immunoglobulin m decreased	1 (4.0)	0	0	1 (4.0)	0
Immunodeficiency	1 (4.0)	0	0	1 (4.0)	0
Serious neurological adverse reactions					
-Total	1 (4.0)	0	1 (4.0)	0	0
Mental status changes	1 (4.0)	0	1 (4.0)	0	0
Tumour Lysis Syndrome					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.0)	0	0	0	1 (4.0)
Tumour lysis syndrome	1 (4.0)	0	0	0	1 (4.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (80.0)	6 (12.0)	13 (26.0)	10 (20.0)	11 (22.0)
Hematological disorders including cytopenias					
-Total	18 (36.0)	5 (10.0)	2 (4.0)	5 (10.0)	6 (12.0)
Neutrophil count decreased	9 (18.0)	2 (4.0)	1 (2.0)	3 (6.0)	3 (6.0)
White blood cell count decreased	9 (18.0)	3 (6.0)	2 (4.0)	3 (6.0)	1 (2.0)
Anaemia	5 (10.0)	3 (6.0)	0	2 (4.0)	0
Lymphocyte count decreased	3 (6.0)	1 (2.0)	0	2 (4.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Neutropenia	2 (4.0)	0	0	0	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.0)	0	1 (2.0)	0	0
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Thrombocytopenia	1 (2.0)	0	0	0	1 (2.0)
Infections					
-Total	28 (56.0)	3 (6.0)	11 (22.0)	9 (18.0)	5 (10.0)
Upper respiratory tract infection	8 (16.0)	3 (6.0)	3 (6.0)	2 (4.0)	0
Nasopharyngitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Parainfluenzae virus infection	4 (8.0)	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)
Gastroenteritis	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Otitis media	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Respiratory syncytial virus infection	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Rhinovirus infection	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Bacteraemia	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Metapneumovirus infection	2 (4.0)	0	0	2 (4.0)	0
Otitis externa	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Pneumonia	2 (4.0)	0	1 (2.0)	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Skin papilloma	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Adenovirus infection	1 (2.0)	0	0	1 (2.0)	0
Bk virus infection	1 (2.0)	0	0	1 (2.0)	0
Bronchopulmonary aspergillosis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis	1 (2.0)	0	1 (2.0)	0	0
Conjunctivitis	1 (2.0)	0	1 (2.0)	0	0
Cystitis	1 (2.0)	0	1 (2.0)	0	0
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Ear, nose and throat infection	1 (2.0)	0	1 (2.0)	0	0
Encephalitis	1 (2.0)	0	0	0	1 (2.0)
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis clostridial	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal infection	1 (2.0)	1 (2.0)	0	0	0
Gingivitis	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (2.0)	0	1 (2.0)	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	0	1 (2.0)	0	0
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	0	1 (2.0)	0
Respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	0	1 (2.0)	0	0
Sinusitis fungal	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal skin infection	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral haemorrhagic cystitis	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (20.0)	1 (2.0)	9 (18.0)	0	0
Hypogammaglobulinaemia	7 (14.0)	0	7 (14.0)	0	0
B-cell aplasia	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin a decreased	1 (2.0)	1 (2.0)	0	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Immunoglobulins decreased	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Agitation	1 (2.0)	1 (2.0)	0	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Memory impairment	1 (2.0)	0	1 (2.0)	0	0
Mental status changes	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mood altered	1 (2.0)	1 (2.0)	0	0	0
Seizure	1 (2.0)	0	0	1 (2.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (62.5)	1 (6.3)	1 (6.3)	6 (37.5)	2 (12.5)
Hematological disorders including cytopenias					
-Total	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Agranulocytosis	1 (6.3)	0	0	1 (6.3)	0
Anaemia	1 (6.3)	0	1 (6.3)	0	0
Neutropenia	1 (6.3)	0	0	0	1 (6.3)
Thrombocytopenia	1 (6.3)	0	1 (6.3)	0	0
Infections					
-Total	9 (56.3)	1 (6.3)	0	6 (37.5)	2 (12.5)
Conjunctivitis	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Sinusitis	3 (18.8)	0	3 (18.8)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Oral herpes	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Otitis media	2 (12.5)	0	2 (12.5)	0	0
Sepsis	2 (12.5)	0	0	0	2 (12.5)
Skin infection	2 (12.5)	0	2 (12.5)	0	0
Upper respiratory tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Bronchiolitis	1 (6.3)	0	0	1 (6.3)	0
Bronchitis	1 (6.3)	0	1 (6.3)	0	0
Candida infection	1 (6.3)	0	1 (6.3)	0	0
Covid-19	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Ear infection	1 (6.3)	0	0	1 (6.3)	0
Folliculitis	1 (6.3)	0	1 (6.3)	0	0
Gastroenteritis viral	1 (6.3)	0	1 (6.3)	0	0
Herpes virus infection	1 (6.3)	0	1 (6.3)	0	0
Nail infection	1 (6.3)	0	1 (6.3)	0	0
Ophthalmic herpes zoster	1 (6.3)	0	1 (6.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (6.3)	0	0	1 (6.3)	0
Rhinitis	1 (6.3)	1 (6.3)	0	0	0
Rhinovirus infection	1 (6.3)	0	1 (6.3)	0	0
Staphylococcal bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Streptococcal sepsis	1 (6.3)	0	1 (6.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (6.3)	0	1 (6.3)	0	0
Hypogammaglobulinaemia	1 (6.3)	0	1 (6.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (50.0)	2 (5.9)	8 (23.5)	4 (11.8)	3 (8.8)
Cytokine Release Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	5 (14.7)	3 (8.8)	0	1 (2.9)	1 (2.9)
Neutrophil count decreased	3 (8.8)	2 (5.9)	0	0	1 (2.9)
Platelet count decreased	2 (5.9)	2 (5.9)	0	0	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Infections					

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (41.2)	1 (2.9)	7 (20.6)	4 (11.8)	2 (5.9)
Rhinovirus infection	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Sinusitis	3 (8.8)	0	3 (8.8)	0	0
Upper respiratory tract infection	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Fungal infection	2 (5.9)	0	2 (5.9)	0	0
Influenza	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Pneumonia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Urinary tract infection	2 (5.9)	0	2 (5.9)	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Bronchitis	1 (2.9)	0	1 (2.9)	0	0
Clostridium difficile colitis	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	1 (2.9)	0	0	0
Covid-19	1 (2.9)	1 (2.9)	0	0	0
Covid-19 pneumonia	1 (2.9)	0	0	0	1 (2.9)
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis escherichia coli	1 (2.9)	0	0	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	1 (2.9)	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Syphilis	1 (2.9)	0	1 (2.9)	0	0
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Varicella zoster virus infection	1 (2.9)	0	1 (2.9)	0	0
Viral skin infection	1 (2.9)	1 (2.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (8.8)	0	3 (8.8)	0	0
Hypogammaglobulinaemia	2 (5.9)	0	2 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Dysarthria	1 (2.9)	0	1 (2.9)	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (100)	1 (3.7)	3 (11.1)	9 (33.3)	14 (51.9)
Cytokine Release Syndrome					
-Total	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Hematological disorders including cytopenias					
-Total	17 (63.0)	1 (3.7)	1 (3.7)	6 (22.2)	9 (33.3)
White blood cell count decreased	8 (29.6)	1 (3.7)	1 (3.7)	1 (3.7)	5 (18.5)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
Platelet count decreased	7 (25.9)	2 (7.4)	1 (3.7)	2 (7.4)	2 (7.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	6 (22.2)	3 (11.1)	3 (11.1)	0	0
Lymphocyte count decreased	6 (22.2)	1 (3.7)	1 (3.7)	2 (7.4)	2 (7.4)
Neutropenia	5 (18.5)	0	1 (3.7)	1 (3.7)	3 (11.1)
Febrile neutropenia	4 (14.8)	0	0	4 (14.8)	0
Thrombocytopenia	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Agranulocytosis	1 (3.7)	0	0	1 (3.7)	0
Haemoglobin decreased	1 (3.7)	0	0	1 (3.7)	0
Infections					
-Total	21 (77.8)	4 (14.8)	1 (3.7)	10 (37.0)	6 (22.2)
Conjunctivitis	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nail infection	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Nasopharyngitis	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Rhinovirus infection	3 (11.1)	0	3 (11.1)	0	0
Sinusitis	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Clostridium difficile infection	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Ear infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Gastroenteritis	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Gastroenteritis viral	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Herpes zoster	2 (7.4)	0	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Oral infection	2 (7.4)	0	2 (7.4)	0	0
Otitis media	2 (7.4)	0	2 (7.4)	0	0
Pneumonia	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Respiratory tract infection	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Sepsis	2 (7.4)	0	0	0	2 (7.4)
Skin infection	2 (7.4)	0	2 (7.4)	0	0
Staphylococcal infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Upper respiratory tract infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Anal abscess	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Bk virus infection	1 (3.7)	1 (3.7)	0	0	0
Bronchiolitis	1 (3.7)	0	0	1 (3.7)	0
Bronchitis	1 (3.7)	0	1 (3.7)	0	0
Bronchopulmonary aspergillosis	1 (3.7)	0	0	1 (3.7)	0
Candida infection	1 (3.7)	0	1 (3.7)	0	0
Cholecystitis infective	1 (3.7)	0	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coronavirus infection	1 (3.7)	0	0	1 (3.7)	0
Covid-19	1 (3.7)	0	0	1 (3.7)	0
Device related infection	1 (3.7)	0	0	1 (3.7)	0
Device related sepsis	1 (3.7)	0	0	1 (3.7)	0
Encephalitis	1 (3.7)	0	0	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Folliculitis	1 (3.7)	0	1 (3.7)	0	0
Gastroenteritis norovirus	1 (3.7)	1 (3.7)	0	0	0
Herpes virus infection	1 (3.7)	0	1 (3.7)	0	0
Influenza	1 (3.7)	0	1 (3.7)	0	0
Localised infection	1 (3.7)	1 (3.7)	0	0	0
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Metapneumovirus infection	1 (3.7)	0	0	1 (3.7)	0
Myringitis	1 (3.7)	1 (3.7)	0	0	0
Ophthalmic herpes zoster	1 (3.7)	0	1 (3.7)	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Paronychia	1 (3.7)	0	1 (3.7)	0	0
Pneumocystis jirovecii pneumonia	1 (3.7)	0	0	0	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (3.7)	0	0	1 (3.7)	0
Rhinitis	1 (3.7)	1 (3.7)	0	0	0
Salmonellosis	1 (3.7)	0	1 (3.7)	0	0
Septic shock	1 (3.7)	0	0	0	1 (3.7)
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Staphylococcal sepsis	1 (3.7)	0	0	0	1 (3.7)
Streptococcal sepsis	1 (3.7)	0	1 (3.7)	0	0
Tinea pedis	1 (3.7)	1 (3.7)	0	0	0
Viral infection	1 (3.7)	0	1 (3.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (59.3)	1 (3.7)	9 (33.3)	6 (22.2)	0
Hypogammaglobulinaemia	11 (40.7)	1 (3.7)	7 (25.9)	3 (11.1)	0
Blood immunoglobulin m decreased	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Blood immunoglobulin a decreased	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Immunodeficiency	2 (7.4)	0	0	2 (7.4)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0
Immunoglobulins decreased	1 (3.7)	0	1 (3.7)	0	0
Serious neurological adverse reactions					
-Total	9 (33.3)	5 (18.5)	2 (7.4)	2 (7.4)	0
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Mental status changes	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Confusional state	2 (7.4)	2 (7.4)	0	0	0
Agitation	1 (3.7)	0	1 (3.7)	0	0
Dysphagia	1 (3.7)	0	0	1 (3.7)	0
Generalised tonic-clonic seizure	1 (3.7)	0	1 (3.7)	0	0
Irritability	1 (3.7)	1 (3.7)	0	0	0
Seizure	1 (3.7)	0	1 (3.7)	0	0
Somnolence	1 (3.7)	0	0	1 (3.7)	0
Tumour Lysis Syndrome					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (11.1)	0	0	2 (7.4)	1 (3.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229j
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (100)	0	5 (9.4)	13 (24.5)	35 (66.0)
Cytokine Release Syndrome					
-Total	41 (77.4)	5 (9.4)	14 (26.4)	9 (17.0)	13 (24.5)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Haemophagocytic lymphohistiocytosis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Hematological disorders including cytopenias					
-Total	39 (73.6)	0	1 (1.9)	16 (30.2)	22 (41.5)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	19 (35.8)	4 (7.5)	6 (11.3)	9 (17.0)	0
Neutrophil count decreased	17 (32.1)	1 (1.9)	1 (1.9)	4 (7.5)	11 (20.8)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	17 (32.1)	4 (7.5)	2 (3.8)	5 (9.4)	6 (11.3)
White blood cell count decreased	17 (32.1)	2 (3.8)	3 (5.7)	1 (1.9)	11 (20.8)
Lymphocyte count decreased	11 (20.8)	0	0	8 (15.1)	3 (5.7)
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Leukopenia	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)
Lymphopenia	2 (3.8)	0	0	2 (3.8)	0
Pancytopenia	2 (3.8)	0	0	2 (3.8)	0
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0
Neutropenic infection	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	40 (75.5)	4 (7.5)	13 (24.5)	15 (28.3)	8 (15.1)
Upper respiratory tract infection	11 (20.8)	5 (9.4)	4 (7.5)	2 (3.8)	0
Rhinovirus infection	6 (11.3)	0	4 (7.5)	2 (3.8)	0
Parainfluenzae virus infection	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Gastroenteritis	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Nasopharyngitis	4 (7.5)	2 (3.8)	2 (3.8)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (7.5)	0	1 (1.9)	1 (1.9)	2 (3.8)
Sinusitis	4 (7.5)	0	3 (5.7)	1 (1.9)	0
Staphylococcal bacteraemia	4 (7.5)	0	0	4 (7.5)	0
Candida infection	3 (5.7)	0	2 (3.8)	0	1 (1.9)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Oral candidiasis	3 (5.7)	0	3 (5.7)	0	0
Otitis media	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Respiratory syncytial virus infection	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Staphylococcal infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Urinary tract infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Acute sinusitis	2 (3.8)	0	2 (3.8)	0	0
Adenovirus infection	2 (3.8)	0	0	2 (3.8)	0
Bacteraemia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Clostridium difficile infection	2 (3.8)	0	0	2 (3.8)	0
Fungal infection	2 (3.8)	0	2 (3.8)	0	0
Gingivitis	2 (3.8)	2 (3.8)	0	0	0
Herpes simplex	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	2 (3.8)	0	0	2 (3.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Metapneumovirus infection	2 (3.8)	0	0	2 (3.8)	0
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Otitis externa	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Rhinitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Skin papilloma	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Varicella zoster virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bk virus infection	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis	1 (1.9)	0	1 (1.9)	0	0
Clostridium difficile colitis	1 (1.9)	0	0	1 (1.9)	0
Covid-19	1 (1.9)	1 (1.9)	0	0	0
Covid-19 pneumonia	1 (1.9)	0	0	0	1 (1.9)
Cystitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (1.9)	0	1 (1.9)	0	0
Ear, nose and throat infection	1 (1.9)	0	1 (1.9)	0	0
Encephalitis	1 (1.9)	0	0	0	1 (1.9)
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis clostridial	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis escherichia coli	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis salmonella	1 (1.9)	0	0	1 (1.9)	0
Gastrointestinal infection	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (1.9)	0	0	1 (1.9)	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0
Pneumocystis jirovecii pneumonia	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection viral	1 (1.9)	0	1 (1.9)	0	0
Sepsis	1 (1.9)	0	0	1 (1.9)	0
Septic shock	1 (1.9)	0	0	0	1 (1.9)
Sinusitis fungal	1 (1.9)	0	0	1 (1.9)	0
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal skin infection	1 (1.9)	0	1 (1.9)	0	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Syphilis	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection pseudomonal	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Viral haemorrhagic cystitis	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	0	0	1 (1.9)	0
Viral skin infection	1 (1.9)	1 (1.9)	0	0	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	31 (58.5)	4 (7.5)	20 (37.7)	7 (13.2)	0
Hypogammaglobulinaemia	22 (41.5)	1 (1.9)	17 (32.1)	4 (7.5)	0
Blood immunoglobulin a decreased	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Blood immunoglobulin g decreased	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Immunodeficiency	2 (3.8)	0	0	2 (3.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (1.9)	0	1 (1.9)	0	0
Immunoglobulins decreased	1 (1.9)	0	1 (1.9)	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	26 (49.1)	7 (13.2)	8 (15.1)	11 (20.8)	0
Agitation	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Confusional state	5 (9.4)	5 (9.4)	0	0	0
Delirium	5 (9.4)	0	2 (3.8)	3 (5.7)	0
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Somnolence	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Cognitive disorder	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Hallucination	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Lethargy	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Seizure	3 (5.7)	0	0	3 (5.7)	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Dysarthria	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Irritability	2 (3.8)	2 (3.8)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Muscular weakness	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Memory impairment	1 (1.9)	0	1 (1.9)	0	0
Mood altered	1 (1.9)	1 (1.9)	0	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.8)	0	0	2 (3.8)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (92.9)	2 (7.1)	3 (10.7)	7 (25.0)	14 (50.0)
Cytokine Release Syndrome					
-Total	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Haemophagocytic lymphohistiocytosis	1 (3.6)	1 (3.6)	0	0	0
Hematological disorders including cytopenias					
-Total	16 (57.1)	1 (3.6)	0	7 (25.0)	8 (28.6)
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)
Febrile neutropenia	6 (21.4)	0	0	6 (21.4)	0
Neutrophil count decreased	6 (21.4)	0	1 (3.6)	0	5 (17.9)

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Anaemia	5 (17.9)	1 (3.6)	0	4 (14.3)	0
Platelet count decreased	5 (17.9)	1 (3.6)	1 (3.6)	1 (3.6)	2 (7.1)
Neutropenia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
Thrombocytopenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Leukopenia	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	12 (42.9)	2 (7.1)	5 (17.9)	5 (17.9)	0
Conjunctivitis	3 (10.7)	0	3 (10.7)	0	0
Nail infection	2 (7.1)	2 (7.1)	0	0	0
Oral infection	2 (7.1)	0	2 (7.1)	0	0
Staphylococcal infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Adenovirus infection	1 (3.6)	0	0	1 (3.6)	0
Bronchopulmonary aspergillosis	1 (3.6)	0	0	1 (3.6)	0
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myringitis	1 (3.6)	1 (3.6)	0	0	0
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (53.6)	1 (3.6)	7 (25.0)	7 (25.0)	0
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	3 (10.7)	0	0	3 (10.7)	0
Immunoglobulins decreased	2 (7.1)	0	2 (7.1)	0	0
Serious neurological adverse reactions					
-Total	8 (28.6)	3 (10.7)	3 (10.7)	2 (7.1)	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Hallucination	2 (7.1)	0	2 (7.1)	0	0
Tremor	2 (7.1)	2 (7.1)	0	0	0
Amnesia	1 (3.6)	0	1 (3.6)	0	0
Hallucination, visual	1 (3.6)	0	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (95.6)	1 (2.2)	6 (13.3)	12 (26.7)	24 (53.3)
Cytokine Release Syndrome					
-Total	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Hematological disorders including cytopenias					
-Total	31 (68.9)	1 (2.2)	2 (4.4)	12 (26.7)	16 (35.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	15 (33.3)	4 (8.9)	7 (15.6)	4 (8.9)	0
Platelet count decreased	14 (31.1)	3 (6.7)	2 (4.4)	4 (8.9)	5 (11.1)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	14 (31.1)	2 (4.4)	3 (6.7)	1 (2.2)	8 (17.8)
Neutrophil count decreased	11 (24.4)	0	2 (4.4)	2 (4.4)	7 (15.6)
Lymphocyte count decreased	8 (17.8)	1 (2.2)	0	5 (11.1)	2 (4.4)
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Leukopenia	1 (2.2)	0	1 (2.2)	0	0
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Infections					
-Total	18 (40.0)	2 (4.4)	4 (8.9)	10 (22.2)	2 (4.4)
Clostridium difficile infection	4 (8.9)	1 (2.2)	0	3 (6.7)	0
Candida infection	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Staphylococcal bacteraemia	3 (6.7)	0	0	3 (6.7)	0
Staphylococcal infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Conjunctivitis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Oral herpes	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Rhinovirus infection	2 (4.4)	0	2 (4.4)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Gastroenteritis norovirus	1 (2.2)	1 (2.2)	0	0	0
Granulicatella infection	1 (2.2)	0	0	1 (2.2)	0
Herpes simplex	1 (2.2)	0	0	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Localised infection	1 (2.2)	1 (2.2)	0	0	0
Oral candidiasis	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Sinusitis	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Stomatococcal infection	1 (2.2)	0	1 (2.2)	0	0
Systemic candida	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (42.2)	6 (13.3)	9 (20.0)	4 (8.9)	0
Hypogammaglobulinaemia	11 (24.4)	1 (2.2)	7 (15.6)	3 (6.7)	0
Blood immunoglobulin m decreased	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin a decreased	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Blood immunoglobulin g decreased	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	22 (48.9)	10 (22.2)	4 (8.9)	8 (17.8)	0
Delirium	7 (15.6)	2 (4.4)	2 (4.4)	3 (6.7)	0
Agitation	5 (11.1)	2 (4.4)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Tremor	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Cognitive disorder	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Irritability	3 (6.7)	3 (6.7)	0	0	0
Lethargy	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Mental status changes	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Affect lability	1 (2.2)	0	1 (2.2)	0	0
Aphasia	1 (2.2)	1 (2.2)	0	0	0
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Generalised tonic-clonic seizure	1 (2.2)	0	1 (2.2)	0	0
Hallucination	1 (2.2)	1 (2.2)	0	0	0
Muscular weakness	1 (2.2)	0	0	1 (2.2)	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Sluggishness	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Social avoidant behaviour	1 (2.2)	0	1 (2.2)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.4)	0	0	2 (4.4)	0
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Cytokine Release Syndrome					
-Total	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hematological disorders including cytopenias					
-Total	6 (85.7)	0	0	0	6 (85.7)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Infections					
-Total	5 (71.4)	2 (28.6)	1 (14.3)	1 (14.3)	1 (14.3)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (42.9)	0	3 (42.9)	0	0
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (14.3)	0	1 (14.3)	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tumour Lysis Syndrome					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (75.0)	3 (10.7)	6 (21.4)	3 (10.7)	9 (32.1)
Hematological disorders including cytopenias					
-Total	7 (25.0)	2 (7.1)	0	2 (7.1)	3 (10.7)
White blood cell count decreased	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Anaemia	2 (7.1)	2 (7.1)	0	0	0
Neutropenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Neutrophil count decreased	2 (7.1)	0	0	0	2 (7.1)
Platelet count decreased	2 (7.1)	2 (7.1)	0	0	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	21 (75.0)	4 (14.3)	8 (28.6)	3 (10.7)	6 (21.4)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Gastroenteritis	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Pneumonia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Rhinitis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Skin papilloma	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0	0	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Conjunctivitis	1 (3.6)	0	1 (3.6)	0	0
Cystitis	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Nail infection	1 (3.6)	1 (3.6)	0	0	0
Oral candidiasis	1 (3.6)	0	1 (3.6)	0	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Rhinovirus infection	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)
Staphylococcal skin infection	1 (3.6)	0	1 (3.6)	0	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Viral infection	1 (3.6)	0	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Immunodeficiency	1 (3.6)	0	0	1 (3.6)	0
Immunoglobulins decreased	1 (3.6)	0	1 (3.6)	0	0
Serious neurological adverse reactions					
-Total	1 (3.6)	0	0	1 (3.6)	0
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0

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Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (72.5)	3 (7.5)	11 (27.5)	11 (27.5)	4 (10.0)
Hematological disorders including cytopenias					
-Total	14 (35.0)	3 (7.5)	3 (7.5)	6 (15.0)	2 (5.0)
Neutrophil count decreased	7 (17.5)	2 (5.0)	1 (2.5)	3 (7.5)	1 (2.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	2 (5.0)	1 (2.5)	1 (2.5)
Lymphocyte count decreased	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Anaemia	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Platelet count decreased	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Leukopenia	1 (2.5)	0	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	17 (42.5)	0	7 (17.5)	8 (20.0)	2 (5.0)
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Metapneumovirus infection	3 (7.5)	0	0	3 (7.5)	0
Rhinovirus infection	3 (7.5)	0	3 (7.5)	0	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Otitis media	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumocystis jirovecii pneumonia	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.5)	1 (2.5)	0	0	0
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	11 (27.5)	1 (2.5)	9 (22.5)	1 (2.5)	0
Hypogammaglobulinaemia	8 (20.0)	0	8 (20.0)	0	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Mental status changes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	0	1 (2.5)
Tumour lysis syndrome	1 (2.5)	0	0	0	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Hematological disorders including cytopenias					
-Total	5 (71.4)	1 (14.3)	0	1 (14.3)	3 (42.9)
Neutropenia	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Anaemia	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	0	1 (14.3)	0
Infections					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (28.6)	0	2 (28.6)	0	0
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (54.5)	2 (9.1)	3 (13.6)	4 (18.2)	3 (13.6)
Cytokine Release Syndrome					
-Total	1 (4.5)	0	0	0	1 (4.5)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	0	0	1 (4.5)
Hematological disorders including cytopenias					
-Total	4 (18.2)	1 (4.5)	0	2 (9.1)	1 (4.5)
Agranulocytosis	1 (4.5)	0	0	1 (4.5)	0
Anaemia	1 (4.5)	0	1 (4.5)	0	0
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Neutropenic infection	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (4.5)	1 (4.5)	0	0	0
Thrombocytopenia	1 (4.5)	0	1 (4.5)	0	0
Infections					
-Total	11 (50.0)	2 (9.1)	2 (9.1)	4 (18.2)	3 (13.6)
Conjunctivitis	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Sepsis	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Covid-19	1 (4.5)	0	0	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Fungal infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Herpes virus infection	1 (4.5)	0	1 (4.5)	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Influenza	1 (4.5)	0	0	0	1 (4.5)
Neutropenic infection	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Pneumonia	1 (4.5)	0	0	0	1 (4.5)
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Rhinovirus infection	1 (4.5)	0	0	1 (4.5)	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Streptococcal sepsis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Viral skin infection	1 (4.5)	1 (4.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (4.5)	0	1 (4.5)	0	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Serious neurological adverse reactions					

Timing: >1 year post-CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (4.5)	0	1 (4.5)	0	0
Dysarthria	1 (4.5)	0	1 (4.5)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (56.5)	1 (4.3)	6 (26.1)	5 (21.7)	1 (4.3)
Hematological disorders including cytopenias					
-Total	2 (8.7)	2 (8.7)	0	0	0
Neutrophil count decreased	2 (8.7)	2 (8.7)	0	0	0
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Infections					
-Total	10 (43.5)	0	4 (17.4)	5 (21.7)	1 (4.3)
Sinusitis	4 (17.4)	0	4 (17.4)	0	0
Upper respiratory tract infection	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Rhinovirus infection	2 (8.7)	0	2 (8.7)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (8.7)	0	2 (8.7)	0	0
Acute sinusitis	1 (4.3)	0	1 (4.3)	0	0
Bronchiolitis	1 (4.3)	0	0	1 (4.3)	0
Bronchitis	1 (4.3)	0	1 (4.3)	0	0
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Conjunctivitis	1 (4.3)	0	1 (4.3)	0	0
Covid-19	1 (4.3)	1 (4.3)	0	0	0
Ear infection	1 (4.3)	0	0	1 (4.3)	0
Folliculitis	1 (4.3)	0	1 (4.3)	0	0
Fungal infection	1 (4.3)	0	1 (4.3)	0	0
Fungal skin infection	1 (4.3)	0	1 (4.3)	0	0
Gastroenteritis escherichia coli	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis salmonella	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis viral	1 (4.3)	0	1 (4.3)	0	0
Herpes zoster	1 (4.3)	0	1 (4.3)	0	0
Influenza	1 (4.3)	0	1 (4.3)	0	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Nail infection	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (4.3)	0	1 (4.3)	0	0
Oral herpes	1 (4.3)	1 (4.3)	0	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	0	1 (4.3)	0
Pneumonia respiratory syncytial viral	1 (4.3)	0	0	1 (4.3)	0
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Syphilis	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection pseudomonal	1 (4.3)	0	1 (4.3)	0	0
Varicella zoster virus infection	1 (4.3)	0	1 (4.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (13.0)	0	3 (13.0)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	3 (13.0)	0	3 (13.0)	0	0
Serious neurological adverse reactions					
-Total	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Hematological disorders including cytopenias					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Infections					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Otitis media	1 (20.0)	0	1 (20.0)	0	0
Rhinovirus infection	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (20.0)	0	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	1 (3.6)	2 (7.1)	8 (28.6)	17 (60.7)
Cytokine Release Syndrome					
-Total	19 (67.9)	0	5 (17.9)	5 (17.9)	9 (32.1)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Haemophagocytic lymphohistiocytosis	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Hematological disorders including cytopenias					
-Total	17 (60.7)	0	0	8 (28.6)	9 (32.1)
Anaemia	8 (28.6)	3 (10.7)	1 (3.6)	4 (14.3)	0
Febrile neutropenia	7 (25.0)	0	0	7 (25.0)	0
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	6 (21.4)	0	0	0	6 (21.4)
Platelet count decreased	6 (21.4)	2 (7.1)	1 (3.6)	1 (3.6)	2 (7.1)
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Neutropenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Thrombocytopenia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
Agranulocytosis	1 (3.6)	0	0	1 (3.6)	0
Leukopenia	1 (3.6)	0	0	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	26 (92.9)	5 (17.9)	6 (21.4)	7 (25.0)	8 (28.6)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Conjunctivitis	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Gastroenteritis	4 (14.3)	2 (7.1)	0	2 (7.1)	0
Nail infection	3 (10.7)	3 (10.7)	0	0	0
Pneumonia	3 (10.7)	0	1 (3.6)	0	2 (7.1)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Rhinitis	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Sepsis	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Upper respiratory tract infection	3 (10.7)	3 (10.7)	0	0	0
Bronchopulmonary aspergillosis	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Herpes zoster	2 (7.1)	0	0	2 (7.1)	0
Oral infection	2 (7.1)	0	2 (7.1)	0	0
Parainfluenzae virus infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Rhinovirus infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Skin papilloma	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Staphylococcal infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Adenovirus infection	1 (3.6)	0	0	1 (3.6)	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchitis	1 (3.6)	0	1 (3.6)	0	0
Candida infection	1 (3.6)	0	1 (3.6)	0	0
Covid-19	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Device related sepsis	1 (3.6)	0	0	1 (3.6)	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Fungal infection	1 (3.6)	0	1 (3.6)	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Herpes virus infection	1 (3.6)	0	1 (3.6)	0	0
Influenza	1 (3.6)	0	0	0	1 (3.6)
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Myringitis	1 (3.6)	1 (3.6)	0	0	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Ophthalmic herpes zoster	1 (3.6)	0	1 (3.6)	0	0
Oral candidiasis	1 (3.6)	0	1 (3.6)	0	0
Oral herpes	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)
Staphylococcal skin infection	1 (3.6)	0	1 (3.6)	0	0
Streptococcal sepsis	1 (3.6)	0	1 (3.6)	0	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Viral infection	1 (3.6)	0	1 (3.6)	0	0
Viral skin infection	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	16 (57.1)	1 (3.6)	7 (25.0)	8 (28.6)	0
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	4 (14.3)	0	0	4 (14.3)	0
Immunoglobulins decreased	2 (7.1)	0	2 (7.1)	0	0
Blood immunoglobulin g decreased	1 (3.6)	0	1 (3.6)	0	0
Serious neurological adverse reactions					
-Total	9 (32.1)	3 (10.7)	3 (10.7)	3 (10.7)	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Hallucination	2 (7.1)	0	2 (7.1)	0	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Tremor	2 (7.1)	2 (7.1)	0	0	0
Amnesia	1 (3.6)	0	1 (3.6)	0	0
Dysarthria	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination, visual	1 (3.6)	0	1 (3.6)	0	0
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	0	6 (13.3)	13 (28.9)	26 (57.8)
Cytokine Release Syndrome					
-Total	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Hematological disorders including cytopenias					
-Total	33 (73.3)	1 (2.2)	2 (4.4)	14 (31.1)	16 (35.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	16 (35.6)	4 (8.9)	7 (15.6)	5 (11.1)	0
Platelet count decreased	16 (35.6)	4 (8.9)	2 (4.4)	5 (11.1)	5 (11.1)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	15 (33.3)	1 (2.2)	2 (4.4)	4 (8.9)	8 (17.8)
White blood cell count decreased	15 (33.3)	2 (4.4)	4 (8.9)	1 (2.2)	8 (17.8)
Lymphocyte count decreased	10 (22.2)	0	1 (2.2)	7 (15.6)	2 (4.4)
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Lymphopenia	2 (4.4)	0	0	2 (4.4)	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Leukopenia	1 (2.2)	0	1 (2.2)	0	0
Infections					
-Total	29 (64.4)	1 (2.2)	8 (17.8)	15 (33.3)	5 (11.1)
Upper respiratory tract infection	8 (17.8)	2 (4.4)	5 (11.1)	1 (2.2)	0
Rhinovirus infection	6 (13.3)	0	6 (13.3)	0	0
Sinusitis	5 (11.1)	0	4 (8.9)	1 (2.2)	0
Clostridium difficile infection	4 (8.9)	1 (2.2)	0	3 (6.7)	0
Staphylococcal bacteraemia	4 (8.9)	0	0	4 (8.9)	0
Candida infection	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Conjunctivitis	3 (6.7)	1 (2.2)	2 (4.4)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	3 (6.7)	0	0	3 (6.7)	0
Oral herpes	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Otitis media	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Staphylococcal infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Acute sinusitis	2 (4.4)	0	2 (4.4)	0	0
Ear infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Gastroenteritis	2 (4.4)	2 (4.4)	0	0	0
Gastroenteritis viral	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Herpes simplex	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Human herpesvirus 6 infection	2 (4.4)	0	0	2 (4.4)	0
Influenza	2 (4.4)	0	2 (4.4)	0	0
Oral candidiasis	2 (4.4)	0	2 (4.4)	0	0
Otitis externa	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Parainfluenzae virus infection	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Pneumonia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Respiratory syncytial virus infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Septic shock	2 (4.4)	0	0	0	2 (4.4)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (4.4)	0	2 (4.4)	0	0
Varicella zoster virus infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Adenovirus infection	1 (2.2)	0	0	1 (2.2)	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Bk virus infection	1 (2.2)	0	0	1 (2.2)	0
Bronchiolitis	1 (2.2)	0	0	1 (2.2)	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Cellulitis	1 (2.2)	0	1 (2.2)	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Coronavirus infection	1 (2.2)	0	0	1 (2.2)	0
Covid-19	1 (2.2)	1 (2.2)	0	0	0
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Enterobacter infection	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (2.2)	0	1 (2.2)	0	0
Fungal infection	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis clostridial	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis norovirus	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Gastrointestinal infection	1 (2.2)	1 (2.2)	0	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Granulicatella infection	1 (2.2)	0	0	1 (2.2)	0
Herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Localised infection	1 (2.2)	1 (2.2)	0	0	0
Mastoiditis	1 (2.2)	0	0	1 (2.2)	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0
Nail infection	1 (2.2)	0	1 (2.2)	0	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Pharyngitis streptococcal	1 (2.2)	0	0	1 (2.2)	0
Pneumocystis jirovecii pneumonia	1 (2.2)	0	0	1 (2.2)	0
Pneumonia respiratory syncytial viral	1 (2.2)	0	0	1 (2.2)	0
Salmonellosis	1 (2.2)	0	1 (2.2)	0	0
Sinusitis fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Stomatococcal infection	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Systemic candida	1 (2.2)	0	0	1 (2.2)	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection pseudomonal	1 (2.2)	0	1 (2.2)	0	0
Viral infection	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (60.0)	4 (8.9)	18 (40.0)	5 (11.1)	0
Hypogammaglobulinaemia	19 (42.2)	1 (2.2)	15 (33.3)	3 (6.7)	0
Blood immunoglobulin a decreased	7 (15.6)	5 (11.1)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	7 (15.6)	4 (8.9)	1 (2.2)	2 (4.4)	0
Blood immunoglobulin g decreased	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	25 (55.6)	9 (20.0)	6 (13.3)	10 (22.2)	0
Delirium	8 (17.8)	2 (4.4)	3 (6.7)	3 (6.7)	0
Agitation	6 (13.3)	3 (6.7)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Mental status changes	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Tremor	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Cognitive disorder	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Irritability	3 (6.7)	3 (6.7)	0	0	0
Lethargy	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Affect lability	1 (2.2)	0	1 (2.2)	0	0
Aphasia	1 (2.2)	1 (2.2)	0	0	0
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Generalised tonic-clonic seizure	1 (2.2)	0	1 (2.2)	0	0
Hallucination	1 (2.2)	1 (2.2)	0	0	0
Mood altered	1 (2.2)	1 (2.2)	0	0	0
Muscular weakness	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Sluggishness	1 (2.2)	0	1 (2.2)	0	0
Social avoidant behaviour	1 (2.2)	0	1 (2.2)	0	0
Tumour Lysis Syndrome					
-Total	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Tumour lysis syndrome	3 (6.7)	0	0	2 (4.4)	1 (2.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229k
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Cytokine Release Syndrome					
-Total	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hematological disorders including cytopenias					
-Total	6 (85.7)	0	0	0	6 (85.7)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Infections					
-Total	6 (85.7)	2 (28.6)	0	3 (42.9)	1 (14.3)
Upper respiratory tract infection	2 (28.6)	0	0	2 (28.6)	0
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	4 (57.1)	0	0
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Serious neurological adverse reactions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tumour Lysis Syndrome					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (95.8)	2 (4.2)	4 (8.3)	15 (31.3)	25 (52.1)
Cytokine Release Syndrome					
-Total	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Hematological disorders including cytopenias					
-Total	32 (66.7)	2 (4.2)	1 (2.1)	12 (25.0)	17 (35.4)
Febrile neutropenia	14 (29.2)	0	0	14 (29.2)	0
Anaemia	13 (27.1)	2 (4.2)	4 (8.3)	7 (14.6)	0
Neutrophil count decreased	13 (27.1)	0	2 (4.2)	1 (2.1)	10 (20.8)
Platelet count decreased	13 (27.1)	2 (4.2)	1 (2.1)	5 (10.4)	5 (10.4)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	13 (27.1)	3 (6.3)	0	1 (2.1)	9 (18.8)
Lymphocyte count decreased	10 (20.8)	1 (2.1)	0	4 (8.3)	5 (10.4)
Neutropenia	5 (10.4)	0	1 (2.1)	1 (2.1)	3 (6.3)
Thrombocytopenia	4 (8.3)	0	0	1 (2.1)	3 (6.3)
Leukopenia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Pancytopenia	2 (4.2)	0	0	2 (4.2)	0
Haemoglobin decreased	1 (2.1)	0	0	1 (2.1)	0
Lymphopenia	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	23 (47.9)	4 (8.3)	6 (12.5)	12 (25.0)	1 (2.1)
Conjunctivitis	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Candida infection	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Nail infection	2 (4.2)	2 (4.2)	0	0	0
Oral herpes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Oral infection	2 (4.2)	0	2 (4.2)	0	0
Staphylococcal infection	2 (4.2)	0	0	2 (4.2)	0
Adenovirus infection	1 (2.1)	0	0	1 (2.1)	0
Anal abscess	1 (2.1)	0	0	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (2.1)	1 (2.1)	0	0	0
Bronchopulmonary aspergillosis	1 (2.1)	0	0	1 (2.1)	0
Cholecystitis infective	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile infection	1 (2.1)	0	0	1 (2.1)	0
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis norovirus	1 (2.1)	1 (2.1)	0	0	0
Gingivitis	1 (2.1)	1 (2.1)	0	0	0
Granulicatella infection	1 (2.1)	0	0	1 (2.1)	0
Herpes simplex	1 (2.1)	0	0	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Myringitis	1 (2.1)	1 (2.1)	0	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis externa	1 (2.1)	0	1 (2.1)	0	0
Paronychia	1 (2.1)	0	1 (2.1)	0	0
Pneumonia	1 (2.1)	0	0	1 (2.1)	0
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (2.1)	0	1 (2.1)	0	0
Sinusitis	1 (2.1)	0	0	1 (2.1)	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Stomatococcal infection	1 (2.1)	0	1 (2.1)	0	0
Systemic candida	1 (2.1)	0	0	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	0	0	1 (2.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	24 (50.0)	5 (10.4)	12 (25.0)	7 (14.6)	0
Hypogammaglobulinaemia	14 (29.2)	0	9 (18.8)	5 (10.4)	0
Blood immunoglobulin a decreased	4 (8.3)	4 (8.3)	0	0	0
Blood immunoglobulin m decreased	4 (8.3)	4 (8.3)	0	0	0
Immunodeficiency	2 (4.2)	0	0	2 (4.2)	0
Immunoglobulins decreased	2 (4.2)	0	2 (4.2)	0	0
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	14 (29.2)	6 (12.5)	5 (10.4)	3 (6.3)	0
Confusional state	4 (8.3)	4 (8.3)	0	0	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Hallucination	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Tremor	3 (6.3)	3 (6.3)	0	0	0
Agitation	2 (4.2)	2 (4.2)	0	0	0
Delirium	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Irritability	2 (4.2)	2 (4.2)	0	0	0
Lethargy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Somnolence	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Affect lability	1 (2.1)	0	1 (2.1)	0	0
Amnesia	1 (2.1)	0	1 (2.1)	0	0
Aphasia	1 (2.1)	1 (2.1)	0	0	0
Cognitive disorder	1 (2.1)	0	1 (2.1)	0	0
Depressed level of consciousness	1 (2.1)	0	0	1 (2.1)	0
Disturbance in attention	1 (2.1)	1 (2.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (2.1)	0	1 (2.1)	0	0
Restlessness	1 (2.1)	0	1 (2.1)	0	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Sluggishness	1 (2.1)	0	1 (2.1)	0	0
Social avoidant behaviour	1 (2.1)	0	1 (2.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.2)	0	0	2 (4.2)	0
Tumour lysis syndrome	2 (4.2)	0	0	2 (4.2)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (93.8)	1 (3.1)	5 (15.6)	5 (15.6)	19 (59.4)
Cytokine Release Syndrome					
-Total	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Hematological disorders including cytopenias					
-Total	21 (65.6)	0	1 (3.1)	7 (21.9)	13 (40.6)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Anaemia	8 (25.0)	3 (9.4)	4 (12.5)	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Neutrophil count decreased	7 (21.9)	0	1 (3.1)	1 (3.1)	5 (15.6)
Lymphocyte count decreased	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Infections					
-Total	12 (37.5)	2 (6.3)	4 (12.5)	4 (12.5)	2 (6.3)
Clostridium difficile infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Staphylococcal infection	3 (9.4)	0	3 (9.4)	0	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Atypical pneumonia	1 (3.1)	1 (3.1)	0	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)
Klebsiella bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Localised infection	1 (3.1)	1 (3.1)	0	0	0
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection viral	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (40.6)	2 (6.3)	7 (21.9)	4 (12.5)	0
Hypogammaglobulinaemia	9 (28.1)	2 (6.3)	5 (15.6)	2 (6.3)	0
Blood immunoglobulin g decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0
Immunodeficiency	1 (3.1)	0	0	1 (3.1)	0
Selective igg subclass deficiency	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	17 (53.1)	7 (21.9)	3 (9.4)	7 (21.9)	0
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	3 (9.4)	0	3 (9.4)	0	0
Confusional state	3 (9.4)	3 (9.4)	0	0	0
Mental status changes	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Somnolence	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Tremor	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Cognitive disorder	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Muscular weakness	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Dysphagia	1 (3.1)	0	0	1 (3.1)	0
Generalised tonic-clonic seizure	1 (3.1)	0	1 (3.1)	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Lethargy	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (77.1)	4 (8.3)	11 (22.9)	8 (16.7)	14 (29.2)
Hematological disorders including cytopenias					
-Total	17 (35.4)	4 (8.3)	2 (4.2)	4 (8.3)	7 (14.6)
Neutrophil count decreased	7 (14.6)	1 (2.1)	1 (2.1)	1 (2.1)	4 (8.3)
White blood cell count decreased	6 (12.5)	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)
Anaemia	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Platelet count decreased	4 (8.3)	2 (4.2)	0	1 (2.1)	1 (2.1)
Febrile neutropenia	3 (6.3)	0	0	3 (6.3)	0
Neutropenia	3 (6.3)	0	0	1 (2.1)	2 (4.2)
Lymphocyte count decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Leukopenia	1 (2.1)	0	1 (2.1)	0	0
Lymphopenia	1 (2.1)	0	0	1 (2.1)	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	29 (60.4)	3 (6.3)	10 (20.8)	9 (18.8)	7 (14.6)
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Gastroenteritis	4 (8.3)	2 (4.2)	0	2 (4.2)	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Upper respiratory tract infection	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Metapneumovirus infection	3 (6.3)	0	0	3 (6.3)	0
Respiratory syncytial virus infection	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Otitis media	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Pneumocystis jirovecii pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Pneumonia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Respiratory tract infection	2 (4.2)	0	2 (4.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Sinusitis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Skin papilloma	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Viral infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)
Bronchopulmonary aspergillosis	1 (2.1)	0	0	0	1 (2.1)
Coronavirus infection	1 (2.1)	0	0	1 (2.1)	0
Cystitis	1 (2.1)	0	1 (2.1)	0	0
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Ear, nose and throat infection	1 (2.1)	0	1 (2.1)	0	0
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis viral	1 (2.1)	1 (2.1)	0	0	0
Gingivitis	1 (2.1)	1 (2.1)	0	0	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Influenza	1 (2.1)	0	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Oral herpes	1 (2.1)	0	1 (2.1)	0	0
Otitis externa	1 (2.1)	0	0	1 (2.1)	0
Paronychia	1 (2.1)	0	1 (2.1)	0	0
Respiratory tract infection viral	1 (2.1)	0	1 (2.1)	0	0
Salmonellosis	1 (2.1)	0	1 (2.1)	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal skin infection	1 (2.1)	0	1 (2.1)	0	0
Tinea pedis	1 (2.1)	1 (2.1)	0	0	0
Urinary tract infection	1 (2.1)	0	0	1 (2.1)	0
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (25.0)	1 (2.1)	10 (20.8)	1 (2.1)	0
Hypogammaglobulinaemia	9 (18.8)	0	9 (18.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0
Blood immunoglobulin m decreased	1 (2.1)	0	0	1 (2.1)	0
Immunoglobulins decreased	1 (2.1)	0	1 (2.1)	0	0
Serious neurological adverse reactions					
-Total	5 (10.4)	1 (2.1)	2 (4.2)	2 (4.2)	0
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Agitation	1 (2.1)	1 (2.1)	0	0	0
Delirium	1 (2.1)	0	1 (2.1)	0	0
Memory impairment	1 (2.1)	0	1 (2.1)	0	0
Mood altered	1 (2.1)	1 (2.1)	0	0	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Tumour Lysis Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Tumour lysis syndrome	1 (2.1)	0	0	0	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (66.7)	2 (7.4)	6 (22.2)	8 (29.6)	2 (7.4)
Hematological disorders including cytopenias					
-Total	9 (33.3)	2 (7.4)	1 (3.7)	5 (18.5)	1 (3.7)
White blood cell count decreased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Neutrophil count decreased	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Lymphocyte count decreased	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Neutropenia	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Platelet count decreased	1 (3.7)	1 (3.7)	0	0	0
Infections					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (40.7)	2 (7.4)	5 (18.5)	3 (11.1)	1 (3.7)
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Ear infection	2 (7.4)	0	2 (7.4)	0	0
Nasopharyngitis	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Parainfluenzae virus infection	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Acute sinusitis	1 (3.7)	0	1 (3.7)	0	0
Adenovirus infection	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	1 (3.7)	0	0
Bk virus infection	1 (3.7)	0	0	1 (3.7)	0
Cellulitis	1 (3.7)	0	1 (3.7)	0	0
Conjunctivitis	1 (3.7)	0	1 (3.7)	0	0
Gastroenteritis	1 (3.7)	1 (3.7)	0	0	0
Gastroenteritis clostridial	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal infection	1 (3.7)	1 (3.7)	0	0	0
Herpes simplex	1 (3.7)	0	1 (3.7)	0	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Molluscum contagiosum	1 (3.7)	1 (3.7)	0	0	0
Nail infection	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Pharyngitis streptococcal	1 (3.7)	0	0	1 (3.7)	0
Pneumonia	1 (3.7)	0	0	0	1 (3.7)
Respiratory tract infection	1 (3.7)	1 (3.7)	0	0	0
Rhinovirus infection	1 (3.7)	0	1 (3.7)	0	0
Sinusitis	1 (3.7)	0	1 (3.7)	0	0
Sinusitis fungal	1 (3.7)	0	0	1 (3.7)	0
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Viral upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0
Hypogammaglobulinaemia	1 (3.7)	0	1 (3.7)	0	0
Immunodeficiency	1 (3.7)	0	0	1 (3.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (57.6)	3 (9.1)	5 (15.2)	7 (21.2)	4 (12.1)
Hematological disorders including cytopenias					
-Total	7 (21.2)	3 (9.1)	0	2 (6.1)	2 (6.1)
Neutrophil count decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Platelet count decreased	2 (6.1)	2 (6.1)	0	0	0
Agranulocytosis	1 (3.0)	0	0	1 (3.0)	0
Anaemia	1 (3.0)	0	1 (3.0)	0	0
Neutropenia	1 (3.0)	0	0	0	1 (3.0)
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0
Thrombocytopenia	1 (3.0)	0	1 (3.0)	0	0
Infections					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (51.5)	2 (6.1)	5 (15.2)	7 (21.2)	3 (9.1)
Sinusitis	4 (12.1)	0	4 (12.1)	0	0
Conjunctivitis	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Sepsis	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Upper respiratory tract infection	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Fungal infection	2 (6.1)	0	2 (6.1)	0	0
Herpes zoster	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Oral herpes	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Skin infection	2 (6.1)	0	2 (6.1)	0	0
Urinary tract infection	2 (6.1)	0	2 (6.1)	0	0
Acute sinusitis	1 (3.0)	0	1 (3.0)	0	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Covid-19	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	0	1 (3.0)	0
Fungal skin infection	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes virus infection	1 (3.0)	0	1 (3.0)	0	0
Influenza	1 (3.0)	0	1 (3.0)	0	0
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Otitis media	1 (3.0)	0	1 (3.0)	0	0
Otitis media acute	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	1 (3.0)	0	0	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Septic shock	1 (3.0)	0	0	0	1 (3.0)
Staphylococcal abscess	1 (3.0)	0	0	1 (3.0)	0
Streptococcal sepsis	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection pseudomonal	1 (3.0)	0	1 (3.0)	0	0
Varicella zoster virus infection	1 (3.0)	0	1 (3.0)	0	0
Viral skin infection	1 (3.0)	1 (3.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (6.1)	0	2 (6.1)	0	0
Hypogammaglobulinaemia	2 (6.1)	0	2 (6.1)	0	0
Serious neurological adverse reactions					
-Total	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Dysarthria	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	0	4 (23.5)	3 (17.6)	1 (5.9)
Cytokine Release Syndrome					
-Total	1 (5.9)	0	0	0	1 (5.9)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	6 (35.3)	0	2 (11.8)	3 (17.6)	1 (5.9)
Rhinovirus infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Pneumonia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Sinusitis	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	0	2 (11.8)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (5.9)	0	0	1 (5.9)	0
Bronchitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile colitis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Covid-19	1 (5.9)	1 (5.9)	0	0	0
Covid-19 pneumonia	1 (5.9)	0	0	0	1 (5.9)
Enterovirus infection	1 (5.9)	0	0	1 (5.9)	0
Folliculitis	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis escherichia coli	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis salmonella	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis viral	1 (5.9)	0	1 (5.9)	0	0
Influenza	1 (5.9)	0	0	0	1 (5.9)
Nail infection	1 (5.9)	0	1 (5.9)	0	0
Otitis media	1 (5.9)	0	1 (5.9)	0	0
Parainfluenzae virus infection	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (5.9)	0	1 (5.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (11.8)	0	2 (11.8)	0	0
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)	0	0
Hypogammaglobulinaemia	1 (5.9)	0	1 (5.9)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (100)	1 (2.1)	4 (8.3)	14 (29.2)	29 (60.4)
Cytokine Release Syndrome					
-Total	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Hematological disorders including cytopenias					
-Total	34 (70.8)	1 (2.1)	1 (2.1)	14 (29.2)	18 (37.5)
Anaemia	16 (33.3)	4 (8.3)	5 (10.4)	7 (14.6)	0
Neutrophil count decreased	16 (33.3)	1 (2.1)	1 (2.1)	2 (4.2)	12 (25.0)
Platelet count decreased	16 (33.3)	4 (8.3)	1 (2.1)	6 (12.5)	5 (10.4)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	15 (31.3)	0	0	15 (31.3)	0
White blood cell count decreased	14 (29.2)	3 (6.3)	1 (2.1)	1 (2.1)	9 (18.8)
Lymphocyte count decreased	11 (22.9)	1 (2.1)	0	5 (10.4)	5 (10.4)
Neutropenia	7 (14.6)	0	1 (2.1)	2 (4.2)	4 (8.3)
Thrombocytopenia	5 (10.4)	0	0	2 (4.2)	3 (6.3)
Leukopenia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Lymphopenia	2 (4.2)	0	0	2 (4.2)	0
Pancytopenia	2 (4.2)	0	0	2 (4.2)	0
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
Haemoglobin decreased	1 (2.1)	0	0	1 (2.1)	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	40 (83.3)	4 (8.3)	8 (16.7)	18 (37.5)	10 (20.8)
Upper respiratory tract infection	7 (14.6)	3 (6.3)	1 (2.1)	3 (6.3)	0
Conjunctivitis	6 (12.5)	2 (4.2)	4 (8.3)	0	0
Gastroenteritis	5 (10.4)	3 (6.3)	0	2 (4.2)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Rhinovirus infection	5 (10.4)	0	4 (8.3)	1 (2.1)	0
Sinusitis	5 (10.4)	0	3 (6.3)	2 (4.2)	0
Oral herpes	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Candida infection	3 (6.3)	0	2 (4.2)	0	1 (2.1)
Metapneumovirus infection	3 (6.3)	0	0	3 (6.3)	0
Oral candidiasis	3 (6.3)	0	3 (6.3)	0	0
Otitis media	3 (6.3)	0	2 (4.2)	1 (2.1)	0
Pneumonia	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Respiratory syncytial virus infection	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Rhinitis	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Sepsis	3 (6.3)	0	0	1 (2.1)	2 (4.2)
Urinary tract infection	3 (6.3)	0	2 (4.2)	1 (2.1)	0
Bronchopulmonary aspergillosis	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Fungal infection	2 (4.2)	0	2 (4.2)	0	0
Gingivitis	2 (4.2)	2 (4.2)	0	0	0
Herpes zoster	2 (4.2)	0	1 (2.1)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	2 (4.2)	0	0	2 (4.2)	0
Influenza	2 (4.2)	0	2 (4.2)	0	0
Nail infection	2 (4.2)	2 (4.2)	0	0	0
Oral infection	2 (4.2)	0	2 (4.2)	0	0
Otitis externa	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Paronychia	2 (4.2)	0	2 (4.2)	0	0
Pneumocystis jirovecii pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Respiratory tract infection	2 (4.2)	0	2 (4.2)	0	0
Septic shock	2 (4.2)	0	0	0	2 (4.2)
Skin infection	2 (4.2)	0	2 (4.2)	0	0
Skin papilloma	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Staphylococcal infection	2 (4.2)	0	0	2 (4.2)	0
Varicella zoster virus infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Viral infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Adenovirus infection	1 (2.1)	0	0	1 (2.1)	0
Anal abscess	1 (2.1)	0	0	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)
Bk virus infection	1 (2.1)	1 (2.1)	0	0	0
Bronchitis	1 (2.1)	0	1 (2.1)	0	0
Cholecystitis infective	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile infection	1 (2.1)	0	0	1 (2.1)	0
Coronavirus infection	1 (2.1)	0	0	1 (2.1)	0
Covid-19	1 (2.1)	0	0	1 (2.1)	0
Cystitis	1 (2.1)	0	1 (2.1)	0	0
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Ear, nose and throat infection	1 (2.1)	0	1 (2.1)	0	0
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis norovirus	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.1)	1 (2.1)	0	0	0
Granulicatella infection	1 (2.1)	0	0	1 (2.1)	0
Herpes simplex	1 (2.1)	0	0	1 (2.1)	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Myringitis	1 (2.1)	1 (2.1)	0	0	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0
Respiratory tract infection viral	1 (2.1)	0	1 (2.1)	0	0
Salmonellosis	1 (2.1)	0	1 (2.1)	0	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (2.1)	0	1 (2.1)	0	0
Stomatococcal infection	1 (2.1)	0	1 (2.1)	0	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Systemic candida	1 (2.1)	0	0	1 (2.1)	0
Tinea pedis	1 (2.1)	1 (2.1)	0	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (62.5)	3 (6.3)	19 (39.6)	8 (16.7)	0
Hypogammaglobulinaemia	22 (45.8)	0	17 (35.4)	5 (10.4)	0
Blood immunoglobulin a decreased	6 (12.5)	5 (10.4)	0	1 (2.1)	0
Blood immunoglobulin m decreased	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Immunodeficiency	2 (4.2)	0	0	2 (4.2)	0
Immunoglobulins decreased	2 (4.2)	0	2 (4.2)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0
Serious neurological adverse reactions					
-Total	18 (37.5)	5 (10.4)	7 (14.6)	6 (12.5)	0
Confusional state	4 (8.3)	4 (8.3)	0	0	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Agitation	3 (6.3)	3 (6.3)	0	0	0
Delirium	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Hallucination	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Seizure	3 (6.3)	0	0	3 (6.3)	0
Tremor	3 (6.3)	3 (6.3)	0	0	0
Irritability	2 (4.2)	2 (4.2)	0	0	0
Lethargy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Somnolence	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Affect lability	1 (2.1)	0	1 (2.1)	0	0
Amnesia	1 (2.1)	0	1 (2.1)	0	0
Aphasia	1 (2.1)	1 (2.1)	0	0	0
Cognitive disorder	1 (2.1)	0	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (2.1)	0	0	1 (2.1)	0
Disturbance in attention	1 (2.1)	1 (2.1)	0	0	0
Dysarthria	1 (2.1)	0	1 (2.1)	0	0
Hallucination, visual	1 (2.1)	0	1 (2.1)	0	0
Memory impairment	1 (2.1)	0	1 (2.1)	0	0
Mood altered	1 (2.1)	1 (2.1)	0	0	0
Restlessness	1 (2.1)	0	1 (2.1)	0	0
Sluggishness	1 (2.1)	0	1 (2.1)	0	0
Social avoidant behaviour	1 (2.1)	0	1 (2.1)	0	0
Tumour Lysis Syndrome					
-Total	3 (6.3)	0	0	2 (4.2)	1 (2.1)
Tumour lysis syndrome	3 (6.3)	0	0	2 (4.2)	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229l
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	4 (12.5)	8 (25.0)	20 (62.5)
Cytokine Release Syndrome					
-Total	24 (75.0)	2 (6.3)	6 (18.8)	5 (15.6)	11 (34.4)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Hematological disorders including cytopenias					
-Total	22 (68.8)	0	1 (3.1)	8 (25.0)	13 (40.6)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Anaemia	9 (28.1)	3 (9.4)	4 (12.5)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (25.0)	0	1 (3.1)	2 (6.3)	5 (15.6)
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Lymphocyte count decreased	6 (18.8)	0	1 (3.1)	5 (15.6)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Infections					
-Total	21 (65.6)	4 (12.5)	6 (18.8)	7 (21.9)	4 (12.5)
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Rhinovirus infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Staphylococcal bacteraemia	4 (12.5)	0	0	4 (12.5)	0
Clostridium difficile infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Parainfluenzae virus infection	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Pneumonia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Staphylococcal infection	3 (9.4)	0	3 (9.4)	0	0
Bacteraemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Ear infection	2 (6.3)	0	2 (6.3)	0	0
Nail infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Otitis media	2 (6.3)	0	2 (6.3)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Adenovirus infection	1 (3.1)	0	0	1 (3.1)	0
Atypical pneumonia	1 (3.1)	1 (3.1)	0	0	0
Bk virus infection	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Cellulitis	1 (3.1)	0	1 (3.1)	0	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Covid-19	1 (3.1)	1 (3.1)	0	0	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis escherichia coli	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis salmonella	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis viral	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal infection	1 (3.1)	1 (3.1)	0	0	0
Herpes simplex	1 (3.1)	0	1 (3.1)	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Influenza	1 (3.1)	0	0	0	1 (3.1)
Klebsiella bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Localised infection	1 (3.1)	1 (3.1)	0	0	0
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia respiratory syncytial viral	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Sinusitis fungal	1 (3.1)	0	0	1 (3.1)	0
Skin infection	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection viral	1 (3.1)	1 (3.1)	0	0	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (53.1)	2 (6.3)	10 (31.3)	5 (15.6)	0
Hypogammaglobulinaemia	11 (34.4)	2 (6.3)	7 (21.9)	2 (6.3)	0
Blood immunoglobulin g decreased	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Immunodeficiency	2 (6.3)	0	0	2 (6.3)	0
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0
Selective igg subclass deficiency	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	17 (53.1)	7 (21.9)	3 (9.4)	7 (21.9)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Agitation	3 (9.4)	0	3 (9.4)	0	0
Confusional state	3 (9.4)	3 (9.4)	0	0	0
Mental status changes	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Somnolence	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Tremor	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Cognitive disorder	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Muscular weakness	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Dysphagia	1 (3.1)	0	0	1 (3.1)	0
Generalised tonic-clonic seizure	1 (3.1)	0	1 (3.1)	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Lethargy	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	1 (7.7)	0	5 (38.5)	7 (53.8)
Cytokine Release Syndrome					
-Total	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hematological disorders including cytopenias					
-Total	12 (92.3)	1 (7.7)	0	4 (30.8)	7 (53.8)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0
Platelet count decreased	8 (61.5)	3 (23.1)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	8 (61.5)	1 (7.7)	2 (15.4)	0	5 (38.5)
Lymphocyte count decreased	7 (53.8)	1 (7.7)	0	4 (30.8)	2 (15.4)
Neutrophil count decreased	7 (53.8)	0	2 (15.4)	0	5 (38.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Haemoglobin decreased	1 (7.7)	0	0	1 (7.7)	0
Leukopenia	1 (7.7)	0	0	0	1 (7.7)
Infections					
-Total	5 (38.5)	1 (7.7)	1 (7.7)	3 (23.1)	0
Anal abscess	1 (7.7)	0	0	1 (7.7)	0
Otitis externa	1 (7.7)	0	1 (7.7)	0	0
Paronychia	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	1 (7.7)	0
Urinary tract infection viral	1 (7.7)	1 (7.7)	0	0	0
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (53.8)	5 (38.5)	2 (15.4)	0	0
Blood immunoglobulin a decreased	4 (30.8)	4 (30.8)	0	0	0
Blood immunoglobulin m decreased	4 (30.8)	4 (30.8)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (15.4)	0	2 (15.4)	0	0
Serious neurological adverse reactions					
-Total	5 (38.5)	5 (38.5)	0	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Irritability	1 (7.7)	1 (7.7)	0	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Mental status changes	1 (7.7)	1 (7.7)	0	0	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.7)	0	0	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (94.0)	2 (3.0)	9 (13.4)	15 (22.4)	37 (55.2)
Cytokine Release Syndrome					
-Total	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Hematological disorders including cytopenias					
-Total	41 (61.2)	1 (1.5)	2 (3.0)	15 (22.4)	23 (34.3)
Febrile neutropenia	20 (29.9)	0	0	18 (26.9)	2 (3.0)
White blood cell count decreased	16 (23.9)	2 (3.0)	1 (1.5)	2 (3.0)	11 (16.4)
Anaemia	13 (19.4)	2 (3.0)	3 (4.5)	8 (11.9)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	13 (19.4)	0	1 (1.5)	2 (3.0)	10 (14.9)
Platelet count decreased	13 (19.4)	1 (1.5)	2 (3.0)	2 (3.0)	8 (11.9)
Lymphocyte count decreased	8 (11.9)	1 (1.5)	0	4 (6.0)	3 (4.5)
Thrombocytopenia	8 (11.9)	0	0	2 (3.0)	6 (9.0)
Neutropenia	7 (10.4)	0	2 (3.0)	1 (1.5)	4 (6.0)
Leukopenia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Pancytopenia	2 (3.0)	0	0	2 (3.0)	0
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	30 (44.8)	5 (7.5)	9 (13.4)	13 (19.4)	3 (4.5)
Conjunctivitis	5 (7.5)	1 (1.5)	4 (6.0)	0	0
Staphylococcal infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0
Clostridium difficile infection	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Candida infection	3 (4.5)	0	2 (3.0)	0	1 (1.5)
Staphylococcal bacteraemia	3 (4.5)	0	0	3 (4.5)	0
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Nail infection	2 (3.0)	2 (3.0)	0	0	0
Oral herpes	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Oral infection	2 (3.0)	0	2 (3.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (3.0)	0	2 (3.0)	0	0
Adenovirus infection	1 (1.5)	0	0	1 (1.5)	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis norovirus	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (1.5)	0	1 (1.5)	0	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (44.8)	2 (3.0)	17 (25.4)	11 (16.4)	0
Hypogammaglobulinaemia	21 (31.3)	2 (3.0)	12 (17.9)	7 (10.4)	0
Immunodeficiency	3 (4.5)	0	0	3 (4.5)	0
Blood immunoglobulin g decreased	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Immunoglobulins decreased	2 (3.0)	0	2 (3.0)	0	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	26 (38.8)	8 (11.9)	8 (11.9)	10 (14.9)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Delirium	7 (10.4)	2 (3.0)	2 (3.0)	3 (4.5)	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Somnolence	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Tremor	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Agitation	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Cognitive disorder	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Hallucination	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Irritability	2 (3.0)	2 (3.0)	0	0	0
Lethargy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Mental status changes	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Muscular weakness	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Seizure	2 (3.0)	0	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					
-Total	3 (4.5)	0	0	3 (4.5)	0
Tumour lysis syndrome	3 (4.5)	0	0	3 (4.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (76.9)	2 (15.4)	3 (23.1)	2 (15.4)	3 (23.1)
Hematological disorders including cytopenias					
-Total	8 (61.5)	2 (15.4)	2 (15.4)	1 (7.7)	3 (23.1)
Neutrophil count decreased	4 (30.8)	1 (7.7)	1 (7.7)	1 (7.7)	1 (7.7)
White blood cell count decreased	3 (23.1)	2 (15.4)	0	1 (7.7)	0
Lymphocyte count decreased	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Anaemia	1 (7.7)	1 (7.7)	0	0	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Infections					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Nasopharyngitis	1 (7.7)	1 (7.7)	0	0	0
Sinusitis	1 (7.7)	0	1 (7.7)	0	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (38.5)	1 (7.7)	3 (23.1)	1 (7.7)	0
Hypogammaglobulinaemia	3 (23.1)	0	3 (23.1)	0	0
Blood immunoglobulin a decreased	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Blood immunoglobulin m decreased	1 (7.7)	0	0	1 (7.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (72.6)	4 (6.5)	14 (22.6)	14 (22.6)	13 (21.0)
Hematological disorders including cytopenias					
-Total	18 (29.0)	4 (6.5)	1 (1.6)	8 (12.9)	5 (8.1)
White blood cell count decreased	7 (11.3)	2 (3.2)	2 (3.2)	2 (3.2)	1 (1.6)
Neutrophil count decreased	6 (9.7)	1 (1.6)	0	2 (3.2)	3 (4.8)
Anaemia	5 (8.1)	3 (4.8)	0	2 (3.2)	0
Platelet count decreased	4 (6.5)	2 (3.2)	0	1 (1.6)	1 (1.6)
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Neutropenia	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Lymphocyte count decreased	2 (3.2)	0	0	2 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Leukopenia	1 (1.6)	0	1 (1.6)	0	0
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	38 (61.3)	4 (6.5)	14 (22.6)	12 (19.4)	8 (12.9)
Upper respiratory tract infection	8 (12.9)	3 (4.8)	3 (4.8)	2 (3.2)	0
Nasopharyngitis	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Rhinovirus infection	5 (8.1)	0	4 (6.5)	1 (1.6)	0
Gastroenteritis	4 (6.5)	2 (3.2)	0	2 (3.2)	0
Parainfluenzae virus infection	4 (6.5)	1 (1.6)	1 (1.6)	1 (1.6)	1 (1.6)
Metapneumovirus infection	3 (4.8)	0	0	3 (4.8)	0
Otitis media	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Pneumonia	3 (4.8)	1 (1.6)	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Respiratory tract infection	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Bacteraemia	2 (3.2)	0	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (3.2)	0	2 (3.2)	0	0
Otitis externa	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Rhinitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Sinusitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Skin papilloma	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Viral infection	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Adenovirus infection	1 (1.6)	0	0	1 (1.6)	0
Bk virus infection	1 (1.6)	0	0	1 (1.6)	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis clostridial	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Herpes simplex	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	0	1 (1.6)	0	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Septic shock	1 (1.6)	0	0	0	1 (1.6)
Sinusitis fungal	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (16.1)	0	9 (14.5)	1 (1.6)	0
Hypogammaglobulinaemia	7 (11.3)	0	7 (11.3)	0	0
B-cell aplasia	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0
Serious neurological adverse reactions					
-Total	5 (8.1)	1 (1.6)	2 (3.2)	2 (3.2)	0
Mental status changes	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Agitation	1 (1.6)	1 (1.6)	0	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Memory impairment	1 (1.6)	0	1 (1.6)	0	0
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Seizure	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	0	1 (1.6)
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	1 (12.5)	2 (25.0)	3 (37.5)	0
Hematological disorders including cytopenias					
-Total	2 (25.0)	2 (25.0)	0	0	0
Neutrophil count decreased	2 (25.0)	2 (25.0)	0	0	0
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					
-Total	3 (37.5)	0	0	3 (37.5)	0
Upper respiratory tract infection	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Acute sinusitis	1 (12.5)	0	1 (12.5)	0	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (12.5)	0	0	1 (12.5)	0
Herpes zoster	1 (12.5)	0	1 (12.5)	0	0
Influenza	1 (12.5)	0	1 (12.5)	0	0
Oral herpes	1 (12.5)	1 (12.5)	0	0	0
Otitis media	1 (12.5)	0	1 (12.5)	0	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (25.0)	0	2 (25.0)	0	0
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)	0	0

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Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (50.0)	2 (4.8)	7 (16.7)	7 (16.7)	5 (11.9)
Cytokine Release Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Hematological disorders including cytopenias					
-Total	5 (11.9)	1 (2.4)	0	2 (4.8)	2 (4.8)
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (2.4)	0	0	0	1 (2.4)
Platelet count decreased	1 (2.4)	1 (2.4)	0	0	0
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Infections					
-Total	20 (47.6)	2 (4.8)	7 (16.7)	7 (16.7)	4 (9.5)
Sinusitis	5 (11.9)	0	5 (11.9)	0	0
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Conjunctivitis	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Upper respiratory tract infection	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Bronchitis	2 (4.8)	0	2 (4.8)	0	0
Covid-19	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Fungal infection	2 (4.8)	0	2 (4.8)	0	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Skin infection	2 (4.8)	0	2 (4.8)	0	0
Urinary tract infection	2 (4.8)	0	2 (4.8)	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Folliculitis	1 (2.4)	0	1 (2.4)	0	0
Fungal skin infection	1 (2.4)	0	1 (2.4)	0	0
Gastroenteritis	1 (2.4)	1 (2.4)	0	0	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis viral	1 (2.4)	0	1 (2.4)	0	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	0	0	1 (2.4)
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	0	1 (2.4)	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0
Oral herpes	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (2.4)	0	1 (2.4)	0	0
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Rhinitis	1 (2.4)	1 (2.4)	0	0	0
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Syphilis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Varicella zoster virus infection	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (4.8)	0	2 (4.8)	0	0
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (2.4)	0	1 (2.4)	0	0
Serious neurological adverse reactions					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Dysarthria	1 (2.4)	0	1 (2.4)	0	0
Seizure	1 (2.4)	0	0	1 (2.4)	0

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Table 229m
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	1 (7.7)	5 (38.5)	7 (53.8)
Cytokine Release Syndrome					
-Total	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hematological disorders including cytopenias					
-Total	12 (92.3)	1 (7.7)	0	4 (30.8)	7 (53.8)
Neutrophil count decreased	9 (69.2)	1 (7.7)	2 (15.4)	1 (7.7)	5 (38.5)
Platelet count decreased	9 (69.2)	4 (30.8)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	9 (69.2)	2 (15.4)	2 (15.4)	0	5 (38.5)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (53.8)	0	1 (7.7)	4 (30.8)	2 (15.4)
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Haemoglobin decreased	1 (7.7)	0	0	1 (7.7)	0
Leukopenia	1 (7.7)	0	0	0	1 (7.7)
Infections					
-Total	5 (38.5)	1 (7.7)	0	4 (30.8)	0
Upper respiratory tract infection	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Acute sinusitis	1 (7.7)	0	1 (7.7)	0	0
Anal abscess	1 (7.7)	0	0	1 (7.7)	0
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Ear infection	1 (7.7)	0	0	1 (7.7)	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Herpes zoster	1 (7.7)	0	1 (7.7)	0	0
Influenza	1 (7.7)	0	1 (7.7)	0	0
Nasopharyngitis	1 (7.7)	1 (7.7)	0	0	0
Oral herpes	1 (7.7)	1 (7.7)	0	0	0
Otitis externa	1 (7.7)	0	1 (7.7)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (7.7)	0	1 (7.7)	0	0
Paronychia	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	1 (7.7)	0
Sinusitis	1 (7.7)	0	1 (7.7)	0	0
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Staphylococcal abscess	1 (7.7)	0	0	1 (7.7)	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0
Urinary tract infection viral	1 (7.7)	1 (7.7)	0	0	0
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (76.9)	3 (23.1)	6 (46.2)	1 (7.7)	0
Blood immunoglobulin a decreased	6 (46.2)	5 (38.5)	0	1 (7.7)	0
Hypogammaglobulinaemia	6 (46.2)	0	6 (46.2)	0	0
Blood immunoglobulin m decreased	5 (38.5)	4 (30.8)	0	1 (7.7)	0
Serious neurological adverse reactions					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (38.5)	5 (38.5)	0	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Irritability	1 (7.7)	1 (7.7)	0	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Mental status changes	1 (7.7)	1 (7.7)	0	0	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.7)	0	0	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0

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Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (100)	1 (1.5)	7 (10.4)	17 (25.4)	42 (62.7)
Cytokine Release Syndrome					
-Total	50 (74.6)	5 (7.5)	12 (17.9)	12 (17.9)	21 (31.3)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	6 (9.0)	1 (1.5)	1 (1.5)	2 (3.0)	2 (3.0)
Hematological disorders including cytopenias					
-Total	44 (65.7)	0	2 (3.0)	18 (26.9)	24 (35.8)
Febrile neutropenia	21 (31.3)	0	0	19 (28.4)	2 (3.0)
Anaemia	17 (25.4)	4 (6.0)	4 (6.0)	9 (13.4)	0
White blood cell count decreased	16 (23.9)	1 (1.5)	2 (3.0)	2 (3.0)	11 (16.4)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	15 (22.4)	0	0	3 (4.5)	12 (17.9)
Platelet count decreased	15 (22.4)	2 (3.0)	2 (3.0)	3 (4.5)	8 (11.9)
Lymphocyte count decreased	10 (14.9)	1 (1.5)	0	6 (9.0)	3 (4.5)
Neutropenia	9 (13.4)	0	2 (3.0)	2 (3.0)	5 (7.5)
Thrombocytopenia	9 (13.4)	0	0	3 (4.5)	6 (9.0)
Leukopenia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Lymphopenia	2 (3.0)	0	0	2 (3.0)	0
Pancytopenia	2 (3.0)	0	0	2 (3.0)	0
Agranulocytosis	1 (1.5)	0	0	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Infections					
-Total	56 (83.6)	7 (10.4)	14 (20.9)	21 (31.3)	14 (20.9)
Upper respiratory tract infection	11 (16.4)	4 (6.0)	5 (7.5)	2 (3.0)	0
Rhinovirus infection	9 (13.4)	0	7 (10.4)	2 (3.0)	0
Conjunctivitis	7 (10.4)	2 (3.0)	5 (7.5)	0	0
Nasopharyngitis	6 (9.0)	3 (4.5)	3 (4.5)	0	0
Sinusitis	6 (9.0)	0	4 (6.0)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	5 (7.5)	3 (4.5)	0	2 (3.0)	0
Parainfluenzae virus infection	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Pneumonia	5 (7.5)	1 (1.5)	1 (1.5)	1 (1.5)	2 (3.0)
Staphylococcal bacteraemia	5 (7.5)	0	0	5 (7.5)	0
Staphylococcal infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0
Candida infection	4 (6.0)	0	3 (4.5)	0	1 (1.5)
Clostridium difficile infection	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Nail infection	4 (6.0)	3 (4.5)	1 (1.5)	0	0
Otitis media	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Bacteraemia	3 (4.5)	0	1 (1.5)	1 (1.5)	1 (1.5)
Metapneumovirus infection	3 (4.5)	0	0	3 (4.5)	0
Oral candidiasis	3 (4.5)	0	3 (4.5)	0	0
Oral herpes	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Respiratory syncytial virus infection	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Respiratory tract infection	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Rhinitis	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Sepsis	3 (4.5)	0	0	1 (1.5)	2 (3.0)
Urinary tract infection	3 (4.5)	0	2 (3.0)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	2 (3.0)	0	0	2 (3.0)	0
Bk virus infection	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Bronchitis	2 (3.0)	0	2 (3.0)	0	0
Bronchopulmonary aspergillosis	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Covid-19	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Ear infection	2 (3.0)	0	2 (3.0)	0	0
Encephalitis	2 (3.0)	0	0	0	2 (3.0)
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Fungal infection	2 (3.0)	0	2 (3.0)	0	0
Gastroenteritis viral	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gingivitis	2 (3.0)	2 (3.0)	0	0	0
Herpes simplex	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Herpes zoster	2 (3.0)	0	0	2 (3.0)	0
Human herpesvirus 6 infection	2 (3.0)	0	0	2 (3.0)	0
Influenza	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Oral infection	2 (3.0)	0	2 (3.0)	0	0
Otitis externa	2 (3.0)	0	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (3.0)	0	0	0	2 (3.0)
Skin infection	2 (3.0)	0	2 (3.0)	0	0
Skin papilloma	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Viral infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bronchiolitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Coronavirus infection	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis clostridial	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	1 (1.5)	0	0	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes virus infection	1 (1.5)	0	1 (1.5)	0	0
Klebsiella bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	0	1 (1.5)	0	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Salmonellosis	1 (1.5)	0	1 (1.5)	0	0
Sinusitis fungal	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal skin infection	1 (1.5)	0	1 (1.5)	0	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Streptococcal sepsis	1 (1.5)	0	1 (1.5)	0	0
Syphilis	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Varicella zoster virus infection	1 (1.5)	0	1 (1.5)	0	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	37 (55.2)	2 (3.0)	23 (34.3)	12 (17.9)	0
Hypogammaglobulinaemia	27 (40.3)	2 (3.0)	18 (26.9)	7 (10.4)	0
Blood immunoglobulin g decreased	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Immunodeficiency	4 (6.0)	0	0	4 (6.0)	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Immunoglobulins decreased	2 (3.0)	0	2 (3.0)	0	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	30 (44.8)	7 (10.4)	10 (14.9)	13 (19.4)	0
Delirium	8 (11.9)	2 (3.0)	3 (4.5)	3 (4.5)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Agitation	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Somnolence	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Tremor	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Mental status changes	4 (6.0)	0	2 (3.0)	2 (3.0)	0
Seizure	4 (6.0)	0	1 (1.5)	3 (4.5)	0
Cognitive disorder	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Hallucination	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Dysarthria	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Irritability	2 (3.0)	2 (3.0)	0	0	0
Lethargy	2 (3.0)	1 (1.5)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					
-Total	4 (6.0)	0	0	3 (4.5)	1 (1.5)
Tumour lysis syndrome	4 (6.0)	0	0	3 (4.5)	1 (1.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (96.2)	0	4 (15.4)	9 (34.6)	12 (46.2)
Cytokine Release Syndrome					
-Total	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	1 (3.8)	0	0	0	1 (3.8)
Hematological disorders including cytopenias					
-Total	21 (80.8)	0	1 (3.8)	10 (38.5)	10 (38.5)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Neutrophil count decreased	6 (23.1)	0	1 (3.8)	1 (3.8)	4 (15.4)
Lymphocyte count decreased	4 (15.4)	0	0	4 (15.4)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Pancytopenia	2 (7.7)	0	0	2 (7.7)	0
Infections					
-Total	7 (26.9)	2 (7.7)	2 (7.7)	2 (7.7)	1 (3.8)
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Clostridium difficile infection	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Encephalitis	1 (3.8)	0	0	0	1 (3.8)
Localised infection	1 (3.8)	1 (3.8)	0	0	0
Nail infection	1 (3.8)	1 (3.8)	0	0	0
Staphylococcal bacteraemia	1 (3.8)	0	0	1 (3.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	15 (57.7)	2 (7.7)	8 (30.8)	5 (19.2)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	9 (34.6)	1 (3.8)	6 (23.1)	2 (7.7)	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Blood immunoglobulin a decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Blood immunoglobulin g decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Immunodeficiency	2 (7.7)	0	0	2 (7.7)	0
B-cell aplasia	1 (3.8)	0	1 (3.8)	0	0
Serious neurological adverse reactions					
-Total	9 (34.6)	4 (15.4)	2 (7.7)	3 (11.5)	0
Cognitive disorder	2 (7.7)	0	2 (7.7)	0	0
Confusional state	2 (7.7)	2 (7.7)	0	0	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0
Irritability	1 (3.8)	1 (3.8)	0	0	0
Lethargy	1 (3.8)	1 (3.8)	0	0	0
Seizure	1 (3.8)	0	0	1 (3.8)	0
Tremor	1 (3.8)	1 (3.8)	0	0	0
Tumour Lysis Syndrome					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.8)	0	0	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (94.4)	3 (5.6)	5 (9.3)	11 (20.4)	32 (59.3)
Cytokine Release Syndrome					
-Total	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Haemophagocytic lymphohistiocytosis	4 (7.4)	1 (1.9)	1 (1.9)	2 (3.7)	0
Hematological disorders including cytopenias					
-Total	32 (59.3)	2 (3.7)	1 (1.9)	9 (16.7)	20 (37.0)
Febrile neutropenia	16 (29.6)	0	0	15 (27.8)	1 (1.9)
White blood cell count decreased	16 (29.6)	2 (3.7)	1 (1.9)	1 (1.9)	12 (22.2)
Neutrophil count decreased	14 (25.9)	0	2 (3.7)	1 (1.9)	11 (20.4)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	14 (25.9)	2 (3.7)	2 (3.7)	6 (11.1)	4 (7.4)
Anaemia	13 (24.1)	2 (3.7)	6 (11.1)	5 (9.3)	0
Lymphocyte count decreased	11 (20.4)	2 (3.7)	0	4 (7.4)	5 (9.3)
Neutropenia	5 (9.3)	0	1 (1.9)	0	4 (7.4)
Thrombocytopenia	4 (7.4)	0	0	0	4 (7.4)
Haemoglobin decreased	1 (1.9)	0	0	1 (1.9)	0
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	28 (51.9)	4 (7.4)	8 (14.8)	14 (25.9)	2 (3.7)
Staphylococcal infection	5 (9.3)	0	3 (5.6)	2 (3.7)	0
Candida infection	3 (5.6)	0	2 (3.7)	0	1 (1.9)
Clostridium difficile infection	2 (3.7)	0	0	2 (3.7)	0
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Oral herpes	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Oral infection	2 (3.7)	0	2 (3.7)	0	0
Rhinovirus infection	2 (3.7)	0	2 (3.7)	0	0
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Adenovirus infection	1 (1.9)	0	0	1 (1.9)	0
Anal abscess	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bk virus infection	1 (1.9)	1 (1.9)	0	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	1 (1.9)	0	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	1 (1.9)	0	0	0
Gingivitis	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes simplex	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Myringitis	1 (1.9)	1 (1.9)	0	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pneumonia	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	22 (40.7)	5 (9.3)	11 (20.4)	6 (11.1)	0
Hypogammaglobulinaemia	14 (25.9)	1 (1.9)	8 (14.8)	5 (9.3)	0
Blood immunoglobulin a decreased	3 (5.6)	3 (5.6)	0	0	0
Blood immunoglobulin m decreased	3 (5.6)	3 (5.6)	0	0	0
Immunoglobulins decreased	2 (3.7)	0	2 (3.7)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (1.9)	0	0	1 (1.9)	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	22 (40.7)	9 (16.7)	6 (11.1)	7 (13.0)	0
Delirium	7 (13.0)	2 (3.7)	2 (3.7)	3 (5.6)	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Agitation	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Confusional state	5 (9.3)	5 (9.3)	0	0	0
Somnolence	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Tremor	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Hallucination	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Mental status changes	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Irritability	2 (3.7)	2 (3.7)	0	0	0
Lethargy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Muscular weakness	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Cognitive disorder	1 (1.9)	0	0	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Generalised tonic-clonic seizure	1 (1.9)	0	1 (1.9)	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Seizure	1 (1.9)	0	1 (1.9)	0	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tumour Lysis Syndrome					
-Total	3 (5.6)	0	0	3 (5.6)	0
Tumour lysis syndrome	3 (5.6)	0	0	3 (5.6)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (72.0)	2 (8.0)	7 (28.0)	5 (20.0)	4 (16.0)
Hematological disorders including cytopenias					
-Total	9 (36.0)	3 (12.0)	2 (8.0)	2 (8.0)	2 (8.0)
Neutrophil count decreased	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)	1 (4.0)
White blood cell count decreased	4 (16.0)	2 (8.0)	1 (4.0)	0	1 (4.0)
Anaemia	3 (12.0)	2 (8.0)	0	1 (4.0)	0
Lymphocyte count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Platelet count decreased	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Leukopenia	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Infections					
-Total	12 (48.0)	1 (4.0)	5 (20.0)	4 (16.0)	2 (8.0)
Upper respiratory tract infection	4 (16.0)	2 (8.0)	0	2 (8.0)	0
Respiratory syncytial virus infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Otitis media	2 (8.0)	0	2 (8.0)	0	0
Parainfluenzae virus infection	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Rhinovirus infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Bronchopulmonary aspergillosis	1 (4.0)	0	0	0	1 (4.0)
Cellulitis	1 (4.0)	0	1 (4.0)	0	0
Conjunctivitis	1 (4.0)	0	1 (4.0)	0	0
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Ear, nose and throat infection	1 (4.0)	0	1 (4.0)	0	0
Encephalitis	1 (4.0)	0	0	0	1 (4.0)
Gastroenteritis	1 (4.0)	0	0	1 (4.0)	0
Gastrointestinal infection	1 (4.0)	1 (4.0)	0	0	0
Herpes zoster	1 (4.0)	0	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (4.0)	0	0	1 (4.0)	0
Molluscum contagiosum	1 (4.0)	1 (4.0)	0	0	0
Nasopharyngitis	1 (4.0)	0	1 (4.0)	0	0
Otitis externa	1 (4.0)	0	1 (4.0)	0	0
Paronychia	1 (4.0)	0	1 (4.0)	0	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	0	1 (4.0)	0
Pneumonia	1 (4.0)	0	1 (4.0)	0	0
Respiratory tract infection	1 (4.0)	0	1 (4.0)	0	0
Respiratory tract infection viral	1 (4.0)	0	1 (4.0)	0	0
Rhinitis	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal bacteraemia	1 (4.0)	0	0	1 (4.0)	0
Viral haemorrhagic cystitis	1 (4.0)	0	0	1 (4.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (20.0)	0	5 (20.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
B-cell aplasia	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (4.0)	0	0	1 (4.0)	0
Memory impairment	1 (4.0)	0	1 (4.0)	0	0
Seizure	1 (4.0)	0	0	1 (4.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (74.0)	4 (8.0)	10 (20.0)	11 (22.0)	12 (24.0)
Hematological disorders including cytopenias					
-Total	17 (34.0)	3 (6.0)	1 (2.0)	7 (14.0)	6 (12.0)
Neutrophil count decreased	6 (12.0)	1 (2.0)	0	2 (4.0)	3 (6.0)
White blood cell count decreased	6 (12.0)	2 (4.0)	1 (2.0)	3 (6.0)	0
Neutropenia	4 (8.0)	0	0	2 (4.0)	2 (4.0)
Anaemia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Lymphocyte count decreased	2 (4.0)	0	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	28 (56.0)	4 (8.0)	10 (20.0)	8 (16.0)	6 (12.0)
Nasopharyngitis	6 (12.0)	4 (8.0)	2 (4.0)	0	0
Gastroenteritis	4 (8.0)	3 (6.0)	0	1 (2.0)	0
Upper respiratory tract infection	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Rhinovirus infection	3 (6.0)	0	3 (6.0)	0	0
Sinusitis	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Bacteraemia	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Metapneumovirus infection	2 (4.0)	0	0	2 (4.0)	0
Parainfluenzae virus infection	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Pneumonia	2 (4.0)	1 (2.0)	0	0	1 (2.0)
Respiratory tract infection	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Skin papilloma	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Viral infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	1 (2.0)	0	0	1 (2.0)	0
Bk virus infection	1 (2.0)	0	0	1 (2.0)	0
Coronavirus infection	1 (2.0)	0	0	1 (2.0)	0
Cystitis	1 (2.0)	0	1 (2.0)	0	0
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Device related infection	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis clostridial	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Gingivitis	1 (2.0)	1 (2.0)	0	0	0
Herpes simplex	1 (2.0)	0	1 (2.0)	0	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Influenza	1 (2.0)	0	1 (2.0)	0	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	0	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	0	0	1 (2.0)
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Salmonellosis	1 (2.0)	0	1 (2.0)	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Sinusitis fungal	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal sepsis	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal skin infection	1 (2.0)	0	1 (2.0)	0	0
Tinea pedis	1 (2.0)	1 (2.0)	0	0	0
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (20.0)	1 (2.0)	7 (14.0)	2 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	5 (10.0)	0	5 (10.0)	0	0
Blood immunoglobulin a decreased	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin m decreased	1 (2.0)	0	0	1 (2.0)	0
Immunodeficiency	1 (2.0)	0	0	1 (2.0)	0
Immunoglobulins decreased	1 (2.0)	0	1 (2.0)	0	0
Serious neurological adverse reactions					
-Total	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Mental status changes	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Agitation	1 (2.0)	1 (2.0)	0	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Mood altered	1 (2.0)	1 (2.0)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Tumour lysis syndrome	1 (2.0)	0	0	0	1 (2.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (60.0)	0	6 (30.0)	4 (20.0)	2 (10.0)
Cytokine Release Syndrome					
-Total	1 (5.0)	0	0	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)
Hematological disorders including cytopenias					
-Total	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	10 (50.0)	0	5 (25.0)	4 (20.0)	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Sinusitis	3 (15.0)	0	3 (15.0)	0	0
Pneumonia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Conjunctivitis	1 (5.0)	1 (5.0)	0	0	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0
Influenza	1 (5.0)	0	0	0	1 (5.0)
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	1 (5.0)	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=20 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0
Varicella zoster virus infection	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (10.0)	0	2 (10.0)	0	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	1 (5.0)	0	0
Dysarthria	1 (5.0)	0	1 (5.0)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (50.0)	3 (10.0)	3 (10.0)	6 (20.0)	3 (10.0)
Hematological disorders including cytopenias					
-Total	5 (16.7)	3 (10.0)	0	1 (3.3)	1 (3.3)
Neutrophil count decreased	2 (6.7)	2 (6.7)	0	0	0
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Agranulocytosis	1 (3.3)	0	0	1 (3.3)	0
Anaemia	1 (3.3)	0	1 (3.3)	0	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Thrombocytopenia	1 (3.3)	0	1 (3.3)	0	0
Infections					
-Total	13 (43.3)	2 (6.7)	2 (6.7)	6 (20.0)	3 (10.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Bronchitis	2 (6.7)	0	2 (6.7)	0	0
Covid-19	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Oral herpes	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Otitis media	2 (6.7)	0	2 (6.7)	0	0
Sepsis	2 (6.7)	0	0	0	2 (6.7)
Skin infection	2 (6.7)	0	2 (6.7)	0	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	0	1 (3.3)	0
Folliculitis	1 (3.3)	0	1 (3.3)	0	0
Fungal infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (3.3)	0	1 (3.3)	0	0
Herpes virus infection	1 (3.3)	0	1 (3.3)	0	0
Influenza	1 (3.3)	0	1 (3.3)	0	0
Meningitis pneumococcal	1 (3.3)	0	0	1 (3.3)	0
Nail infection	1 (3.3)	0	1 (3.3)	0	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Oral candidiasis	1 (3.3)	0	1 (3.3)	0	0
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Rhinitis	1 (3.3)	1 (3.3)	0	0	0
Rhinovirus infection	1 (3.3)	0	1 (3.3)	0	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Streptococcal sepsis	1 (3.3)	0	1 (3.3)	0	0
Syphilis	1 (3.3)	0	1 (3.3)	0	0
Urinary tract infection	1 (3.3)	0	1 (3.3)	0	0
Urinary tract infection pseudomonal	1 (3.3)	0	1 (3.3)	0	0
Viral skin infection	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=30 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (6.7)	0	2 (6.7)	0	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Seizure	1 (3.3)	0	0	1 (3.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (100)	0	4 (15.4)	9 (34.6)	13 (50.0)
Cytokine Release Syndrome					
-Total	18 (69.2)	3 (11.5)	7 (26.9)	3 (11.5)	5 (19.2)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	2 (7.7)	0	0	0	2 (7.7)
Hematological disorders including cytopenias					
-Total	21 (80.8)	0	1 (3.8)	10 (38.5)	10 (38.5)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
Neutrophil count decreased	8 (30.8)	0	1 (3.8)	2 (7.7)	5 (19.2)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Lymphocyte count decreased	5 (19.2)	0	0	5 (19.2)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Pancytopenia	2 (7.7)	0	0	2 (7.7)	0
Neutropenic infection	1 (3.8)	0	0	1 (3.8)	0
Infections					
-Total	19 (73.1)	2 (7.7)	7 (26.9)	6 (23.1)	4 (15.4)
Upper respiratory tract infection	6 (23.1)	3 (11.5)	1 (3.8)	2 (7.7)	0
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Rhinovirus infection	4 (15.4)	0	2 (7.7)	2 (7.7)	0
Parainfluenzae virus infection	3 (11.5)	1 (3.8)	0	2 (7.7)	0
Pneumonia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Respiratory syncytial virus infection	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Sinusitis	3 (11.5)	0	3 (11.5)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	3 (11.5)	0	0	3 (11.5)	0
Clostridium difficile infection	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Encephalitis	2 (7.7)	0	0	0	2 (7.7)
Otitis media	2 (7.7)	0	2 (7.7)	0	0
Bronchopulmonary aspergillosis	1 (3.8)	0	0	0	1 (3.8)
Cellulitis	1 (3.8)	0	1 (3.8)	0	0
Clostridium difficile colitis	1 (3.8)	0	0	1 (3.8)	0
Covid-19 pneumonia	1 (3.8)	0	0	0	1 (3.8)
Ear infection	1 (3.8)	0	1 (3.8)	0	0
Ear, nose and throat infection	1 (3.8)	0	1 (3.8)	0	0
Enterovirus infection	1 (3.8)	0	0	1 (3.8)	0
Fungal infection	1 (3.8)	0	1 (3.8)	0	0
Fungal skin infection	1 (3.8)	0	1 (3.8)	0	0
Gastroenteritis	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis escherichia coli	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis salmonella	1 (3.8)	0	0	1 (3.8)	0
Gastrointestinal infection	1 (3.8)	1 (3.8)	0	0	0
Herpes zoster	1 (3.8)	0	0	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.8)	0	0	0	1 (3.8)
Localised infection	1 (3.8)	1 (3.8)	0	0	0
Metapneumovirus infection	1 (3.8)	0	0	1 (3.8)	0
Molluscum contagiosum	1 (3.8)	1 (3.8)	0	0	0
Nail infection	1 (3.8)	1 (3.8)	0	0	0
Nasopharyngitis	1 (3.8)	0	1 (3.8)	0	0
Neutropenic infection	1 (3.8)	0	0	1 (3.8)	0
Otitis externa	1 (3.8)	0	1 (3.8)	0	0
Otitis media acute	1 (3.8)	0	1 (3.8)	0	0
Paronychia	1 (3.8)	0	1 (3.8)	0	0
Pneumocystis jirovecii pneumonia	1 (3.8)	0	0	1 (3.8)	0
Respiratory tract infection	1 (3.8)	0	1 (3.8)	0	0
Respiratory tract infection viral	1 (3.8)	0	1 (3.8)	0	0
Rhinitis	1 (3.8)	0	1 (3.8)	0	0
Sepsis	1 (3.8)	0	0	1 (3.8)	0
Skin infection	1 (3.8)	0	1 (3.8)	0	0
Urinary tract infection	1 (3.8)	0	1 (3.8)	0	0
Varicella zoster virus infection	1 (3.8)	0	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (3.8)	0	0	1 (3.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	18 (69.2)	1 (3.8)	12 (46.2)	5 (19.2)	0
Hypogammaglobulinaemia	14 (53.8)	1 (3.8)	11 (42.3)	2 (7.7)	0
Blood immunoglobulin g decreased	3 (11.5)	1 (3.8)	2 (7.7)	0	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Blood immunoglobulin a decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Immunodeficiency	2 (7.7)	0	0	2 (7.7)	0
B-cell aplasia	1 (3.8)	0	1 (3.8)	0	0
Serious neurological adverse reactions					
-Total	10 (38.5)	4 (15.4)	2 (7.7)	4 (15.4)	0
Cognitive disorder	2 (7.7)	0	2 (7.7)	0	0
Confusional state	2 (7.7)	2 (7.7)	0	0	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0
Seizure	2 (7.7)	0	0	2 (7.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (3.8)	0	1 (3.8)	0	0
Irritability	1 (3.8)	1 (3.8)	0	0	0
Lethargy	1 (3.8)	1 (3.8)	0	0	0
Memory impairment	1 (3.8)	0	1 (3.8)	0	0
Tremor	1 (3.8)	1 (3.8)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.8)	0	0	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229n
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (100)	1 (1.9)	4 (7.4)	13 (24.1)	36 (66.7)
Cytokine Release Syndrome					
-Total	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Haemophagocytic lymphohistiocytosis	4 (7.4)	1 (1.9)	1 (1.9)	2 (3.7)	0
Hematological disorders including cytopenias					
-Total	35 (64.8)	1 (1.9)	1 (1.9)	12 (22.2)	21 (38.9)
Anaemia	17 (31.5)	4 (7.4)	7 (13.0)	6 (11.1)	0
Febrile neutropenia	17 (31.5)	0	0	16 (29.6)	1 (1.9)
Platelet count decreased	17 (31.5)	4 (7.4)	2 (3.7)	7 (13.0)	4 (7.4)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	17 (31.5)	2 (3.7)	2 (3.7)	1 (1.9)	12 (22.2)
Neutrophil count decreased	16 (29.6)	1 (1.9)	1 (1.9)	2 (3.7)	12 (22.2)
Lymphocyte count decreased	12 (22.2)	1 (1.9)	1 (1.9)	5 (9.3)	5 (9.3)
Neutropenia	7 (13.0)	0	1 (1.9)	1 (1.9)	5 (9.3)
Thrombocytopenia	5 (9.3)	0	0	1 (1.9)	4 (7.4)
Lymphopenia	2 (3.7)	0	0	2 (3.7)	0
Agranulocytosis	1 (1.9)	0	0	1 (1.9)	0
Haemoglobin decreased	1 (1.9)	0	0	1 (1.9)	0
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0
Infections					
-Total	42 (77.8)	6 (11.1)	7 (13.0)	19 (35.2)	10 (18.5)
Upper respiratory tract infection	7 (13.0)	2 (3.7)	4 (7.4)	1 (1.9)	0
Nasopharyngitis	6 (11.1)	4 (7.4)	2 (3.7)	0	0
Gastroenteritis	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Rhinovirus infection	5 (9.3)	0	5 (9.3)	0	0
Staphylococcal infection	5 (9.3)	0	3 (5.6)	2 (3.7)	0
Candida infection	4 (7.4)	0	3 (5.6)	0	1 (1.9)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Oral herpes	4 (7.4)	1 (1.9)	2 (3.7)	1 (1.9)	0
Sinusitis	4 (7.4)	0	2 (3.7)	2 (3.7)	0
Bacteraemia	3 (5.6)	0	1 (1.9)	1 (1.9)	1 (1.9)
Nail infection	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Oral candidiasis	3 (5.6)	0	3 (5.6)	0	0
Otitis media	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Pneumonia	3 (5.6)	1 (1.9)	0	1 (1.9)	1 (1.9)
Acute sinusitis	2 (3.7)	0	2 (3.7)	0	0
Adenovirus infection	2 (3.7)	0	0	2 (3.7)	0
Bk virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bronchitis	2 (3.7)	0	2 (3.7)	0	0
Clostridium difficile infection	2 (3.7)	0	0	2 (3.7)	0
Covid-19	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Ear infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Gastroenteritis viral	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Gingivitis	2 (3.7)	2 (3.7)	0	0	0
Herpes simplex	2 (3.7)	0	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	2 (3.7)	0	0	2 (3.7)	0
Influenza	2 (3.7)	0	2 (3.7)	0	0
Metapneumovirus infection	2 (3.7)	0	0	2 (3.7)	0
Oral infection	2 (3.7)	0	2 (3.7)	0	0
Otitis externa	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Respiratory tract infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Rhinitis	2 (3.7)	2 (3.7)	0	0	0
Sepsis	2 (3.7)	0	0	0	2 (3.7)
Septic shock	2 (3.7)	0	0	0	2 (3.7)
Skin infection	2 (3.7)	0	2 (3.7)	0	0
Skin papilloma	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Urinary tract infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Viral infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Anal abscess	1 (1.9)	0	0	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bronchiolitis	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	1 (1.9)	0	0
Coronavirus infection	1 (1.9)	0	0	1 (1.9)	0
Cystitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Device related sepsis	1 (1.9)	0	0	1 (1.9)	0
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis clostridial	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes virus infection	1 (1.9)	0	1 (1.9)	0	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Myringitis	1 (1.9)	1 (1.9)	0	0	0
Ophthalmic herpes zoster	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0
Pneumocystis jirovecii pneumonia	1 (1.9)	0	0	0	1 (1.9)
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia respiratory syncytial viral	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Salmonellosis	1 (1.9)	0	1 (1.9)	0	0
Sinusitis fungal	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Staphylococcal skin infection	1 (1.9)	0	1 (1.9)	0	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (1.9)	0	1 (1.9)	0	0
Syphilis	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Tinea pedis	1 (1.9)	1 (1.9)	0	0	0
Urinary tract infection pseudomonal	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Viral skin infection	1 (1.9)	1 (1.9)	0	0	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	29 (53.7)	4 (7.4)	17 (31.5)	8 (14.8)	0
Hypogammaglobulinaemia	19 (35.2)	1 (1.9)	13 (24.1)	5 (9.3)	0
Blood immunoglobulin a decreased	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Blood immunoglobulin m decreased	4 (7.4)	3 (5.6)	0	1 (1.9)	0
Immunodeficiency	2 (3.7)	0	0	2 (3.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunoglobulins decreased	2 (3.7)	0	2 (3.7)	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Serious neurological adverse reactions					
-Total	25 (46.3)	8 (14.8)	8 (14.8)	9 (16.7)	0
Delirium	8 (14.8)	2 (3.7)	3 (5.6)	3 (5.6)	0
Agitation	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Confusional state	5 (9.3)	5 (9.3)	0	0	0
Mental status changes	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Somnolence	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Tremor	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Hallucination	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Irritability	2 (3.7)	2 (3.7)	0	0	0
Lethargy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Muscular weakness	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Seizure	2 (3.7)	0	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Cognitive disorder	1 (1.9)	0	0	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Generalised tonic-clonic seizure	1 (1.9)	0	1 (1.9)	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Mood altered	1 (1.9)	1 (1.9)	0	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tumour Lysis Syndrome					
-Total	4 (7.4)	0	0	3 (5.6)	1 (1.9)
Tumour lysis syndrome	4 (7.4)	0	0	3 (5.6)	1 (1.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	4 (36.4)	3 (27.3)	3 (27.3)
Cytokine Release Syndrome					
-Total	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hematological disorders including cytopenias					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Anaemia	1 (9.1)	0	1 (9.1)	0	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Infections					
-Total	2 (18.2)	0	2 (18.2)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (36.4)	1 (9.1)	1 (9.1)	2 (18.2)	0
Hypogammaglobulinaemia	3 (27.3)	1 (9.1)	0	2 (18.2)	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	1 (9.1)	0	0	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (95.7)	3 (4.3)	5 (7.2)	17 (24.6)	41 (59.4)
Cytokine Release Syndrome					
-Total	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Haemophagocytic lymphohistiocytosis	5 (7.2)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Hematological disorders including cytopenias					
-Total	47 (68.1)	2 (2.9)	1 (1.4)	17 (24.6)	27 (39.1)
Febrile neutropenia	25 (36.2)	0	0	23 (33.3)	2 (2.9)
White blood cell count decreased	23 (33.3)	3 (4.3)	3 (4.3)	2 (2.9)	15 (21.7)
Anaemia	20 (29.0)	5 (7.2)	7 (10.1)	8 (11.6)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (26.1)	0	3 (4.3)	2 (2.9)	13 (18.8)
Platelet count decreased	18 (26.1)	4 (5.8)	3 (4.3)	6 (8.7)	5 (7.2)
Lymphocyte count decreased	13 (18.8)	2 (2.9)	0	8 (11.6)	3 (4.3)
Neutropenia	8 (11.6)	0	2 (2.9)	1 (1.4)	5 (7.2)
Thrombocytopenia	8 (11.6)	0	0	2 (2.9)	6 (8.7)
Leukopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	33 (47.8)	6 (8.7)	8 (11.6)	16 (23.2)	3 (4.3)
Clostridium difficile infection	4 (5.8)	1 (1.4)	0	3 (4.3)	0
Conjunctivitis	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Staphylococcal infection	4 (5.8)	0	2 (2.9)	2 (2.9)	0
Candida infection	3 (4.3)	0	2 (2.9)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.3)	0	0	3 (4.3)	0
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.9)	2 (2.9)	0	0	0
Oral herpes	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Rhinovirus infection	2 (2.9)	0	2 (2.9)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	33 (47.8)	6 (8.7)	18 (26.1)	9 (13.0)	0
Hypogammaglobulinaemia	20 (29.0)	1 (1.4)	14 (20.3)	5 (7.2)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (8.7)	4 (5.8)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	5 (7.2)	4 (5.8)	1 (1.4)	0	0
Immunodeficiency	3 (4.3)	0	0	3 (4.3)	0
Blood immunoglobulin g decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	30 (43.5)	12 (17.4)	8 (11.6)	10 (14.5)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Delirium	7 (10.1)	2 (2.9)	2 (2.9)	3 (4.3)	0
Confusional state	6 (8.7)	6 (8.7)	0	0	0
Tremor	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Agitation	5 (7.2)	2 (2.9)	3 (4.3)	0	0
Somnolence	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Cognitive disorder	3 (4.3)	0	2 (2.9)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Irritability	3 (4.3)	3 (4.3)	0	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Mental status changes	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Seizure	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.8)	0	0	4 (5.8)	0
Tumour lysis syndrome	4 (5.8)	0	0	4 (5.8)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (45.5)	0	3 (27.3)	1 (9.1)	1 (9.1)
Hematological disorders including cytopenias					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Anaemia	1 (9.1)	1 (9.1)	0	0	0
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Infections					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	1 (9.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (27.3)	0	3 (27.3)	0	0
Hypogammaglobulinaemia	3 (27.3)	0	3 (27.3)	0	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Memory impairment	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	0	1 (9.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (78.1)	6 (9.4)	14 (21.9)	15 (23.4)	15 (23.4)
Hematological disorders including cytopenias					
-Total	24 (37.5)	5 (7.8)	2 (3.1)	9 (14.1)	8 (12.5)
Neutrophil count decreased	10 (15.6)	2 (3.1)	1 (1.6)	3 (4.7)	4 (6.3)
White blood cell count decreased	10 (15.6)	4 (6.3)	2 (3.1)	3 (4.7)	1 (1.6)
Anaemia	5 (7.8)	3 (4.7)	0	2 (3.1)	0
Neutropenia	5 (7.8)	0	0	2 (3.1)	3 (4.7)
Platelet count decreased	5 (7.8)	3 (4.7)	0	1 (1.6)	1 (1.6)
Lymphocyte count decreased	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	37 (57.8)	5 (7.8)	14 (21.9)	11 (17.2)	7 (10.9)
Nasopharyngitis	7 (10.9)	4 (6.3)	3 (4.7)	0	0
Upper respiratory tract infection	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Gastroenteritis	5 (7.8)	3 (4.7)	0	2 (3.1)	0
Rhinovirus infection	4 (6.3)	0	4 (6.3)	0	0
Metapneumovirus infection	3 (4.7)	0	0	3 (4.7)	0
Otitis media	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Parainfluenzae virus infection	3 (4.7)	1 (1.6)	1 (1.6)	0	1 (1.6)
Sinusitis	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Bacteraemia	2 (3.1)	0	1 (1.6)	0	1 (1.6)
Ear infection	2 (3.1)	0	2 (3.1)	0	0
Otitis externa	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	2 (3.1)	0	0	1 (1.6)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.1)	1 (1.6)	0	0	1 (1.6)
Respiratory syncytial virus infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Respiratory tract infection	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Rhinitis	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Skin papilloma	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Viral infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Adenovirus infection	1 (1.6)	0	0	1 (1.6)	0
Bk virus infection	1 (1.6)	0	0	1 (1.6)	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis clostridial	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Herpes simplex	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Septic shock	1 (1.6)	0	0	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis fungal	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	12 (18.8)	1 (1.6)	9 (14.1)	2 (3.1)	0
Hypogammaglobulinaemia	7 (10.9)	0	7 (10.9)	0	0
Blood immunoglobulin a decreased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=64 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Mental status changes	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Agitation	1 (1.6)	1 (1.6)	0	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	0	1 (1.6)
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (44.4)	1 (11.1)	1 (11.1)	1 (11.1)	1 (11.1)
Hematological disorders including cytopenias					
-Total	1 (11.1)	0	0	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Sinusitis	2 (22.2)	0	2 (22.2)	0	0
Fungal skin infection	1 (11.1)	0	1 (11.1)	0	0
Rhinitis	1 (11.1)	1 (11.1)	0	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (11.1)	0	0	1 (11.1)	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Varicella zoster virus infection	1 (11.1)	0	1 (11.1)	0	0
Serious neurological adverse reactions					
-Total	1 (11.1)	0	1 (11.1)	0	0
Dysarthria	1 (11.1)	0	1 (11.1)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (56.1)	2 (4.9)	8 (19.5)	9 (22.0)	4 (9.8)
Cytokine Release Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Hematological disorders including cytopenias					
-Total	6 (14.6)	3 (7.3)	0	2 (4.9)	1 (2.4)
Neutrophil count decreased	2 (4.9)	2 (4.9)	0	0	0
Platelet count decreased	2 (4.9)	2 (4.9)	0	0	0
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Anaemia	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Infections					
-Total	19 (46.3)	1 (2.4)	5 (12.2)	9 (22.0)	4 (9.8)
Upper respiratory tract infection	5 (12.2)	2 (4.9)	2 (4.9)	1 (2.4)	0
Conjunctivitis	4 (9.8)	2 (4.9)	2 (4.9)	0	0
Sinusitis	4 (9.8)	0	4 (9.8)	0	0
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Skin infection	3 (7.3)	0	3 (7.3)	0	0
Bronchitis	2 (4.9)	0	2 (4.9)	0	0
Covid-19	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Fungal infection	2 (4.9)	0	2 (4.9)	0	0
Herpes zoster	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Influenza	2 (4.9)	0	1 (2.4)	0	1 (2.4)
Oral herpes	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Otitis media	2 (4.9)	0	2 (4.9)	0	0
Pneumonia	2 (4.9)	0	0	1 (2.4)	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (4.9)	0	0	0	2 (4.9)
Acute sinusitis	1 (2.4)	0	1 (2.4)	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Ear infection	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Folliculitis	1 (2.4)	0	1 (2.4)	0	0
Gastroenteritis	1 (2.4)	1 (2.4)	0	0	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis viral	1 (2.4)	0	1 (2.4)	0	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	0	1 (2.4)	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Syphilis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (9.8)	0	4 (9.8)	0	0
Hypogammaglobulinaemia	3 (7.3)	0	3 (7.3)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0
Serious neurological adverse reactions					
-Total	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	0	1 (2.4)	0

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Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	1 (9.1)	4 (36.4)	2 (18.2)	4 (36.4)
Cytokine Release Syndrome					
-Total	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hematological disorders including cytopenias					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Anaemia	1 (9.1)	0	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Infections					
-Total	7 (63.6)	1 (9.1)	4 (36.4)	1 (9.1)	1 (9.1)
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Rhinitis	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0
Hypogammaglobulinaemia	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0
Dysarthria	1 (9.1)	0	1 (9.1)	0	0
Memory impairment	1 (9.1)	0	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (9.1)	0	0	1 (9.1)	0

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Table 229o
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (100)	0	4 (5.8)	20 (29.0)	45 (65.2)
Cytokine Release Syndrome					
-Total	55 (79.7)	4 (5.8)	14 (20.3)	16 (23.2)	21 (30.4)
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Haemophagocytic lymphohistiocytosis	6 (8.7)	1 (1.4)	1 (1.4)	2 (2.9)	2 (2.9)
Hematological disorders including cytopenias					
-Total	50 (72.5)	1 (1.4)	1 (1.4)	20 (29.0)	28 (40.6)
Febrile neutropenia	26 (37.7)	0	0	24 (34.8)	2 (2.9)
Anaemia	24 (34.8)	7 (10.1)	8 (11.6)	9 (13.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	24 (34.8)	3 (4.3)	4 (5.8)	2 (2.9)	15 (21.7)
Neutrophil count decreased	22 (31.9)	1 (1.4)	2 (2.9)	4 (5.8)	15 (21.7)
Platelet count decreased	21 (30.4)	6 (8.7)	3 (4.3)	7 (10.1)	5 (7.2)
Lymphocyte count decreased	15 (21.7)	1 (1.4)	1 (1.4)	10 (14.5)	3 (4.3)
Neutropenia	10 (14.5)	0	2 (2.9)	2 (2.9)	6 (8.7)
Thrombocytopenia	9 (13.0)	0	0	3 (4.3)	6 (8.7)
Leukopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Lymphopenia	2 (2.9)	0	0	2 (2.9)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	54 (78.3)	7 (10.1)	10 (14.5)	24 (34.8)	13 (18.8)
Upper respiratory tract infection	12 (17.4)	5 (7.2)	5 (7.2)	2 (2.9)	0
Rhinovirus infection	8 (11.6)	0	7 (10.1)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	7 (10.1)	2 (2.9)	5 (7.2)	0	0
Nasopharyngitis	7 (10.1)	4 (5.8)	3 (4.3)	0	0
Gastroenteritis	6 (8.7)	4 (5.8)	0	2 (2.9)	0
Otitis media	5 (7.2)	0	4 (5.8)	1 (1.4)	0
Pneumonia	5 (7.2)	1 (1.4)	0	2 (2.9)	2 (2.9)
Sinusitis	5 (7.2)	0	3 (4.3)	2 (2.9)	0
Staphylococcal bacteraemia	5 (7.2)	0	0	5 (7.2)	0
Candida infection	4 (5.8)	0	3 (4.3)	0	1 (1.4)
Clostridium difficile infection	4 (5.8)	1 (1.4)	0	3 (4.3)	0
Nail infection	4 (5.8)	3 (4.3)	1 (1.4)	0	0
Oral herpes	4 (5.8)	1 (1.4)	2 (2.9)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.8)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Staphylococcal infection	4 (5.8)	0	2 (2.9)	2 (2.9)	0
Bacteraemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Ear infection	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Herpes zoster	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Influenza	3 (4.3)	0	2 (2.9)	0	1 (1.4)
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Skin infection	3 (4.3)	0	3 (4.3)	0	0
Acute sinusitis	2 (2.9)	0	2 (2.9)	0	0
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0
Bk virus infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Bronchitis	2 (2.9)	0	2 (2.9)	0	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Covid-19	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.9)	0	2 (2.9)	0	0
Gastroenteritis viral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gingivitis	2 (2.9)	2 (2.9)	0	0	0
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	41 (59.4)	4 (5.8)	26 (37.7)	11 (15.9)	0
Hypogammaglobulinaemia	27 (39.1)	1 (1.4)	21 (30.4)	5 (7.2)	0
Blood immunoglobulin a decreased	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	7 (10.1)	4 (5.8)	1 (1.4)	2 (2.9)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Immunodeficiency	4 (5.8)	0	0	4 (5.8)	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	33 (47.8)	11 (15.9)	10 (14.5)	12 (17.4)	0
Delirium	8 (11.6)	2 (2.9)	3 (4.3)	3 (4.3)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Agitation	6 (8.7)	3 (4.3)	3 (4.3)	0	0
Confusional state	6 (8.7)	6 (8.7)	0	0	0
Tremor	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Mental status changes	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Somnolence	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Cognitive disorder	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Irritability	3 (4.3)	3 (4.3)	0	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	5 (7.2)	0	0	4 (5.8)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	5 (7.2)	0	0	4 (5.8)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Cytokine Release Syndrome					
-Total	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Hematological disorders including cytopenias					
-Total	6 (100)	0	0	3 (50.0)	3 (50.0)
White blood cell count decreased	4 (66.7)	1 (16.7)	0	0	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Neutrophil count decreased	2 (33.3)	0	0	0	2 (33.3)
Infections					
-Total	2 (33.3)	0	2 (33.3)	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0
Serious neurological adverse reactions					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Agitation	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (16.7)	0	0	1 (16.7)	0
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (94.6)	3 (4.1)	9 (12.2)	19 (25.7)	39 (52.7)
Cytokine Release Syndrome					
-Total	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	0	2 (2.7)	1 (1.4)
Hematological disorders including cytopenias					
-Total	47 (63.5)	2 (2.7)	2 (2.7)	16 (21.6)	27 (36.5)
Febrile neutropenia	23 (31.1)	0	0	21 (28.4)	2 (2.7)
White blood cell count decreased	20 (27.0)	2 (2.7)	3 (4.1)	2 (2.7)	13 (17.6)
Anaemia	19 (25.7)	5 (6.8)	7 (9.5)	7 (9.5)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (24.3)	0	3 (4.1)	2 (2.7)	13 (17.6)
Platelet count decreased	18 (24.3)	4 (5.4)	2 (2.7)	5 (6.8)	7 (9.5)
Lymphocyte count decreased	15 (20.3)	2 (2.7)	0	8 (10.8)	5 (6.8)
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	8 (10.8)	0	0	2 (2.7)	6 (8.1)
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	33 (44.6)	6 (8.1)	8 (10.8)	16 (21.6)	3 (4.1)
Conjunctivitis	5 (6.8)	1 (1.4)	4 (5.4)	0	0
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Candida infection	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.1)	0	0	3 (4.1)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.7)	2 (2.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	34 (45.9)	7 (9.5)	18 (24.3)	9 (12.2)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Blood immunoglobulin a decreased	4 (5.4)	4 (5.4)	0	0	0
Immunodeficiency	3 (4.1)	0	0	3 (4.1)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	29 (39.2)	12 (16.2)	8 (10.8)	9 (12.2)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Delirium	6 (8.1)	2 (2.7)	1 (1.4)	3 (4.1)	0
Tremor	5 (6.8)	5 (6.8)	0	0	0
Agitation	4 (5.4)	2 (2.7)	2 (2.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Irritability	2 (2.7)	2 (2.7)	0	0	0
Mental status changes	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Seizure	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	3 (4.1)	0	0	3 (4.1)	0
Tumour lysis syndrome	3 (4.1)	0	0	3 (4.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	2 (40.0)	1 (20.0)
Hematological disorders including cytopenias					
-Total	3 (60.0)	0	0	2 (40.0)	1 (20.0)
Lymphocyte count decreased	2 (40.0)	0	0	2 (40.0)	0
Neutrophil count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)	0	0
Infections					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Cellulitis	1 (20.0)	0	1 (20.0)	0	0
Ear infection	1 (20.0)	0	1 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (20.0)	0	0	1 (20.0)	0
Nasopharyngitis	1 (20.0)	1 (20.0)	0	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypogammaglobulinaemia	1 (20.0)	0	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (72.9)	6 (8.6)	16 (22.9)	14 (20.0)	15 (21.4)
Hematological disorders including cytopenias					
-Total	23 (32.9)	6 (8.6)	3 (4.3)	7 (10.0)	7 (10.0)
Neutrophil count decreased	8 (11.4)	2 (2.9)	1 (1.4)	2 (2.9)	3 (4.3)
White blood cell count decreased	8 (11.4)	4 (5.7)	0	3 (4.3)	1 (1.4)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Lymphocyte count decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	36 (51.4)	4 (5.7)	13 (18.6)	11 (15.7)	8 (11.4)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0
Nasopharyngitis	6 (8.6)	3 (4.3)	3 (4.3)	0	0
Gastroenteritis	5 (7.1)	3 (4.3)	0	2 (2.9)	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.7)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Pneumonia	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Respiratory tract infection	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Bacteraemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear infection	1 (1.4)	0	1 (1.4)	0	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (20.0)	1 (1.4)	11 (15.7)	2 (2.9)	0
Hypogammaglobulinaemia	9 (12.9)	0	9 (12.9)	0	0
Blood immunoglobulin a decreased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Infections					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Upper respiratory tract infection	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Otitis media	2 (50.0)	0	2 (50.0)	0	0
Bronchiolitis	1 (25.0)	0	0	1 (25.0)	0
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Folliculitis	1 (25.0)	0	1 (25.0)	0	0
Gastroenteritis viral	1 (25.0)	0	1 (25.0)	0	0
Nail infection	1 (25.0)	0	1 (25.0)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (25.0)	0	0	1 (25.0)	0
Rhinovirus infection	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Skin infection	1 (25.0)	0	1 (25.0)	0	0

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Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (52.2)	3 (6.5)	8 (17.4)	8 (17.4)	5 (10.9)
Cytokine Release Syndrome					
-Total	1 (2.2)	0	0	0	1 (2.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Hematological disorders including cytopenias					
-Total	7 (15.2)	3 (6.5)	0	2 (4.3)	2 (4.3)
Neutrophil count decreased	3 (6.5)	2 (4.3)	0	0	1 (2.2)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Agranulocytosis	1 (2.2)	0	0	1 (2.2)	0
Anaemia	1 (2.2)	0	1 (2.2)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Neutropenic infection	1 (2.2)	0	0	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	1 (2.2)	0	0
Infections					
-Total	20 (43.5)	2 (4.3)	6 (13.0)	8 (17.4)	4 (8.7)
Sinusitis	5 (10.9)	0	5 (10.9)	0	0
Conjunctivitis	4 (8.7)	2 (4.3)	2 (4.3)	0	0
Rhinovirus infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Sepsis	3 (6.5)	0	0	1 (2.2)	2 (4.3)
Covid-19	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Fungal infection	2 (4.3)	0	2 (4.3)	0	0
Herpes zoster	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Influenza	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Oral herpes	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Pneumonia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Skin infection	2 (4.3)	0	2 (4.3)	0	0
Upper respiratory tract infection	2 (4.3)	2 (4.3)	0	0	0
Urinary tract infection	2 (4.3)	0	2 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Candida infection	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Device related sepsis	1 (2.2)	0	0	1 (2.2)	0
Ear infection	1 (2.2)	0	0	1 (2.2)	0
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Herpes virus infection	1 (2.2)	0	1 (2.2)	0	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0
Neutropenic infection	1 (2.2)	0	0	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Oral candidiasis	1 (2.2)	0	1 (2.2)	0	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (2.2)	1 (2.2)	0	0	0
Septic shock	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Streptococcal sepsis	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection pseudomonal	1 (2.2)	0	1 (2.2)	0	0
Varicella zoster virus infection	1 (2.2)	0	1 (2.2)	0	0
Viral skin infection	1 (2.2)	1 (2.2)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (8.7)	0	4 (8.7)	0	0
Hypogammaglobulinaemia	3 (6.5)	0	3 (6.5)	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Serious neurological adverse reactions					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (2.2)	0	1 (2.2)	0	0
Seizure	1 (2.2)	0	0	1 (2.2)	0

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Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Cytokine Release Syndrome					
-Total	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Hematological disorders including cytopenias					
-Total	6 (100)	0	0	3 (50.0)	3 (50.0)
White blood cell count decreased	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Lymphocyte count decreased	2 (33.3)	0	0	2 (33.3)	0
Infections					
-Total	5 (83.3)	0	2 (33.3)	3 (50.0)	0
Upper respiratory tract infection	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Otitis media	2 (33.3)	0	2 (33.3)	0	0
Bronchiolitis	1 (16.7)	0	0	1 (16.7)	0
Bronchitis	1 (16.7)	0	1 (16.7)	0	0
Cellulitis	1 (16.7)	0	1 (16.7)	0	0
Ear infection	1 (16.7)	0	1 (16.7)	0	0
Folliculitis	1 (16.7)	0	1 (16.7)	0	0
Gastroenteritis viral	1 (16.7)	0	1 (16.7)	0	0
Metapneumovirus infection	1 (16.7)	0	0	1 (16.7)	0
Nail infection	1 (16.7)	0	1 (16.7)	0	0
Nasopharyngitis	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Skin infection	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (66.7)	0	2 (33.3)	2 (33.3)	0
Hypogammaglobulinaemia	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0
Serious neurological adverse reactions					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Agitation	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (16.7)	0	0	1 (16.7)	0
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229p
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	1 (1.4)	8 (10.8)	21 (28.4)	44 (59.5)
Cytokine Release Syndrome					
-Total	55 (74.3)	3 (4.1)	16 (21.6)	17 (23.0)	19 (25.7)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Hematological disorders including cytopenias					
-Total	50 (67.6)	1 (1.4)	2 (2.7)	19 (25.7)	28 (37.8)
Febrile neutropenia	24 (32.4)	0	0	22 (29.7)	2 (2.7)
Anaemia	23 (31.1)	7 (9.5)	8 (10.8)	8 (10.8)	0
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (28.4)	6 (8.1)	2 (2.7)	6 (8.1)	7 (9.5)
White blood cell count decreased	21 (28.4)	3 (4.1)	3 (4.1)	2 (2.7)	13 (17.6)
Lymphocyte count decreased	15 (20.3)	1 (1.4)	1 (1.4)	8 (10.8)	5 (6.8)
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	9 (12.2)	0	0	3 (4.1)	6 (8.1)
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Lymphopenia	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	56 (75.7)	8 (10.8)	12 (16.2)	22 (29.7)	14 (18.9)
Upper respiratory tract infection	9 (12.2)	4 (5.4)	3 (4.1)	2 (2.7)	0
Conjunctivitis	8 (10.8)	2 (2.7)	6 (8.1)	0	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Pneumonia	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Parainfluenzae virus infection	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Staphylococcal bacteraemia	5 (6.8)	0	0	5 (6.8)	0
Candida infection	4 (5.4)	0	3 (4.1)	0	1 (1.4)
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Oral herpes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Bacteraemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Herpes zoster	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Influenza	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Nail infection	3 (4.1)	3 (4.1)	0	0	0
Oral candidiasis	3 (4.1)	0	3 (4.1)	0	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Urinary tract infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Acute sinusitis	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	2 (2.7)	0	0	2 (2.7)	0
Bk virus infection	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Bronchopulmonary aspergillosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Covid-19	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Ear infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Encephalitis	2 (2.7)	0	0	0	2 (2.7)
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.7)	0	2 (2.7)	0	0
Gingivitis	2 (2.7)	2 (2.7)	0	0	0
Herpes simplex	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.7)	0	0	2 (2.7)	0
Metapneumovirus infection	2 (2.7)	0	0	2 (2.7)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	2 (2.7)	0	2 (2.7)	0	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Varicella zoster virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	43 (58.1)	5 (6.8)	27 (36.5)	11 (14.9)	0
Hypogammaglobulinaemia	30 (40.5)	2 (2.7)	22 (29.7)	6 (8.1)	0
Blood immunoglobulin a decreased	6 (8.1)	5 (6.8)	0	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	1 (1.4)	1 (1.4)	0
Immunodeficiency	4 (5.4)	0	0	4 (5.4)	0
Blood immunoglobulin g decreased	3 (4.1)	0	3 (4.1)	0	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	33 (44.6)	11 (14.9)	10 (13.5)	12 (16.2)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Agitation	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Tremor	5 (6.8)	5 (6.8)	0	0	0
Mental status changes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Seizure	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Irritability	2 (2.7)	2 (2.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.4)	0	0	3 (4.1)	1 (1.4)
Tumour lysis syndrome	4 (5.4)	0	0	3 (4.1)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	1 (2.5)	2 (5.0)	10 (25.0)	25 (62.5)
Cytokine Release Syndrome					
-Total	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Haemophagocytic lymphohistiocytosis	1 (2.5)	1 (2.5)	0	0	0
Hematological disorders including cytopenias					
-Total	29 (72.5)	1 (2.5)	0	9 (22.5)	19 (47.5)
White blood cell count decreased	12 (30.0)	2 (5.0)	0	1 (2.5)	9 (22.5)
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Neutrophil count decreased	11 (27.5)	0	1 (2.5)	1 (2.5)	9 (22.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	11 (27.5)	2 (5.0)	1 (2.5)	4 (10.0)	4 (10.0)
Anaemia	10 (25.0)	1 (2.5)	3 (7.5)	6 (15.0)	0
Lymphocyte count decreased	7 (17.5)	1 (2.5)	0	3 (7.5)	3 (7.5)
Neutropenia	7 (17.5)	0	1 (2.5)	1 (2.5)	5 (12.5)
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Leukopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pancytopenia	2 (5.0)	0	0	2 (5.0)	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	21 (52.5)	3 (7.5)	5 (12.5)	11 (27.5)	2 (5.0)
Conjunctivitis	3 (7.5)	0	3 (7.5)	0	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Paronychia	1 (2.5)	0	1 (2.5)	0	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Stomatococcal infection	1 (2.5)	0	1 (2.5)	0	0
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	20 (50.0)	2 (5.0)	9 (22.5)	9 (22.5)	0
Hypogammaglobulinaemia	14 (35.0)	1 (2.5)	7 (17.5)	6 (15.0)	0
Immunodeficiency	3 (7.5)	0	0	3 (7.5)	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	12 (30.0)	3 (7.5)	6 (15.0)	3 (7.5)	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Seizure	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Affect lability	1 (2.5)	0	1 (2.5)	0	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0
Sluggishness	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	2 (5.0)	7 (17.5)	10 (25.0)	19 (47.5)
Cytokine Release Syndrome					
-Total	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hematological disorders including cytopenias					
-Total	24 (60.0)	1 (2.5)	2 (5.0)	10 (25.0)	11 (27.5)
Febrile neutropenia	15 (37.5)	0	0	14 (35.0)	1 (2.5)
White blood cell count decreased	12 (30.0)	1 (2.5)	3 (7.5)	1 (2.5)	7 (17.5)
Anaemia	11 (27.5)	4 (10.0)	5 (12.5)	2 (5.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	2 (5.0)	4 (10.0)
Neutrophil count decreased	9 (22.5)	0	2 (5.0)	1 (2.5)	6 (15.0)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	5 (12.5)	2 (5.0)
Thrombocytopenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Leukopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	14 (35.0)	3 (7.5)	5 (12.5)	5 (12.5)	1 (2.5)
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rhinovirus infection	2 (5.0)	0	2 (5.0)	0	0
Staphylococcal infection	2 (5.0)	0	2 (5.0)	0	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (42.5)	5 (12.5)	10 (25.0)	2 (5.0)	0
Hypogammaglobulinaemia	9 (22.5)	1 (2.5)	7 (17.5)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood immunoglobulin a decreased	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Blood immunoglobulin g decreased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	19 (47.5)	10 (25.0)	2 (5.0)	7 (17.5)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Mental status changes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Somnolence	2 (5.0)	0	0	2 (5.0)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (77.5)	3 (7.5)	7 (17.5)	9 (22.5)	12 (30.0)
Hematological disorders including cytopenias					
-Total	14 (35.0)	3 (7.5)	0	4 (10.0)	7 (17.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Neutropenia	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Neutrophil count decreased	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Anaemia	3 (7.5)	3 (7.5)	0	0	0
Platelet count decreased	2 (5.0)	2 (5.0)	0	0	0
Febrile neutropenia	1 (2.5)	0	0	1 (2.5)	0
Lymphocyte count decreased	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	27 (67.5)	5 (12.5)	10 (25.0)	7 (17.5)	5 (12.5)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Upper respiratory tract infection	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)	0
Parainfluenzae virus infection	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Respiratory tract infection	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Otitis media	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Rhinitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rhinovirus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bacteraemia	1 (2.5)	0	0	0	1 (2.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (2.5)	0	0	0	1 (2.5)
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	1 (2.5)	0	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal skin infection	1 (2.5)	0	1 (2.5)	0	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Hypogammaglobulinaemia	2 (5.0)	0	2 (5.0)	0	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Seizure	1 (2.5)	0	0	1 (2.5)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (68.6)	3 (8.6)	10 (28.6)	7 (20.0)	4 (11.4)
Hematological disorders including cytopenias					
-Total	12 (34.3)	3 (8.6)	3 (8.6)	5 (14.3)	1 (2.9)
Neutrophil count decreased	5 (14.3)	2 (5.7)	1 (2.9)	1 (2.9)	1 (2.9)
White blood cell count decreased	4 (11.4)	2 (5.7)	1 (2.9)	0	1 (2.9)
Anaemia	3 (8.6)	1 (2.9)	0	2 (5.7)	0
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Platelet count decreased	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Leukopenia	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	13 (37.1)	0	5 (14.3)	5 (14.3)	3 (8.6)
Rhinovirus infection	3 (8.6)	0	3 (8.6)	0	0
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Metapneumovirus infection	2 (5.7)	0	0	2 (5.7)	0
Pneumocystis jirovecii pneumonia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Respiratory syncytial virus infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	1 (2.9)	0	0
Bk virus infection	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	1 (2.9)	0	0
Coronavirus infection	1 (2.9)	0	0	1 (2.9)	0
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis clostridial	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal infection	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	0	1 (2.9)	0	0
Influenza	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	1 (2.9)	1 (2.9)	0	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Sinusitis	1 (2.9)	0	1 (2.9)	0	0
Sinusitis fungal	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Viral infection	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (28.6)	1 (2.9)	9 (25.7)	0	0
Hypogammaglobulinaemia	8 (22.9)	0	8 (22.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	1 (2.9)	0	1 (2.9)	0	0
Mental status changes	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (46.7)	2 (6.7)	3 (10.0)	6 (20.0)	3 (10.0)
Cytokine Release Syndrome					
-Total	1 (3.3)	0	0	0	1 (3.3)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Hematological disorders including cytopenias					
-Total	5 (16.7)	2 (6.7)	0	1 (3.3)	2 (6.7)
Neutrophil count decreased	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Neutropenic infection	1 (3.3)	0	0	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	13 (43.3)	2 (6.7)	3 (10.0)	6 (20.0)	2 (6.7)
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Conjunctivitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Influenza	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Rhinovirus infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Sepsis	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	0	1 (3.3)	0
Enterovirus infection	1 (3.3)	0	0	1 (3.3)	0
Fungal infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Neutropenic infection	1 (3.3)	0	0	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (3.3)	1 (3.3)	0	0	0
Otitis media	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Pneumonia	1 (3.3)	0	0	0	1 (3.3)
Rhinitis	1 (3.3)	1 (3.3)	0	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	1 (3.3)	0	0
Viral skin infection	1 (3.3)	1 (3.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.3)	0	1 (3.3)	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	1 (3.3)	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	1 (5.0)	6 (30.0)	4 (20.0)	2 (10.0)
Hematological disorders including cytopenias					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Agranulocytosis	1 (5.0)	0	0	1 (5.0)	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Infections					
-Total	10 (50.0)	0	4 (20.0)	4 (20.0)	2 (10.0)
Sinusitis	3 (15.0)	0	3 (15.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Covid-19	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0
Skin infection	2 (10.0)	0	2 (10.0)	0	0
Upper respiratory tract infection	2 (10.0)	0	2 (10.0)	0	0
Bronchiolitis	1 (5.0)	0	0	1 (5.0)	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis viral	1 (5.0)	0	1 (5.0)	0	0
Herpes virus infection	1 (5.0)	0	1 (5.0)	0	0
Meningitis pneumococcal	1 (5.0)	0	0	1 (5.0)	0
Nail infection	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Oral candidiasis	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Pneumonia respiratory syncytial viral	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Septic shock	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal sepsis	1 (5.0)	0	1 (5.0)	0	0
Syphilis	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection pseudomonal	1 (5.0)	0	1 (5.0)	0	0
Varicella zoster virus infection	1 (5.0)	0	1 (5.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.0)	0	3 (15.0)	0	0
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	1 (2.5)	2 (5.0)	10 (25.0)	27 (67.5)
Cytokine Release Syndrome					
-Total	31 (77.5)	3 (7.5)	7 (17.5)	10 (25.0)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	29 (72.5)	0	0	9 (22.5)	20 (50.0)
Neutrophil count decreased	13 (32.5)	1 (2.5)	0	2 (5.0)	10 (25.0)
Anaemia	12 (30.0)	3 (7.5)	3 (7.5)	6 (15.0)	0
Platelet count decreased	12 (30.0)	3 (7.5)	1 (2.5)	4 (10.0)	4 (10.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	12 (30.0)	1 (2.5)	1 (2.5)	1 (2.5)	9 (22.5)
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Neutropenia	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	4 (10.0)	3 (7.5)
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Leukopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Lymphopenia	2 (5.0)	0	0	2 (5.0)	0
Pancytopenia	2 (5.0)	0	0	2 (5.0)	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	37 (92.5)	7 (17.5)	7 (17.5)	14 (35.0)	9 (22.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	6 (15.0)	4 (10.0)	0	2 (5.0)	0
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Herpes zoster	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Oral herpes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Respiratory tract infection	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Rhinitis	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Bacteraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Bronchopulmonary aspergillosis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Gingivitis	2 (5.0)	2 (5.0)	0	0	0
Human herpesvirus 6 infection	2 (5.0)	0	0	2 (5.0)	0
Influenza	2 (5.0)	0	1 (2.5)	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	2 (5.0)	2 (5.0)	0	0	0
Oral candidiasis	2 (5.0)	0	2 (5.0)	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Paronychia	2 (5.0)	0	2 (5.0)	0	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Urinary tract infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal skin infection	1 (2.5)	0	1 (2.5)	0	0
Stomatococcal infection	1 (2.5)	0	1 (2.5)	0	0
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral skin infection	1 (2.5)	1 (2.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	23 (57.5)	2 (5.0)	10 (25.0)	11 (27.5)	0
Hypogammaglobulinaemia	16 (40.0)	1 (2.5)	9 (22.5)	6 (15.0)	0
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	14 (35.0)	2 (5.0)	7 (17.5)	5 (12.5)	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Seizure	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Agitation	2 (5.0)	2 (5.0)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (2.5)	0	1 (2.5)	0	0
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	1 (2.5)	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0
Sluggishness	1 (2.5)	0	1 (2.5)	0	0
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229q
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	6 (15.0)	12 (30.0)	22 (55.0)
Cytokine Release Syndrome					
-Total	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hematological disorders including cytopenias					
-Total	27 (67.5)	1 (2.5)	2 (5.0)	13 (32.5)	11 (27.5)
Febrile neutropenia	16 (40.0)	0	0	15 (37.5)	1 (2.5)
Anaemia	13 (32.5)	4 (10.0)	6 (15.0)	3 (7.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	13 (32.5)	2 (5.0)	3 (7.5)	1 (2.5)	7 (17.5)
Platelet count decreased	12 (30.0)	3 (7.5)	2 (5.0)	3 (7.5)	4 (10.0)
Neutrophil count decreased	11 (27.5)	0	2 (5.0)	2 (5.0)	7 (17.5)
Lymphocyte count decreased	9 (22.5)	0	1 (2.5)	6 (15.0)	2 (5.0)
Thrombocytopenia	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Agranulocytosis	1 (2.5)	0	0	1 (2.5)	0
Leukopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	24 (60.0)	1 (2.5)	7 (17.5)	11 (27.5)	5 (12.5)
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Conjunctivitis	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Sinusitis	3 (7.5)	0	3 (7.5)	0	0
Candida infection	2 (5.0)	0	2 (5.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gastroenteritis viral	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Metapneumovirus infection	2 (5.0)	0	0	2 (5.0)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Pneumocystis jirovecii pneumonia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pneumonia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Staphylococcal infection	2 (5.0)	0	2 (5.0)	0	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes virus infection	1 (2.5)	0	1 (2.5)	0	0
Influenza	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Streptococcal sepsis	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Varicella zoster virus infection	1 (2.5)	0	1 (2.5)	0	0
Viral infection	1 (2.5)	0	1 (2.5)	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	24 (60.0)	3 (7.5)	19 (47.5)	2 (5.0)	0
Hypogammaglobulinaemia	17 (42.5)	1 (2.5)	15 (37.5)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Blood immunoglobulin g decreased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	21 (52.5)	10 (25.0)	3 (7.5)	8 (20.0)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Somnolence	2 (5.0)	0	0	2 (5.0)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour Lysis Syndrome					
-Total	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Tumour lysis syndrome	3 (7.5)	0	0	2 (5.0)	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	0	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine Release Syndrome					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	2 (9.1)	2 (9.1)	3 (13.6)	15 (68.2)
Cytokine Release Syndrome					
-Total	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	2 (9.1)	0	0	2 (9.1)	0
Hematological disorders including cytopenias					
-Total	15 (68.2)	1 (4.5)	0	3 (13.6)	11 (50.0)
White blood cell count decreased	8 (36.4)	0	1 (4.5)	2 (9.1)	5 (22.7)
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Anaemia	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (22.7)	1 (4.5)	1 (4.5)	1 (4.5)	2 (9.1)
Lymphocyte count decreased	4 (18.2)	0	0	3 (13.6)	1 (4.5)
Neutrophil count decreased	4 (18.2)	0	0	0	4 (18.2)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	9 (40.9)	1 (4.5)	4 (18.2)	3 (13.6)	1 (4.5)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Atypical pneumonia	1 (4.5)	1 (4.5)	0	0	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Cholecystitis infective	1 (4.5)	0	1 (4.5)	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Klebsiella bacteraemia	1 (4.5)	0	1 (4.5)	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	13 (59.1)	3 (13.6)	7 (31.8)	3 (13.6)	0
Hypogammaglobulinaemia	9 (40.9)	1 (4.5)	7 (31.8)	1 (4.5)	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Blood immunoglobulin a decreased	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Blood immunoglobulin g decreased	1 (4.5)	1 (4.5)	0	0	0
Immunodeficiency	1 (4.5)	0	0	1 (4.5)	0
Serious neurological adverse reactions					
-Total	13 (59.1)	7 (31.8)	2 (9.1)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Agitation	2 (9.1)	0	2 (9.1)	0	0
Cognitive disorder	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (9.1)	2 (9.1)	0	0	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0
Lethargy	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	0	1 (4.5)	0	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	1 (4.5)	0	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Tumour Lysis Syndrome					
-Total	2 (9.1)	0	0	2 (9.1)	0
Tumour lysis syndrome	2 (9.1)	0	0	2 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	0	4 (23.5)	3 (17.6)	9 (52.9)
Cytokine Release Syndrome					
-Total	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Hematological disorders including cytopenias					
-Total	11 (64.7)	0	1 (5.9)	4 (23.5)	6 (35.3)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Neutrophil count decreased	3 (17.6)	0	0	0	3 (17.6)
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	4 (23.5)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Bronchopulmonary aspergillosis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (23.5)	2 (11.8)	1 (5.9)	1 (5.9)	0
Hypogammaglobulinaemia	2 (11.8)	1 (5.9)	0	1 (5.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0
Selective igg subclass deficiency	1 (5.9)	0	1 (5.9)	0	0
Serious neurological adverse reactions					
-Total	6 (35.3)	3 (17.6)	1 (5.9)	2 (11.8)	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Cognitive disorder	1 (5.9)	0	1 (5.9)	0	0
Dysphagia	1 (5.9)	0	0	1 (5.9)	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Generalised tonic-clonic seizure	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Muscular weakness	1 (5.9)	0	0	1 (5.9)	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	1 (5.9)	0	1 (5.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (94.3)	1 (2.9)	2 (5.7)	13 (37.1)	17 (48.6)
Cytokine Release Syndrome					
-Total	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Hematological disorders including cytopenias					
-Total	23 (65.7)	1 (2.9)	1 (2.9)	11 (31.4)	10 (28.6)
Anaemia	10 (28.6)	2 (5.7)	2 (5.7)	6 (17.1)	0
Neutrophil count decreased	10 (28.6)	0	3 (8.6)	1 (2.9)	6 (17.1)
Platelet count decreased	10 (28.6)	3 (8.6)	1 (2.9)	3 (8.6)	3 (8.6)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	9 (25.7)	0	0	9 (25.7)	0
White blood cell count decreased	9 (25.7)	3 (8.6)	1 (2.9)	0	5 (14.3)
Lymphocyte count decreased	7 (20.0)	2 (5.7)	0	2 (5.7)	3 (8.6)
Neutropenia	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Thrombocytopenia	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Leukopenia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Pancytopenia	2 (5.7)	0	0	2 (5.7)	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	18 (51.4)	4 (11.4)	4 (11.4)	9 (25.7)	1 (2.9)
Candida infection	2 (5.7)	0	1 (2.9)	0	1 (2.9)
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Oral infection	2 (5.7)	0	2 (5.7)	0	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Anal abscess	1 (2.9)	0	0	1 (2.9)	0
Bk virus infection	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	0	1 (2.9)	0
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (48.6)	2 (5.7)	9 (25.7)	6 (17.1)	0
Hypogammaglobulinaemia	10 (28.6)	0	6 (17.1)	4 (11.4)	0
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0	0	0
Immunodeficiency	2 (5.7)	0	0	2 (5.7)	0
Immunoglobulins decreased	2 (5.7)	0	2 (5.7)	0	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0	0	0
Serious neurological adverse reactions					
-Total	9 (25.7)	2 (5.7)	4 (11.4)	3 (8.6)	0
Tremor	4 (11.4)	4 (11.4)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Hallucination	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Lethargy	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Agitation	1 (2.9)	1 (2.9)	0	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Depressed level of consciousness	1 (2.9)	0	0	1 (2.9)	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Restlessness	1 (2.9)	0	1 (2.9)	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=35 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Hematological disorders including cytopenias					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Infections					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=5 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	2 (10.0)	2 (10.0)	6 (30.0)	3 (15.0)
Hematological disorders including cytopenias					
-Total	8 (40.0)	2 (10.0)	0	4 (20.0)	2 (10.0)
White blood cell count decreased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	3 (15.0)	0	0	0
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Neutrophil count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Anaemia	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Infections					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (40.0)	1 (5.0)	3 (15.0)	3 (15.0)	1 (5.0)
Nasopharyngitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Parainfluenzae virus infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0
Upper respiratory tract infection	2 (10.0)	2 (10.0)	0	0	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Cellulitis	1 (5.0)	0	1 (5.0)	0	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Coronavirus infection	1 (5.0)	0	0	1 (5.0)	0
Cystitis	1 (5.0)	0	1 (5.0)	0	0
Ear infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis viral	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Influenza	1 (5.0)	0	1 (5.0)	0	0
Metapneumovirus infection	1 (5.0)	0	0	1 (5.0)	0
Molluscum contagiosum	1 (5.0)	1 (5.0)	0	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Pharyngitis streptococcal	1 (5.0)	0	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (73.3)	1 (6.7)	4 (26.7)	3 (20.0)	3 (20.0)
Hematological disorders including cytopenias					
-Total	4 (26.7)	1 (6.7)	0	0	3 (20.0)
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Neutrophil count decreased	2 (13.3)	1 (6.7)	0	0	1 (6.7)
White blood cell count decreased	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Lymphopenia	1 (6.7)	0	0	1 (6.7)	0
Neutropenia	1 (6.7)	0	0	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (6.7)	0	0	0	1 (6.7)
Infections					
-Total	7 (46.7)	1 (6.7)	2 (13.3)	4 (26.7)	0
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Respiratory tract infection	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Upper respiratory tract infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Adenovirus infection	1 (6.7)	0	0	1 (6.7)	0
Bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Bk virus infection	1 (6.7)	0	0	1 (6.7)	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Ear infection	1 (6.7)	0	1 (6.7)	0	0
Gastroenteritis clostridial	1 (6.7)	0	1 (6.7)	0	0
Herpes simplex	1 (6.7)	0	1 (6.7)	0	0
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Metapneumovirus infection	1 (6.7)	0	0	1 (6.7)	0
Nail infection	1 (6.7)	1 (6.7)	0	0	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (6.7)	0	1 (6.7)	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Pneumocystis jirovecii pneumonia	1 (6.7)	0	0	1 (6.7)	0
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Sinusitis fungal	1 (6.7)	0	0	1 (6.7)	0
Viral infection	1 (6.7)	0	0	1 (6.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Hypogammaglobulinaemia	3 (20.0)	0	3 (20.0)	0	0
Immunodeficiency	1 (6.7)	0	0	1 (6.7)	0
Serious neurological adverse reactions					
-Total	1 (6.7)	0	1 (6.7)	0	0
Delirium	1 (6.7)	0	1 (6.7)	0	0

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in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (77.1)	2 (5.7)	9 (25.7)	6 (17.1)	10 (28.6)
Hematological disorders including cytopenias					
-Total	12 (34.3)	2 (5.7)	3 (8.6)	4 (11.4)	3 (8.6)
Anaemia	4 (11.4)	4 (11.4)	0	0	0
Neutrophil count decreased	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
White blood cell count decreased	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Neutropenia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Leukopenia	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Platelet count decreased	1 (2.9)	0	0	1 (2.9)	0
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	23 (65.7)	3 (8.6)	8 (22.9)	5 (14.3)	7 (20.0)
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Pneumonia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Rhinitis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Sinusitis	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Skin papilloma	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)
Device related infection	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0
Tinea pedis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral infection	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (22.9)	0	7 (20.0)	1 (2.9)	0
Hypogammaglobulinaemia	6 (17.1)	0	6 (17.1)	0	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	0	0	1 (2.9)	0
Blood immunoglobulin m decreased	1 (2.9)	0	0	1 (2.9)	0
Immunoglobulins decreased	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Agitation	1 (2.9)	1 (2.9)	0	0	0
Memory impairment	1 (2.9)	0	1 (2.9)	0	0
Mood altered	1 (2.9)	1 (2.9)	0	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (46.2)	0	4 (30.8)	1 (7.7)	1 (7.7)
Cytokine Release Syndrome					
-Total	1 (7.7)	0	0	0	1 (7.7)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Hematological disorders including cytopenias					
-Total	1 (7.7)	1 (7.7)	0	0	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Infections					
-Total	5 (38.5)	0	3 (23.1)	1 (7.7)	1 (7.7)
Bronchitis	1 (7.7)	0	1 (7.7)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (7.7)	1 (7.7)	0	0	0
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Enterovirus infection	1 (7.7)	0	0	1 (7.7)	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Influenza	1 (7.7)	0	0	0	1 (7.7)
Otitis media acute	1 (7.7)	0	1 (7.7)	0	0
Parainfluenzae virus infection	1 (7.7)	0	0	1 (7.7)	0
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Rhinovirus infection	1 (7.7)	0	0	1 (7.7)	0
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	0	1 (7.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (7.7)	0	1 (7.7)	0	0
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0
Hematological disorders including cytopenias					
-Total	1 (9.1)	1 (9.1)	0	0	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Infections					
-Total	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Bronchiolitis	1 (9.1)	0	0	1 (9.1)	0
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Covid-19	1 (9.1)	1 (9.1)	0	0	0
Device related sepsis	1 (9.1)	0	0	1 (9.1)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (9.1)	0	1 (9.1)	0	0
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0
Gastroenteritis viral	1 (9.1)	0	1 (9.1)	0	0
Nail infection	1 (9.1)	0	1 (9.1)	0	0
Otitis media	1 (9.1)	0	1 (9.1)	0	0
Pneumonia respiratory syncytial viral	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Syphilis	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypogammaglobulinaemia	1 (9.1)	0	1 (9.1)	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported

in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (60.9)	2 (8.7)	2 (8.7)	6 (26.1)	4 (17.4)
Hematological disorders including cytopenias					
-Total	5 (21.7)	1 (4.3)	0	2 (8.7)	2 (8.7)
Neutrophil count decreased	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Agranulocytosis	1 (4.3)	0	0	1 (4.3)	0
Anaemia	1 (4.3)	0	1 (4.3)	0	0
Neutropenia	1 (4.3)	0	0	0	1 (4.3)
Neutropenic infection	1 (4.3)	0	0	1 (4.3)	0
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Thrombocytopenia	1 (4.3)	0	1 (4.3)	0	0
Infections					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (56.5)	2 (8.7)	2 (8.7)	6 (26.1)	3 (13.0)
Conjunctivitis	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Sepsis	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Sinusitis	3 (13.0)	0	3 (13.0)	0	0
Upper respiratory tract infection	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Fungal infection	2 (8.7)	0	2 (8.7)	0	0
Herpes zoster	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Oral herpes	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Skin infection	2 (8.7)	0	2 (8.7)	0	0
Urinary tract infection	2 (8.7)	0	2 (8.7)	0	0
Acute sinusitis	1 (4.3)	0	1 (4.3)	0	0
Candida infection	1 (4.3)	0	1 (4.3)	0	0
Covid-19	1 (4.3)	0	0	1 (4.3)	0
Ear infection	1 (4.3)	0	0	1 (4.3)	0
Herpes virus infection	1 (4.3)	0	1 (4.3)	0	0
Influenza	1 (4.3)	0	1 (4.3)	0	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Neutropenic infection	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (4.3)	0	1 (4.3)	0	0
Oral candidiasis	1 (4.3)	0	1 (4.3)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Rhinitis	1 (4.3)	1 (4.3)	0	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Streptococcal sepsis	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection pseudomonal	1 (4.3)	0	1 (4.3)	0	0
Viral skin infection	1 (4.3)	1 (4.3)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (8.7)	0	2 (8.7)	0	0
Hypogammaglobulinaemia	2 (8.7)	0	2 (8.7)	0	0
Serious neurological adverse reactions					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Dysarthria	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
			All patients N=23		
Seizure	1 (4.3)	0	0	1 (4.3)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	3 (13.6)	3 (13.6)	16 (72.7)
Cytokine Release Syndrome					
-Total	15 (68.2)	1 (4.5)	3 (13.6)	4 (18.2)	7 (31.8)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Hematological disorders including cytopenias					
-Total	16 (72.7)	1 (4.5)	0	4 (18.2)	11 (50.0)
White blood cell count decreased	9 (40.9)	1 (4.5)	1 (4.5)	2 (9.1)	5 (22.7)
Platelet count decreased	7 (31.8)	3 (13.6)	1 (4.5)	1 (4.5)	2 (9.1)
Anaemia	6 (27.3)	2 (9.1)	2 (9.1)	2 (9.1)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Lymphocyte count decreased	5 (22.7)	0	0	4 (18.2)	1 (4.5)
Neutrophil count decreased	5 (22.7)	0	0	1 (4.5)	4 (18.2)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	15 (68.2)	2 (9.1)	6 (27.3)	4 (18.2)	3 (13.6)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Parainfluenzae virus infection	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Staphylococcal bacteraemia	3 (13.6)	0	0	3 (13.6)	0
Upper respiratory tract infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Influenza	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Nasopharyngitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pneumonia	2 (9.1)	0	0	0	2 (9.1)
Acute sinusitis	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (4.5)	1 (4.5)	0	0	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Cellulitis	1 (4.5)	0	1 (4.5)	0	0
Cholecystitis infective	1 (4.5)	0	1 (4.5)	0	0
Coronavirus infection	1 (4.5)	0	0	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)
Cystitis	1 (4.5)	0	1 (4.5)	0	0
Ear infection	1 (4.5)	0	1 (4.5)	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Gastroenteritis viral	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Klebsiella bacteraemia	1 (4.5)	0	1 (4.5)	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Metapneumovirus infection	1 (4.5)	0	0	1 (4.5)	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (4.5)	0	1 (4.5)	0	0
Otitis media acute	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis streptococcal	1 (4.5)	0	0	1 (4.5)	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Viral upper respiratory tract infection	1 (4.5)	0	0	1 (4.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (63.6)	2 (9.1)	9 (40.9)	3 (13.6)	0
Hypogammaglobulinaemia	10 (45.5)	1 (4.5)	8 (36.4)	1 (4.5)	0
Blood immunoglobulin a decreased	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin g decreased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Immunodeficiency	1 (4.5)	0	0	1 (4.5)	0
Serious neurological adverse reactions					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (59.1)	7 (31.8)	2 (9.1)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Agitation	2 (9.1)	0	2 (9.1)	0	0
Cognitive disorder	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0
Irritability	2 (9.1)	2 (9.1)	0	0	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0
Lethargy	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	0	1 (4.5)	0	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	1 (4.5)	0	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Tumour Lysis Syndrome					
-Total	2 (9.1)	0	0	2 (9.1)	0
Tumour lysis syndrome	2 (9.1)	0	0	2 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	3 (17.6)	5 (29.4)	9 (52.9)
Cytokine Release Syndrome					
-Total	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Hematological disorders including cytopenias					
-Total	11 (64.7)	0	1 (5.9)	4 (23.5)	6 (35.3)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Neutrophil count decreased	4 (23.5)	0	0	0	4 (23.5)
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Lymphopenia	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	12 (70.6)	2 (11.8)	3 (17.6)	7 (41.2)	0
Upper respiratory tract infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Nail infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Respiratory syncytial virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Sinusitis	2 (11.8)	0	2 (11.8)	0	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Adenovirus infection	1 (5.9)	0	0	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (5.9)	0	1 (5.9)	0	0
Bk virus infection	1 (5.9)	0	0	1 (5.9)	0
Bronchiolitis	1 (5.9)	0	0	1 (5.9)	0
Bronchitis	1 (5.9)	0	1 (5.9)	0	0
Bronchopulmonary aspergillosis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Covid-19	1 (5.9)	1 (5.9)	0	0	0
Cytomegalovirus infection reactivation	1 (5.9)	0	0	1 (5.9)	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Ear infection	1 (5.9)	0	1 (5.9)	0	0
Folliculitis	1 (5.9)	0	1 (5.9)	0	0
Fungal skin infection	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis clostridial	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis viral	1 (5.9)	0	1 (5.9)	0	0
Herpes simplex	1 (5.9)	0	1 (5.9)	0	0
Human herpesvirus 6 infection	1 (5.9)	0	0	1 (5.9)	0
Metapneumovirus infection	1 (5.9)	0	0	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	1 (5.9)	1 (5.9)	0	0	0
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Pneumocystis jirovecii pneumonia	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Rhinovirus infection	1 (5.9)	0	1 (5.9)	0	0
Sinusitis fungal	1 (5.9)	0	0	1 (5.9)	0
Syphilis	1 (5.9)	0	1 (5.9)	0	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Varicella zoster virus infection	1 (5.9)	0	1 (5.9)	0	0
Viral infection	1 (5.9)	0	0	1 (5.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (52.9)	2 (11.8)	5 (29.4)	2 (11.8)	0
Hypogammaglobulinaemia	6 (35.3)	1 (5.9)	4 (23.5)	1 (5.9)	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (5.9)	0	0	1 (5.9)	0
Selective igg subclass deficiency	1 (5.9)	0	1 (5.9)	0	0
Serious neurological adverse reactions					
-Total	7 (41.2)	3 (17.6)	2 (11.8)	2 (11.8)	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0
Delirium	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Cognitive disorder	1 (5.9)	0	1 (5.9)	0	0
Dysphagia	1 (5.9)	0	0	1 (5.9)	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Generalised tonic-clonic seizure	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Muscular weakness	1 (5.9)	0	0	1 (5.9)	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0
Tremor	1 (5.9)	0	1 (5.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 229r
Adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (100)	1 (2.9)	1 (2.9)	12 (34.3)	21 (60.0)
Cytokine Release Syndrome					
-Total	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Hematological disorders including cytopenias					
-Total	25 (71.4)	0	1 (2.9)	13 (37.1)	11 (31.4)
Anaemia	13 (37.1)	4 (11.4)	3 (8.6)	6 (17.1)	0
Neutrophil count decreased	12 (34.3)	1 (2.9)	2 (5.7)	2 (5.7)	7 (20.0)
Platelet count decreased	11 (31.4)	3 (8.6)	1 (2.9)	4 (11.4)	3 (8.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	10 (28.6)	0	0	10 (28.6)	0
White blood cell count decreased	9 (25.7)	2 (5.7)	2 (5.7)	0	5 (14.3)
Lymphocyte count decreased	8 (22.9)	1 (2.9)	1 (2.9)	3 (8.6)	3 (8.6)
Neutropenia	6 (17.1)	0	1 (2.9)	2 (5.7)	3 (8.6)
Thrombocytopenia	4 (11.4)	0	0	2 (5.7)	2 (5.7)
Leukopenia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Pancytopenia	2 (5.7)	0	0	2 (5.7)	0
Agranulocytosis	1 (2.9)	0	0	1 (2.9)	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	31 (88.6)	4 (11.4)	4 (11.4)	13 (37.1)	10 (28.6)
Upper respiratory tract infection	6 (17.1)	3 (8.6)	1 (2.9)	2 (5.7)	0
Conjunctivitis	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Sinusitis	4 (11.4)	0	2 (5.7)	2 (5.7)	0
Candida infection	3 (8.6)	0	2 (5.7)	0	1 (2.9)
Oral candidiasis	3 (8.6)	0	3 (8.6)	0	0
Oral herpes	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Pneumonia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Rhinitis	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Sepsis	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Urinary tract infection	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Fungal infection	2 (5.7)	0	2 (5.7)	0	0
Gingivitis	2 (5.7)	2 (5.7)	0	0	0
Herpes zoster	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Oral infection	2 (5.7)	0	2 (5.7)	0	0
Otitis externa	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Otitis media	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Paronychia	2 (5.7)	0	2 (5.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	2 (5.7)	0	0	0	2 (5.7)
Skin infection	2 (5.7)	0	2 (5.7)	0	0
Skin papilloma	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Anal abscess	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bk virus infection	1 (2.9)	1 (2.9)	0	0	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Covid-19	1 (2.9)	0	0	1 (2.9)	0
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	0	1 (2.9)	0
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Herpes virus infection	1 (2.9)	0	1 (2.9)	0	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Influenza	1 (2.9)	0	1 (2.9)	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Ophthalmic herpes zoster	1 (2.9)	0	1 (2.9)	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Streptococcal sepsis	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Tinea pedis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral infection	1 (2.9)	0	1 (2.9)	0	0
Viral skin infection	1 (2.9)	1 (2.9)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (60.0)	1 (2.9)	13 (37.1)	7 (20.0)	0
Hypogammaglobulinaemia	15 (42.9)	0	11 (31.4)	4 (11.4)	0
Blood immunoglobulin a decreased	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Blood immunoglobulin m decreased	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Immunodeficiency	2 (5.7)	0	0	2 (5.7)	0
Immunoglobulins decreased	2 (5.7)	0	2 (5.7)	0	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	12 (34.3)	1 (2.9)	5 (14.3)	6 (17.1)	0
Tremor	4 (11.4)	4 (11.4)	0	0	0
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Hallucination	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Mental status changes	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Seizure	3 (8.6)	0	0	3 (8.6)	0
Agitation	2 (5.7)	2 (5.7)	0	0	0
Lethargy	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Depressed level of consciousness	1 (2.9)	0	0	1 (2.9)	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	0	1 (2.9)	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Memory impairment	1 (2.9)	0	1 (2.9)	0	0
Mood altered	1 (2.9)	1 (2.9)	0	0	0
Restlessness	1 (2.9)	0	1 (2.9)	0	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Tumour lysis syndrome	2 (5.7)	0	0	1 (2.9)	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (78.0)	1 (2.4)	2 (4.9)	14 (34.1)	15 (36.6)
Hematological disorders including cytopenias					
-Total	25 (61.0)	0	2 (4.9)	12 (29.3)	11 (26.8)
Febrile neutropenia	11 (26.8)	0	0	11 (26.8)	0
Anaemia	9 (22.0)	1 (2.4)	2 (4.9)	6 (14.6)	0
Neutrophil count decreased	7 (17.1)	0	0	3 (7.3)	4 (9.8)
Neutropenia	4 (9.8)	0	0	0	4 (9.8)
Thrombocytopenia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Leukopenia	3 (7.3)	0	0	0	3 (7.3)
White blood cell count decreased	3 (7.3)	0	0	0	3 (7.3)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	2 (4.9)	0	0	0	2 (4.9)
Eosinophil count decreased	1 (2.4)	1 (2.4)	0	0	0
Haematocrit decreased	1 (2.4)	1 (2.4)	0	0	0
Lymphocyte count decreased	1 (2.4)	0	0	1 (2.4)	0
Lymphopenia	1 (2.4)	0	0	0	1 (2.4)
Pancytopenia	1 (2.4)	0	1 (2.4)	0	0
Red blood cell count decreased	1 (2.4)	1 (2.4)	0	0	0
Infections					
-Total	15 (36.6)	1 (2.4)	1 (2.4)	10 (24.4)	3 (7.3)
Escherichia bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Sialoadenitis	2 (4.9)	0	0	2 (4.9)	0
Acute sinusitis	1 (2.4)	0	0	1 (2.4)	0
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	1 (2.4)	0
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	0	0	1 (2.4)	0
Haemophilus bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Oral herpes	1 (2.4)	0	0	1 (2.4)	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Pneumonia	1 (2.4)	0	0	1 (2.4)	0
Pneumonia fungal	1 (2.4)	0	0	0	1 (2.4)
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	6 (14.6)	0	4 (9.8)	2 (4.9)	0
Hypogammaglobulinaemia	4 (9.8)	0	3 (7.3)	1 (2.4)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0
Blood immunoglobulin m decreased	1 (2.4)	0	1 (2.4)	0	0
Immunodeficiency	1 (2.4)	0	0	1 (2.4)	0
Serious neurological adverse reactions					
-Total	2 (4.9)	0	0	2 (4.9)	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Mental status changes	1 (2.4)	0	0	1 (2.4)	0
Tumour Lysis Syndrome					
-Total	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Tumour lysis syndrome	2 (4.9)	0	0	1 (2.4)	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (75.0)	1 (2.5)	2 (5.0)	13 (32.5)	14 (35.0)
Hematological disorders including cytopenias					
-Total	18 (45.0)	1 (2.5)	0	8 (20.0)	9 (22.5)
Anaemia	10 (25.0)	1 (2.5)	1 (2.5)	7 (17.5)	1 (2.5)
Febrile neutropenia	6 (15.0)	0	0	6 (15.0)	0
Neutropenia	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	0	3 (7.5)
Thrombocytopenia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
White blood cell count decreased	2 (5.0)	1 (2.5)	0	0	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (2.5)	1 (2.5)	0	0	0
Infections					
-Total	24 (60.0)	0	4 (10.0)	14 (35.0)	6 (15.0)
Bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Epstein-barr virus infection	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis	1 (2.5)	0	1 (2.5)	0	0
Skin papilloma	1 (2.5)	1 (2.5)	0	0	0
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Cognitive disorder	1 (2.5)	0	0	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are

summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230a
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (88.2)	0	1 (5.9)	7 (41.2)	7 (41.2)
Hematological disorders including cytopenias					
-Total	12 (70.6)	0	0	5 (29.4)	7 (41.2)
Febrile neutropenia	6 (35.3)	0	0	5 (29.4)	1 (5.9)
Anaemia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Platelet count decreased	4 (23.5)	0	0	0	4 (23.5)
Neutropenia	3 (17.6)	0	0	0	3 (17.6)
Pancytopenia	3 (17.6)	0	0	1 (5.9)	2 (11.8)
White blood cell count decreased	3 (17.6)	0	0	0	3 (17.6)
Lymphocyte count decreased	2 (11.8)	0	0	0	2 (11.8)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)
Thrombocytopenia	1 (5.9)	0	0	1 (5.9)	0
Infections					
-Total	12 (70.6)	1 (5.9)	2 (11.8)	6 (35.3)	3 (17.6)
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Cellulitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile colitis	1 (5.9)	0	1 (5.9)	0	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Gastroenteritis	1 (5.9)	0	1 (5.9)	0	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0
Herpes simplex	1 (5.9)	0	1 (5.9)	0	0
Parainfluenzae virus infection	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	0	1 (5.9)	0
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	1 (5.9)	0	1 (5.9)	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	0	0	1 (5.9)
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (11.8)	0	2 (11.8)	0	0
Hypogammaglobulinaemia	2 (11.8)	0	2 (11.8)	0	0
Serious neurological adverse reactions					
-Total	1 (5.9)	0	1 (5.9)	0	0
Lethargy	1 (5.9)	1 (5.9)	0	0	0
Mental status changes	1 (5.9)	0	1 (5.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are

summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230b
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (72.7)	1 (1.8)	2 (3.6)	16 (29.1)	21 (38.2)
Hematological disorders including cytopenias					
-Total	30 (54.5)	0	2 (3.6)	12 (21.8)	16 (29.1)
Anaemia	16 (29.1)	1 (1.8)	4 (7.3)	10 (18.2)	1 (1.8)
Febrile neutropenia	9 (16.4)	0	0	9 (16.4)	0
Neutropenia	8 (14.5)	0	0	1 (1.8)	7 (12.7)
Neutrophil count decreased	7 (12.7)	1 (1.8)	0	2 (3.6)	4 (7.3)
Thrombocytopenia	6 (10.9)	1 (1.8)	1 (1.8)	2 (3.6)	2 (3.6)
White blood cell count decreased	4 (7.3)	1 (1.8)	0	0	3 (5.5)
Leukopenia	3 (5.5)	0	0	0	3 (5.5)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	3 (5.5)	0	0	0	3 (5.5)
Lymphocyte count decreased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	1 (1.8)	0	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Infections					
-Total	26 (47.3)	1 (1.8)	2 (3.6)	18 (32.7)	5 (9.1)
Oral herpes	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Catheter site infection	2 (3.6)	0	0	2 (3.6)	0
Escherichia bacteraemia	2 (3.6)	0	0	2 (3.6)	0
Respiratory tract infection	2 (3.6)	0	0	2 (3.6)	0
Sinusitis	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Staphylococcal sepsis	2 (3.6)	0	0	0	2 (3.6)
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection reactivation	1 (1.8)	0	1 (1.8)	0	0
Device related bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Epstein-barr virus infection reactivation	1 (1.8)	1 (1.8)	0	0	0
Fungal infection	1 (1.8)	0	1 (1.8)	0	0
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Paronychia	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	0	1 (1.8)	0
Pneumonia fungal	1 (1.8)	0	0	1 (1.8)	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Skin papilloma	1 (1.8)	1 (1.8)	0	0	0
Staphylococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Tonsillitis	1 (1.8)	0	1 (1.8)	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (9.1)	0	3 (5.5)	2 (3.6)	0
Hypogammaglobulinaemia	3 (5.5)	0	3 (5.5)	0	0
Immunodeficiency	2 (3.6)	0	0	2 (3.6)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	6 (10.9)	1 (1.8)	2 (3.6)	3 (5.5)	0
Mental status changes	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Agitation	1 (1.8)	1 (1.8)	0	0	0
Cognitive disorder	1 (1.8)	0	0	1 (1.8)	0
Encephalopathy	1 (1.8)	0	0	1 (1.8)	0
Lethargy	1 (1.8)	1 (1.8)	0	0	0
Seizure	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Tumour lysis syndrome	2 (3.6)	0	0	1 (1.8)	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230b
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (86.0)	1 (2.3)	3 (7.0)	18 (41.9)	15 (34.9)
Hematological disorders including cytopenias					
-Total	25 (58.1)	1 (2.3)	0	13 (30.2)	11 (25.6)
Febrile neutropenia	14 (32.6)	0	0	13 (30.2)	1 (2.3)
Anaemia	7 (16.3)	1 (2.3)	0	6 (14.0)	0
Neutrophil count decreased	5 (11.6)	0	0	1 (2.3)	4 (9.3)
Platelet count decreased	5 (11.6)	0	0	0	5 (11.6)
White blood cell count decreased	4 (9.3)	0	0	0	4 (9.3)
Neutropenia	3 (7.0)	1 (2.3)	0	0	2 (4.7)
Pancytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Lymphocyte count decreased	2 (4.7)	0	0	0	2 (4.7)
Infections					
-Total	25 (58.1)	1 (2.3)	5 (11.6)	12 (27.9)	7 (16.3)
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Bacteraemia	2 (4.7)	0	0	2 (4.7)	0
Septic shock	2 (4.7)	0	0	0	2 (4.7)
Staphylococcal bacteraemia	2 (4.7)	0	0	2 (4.7)	0
Urinary tract infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Acute sinusitis	1 (2.3)	0	0	1 (2.3)	0
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	1 (2.3)	0	0
Cellulitis	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Epstein-barr virus infection	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	1 (2.3)	0	0	0	1 (2.3)
Fungal skin infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis adenovirus	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	0	1 (2.3)	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Haemophilus bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Herpes simplex	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Localised infection	1 (2.3)	1 (2.3)	0	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia fungal	1 (2.3)	0	0	0	1 (2.3)
Post herpetic neuralgia	1 (2.3)	0	0	1 (2.3)	0
Sialoadenitis	1 (2.3)	0	0	1 (2.3)	0
Sinusitis	1 (2.3)	0	1 (2.3)	0	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal skin infection	1 (2.3)	0	0	1 (2.3)	0
Stomatococcal infection	1 (2.3)	0	0	0	1 (2.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Hypogammaglobulinaemia	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin m decreased	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	1 (2.3)	0	0	1 (2.3)	0
Mental status changes	1 (2.3)	0	0	1 (2.3)	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (81.4)	1 (1.4)	3 (4.3)	26 (37.1)	27 (38.6)
Hematological disorders including cytopenias					
-Total	41 (58.6)	0	2 (2.9)	20 (28.6)	19 (27.1)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Febrile neutropenia	16 (22.9)	0	0	16 (22.9)	0
Neutrophil count decreased	11 (15.7)	1 (1.4)	0	3 (4.3)	7 (10.0)
Neutropenia	7 (10.0)	1 (1.4)	0	1 (1.4)	5 (7.1)
Platelet count decreased	6 (8.6)	0	0	0	6 (8.6)
Thrombocytopenia	6 (8.6)	1 (1.4)	1 (1.4)	2 (2.9)	2 (2.9)
White blood cell count decreased	6 (8.6)	1 (1.4)	0	0	5 (7.1)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	4 (5.7)	0	1 (1.4)	1 (1.4)	2 (2.9)
Lymphocyte count decreased	3 (4.3)	1 (1.4)	0	1 (1.4)	1 (1.4)
Leukopenia	2 (2.9)	0	0	0	2 (2.9)
Infections					
-Total	42 (60.0)	2 (2.9)	4 (5.7)	26 (37.1)	10 (14.3)
Pneumonia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Staphylococcal bacteraemia	3 (4.3)	0	0	3 (4.3)	0
Acute sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Localised infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Oral herpes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Sialoadenitis	2 (2.9)	0	0	2 (2.9)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Fungal infection	1 (1.4)	0	1 (1.4)	0	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Pseudomonal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Skin papilloma	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal skin infection	1 (1.4)	0	0	1 (1.4)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tonsillitis	1 (1.4)	0	1 (1.4)	0	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (12.9)	0	6 (8.6)	3 (4.3)	0
Hypogammaglobulinaemia	6 (8.6)	0	5 (7.1)	1 (1.4)	0
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	7 (10.0)	1 (1.4)	2 (2.9)	4 (5.7)	0
Mental status changes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Lethargy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.4)	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	10 (66.7)	0	2 (13.3)	5 (33.3)	3 (20.0)
Hematological disorders including cytopenias					
-Total	4 (26.7)	0	0	2 (13.3)	2 (13.3)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Thrombocytopenia	2 (13.3)	0	0	0	2 (13.3)
Eosinophil count decreased	1 (6.7)	1 (6.7)	0	0	0
Haematocrit decreased	1 (6.7)	1 (6.7)	0	0	0
Leukopenia	1 (6.7)	0	0	0	1 (6.7)
Lymphopenia	1 (6.7)	0	0	0	1 (6.7)
Neutropenia	1 (6.7)	0	0	0	1 (6.7)

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Red blood cell count decreased	1 (6.7)	1 (6.7)	0	0	0
Infections					
-Total	6 (40.0)	0	2 (13.3)	3 (20.0)	1 (6.7)
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Catheter site infection	1 (6.7)	0	1 (6.7)	0	0
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Escherichia bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (6.7)	0	0	1 (6.7)	0
Tumour lysis syndrome	1 (6.7)	0	0	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230c
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (76.9)	1 (7.7)	0	3 (23.1)	6 (46.2)
Hematological disorders including cytopenias					
-Total	10 (76.9)	1 (7.7)	0	3 (23.1)	6 (46.2)
Febrile neutropenia	5 (38.5)	0	0	4 (30.8)	1 (7.7)
Anaemia	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Neutropenia	3 (23.1)	0	0	0	3 (23.1)
Platelet count decreased	2 (15.4)	0	0	0	2 (15.4)
White blood cell count decreased	2 (15.4)	0	0	0	2 (15.4)
Lymphocyte count decreased	1 (7.7)	0	0	0	1 (7.7)
Neutrophil count decreased	1 (7.7)	0	0	0	1 (7.7)

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	1 (7.7)	0	0	1 (7.7)	0
Infections					
-Total	3 (23.1)	0	1 (7.7)	1 (7.7)	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (7.7)	0	1 (7.7)	0	0
Hypogammaglobulinaemia	1 (7.7)	0	1 (7.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230d
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	1 (5.6)	0	6 (33.3)	7 (38.9)
Hematological disorders including cytopenias					
-Total	9 (50.0)	1 (5.6)	0	3 (16.7)	5 (27.8)
Anaemia	4 (22.2)	1 (5.6)	1 (5.6)	1 (5.6)	1 (5.6)
Platelet count decreased	3 (16.7)	0	0	0	3 (16.7)
Febrile neutropenia	2 (11.1)	0	0	2 (11.1)	0
Neutrophil count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Thrombocytopenia	2 (11.1)	0	0	2 (11.1)	0
White blood cell count decreased	2 (11.1)	0	0	0	2 (11.1)
Lymphocyte count decreased	1 (5.6)	0	0	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Infections					
-Total	11 (61.1)	0	1 (5.6)	8 (44.4)	2 (11.1)
Bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Localised infection	1 (5.6)	1 (5.6)	0	0	0
Oral herpes	1 (5.6)	0	1 (5.6)	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia fungal	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (11.1)	0	2 (11.1)	0	0
Hypogammaglobulinaemia	2 (11.1)	0	2 (11.1)	0	0
Serious neurological adverse reactions					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Mental status changes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Lethargy	1 (5.6)	1 (5.6)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230d
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (78.8)	1 (1.3)	5 (6.3)	28 (35.0)	29 (36.3)
Hematological disorders including cytopenias					
-Total	46 (57.5)	0	2 (2.5)	22 (27.5)	22 (27.5)
Febrile neutropenia	21 (26.3)	0	0	20 (25.0)	1 (1.3)
Anaemia	19 (23.8)	1 (1.3)	3 (3.8)	15 (18.8)	0
Neutropenia	10 (12.5)	1 (1.3)	0	1 (1.3)	8 (10.0)
Neutrophil count decreased	10 (12.5)	1 (1.3)	0	2 (2.5)	7 (8.8)
Thrombocytopenia	7 (8.8)	1 (1.3)	1 (1.3)	1 (1.3)	4 (5.0)
White blood cell count decreased	6 (7.5)	1 (1.3)	0	0	5 (6.3)
Platelet count decreased	5 (6.3)	0	0	0	5 (6.3)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	4 (5.0)	0	1 (1.3)	1 (1.3)	2 (2.5)
Leukopenia	3 (3.8)	0	0	0	3 (3.8)
Lymphocyte count decreased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Eosinophil count decreased	1 (1.3)	1 (1.3)	0	0	0
Haematocrit decreased	1 (1.3)	1 (1.3)	0	0	0
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Red blood cell count decreased	1 (1.3)	1 (1.3)	0	0	0
Infections					
-Total	40 (50.0)	2 (2.5)	6 (7.5)	22 (27.5)	10 (12.5)
Pneumonia	4 (5.0)	0	1 (1.3)	2 (2.5)	1 (1.3)
Catheter site infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Oral herpes	2 (2.5)	0	0	2 (2.5)	0
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0
Sinusitis	2 (2.5)	0	2 (2.5)	0	0
Staphylococcal infection	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Acute sinusitis	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cytomegalovirus infection reactivation	1 (1.3)	0	1 (1.3)	0	0
Device related bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Epstein-barr virus infection	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epstein-barr virus infection reactivation	1 (1.3)	1 (1.3)	0	0	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Fungal infection	1 (1.3)	0	1 (1.3)	0	0
Fungal pharyngitis	1 (1.3)	0	0	1 (1.3)	0
Fungal sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis adenovirus	1 (1.3)	0	0	1 (1.3)	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Haemophilus bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Herpes simplex	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	0	0	1 (1.3)	0
Paronychia	1 (1.3)	0	0	1 (1.3)	0
Peritonitis	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	0	1 (1.3)
Post herpetic neuralgia	1 (1.3)	0	0	1 (1.3)	0
Pseudomonal bacteraemia	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	1 (1.3)	0	0	0	1 (1.3)
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Skin papilloma	1 (1.3)	1 (1.3)	0	0	0
Staphylococcal skin infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	0	0	1 (1.3)
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0
Tonsillitis	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection	1 (1.3)	0	1 (1.3)	0	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (10.0)	0	5 (6.3)	3 (3.8)	0
Hypogammaglobulinaemia	5 (6.3)	0	4 (5.0)	1 (1.3)	0
Immunodeficiency	2 (2.5)	0	0	2 (2.5)	0
Blood immunoglobulin g decreased	1 (1.3)	0	1 (1.3)	0	0
Blood immunoglobulin m decreased	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	5 (6.3)	1 (1.3)	1 (1.3)	3 (3.8)	0
Agitation	1 (1.3)	1 (1.3)	0	0	0
Cognitive disorder	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Tumour lysis syndrome	3 (3.8)	0	0	2 (2.5)	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230e
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Hematological disorders including cytopenias					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (25.0)	0	2 (25.0)	0	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (12.5)	0	0	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230e
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (78.9)	2 (2.2)	5 (5.6)	31 (34.4)	33 (36.7)
Hematological disorders including cytopenias					
-Total	51 (56.7)	1 (1.1)	2 (2.2)	22 (24.4)	26 (28.9)
Anaemia	21 (23.3)	2 (2.2)	4 (4.4)	14 (15.6)	1 (1.1)
Febrile neutropenia	21 (23.3)	0	0	20 (22.2)	1 (1.1)
Neutropenia	11 (12.2)	1 (1.1)	0	1 (1.1)	9 (10.0)
Neutrophil count decreased	11 (12.2)	1 (1.1)	0	3 (3.3)	7 (7.8)
Platelet count decreased	8 (8.9)	0	0	0	8 (8.9)
Thrombocytopenia	8 (8.9)	1 (1.1)	1 (1.1)	3 (3.3)	3 (3.3)
White blood cell count decreased	7 (7.8)	0	0	0	7 (7.8)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	4 (4.4)	0	1 (1.1)	1 (1.1)	2 (2.2)
Leukopenia	3 (3.3)	0	0	0	3 (3.3)
Lymphocyte count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	45 (50.0)	2 (2.2)	7 (7.8)	26 (28.9)	10 (11.1)
Pneumonia	4 (4.4)	0	1 (1.1)	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Oral herpes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Acute sinusitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Escherichia bacteraemia	2 (2.2)	0	0	2 (2.2)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Staphylococcal bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Urinary tract infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (8.9)	0	5 (5.6)	3 (3.3)	0
Hypogammaglobulinaemia	6 (6.7)	0	5 (5.6)	1 (1.1)	0
Immunodeficiency	2 (2.2)	0	0	2 (2.2)	0
Serious neurological adverse reactions					

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=90 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (6.7)	1 (1.1)	2 (2.2)	3 (3.3)	0
Mental status changes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Tumour lysis syndrome	3 (3.3)	0	0	2 (2.2)	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230f
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	0	1 (50.0)
Hematological disorders including cytopenias					
-Total	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0
Fungal infection	1 (50.0)	0	1 (50.0)	0	0
Tonsillitis	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230f
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	76 (79.2)	2 (2.1)	5 (5.2)	34 (35.4)	35 (36.5)
Hematological disorders including cytopenias					
-Total	54 (56.3)	1 (1.0)	2 (2.1)	25 (26.0)	26 (27.1)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	23 (24.0)	0	0	22 (22.9)	1 (1.0)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Neutropenia	10 (10.4)	1 (1.0)	0	1 (1.0)	8 (8.3)
Thrombocytopenia	9 (9.4)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.2)
Platelet count decreased	8 (8.3)	0	0	0	8 (8.3)
White blood cell count decreased	8 (8.3)	1 (1.0)	0	0	7 (7.3)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (4.2)	1 (1.0)	0	1 (1.0)	2 (2.1)
Pancytopenia	4 (4.2)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	50 (52.1)	2 (2.1)	7 (7.3)	29 (30.2)	12 (12.5)
Pneumonia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Acute sinusitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Gingivitis	1 (1.0)	1 (1.0)	0	0	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (10.4)	0	7 (7.3)	3 (3.1)	0
Hypogammaglobulinaemia	7 (7.3)	0	6 (6.3)	1 (1.0)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230g
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	77 (79.4)	2 (2.1)	5 (5.2)	34 (35.1)	36 (37.1)
Hematological disorders including cytopenias					
-Total	55 (56.7)	1 (1.0)	2 (2.1)	25 (25.8)	27 (27.8)
Anaemia	23 (23.7)	2 (2.1)	4 (4.1)	16 (16.5)	1 (1.0)
Febrile neutropenia	23 (23.7)	0	0	22 (22.7)	1 (1.0)
Neutrophil count decreased	12 (12.4)	1 (1.0)	0	3 (3.1)	8 (8.2)
Neutropenia	11 (11.3)	1 (1.0)	0	1 (1.0)	9 (9.3)
Thrombocytopenia	9 (9.3)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.1)
Platelet count decreased	8 (8.2)	0	0	0	8 (8.2)
White blood cell count decreased	8 (8.2)	1 (1.0)	0	0	7 (7.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (4.1)	1 (1.0)	0	1 (1.0)	2 (2.1)
Pancytopenia	4 (4.1)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	51 (52.6)	2 (2.1)	7 (7.2)	30 (30.9)	12 (12.4)
Pneumonia	4 (4.1)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Acute sinusitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal infection	1 (1.0)	0	1 (1.0)	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Gingivitis	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (10.3)	0	7 (7.2)	3 (3.1)	0
Hypogammaglobulinaemia	7 (7.2)	0	6 (6.2)	1 (1.0)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	7 (7.2)	1 (1.0)	2 (2.1)	4 (4.1)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230h
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Hematological disorders including cytopenias					
-Total	2 (66.7)	0	0	2 (66.7)	0
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0	0	0
Infections					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Serious neurological adverse reactions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230h
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (77.9)	2 (2.1)	5 (5.3)	33 (34.7)	34 (35.8)
Hematological disorders including cytopenias					
-Total	53 (55.8)	1 (1.1)	2 (2.1)	23 (24.2)	27 (28.4)
Febrile neutropenia	23 (24.2)	0	0	22 (23.2)	1 (1.1)
Anaemia	22 (23.2)	2 (2.1)	4 (4.2)	15 (15.8)	1 (1.1)
Neutropenia	11 (11.6)	1 (1.1)	0	1 (1.1)	9 (9.5)
Neutrophil count decreased	11 (11.6)	1 (1.1)	0	2 (2.1)	8 (8.4)
Thrombocytopenia	9 (9.5)	1 (1.1)	1 (1.1)	3 (3.2)	4 (4.2)
Platelet count decreased	8 (8.4)	0	0	0	8 (8.4)
White blood cell count decreased	7 (7.4)	0	0	0	7 (7.4)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	4 (4.2)	0	1 (1.1)	1 (1.1)	2 (2.1)
Leukopenia	3 (3.2)	0	0	0	3 (3.2)
Lymphocyte count decreased	3 (3.2)	0	0	1 (1.1)	2 (2.1)
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	48 (50.5)	2 (2.1)	7 (7.4)	29 (30.5)	10 (10.5)
Pneumonia	4 (4.2)	0	1 (1.1)	2 (2.1)	1 (1.1)
Catheter site infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Oral herpes	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Sinusitis	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Staphylococcal bacteraemia	3 (3.2)	0	0	3 (3.2)	0
Acute sinusitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (10.5)	0	7 (7.4)	3 (3.2)	0
Hypogammaglobulinaemia	7 (7.4)	0	6 (6.3)	1 (1.1)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	6 (6.3)	1 (1.1)	2 (2.1)	3 (3.2)	0
Mental status changes	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Tumour lysis syndrome	3 (3.2)	0	0	2 (2.1)	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230i
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Febrile neutropenia	2 (100)	0	0	2 (100)	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230i
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	75 (78.1)	2 (2.1)	5 (5.2)	33 (34.4)	35 (36.5)
Hematological disorders including cytopenias					
-Total	53 (55.2)	1 (1.0)	2 (2.1)	24 (25.0)	26 (27.1)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	21 (21.9)	0	0	20 (20.8)	1 (1.0)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Neutropenia	11 (11.5)	1 (1.0)	0	1 (1.0)	9 (9.4)
Thrombocytopenia	9 (9.4)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.2)
Platelet count decreased	8 (8.3)	0	0	0	8 (8.3)
White blood cell count decreased	7 (7.3)	1 (1.0)	0	0	6 (6.3)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (4.2)	1 (1.0)	0	1 (1.0)	2 (2.1)
Pancytopenia	4 (4.2)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	50 (52.1)	2 (2.1)	7 (7.3)	29 (30.2)	12 (12.5)
Pneumonia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related infection	2 (2.1)	0	0	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Acute sinusitis	1 (1.0)	0	1 (1.0)	0	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal infection	1 (1.0)	0	1 (1.0)	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Gingivitis	1 (1.0)	1 (1.0)	0	0	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (10.4)	0	7 (7.3)	3 (3.1)	0
Hypogammaglobulinaemia	7 (7.3)	0	6 (6.3)	1 (1.0)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230j
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (80.0)	1 (3.3)	3 (10.0)	8 (26.7)	12 (40.0)
Hematological disorders including cytopenias					
-Total	18 (60.0)	0	2 (6.7)	7 (23.3)	9 (30.0)
Anaemia	9 (30.0)	1 (3.3)	2 (6.7)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	0	0	6 (20.0)	0
Neutrophil count decreased	6 (20.0)	1 (3.3)	0	0	5 (16.7)
Platelet count decreased	4 (13.3)	0	0	0	4 (13.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
Neutropenia	3 (10.0)	1 (3.3)	0	0	2 (6.7)
White blood cell count decreased	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Thrombocytopenia	2 (6.7)	1 (3.3)	0	0	1 (3.3)

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	1 (3.3)	0	0
Infections					
-Total	16 (53.3)	1 (3.3)	3 (10.0)	8 (26.7)	4 (13.3)
Pneumonia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Staphylococcal infection	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Staphylococcal sepsis	2 (6.7)	0	0	0	2 (6.7)
Urinary tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Catheter site infection	1 (3.3)	0	0	1 (3.3)	0
Cytomegalovirus infection reactivation	1 (3.3)	0	1 (3.3)	0	0
Epstein-barr virus infection reactivation	1 (3.3)	1 (3.3)	0	0	0
Fungal pharyngitis	1 (3.3)	0	0	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Paronychia	1 (3.3)	0	0	1 (3.3)	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Blood immunoglobulin m decreased	1 (3.3)	0	1 (3.3)	0	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Serious neurological adverse reactions					
-Total	2 (6.7)	0	0	2 (6.7)	0
Cognitive disorder	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Tumour Lysis Syndrome					

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

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (3.3)	0	0	1 (3.3)	0
Tumour lysis syndrome	1 (3.3)	0	0	1 (3.3)	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230j
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (77.9)	1 (1.5)	2 (2.9)	26 (38.2)	24 (35.3)
Hematological disorders including cytopenias					
-Total	37 (54.4)	1 (1.5)	0	18 (26.5)	18 (26.5)
Febrile neutropenia	17 (25.0)	0	0	16 (23.5)	1 (1.5)
Anaemia	14 (20.6)	1 (1.5)	2 (2.9)	10 (14.7)	1 (1.5)
Neutropenia	8 (11.8)	0	0	1 (1.5)	7 (10.3)
Thrombocytopenia	7 (10.3)	0	1 (1.5)	3 (4.4)	3 (4.4)
Neutrophil count decreased	6 (8.8)	0	0	3 (4.4)	3 (4.4)
White blood cell count decreased	5 (7.4)	0	0	0	5 (7.4)
Platelet count decreased	4 (5.9)	0	0	0	4 (5.9)

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	3 (4.4)	0	0	1 (1.5)	2 (2.9)
Leukopenia	2 (2.9)	0	0	0	2 (2.9)
Eosinophil count decreased	1 (1.5)	1 (1.5)	0	0	0
Haematocrit decreased	1 (1.5)	1 (1.5)	0	0	0
Lymphocyte count decreased	1 (1.5)	0	0	0	1 (1.5)
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Red blood cell count decreased	1 (1.5)	1 (1.5)	0	0	0
Infections					
-Total	35 (51.5)	1 (1.5)	4 (5.9)	22 (32.4)	8 (11.8)
Oral herpes	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Sinusitis	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Acute sinusitis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Catheter site infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Escherichia bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Pneumonia fungal	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Device related bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Epstein-barr virus infection	1 (1.5)	0	1 (1.5)	0	0
Fungal infection	1 (1.5)	0	1 (1.5)	0	0
Fungal sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis adenovirus	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Haemophilus bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Herpes simplex	1 (1.5)	0	1 (1.5)	0	0
Klebsiella bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0	1 (1.5)	0
Peritonitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pneumonia	1 (1.5)	0	0	0	1 (1.5)
Post herpetic neuralgia	1 (1.5)	0	0	1 (1.5)	0
Pseudomonal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Skin papilloma	1 (1.5)	1 (1.5)	0	0	0
Staphylococcal skin infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.5)	0	0	0	1 (1.5)
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Tonsillitis	1 (1.5)	0	1 (1.5)	0	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Hypogammaglobulinaemia	5 (7.4)	0	4 (5.9)	1 (1.5)	0
Immunodeficiency	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	5 (7.4)	1 (1.5)	2 (2.9)	2 (2.9)	0
Mental status changes	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Agitation	1 (1.5)	1 (1.5)	0	0	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Lethargy	1 (1.5)	1 (1.5)	0	0	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.5)	1 (1.5)

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230k
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (90.6)	1 (3.1)	1 (3.1)	9 (28.1)	18 (56.3)
Hematological disorders including cytopenias					
-Total	22 (68.8)	0	0	7 (21.9)	15 (46.9)
Febrile neutropenia	8 (25.0)	0	0	7 (21.9)	1 (3.1)
Anaemia	7 (21.9)	0	1 (3.1)	6 (18.8)	0
Neutropenia	7 (21.9)	0	0	0	7 (21.9)
Neutrophil count decreased	6 (18.8)	1 (3.1)	0	1 (3.1)	4 (12.5)
White blood cell count decreased	5 (15.6)	0	0	0	5 (15.6)
Platelet count decreased	4 (12.5)	0	0	0	4 (12.5)
Leukopenia	2 (6.3)	0	0	0	2 (6.3)

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Pancytopenia	1 (3.1)	0	0	1 (3.1)	0
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	20 (62.5)	2 (6.3)	3 (9.4)	11 (34.4)	4 (12.5)
Pneumonia	3 (9.4)	0	0	2 (6.3)	1 (3.1)
Device related infection	2 (6.3)	0	0	2 (6.3)	0
Herpes zoster	2 (6.3)	0	0	2 (6.3)	0
Respiratory tract infection	2 (6.3)	0	0	2 (6.3)	0
Staphylococcal sepsis	2 (6.3)	0	0	0	2 (6.3)
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus infection reactivation	1 (3.1)	0	1 (3.1)	0	0
Device related bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Device related sepsis	1 (3.1)	0	0	1 (3.1)	0
Epstein-barr virus infection reactivation	1 (3.1)	1 (3.1)	0	0	0
Fungal infection	1 (3.1)	0	1 (3.1)	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis adenovirus	1 (3.1)	0	0	1 (3.1)	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0
Haemophilus bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Paronychia	1 (3.1)	0	0	1 (3.1)	0
Post herpetic neuralgia	1 (3.1)	0	0	1 (3.1)	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0
Skin papilloma	1 (3.1)	1 (3.1)	0	0	0
Tonsillitis	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection	1 (3.1)	0	1 (3.1)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (21.9)	0	4 (12.5)	3 (9.4)	0
Hypogammaglobulinaemia	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Immunodeficiency	2 (6.3)	0	0	2 (6.3)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Agitation	1 (3.1)	1 (3.1)	0	0	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	1 (3.1)	1 (3.1)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230k
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (75.4)	1 (1.8)	3 (5.3)	21 (36.8)	18 (31.6)
Hematological disorders including cytopenias					
-Total	32 (56.1)	1 (1.8)	2 (3.5)	17 (29.8)	12 (21.1)
Anaemia	16 (28.1)	2 (3.5)	3 (5.3)	10 (17.5)	1 (1.8)
Febrile neutropenia	14 (24.6)	0	0	14 (24.6)	0
Thrombocytopenia	8 (14.0)	1 (1.8)	1 (1.8)	2 (3.5)	4 (7.0)
Neutrophil count decreased	6 (10.5)	0	0	2 (3.5)	4 (7.0)
Neutropenia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Platelet count decreased	4 (7.0)	0	0	0	4 (7.0)
Pancytopenia	3 (5.3)	0	1 (1.8)	0	2 (3.5)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	3 (5.3)	1 (1.8)	0	0	2 (3.5)
Lymphocyte count decreased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Infections					
-Total	28 (49.1)	0	3 (5.3)	17 (29.8)	8 (14.0)
Catheter site infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Oral herpes	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Sinusitis	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Staphylococcal bacteraemia	3 (5.3)	0	0	3 (5.3)	0
Acute sinusitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Clostridium difficile colitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Septic shock	2 (3.5)	0	0	0	2 (3.5)
Staphylococcal infection	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Fungal sepsis	1 (1.8)	0	0	0	1 (1.8)
Fungal skin infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	0	0	1 (1.8)	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	1 (1.8)	0	0	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Stomatococcal infection	1 (1.8)	0	0	0	1 (1.8)
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (5.3)	0	3 (5.3)	0	0
Hypogammaglobulinaemia	2 (3.5)	0	2 (3.5)	0	0
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin m decreased	1 (1.8)	0	1 (1.8)	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	5 (8.8)	0	2 (3.5)	3 (5.3)	0
Mental status changes	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Cognitive disorder	1 (1.8)	0	0	1 (1.8)	0
Lethargy	1 (1.8)	1 (1.8)	0	0	0
Seizure	1 (1.8)	0	1 (1.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230k
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	5 (55.6)	0	1 (11.1)	4 (44.4)	0
Hematological disorders including cytopenias					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Infections					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Tumour Lysis Syndrome					

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	0	0	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230l
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (77.6)	1 (1.7)	4 (6.9)	20 (34.5)	20 (34.5)
Hematological disorders including cytopenias					
-Total	31 (53.4)	0	1 (1.7)	14 (24.1)	16 (27.6)
Febrile neutropenia	14 (24.1)	0	0	13 (22.4)	1 (1.7)
Neutrophil count decreased	11 (19.0)	1 (1.7)	0	3 (5.2)	7 (12.1)
Anaemia	10 (17.2)	0	2 (3.4)	8 (13.8)	0
Neutropenia	6 (10.3)	0	0	0	6 (10.3)
Platelet count decreased	6 (10.3)	0	0	0	6 (10.3)
White blood cell count decreased	5 (8.6)	0	0	0	5 (8.6)
Pancytopenia	3 (5.2)	0	0	1 (1.7)	2 (3.4)

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	3 (5.2)	0	1 (1.7)	1 (1.7)	1 (1.7)
Leukopenia	2 (3.4)	0	0	0	2 (3.4)
Lymphocyte count decreased	2 (3.4)	0	0	0	2 (3.4)
Eosinophil count decreased	1 (1.7)	1 (1.7)	0	0	0
Haematocrit decreased	1 (1.7)	1 (1.7)	0	0	0
Lymphopenia	1 (1.7)	0	0	0	1 (1.7)
Red blood cell count decreased	1 (1.7)	1 (1.7)	0	0	0
Infections					
-Total	32 (55.2)	2 (3.4)	6 (10.3)	17 (29.3)	7 (12.1)
Catheter site infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Pneumonia	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Sinusitis	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Device related infection	2 (3.4)	0	0	2 (3.4)	0
Herpes zoster	2 (3.4)	0	0	2 (3.4)	0
Parainfluenzae virus infection	2 (3.4)	0	0	2 (3.4)	0
Septic shock	2 (3.4)	0	0	0	2 (3.4)

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	2 (3.4)	0	0	0	2 (3.4)
Abscess limb	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile colitis	1 (1.7)	0	1 (1.7)	0	0
Cytomegalovirus infection reactivation	1 (1.7)	0	1 (1.7)	0	0
Device related bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0
Epstein-barr virus infection	1 (1.7)	0	1 (1.7)	0	0
Epstein-barr virus infection reactivation	1 (1.7)	1 (1.7)	0	0	0
Escherichia bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Fungal infection	1 (1.7)	0	1 (1.7)	0	0
Fungal pharyngitis	1 (1.7)	0	0	1 (1.7)	0
Fungal sepsis	1 (1.7)	0	0	0	1 (1.7)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis adenovirus	1 (1.7)	0	0	1 (1.7)	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Haemophilus bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Herpes simplex	1 (1.7)	0	1 (1.7)	0	0
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Oral herpes	1 (1.7)	0	0	1 (1.7)	0
Paronychia	1 (1.7)	0	0	1 (1.7)	0
Peritonitis	1 (1.7)	0	0	1 (1.7)	0
Post herpetic neuralgia	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Skin papilloma	1 (1.7)	1 (1.7)	0	0	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal skin infection	1 (1.7)	0	0	1 (1.7)	0
Stomatococcal infection	1 (1.7)	0	0	0	1 (1.7)
Tonsillitis	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection	1 (1.7)	0	1 (1.7)	0	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (12.1)	0	5 (8.6)	2 (3.4)	0
Hypogammaglobulinaemia	6 (10.3)	0	5 (8.6)	1 (1.7)	0
Immunodeficiency	1 (1.7)	0	0	1 (1.7)	0
Serious neurological adverse reactions					
-Total	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Agitation	1 (1.7)	1 (1.7)	0	0	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0
Seizure	1 (1.7)	0	1 (1.7)	0	0
Tumour Lysis Syndrome					
-Total	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Tumour lysis syndrome	2 (3.4)	0	0	1 (1.7)	1 (1.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230l
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (80.0)	1 (2.5)	1 (2.5)	14 (35.0)	16 (40.0)
Hematological disorders including cytopenias					
-Total	24 (60.0)	1 (2.5)	1 (2.5)	11 (27.5)	11 (27.5)
Anaemia	13 (32.5)	2 (5.0)	2 (5.0)	8 (20.0)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	0	2 (5.0)	3 (7.5)
Neutropenia	5 (12.5)	1 (2.5)	0	1 (2.5)	3 (7.5)
White blood cell count decreased	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Lymphocyte count decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	19 (47.5)	0	1 (2.5)	13 (32.5)	5 (12.5)
Acute sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia fungal	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Sialoadenitis	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)	0	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	1 (2.5)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Mental status changes	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Cognitive disorder	1 (2.5)	0	0	1 (2.5)	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230m
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	10 (58.8)	0	1 (5.9)	7 (41.2)	2 (11.8)
Hematological disorders including cytopenias					
-Total	7 (41.2)	0	0	6 (35.3)	1 (5.9)
Febrile neutropenia	7 (41.2)	0	0	7 (41.2)	0
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	7 (41.2)	0	1 (5.9)	5 (29.4)	1 (5.9)
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Acute sinusitis	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungal pharyngitis	1 (5.9)	0	0	1 (5.9)	0
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Peritonitis	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Serious neurological adverse reactions					
-Total	1 (5.9)	0	0	1 (5.9)	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230m
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (82.7)	2 (2.5)	4 (4.9)	27 (33.3)	34 (42.0)
Hematological disorders including cytopenias					
-Total	48 (59.3)	1 (1.2)	2 (2.5)	19 (23.5)	26 (32.1)
Anaemia	23 (28.4)	2 (2.5)	4 (4.9)	16 (19.8)	1 (1.2)
Febrile neutropenia	16 (19.8)	0	0	15 (18.5)	1 (1.2)
Neutropenia	11 (13.6)	1 (1.2)	0	1 (1.2)	9 (11.1)
Neutrophil count decreased	11 (13.6)	1 (1.2)	0	3 (3.7)	7 (8.6)
Thrombocytopenia	9 (11.1)	1 (1.2)	1 (1.2)	3 (3.7)	4 (4.9)
Platelet count decreased	8 (9.9)	0	0	0	8 (9.9)
White blood cell count decreased	8 (9.9)	1 (1.2)	0	0	7 (8.6)

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphocyte count decreased	4 (4.9)	1 (1.2)	0	1 (1.2)	2 (2.5)
Pancytopenia	4 (4.9)	0	1 (1.2)	1 (1.2)	2 (2.5)
Leukopenia	3 (3.7)	0	0	0	3 (3.7)
Eosinophil count decreased	1 (1.2)	1 (1.2)	0	0	0
Haematocrit decreased	1 (1.2)	1 (1.2)	0	0	0
Lymphopenia	1 (1.2)	0	0	0	1 (1.2)
Red blood cell count decreased	1 (1.2)	1 (1.2)	0	0	0
Infections					
-Total	44 (54.3)	2 (2.5)	6 (7.4)	25 (30.9)	11 (13.6)
Pneumonia	4 (4.9)	0	1 (1.2)	2 (2.5)	1 (1.2)
Oral herpes	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Sinusitis	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Escherichia bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0
Pneumonia fungal	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Urinary tract infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Abscess limb	1 (1.2)	0	0	1 (1.2)	0
Acute sinusitis	1 (1.2)	0	1 (1.2)	0	0
Bacterial sepsis	1 (1.2)	0	0	0	1 (1.2)
Bronchiolitis	1 (1.2)	0	0	1 (1.2)	0
Bronchitis	1 (1.2)	0	1 (1.2)	0	0
Bronchopulmonary aspergillosis	1 (1.2)	0	0	1 (1.2)	0
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0
Cellulitis	1 (1.2)	0	1 (1.2)	0	0
Cytomegalovirus infection reactivation	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.2)	0	1 (1.2)	0	0
Device related sepsis	1 (1.2)	0	0	1 (1.2)	0
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Epstein-barr virus infection reactivation	1 (1.2)	1 (1.2)	0	0	0
Fungal infection	1 (1.2)	0	1 (1.2)	0	0
Fungal sepsis	1 (1.2)	0	0	0	1 (1.2)
Gastroenteritis	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis adenovirus	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis viral	1 (1.2)	0	0	1 (1.2)	0
Gingivitis	1 (1.2)	1 (1.2)	0	0	0
Haemophilus bacteraemia	1 (1.2)	0	0	0	1 (1.2)
Herpes simplex	1 (1.2)	0	1 (1.2)	0	0
Klebsiella bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Paronychia	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Post herpetic neuralgia	1 (1.2)	0	0	1 (1.2)	0
Pseudomonal bacteraemia	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.2)	0	0	0	1 (1.2)
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Skin papilloma	1 (1.2)	1 (1.2)	0	0	0
Staphylococcal bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Staphylococcal infection	1 (1.2)	0	0	0	1 (1.2)
Staphylococcal skin infection	1 (1.2)	0	0	1 (1.2)	0
Stomatococcal infection	1 (1.2)	0	0	0	1 (1.2)
Tonsillitis	1 (1.2)	0	1 (1.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (12.3)	0	7 (8.6)	3 (3.7)	0
Hypogammaglobulinaemia	7 (8.6)	0	6 (7.4)	1 (1.2)	0
Immunodeficiency	2 (2.5)	0	0	2 (2.5)	0
Blood immunoglobulin g decreased	1 (1.2)	0	1 (1.2)	0	0
Blood immunoglobulin m decreased	1 (1.2)	0	1 (1.2)	0	0
Serious neurological adverse reactions					

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (7.4)	1 (1.2)	2 (2.5)	3 (3.7)	0
Mental status changes	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Agitation	1 (1.2)	1 (1.2)	0	0	0
Cognitive disorder	1 (1.2)	0	0	1 (1.2)	0
Encephalopathy	1 (1.2)	0	0	1 (1.2)	0
Lethargy	1 (1.2)	1 (1.2)	0	0	0
Seizure	1 (1.2)	0	1 (1.2)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Tumour lysis syndrome	3 (3.7)	0	0	2 (2.5)	1 (1.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230n
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (71.4)	1 (3.6)	2 (7.1)	11 (39.3)	6 (21.4)
Hematological disorders including cytopenias					
-Total	16 (57.1)	1 (3.6)	0	9 (32.1)	6 (21.4)
Anaemia	7 (25.0)	1 (3.6)	1 (3.6)	5 (17.9)	0
Febrile neutropenia	5 (17.9)	0	0	5 (17.9)	0
Thrombocytopenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Neutropenia	3 (10.7)	0	0	0	3 (10.7)
Neutrophil count decreased	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Lymphocyte count decreased	1 (3.6)	0	0	1 (3.6)	0
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	11 (39.3)	1 (3.6)	3 (10.7)	7 (25.0)	0
Sinusitis	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Abscess limb	1 (3.6)	0	0	1 (3.6)	0
Catheter site infection	1 (3.6)	0	1 (3.6)	0	0
Clostridium difficile colitis	1 (3.6)	0	0	1 (3.6)	0
Device related bacteraemia	1 (3.6)	0	1 (3.6)	0	0
Epstein-barr virus infection	1 (3.6)	0	1 (3.6)	0	0
Fungal infection	1 (3.6)	0	1 (3.6)	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Localised infection	1 (3.6)	0	0	1 (3.6)	0
Pseudomonal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Sialoadenitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Tonsillitis	1 (3.6)	0	1 (3.6)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Blood immunoglobulin g decreased	1 (3.6)	0	1 (3.6)	0	0
Blood immunoglobulin m decreased	1 (3.6)	0	1 (3.6)	0	0
Hypogammaglobulinaemia	1 (3.6)	0	0	1 (3.6)	0
Immunodeficiency	1 (3.6)	0	0	1 (3.6)	0
Serious neurological adverse reactions					
-Total	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230n
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (81.4)	1 (1.4)	3 (4.3)	23 (32.9)	30 (42.9)
Hematological disorders including cytopenias					
-Total	39 (55.7)	0	2 (2.9)	16 (22.9)	21 (30.0)
Febrile neutropenia	18 (25.7)	0	0	17 (24.3)	1 (1.4)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Neutrophil count decreased	10 (14.3)	1 (1.4)	0	2 (2.9)	7 (10.0)
Neutropenia	8 (11.4)	1 (1.4)	0	1 (1.4)	6 (8.6)
Platelet count decreased	8 (11.4)	0	0	0	8 (11.4)
White blood cell count decreased	7 (10.0)	1 (1.4)	0	0	6 (8.6)
Pancytopenia	4 (5.7)	0	1 (1.4)	1 (1.4)	2 (2.9)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)
Leukopenia	3 (4.3)	0	0	0	3 (4.3)
Lymphocyte count decreased	3 (4.3)	1 (1.4)	0	0	2 (2.9)
Eosinophil count decreased	1 (1.4)	1 (1.4)	0	0	0
Haematocrit decreased	1 (1.4)	1 (1.4)	0	0	0
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Red blood cell count decreased	1 (1.4)	1 (1.4)	0	0	0
Infections					
-Total	40 (57.1)	1 (1.4)	4 (5.7)	23 (32.9)	12 (17.1)
Pneumonia	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)
Oral herpes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Acute sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Escherichia bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (2.9)	0	0	2 (2.9)	0
Pneumonia fungal	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Peritonitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Skin papilloma	1 (1.4)	1 (1.4)	0	0	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (10.0)	0	6 (8.6)	1 (1.4)	0
Hypogammaglobulinaemia	6 (8.6)	0	6 (8.6)	0	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	6 (8.6)	1 (1.4)	1 (1.4)	4 (5.7)	0
Mental status changes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	1 (1.4)	1 (1.4)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Tumour lysis syndrome	3 (4.3)	0	0	2 (2.9)	1 (1.4)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230o
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	1 (9.1)	5 (45.5)	4 (36.4)
Hematological disorders including cytopenias					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Infections					

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (63.6)	0	2 (18.2)	4 (36.4)	1 (9.1)
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Abscess limb	1 (9.1)	0	0	1 (9.1)	0
Catheter site infection	1 (9.1)	0	1 (9.1)	0	0
Device related bacteraemia	1 (9.1)	0	1 (9.1)	0	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Fungal infection	1 (9.1)	0	1 (9.1)	0	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	0	1 (9.1)	0
Post herpetic neuralgia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Tonsillitis	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230o
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (77.0)	2 (2.3)	4 (4.6)	29 (33.3)	32 (36.8)
Hematological disorders including cytopenias					
-Total	49 (56.3)	1 (1.1)	2 (2.3)	22 (25.3)	24 (27.6)
Anaemia	22 (25.3)	2 (2.3)	4 (4.6)	15 (17.2)	1 (1.1)
Febrile neutropenia	20 (23.0)	0	0	19 (21.8)	1 (1.1)
Neutrophil count decreased	12 (13.8)	1 (1.1)	0	3 (3.4)	8 (9.2)
Neutropenia	10 (11.5)	1 (1.1)	0	1 (1.1)	8 (9.2)
Thrombocytopenia	8 (9.2)	1 (1.1)	0	3 (3.4)	4 (4.6)
Platelet count decreased	7 (8.0)	0	0	0	7 (8.0)
White blood cell count decreased	7 (8.0)	1 (1.1)	0	0	6 (6.9)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (4.6)	1 (1.1)	0	1 (1.1)	2 (2.3)
Pancytopenia	4 (4.6)	0	1 (1.1)	1 (1.1)	2 (2.3)
Leukopenia	3 (3.4)	0	0	0	3 (3.4)
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	44 (50.6)	2 (2.3)	5 (5.7)	26 (29.9)	11 (12.6)
Pneumonia	4 (4.6)	0	1 (1.1)	2 (2.3)	1 (1.1)
Oral herpes	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Staphylococcal bacteraemia	3 (3.4)	0	0	3 (3.4)	0
Acute sinusitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.3)	0	0	2 (2.3)	0
Catheter site infection	2 (2.3)	0	0	2 (2.3)	0
Clostridium difficile colitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	2 (2.3)	0	0	2 (2.3)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.3)	0	0	2 (2.3)	0
Pneumonia fungal	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.3)	0	0	2 (2.3)	0
Septic shock	2 (2.3)	0	0	0	2 (2.3)
Sialoadenitis	2 (2.3)	0	0	2 (2.3)	0
Staphylococcal infection	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related infection	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Herpes zoster	1 (1.1)	0	0	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (11.5)	0	7 (8.0)	3 (3.4)	0
Hypogammaglobulinaemia	7 (8.0)	0	6 (6.9)	1 (1.1)	0
Immunodeficiency	2 (2.3)	0	0	2 (2.3)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (6.9)	1 (1.1)	1 (1.1)	4 (4.6)	0
Mental status changes	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Cognitive disorder	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Tumour lysis syndrome	3 (3.4)	0	0	2 (2.3)	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230p
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	4 (57.1)	1 (14.3)
Hematological disorders including cytopenias					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Infections					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230p
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	72 (79.1)	2 (2.2)	5 (5.5)	30 (33.0)	35 (38.5)
Hematological disorders including cytopenias					
-Total	52 (57.1)	1 (1.1)	2 (2.2)	23 (25.3)	26 (28.6)
Anaemia	23 (25.3)	2 (2.2)	4 (4.4)	16 (17.6)	1 (1.1)
Febrile neutropenia	22 (24.2)	0	0	21 (23.1)	1 (1.1)
Neutrophil count decreased	11 (12.1)	1 (1.1)	0	2 (2.2)	8 (8.8)
Neutropenia	10 (11.0)	0	0	1 (1.1)	9 (9.9)
Thrombocytopenia	9 (9.9)	1 (1.1)	1 (1.1)	3 (3.3)	4 (4.4)
Platelet count decreased	8 (8.8)	0	0	0	8 (8.8)
White blood cell count decreased	7 (7.7)	1 (1.1)	0	0	6 (6.6)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (4.4)	1 (1.1)	0	1 (1.1)	2 (2.2)
Pancytopenia	4 (4.4)	0	1 (1.1)	1 (1.1)	2 (2.2)
Leukopenia	3 (3.3)	0	0	0	3 (3.3)
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	48 (52.7)	2 (2.2)	6 (6.6)	28 (30.8)	12 (13.2)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Oral herpes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Pneumonia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Staphylococcal bacteraemia	3 (3.3)	0	0	3 (3.3)	0
Acute sinusitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Clostridium difficile colitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Localised infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Sialoadenitis	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal infection	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Urinary tract infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (11.0)	0	7 (7.7)	3 (3.3)	0
Hypogammaglobulinaemia	7 (7.7)	0	6 (6.6)	1 (1.1)	0

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency	2 (2.2)	0	0	2 (2.2)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	7 (7.7)	1 (1.1)	2 (2.2)	4 (4.4)	0
Mental status changes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Cognitive disorder	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Tumour lysis syndrome	3 (3.3)	0	0	2 (2.2)	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (77.5)	0	1 (2.5)	12 (30.0)	18 (45.0)
Hematological disorders including cytopenias					
-Total	24 (60.0)	0	0	8 (20.0)	16 (40.0)
Febrile neutropenia	10 (25.0)	0	0	10 (25.0)	0
Anaemia	9 (22.5)	0	1 (2.5)	8 (20.0)	0
Neutropenia	9 (22.5)	0	0	0	9 (22.5)
Neutrophil count decreased	7 (17.5)	0	0	2 (5.0)	5 (12.5)
Platelet count decreased	5 (12.5)	0	0	0	5 (12.5)
White blood cell count decreased	5 (12.5)	0	0	0	5 (12.5)
Leukopenia	3 (7.5)	0	0	0	3 (7.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (5.0)	0	0	0	2 (5.0)
Thrombocytopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Eosinophil count decreased	1 (2.5)	1 (2.5)	0	0	0
Haematocrit decreased	1 (2.5)	1 (2.5)	0	0	0
Lymphopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	0	0	1 (2.5)
Red blood cell count decreased	1 (2.5)	1 (2.5)	0	0	0
Infections					
-Total	20 (50.0)	1 (2.5)	3 (7.5)	13 (32.5)	3 (7.5)
Catheter site infection	2 (5.0)	0	0	2 (5.0)	0
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (2.5)	0	1 (2.5)	0	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis adenovirus	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Haemophilus bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Skin papilloma	1 (2.5)	1 (2.5)	0	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal skin infection	1 (2.5)	0	0	1 (2.5)	0
Stomatococcal infection	1 (2.5)	0	0	0	1 (2.5)
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (20.0)	0	5 (12.5)	3 (7.5)	0
Hypogammaglobulinaemia	6 (15.0)	0	5 (12.5)	1 (2.5)	0
Immunodeficiency	2 (5.0)	0	0	2 (5.0)	0
Serious neurological adverse reactions					
-Total	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	1 (2.5)	1 (2.5)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (72.5)	2 (5.0)	3 (7.5)	16 (40.0)	8 (20.0)
Hematological disorders including cytopenias					
-Total	23 (57.5)	1 (2.5)	2 (5.0)	13 (32.5)	7 (17.5)
Anaemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	1 (2.5)	2 (5.0)	2 (5.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Neutropenia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
White blood cell count decreased	2 (5.0)	0	0	0	2 (5.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	17 (42.5)	1 (2.5)	3 (7.5)	11 (27.5)	2 (5.0)
Sinusitis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Catheter site infection	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Epstein-barr virus infection reactivation	1 (2.5)	1 (2.5)	0	0	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (5.0)	0	2 (5.0)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	1 (2.5)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	2 (5.0)	0	2 (5.0)	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Mental status changes	1 (2.5)	0	1 (2.5)	0	0
Seizure	1 (2.5)	0	1 (2.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230q
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	0	1 (5.6)	6 (33.3)	10 (55.6)
Hematological disorders including cytopenias					
-Total	8 (44.4)	0	0	4 (22.2)	4 (22.2)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Infections					
-Total	14 (77.8)	0	1 (5.6)	6 (33.3)	7 (38.9)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0
Peritonitis	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Serious neurological adverse reactions					
-Total	4 (22.2)	0	0	4 (22.2)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Tumour Lysis Syndrome					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are

summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Hematological disorders including cytopenias					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Infections					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (25.0)	0	2 (25.0)	0	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (12.5)	0	0	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (70.0)	1 (3.3)	0	11 (36.7)	9 (30.0)
Hematological disorders including cytopenias					
-Total	14 (46.7)	1 (3.3)	0	7 (23.3)	6 (20.0)
Anaemia	7 (23.3)	1 (3.3)	1 (3.3)	5 (16.7)	0
Thrombocytopenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Neutropenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Lymphocyte count decreased	1 (3.3)	0	0	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	0	0	1 (3.3)	0
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (3.3)	0	0	0	1 (3.3)
White blood cell count decreased	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	11 (36.7)	0	0	8 (26.7)	3 (10.0)
Pneumonia fungal	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Acute sinusitis	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis adenovirus	1 (3.3)	0	0	1 (3.3)	0
Haemophilus bacteraemia	1 (3.3)	0	0	0	1 (3.3)
Klebsiella bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Oral herpes	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.3)	0	0	1 (3.3)	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Serious neurological adverse reactions					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Mental status changes	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Lethargy	1 (3.3)	1 (3.3)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (6.7)	0	0	2 (6.7)	0
Tumour lysis syndrome	2 (6.7)	0	0	2 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	0	2 (11.1)	8 (44.4)	6 (33.3)
Hematological disorders including cytopenias					
-Total	13 (72.2)	0	1 (5.6)	7 (38.9)	5 (27.8)
Febrile neutropenia	7 (38.9)	0	0	7 (38.9)	0
Anaemia	6 (33.3)	1 (5.6)	2 (11.1)	2 (11.1)	1 (5.6)
Neutropenia	3 (16.7)	1 (5.6)	0	0	2 (11.1)
Thrombocytopenia	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Eosinophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Haematocrit decreased	1 (5.6)	1 (5.6)	0	0	0
Leukopenia	1 (5.6)	0	0	0	1 (5.6)

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (5.6)	0	0	0	1 (5.6)
Neutrophil count decreased	1 (5.6)	0	0	1 (5.6)	0
Pancytopenia	1 (5.6)	0	1 (5.6)	0	0
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Red blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
White blood cell count decreased	1 (5.6)	0	0	0	1 (5.6)
Infections					
-Total	10 (55.6)	0	2 (11.1)	7 (38.9)	1 (5.6)
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Sinusitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal infection	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Serious neurological adverse reactions					
-Total	1 (5.6)	0	0	1 (5.6)	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 230r
Adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (81.0)	1 (2.4)	3 (7.1)	12 (28.6)	18 (42.9)
Hematological disorders including cytopenias					
-Total	24 (57.1)	0	1 (2.4)	8 (19.0)	15 (35.7)
Febrile neutropenia	11 (26.2)	0	0	10 (23.8)	1 (2.4)
Neutrophil count decreased	9 (21.4)	1 (2.4)	0	1 (2.4)	7 (16.7)
Anaemia	8 (19.0)	0	1 (2.4)	7 (16.7)	0
Platelet count decreased	6 (14.3)	0	0	0	6 (14.3)
Neutropenia	5 (11.9)	0	0	0	5 (11.9)
White blood cell count decreased	5 (11.9)	0	0	0	5 (11.9)
Lymphocyte count decreased	2 (4.8)	0	0	0	2 (4.8)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (4.8)	0	0	0	2 (4.8)
Leukopenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Infections					
-Total	24 (57.1)	2 (4.8)	5 (11.9)	11 (26.2)	6 (14.3)
Bacteraemia	2 (4.8)	0	0	2 (4.8)	0
Catheter site infection	2 (4.8)	0	0	2 (4.8)	0
Herpes zoster	2 (4.8)	0	0	2 (4.8)	0
Parainfluenzae virus infection	2 (4.8)	0	0	2 (4.8)	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Septic shock	2 (4.8)	0	0	0	2 (4.8)
Staphylococcal sepsis	2 (4.8)	0	0	0	2 (4.8)
Abscess limb	1 (2.4)	0	0	1 (2.4)	0
Bacterial sepsis	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Cellulitis	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0
Device related bacteraemia	1 (2.4)	0	1 (2.4)	0	0
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection	1 (2.4)	0	1 (2.4)	0	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Fungal infection	1 (2.4)	0	1 (2.4)	0	0
Fungal pharyngitis	1 (2.4)	0	0	1 (2.4)	0
Fungal sepsis	1 (2.4)	0	0	0	1 (2.4)
Gastroenteritis	1 (2.4)	0	1 (2.4)	0	0
Gingivitis	1 (2.4)	1 (2.4)	0	0	0
Herpes simplex	1 (2.4)	0	1 (2.4)	0	0
Paronychia	1 (2.4)	0	0	1 (2.4)	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Post herpetic neuralgia	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	1 (2.4)	0	0
Skin papilloma	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal skin infection	1 (2.4)	0	0	1 (2.4)	0
Stomatococcal infection	1 (2.4)	0	0	0	1 (2.4)
Tonsillitis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection	1 (2.4)	0	1 (2.4)	0	0
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	7 (16.7)	0	5 (11.9)	2 (4.8)	0
Hypogammaglobulinaemia	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Immunodeficiency	1 (2.4)	0	0	1 (2.4)	0
Serious neurological adverse reactions					
-Total	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Agitation	1 (2.4)	1 (2.4)	0	0	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	1 (2.4)	0	0
Tumour Lysis Syndrome					

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (2.4)	0	0	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (52.9)	1 (2.9)	3 (8.8)	1 (2.9)	13 (38.2)
Hematological disorders including cytopenias					
-Total	13 (38.2)	0	1 (2.9)	0	12 (35.3)
White blood cell count decreased	7 (20.6)	0	1 (2.9)	1 (2.9)	5 (14.7)
Lymphocyte count decreased	5 (14.7)	0	0	0	5 (14.7)
Platelet count decreased	5 (14.7)	0	0	1 (2.9)	4 (11.8)
Anaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Neutrophil count decreased	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Lymphopenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)

Age: <10 years

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections					
-Total	5 (14.7)	1 (2.9)	2 (5.9)	1 (2.9)	1 (2.9)
Conjunctivitis	1 (2.9)	1 (2.9)	0	0	0
Device related infection	1 (2.9)	0	1 (2.9)	0	0
Fungaemia	1 (2.9)	0	0	0	1 (2.9)
Nasopharyngitis	1 (2.9)	1 (2.9)	0	0	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Vulval cellulitis	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	1 (2.9)	0	0	1 (2.9)	0
Irritability	1 (2.9)	0	0	1 (2.9)	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (41.9)	2 (6.5)	3 (9.7)	2 (6.5)	6 (19.4)
Hematological disorders including cytopenias					
-Total	7 (22.6)	0	0	1 (3.2)	6 (19.4)
Anaemia	4 (12.9)	1 (3.2)	0	3 (9.7)	0
White blood cell count decreased	4 (12.9)	0	0	1 (3.2)	3 (9.7)
Neutrophil count decreased	3 (9.7)	0	1 (3.2)	0	2 (6.5)
Febrile neutropenia	2 (6.5)	0	0	2 (6.5)	0
Leukopenia	1 (3.2)	0	0	0	1 (3.2)
Lymphocyte count decreased	1 (3.2)	0	0	0	1 (3.2)
Neutropenia	1 (3.2)	0	0	0	1 (3.2)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	1 (3.2)	0	0	0	1 (3.2)
Infections					
-Total	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Paronychia	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Tinea pedis	1 (3.2)	1 (3.2)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Hypogammaglobulinaemia	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Serious neurological adverse reactions					
-Total	1 (3.2)	0	1 (3.2)	0	0
Muscular weakness	1 (3.2)	0	1 (3.2)	0	0
Posterior reversible encephalopathy syndrome	1 (3.2)	0	1 (3.2)	0	0
Seizure	1 (3.2)	0	1 (3.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231a
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (23.1)	0	0	2 (15.4)	1 (7.7)
Hematological disorders including cytopenias					
-Total	2 (15.4)	0	0	2 (15.4)	0
Febrile neutropenia	2 (15.4)	0	0	2 (15.4)	0
Infections					
-Total	3 (23.1)	0	0	2 (15.4)	1 (7.7)
Bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Oral herpes	1 (7.7)	0	0	1 (7.7)	0

Age: >=18

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231b
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (41.3)	2 (4.3)	3 (6.5)	1 (2.2)	13 (28.3)
Hematological disorders including cytopenias					
-Total	13 (28.3)	0	1 (2.2)	0	12 (26.1)
White blood cell count decreased	6 (13.0)	0	1 (2.2)	1 (2.2)	4 (8.7)
Anaemia	5 (10.9)	0	0	5 (10.9)	0
Lymphocyte count decreased	4 (8.7)	0	0	0	4 (8.7)
Platelet count decreased	4 (8.7)	0	0	1 (2.2)	3 (6.5)
Neutrophil count decreased	3 (6.5)	0	0	0	3 (6.5)
Febrile neutropenia	1 (2.2)	0	0	1 (2.2)	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)

Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (2.2)	0	0	0	1 (2.2)
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	4 (8.7)	2 (4.3)	1 (2.2)	0	1 (2.2)
Conjunctivitis	1 (2.2)	1 (2.2)	0	0	0
Fungaemia	1 (2.2)	0	0	0	1 (2.2)
Nasopharyngitis	1 (2.2)	1 (2.2)	0	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hypogammaglobulinaemia	2 (4.3)	0	1 (2.2)	1 (2.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were

infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231b
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (46.9)	1 (3.1)	3 (9.4)	4 (12.5)	7 (21.9)
Hematological disorders including cytopenias					
-Total	9 (28.1)	0	0	3 (9.4)	6 (18.8)
White blood cell count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Neutrophil count decreased	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Anaemia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Febrile neutropenia	3 (9.4)	0	0	3 (9.4)	0
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Platelet count decreased	2 (6.3)	0	0	0	2 (6.3)
Infections					

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (21.9)	1 (3.1)	2 (6.3)	3 (9.4)	1 (3.1)
Paronychia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	1 (3.1)	0	0
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Oral herpes	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vulval cellulitis	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Irritability	1 (3.1)	0	0	1 (3.1)	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Posterior reversible encephalopathy syndrome	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (43.9)	2 (3.5)	5 (8.8)	4 (7.0)	14 (24.6)
Hematological disorders including cytopenias					
-Total	17 (29.8)	0	1 (1.8)	2 (3.5)	14 (24.6)
White blood cell count decreased	9 (15.8)	0	1 (1.8)	2 (3.5)	6 (10.5)
Anaemia	6 (10.5)	1 (1.8)	0	5 (8.8)	0
Neutrophil count decreased	6 (10.5)	0	1 (1.8)	1 (1.8)	4 (7.0)
Lymphocyte count decreased	4 (7.0)	0	0	0	4 (7.0)
Platelet count decreased	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Febrile neutropenia	2 (3.5)	0	0	2 (3.5)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	0	0	1 (1.8)
Infections					
-Total	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Paronychia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Conjunctivitis	1 (1.8)	1 (1.8)	0	0	0
Device related infection	1 (1.8)	0	1 (1.8)	0	0
Nasopharyngitis	1 (1.8)	1 (1.8)	0	0	0
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulval cellulitis	1 (1.8)	0	0	1 (1.8)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypogammaglobulinaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	0	0	1 (1.8)	0
Somnolence	1 (1.8)	1 (1.8)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Infections					
-Total	1 (10.0)	1 (10.0)	0	0	0
Tinea pedis	1 (10.0)	1 (10.0)	0	0	0
Serious neurological adverse reactions					
-Total	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	1 (10.0)	0	0
Posterior reversible encephalopathy syndrome	1 (10.0)	0	1 (10.0)	0	0
Seizure	1 (10.0)	0	1 (10.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231c
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	7 (63.6)	0	0	1 (9.1)	6 (54.5)
Hematological disorders including cytopenias					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Platelet count decreased	2 (18.2)	0	0	0	2 (18.2)
White blood cell count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	1 (9.1)	0	0	0	1 (9.1)
Infections					

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Escherichia bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Fungaemia	1 (9.1)	0	0	0	1 (9.1)
Gastroenteritis	1 (9.1)	0	1 (9.1)	0	0
Oral herpes	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231d
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	0	1 (7.1)	2 (14.3)	5 (35.7)
Hematological disorders including cytopenias					
-Total	6 (42.9)	0	0	2 (14.3)	4 (28.6)
Anaemia	3 (21.4)	1 (7.1)	0	2 (14.3)	0
Neutrophil count decreased	3 (21.4)	0	1 (7.1)	0	2 (14.3)
White blood cell count decreased	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Platelet count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Lymphocyte count decreased	1 (7.1)	0	0	0	1 (7.1)
Infections					

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Conjunctivitis	1 (7.1)	1 (7.1)	0	0	0
Escherichia bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Gastroenteritis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231d
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (40.6)	3 (4.7)	5 (7.8)	3 (4.7)	15 (23.4)
Hematological disorders including cytopenias					
-Total	16 (25.0)	0	1 (1.6)	1 (1.6)	14 (21.9)
White blood cell count decreased	8 (12.5)	0	1 (1.6)	1 (1.6)	6 (9.4)
Anaemia	5 (7.8)	0	1 (1.6)	4 (6.3)	0
Lymphocyte count decreased	5 (7.8)	0	0	0	5 (7.8)
Neutrophil count decreased	4 (6.3)	0	0	1 (1.6)	3 (4.7)
Platelet count decreased	4 (6.3)	0	0	0	4 (6.3)
Febrile neutropenia	2 (3.1)	0	0	2 (3.1)	0
Leukopenia	1 (1.6)	0	0	0	1 (1.6)

Ethnicity: Other

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.6)	0	0	0	1 (1.6)
Neutropenia	1 (1.6)	0	0	0	1 (1.6)
Thrombocytopenia	1 (1.6)	0	0	0	1 (1.6)
Infections					
-Total	8 (12.5)	3 (4.7)	2 (3.1)	2 (3.1)	1 (1.6)
Paronychia	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	1 (1.6)	0	0
Fungaemia	1 (1.6)	0	0	0	1 (1.6)
Nasopharyngitis	1 (1.6)	1 (1.6)	0	0	0
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0
Vulval cellulitis	1 (1.6)	0	0	1 (1.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Hypogammaglobulinaemia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Serious neurological adverse reactions					

Ethnicity: Other

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Irritability	1 (1.6)	0	0	1 (1.6)	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Posterior reversible encephalopathy syndrome	1 (1.6)	0	1 (1.6)	0	0
Seizure	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231e
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Hematological disorders including cytopenias					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Infections					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231e
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (43.1)	3 (4.2)	5 (6.9)	3 (4.2)	20 (27.8)
Hematological disorders including cytopenias					
-Total	21 (29.2)	0	1 (1.4)	2 (2.8)	18 (25.0)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	1 (1.4)	8 (11.1)
Anaemia	7 (9.7)	0	1 (1.4)	6 (8.3)	0
Lymphocyte count decreased	6 (8.3)	0	0	0	6 (8.3)
Neutrophil count decreased	6 (8.3)	0	0	1 (1.4)	5 (6.9)
Platelet count decreased	6 (8.3)	0	0	1 (1.4)	5 (6.9)
Febrile neutropenia	4 (5.6)	0	0	4 (5.6)	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Neutropenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	10 (13.9)	3 (4.2)	3 (4.2)	2 (2.8)	2 (2.8)
Paronychia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	1 (1.4)	0	0	0
Device related infection	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Nasopharyngitis	1 (1.4)	1 (1.4)	0	0	0
Oral herpes	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract infection	1 (1.4)	0	1 (1.4)	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.4)	0	0	1 (1.4)	0
Hypogammaglobulinaemia	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	1 (1.4)	0	1 (1.4)	0	0
Muscular weakness	1 (1.4)	0	1 (1.4)	0	0
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	1 (1.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231f
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	0	1 (100)	0
Hypogammaglobulinaemia	1 (100)	0	0	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in

the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231f
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (42.9)	3 (3.9)	6 (7.8)	4 (5.2)	20 (26.0)
Hematological disorders including cytopenias					
-Total	22 (28.6)	0	1 (1.3)	3 (3.9)	18 (23.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.3)	0	1 (1.3)	0	0
Hypogammaglobulinaemia	1 (1.3)	0	1 (1.3)	0	0
Serious neurological adverse reactions					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231g
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (44.2)	3 (3.9)	6 (7.8)	5 (6.5)	20 (26.0)
Hematological disorders including cytopenias					
-Total	22 (28.6)	0	1 (1.3)	3 (3.9)	18 (23.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Serious neurological adverse reactions					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231h
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematological disorders including cytopenias					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231h
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (42.9)	3 (3.9)	6 (7.8)	5 (6.5)	19 (24.7)
Hematological disorders including cytopenias					
-Total	21 (27.3)	0	1 (1.3)	3 (3.9)	17 (22.1)
White blood cell count decreased	10 (13.0)	0	1 (1.3)	2 (2.6)	7 (9.1)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Neutrophil count decreased	6 (7.8)	0	1 (1.3)	0	5 (6.5)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Lymphocyte count decreased	5 (6.5)	0	0	0	5 (6.5)
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)

Hypodiploidy: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0

Hypodiploidy: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Serious neurological adverse reactions					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231i
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (44.2)	3 (3.9)	6 (7.8)	5 (6.5)	20 (26.0)
Hematological disorders including cytopenias					
-Total	22 (28.6)	0	1 (1.3)	3 (3.9)	18 (23.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)

BCR-ABL1-like: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Serious neurological adverse reactions					
-Total	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231j
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (33.3)	2 (7.4)	1 (3.7)	2 (7.4)	4 (14.8)
Hematological disorders including cytopenias					
-Total	5 (18.5)	0	1 (3.7)	1 (3.7)	3 (11.1)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Neutropenia	1 (3.7)	0	0	0	1 (3.7)
Neutrophil count decreased	1 (3.7)	0	0	0	1 (3.7)
Thrombocytopenia	1 (3.7)	0	0	0	1 (3.7)
White blood cell count decreased	1 (3.7)	0	1 (3.7)	0	0
Infections					
-Total	5 (18.5)	2 (7.4)	0	2 (7.4)	1 (3.7)

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

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Fungaemia	1 (3.7)	0	0	0	1 (3.7)
Nasopharyngitis	1 (3.7)	1 (3.7)	0	0	0
Paronychia	1 (3.7)	1 (3.7)	0	0	0
Vulval cellulitis	1 (3.7)	0	0	1 (3.7)	0
Serious neurological adverse reactions					
-Total	1 (3.7)	0	0	1 (3.7)	0
Irritability	1 (3.7)	0	0	1 (3.7)	0
Somnolence	1 (3.7)	1 (3.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231j
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (49.0)	1 (2.0)	5 (9.8)	3 (5.9)	16 (31.4)
Hematological disorders including cytopenias					
-Total	17 (33.3)	0	0	2 (3.9)	15 (29.4)
White blood cell count decreased	10 (19.6)	0	0	2 (3.9)	8 (15.7)
Anaemia	7 (13.7)	1 (2.0)	1 (2.0)	5 (9.8)	0
Lymphocyte count decreased	6 (11.8)	0	0	0	6 (11.8)
Neutrophil count decreased	6 (11.8)	0	1 (2.0)	1 (2.0)	4 (7.8)
Platelet count decreased	6 (11.8)	0	0	1 (2.0)	5 (9.8)
Febrile neutropenia	2 (3.9)	0	0	2 (3.9)	0
Leukopenia	1 (2.0)	0	0	0	1 (2.0)

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

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.0)	0	0	0	1 (2.0)
Infections					
-Total	6 (11.8)	1 (2.0)	3 (5.9)	1 (2.0)	1 (2.0)
Conjunctivitis	1 (2.0)	1 (2.0)	0	0	0
Device related infection	1 (2.0)	0	1 (2.0)	0	0
Escherichia bacteraemia	1 (2.0)	0	0	0	1 (2.0)
Gastroenteritis	1 (2.0)	0	1 (2.0)	0	0
Oral herpes	1 (2.0)	0	0	1 (2.0)	0
Paronychia	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Tinea pedis	1 (2.0)	1 (2.0)	0	0	0
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Hypogammaglobulinaemia	2 (3.9)	0	1 (2.0)	1 (2.0)	0

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

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	1 (2.0)	0	1 (2.0)	0	0
Muscular weakness	1 (2.0)	0	1 (2.0)	0	0
Posterior reversible encephalopathy syndrome	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	1 (2.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231k
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	13 (48.1)	1 (3.7)	1 (3.7)	2 (7.4)	9 (33.3)
Hematological disorders including cytopenias					
-Total	10 (37.0)	0	0	2 (7.4)	8 (29.6)
Lymphocyte count decreased	5 (18.5)	0	0	0	5 (18.5)
White blood cell count decreased	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Anaemia	2 (7.4)	0	0	2 (7.4)	0
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Neutrophil count decreased	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Platelet count decreased	2 (7.4)	0	0	0	2 (7.4)
Thrombocytopenia	1 (3.7)	0	0	0	1 (3.7)

Region: Europe

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections					
-Total	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Device related infection	1 (3.7)	0	1 (3.7)	0	0
Escherichia bacteraemia	1 (3.7)	0	0	0	1 (3.7)
Gastroenteritis	1 (3.7)	0	1 (3.7)	0	0
Nasopharyngitis	1 (3.7)	1 (3.7)	0	0	0
Oral herpes	1 (3.7)	0	0	1 (3.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.7)	0	0	1 (3.7)	0
Hypogammaglobulinaemia	1 (3.7)	0	0	1 (3.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231k
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (45.5)	1 (2.3)	5 (11.4)	3 (6.8)	11 (25.0)
Hematological disorders including cytopenias					
-Total	12 (27.3)	0	1 (2.3)	1 (2.3)	10 (22.7)
White blood cell count decreased	7 (15.9)	0	1 (2.3)	1 (2.3)	5 (11.4)
Anaemia	6 (13.6)	1 (2.3)	1 (2.3)	4 (9.1)	0
Neutrophil count decreased	5 (11.4)	0	1 (2.3)	0	4 (9.1)
Platelet count decreased	4 (9.1)	0	0	1 (2.3)	3 (6.8)
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphocyte count decreased	1 (2.3)	0	0	0	1 (2.3)

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (2.3)	0	0	0	1 (2.3)
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	6 (13.6)	1 (2.3)	2 (4.5)	2 (4.5)	1 (2.3)
Paronychia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	1 (2.3)	0	0	0
Fungaemia	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Vulval cellulitis	1 (2.3)	0	0	1 (2.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.3)	0	1 (2.3)	0	0
Hypogammaglobulinaemia	1 (2.3)	0	1 (2.3)	0	0
Serious neurological adverse reactions					
-Total	2 (4.5)	0	1 (2.3)	1 (2.3)	0

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	1 (2.3)	0	0	1 (2.3)	0
Muscular weakness	1 (2.3)	0	1 (2.3)	0	0
Posterior reversible encephalopathy syndrome	1 (2.3)	0	1 (2.3)	0	0
Seizure	1 (2.3)	0	1 (2.3)	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231k
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (14.3)	1 (14.3)	0	0	0
Infections					
-Total	1 (14.3)	1 (14.3)	0	0	0
Tinea pedis	1 (14.3)	1 (14.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231l
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (45.7)	2 (4.3)	3 (6.5)	2 (4.3)	14 (30.4)
Hematological disorders including cytopenias					
-Total	14 (30.4)	0	0	2 (4.3)	12 (26.1)
White blood cell count decreased	8 (17.4)	0	0	1 (2.2)	7 (15.2)
Neutrophil count decreased	5 (10.9)	0	0	1 (2.2)	4 (8.7)
Anaemia	4 (8.7)	0	1 (2.2)	3 (6.5)	0
Lymphocyte count decreased	4 (8.7)	0	0	0	4 (8.7)
Platelet count decreased	4 (8.7)	0	0	1 (2.2)	3 (6.5)
Febrile neutropenia	2 (4.3)	0	0	2 (4.3)	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)

Prior SCT therapy: Yes

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	8 (17.4)	2 (4.3)	3 (6.5)	1 (2.2)	2 (4.3)
Bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Conjunctivitis	1 (2.2)	1 (2.2)	0	0	0
Device related infection	1 (2.2)	0	1 (2.2)	0	0
Escherichia bacteraemia	1 (2.2)	0	0	0	1 (2.2)
Fungaemia	1 (2.2)	0	0	0	1 (2.2)
Gastroenteritis	1 (2.2)	0	1 (2.2)	0	0
Nasopharyngitis	1 (2.2)	1 (2.2)	0	0	0
Oral herpes	1 (2.2)	0	0	1 (2.2)	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Prior SCT therapy: Yes

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (2.2)	0	0	1 (2.2)	0
Hypogammaglobulinaemia	1 (2.2)	0	0	1 (2.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231l
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (40.6)	1 (3.1)	3 (9.4)	3 (9.4)	6 (18.8)
Hematological disorders including cytopenias					
-Total	8 (25.0)	0	1 (3.1)	1 (3.1)	6 (18.8)
Anaemia	4 (12.5)	1 (3.1)	0	3 (9.4)	0
White blood cell count decreased	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Neutrophil count decreased	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Platelet count decreased	2 (6.3)	0	0	0	2 (6.3)
Neutropenia	1 (3.1)	0	0	0	1 (3.1)

Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vulval cellulitis	1 (3.1)	0	0	1 (3.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (3.1)	0	1 (3.1)	0	0
Hypogammaglobulinaemia	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Irritability	1 (3.1)	0	0	1 (3.1)	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Posterior reversible encephalopathy syndrome	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231m
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (7.7)	1 (7.7)	0	0	0
Infections					
-Total	1 (7.7)	1 (7.7)	0	0	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231m
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (50.8)	2 (3.1)	6 (9.2)	5 (7.7)	20 (30.8)
Hematological disorders including cytopenias					
-Total	22 (33.8)	0	1 (1.5)	3 (4.6)	18 (27.7)
White blood cell count decreased	11 (16.9)	0	1 (1.5)	2 (3.1)	8 (12.3)
Anaemia	8 (12.3)	1 (1.5)	1 (1.5)	6 (9.2)	0
Neutrophil count decreased	7 (10.8)	0	1 (1.5)	1 (1.5)	5 (7.7)
Lymphocyte count decreased	6 (9.2)	0	0	0	6 (9.2)
Platelet count decreased	6 (9.2)	0	0	1 (1.5)	5 (7.7)
Febrile neutropenia	4 (6.2)	0	0	4 (6.2)	0
Leukopenia	1 (1.5)	0	0	0	1 (1.5)

Eligibility for SCT: No

Group term Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Neutropenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	10 (15.4)	2 (3.1)	3 (4.6)	3 (4.6)	2 (3.1)
Paronychia	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	1 (1.5)	0	0	0
Device related infection	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Nasopharyngitis	1 (1.5)	1 (1.5)	0	0	0
Oral herpes	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	0	1 (1.5)	0	0
Vulval cellulitis	1 (1.5)	0	0	1 (1.5)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Hypogammaglobulinaemia	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Serious neurological adverse reactions					
-Total	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Irritability	1 (1.5)	0	0	1 (1.5)	0
Muscular weakness	1 (1.5)	0	1 (1.5)	0	0
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Somnolence	1 (1.5)	1 (1.5)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231n
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (56.0)	1 (4.0)	4 (16.0)	2 (8.0)	7 (28.0)
Hematological disorders including cytopenias					
-Total	8 (32.0)	0	1 (4.0)	0	7 (28.0)
Anaemia	3 (12.0)	0	0	3 (12.0)	0
White blood cell count decreased	3 (12.0)	0	1 (4.0)	0	2 (8.0)
Febrile neutropenia	2 (8.0)	0	0	2 (8.0)	0
Lymphocyte count decreased	2 (8.0)	0	0	0	2 (8.0)
Neutrophil count decreased	2 (8.0)	0	0	0	2 (8.0)
Platelet count decreased	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Leukopenia	1 (4.0)	0	0	0	1 (4.0)

Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Infections					
-Total	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Conjunctivitis	1 (4.0)	1 (4.0)	0	0	0
Device related infection	1 (4.0)	0	1 (4.0)	0	0
Tinea pedis	1 (4.0)	1 (4.0)	0	0	0
Upper respiratory tract infection	1 (4.0)	0	1 (4.0)	0	0
Vulval cellulitis	1 (4.0)	0	0	1 (4.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Hypogammaglobulinaemia	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Serious neurological adverse reactions					
-Total	1 (4.0)	0	0	1 (4.0)	0
Irritability	1 (4.0)	0	0	1 (4.0)	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 231n
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (37.7)	2 (3.8)	2 (3.8)	3 (5.7)	13 (24.5)
Hematological disorders including cytopenias					
-Total	14 (26.4)	0	0	3 (5.7)	11 (20.8)
White blood cell count decreased	8 (15.1)	0	0	2 (3.8)	6 (11.3)
Anaemia	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Neutrophil count decreased	5 (9.4)	0	1 (1.9)	1 (1.9)	3 (5.7)
Lymphocyte count decreased	4 (7.5)	0	0	0	4 (7.5)
Platelet count decreased	4 (7.5)	0	0	0	4 (7.5)
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Lymphopenia	1 (1.9)	0	0	0	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	7 (13.2)	2 (3.8)	1 (1.9)	2 (3.8)	2 (3.8)
Paronychia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	0	1 (1.9)
Fungaemia	1 (1.9)	0	0	0	1 (1.9)
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Nasopharyngitis	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	1 (1.9)	0	1 (1.9)	0	0
Muscular weakness	1 (1.9)	0	1 (1.9)	0	0
Posterior reversible encephalopathy syndrome	1 (1.9)	0	1 (1.9)	0	0
Seizure	1 (1.9)	0	1 (1.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231o
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hematological disorders including cytopenias					
-Total	2 (18.2)	0	0	0	2 (18.2)
Leukopenia	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (9.1)	0	0	1 (9.1)	0
Hypogammaglobulinaemia	1 (9.1)	0	0	1 (9.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 231o
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (46.3)	3 (4.5)	6 (9.0)	4 (6.0)	18 (26.9)
Hematological disorders including cytopenias					
-Total	20 (29.9)	0	1 (1.5)	3 (4.5)	16 (23.9)
White blood cell count decreased	10 (14.9)	0	1 (1.5)	2 (3.0)	7 (10.4)
Anaemia	8 (11.9)	1 (1.5)	1 (1.5)	6 (9.0)	0
Neutrophil count decreased	7 (10.4)	0	1 (1.5)	1 (1.5)	5 (7.5)
Lymphocyte count decreased	6 (9.0)	0	0	0	6 (9.0)
Platelet count decreased	6 (9.0)	0	0	1 (1.5)	5 (7.5)
Febrile neutropenia	4 (6.0)	0	0	4 (6.0)	0
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	11 (16.4)	3 (4.5)	3 (4.5)	3 (4.5)	2 (3.0)
Paronychia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	1 (1.5)	0	0	0
Device related infection	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Nasopharyngitis	1 (1.5)	1 (1.5)	0	0	0
Oral herpes	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Upper respiratory tract infection	1 (1.5)	0	1 (1.5)	0	0
Vulval cellulitis	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (1.5)	0	1 (1.5)	0	0
Hypogammaglobulinaemia	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Irritability	1 (1.5)	0	0	1 (1.5)	0
Muscular weakness	1 (1.5)	0	1 (1.5)	0	0
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Somnolence	1 (1.5)	1 (1.5)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231p
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	1 (16.7)	0	0	3 (50.0)
Hematological disorders including cytopenias					
-Total	3 (50.0)	0	0	0	3 (50.0)
Platelet count decreased	2 (33.3)	0	0	0	2 (33.3)
Anaemia	1 (16.7)	0	0	1 (16.7)	0
Lymphocyte count decreased	1 (16.7)	0	0	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Infections					
-Total	1 (16.7)	1 (16.7)	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231p
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (41.7)	2 (2.8)	6 (8.3)	5 (6.9)	17 (23.6)
Hematological disorders including cytopenias					
-Total	19 (26.4)	0	1 (1.4)	3 (4.2)	15 (20.8)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	2 (2.8)	7 (9.7)
Anaemia	7 (9.7)	1 (1.4)	1 (1.4)	5 (6.9)	0
Neutrophil count decreased	6 (8.3)	0	1 (1.4)	1 (1.4)	4 (5.6)
Lymphocyte count decreased	5 (6.9)	0	0	0	5 (6.9)
Febrile neutropenia	4 (5.6)	0	0	4 (5.6)	0
Platelet count decreased	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Neutropenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	10 (13.9)	2 (2.8)	3 (4.2)	3 (4.2)	2 (2.8)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	1 (1.4)	0	0	0
Device related infection	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Nasopharyngitis	1 (1.4)	1 (1.4)	0	0	0
Oral herpes	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract infection	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulval cellulitis	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hypogammaglobulinaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Irritability	1 (1.4)	0	0	1 (1.4)	0
Muscular weakness	1 (1.4)	0	1 (1.4)	0	0
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Somnolence	1 (1.4)	1 (1.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (44.7)	1 (2.6)	1 (2.6)	3 (7.9)	12 (31.6)
Hematological disorders including cytopenias					
-Total	14 (36.8)	0	0	3 (7.9)	11 (28.9)
White blood cell count decreased	8 (21.1)	0	0	2 (5.3)	6 (15.8)
Anaemia	5 (13.2)	1 (2.6)	1 (2.6)	3 (7.9)	0
Lymphocyte count decreased	5 (13.2)	0	0	0	5 (13.2)
Neutrophil count decreased	4 (10.5)	0	1 (2.6)	1 (2.6)	2 (5.3)
Platelet count decreased	4 (10.5)	0	0	0	4 (10.5)
Febrile neutropenia	2 (5.3)	0	0	2 (5.3)	0
Lymphopenia	1 (2.6)	0	0	0	1 (2.6)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	1 (2.6)	0	0	0	1 (2.6)
Infections					
-Total	4 (10.5)	1 (2.6)	1 (2.6)	1 (2.6)	1 (2.6)
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Device related infection	1 (2.6)	0	1 (2.6)	0	0
Escherichia bacteraemia	1 (2.6)	0	0	0	1 (2.6)
Gastroenteritis	1 (2.6)	0	1 (2.6)	0	0
Oral herpes	1 (2.6)	0	0	1 (2.6)	0
Tinea pedis	1 (2.6)	1 (2.6)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.6)	0	0	1 (2.6)	0
Hypogammaglobulinaemia	1 (2.6)	0	0	1 (2.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (41.0)	2 (5.1)	5 (12.8)	2 (5.1)	7 (17.9)
Hematological disorders including cytopenias					
-Total	8 (20.5)	0	1 (2.6)	0	7 (17.9)
Anaemia	3 (7.7)	0	0	3 (7.7)	0
Neutrophil count decreased	3 (7.7)	0	0	0	3 (7.7)
White blood cell count decreased	3 (7.7)	0	1 (2.6)	0	2 (5.1)
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Platelet count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Leukopenia	1 (2.6)	0	0	0	1 (2.6)
Lymphocyte count decreased	1 (2.6)	0	0	0	1 (2.6)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Infections					
-Total	6 (15.4)	2 (5.1)	2 (5.1)	2 (5.1)	0
Paronychia	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Conjunctivitis	1 (2.6)	1 (2.6)	0	0	0
Nasopharyngitis	1 (2.6)	1 (2.6)	0	0	0
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Vulval cellulitis	1 (2.6)	0	0	1 (2.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.6)	0	1 (2.6)	0	0
Hypogammaglobulinaemia	1 (2.6)	0	1 (2.6)	0	0
Serious neurological adverse reactions					
-Total	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Irritability	1 (2.6)	0	0	1 (2.6)	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscular weakness	1 (2.6)	0	1 (2.6)	0	0
Posterior reversible encephalopathy syndrome	1 (2.6)	0	1 (2.6)	0	0
Seizure	1 (2.6)	0	1 (2.6)	0	0
Somnolence	1 (2.6)	1 (2.6)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231q
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections					
-Total	1 (100)	0	0	0	1 (100)
Fungaemia	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Hematological disorders including cytopenias					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Infections					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (50.0)	1 (4.5)	2 (9.1)	1 (4.5)	7 (31.8)
Hematological disorders including cytopenias					
-Total	8 (36.4)	0	1 (4.5)	0	7 (31.8)
Anaemia	3 (13.6)	0	0	3 (13.6)	0
Lymphocyte count decreased	3 (13.6)	0	0	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Febrile neutropenia	2 (9.1)	0	0	2 (9.1)	0
Neutrophil count decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
Neutropenia	1 (4.5)	0	0	0	1 (4.5)

Number of previous relapses: 1

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Conjunctivitis	1 (4.5)	1 (4.5)	0	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Tinea pedis	1 (4.5)	1 (4.5)	0	0	0
Upper respiratory tract infection	1 (4.5)	0	1 (4.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (20.0)	1 (6.7)	1 (6.7)	0	1 (6.7)
Hematological disorders including cytopenias					
-Total	1 (6.7)	0	0	0	1 (6.7)
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Neutrophil count decreased	1 (6.7)	0	0	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	1 (6.7)	0
White blood cell count decreased	1 (6.7)	0	0	0	1 (6.7)
Infections					
-Total	1 (6.7)	1 (6.7)	0	0	0
Paronychia	1 (6.7)	1 (6.7)	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	1 (6.7)	0	1 (6.7)	0	0
Muscular weakness	1 (6.7)	0	1 (6.7)	0	0
Posterior reversible encephalopathy syndrome	1 (6.7)	0	1 (6.7)	0	0
Seizure	1 (6.7)	0	1 (6.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 231r
Adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (48.6)	1 (2.9)	2 (5.7)	2 (5.7)	12 (34.3)
Hematological disorders including cytopenias					
-Total	12 (34.3)	0	0	2 (5.7)	10 (28.6)
White blood cell count decreased	6 (17.1)	0	0	1 (2.9)	5 (14.3)
Anaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Lymphocyte count decreased	3 (8.6)	0	0	0	3 (8.6)
Neutrophil count decreased	3 (8.6)	0	0	0	3 (8.6)
Platelet count decreased	3 (8.6)	0	0	0	3 (8.6)
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Leukopenia	1 (2.9)	0	0	0	1 (2.9)

Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	6 (17.1)	1 (2.9)	2 (5.7)	1 (2.9)	2 (5.7)
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Device related infection	1 (2.9)	0	1 (2.9)	0	0
Escherichia bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Fungaemia	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis	1 (2.9)	0	1 (2.9)	0	0
Nasopharyngitis	1 (2.9)	1 (2.9)	0	0	0
Oral herpes	1 (2.9)	0	0	1 (2.9)	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (2.9)	0	0	1 (2.9)	0
Hypogammaglobulinaemia	1 (2.9)	0	0	1 (2.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the

manufacturing facility.
-Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (97.6)	0	3 (7.3)	9 (22.0)	28 (68.3)
Cytokine Release Syndrome					
-Total	24 (58.5)	3 (7.3)	9 (22.0)	3 (7.3)	9 (22.0)
Cytokine release syndrome	24 (58.5)	3 (7.3)	10 (24.4)	3 (7.3)	8 (19.5)
Haemophagocytic lymphohistiocytosis	3 (7.3)	1 (2.4)	0	0	2 (4.9)
Hematological disorders including cytopenias					
-Total	34 (82.9)	1 (2.4)	1 (2.4)	11 (26.8)	21 (51.2)
Anaemia	23 (56.1)	4 (9.8)	5 (12.2)	14 (34.1)	0
Febrile neutropenia	20 (48.8)	0	0	20 (48.8)	0
White blood cell count decreased	20 (48.8)	2 (4.9)	1 (2.4)	1 (2.4)	16 (39.0)

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (43.9)	0	1 (2.4)	2 (4.9)	15 (36.6)
Platelet count decreased	16 (39.0)	4 (9.8)	1 (2.4)	4 (9.8)	7 (17.1)
Lymphocyte count decreased	14 (34.1)	0	0	6 (14.6)	8 (19.5)
Thrombocytopenia	8 (19.5)	1 (2.4)	0	2 (4.9)	5 (12.2)
Neutropenia	7 (17.1)	0	1 (2.4)	1 (2.4)	5 (12.2)
Leukopenia	4 (9.8)	0	0	1 (2.4)	3 (7.3)
Lymphopenia	2 (4.9)	0	0	0	2 (4.9)
Pancytopenia	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Eosinophil count decreased	1 (2.4)	1 (2.4)	0	0	0
Haematocrit decreased	1 (2.4)	1 (2.4)	0	0	0
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Red blood cell count decreased	1 (2.4)	1 (2.4)	0	0	0
Infections					
-Total	32 (78.0)	3 (7.3)	6 (14.6)	12 (29.3)	11 (26.8)
Upper respiratory tract infection	7 (17.1)	4 (9.8)	3 (7.3)	0	0
Conjunctivitis	6 (14.6)	2 (4.9)	4 (9.8)	0	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Pneumonia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Device related infection	3 (7.3)	0	1 (2.4)	2 (4.9)	0
Gastroenteritis	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Otitis media	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Parainfluenzae virus infection	3 (7.3)	0	0	2 (4.9)	1 (2.4)
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Bronchopulmonary aspergillosis	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Candida infection	2 (4.9)	0	2 (4.9)	0	0
Clostridium difficile infection	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Cytomegalovirus infection reactivation	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Escherichia bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Metapneumovirus infection	2 (4.9)	0	0	2 (4.9)	0
Oral herpes	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Oral infection	2 (4.9)	0	2 (4.9)	0	0
Pneumocystis jirovecii pneumonia	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Sialoadenitis	2 (4.9)	0	0	2 (4.9)	0
Staphylococcal bacteraemia	2 (4.9)	0	0	2 (4.9)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Viral infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Acute sinusitis	1 (2.4)	0	0	1 (2.4)	0
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bk virus infection	1 (2.4)	1 (2.4)	0	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchitis	1 (2.4)	0	1 (2.4)	0	0
Cellulitis	1 (2.4)	0	1 (2.4)	0	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Cystitis	1 (2.4)	0	1 (2.4)	0	0
Ear infection	1 (2.4)	0	1 (2.4)	0	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Fungaemia	1 (2.4)	0	0	0	1 (2.4)
Fungal infection	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	0	0	1 (2.4)	0
Gingivitis	1 (2.4)	1 (2.4)	0	0	0
Haemophilus bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Human herpesvirus 6 infection	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	0	0	1 (2.4)
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Localised infection	1 (2.4)	1 (2.4)	0	0	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	1 (2.4)	0	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0
Otitis externa	1 (2.4)	0	0	1 (2.4)	0
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (2.4)	0	0	0	1 (2.4)
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Respiratory syncytial virus infection	1 (2.4)	0	1 (2.4)	0	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection viral	1 (2.4)	0	1 (2.4)	0	0
Rhinitis	1 (2.4)	0	1 (2.4)	0	0
Salmonellosis	1 (2.4)	0	1 (2.4)	0	0
Sepsis	1 (2.4)	0	0	0	1 (2.4)
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Skin infection	1 (2.4)	0	1 (2.4)	0	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal skin infection	1 (2.4)	0	1 (2.4)	0	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Vulval cellulitis	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	24 (58.5)	3 (7.3)	15 (36.6)	6 (14.6)	0
Hypogammaglobulinaemia	17 (41.5)	1 (2.4)	13 (31.7)	3 (7.3)	0
Blood immunoglobulin m decreased	6 (14.6)	4 (9.8)	1 (2.4)	1 (2.4)	0
Blood immunoglobulin a decreased	5 (12.2)	4 (9.8)	1 (2.4)	0	0
Blood immunoglobulin g decreased	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Immunodeficiency	2 (4.9)	0	0	2 (4.9)	0
Immunoglobulins decreased	1 (2.4)	0	1 (2.4)	0	0
Serious neurological adverse reactions					
-Total	18 (43.9)	8 (19.5)	3 (7.3)	7 (17.1)	0
Encephalopathy	5 (12.2)	0	2 (4.9)	3 (7.3)	0
Confusional state	4 (9.8)	4 (9.8)	0	0	0
Delirium	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Irritability	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Agitation	2 (4.9)	2 (4.9)	0	0	0
Hallucination	2 (4.9)	0	2 (4.9)	0	0
Lethargy	2 (4.9)	2 (4.9)	0	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (4.9)	0	0	2 (4.9)	0
Somnolence	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Tremor	2 (4.9)	2 (4.9)	0	0	0
Depressed level of consciousness	1 (2.4)	0	0	1 (2.4)	0
Mood altered	1 (2.4)	1 (2.4)	0	0	0
Muscular weakness	1 (2.4)	1 (2.4)	0	0	0
Restlessness	1 (2.4)	0	1 (2.4)	0	0
Seizure	1 (2.4)	0	0	1 (2.4)	0
Tumour Lysis Syndrome					
-Total	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Tumour lysis syndrome	2 (4.9)	0	0	1 (2.4)	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	2 (5.0)	9 (22.5)	29 (72.5)
Cytokine Release Syndrome					
-Total	25 (62.5)	1 (2.5)	5 (12.5)	10 (25.0)	9 (22.5)
Cytokine release syndrome	25 (62.5)	1 (2.5)	5 (12.5)	10 (25.0)	9 (22.5)
Haemophagocytic lymphohistiocytosis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hematological disorders including cytopenias					
-Total	29 (72.5)	0	0	8 (20.0)	21 (52.5)
Anaemia	16 (40.0)	2 (5.0)	4 (10.0)	9 (22.5)	1 (2.5)
Febrile neutropenia	16 (40.0)	0	0	14 (35.0)	2 (5.0)
White blood cell count decreased	11 (27.5)	1 (2.5)	2 (5.0)	0	8 (20.0)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (25.0)	1 (2.5)	1 (2.5)	1 (2.5)	7 (17.5)
Neutropenia	9 (22.5)	1 (2.5)	0	1 (2.5)	7 (17.5)
Platelet count decreased	9 (22.5)	1 (2.5)	1 (2.5)	1 (2.5)	6 (15.0)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	1 (2.5)	3 (7.5)	3 (7.5)
Thrombocytopenia	5 (12.5)	0	1 (2.5)	1 (2.5)	3 (7.5)
Leukopenia	2 (5.0)	0	0	0	2 (5.0)
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	34 (85.0)	1 (2.5)	5 (12.5)	18 (45.0)	10 (25.0)
Paronychia	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Upper respiratory tract infection	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Bacteraemia	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Herpes zoster	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Pneumonia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Rhinovirus infection	4 (10.0)	0	4 (10.0)	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Oral herpes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Sepsis	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Staphylococcal infection	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Fungal infection	2 (5.0)	0	2 (5.0)	0	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Otitis externa	2 (5.0)	0	2 (5.0)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Respiratory tract infection	2 (5.0)	0	2 (5.0)	0	0
Rhinitis	2 (5.0)	2 (5.0)	0	0	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Tinea pedis	2 (5.0)	2 (5.0)	0	0	0
Urinary tract infection	2 (5.0)	0	2 (5.0)	0	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Epstein-barr virus infection	1 (2.5)	0	1 (2.5)	0	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	22 (55.0)	0	14 (35.0)	8 (20.0)	0
Hypogammaglobulinaemia	18 (45.0)	0	12 (30.0)	6 (15.0)	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	18 (45.0)	5 (12.5)	6 (15.0)	7 (17.5)	0
Seizure	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Mental status changes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Agitation	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Confusional state	3 (7.5)	3 (7.5)	0	0	0
Delirium	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Dysarthria	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Somnolence	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tremor	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	4 (10.0)	0	0	3 (7.5)	1 (2.5)
Tumour lysis syndrome	4 (10.0)	0	0	3 (7.5)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232a
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	0	5 (29.4)	12 (70.6)
Cytokine Release Syndrome					
-Total	12 (70.6)	1 (5.9)	3 (17.6)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	1 (5.9)	3 (17.6)	4 (23.5)	4 (23.5)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	1 (5.9)	0
Hematological disorders including cytopenias					
-Total	14 (82.4)	0	0	5 (29.4)	9 (52.9)
Febrile neutropenia	9 (52.9)	0	0	8 (47.1)	1 (5.9)
Anaemia	7 (41.2)	0	3 (17.6)	4 (23.5)	0
Platelet count decreased	7 (41.2)	1 (5.9)	0	1 (5.9)	5 (29.4)

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	6 (35.3)	0	1 (5.9)	1 (5.9)	4 (23.5)
White blood cell count decreased	4 (23.5)	0	0	0	4 (23.5)
Neutrophil count decreased	3 (17.6)	1 (5.9)	0	0	2 (11.8)
Pancytopenia	3 (17.6)	0	0	1 (5.9)	2 (11.8)
Lymphocyte count decreased	2 (11.8)	0	0	0	2 (11.8)
Thrombocytopenia	2 (11.8)	0	0	2 (11.8)	0
Infections					
-Total	17 (100)	1 (5.9)	2 (11.8)	10 (58.8)	4 (23.5)
Parainfluenzae virus infection	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Sinusitis	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Urinary tract infection	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Acute sinusitis	2 (11.8)	0	2 (11.8)	0	0
Bacteraemia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Candida infection	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Gastroenteritis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Nasopharyngitis	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Oral herpes	2 (11.8)	0	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Rhinovirus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Varicella zoster virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Adenovirus infection	1 (5.9)	0	0	1 (5.9)	0
Atypical pneumonia	1 (5.9)	1 (5.9)	0	0	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Cellulitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile colitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile infection	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	0	1 (5.9)	0	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Ear, nose and throat infection	1 (5.9)	0	1 (5.9)	0	0
Encephalitis viral	1 (5.9)	0	0	1 (5.9)	0
Escherichia bacteraemia	1 (5.9)	0	0	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (5.9)	0	1 (5.9)	0	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0
Granulicatella infection	1 (5.9)	0	0	1 (5.9)	0
Herpes simplex	1 (5.9)	0	0	1 (5.9)	0
Human herpesvirus 6 infection	1 (5.9)	0	0	1 (5.9)	0
Influenza	1 (5.9)	0	1 (5.9)	0	0
Klebsiella bacteraemia	1 (5.9)	0	1 (5.9)	0	0
Myringitis	1 (5.9)	1 (5.9)	0	0	0
Nail infection	1 (5.9)	1 (5.9)	0	0	0
Oral candidiasis	1 (5.9)	0	1 (5.9)	0	0
Pharyngitis streptococcal	1 (5.9)	0	0	1 (5.9)	0
Pneumonia fungal	1 (5.9)	0	0	1 (5.9)	0
Respiratory syncytial virus infection	1 (5.9)	0	0	1 (5.9)	0
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	0	0	1 (5.9)

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Viral upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (52.9)	2 (11.8)	6 (35.3)	1 (5.9)	0
Hypogammaglobulinaemia	6 (35.3)	1 (5.9)	5 (29.4)	0	0
B-cell aplasia	1 (5.9)	0	1 (5.9)	0	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)	0	0
Immunodeficiency	1 (5.9)	0	0	1 (5.9)	0
Serious neurological adverse reactions					
-Total	5 (29.4)	0	2 (11.8)	3 (17.6)	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	0	0	2 (11.8)	0
Lethargy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Somnolence	2 (11.8)	1 (5.9)	0	1 (5.9)	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	2 (11.8)	2 (11.8)	0	0	0
Affect lability	1 (5.9)	0	1 (5.9)	0	0
Amnesia	1 (5.9)	0	1 (5.9)	0	0
Aphasia	1 (5.9)	1 (5.9)	0	0	0
Cognitive disorder	1 (5.9)	0	0	1 (5.9)	0
Disturbance in attention	1 (5.9)	1 (5.9)	0	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Hallucination	1 (5.9)	1 (5.9)	0	0	0
Hallucination, visual	1 (5.9)	0	1 (5.9)	0	0
Irritability	1 (5.9)	1 (5.9)	0	0	0
Mental status changes	1 (5.9)	0	1 (5.9)	0	0
Sluggishness	1 (5.9)	0	1 (5.9)	0	0
Social avoidant behaviour	1 (5.9)	0	1 (5.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the

manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232b
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (98.2)	0	3 (5.5)	12 (21.8)	39 (70.9)
Cytokine Release Syndrome					
-Total	31 (56.4)	3 (5.5)	8 (14.5)	8 (14.5)	12 (21.8)
Cytokine release syndrome	31 (56.4)	3 (5.5)	9 (16.4)	8 (14.5)	11 (20.0)
Haemophagocytic lymphohistiocytosis	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Hematological disorders including cytopenias					
-Total	41 (74.5)	0	1 (1.8)	12 (21.8)	28 (50.9)
Anaemia	25 (45.5)	2 (3.6)	7 (12.7)	15 (27.3)	1 (1.8)
Febrile neutropenia	21 (38.2)	0	0	21 (38.2)	0
Neutrophil count decreased	17 (30.9)	2 (3.6)	0	2 (3.6)	13 (23.6)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	17 (30.9)	1 (1.8)	1 (1.8)	1 (1.8)	14 (25.5)
Platelet count decreased	15 (27.3)	2 (3.6)	1 (1.8)	4 (7.3)	8 (14.5)
Lymphocyte count decreased	12 (21.8)	1 (1.8)	0	4 (7.3)	7 (12.7)
Neutropenia	12 (21.8)	0	1 (1.8)	1 (1.8)	10 (18.2)
Thrombocytopenia	10 (18.2)	1 (1.8)	1 (1.8)	2 (3.6)	6 (10.9)
Leukopenia	5 (9.1)	0	0	0	5 (9.1)
Lymphopenia	2 (3.6)	0	0	0	2 (3.6)
Pancytopenia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Agranulocytosis	1 (1.8)	0	0	1 (1.8)	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Haemoglobin decreased	1 (1.8)	0	0	1 (1.8)	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Infections					
-Total	47 (85.5)	4 (7.3)	9 (16.4)	22 (40.0)	12 (21.8)
Upper respiratory tract infection	9 (16.4)	4 (7.3)	3 (5.5)	2 (3.6)	0
Conjunctivitis	7 (12.7)	3 (5.5)	4 (7.3)	0	0
Pneumonia	7 (12.7)	1 (1.8)	1 (1.8)	3 (5.5)	2 (3.6)

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	6 (10.9)	4 (7.3)	2 (3.6)	0	0
Oral herpes	5 (9.1)	1 (1.8)	2 (3.6)	2 (3.6)	0
Parainfluenzae virus infection	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Sinusitis	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Staphylococcal bacteraemia	4 (7.3)	0	0	4 (7.3)	0
Staphylococcal infection	4 (7.3)	0	2 (3.6)	1 (1.8)	1 (1.8)
Candida infection	3 (5.5)	0	3 (5.5)	0	0
Clostridium difficile infection	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Herpes zoster	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Influenza	3 (5.5)	0	2 (3.6)	0	1 (1.8)
Metapneumovirus infection	3 (5.5)	0	0	3 (5.5)	0
Otitis media	3 (5.5)	0	3 (5.5)	0	0
Paronychia	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Respiratory tract infection	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Sepsis	3 (5.5)	0	0	1 (1.8)	2 (3.6)
Staphylococcal sepsis	3 (5.5)	0	0	0	3 (5.5)
Acute sinusitis	2 (3.6)	0	2 (3.6)	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bk virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Catheter site infection	2 (3.6)	0	0	2 (3.6)	0
Covid-19	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Cytomegalovirus infection reactivation	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Device related infection	2 (3.6)	0	0	2 (3.6)	0
Ear infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	2 (3.6)	0	0	2 (3.6)	0
Gastroenteritis	2 (3.6)	2 (3.6)	0	0	0
Gingivitis	2 (3.6)	2 (3.6)	0	0	0
Klebsiella bacteraemia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Nail infection	2 (3.6)	2 (3.6)	0	0	0
Oral infection	2 (3.6)	0	2 (3.6)	0	0
Otitis externa	2 (3.6)	0	2 (3.6)	0	0
Pneumocystis jirovecii pneumonia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Pneumonia fungal	2 (3.6)	0	0	2 (3.6)	0
Respiratory syncytial virus infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Rhinitis	2 (3.6)	2 (3.6)	0	0	0
Skin infection	2 (3.6)	0	2 (3.6)	0	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Tinea pedis	2 (3.6)	2 (3.6)	0	0	0
Viral infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0
Anal abscess	1 (1.8)	0	0	1 (1.8)	0
Atypical pneumonia	1 (1.8)	1 (1.8)	0	0	0
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Cholecystitis infective	1 (1.8)	0	1 (1.8)	0	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Covid-19 pneumonia	1 (1.8)	0	0	0	1 (1.8)
Device related bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Epstein-barr virus infection reactivation	1 (1.8)	1 (1.8)	0	0	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Fungal infection	1 (1.8)	0	1 (1.8)	0	0
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0
Herpes virus infection	1 (1.8)	0	1 (1.8)	0	0
Human herpesvirus 6 infection	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Ophthalmic herpes zoster	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Peritonitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Streptococcal sepsis	1 (1.8)	0	1 (1.8)	0	0
Syphilis	1 (1.8)	0	1 (1.8)	0	0
Tonsillitis	1 (1.8)	0	1 (1.8)	0	0
Varicella zoster virus infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Viral skin infection	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	32 (58.2)	3 (5.5)	20 (36.4)	9 (16.4)	0
Hypogammaglobulinaemia	22 (40.0)	1 (1.8)	17 (30.9)	4 (7.3)	0
Blood immunoglobulin a decreased	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Blood immunoglobulin m decreased	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Immunodeficiency	3 (5.5)	0	0	3 (5.5)	0
Blood immunoglobulin g decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Immunoglobulins decreased	2 (3.6)	0	2 (3.6)	0	0
Selective igg subclass deficiency	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	20 (36.4)	9 (16.4)	4 (7.3)	7 (12.7)	0
Delirium	6 (10.9)	2 (3.6)	2 (3.6)	2 (3.6)	0
Encephalopathy	5 (9.1)	1 (1.8)	2 (3.6)	2 (3.6)	0
Agitation	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Confusional state	4 (7.3)	4 (7.3)	0	0	0
Cognitive disorder	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Dysarthria	2 (3.6)	0	1 (1.8)	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	2 (3.6)	2 (3.6)	0	0	0
Mental status changes	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Seizure	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Somnolence	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Depressed level of consciousness	1 (1.8)	0	0	1 (1.8)	0
Hallucination	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Memory impairment	1 (1.8)	0	1 (1.8)	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	1 (1.8)	0	0	0
Restlessness	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	5 (9.1)	0	0	4 (7.3)	1 (1.8)
Tumour lysis syndrome	5 (9.1)	0	0	4 (7.3)	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232b
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (100)	0	2 (4.7)	11 (25.6)	30 (69.8)
Cytokine Release Syndrome					
-Total	30 (69.8)	2 (4.7)	9 (20.9)	9 (20.9)	10 (23.3)
Cytokine release syndrome	30 (69.8)	2 (4.7)	9 (20.9)	9 (20.9)	10 (23.3)
Haemophagocytic lymphohistiocytosis	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Hematological disorders including cytopenias					
-Total	36 (83.7)	1 (2.3)	0	12 (27.9)	23 (53.5)
Febrile neutropenia	24 (55.8)	0	0	21 (48.8)	3 (7.0)
Anaemia	21 (48.8)	4 (9.3)	5 (11.6)	12 (27.9)	0
White blood cell count decreased	18 (41.9)	2 (4.7)	2 (4.7)	0	14 (32.6)

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	17 (39.5)	4 (9.3)	1 (2.3)	2 (4.7)	10 (23.3)
Neutrophil count decreased	14 (32.6)	0	2 (4.7)	1 (2.3)	11 (25.6)
Lymphocyte count decreased	12 (27.9)	0	1 (2.3)	5 (11.6)	6 (14.0)
Neutropenia	10 (23.3)	1 (2.3)	1 (2.3)	2 (4.7)	6 (14.0)
Thrombocytopenia	5 (11.6)	0	0	3 (7.0)	2 (4.7)
Pancytopenia	4 (9.3)	0	0	2 (4.7)	2 (4.7)
Leukopenia	1 (2.3)	0	0	1 (2.3)	0
Myelodysplastic syndrome	1 (2.3)	0	0	1 (2.3)	0
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0
Infections					
-Total	36 (83.7)	1 (2.3)	4 (9.3)	18 (41.9)	13 (30.2)
Bacteraemia	5 (11.6)	0	0	4 (9.3)	1 (2.3)
Gastroenteritis	5 (11.6)	2 (4.7)	1 (2.3)	2 (4.7)	0
Rhinovirus infection	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Sinusitis	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Upper respiratory tract infection	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Urinary tract infection	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Staphylococcal bacteraemia	4 (9.3)	0	0	4 (9.3)	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	3 (7.0)	0	3 (7.0)	0	0
Parainfluenzae virus infection	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Septic shock	3 (7.0)	0	0	0	3 (7.0)
Staphylococcal infection	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Acute sinusitis	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Bronchitis	2 (4.7)	0	2 (4.7)	0	0
Bronchopulmonary aspergillosis	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Conjunctivitis	2 (4.7)	0	2 (4.7)	0	0
Device related infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Device related sepsis	2 (4.7)	0	0	2 (4.7)	0
Encephalitis viral	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Fungal infection	2 (4.7)	0	2 (4.7)	0	0
Fungal skin infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Gastroenteritis viral	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Herpes zoster	2 (4.7)	0	0	2 (4.7)	0
Localised infection	2 (4.7)	2 (4.7)	0	0	0
Nail infection	2 (4.7)	1 (2.3)	1 (2.3)	0	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Oral herpes	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Otitis media	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Paronychia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Staphylococcal skin infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Adenovirus infection	1 (2.3)	0	0	1 (2.3)	0
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Bronchiolitis	1 (2.3)	0	0	1 (2.3)	0
Candida infection	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	1 (2.3)	0	0
Cellulitis	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile infection	1 (2.3)	0	0	1 (2.3)	0
Cystitis	1 (2.3)	0	1 (2.3)	0	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0
Ear, nose and throat infection	1 (2.3)	0	1 (2.3)	0	0
Encephalitis	1 (2.3)	0	0	0	1 (2.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterobacter infection	1 (2.3)	0	0	1 (2.3)	0
Epstein-barr virus infection	1 (2.3)	0	1 (2.3)	0	0
Escherichia bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Fungal sepsis	1 (2.3)	0	0	0	1 (2.3)
Gastroenteritis adenovirus	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Granulicatella infection	1 (2.3)	0	0	1 (2.3)	0
Haemophilus bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Herpes simplex	1 (2.3)	0	0	1 (2.3)	0
Human herpesvirus 6 infection	1 (2.3)	0	0	1 (2.3)	0
Klebsiella infection	1 (2.3)	0	0	1 (2.3)	0
Mastoiditis	1 (2.3)	0	0	1 (2.3)	0
Meningitis bacterial	1 (2.3)	0	0	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Myringitis	1 (2.3)	1 (2.3)	0	0	0
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis externa	1 (2.3)	0	0	1 (2.3)	0
Pharyngitis streptococcal	1 (2.3)	0	0	1 (2.3)	0
Pneumonia fungal	1 (2.3)	0	0	0	1 (2.3)
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0
Pneumonia viral	1 (2.3)	0	0	1 (2.3)	0
Post herpetic neuralgia	1 (2.3)	0	0	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection viral	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	0	1 (2.3)	0	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Sialoadenitis	1 (2.3)	0	0	1 (2.3)	0
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Stomatococcal infection	1 (2.3)	0	0	0	1 (2.3)
Systemic candida	1 (2.3)	0	0	1 (2.3)	0
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection pseudomonal	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection viral	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (2.3)	0	1 (2.3)	0	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Vulval cellulitis	1 (2.3)	0	0	1 (2.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	23 (53.5)	2 (4.7)	15 (34.9)	6 (14.0)	0
Hypogammaglobulinaemia	19 (44.2)	1 (2.3)	13 (30.2)	5 (11.6)	0
Blood immunoglobulin m decreased	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Blood immunoglobulin a decreased	3 (7.0)	3 (7.0)	0	0	0
Blood immunoglobulin g decreased	2 (4.7)	0	2 (4.7)	0	0
B-cell aplasia	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency	1 (2.3)	0	0	1 (2.3)	0
Serious neurological adverse reactions					
-Total	21 (48.8)	4 (9.3)	7 (16.3)	10 (23.3)	0
Tremor	6 (14.0)	5 (11.6)	1 (2.3)	0	0
Mental status changes	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Encephalopathy	4 (9.3)	0	1 (2.3)	3 (7.0)	0
Seizure	4 (9.3)	0	2 (4.7)	2 (4.7)	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Agitation	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Confusional state	3 (7.0)	3 (7.0)	0	0	0
Irritability	3 (7.0)	2 (4.7)	0	1 (2.3)	0
Cognitive disorder	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Delirium	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hallucination	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Lethargy	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Affect lability	1 (2.3)	0	1 (2.3)	0	0
Amnesia	1 (2.3)	0	1 (2.3)	0	0
Aphasia	1 (2.3)	1 (2.3)	0	0	0
Disturbance in attention	1 (2.3)	1 (2.3)	0	0	0
Dysphagia	1 (2.3)	0	0	1 (2.3)	0
Generalised tonic-clonic seizure	1 (2.3)	0	1 (2.3)	0	0
Hallucination, visual	1 (2.3)	0	1 (2.3)	0	0
Muscular weakness	1 (2.3)	0	0	1 (2.3)	0
Posterior reversible encephalopathy syndrome	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sluggishness	1 (2.3)	0	1 (2.3)	0	0
Social avoidant behaviour	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Tumour lysis syndrome	2 (4.7)	0	0	1 (2.3)	1 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (98.6)	0	3 (4.3)	18 (25.7)	48 (68.6)
Cytokine Release Syndrome					
-Total	43 (61.4)	3 (4.3)	14 (20.0)	14 (20.0)	12 (17.1)
Cytokine release syndrome	43 (61.4)	3 (4.3)	14 (20.0)	14 (20.0)	12 (17.1)
Haemophagocytic lymphohistiocytosis	5 (7.1)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Hematological disorders including cytopenias					
-Total	55 (78.6)	1 (1.4)	1 (1.4)	19 (27.1)	34 (48.6)
Anaemia	34 (48.6)	5 (7.1)	10 (14.3)	18 (25.7)	1 (1.4)
Febrile neutropenia	30 (42.9)	0	0	29 (41.4)	1 (1.4)
Platelet count decreased	24 (34.3)	5 (7.1)	2 (2.9)	4 (5.7)	13 (18.6)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	24 (34.3)	3 (4.3)	3 (4.3)	1 (1.4)	17 (24.3)
Neutrophil count decreased	23 (32.9)	2 (2.9)	2 (2.9)	3 (4.3)	16 (22.9)
Lymphocyte count decreased	19 (27.1)	1 (1.4)	1 (1.4)	8 (11.4)	9 (12.9)
Neutropenia	15 (21.4)	1 (1.4)	2 (2.9)	3 (4.3)	9 (12.9)
Thrombocytopenia	10 (14.3)	1 (1.4)	1 (1.4)	3 (4.3)	5 (7.1)
Pancytopenia	6 (8.6)	0	1 (1.4)	3 (4.3)	2 (2.9)
Leukopenia	4 (5.7)	0	0	1 (1.4)	3 (4.3)
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	60 (85.7)	2 (2.9)	9 (12.9)	30 (42.9)	19 (27.1)
Upper respiratory tract infection	10 (14.3)	4 (5.7)	5 (7.1)	1 (1.4)	0
Conjunctivitis	8 (11.4)	3 (4.3)	5 (7.1)	0	0
Sinusitis	8 (11.4)	0	5 (7.1)	3 (4.3)	0
Pneumonia	7 (10.0)	1 (1.4)	2 (2.9)	3 (4.3)	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	7 (10.0)	0	6 (8.6)	1 (1.4)	0
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Gastroenteritis	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Nasopharyngitis	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Oral herpes	5 (7.1)	1 (1.4)	3 (4.3)	1 (1.4)	0
Parainfluenzae virus infection	5 (7.1)	1 (1.4)	0	3 (4.3)	1 (1.4)
Paronychia	5 (7.1)	1 (1.4)	3 (4.3)	1 (1.4)	0
Staphylococcal bacteraemia	5 (7.1)	0	0	5 (7.1)	0
Acute sinusitis	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Bacteraemia	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Candida infection	4 (5.7)	0	3 (4.3)	0	1 (1.4)
Clostridium difficile infection	4 (5.7)	1 (1.4)	0	3 (4.3)	0
Device related infection	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Herpes zoster	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Sepsis	4 (5.7)	0	0	1 (1.4)	3 (4.3)
Urinary tract infection	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Bronchitis	3 (4.3)	0	3 (4.3)	0	0
Fungal infection	3 (4.3)	0	3 (4.3)	0	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gingivitis	3 (4.3)	3 (4.3)	0	0	0
Localised infection	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Nail infection	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0
Respiratory tract infection	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Rhinitis	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Staphylococcal sepsis	3 (4.3)	0	0	0	3 (4.3)
Bronchiolitis	2 (2.9)	0	0	2 (2.9)	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Cellulitis	2 (2.9)	0	2 (2.9)	0	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Device related sepsis	2 (2.9)	0	0	2 (2.9)	0
Ear infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Encephalitis	2 (2.9)	0	0	0	2 (2.9)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Influenza	2 (2.9)	0	2 (2.9)	0	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Otitis media	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.9)	0	0	2 (2.9)	0
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Sialoadenitis	2 (2.9)	0	0	2 (2.9)	0
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Staphylococcal skin infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Pseudomonal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Tonsillitis	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral infection	1 (1.4)	0	1 (1.4)	0	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Vulval cellulitis	1 (1.4)	0	0	1 (1.4)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	42 (60.0)	3 (4.3)	25 (35.7)	14 (20.0)	0
Hypogammaglobulinaemia	31 (44.3)	1 (1.4)	21 (30.0)	9 (12.9)	0
Blood immunoglobulin a decreased	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.6)	3 (4.3)	1 (1.4)	2 (2.9)	0
Blood immunoglobulin g decreased	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Immunodeficiency	3 (4.3)	0	0	3 (4.3)	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	31 (44.3)	11 (15.7)	6 (8.6)	14 (20.0)	0
Encephalopathy	9 (12.9)	1 (1.4)	3 (4.3)	5 (7.1)	0
Delirium	7 (10.0)	2 (2.9)	2 (2.9)	3 (4.3)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	6 (8.6)	3 (4.3)	3 (4.3)	0	0
Mental status changes	6 (8.6)	1 (1.4)	2 (2.9)	3 (4.3)	0
Somnolence	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Confusional state	5 (7.1)	5 (7.1)	0	0	0
Tremor	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Irritability	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Seizure	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Dysarthria	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Muscular weakness	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.7)	0	0	2 (2.9)	2 (2.9)
Tumour lysis syndrome	4 (5.7)	0	0	2 (2.9)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	2 (13.3)	5 (33.3)	8 (53.3)
Cytokine Release Syndrome					
-Total	8 (53.3)	1 (6.7)	2 (13.3)	2 (13.3)	3 (20.0)
Cytokine release syndrome	8 (53.3)	1 (6.7)	2 (13.3)	2 (13.3)	3 (20.0)
Hematological disorders including cytopenias					
-Total	9 (60.0)	0	0	2 (13.3)	7 (46.7)
Febrile neutropenia	4 (26.7)	0	0	4 (26.7)	0
Neutropenia	4 (26.7)	0	0	0	4 (26.7)
White blood cell count decreased	4 (26.7)	0	0	0	4 (26.7)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Thrombocytopenia	3 (20.0)	0	0	0	3 (20.0)

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (13.3)	0	0	0	2 (13.3)
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Eosinophil count decreased	1 (6.7)	1 (6.7)	0	0	0
Haematocrit decreased	1 (6.7)	1 (6.7)	0	0	0
Lymphopenia	1 (6.7)	0	0	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	1 (6.7)	0
Red blood cell count decreased	1 (6.7)	1 (6.7)	0	0	0
Infections					
-Total	13 (86.7)	3 (20.0)	2 (13.3)	6 (40.0)	2 (13.3)
Bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Bk virus infection	1 (6.7)	1 (6.7)	0	0	0
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Catheter site infection	1 (6.7)	0	1 (6.7)	0	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Encephalitis viral	1 (6.7)	0	0	0	1 (6.7)
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Escherichia bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Fungal skin infection	1 (6.7)	0	1 (6.7)	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Meningitis bacterial	1 (6.7)	0	0	1 (6.7)	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Otitis externa	1 (6.7)	0	1 (6.7)	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia	1 (6.7)	0	0	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Tinea pedis	1 (6.7)	1 (6.7)	0	0	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Urinary tract infection viral	1 (6.7)	1 (6.7)	0	0	0
Varicella zoster virus infection	1 (6.7)	0	1 (6.7)	0	0
Viral infection	1 (6.7)	0	0	1 (6.7)	0

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (33.3)	0	5 (33.3)	0	0
Hypogammaglobulinaemia	5 (33.3)	0	5 (33.3)	0	0
Serious neurological adverse reactions					
-Total	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Seizure	2 (13.3)	0	2 (13.3)	0	0
Delirium	1 (6.7)	0	1 (6.7)	0	0
Muscular weakness	1 (6.7)	0	0	1 (6.7)	0
Posterior reversible encephalopathy syndrome	1 (6.7)	0	1 (6.7)	0	0
Tumour Lysis Syndrome					
-Total	2 (13.3)	0	0	2 (13.3)	0
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232c
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	0	0	13 (100)
Cytokine Release Syndrome					
-Total	10 (76.9)	1 (7.7)	1 (7.7)	1 (7.7)	7 (53.8)
Cytokine release syndrome	10 (76.9)	1 (7.7)	2 (15.4)	1 (7.7)	6 (46.2)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Hematological disorders including cytopenias					
-Total	13 (100)	0	0	3 (23.1)	10 (76.9)
Febrile neutropenia	11 (84.6)	0	0	9 (69.2)	2 (15.4)
Anaemia	9 (69.2)	1 (7.7)	2 (15.4)	6 (46.2)	0
Platelet count decreased	7 (53.8)	1 (7.7)	0	1 (7.7)	5 (38.5)

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	7 (53.8)	0	0	0	7 (53.8)
Neutrophil count decreased	6 (46.2)	0	0	0	6 (46.2)
Lymphocyte count decreased	5 (38.5)	0	0	1 (7.7)	4 (30.8)
Neutropenia	3 (23.1)	0	0	0	3 (23.1)
Thrombocytopenia	2 (15.4)	0	0	2 (15.4)	0
Infections					
-Total	10 (76.9)	0	2 (15.4)	4 (30.8)	4 (30.8)
Upper respiratory tract infection	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Nasopharyngitis	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Otitis media	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Parainfluenzae virus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Pneumonia	2 (15.4)	0	0	0	2 (15.4)
Rhinovirus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Staphylococcal bacteraemia	2 (15.4)	0	0	2 (15.4)	0
Adenovirus infection	1 (7.7)	0	0	1 (7.7)	0
Bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Covid-19	1 (7.7)	1 (7.7)	0	0	0

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Ear infection	1 (7.7)	0	1 (7.7)	0	0
Encephalitis viral	1 (7.7)	0	0	1 (7.7)	0
Enterobacter infection	1 (7.7)	0	0	1 (7.7)	0
Enterovirus infection	1 (7.7)	0	0	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Fungaemia	1 (7.7)	0	0	0	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Herpes zoster	1 (7.7)	0	0	1 (7.7)	0
Influenza	1 (7.7)	0	0	0	1 (7.7)
Klebsiella infection	1 (7.7)	0	0	1 (7.7)	0
Mastoiditis	1 (7.7)	0	0	1 (7.7)	0
Nail infection	1 (7.7)	1 (7.7)	0	0	0
Oral herpes	1 (7.7)	0	0	1 (7.7)	0
Otitis externa	1 (7.7)	0	0	1 (7.7)	0
Pharyngitis streptococcal	1 (7.7)	0	0	1 (7.7)	0
Respiratory syncytial virus infection	1 (7.7)	0	0	1 (7.7)	0
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Syphilis	1 (7.7)	0	1 (7.7)	0	0
Urinary tract infection	1 (7.7)	0	0	1 (7.7)	0
Viral upper respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	8 (61.5)	2 (15.4)	5 (38.5)	1 (7.7)	0
Hypogammaglobulinaemia	5 (38.5)	1 (7.7)	4 (30.8)	0	0
Blood immunoglobulin a decreased	1 (7.7)	1 (7.7)	0	0	0
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)	0	0
Blood immunoglobulin m decreased	1 (7.7)	1 (7.7)	0	0	0
Immunodeficiency	1 (7.7)	0	0	1 (7.7)	0
Serious neurological adverse reactions					
-Total	7 (53.8)	2 (15.4)	3 (23.1)	2 (15.4)	0
Cognitive disorder	3 (23.1)	0	2 (15.4)	1 (7.7)	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Amnesia	1 (7.7)	0	1 (7.7)	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hallucination, visual	1 (7.7)	0	1 (7.7)	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Mental status changes	1 (7.7)	0	0	1 (7.7)	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (7.7)	0	0	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232d
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	1 (5.6)	16 (88.9)
Cytokine Release Syndrome					
-Total	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Cytokine release syndrome	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Haemophagocytic lymphohistiocytosis	1 (5.6)	0	0	1 (5.6)	0
Hematological disorders including cytopenias					
-Total	14 (77.8)	0	0	5 (27.8)	9 (50.0)
Febrile neutropenia	11 (61.1)	0	0	9 (50.0)	2 (11.1)
Anaemia	7 (38.9)	0	1 (5.6)	5 (27.8)	1 (5.6)
Platelet count decreased	6 (33.3)	0	0	0	6 (33.3)

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (27.8)	0	0	0	5 (27.8)
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Thrombocytopenia	3 (16.7)	0	0	3 (16.7)	0
Lymphocyte count decreased	2 (11.1)	0	0	0	2 (11.1)
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Infections					
-Total	16 (88.9)	0	3 (16.7)	9 (50.0)	4 (22.2)
Upper respiratory tract infection	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Bacteraemia	4 (22.2)	0	1 (5.6)	2 (11.1)	1 (5.6)
Adenovirus infection	2 (11.1)	0	0	2 (11.1)	0
Conjunctivitis	2 (11.1)	2 (11.1)	0	0	0
Escherichia bacteraemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Urinary tract infection	2 (11.1)	0	0	2 (11.1)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Atypical pneumonia	1 (5.6)	1 (5.6)	0	0	0
Bk virus infection	1 (5.6)	0	0	1 (5.6)	0
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Candida infection	1 (5.6)	0	1 (5.6)	0	0
Covid-19	1 (5.6)	1 (5.6)	0	0	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Encephalitis viral	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis clostridial	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis norovirus	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Herpes simplex	1 (5.6)	0	1 (5.6)	0	0
Klebsiella bacteraemia	1 (5.6)	0	1 (5.6)	0	0
Localised infection	1 (5.6)	1 (5.6)	0	0	0
Metapneumovirus infection	1 (5.6)	0	0	1 (5.6)	0
Otitis media	1 (5.6)	0	1 (5.6)	0	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis streptococcal	1 (5.6)	0	0	1 (5.6)	0
Pneumocystis jirovecii pneumonia	1 (5.6)	0	0	1 (5.6)	0
Pneumonia fungal	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Septic shock	1 (5.6)	0	0	0	1 (5.6)
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Sinusitis fungal	1 (5.6)	0	0	1 (5.6)	0
Skin infection	1 (5.6)	0	1 (5.6)	0	0
Staphylococcal infection	1 (5.6)	0	1 (5.6)	0	0
Syphilis	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (55.6)	1 (5.6)	8 (44.4)	1 (5.6)	0
Hypogammaglobulinaemia	8 (44.4)	1 (5.6)	6 (33.3)	1 (5.6)	0
Blood immunoglobulin g decreased	1 (5.6)	0	1 (5.6)	0	0
Selective igg subclass deficiency	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	8 (44.4)	0	5 (27.8)	3 (16.7)	0
Cognitive disorder	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Mental status changes	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Somnolence	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Agitation	1 (5.6)	0	1 (5.6)	0	0
Amnesia	1 (5.6)	0	1 (5.6)	0	0
Delirium	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Hallucination, visual	1 (5.6)	0	1 (5.6)	0	0
Lethargy	1 (5.6)	1 (5.6)	0	0	0
Tremor	1 (5.6)	1 (5.6)	0	0	0
Tumour Lysis Syndrome					
-Total	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Tumour lysis syndrome	3 (16.7)	0	0	2 (11.1)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232d
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (98.8)	0	4 (5.0)	22 (27.5)	53 (66.3)
Cytokine Release Syndrome					
-Total	48 (60.0)	5 (6.3)	13 (16.3)	16 (20.0)	14 (17.5)
Cytokine release syndrome	48 (60.0)	5 (6.3)	14 (17.5)	16 (20.0)	13 (16.3)
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	1 (1.3)	2 (2.5)
Hematological disorders including cytopenias					
-Total	63 (78.8)	1 (1.3)	1 (1.3)	19 (23.8)	42 (52.5)
Anaemia	39 (48.8)	6 (7.5)	11 (13.8)	22 (27.5)	0
Febrile neutropenia	34 (42.5)	0	0	33 (41.3)	1 (1.3)
White blood cell count decreased	30 (37.5)	3 (3.8)	3 (3.8)	1 (1.3)	23 (28.8)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	27 (33.8)	2 (2.5)	2 (2.5)	3 (3.8)	20 (25.0)
Platelet count decreased	26 (32.5)	6 (7.5)	2 (2.5)	6 (7.5)	12 (15.0)
Lymphocyte count decreased	22 (27.5)	1 (1.3)	1 (1.3)	9 (11.3)	11 (13.8)
Neutropenia	21 (26.3)	1 (1.3)	2 (2.5)	3 (3.8)	15 (18.8)
Thrombocytopenia	12 (15.0)	1 (1.3)	1 (1.3)	2 (2.5)	8 (10.0)
Leukopenia	6 (7.5)	0	0	1 (1.3)	5 (6.3)
Pancytopenia	6 (7.5)	0	1 (1.3)	3 (3.8)	2 (2.5)
Lymphopenia	2 (2.5)	0	0	0	2 (2.5)
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
Eosinophil count decreased	1 (1.3)	1 (1.3)	0	0	0
Haematocrit decreased	1 (1.3)	1 (1.3)	0	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Red blood cell count decreased	1 (1.3)	1 (1.3)	0	0	0
Infections					
-Total	67 (83.8)	5 (6.3)	10 (12.5)	31 (38.8)	21 (26.3)
Pneumonia	10 (12.5)	1 (1.3)	2 (2.5)	4 (5.0)	3 (3.8)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	9 (11.3)	5 (6.3)	2 (2.5)	2 (2.5)	0
Nasopharyngitis	8 (10.0)	5 (6.3)	3 (3.8)	0	0
Rhinovirus infection	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Sinusitis	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Conjunctivitis	7 (8.8)	1 (1.3)	6 (7.5)	0	0
Parainfluenzae virus infection	6 (7.5)	1 (1.3)	0	4 (5.0)	1 (1.3)
Staphylococcal bacteraemia	6 (7.5)	0	0	6 (7.5)	0
Staphylococcal infection	6 (7.5)	0	2 (2.5)	3 (3.8)	1 (1.3)
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Herpes zoster	5 (6.3)	0	1 (1.3)	4 (5.0)	0
Oral herpes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Paronychia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Clostridium difficile infection	4 (5.0)	1 (1.3)	0	3 (3.8)	0
Device related infection	4 (5.0)	0	1 (1.3)	3 (3.8)	0
Nail infection	4 (5.0)	3 (3.8)	1 (1.3)	0	0
Otitis media	4 (5.0)	0	3 (3.8)	1 (1.3)	0
Respiratory tract infection	4 (5.0)	0	2 (2.5)	2 (2.5)	0
Sepsis	4 (5.0)	0	0	1 (1.3)	3 (3.8)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute sinusitis	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Bronchopulmonary aspergillosis	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Catheter site infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Fungal infection	3 (3.8)	0	3 (3.8)	0	0
Gingivitis	3 (3.8)	3 (3.8)	0	0	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Staphylococcal sepsis	3 (3.8)	0	0	0	3 (3.8)
Urinary tract infection	3 (3.8)	0	3 (3.8)	0	0
Bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Bronchiolitis	2 (2.5)	0	0	2 (2.5)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0
Cellulitis	2 (2.5)	0	2 (2.5)	0	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytomegalovirus infection reactivation	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Device related sepsis	2 (2.5)	0	0	2 (2.5)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Fungal skin infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Localised infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Metapneumovirus infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Pneumonia fungal	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0
Skin infection	2 (2.5)	0	2 (2.5)	0	0
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Staphylococcal skin infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Tinea pedis	2 (2.5)	2 (2.5)	0	0	0
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0
Device related bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Encephalitis viral	1 (1.3)	0	0	0	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Epstein-barr virus infection	1 (1.3)	0	1 (1.3)	0	0
Epstein-barr virus infection reactivation	1 (1.3)	1 (1.3)	0	0	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Fungal pharyngitis	1 (1.3)	0	0	1 (1.3)	0
Fungal sepsis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis adenovirus	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Haemophilus bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Peritonitis	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Post herpetic neuralgia	1 (1.3)	0	0	1 (1.3)	0
Pseudomonal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	0	0	1 (1.3)
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0
Tonsillitis	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	45 (56.3)	4 (5.0)	27 (33.8)	14 (17.5)	0
Hypogammaglobulinaemia	33 (41.3)	1 (1.3)	24 (30.0)	8 (10.0)	0
Blood immunoglobulin a decreased	7 (8.8)	5 (6.3)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (8.8)	4 (5.0)	1 (1.3)	2 (2.5)	0
Immunodeficiency	4 (5.0)	0	0	4 (5.0)	0
Blood immunoglobulin g decreased	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serious neurological adverse reactions					
-Total	33 (41.3)	13 (16.3)	6 (7.5)	14 (17.5)	0
Encephalopathy	8 (10.0)	1 (1.3)	3 (3.8)	4 (5.0)	0
Confusional state	7 (8.8)	7 (8.8)	0	0	0
Delirium	7 (8.8)	2 (2.5)	3 (3.8)	2 (2.5)	0
Agitation	6 (7.5)	4 (5.0)	2 (2.5)	0	0
Seizure	6 (7.5)	0	3 (3.8)	3 (3.8)	0
Tremor	5 (6.3)	4 (5.0)	1 (1.3)	0	0
Irritability	4 (5.0)	3 (3.8)	0	1 (1.3)	0
Mental status changes	4 (5.0)	1 (1.3)	0	3 (3.8)	0
Somnolence	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cognitive disorder	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	4 (5.0)	0	0	3 (3.8)	1 (1.3)
Tumour lysis syndrome	4 (5.0)	0	0	3 (3.8)	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232e
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	1 (12.5)	2 (25.0)	5 (62.5)
Cytokine Release Syndrome					
-Total	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Hematological disorders including cytopenias					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Anaemia	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Febrile neutropenia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Infections					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (62.5)	0	4 (50.0)	1 (12.5)	0
Hypogammaglobulinaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Serious neurological adverse reactions					
-Total	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Tremor	1 (12.5)	1 (12.5)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232e
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	89 (98.9)	0	4 (4.4)	21 (23.3)	64 (71.1)
Cytokine Release Syndrome					
-Total	56 (62.2)	4 (4.4)	15 (16.7)	17 (18.9)	20 (22.2)
Cytokine release syndrome	56 (62.2)	4 (4.4)	16 (17.8)	17 (18.9)	19 (21.1)
Haemophagocytic lymphohistiocytosis	5 (5.6)	1 (1.1)	1 (1.1)	2 (2.2)	1 (1.1)
Hematological disorders including cytopenias					
-Total	71 (78.9)	1 (1.1)	1 (1.1)	21 (23.3)	48 (53.3)
Anaemia	42 (46.7)	5 (5.6)	11 (12.2)	25 (27.8)	1 (1.1)
Febrile neutropenia	41 (45.6)	0	0	39 (43.3)	2 (2.2)
White blood cell count decreased	32 (35.6)	2 (2.2)	2 (2.2)	1 (1.1)	27 (30.0)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	31 (34.4)	6 (6.7)	2 (2.2)	6 (6.7)	17 (18.9)
Neutrophil count decreased	28 (31.1)	2 (2.2)	2 (2.2)	2 (2.2)	22 (24.4)
Lymphocyte count decreased	22 (24.4)	0	1 (1.1)	8 (8.9)	13 (14.4)
Neutropenia	22 (24.4)	1 (1.1)	2 (2.2)	3 (3.3)	16 (17.8)
Thrombocytopenia	14 (15.6)	1 (1.1)	1 (1.1)	5 (5.6)	7 (7.8)
Leukopenia	6 (6.7)	0	0	1 (1.1)	5 (5.6)
Pancytopenia	6 (6.7)	0	1 (1.1)	3 (3.3)	2 (2.2)
Lymphopenia	2 (2.2)	0	0	0	2 (2.2)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	77 (85.6)	5 (5.6)	13 (14.4)	37 (41.1)	22 (24.4)
Upper respiratory tract infection	13 (14.4)	5 (5.6)	5 (5.6)	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	9 (10.0)	1 (1.1)	2 (2.2)	3 (3.3)	3 (3.3)
Conjunctivitis	8 (8.9)	3 (3.3)	5 (5.6)	0	0
Nasopharyngitis	8 (8.9)	5 (5.6)	3 (3.3)	0	0
Rhinovirus infection	8 (8.9)	0	6 (6.7)	2 (2.2)	0
Sinusitis	8 (8.9)	0	5 (5.6)	3 (3.3)	0
Oral herpes	7 (7.8)	1 (1.1)	3 (3.3)	3 (3.3)	0
Parainfluenzae virus infection	7 (7.8)	1 (1.1)	1 (1.1)	4 (4.4)	1 (1.1)
Staphylococcal bacteraemia	7 (7.8)	0	0	7 (7.8)	0
Bacteraemia	6 (6.7)	0	1 (1.1)	4 (4.4)	1 (1.1)
Gastroenteritis	6 (6.7)	3 (3.3)	1 (1.1)	2 (2.2)	0
Staphylococcal infection	6 (6.7)	0	3 (3.3)	3 (3.3)	0
Herpes zoster	5 (5.6)	0	1 (1.1)	4 (4.4)	0
Otitis media	5 (5.6)	0	4 (4.4)	1 (1.1)	0
Paronychia	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Urinary tract infection	5 (5.6)	0	3 (3.3)	2 (2.2)	0
Acute sinusitis	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Candida infection	4 (4.4)	0	3 (3.3)	0	1 (1.1)
Clostridium difficile infection	4 (4.4)	1 (1.1)	0	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Nail infection	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Respiratory tract infection	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Bronchitis	3 (3.3)	0	3 (3.3)	0	0
Bronchopulmonary aspergillosis	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Ear infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Escherichia bacteraemia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Fungal infection	3 (3.3)	0	3 (3.3)	0	0
Gingivitis	3 (3.3)	3 (3.3)	0	0	0
Influenza	3 (3.3)	0	2 (2.2)	0	1 (1.1)
Metapneumovirus infection	3 (3.3)	0	0	3 (3.3)	0
Oral candidiasis	3 (3.3)	0	3 (3.3)	0	0
Pneumonia fungal	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Respiratory syncytial virus infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Rhinitis	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Septic shock	3 (3.3)	0	0	0	3 (3.3)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	3 (3.3)	0	3 (3.3)	0	0
Staphylococcal sepsis	3 (3.3)	0	0	0	3 (3.3)
Adenovirus infection	2 (2.2)	0	0	2 (2.2)	0
Bk virus infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.2)	0	0	2 (2.2)	0
Cellulitis	2 (2.2)	0	2 (2.2)	0	0
Covid-19	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Device related sepsis	2 (2.2)	0	0	2 (2.2)	0
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fungal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Herpes simplex	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.2)	0	0	2 (2.2)	0
Klebsiella bacteraemia	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Oral infection	2 (2.2)	0	2 (2.2)	0	0
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Staphylococcal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.2)	2 (2.2)	0	0	0
Varicella zoster virus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	1 (1.1)	0	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	50 (55.6)	5 (5.6)	31 (34.4)	14 (15.6)	0
Hypogammaglobulinaemia	37 (41.1)	2 (2.2)	27 (30.0)	8 (8.9)	0
Blood immunoglobulin a decreased	7 (7.8)	5 (5.6)	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (6.7)	4 (4.4)	0	2 (2.2)	0
Immunodeficiency	4 (4.4)	0	0	4 (4.4)	0
Blood immunoglobulin g decreased	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Immunoglobulins decreased	2 (2.2)	0	2 (2.2)	0	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	37 (41.1)	12 (13.3)	10 (11.1)	15 (16.7)	0
Delirium	8 (8.9)	2 (2.2)	3 (3.3)	3 (3.3)	0
Encephalopathy	8 (8.9)	1 (1.1)	3 (3.3)	4 (4.4)	0
Agitation	7 (7.8)	4 (4.4)	3 (3.3)	0	0
Mental status changes	7 (7.8)	1 (1.1)	2 (2.2)	4 (4.4)	0
Confusional state	6 (6.7)	6 (6.7)	0	0	0
Seizure	6 (6.7)	0	3 (3.3)	3 (3.3)	0
Tremor	5 (5.6)	4 (4.4)	1 (1.1)	0	0
Lethargy	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Somnolence	4 (4.4)	1 (1.1)	1 (1.1)	2 (2.2)	0
Cognitive disorder	3 (3.3)	0	2 (2.2)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Irritability	3 (3.3)	3 (3.3)	0	0	0
Dysarthria	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	7 (7.8)	0	0	5 (5.6)	2 (2.2)
Tumour lysis syndrome	7 (7.8)	0	0	5 (5.6)	2 (2.2)

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232f
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Fungal infection	1 (50.0)	0	1 (50.0)	0	0
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Tonsillitis	1 (50.0)	0	1 (50.0)	0	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Hypogammaglobulinaemia	2 (100)	0	1 (50.0)	1 (50.0)	0
Serious neurological adverse reactions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Tumour Lysis Syndrome					
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232f
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	95 (99.0)	0	5 (5.2)	23 (24.0)	67 (69.8)
Cytokine Release Syndrome					
-Total	59 (61.5)	5 (5.2)	17 (17.7)	16 (16.7)	21 (21.9)
Cytokine release syndrome	59 (61.5)	5 (5.2)	18 (18.8)	16 (16.7)	20 (20.8)
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)
Hematological disorders including cytopenias					
-Total	75 (78.1)	1 (1.0)	1 (1.0)	23 (24.0)	50 (52.1)
Anaemia	46 (47.9)	6 (6.3)	12 (12.5)	27 (28.1)	1 (1.0)
Febrile neutropenia	44 (45.8)	0	0	41 (42.7)	3 (3.1)
White blood cell count decreased	35 (36.5)	3 (3.1)	3 (3.1)	1 (1.0)	28 (29.2)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	32 (33.3)	6 (6.3)	2 (2.1)	6 (6.3)	18 (18.8)
Neutrophil count decreased	31 (32.3)	2 (2.1)	2 (2.1)	3 (3.1)	24 (25.0)
Lymphocyte count decreased	24 (25.0)	1 (1.0)	1 (1.0)	9 (9.4)	13 (13.5)
Neutropenia	21 (21.9)	1 (1.0)	2 (2.1)	3 (3.1)	15 (15.6)
Thrombocytopenia	15 (15.6)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.3)
Leukopenia	6 (6.3)	0	0	1 (1.0)	5 (5.2)
Pancytopenia	5 (5.2)	0	1 (1.0)	2 (2.1)	2 (2.1)
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	81 (84.4)	5 (5.2)	13 (13.5)	39 (40.6)	24 (25.0)
Upper respiratory tract infection	13 (13.5)	5 (5.2)	6 (6.3)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Conjunctivitis	9 (9.4)	3 (3.1)	6 (6.3)	0	0
Rhinovirus infection	9 (9.4)	0	7 (7.3)	2 (2.1)	0
Sinusitis	9 (9.4)	0	6 (6.3)	3 (3.1)	0
Nasopharyngitis	8 (8.3)	5 (5.2)	3 (3.1)	0	0
Staphylococcal bacteraemia	8 (8.3)	0	0	8 (8.3)	0
Gastroenteritis	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Oral herpes	7 (7.3)	1 (1.0)	3 (3.1)	3 (3.1)	0
Parainfluenzae virus infection	7 (7.3)	1 (1.0)	1 (1.0)	4 (4.2)	1 (1.0)
Staphylococcal infection	7 (7.3)	0	3 (3.1)	3 (3.1)	1 (1.0)
Bacteraemia	6 (6.3)	0	1 (1.0)	4 (4.2)	1 (1.0)
Herpes zoster	5 (5.2)	0	1 (1.0)	4 (4.2)	0
Otitis media	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Urinary tract infection	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Acute sinusitis	4 (4.2)	0	3 (3.1)	1 (1.0)	0
Candida infection	4 (4.2)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.2)	1 (1.0)	0	3 (3.1)	0
Device related infection	4 (4.2)	0	1 (1.0)	3 (3.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Paronychia	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Respiratory tract infection	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Pneumonia fungal	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Sepsis	3 (3.1)	0	0	0	3 (3.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Cellulitis	2 (2.1)	0	2 (2.1)	0	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Fungal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory syncytial virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.0)	0	0	0	1 (1.0)
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	53 (55.2)	5 (5.2)	34 (35.4)	14 (14.6)	0
Hypogammaglobulinaemia	39 (40.6)	2 (2.1)	29 (30.2)	8 (8.3)	0
Blood immunoglobulin a decreased	7 (7.3)	5 (5.2)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Blood immunoglobulin g decreased	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	39 (40.6)	13 (13.5)	10 (10.4)	16 (16.7)	0
Encephalopathy	9 (9.4)	1 (1.0)	3 (3.1)	5 (5.2)	0
Delirium	8 (8.3)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.3)	4 (4.2)	3 (3.1)	0	0
Confusional state	7 (7.3)	7 (7.3)	0	0	0
Mental status changes	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.3)	5 (5.2)	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Irritability	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Lethargy	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Cognitive disorder	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Dysarthria	1 (1.0)	0	0	1 (1.0)	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	6 (6.3)	0	0	4 (4.2)	2 (2.1)
Tumour lysis syndrome	6 (6.3)	0	0	4 (4.2)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232g
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Hematological disorders including cytopenias					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (100)	0	1 (100)	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Serious neurological adverse reactions					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232g
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	96 (99.0)	0	4 (4.1)	23 (23.7)	69 (71.1)
Cytokine Release Syndrome					
-Total	61 (62.9)	5 (5.2)	17 (17.5)	17 (17.5)	22 (22.7)
Cytokine release syndrome	61 (62.9)	5 (5.2)	18 (18.6)	17 (17.5)	21 (21.6)
Haemophagocytic lymphohistiocytosis	6 (6.2)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)
Hematological disorders including cytopenias					
-Total	76 (78.4)	0	1 (1.0)	24 (24.7)	51 (52.6)
Anaemia	45 (46.4)	5 (5.2)	12 (12.4)	27 (27.8)	1 (1.0)
Febrile neutropenia	45 (46.4)	0	0	42 (43.3)	3 (3.1)
White blood cell count decreased	34 (35.1)	2 (2.1)	3 (3.1)	1 (1.0)	28 (28.9)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	31 (32.0)	2 (2.1)	2 (2.1)	3 (3.1)	24 (24.7)
Platelet count decreased	31 (32.0)	5 (5.2)	2 (2.1)	6 (6.2)	18 (18.6)
Lymphocyte count decreased	24 (24.7)	1 (1.0)	1 (1.0)	9 (9.3)	13 (13.4)
Neutropenia	22 (22.7)	1 (1.0)	2 (2.1)	3 (3.1)	16 (16.5)
Thrombocytopenia	15 (15.5)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.2)
Leukopenia	6 (6.2)	0	0	1 (1.0)	5 (5.2)
Pancytopenia	6 (6.2)	0	1 (1.0)	3 (3.1)	2 (2.1)
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	83 (85.6)	5 (5.2)	13 (13.4)	40 (41.2)	25 (25.8)
Upper respiratory tract infection	14 (14.4)	5 (5.2)	6 (6.2)	3 (3.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	10 (10.3)	1 (1.0)	2 (2.1)	4 (4.1)	3 (3.1)
Conjunctivitis	9 (9.3)	3 (3.1)	6 (6.2)	0	0
Rhinovirus infection	9 (9.3)	0	7 (7.2)	2 (2.1)	0
Sinusitis	9 (9.3)	0	6 (6.2)	3 (3.1)	0
Nasopharyngitis	8 (8.2)	5 (5.2)	3 (3.1)	0	0
Staphylococcal bacteraemia	8 (8.2)	0	0	8 (8.2)	0
Gastroenteritis	7 (7.2)	4 (4.1)	1 (1.0)	2 (2.1)	0
Oral herpes	7 (7.2)	1 (1.0)	3 (3.1)	3 (3.1)	0
Parainfluenzae virus infection	7 (7.2)	1 (1.0)	1 (1.0)	4 (4.1)	1 (1.0)
Staphylococcal infection	7 (7.2)	0	3 (3.1)	3 (3.1)	1 (1.0)
Bacteraemia	6 (6.2)	0	1 (1.0)	4 (4.1)	1 (1.0)
Herpes zoster	5 (5.2)	0	1 (1.0)	4 (4.1)	0
Otitis media	5 (5.2)	0	4 (4.1)	1 (1.0)	0
Paronychia	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Urinary tract infection	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Acute sinusitis	4 (4.1)	0	3 (3.1)	1 (1.0)	0
Candida infection	4 (4.1)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.1)	1 (1.0)	0	3 (3.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	4 (4.1)	0	1 (1.0)	3 (3.1)	0
Nail infection	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Respiratory tract infection	4 (4.1)	0	2 (2.1)	2 (2.1)	0
Sepsis	4 (4.1)	0	0	1 (1.0)	3 (3.1)
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Fungal infection	3 (3.1)	0	3 (3.1)	0	0
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Pneumonia fungal	3 (3.1)	0	0	2 (2.1)	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Cellulitis	2 (2.1)	0	2 (2.1)	0	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	54 (55.7)	5 (5.2)	34 (35.1)	15 (15.5)	0
Hypogammaglobulinaemia	40 (41.2)	2 (2.1)	29 (29.9)	9 (9.3)	0
Blood immunoglobulin a decreased	6 (6.2)	4 (4.1)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	6 (6.2)	3 (3.1)	1 (1.0)	2 (2.1)	0
Blood immunoglobulin g decreased	4 (4.1)	1 (1.0)	3 (3.1)	0	0
Immunodeficiency	4 (4.1)	0	0	4 (4.1)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	40 (41.2)	12 (12.4)	11 (11.3)	17 (17.5)	0
Encephalopathy	9 (9.3)	1 (1.0)	3 (3.1)	5 (5.2)	0
Delirium	8 (8.2)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.2)	4 (4.1)	3 (3.1)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (7.2)	7 (7.2)	0	0	0
Mental status changes	7 (7.2)	1 (1.0)	2 (2.1)	4 (4.1)	0
Seizure	6 (6.2)	0	3 (3.1)	3 (3.1)	0
Somnolence	6 (6.2)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.2)	5 (5.2)	1 (1.0)	0	0
Cognitive disorder	4 (4.1)	0	2 (2.1)	2 (2.1)	0
Lethargy	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Irritability	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Dysarthria	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0
Memory impairment	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	7 (7.2)	0	0	5 (5.2)	2 (2.1)
Tumour lysis syndrome	7 (7.2)	0	0	5 (5.2)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232h
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Hematological disorders including cytopenias					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Lymphocyte count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
White blood cell count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	1 (33.3)	0	0	0
Infections					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Bronchitis	1 (33.3)	0	1 (33.3)	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cystitis	1 (33.3)	0	1 (33.3)	0	0
Gastroenteritis	1 (33.3)	1 (33.3)	0	0	0
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Nasopharyngitis	1 (33.3)	1 (33.3)	0	0	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	1 (33.3)	0	1 (33.3)	0	0
Hypogammaglobulinaemia	1 (33.3)	0	1 (33.3)	0	0
Serious neurological adverse reactions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232h
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	94 (98.9)	0	5 (5.3)	22 (23.2)	67 (70.5)
Cytokine Release Syndrome					
-Total	61 (64.2)	5 (5.3)	17 (17.9)	17 (17.9)	22 (23.2)
Cytokine release syndrome	61 (64.2)	5 (5.3)	18 (18.9)	17 (17.9)	21 (22.1)
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.1)	1 (1.1)	2 (2.1)	2 (2.1)
Hematological disorders including cytopenias					
-Total	75 (78.9)	1 (1.1)	1 (1.1)	23 (24.2)	50 (52.6)
Anaemia	45 (47.4)	6 (6.3)	12 (12.6)	26 (27.4)	1 (1.1)
Febrile neutropenia	45 (47.4)	0	0	42 (44.2)	3 (3.2)
White blood cell count decreased	33 (34.7)	2 (2.1)	3 (3.2)	1 (1.1)	27 (28.4)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	31 (32.6)	5 (5.3)	2 (2.1)	6 (6.3)	18 (18.9)
Neutrophil count decreased	30 (31.6)	2 (2.1)	2 (2.1)	3 (3.2)	23 (24.2)
Lymphocyte count decreased	22 (23.2)	0	1 (1.1)	9 (9.5)	12 (12.6)
Neutropenia	22 (23.2)	1 (1.1)	2 (2.1)	3 (3.2)	16 (16.8)
Thrombocytopenia	15 (15.8)	1 (1.1)	1 (1.1)	5 (5.3)	8 (8.4)
Leukopenia	6 (6.3)	0	0	1 (1.1)	5 (5.3)
Pancytopenia	6 (6.3)	0	1 (1.1)	3 (3.2)	2 (2.1)
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	80 (84.2)	5 (5.3)	13 (13.7)	39 (41.1)	23 (24.2)
Upper respiratory tract infection	14 (14.7)	5 (5.3)	6 (6.3)	3 (3.2)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	10 (10.5)	1 (1.1)	2 (2.1)	4 (4.2)	3 (3.2)
Conjunctivitis	9 (9.5)	3 (3.2)	6 (6.3)	0	0
Rhinovirus infection	9 (9.5)	0	7 (7.4)	2 (2.1)	0
Sinusitis	9 (9.5)	0	6 (6.3)	3 (3.2)	0
Staphylococcal bacteraemia	8 (8.4)	0	0	8 (8.4)	0
Nasopharyngitis	7 (7.4)	4 (4.2)	3 (3.2)	0	0
Oral herpes	7 (7.4)	1 (1.1)	3 (3.2)	3 (3.2)	0
Parainfluenzae virus infection	7 (7.4)	1 (1.1)	1 (1.1)	4 (4.2)	1 (1.1)
Bacteraemia	6 (6.3)	0	1 (1.1)	4 (4.2)	1 (1.1)
Gastroenteritis	6 (6.3)	3 (3.2)	1 (1.1)	2 (2.1)	0
Staphylococcal infection	6 (6.3)	0	3 (3.2)	3 (3.2)	0
Herpes zoster	5 (5.3)	0	1 (1.1)	4 (4.2)	0
Otitis media	5 (5.3)	0	4 (4.2)	1 (1.1)	0
Paronychia	5 (5.3)	1 (1.1)	3 (3.2)	1 (1.1)	0
Urinary tract infection	5 (5.3)	0	3 (3.2)	2 (2.1)	0
Acute sinusitis	4 (4.2)	0	3 (3.2)	1 (1.1)	0
Candida infection	4 (4.2)	0	3 (3.2)	0	1 (1.1)
Clostridium difficile infection	4 (4.2)	1 (1.1)	0	3 (3.2)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Nail infection	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Respiratory tract infection	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Sepsis	4 (4.2)	0	0	1 (1.1)	3 (3.2)
Bronchopulmonary aspergillosis	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Catheter site infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Ear infection	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Escherichia bacteraemia	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Fungal infection	3 (3.2)	0	3 (3.2)	0	0
Gastroenteritis viral	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Gingivitis	3 (3.2)	3 (3.2)	0	0	0
Influenza	3 (3.2)	0	2 (2.1)	0	1 (1.1)
Localised infection	3 (3.2)	2 (2.1)	0	1 (1.1)	0
Metapneumovirus infection	3 (3.2)	0	0	3 (3.2)	0
Oral candidiasis	3 (3.2)	0	3 (3.2)	0	0
Otitis externa	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Pneumonia fungal	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Respiratory syncytial virus infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Septic shock	3 (3.2)	0	0	0	3 (3.2)
Skin infection	3 (3.2)	0	3 (3.2)	0	0
Staphylococcal sepsis	3 (3.2)	0	0	0	3 (3.2)
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Bronchitis	2 (2.1)	0	2 (2.1)	0	0
Cellulitis	2 (2.1)	0	2 (2.1)	0	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Covid-19	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Fungal skin infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Herpes simplex	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	54 (56.8)	5 (5.3)	34 (35.8)	15 (15.8)	0
Hypogammaglobulinaemia	40 (42.1)	2 (2.1)	29 (30.5)	9 (9.5)	0
Blood immunoglobulin a decreased	7 (7.4)	5 (5.3)	1 (1.1)	1 (1.1)	0
Blood immunoglobulin m decreased	7 (7.4)	4 (4.2)	1 (1.1)	2 (2.1)	0
Blood immunoglobulin g decreased	4 (4.2)	1 (1.1)	3 (3.2)	0	0
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	40 (42.1)	13 (13.7)	11 (11.6)	16 (16.8)	0
Encephalopathy	9 (9.5)	1 (1.1)	3 (3.2)	5 (5.3)	0
Delirium	8 (8.4)	2 (2.1)	3 (3.2)	3 (3.2)	0
Agitation	7 (7.4)	4 (4.2)	3 (3.2)	0	0
Confusional state	7 (7.4)	7 (7.4)	0	0	0
Mental status changes	7 (7.4)	1 (1.1)	2 (2.1)	4 (4.2)	0
Seizure	6 (6.3)	0	3 (3.2)	3 (3.2)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	6 (6.3)	5 (5.3)	1 (1.1)	0	0
Irritability	4 (4.2)	3 (3.2)	0	1 (1.1)	0
Lethargy	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Cognitive disorder	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Hallucination	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Dysarthria	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	7 (7.4)	0	0	5 (5.3)	2 (2.1)
Tumour lysis syndrome	7 (7.4)	0	0	5 (5.3)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232i
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Febrile neutropenia	2 (100)	0	0	2 (100)	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Infections					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	1 (50.0)	0	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232i
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	95 (99.0)	0	5 (5.2)	22 (22.9)	68 (70.8)
Cytokine Release Syndrome					
-Total	61 (63.5)	5 (5.2)	17 (17.7)	17 (17.7)	22 (22.9)
Cytokine release syndrome	61 (63.5)	5 (5.2)	18 (18.8)	17 (17.7)	21 (21.9)
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)
Hematological disorders including cytopenias					
-Total	75 (78.1)	1 (1.0)	1 (1.0)	23 (24.0)	50 (52.1)
Anaemia	46 (47.9)	6 (6.3)	12 (12.5)	27 (28.1)	1 (1.0)
Febrile neutropenia	43 (44.8)	0	0	40 (41.7)	3 (3.1)
White blood cell count decreased	34 (35.4)	3 (3.1)	3 (3.1)	1 (1.0)	27 (28.1)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	32 (33.3)	6 (6.3)	2 (2.1)	6 (6.3)	18 (18.8)
Neutrophil count decreased	31 (32.3)	2 (2.1)	2 (2.1)	3 (3.1)	24 (25.0)
Lymphocyte count decreased	24 (25.0)	1 (1.0)	1 (1.0)	9 (9.4)	13 (13.5)
Neutropenia	22 (22.9)	1 (1.0)	2 (2.1)	3 (3.1)	16 (16.7)
Thrombocytopenia	15 (15.6)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.3)
Leukopenia	6 (6.3)	0	0	1 (1.0)	5 (5.2)
Pancytopenia	6 (6.3)	0	1 (1.0)	3 (3.1)	2 (2.1)
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Infections					
-Total	81 (84.4)	5 (5.2)	12 (12.5)	39 (40.6)	25 (26.0)
Upper respiratory tract infection	14 (14.6)	5 (5.2)	6 (6.3)	3 (3.1)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Conjunctivitis	9 (9.4)	3 (3.1)	6 (6.3)	0	0
Rhinovirus infection	9 (9.4)	0	7 (7.3)	2 (2.1)	0
Sinusitis	9 (9.4)	0	6 (6.3)	3 (3.1)	0
Nasopharyngitis	8 (8.3)	5 (5.2)	3 (3.1)	0	0
Staphylococcal bacteraemia	8 (8.3)	0	0	8 (8.3)	0
Gastroenteritis	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Oral herpes	7 (7.3)	1 (1.0)	3 (3.1)	3 (3.1)	0
Parainfluenzae virus infection	7 (7.3)	1 (1.0)	1 (1.0)	4 (4.2)	1 (1.0)
Bacteraemia	6 (6.3)	0	1 (1.0)	4 (4.2)	1 (1.0)
Staphylococcal infection	6 (6.3)	0	2 (2.1)	3 (3.1)	1 (1.0)
Herpes zoster	5 (5.2)	0	1 (1.0)	4 (4.2)	0
Otitis media	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Paronychia	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Urinary tract infection	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Candida infection	4 (4.2)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.2)	1 (1.0)	0	3 (3.1)	0
Device related infection	4 (4.2)	0	1 (1.0)	3 (3.1)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Respiratory tract infection	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Sepsis	4 (4.2)	0	0	1 (1.0)	3 (3.1)
Acute sinusitis	3 (3.1)	0	3 (3.1)	0	0
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Fungal infection	3 (3.1)	0	3 (3.1)	0	0
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Pneumonia fungal	3 (3.1)	0	0	2 (2.1)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Cellulitis	2 (2.1)	0	2 (2.1)	0	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	55 (57.3)	5 (5.2)	35 (36.5)	15 (15.6)	0
Hypogammaglobulinaemia	41 (42.7)	2 (2.1)	30 (31.3)	9 (9.4)	0
Blood immunoglobulin a decreased	7 (7.3)	5 (5.2)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Blood immunoglobulin g decreased	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Serious neurological adverse reactions					
-Total	41 (42.7)	13 (13.5)	11 (11.5)	17 (17.7)	0
Encephalopathy	9 (9.4)	1 (1.0)	3 (3.1)	5 (5.2)	0
Delirium	8 (8.3)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.3)	4 (4.2)	3 (3.1)	0	0
Confusional state	7 (7.3)	7 (7.3)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
Seizure	6 (6.3)	0	3 (3.1)	3 (3.1)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.3)	5 (5.2)	1 (1.0)	0	0
Cognitive disorder	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Irritability	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Lethargy	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Dysarthria	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Memory impairment	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	7 (7.3)	0	0	5 (5.2)	2 (2.1)
Tumour lysis syndrome	7 (7.3)	0	0	5 (5.2)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232j
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (100)	0	2 (6.7)	6 (20.0)	22 (73.3)
Cytokine Release Syndrome					
-Total	20 (66.7)	0	3 (10.0)	8 (26.7)	9 (30.0)
Cytokine release syndrome	20 (66.7)	0	3 (10.0)	8 (26.7)	9 (30.0)
Haemophagocytic lymphohistiocytosis	4 (13.3)	1 (3.3)	1 (3.3)	1 (3.3)	1 (3.3)
Hematological disorders including cytopenias					
-Total	25 (83.3)	1 (3.3)	1 (3.3)	7 (23.3)	16 (53.3)
Anaemia	14 (46.7)	3 (10.0)	5 (16.7)	6 (20.0)	0
Neutrophil count decreased	11 (36.7)	1 (3.3)	1 (3.3)	0	9 (30.0)
Platelet count decreased	11 (36.7)	2 (6.7)	1 (3.3)	2 (6.7)	6 (20.0)
White blood cell count decreased	11 (36.7)	2 (6.7)	1 (3.3)	1 (3.3)	7 (23.3)

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Lymphocyte count decreased	8 (26.7)	1 (3.3)	1 (3.3)	3 (10.0)	3 (10.0)
Neutropenia	8 (26.7)	1 (3.3)	1 (3.3)	1 (3.3)	5 (16.7)
Thrombocytopenia	5 (16.7)	1 (3.3)	0	1 (3.3)	3 (10.0)
Agranulocytosis	1 (3.3)	0	0	1 (3.3)	0
Haemoglobin decreased	1 (3.3)	0	0	1 (3.3)	0
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	1 (3.3)	0	0
Infections					
-Total	26 (86.7)	2 (6.7)	1 (3.3)	12 (40.0)	11 (36.7)
Conjunctivitis	5 (16.7)	1 (3.3)	4 (13.3)	0	0
Pneumonia	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Nasopharyngitis	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Staphylococcal infection	4 (13.3)	0	1 (3.3)	2 (6.7)	1 (3.3)
Bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Nail infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Paronychia	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	3 (10.0)	0	0
Sinusitis	3 (10.0)	0	2 (6.7)	1 (3.3)	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	3 (10.0)	0	0	0	3 (10.0)
Bronchiolitis	2 (6.7)	0	0	2 (6.7)	0
Clostridium difficile infection	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Ear infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Gastroenteritis	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Gastroenteritis viral	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Oral herpes	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Oral infection	2 (6.7)	0	2 (6.7)	0	0
Otitis media	2 (6.7)	0	2 (6.7)	0	0
Respiratory tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Sepsis	2 (6.7)	0	0	0	2 (6.7)
Skin infection	2 (6.7)	0	2 (6.7)	0	0
Staphylococcal bacteraemia	2 (6.7)	0	0	2 (6.7)	0
Upper respiratory tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Urinary tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Anal abscess	1 (3.3)	0	0	1 (3.3)	0
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bk virus infection	1 (3.3)	1 (3.3)	0	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Bronchopulmonary aspergillosis	1 (3.3)	0	0	1 (3.3)	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Catheter site infection	1 (3.3)	0	0	1 (3.3)	0
Cholecystitis infective	1 (3.3)	0	1 (3.3)	0	0
Coronavirus infection	1 (3.3)	0	0	1 (3.3)	0
Covid-19	1 (3.3)	0	0	1 (3.3)	0
Cytomegalovirus infection reactivation	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Encephalitis	1 (3.3)	0	0	0	1 (3.3)
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Epstein-barr virus infection reactivation	1 (3.3)	1 (3.3)	0	0	0
Folliculitis	1 (3.3)	0	1 (3.3)	0	0
Fungaemia	1 (3.3)	0	0	0	1 (3.3)
Fungal pharyngitis	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis norovirus	1 (3.3)	1 (3.3)	0	0	0
Herpes virus infection	1 (3.3)	0	1 (3.3)	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.3)	0	1 (3.3)	0	0
Localised infection	1 (3.3)	1 (3.3)	0	0	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	0	0	1 (3.3)	0
Myringitis	1 (3.3)	1 (3.3)	0	0	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Otitis externa	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (3.3)	0	0	0	1 (3.3)
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Rhinitis	1 (3.3)	1 (3.3)	0	0	0
Salmonellosis	1 (3.3)	0	1 (3.3)	0	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Streptococcal sepsis	1 (3.3)	0	1 (3.3)	0	0
Tinea pedis	1 (3.3)	1 (3.3)	0	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Vulval cellulitis	1 (3.3)	0	0	1 (3.3)	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	17 (56.7)	1 (3.3)	10 (33.3)	6 (20.0)	0
Hypogammaglobulinaemia	12 (40.0)	1 (3.3)	8 (26.7)	3 (10.0)	0
Blood immunoglobulin m decreased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Blood immunoglobulin a decreased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Immunodeficiency	2 (6.7)	0	0	2 (6.7)	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Immunoglobulins decreased	1 (3.3)	0	1 (3.3)	0	0
Serious neurological adverse reactions					
-Total	11 (36.7)	5 (16.7)	2 (6.7)	4 (13.3)	0
Mental status changes	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Delirium	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Encephalopathy	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Tremor	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Confusional state	2 (6.7)	2 (6.7)	0	0	0
Irritability	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Somnolence	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Agitation	1 (3.3)	0	1 (3.3)	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (3.3)	0	0	1 (3.3)	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0
Generalised tonic-clonic seizure	1 (3.3)	0	1 (3.3)	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Tumour Lysis Syndrome					
-Total	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Tumour lysis syndrome	3 (10.0)	0	0	2 (6.7)	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232j
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (98.5)	0	3 (4.4)	17 (25.0)	47 (69.1)
Cytokine Release Syndrome					
-Total	41 (60.3)	5 (7.4)	14 (20.6)	9 (13.2)	13 (19.1)
Cytokine release syndrome	41 (60.3)	5 (7.4)	15 (22.1)	9 (13.2)	12 (17.6)
Haemophagocytic lymphohistiocytosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Hematological disorders including cytopenias					
-Total	52 (76.5)	0	0	17 (25.0)	35 (51.5)
Febrile neutropenia	35 (51.5)	0	0	32 (47.1)	3 (4.4)
Anaemia	32 (47.1)	3 (4.4)	7 (10.3)	21 (30.9)	1 (1.5)
White blood cell count decreased	24 (35.3)	1 (1.5)	2 (2.9)	0	21 (30.9)

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	21 (30.9)	4 (5.9)	1 (1.5)	4 (5.9)	12 (17.6)
Neutrophil count decreased	20 (29.4)	1 (1.5)	1 (1.5)	3 (4.4)	15 (22.1)
Lymphocyte count decreased	16 (23.5)	0	0	6 (8.8)	10 (14.7)
Neutropenia	14 (20.6)	0	1 (1.5)	2 (2.9)	11 (16.2)
Thrombocytopenia	10 (14.7)	0	1 (1.5)	4 (5.9)	5 (7.4)
Leukopenia	5 (7.4)	0	0	1 (1.5)	4 (5.9)
Pancytopenia	5 (7.4)	0	0	3 (4.4)	2 (2.9)
Lymphopenia	2 (2.9)	0	0	0	2 (2.9)
Eosinophil count decreased	1 (1.5)	1 (1.5)	0	0	0
Haematocrit decreased	1 (1.5)	1 (1.5)	0	0	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Red blood cell count decreased	1 (1.5)	1 (1.5)	0	0	0
Infections					
-Total	57 (83.8)	3 (4.4)	12 (17.6)	28 (41.2)	14 (20.6)
Upper respiratory tract infection	12 (17.6)	5 (7.4)	5 (7.4)	2 (2.9)	0
Parainfluenzae virus infection	6 (8.8)	1 (1.5)	1 (1.5)	3 (4.4)	1 (1.5)
Rhinovirus infection	6 (8.8)	0	4 (5.9)	2 (2.9)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Staphylococcal bacteraemia	6 (8.8)	0	0	6 (8.8)	0
Gastroenteritis	5 (7.4)	3 (4.4)	1 (1.5)	1 (1.5)	0
Oral herpes	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Pneumonia	5 (7.4)	0	1 (1.5)	1 (1.5)	3 (4.4)
Acute sinusitis	4 (5.9)	0	3 (4.4)	1 (1.5)	0
Conjunctivitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Nasopharyngitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Bacteraemia	3 (4.4)	0	1 (1.5)	1 (1.5)	1 (1.5)
Candida infection	3 (4.4)	0	2 (2.9)	0	1 (1.5)
Device related infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Escherichia bacteraemia	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Fungal infection	3 (4.4)	0	3 (4.4)	0	0
Gingivitis	3 (4.4)	3 (4.4)	0	0	0
Herpes zoster	3 (4.4)	0	0	3 (4.4)	0
Oral candidiasis	3 (4.4)	0	3 (4.4)	0	0
Otitis media	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Pneumonia fungal	3 (4.4)	0	0	2 (2.9)	1 (1.5)

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Staphylococcal infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Urinary tract infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0
Bronchitis	2 (2.9)	0	2 (2.9)	0	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Catheter site infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Cellulitis	2 (2.9)	0	2 (2.9)	0	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Clostridium difficile infection	2 (2.9)	0	0	2 (2.9)	0
Fungal skin infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Herpes simplex	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Influenza	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Klebsiella bacteraemia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Localised infection	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Otitis externa	2 (2.9)	0	1 (1.5)	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	2 (2.9)	0	2 (2.9)	0	0
Respiratory tract infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Rhinitis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Sepsis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Skin papilloma	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Staphylococcal skin infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Varicella zoster virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bk virus infection	1 (1.5)	0	0	1 (1.5)	0
Covid-19	1 (1.5)	1 (1.5)	0	0	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Ear infection	1 (1.5)	0	1 (1.5)	0	0
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Encephalitis viral	1 (1.5)	0	0	1 (1.5)	0
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Epstein-barr virus infection	1 (1.5)	0	1 (1.5)	0	0
Fungal sepsis	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis adenovirus	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis clostridial	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Haemophilus bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Nail infection	1 (1.5)	1 (1.5)	0	0	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Peritonitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Post herpetic neuralgia	1 (1.5)	0	0	1 (1.5)	0
Pseudomonal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Sinusitis fungal	1 (1.5)	0	0	1 (1.5)	0
Skin infection	1 (1.5)	0	1 (1.5)	0	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	0	0	1 (1.5)
Syphilis	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Tonsillitis	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral infection	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	38 (55.9)	4 (5.9)	25 (36.8)	9 (13.2)	0
Hypogammaglobulinaemia	29 (42.6)	1 (1.5)	22 (32.4)	6 (8.8)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Blood immunoglobulin m decreased	4 (5.9)	3 (4.4)	0	1 (1.5)	0
Blood immunoglobulin g decreased	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Immunoglobulins decreased	1 (1.5)	0	1 (1.5)	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Serious neurological adverse reactions					
-Total	30 (44.1)	8 (11.8)	9 (13.2)	13 (19.1)	0
Agitation	6 (8.8)	4 (5.9)	2 (2.9)	0	0
Encephalopathy	6 (8.8)	0	3 (4.4)	3 (4.4)	0
Confusional state	5 (7.4)	5 (7.4)	0	0	0
Delirium	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Seizure	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Lethargy	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Somnolence	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Cognitive disorder	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Hallucination	3 (4.4)	1 (1.5)	2 (2.9)	0	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Tremor	3 (4.4)	3 (4.4)	0	0	0
Dysarthria	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Muscular weakness	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0

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

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	4 (5.9)	0	0	3 (4.4)	1 (1.5)
Tumour lysis syndrome	4 (5.9)	0	0	3 (4.4)	1 (1.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232k
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	0	7 (21.9)	25 (78.1)
Cytokine Release Syndrome					
-Total	19 (59.4)	0	5 (15.6)	5 (15.6)	9 (28.1)
Cytokine release syndrome	19 (59.4)	0	6 (18.8)	5 (15.6)	8 (25.0)
Haemophagocytic lymphohistiocytosis	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Hematological disorders including cytopenias					
-Total	27 (84.4)	0	0	7 (21.9)	20 (62.5)
Febrile neutropenia	15 (46.9)	0	0	14 (43.8)	1 (3.1)
Anaemia	14 (43.8)	1 (3.1)	2 (6.3)	11 (34.4)	0
Neutropenia	12 (37.5)	0	1 (3.1)	2 (6.3)	9 (28.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	12 (37.5)	0	0	0	12 (37.5)
Lymphocyte count decreased	11 (34.4)	0	0	1 (3.1)	10 (31.3)
Neutrophil count decreased	10 (31.3)	1 (3.1)	0	0	9 (28.1)
Platelet count decreased	10 (31.3)	2 (6.3)	0	1 (3.1)	7 (21.9)
Thrombocytopenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
Leukopenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Pancytopenia	3 (9.4)	0	0	3 (9.4)	0
Agranulocytosis	1 (3.1)	0	0	1 (3.1)	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0
Neutropenic infection	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	30 (93.8)	1 (3.1)	5 (15.6)	12 (37.5)	12 (37.5)
Nasopharyngitis	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Pneumonia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Conjunctivitis	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Gastroenteritis	5 (15.6)	2 (6.3)	1 (3.1)	2 (6.3)	0
Device related infection	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Herpes zoster	4 (12.5)	0	0	4 (12.5)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Nail infection	3 (9.4)	3 (9.4)	0	0	0
Parainfluenzae virus infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Rhinitis	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Sepsis	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Staphylococcal sepsis	3 (9.4)	0	0	0	3 (9.4)
Upper respiratory tract infection	3 (9.4)	3 (9.4)	0	0	0
Bacteraemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Bronchopulmonary aspergillosis	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Device related sepsis	2 (6.3)	0	0	2 (6.3)	0
Fungal infection	2 (6.3)	0	2 (6.3)	0	0
Gingivitis	2 (6.3)	2 (6.3)	0	0	0
Oral herpes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Oral infection	2 (6.3)	0	2 (6.3)	0	0
Paronychia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Rhinovirus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Skin papilloma	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Staphylococcal infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Adenovirus infection	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Covid-19	1 (3.1)	0	0	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Cystitis	1 (3.1)	0	1 (3.1)	0	0
Cytomegalovirus infection reactivation	1 (3.1)	0	1 (3.1)	0	0
Device related bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Ear, nose and throat infection	1 (3.1)	0	1 (3.1)	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	1 (3.1)	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Epstein-barr virus infection reactivation	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis adenovirus	1 (3.1)	0	0	1 (3.1)	0
Haemophilus bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Herpes virus infection	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Myringitis	1 (3.1)	1 (3.1)	0	0	0
Neutropenic infection	1 (3.1)	0	0	1 (3.1)	0
Ophthalmic herpes zoster	1 (3.1)	0	1 (3.1)	0	0
Oral candidiasis	1 (3.1)	0	1 (3.1)	0	0
Otitis media	1 (3.1)	0	1 (3.1)	0	0
Pneumocystis jirovecii pneumonia	1 (3.1)	0	0	0	1 (3.1)
Pneumonia fungal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia viral	1 (3.1)	0	0	1 (3.1)	0
Post herpetic neuralgia	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection viral	1 (3.1)	0	1 (3.1)	0	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	1 (3.1)	0	0	1 (3.1)	0
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal skin infection	1 (3.1)	0	1 (3.1)	0	0
Streptococcal sepsis	1 (3.1)	0	1 (3.1)	0	0
Tonsillitis	1 (3.1)	0	1 (3.1)	0	0
Viral haemorrhagic cystitis	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	0	1 (3.1)	0	0
Viral skin infection	1 (3.1)	1 (3.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (65.6)	1 (3.1)	10 (31.3)	10 (31.3)	0
Hypogammaglobulinaemia	15 (46.9)	1 (3.1)	8 (25.0)	6 (18.8)	0
Immunodeficiency	4 (12.5)	0	0	4 (12.5)	0
Immunoglobulins decreased	2 (6.3)	0	2 (6.3)	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	11 (34.4)	4 (12.5)	3 (9.4)	4 (12.5)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Confusional state	2 (6.3)	2 (6.3)	0	0	0
Hallucination	2 (6.3)	0	2 (6.3)	0	0
Seizure	2 (6.3)	0	0	2 (6.3)	0
Tremor	2 (6.3)	2 (6.3)	0	0	0
Agitation	1 (3.1)	1 (3.1)	0	0	0
Amnesia	1 (3.1)	0	1 (3.1)	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Hallucination, visual	1 (3.1)	0	1 (3.1)	0	0
Memory impairment	1 (3.1)	0	1 (3.1)	0	0
Muscular weakness	1 (3.1)	1 (3.1)	0	0	0
Tumour Lysis Syndrome					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	1 (3.1)	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232k
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	0	4 (7.0)	14 (24.6)	38 (66.7)
Cytokine Release Syndrome					
-Total	36 (63.2)	4 (7.0)	12 (21.1)	10 (17.5)	10 (17.5)
Cytokine release syndrome	36 (63.2)	4 (7.0)	12 (21.1)	10 (17.5)	10 (17.5)
Haemophagocytic lymphohistiocytosis	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Hematological disorders including cytopenias					
-Total	44 (77.2)	1 (1.8)	1 (1.8)	17 (29.8)	25 (43.9)
Anaemia	31 (54.4)	5 (8.8)	9 (15.8)	16 (28.1)	1 (1.8)
Febrile neutropenia	29 (50.9)	0	0	27 (47.4)	2 (3.5)
Platelet count decreased	20 (35.1)	4 (7.0)	2 (3.5)	4 (7.0)	10 (17.5)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	19 (33.3)	3 (5.3)	3 (5.3)	1 (1.8)	12 (21.1)
Neutrophil count decreased	18 (31.6)	1 (1.8)	2 (3.5)	3 (5.3)	12 (21.1)
Lymphocyte count decreased	13 (22.8)	1 (1.8)	1 (1.8)	8 (14.0)	3 (5.3)
Thrombocytopenia	10 (17.5)	1 (1.8)	1 (1.8)	3 (5.3)	5 (8.8)
Neutropenia	7 (12.3)	1 (1.8)	1 (1.8)	1 (1.8)	4 (7.0)
Pancytopenia	3 (5.3)	0	1 (1.8)	0	2 (3.5)
Leukopenia	2 (3.5)	0	0	0	2 (3.5)
Lymphopenia	2 (3.5)	0	0	0	2 (3.5)
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Haemoglobin decreased	1 (1.8)	0	0	1 (1.8)	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Infections					
-Total	44 (77.2)	1 (1.8)	7 (12.3)	24 (42.1)	12 (21.1)
Upper respiratory tract infection	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0
Sinusitis	7 (12.3)	0	5 (8.8)	2 (3.5)	0
Staphylococcal bacteraemia	7 (12.3)	0	0	7 (12.3)	0
Rhinovirus infection	6 (10.5)	0	6 (10.5)	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oral herpes	5 (8.8)	1 (1.8)	2 (3.5)	2 (3.5)	0
Staphylococcal infection	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Acute sinusitis	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Clostridium difficile infection	4 (7.0)	1 (1.8)	0	3 (5.3)	0
Conjunctivitis	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Bacteraemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Candida infection	3 (5.3)	0	2 (3.5)	0	1 (1.8)
Catheter site infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Gastroenteritis viral	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Metapneumovirus infection	3 (5.3)	0	0	3 (5.3)	0
Otitis media	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Parainfluenzae virus infection	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Paronychia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Pneumonia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Septic shock	3 (5.3)	0	0	0	3 (5.3)
Bronchitis	2 (3.5)	0	2 (3.5)	0	0
Cellulitis	2 (3.5)	0	2 (3.5)	0	0
Clostridium difficile colitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ear infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Fungal skin infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Gastroenteritis	2 (3.5)	2 (3.5)	0	0	0
Herpes simplex	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Human herpesvirus 6 infection	2 (3.5)	0	0	2 (3.5)	0
Influenza	2 (3.5)	0	2 (3.5)	0	0
Klebsiella bacteraemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Localised infection	2 (3.5)	2 (3.5)	0	0	0
Oral candidiasis	2 (3.5)	0	2 (3.5)	0	0
Otitis externa	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Pneumonia fungal	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Respiratory syncytial virus infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Skin infection	2 (3.5)	0	2 (3.5)	0	0
Urinary tract infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Varicella zoster virus infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0
Anal abscess	1 (1.8)	0	0	1 (1.8)	0

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Atypical pneumonia	1 (1.8)	1 (1.8)	0	0	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	1 (1.8)	0	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Covid-19	1 (1.8)	1 (1.8)	0	0	0
Cytomegalovirus infection reactivation	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Enterobacter infection	1 (1.8)	0	0	1 (1.8)	0
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Fungal infection	1 (1.8)	0	1 (1.8)	0	0
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Fungal sepsis	1 (1.8)	0	0	0	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Granulicatella infection	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	1 (1.8)	0	0
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Mastoiditis	1 (1.8)	0	0	1 (1.8)	0
Meningitis pneumococcal	1 (1.8)	0	0	1 (1.8)	0
Nail infection	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis streptococcal	1 (1.8)	0	0	1 (1.8)	0
Pneumocystis jirovecii pneumonia	1 (1.8)	0	0	1 (1.8)	0
Pneumonia respiratory syncytial viral	1 (1.8)	0	0	1 (1.8)	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Stomatococcal infection	1 (1.8)	0	0	0	1 (1.8)
Syphilis	1 (1.8)	0	1 (1.8)	0	0
Systemic candida	1 (1.8)	0	0	1 (1.8)	0
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Tinea pedis	1 (1.8)	1 (1.8)	0	0	0
Urinary tract infection pseudomonal	1 (1.8)	0	1 (1.8)	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Vulval cellulitis	1 (1.8)	0	0	1 (1.8)	0

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	30 (52.6)	4 (7.0)	21 (36.8)	5 (8.8)	0
Hypogammaglobulinaemia	22 (38.6)	1 (1.8)	18 (31.6)	3 (5.3)	0
Blood immunoglobulin a decreased	7 (12.3)	5 (8.8)	1 (1.8)	1 (1.8)	0
Blood immunoglobulin m decreased	7 (12.3)	4 (7.0)	1 (1.8)	2 (3.5)	0
Blood immunoglobulin g decreased	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Selective igg subclass deficiency	1 (1.8)	0	1 (1.8)	0	0
Serious neurological adverse reactions					
-Total	29 (50.9)	9 (15.8)	7 (12.3)	13 (22.8)	0
Delirium	8 (14.0)	2 (3.5)	3 (5.3)	3 (5.3)	0
Mental status changes	7 (12.3)	1 (1.8)	2 (3.5)	4 (7.0)	0
Agitation	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Somnolence	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Confusional state	5 (8.8)	5 (8.8)	0	0	0
Encephalopathy	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Cognitive disorder	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Irritability	4 (7.0)	3 (5.3)	0	1 (1.8)	0

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Tremor	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Affect lability	1 (1.8)	0	1 (1.8)	0	0
Aphasia	1 (1.8)	1 (1.8)	0	0	0
Depressed level of consciousness	1 (1.8)	0	0	1 (1.8)	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0
Dysarthria	1 (1.8)	0	0	1 (1.8)	0
Dysphagia	1 (1.8)	0	0	1 (1.8)	0
Generalised tonic-clonic seizure	1 (1.8)	0	1 (1.8)	0	0
Hallucination	1 (1.8)	1 (1.8)	0	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	0	0	1 (1.8)	0
Posterior reversible encephalopathy syndrome	1 (1.8)	0	1 (1.8)	0	0
Restlessness	1 (1.8)	0	1 (1.8)	0	0
Sluggishness	1 (1.8)	0	1 (1.8)	0	0
Social avoidant behaviour	1 (1.8)	0	1 (1.8)	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Tumour lysis syndrome	3 (5.3)	0	0	2 (3.5)	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232k
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	2 (22.2)	6 (66.7)
Cytokine Release Syndrome					
-Total	6 (66.7)	1 (11.1)	0	2 (22.2)	3 (33.3)
Cytokine release syndrome	6 (66.7)	1 (11.1)	0	2 (22.2)	3 (33.3)
Hematological disorders including cytopenias					
-Total	6 (66.7)	0	0	0	6 (66.7)
White blood cell count decreased	4 (44.4)	0	0	0	4 (44.4)
Neutropenia	3 (33.3)	0	0	0	3 (33.3)
Neutrophil count decreased	3 (33.3)	0	0	0	3 (33.3)
Platelet count decreased	2 (22.2)	0	0	1 (11.1)	1 (11.1)

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaemia	1 (11.1)	0	1 (11.1)	0	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Leukopenia	1 (11.1)	0	0	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Infections					
-Total	9 (100)	3 (33.3)	1 (11.1)	4 (44.4)	1 (11.1)
Upper respiratory tract infection	2 (22.2)	0	0	2 (22.2)	0
Bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Bk virus infection	1 (11.1)	1 (11.1)	0	0	0
Encephalitis viral	1 (11.1)	0	0	0	1 (11.1)
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Meningitis bacterial	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Otitis externa	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Parainfluenzae virus infection	1 (11.1)	0	0	1 (11.1)	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	1 (11.1)	0

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (11.1)	0	0	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	0	1 (11.1)	0
Sinusitis	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Tinea pedis	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Urinary tract infection viral	1 (11.1)	1 (11.1)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (44.4)	0	4 (44.4)	0	0
Hypogammaglobulinaemia	4 (44.4)	0	4 (44.4)	0	0
B-cell aplasia	1 (11.1)	0	1 (11.1)	0	0
Serious neurological adverse reactions					
-Total	1 (11.1)	0	1 (11.1)	0	0
Seizure	1 (11.1)	0	1 (11.1)	0	0
Tumour Lysis Syndrome					
-Total	2 (22.2)	0	0	2 (22.2)	0
Tumour lysis syndrome	2 (22.2)	0	0	2 (22.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232l
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (100)	0	3 (5.2)	16 (27.6)	39 (67.2)
Cytokine Release Syndrome					
-Total	37 (63.8)	3 (5.2)	11 (19.0)	12 (20.7)	11 (19.0)
Cytokine release syndrome	37 (63.8)	3 (5.2)	11 (19.0)	12 (20.7)	11 (19.0)
Haemophagocytic lymphohistiocytosis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hematological disorders including cytopenias					
-Total	45 (77.6)	1 (1.7)	0	12 (20.7)	32 (55.2)
Febrile neutropenia	26 (44.8)	0	0	25 (43.1)	1 (1.7)
Anaemia	25 (43.1)	2 (3.4)	6 (10.3)	17 (29.3)	0
Neutrophil count decreased	22 (37.9)	2 (3.4)	1 (1.7)	1 (1.7)	18 (31.0)

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	22 (37.9)	4 (6.9)	0	5 (8.6)	13 (22.4)
White blood cell count decreased	21 (36.2)	2 (3.4)	0	0	19 (32.8)
Lymphocyte count decreased	15 (25.9)	0	0	4 (6.9)	11 (19.0)
Neutropenia	13 (22.4)	0	1 (1.7)	2 (3.4)	10 (17.2)
Thrombocytopenia	8 (13.8)	0	1 (1.7)	3 (5.2)	4 (6.9)
Leukopenia	5 (8.6)	0	0	1 (1.7)	4 (6.9)
Pancytopenia	5 (8.6)	0	0	3 (5.2)	2 (3.4)
Lymphopenia	2 (3.4)	0	0	0	2 (3.4)
Agranulocytosis	1 (1.7)	0	0	1 (1.7)	0
Eosinophil count decreased	1 (1.7)	1 (1.7)	0	0	0
Haematocrit decreased	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Red blood cell count decreased	1 (1.7)	1 (1.7)	0	0	0
Infections					
-Total	52 (89.7)	3 (5.2)	9 (15.5)	24 (41.4)	16 (27.6)
Upper respiratory tract infection	8 (13.8)	3 (5.2)	2 (3.4)	3 (5.2)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	7 (12.1)	3 (5.2)	4 (6.9)	0	0
Sinusitis	7 (12.1)	0	4 (6.9)	3 (5.2)	0
Gastroenteritis	6 (10.3)	3 (5.2)	1 (1.7)	2 (3.4)	0
Nasopharyngitis	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Pneumonia	6 (10.3)	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.7)
Oral herpes	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Rhinovirus infection	5 (8.6)	0	4 (6.9)	1 (1.7)	0
Bacteraemia	4 (6.9)	0	0	3 (5.2)	1 (1.7)
Device related infection	4 (6.9)	0	1 (1.7)	3 (5.2)	0
Herpes zoster	4 (6.9)	0	1 (1.7)	3 (5.2)	0
Parainfluenzae virus infection	4 (6.9)	0	0	3 (5.2)	1 (1.7)
Paronychia	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Urinary tract infection	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Bronchopulmonary aspergillosis	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Candida infection	3 (5.2)	0	2 (3.4)	0	1 (1.7)
Catheter site infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Fungal infection	3 (5.2)	0	3 (5.2)	0	0
Gingivitis	3 (5.2)	3 (5.2)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	3 (5.2)	0	0	3 (5.2)	0
Oral candidiasis	3 (5.2)	0	3 (5.2)	0	0
Otitis media	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Respiratory syncytial virus infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Respiratory tract infection	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Rhinitis	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Sepsis	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Septic shock	3 (5.2)	0	0	0	3 (5.2)
Staphylococcal sepsis	3 (5.2)	0	0	0	3 (5.2)
Cytomegalovirus infection reactivation	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Device related sepsis	2 (3.4)	0	0	2 (3.4)	0
Escherichia bacteraemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Human herpesvirus 6 infection	2 (3.4)	0	0	2 (3.4)	0
Influenza	2 (3.4)	0	2 (3.4)	0	0
Nail infection	2 (3.4)	2 (3.4)	0	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0
Otitis externa	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pneumocystis jirovecii pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Skin papilloma	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Staphylococcal infection	2 (3.4)	0	0	2 (3.4)	0
Staphylococcal skin infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Tinea pedis	2 (3.4)	2 (3.4)	0	0	0
Varicella zoster virus infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Viral infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Abscess limb	1 (1.7)	0	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Adenovirus infection	1 (1.7)	0	0	1 (1.7)	0
Anal abscess	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bk virus infection	1 (1.7)	1 (1.7)	0	0	0
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Cellulitis	1 (1.7)	0	1 (1.7)	0	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile infection	1 (1.7)	0	0	1 (1.7)	0
Coronavirus infection	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Cystitis	1 (1.7)	0	1 (1.7)	0	0
Device related bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Ear infection	1 (1.7)	0	0	1 (1.7)	0
Ear, nose and throat infection	1 (1.7)	0	1 (1.7)	0	0
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Encephalitis viral	1 (1.7)	0	0	1 (1.7)	0
Enterobacter infection	1 (1.7)	0	0	1 (1.7)	0
Epstein-barr virus infection	1 (1.7)	0	1 (1.7)	0	0
Epstein-barr virus infection reactivation	1 (1.7)	1 (1.7)	0	0	0
Fungaemia	1 (1.7)	0	0	0	1 (1.7)
Fungal pharyngitis	1 (1.7)	0	0	1 (1.7)	0
Fungal sepsis	1 (1.7)	0	0	0	1 (1.7)
Fungal skin infection	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Haemophilus bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Herpes simplex	1 (1.7)	0	0	1 (1.7)	0
Herpes virus infection	1 (1.7)	0	1 (1.7)	0	0
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Mastoiditis	1 (1.7)	0	0	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Peritonitis	1 (1.7)	0	0	1 (1.7)	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post herpetic neuralgia	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	1 (1.7)	0	0
Salmonellosis	1 (1.7)	0	1 (1.7)	0	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Stomatococcal infection	1 (1.7)	0	0	0	1 (1.7)
Streptococcal sepsis	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Tonsillitis	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection pseudomonal	1 (1.7)	0	1 (1.7)	0	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0
Viral skin infection	1 (1.7)	1 (1.7)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	36 (62.1)	3 (5.2)	23 (39.7)	10 (17.2)	0
Hypogammaglobulinaemia	28 (48.3)	0	21 (36.2)	7 (12.1)	0
Blood immunoglobulin a decreased	6 (10.3)	5 (8.6)	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	5 (8.6)	4 (6.9)	0	1 (1.7)	0
Immunodeficiency	2 (3.4)	0	0	2 (3.4)	0
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Serious neurological adverse reactions					
-Total	21 (36.2)	6 (10.3)	8 (13.8)	7 (12.1)	0
Encephalopathy	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Agitation	4 (6.9)	4 (6.9)	0	0	0
Confusional state	4 (6.9)	4 (6.9)	0	0	0
Seizure	4 (6.9)	0	1 (1.7)	3 (5.2)	0
Delirium	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Hallucination	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Tremor	3 (5.2)	3 (5.2)	0	0	0
Irritability	2 (3.4)	2 (3.4)	0	0	0
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Mental status changes	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Somnolence	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amnesia	1 (1.7)	0	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0
Cognitive disorder	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	0	1 (1.7)	0	0
Hallucination, visual	1 (1.7)	0	1 (1.7)	0	0
Memory impairment	1 (1.7)	0	1 (1.7)	0	0
Mood altered	1 (1.7)	1 (1.7)	0	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Tumour Lysis Syndrome					
-Total	5 (8.6)	0	0	3 (5.2)	2 (3.4)
Tumour lysis syndrome	5 (8.6)	0	0	3 (5.2)	2 (3.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232l
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	0	2 (5.0)	7 (17.5)	30 (75.0)
Cytokine Release Syndrome					
-Total	24 (60.0)	2 (5.0)	6 (15.0)	5 (12.5)	11 (27.5)
Cytokine release syndrome	24 (60.0)	2 (5.0)	7 (17.5)	5 (12.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Hematological disorders including cytopenias					
-Total	32 (80.0)	0	1 (2.5)	12 (30.0)	19 (47.5)
Anaemia	21 (52.5)	4 (10.0)	6 (15.0)	10 (25.0)	1 (2.5)
Febrile neutropenia	19 (47.5)	0	0	17 (42.5)	2 (5.0)
White blood cell count decreased	14 (35.0)	1 (2.5)	3 (7.5)	1 (2.5)	9 (22.5)

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	1 (2.5)	5 (12.5)
Lymphocyte count decreased	9 (22.5)	1 (2.5)	1 (2.5)	5 (12.5)	2 (5.0)
Neutropenia	9 (22.5)	1 (2.5)	1 (2.5)	1 (2.5)	6 (15.0)
Neutrophil count decreased	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Thrombocytopenia	7 (17.5)	1 (2.5)	0	2 (5.0)	4 (10.0)
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	31 (77.5)	2 (5.0)	4 (10.0)	16 (40.0)	9 (22.5)
Staphylococcal bacteraemia	6 (15.0)	0	0	6 (15.0)	0
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Staphylococcal infection	5 (12.5)	0	3 (7.5)	1 (2.5)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Rhinovirus infection	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Acute sinusitis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Localised infection	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Parainfluenzae virus infection	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Conjunctivitis	2 (5.0)	0	2 (5.0)	0	0
Ear infection	2 (5.0)	0	2 (5.0)	0	0
Gastroenteritis viral	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Pneumonia fungal	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Sialoadenitis	2 (5.0)	0	0	2 (5.0)	0
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19	1 (2.5)	1 (2.5)	0	0	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Influenza	1 (2.5)	0	0	0	1 (2.5)
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Paronychia	1 (2.5)	1 (2.5)	0	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Vulval cellulitis	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	19 (47.5)	2 (5.0)	12 (30.0)	5 (12.5)	0
Hypogammaglobulinaemia	13 (32.5)	2 (5.0)	9 (22.5)	2 (5.0)	0
Blood immunoglobulin g decreased	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Blood immunoglobulin m decreased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Immunodeficiency	2 (5.0)	0	0	2 (5.0)	0
Blood immunoglobulin a decreased	1 (2.5)	0	1 (2.5)	0	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	20 (50.0)	7 (17.5)	3 (7.5)	10 (25.0)	0
Delirium	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Mental status changes	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Encephalopathy	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Somnolence	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	3 (7.5)	0	3 (7.5)	0	0
Cognitive disorder	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Confusional state	3 (7.5)	3 (7.5)	0	0	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Irritability	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Lethargy	2 (5.0)	2 (5.0)	0	0	0
Muscular weakness	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Seizure	2 (5.0)	0	2 (5.0)	0	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232m
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	2 (11.8)	7 (41.2)	8 (47.1)
Cytokine Release Syndrome					
-Total	11 (64.7)	0	5 (29.4)	5 (29.4)	1 (5.9)
Cytokine release syndrome	11 (64.7)	0	5 (29.4)	5 (29.4)	1 (5.9)
Hematological disorders including cytopenias					
-Total	13 (76.5)	1 (5.9)	0	5 (29.4)	7 (41.2)
Febrile neutropenia	9 (52.9)	0	0	9 (52.9)	0
Neutrophil count decreased	9 (52.9)	1 (5.9)	2 (11.8)	1 (5.9)	5 (29.4)
Platelet count decreased	9 (52.9)	4 (23.5)	1 (5.9)	4 (23.5)	0
White blood cell count decreased	9 (52.9)	2 (11.8)	2 (11.8)	0	5 (29.4)
Anaemia	8 (47.1)	3 (17.6)	5 (29.4)	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (41.2)	0	1 (5.9)	4 (23.5)	2 (11.8)
Neutropenia	2 (11.8)	0	0	0	2 (11.8)
Haemoglobin decreased	1 (5.9)	0	0	1 (5.9)	0
Leukopenia	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	11 (64.7)	2 (11.8)	1 (5.9)	7 (41.2)	1 (5.9)
Acute sinusitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Tinea pedis	2 (11.8)	2 (11.8)	0	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Anal abscess	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Conjunctivitis	1 (5.9)	0	1 (5.9)	0	0
Ear infection	1 (5.9)	0	0	1 (5.9)	0
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungal pharyngitis	1 (5.9)	0	0	1 (5.9)	0
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (5.9)	1 (5.9)	0	0	0
Herpes zoster	1 (5.9)	0	1 (5.9)	0	0
Influenza	1 (5.9)	0	1 (5.9)	0	0
Nasopharyngitis	1 (5.9)	1 (5.9)	0	0	0
Oral herpes	1 (5.9)	1 (5.9)	0	0	0
Otitis externa	1 (5.9)	0	1 (5.9)	0	0
Otitis media	1 (5.9)	0	1 (5.9)	0	0
Paronychia	1 (5.9)	0	1 (5.9)	0	0
Peritonitis	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	1 (5.9)	0
Sinusitis	1 (5.9)	0	1 (5.9)	0	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Varicella zoster virus infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	10 (58.8)	3 (17.6)	6 (35.3)	1 (5.9)	0
Blood immunoglobulin a decreased	6 (35.3)	5 (29.4)	0	1 (5.9)	0
Hypogammaglobulinaemia	6 (35.3)	0	6 (35.3)	0	0
Blood immunoglobulin m decreased	5 (29.4)	4 (23.5)	0	1 (5.9)	0
Serious neurological adverse reactions					
-Total	6 (35.3)	5 (29.4)	0	1 (5.9)	0
Confusional state	2 (11.8)	2 (11.8)	0	0	0
Mental status changes	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Agitation	1 (5.9)	1 (5.9)	0	0	0
Irritability	1 (5.9)	1 (5.9)	0	0	0
Lethargy	1 (5.9)	1 (5.9)	0	0	0
Tremor	1 (5.9)	1 (5.9)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232m
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	80 (98.8)	0	3 (3.7)	16 (19.8)	61 (75.3)
Cytokine Release Syndrome					
-Total	50 (61.7)	5 (6.2)	12 (14.8)	12 (14.8)	21 (25.9)
Cytokine release syndrome	50 (61.7)	5 (6.2)	13 (16.0)	12 (14.8)	20 (24.7)
Haemophagocytic lymphohistiocytosis	6 (7.4)	1 (1.2)	1 (1.2)	2 (2.5)	2 (2.5)
Hematological disorders including cytopenias					
-Total	64 (79.0)	0	1 (1.2)	19 (23.5)	44 (54.3)
Anaemia	38 (46.9)	3 (3.7)	7 (8.6)	27 (33.3)	1 (1.2)
Febrile neutropenia	36 (44.4)	0	0	33 (40.7)	3 (3.7)
White blood cell count decreased	26 (32.1)	1 (1.2)	1 (1.2)	1 (1.2)	23 (28.4)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	23 (28.4)	2 (2.5)	1 (1.2)	2 (2.5)	18 (22.2)
Neutrophil count decreased	22 (27.2)	1 (1.2)	0	2 (2.5)	19 (23.5)
Neutropenia	20 (24.7)	1 (1.2)	2 (2.5)	3 (3.7)	14 (17.3)
Lymphocyte count decreased	17 (21.0)	1 (1.2)	0	5 (6.2)	11 (13.6)
Thrombocytopenia	15 (18.5)	1 (1.2)	1 (1.2)	5 (6.2)	8 (9.9)
Pancytopenia	6 (7.4)	0	1 (1.2)	3 (3.7)	2 (2.5)
Leukopenia	5 (6.2)	0	0	1 (1.2)	4 (4.9)
Lymphopenia	2 (2.5)	0	0	0	2 (2.5)
Agranulocytosis	1 (1.2)	0	0	1 (1.2)	0
Eosinophil count decreased	1 (1.2)	1 (1.2)	0	0	0
Haematocrit decreased	1 (1.2)	1 (1.2)	0	0	0
Myelodysplastic syndrome	1 (1.2)	0	0	1 (1.2)	0
Neutropenic infection	1 (1.2)	0	0	1 (1.2)	0
Red blood cell count decreased	1 (1.2)	1 (1.2)	0	0	0
Infections					
-Total	72 (88.9)	3 (3.7)	12 (14.8)	33 (40.7)	24 (29.6)
Upper respiratory tract infection	12 (14.8)	4 (4.9)	6 (7.4)	2 (2.5)	0
Pneumonia	9 (11.1)	1 (1.2)	2 (2.5)	3 (3.7)	3 (3.7)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	9 (11.1)	0	7 (8.6)	2 (2.5)	0
Conjunctivitis	8 (9.9)	3 (3.7)	5 (6.2)	0	0
Sinusitis	8 (9.9)	0	5 (6.2)	3 (3.7)	0
Nasopharyngitis	7 (8.6)	4 (4.9)	3 (3.7)	0	0
Parainfluenzae virus infection	7 (8.6)	1 (1.2)	1 (1.2)	4 (4.9)	1 (1.2)
Bacteraemia	6 (7.4)	0	1 (1.2)	4 (4.9)	1 (1.2)
Gastroenteritis	6 (7.4)	3 (3.7)	1 (1.2)	2 (2.5)	0
Oral herpes	6 (7.4)	0	3 (3.7)	3 (3.7)	0
Staphylococcal bacteraemia	6 (7.4)	0	0	6 (7.4)	0
Staphylococcal infection	6 (7.4)	0	3 (3.7)	2 (2.5)	1 (1.2)
Urinary tract infection	5 (6.2)	0	3 (3.7)	2 (2.5)	0
Candida infection	4 (4.9)	0	3 (3.7)	0	1 (1.2)
Clostridium difficile infection	4 (4.9)	1 (1.2)	0	3 (3.7)	0
Device related infection	4 (4.9)	0	1 (1.2)	3 (3.7)	0
Herpes zoster	4 (4.9)	0	0	4 (4.9)	0
Nail infection	4 (4.9)	3 (3.7)	1 (1.2)	0	0
Otitis media	4 (4.9)	0	3 (3.7)	1 (1.2)	0
Paronychia	4 (4.9)	1 (1.2)	2 (2.5)	1 (1.2)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	4 (4.9)	0	2 (2.5)	2 (2.5)	0
Sepsis	4 (4.9)	0	0	1 (1.2)	3 (3.7)
Bronchitis	3 (3.7)	0	3 (3.7)	0	0
Bronchopulmonary aspergillosis	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Escherichia bacteraemia	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Fungal infection	3 (3.7)	0	3 (3.7)	0	0
Gastroenteritis viral	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Gingivitis	3 (3.7)	3 (3.7)	0	0	0
Localised infection	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Metapneumovirus infection	3 (3.7)	0	0	3 (3.7)	0
Oral candidiasis	3 (3.7)	0	3 (3.7)	0	0
Pneumonia fungal	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Respiratory syncytial virus infection	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Rhinitis	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Septic shock	3 (3.7)	0	0	0	3 (3.7)
Staphylococcal sepsis	3 (3.7)	0	0	0	3 (3.7)
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Bronchiolitis	2 (2.5)	0	0	2 (2.5)	0
Cellulitis	2 (2.5)	0	2 (2.5)	0	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Covid-19	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Cytomegalovirus infection reactivation	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Device related sepsis	2 (2.5)	0	0	2 (2.5)	0
Ear infection	2 (2.5)	0	2 (2.5)	0	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Herpes simplex	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Influenza	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Klebsiella bacteraemia	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Otitis externa	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (2.5)	0	2 (2.5)	0	0
Skin papilloma	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Staphylococcal skin infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Viral infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Abscess limb	1 (1.2)	0	0	1 (1.2)	0
Atypical pneumonia	1 (1.2)	1 (1.2)	0	0	0
Bacterial sepsis	1 (1.2)	0	0	0	1 (1.2)
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0
Cholecystitis infective	1 (1.2)	0	1 (1.2)	0	0
Coronavirus infection	1 (1.2)	0	0	1 (1.2)	0
Covid-19 pneumonia	1 (1.2)	0	0	0	1 (1.2)
Cystitis	1 (1.2)	0	1 (1.2)	0	0
Device related bacteraemia	1 (1.2)	0	1 (1.2)	0	0
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Ear, nose and throat infection	1 (1.2)	0	1 (1.2)	0	0
Enterobacter infection	1 (1.2)	0	0	1 (1.2)	0
Enterovirus infection	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epstein-barr virus infection reactivation	1 (1.2)	1 (1.2)	0	0	0
Folliculitis	1 (1.2)	0	1 (1.2)	0	0
Fungaemia	1 (1.2)	0	0	0	1 (1.2)
Fungal sepsis	1 (1.2)	0	0	0	1 (1.2)
Fungal skin infection	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis adenovirus	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis clostridial	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis escherichia coli	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis norovirus	1 (1.2)	1 (1.2)	0	0	0
Gastroenteritis salmonella	1 (1.2)	0	0	1 (1.2)	0
Gastrointestinal infection	1 (1.2)	1 (1.2)	0	0	0
Granulicatella infection	1 (1.2)	0	0	1 (1.2)	0
Haemophilus bacteraemia	1 (1.2)	0	0	0	1 (1.2)
Herpes virus infection	1 (1.2)	0	1 (1.2)	0	0
Klebsiella infection	1 (1.2)	0	0	1 (1.2)	0
Mastoiditis	1 (1.2)	0	0	1 (1.2)	0
Meningitis bacterial	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (1.2)	0	0	1 (1.2)	0
Molluscum contagiosum	1 (1.2)	1 (1.2)	0	0	0
Myringitis	1 (1.2)	1 (1.2)	0	0	0
Neutropenic infection	1 (1.2)	0	0	1 (1.2)	0
Ophthalmic herpes zoster	1 (1.2)	0	1 (1.2)	0	0
Otitis media acute	1 (1.2)	0	1 (1.2)	0	0
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis streptococcal	1 (1.2)	0	0	1 (1.2)	0
Pneumonia respiratory syncytial viral	1 (1.2)	0	0	1 (1.2)	0
Pneumonia viral	1 (1.2)	0	0	1 (1.2)	0
Post herpetic neuralgia	1 (1.2)	0	0	1 (1.2)	0
Pseudomonal bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Respiratory tract infection viral	1 (1.2)	0	1 (1.2)	0	0
Salmonellosis	1 (1.2)	0	1 (1.2)	0	0
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Sinusitis fungal	1 (1.2)	0	0	1 (1.2)	0
Soft tissue infection	1 (1.2)	0	0	1 (1.2)	0
Stomatococcal infection	1 (1.2)	0	0	0	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (1.2)	0	1 (1.2)	0	0
Syphilis	1 (1.2)	0	1 (1.2)	0	0
Systemic candida	1 (1.2)	0	0	1 (1.2)	0
Tonsillitis	1 (1.2)	0	1 (1.2)	0	0
Urinary tract infection pseudomonal	1 (1.2)	0	1 (1.2)	0	0
Varicella zoster virus infection	1 (1.2)	0	1 (1.2)	0	0
Viral haemorrhagic cystitis	1 (1.2)	0	0	1 (1.2)	0
Viral skin infection	1 (1.2)	1 (1.2)	0	0	0
Viral upper respiratory tract infection	1 (1.2)	0	0	1 (1.2)	0
Vulval cellulitis	1 (1.2)	0	0	1 (1.2)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	45 (55.6)	2 (2.5)	29 (35.8)	14 (17.3)	0
Hypogammaglobulinaemia	35 (43.2)	2 (2.5)	24 (29.6)	9 (11.1)	0
Blood immunoglobulin g decreased	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Immunodeficiency	4 (4.9)	0	0	4 (4.9)	0
Blood immunoglobulin m decreased	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (1.2)	0	1 (1.2)	0	0
Blood immunoglobulin a decreased	1 (1.2)	0	1 (1.2)	0	0
Selective igg subclass deficiency	1 (1.2)	0	1 (1.2)	0	0
Serious neurological adverse reactions					
-Total	35 (43.2)	8 (9.9)	11 (13.6)	16 (19.8)	0
Encephalopathy	9 (11.1)	1 (1.2)	3 (3.7)	5 (6.2)	0
Delirium	8 (9.9)	2 (2.5)	3 (3.7)	3 (3.7)	0
Agitation	6 (7.4)	3 (3.7)	3 (3.7)	0	0
Seizure	6 (7.4)	0	3 (3.7)	3 (3.7)	0
Somnolence	6 (7.4)	2 (2.5)	2 (2.5)	2 (2.5)	0
Confusional state	5 (6.2)	5 (6.2)	0	0	0
Mental status changes	5 (6.2)	0	2 (2.5)	3 (3.7)	0
Tremor	5 (6.2)	4 (4.9)	1 (1.2)	0	0
Cognitive disorder	4 (4.9)	0	2 (2.5)	2 (2.5)	0
Hallucination	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Irritability	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Lethargy	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Dysarthria	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Affect lability	1 (1.2)	0	1 (1.2)	0	0
Amnesia	1 (1.2)	0	1 (1.2)	0	0
Aphasia	1 (1.2)	1 (1.2)	0	0	0
Depressed level of consciousness	1 (1.2)	0	0	1 (1.2)	0
Disturbance in attention	1 (1.2)	1 (1.2)	0	0	0
Dysphagia	1 (1.2)	0	0	1 (1.2)	0
Generalised tonic-clonic seizure	1 (1.2)	0	1 (1.2)	0	0
Hallucination, visual	1 (1.2)	0	1 (1.2)	0	0
Memory impairment	1 (1.2)	0	1 (1.2)	0	0
Mood altered	1 (1.2)	1 (1.2)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.2)	0	1 (1.2)	0	0
Restlessness	1 (1.2)	0	1 (1.2)	0	0
Sluggishness	1 (1.2)	0	1 (1.2)	0	0
Social avoidant behaviour	1 (1.2)	0	1 (1.2)	0	0
Tumour Lysis Syndrome					
-Total	6 (7.4)	0	0	4 (4.9)	2 (2.5)

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	6 (7.4)	0	0	4 (4.9)	2 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232n
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	0	3 (10.7)	10 (35.7)	15 (53.6)
Cytokine Release Syndrome					
-Total	18 (64.3)	3 (10.7)	7 (25.0)	3 (10.7)	5 (17.9)
Cytokine release syndrome	18 (64.3)	3 (10.7)	8 (28.6)	3 (10.7)	4 (14.3)
Haemophagocytic lymphohistiocytosis	2 (7.1)	0	0	0	2 (7.1)
Hematological disorders including cytopenias					
-Total	23 (82.1)	0	0	10 (35.7)	13 (46.4)
Anaemia	14 (50.0)	3 (10.7)	2 (7.1)	9 (32.1)	0
Febrile neutropenia	13 (46.4)	0	0	12 (42.9)	1 (3.6)
Neutrophil count decreased	9 (32.1)	0	1 (3.6)	2 (7.1)	6 (21.4)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	9 (32.1)	1 (3.6)	2 (7.1)	1 (3.6)	5 (17.9)
Lymphocyte count decreased	7 (25.0)	0	0	5 (17.9)	2 (7.1)
Neutropenia	7 (25.0)	0	1 (3.6)	1 (3.6)	5 (17.9)
Platelet count decreased	7 (25.0)	2 (7.1)	1 (3.6)	0	4 (14.3)
Thrombocytopenia	7 (25.0)	0	1 (3.6)	3 (10.7)	3 (10.7)
Leukopenia	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	23 (82.1)	2 (7.1)	9 (32.1)	8 (28.6)	4 (14.3)
Upper respiratory tract infection	7 (25.0)	3 (10.7)	2 (7.1)	2 (7.1)	0
Conjunctivitis	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Sinusitis	5 (17.9)	0	4 (14.3)	1 (3.6)	0
Rhinovirus infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Staphylococcal bacteraemia	4 (14.3)	0	0	4 (14.3)	0
Parainfluenzae virus infection	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Pneumonia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Respiratory syncytial virus infection	3 (10.7)	0	1 (3.6)	2 (7.1)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Encephalitis	2 (7.1)	0	0	0	2 (7.1)
Fungal infection	2 (7.1)	0	2 (7.1)	0	0
Localised infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Otitis media	2 (7.1)	0	2 (7.1)	0	0
Abscess limb	1 (3.6)	0	0	1 (3.6)	0
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Catheter site infection	1 (3.6)	0	1 (3.6)	0	0
Cellulitis	1 (3.6)	0	1 (3.6)	0	0
Clostridium difficile colitis	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)
Device related bacteraemia	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	1 (3.6)	0	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Epstein-barr virus infection	1 (3.6)	0	1 (3.6)	0	0
Fungal skin infection	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis escherichia coli	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis salmonella	1 (3.6)	0	0	1 (3.6)	0
Gastrointestinal infection	1 (3.6)	1 (3.6)	0	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0
Influenza	1 (3.6)	0	0	0	1 (3.6)
Metapneumovirus infection	1 (3.6)	0	0	1 (3.6)	0
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Nail infection	1 (3.6)	1 (3.6)	0	0	0
Nasopharyngitis	1 (3.6)	0	1 (3.6)	0	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Otitis externa	1 (3.6)	0	1 (3.6)	0	0
Otitis media acute	1 (3.6)	0	1 (3.6)	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	1 (3.6)	0
Pseudomonal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Respiratory tract infection	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Rhinitis	1 (3.6)	0	1 (3.6)	0	0
Sepsis	1 (3.6)	0	0	1 (3.6)	0
Sialoadenitis	1 (3.6)	0	0	1 (3.6)	0
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Tinea pedis	1 (3.6)	1 (3.6)	0	0	0
Tonsillitis	1 (3.6)	0	1 (3.6)	0	0
Urinary tract infection	1 (3.6)	0	1 (3.6)	0	0
Varicella zoster virus infection	1 (3.6)	0	1 (3.6)	0	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Vulval cellulitis	1 (3.6)	0	0	1 (3.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	21 (75.0)	1 (3.6)	13 (46.4)	7 (25.0)	0
Hypogammaglobulinaemia	17 (60.7)	1 (3.6)	12 (42.9)	4 (14.3)	0
Blood immunoglobulin g decreased	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Blood immunoglobulin m decreased	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Immunodeficiency	2 (7.1)	0	0	2 (7.1)	0
B-cell aplasia	1 (3.6)	0	1 (3.6)	0	0
Serious neurological adverse reactions					
-Total	11 (39.3)	4 (14.3)	3 (10.7)	4 (14.3)	0
Seizure	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Cognitive disorder	2 (7.1)	0	2 (7.1)	0	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Encephalopathy	2 (7.1)	0	0	2 (7.1)	0
Irritability	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Dysarthria	1 (3.6)	0	1 (3.6)	0	0
Lethargy	1 (3.6)	1 (3.6)	0	0	0
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Somnolence	1 (3.6)	1 (3.6)	0	0	0
Tremor	1 (3.6)	1 (3.6)	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.6)	0	0	1 (3.6)	0
Tumour lysis syndrome	1 (3.6)	0	0	1 (3.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232n
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (98.6)	0	2 (2.9)	13 (18.6)	54 (77.1)
Cytokine Release Syndrome					
-Total	43 (61.4)	2 (2.9)	10 (14.3)	14 (20.0)	17 (24.3)
Cytokine release syndrome	43 (61.4)	2 (2.9)	10 (14.3)	14 (20.0)	17 (24.3)
Haemophagocytic lymphohistiocytosis	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Hematological disorders including cytopenias					
-Total	54 (77.1)	1 (1.4)	1 (1.4)	14 (20.0)	38 (54.3)
Anaemia	32 (45.7)	3 (4.3)	10 (14.3)	18 (25.7)	1 (1.4)
Febrile neutropenia	32 (45.7)	0	0	30 (42.9)	2 (2.9)
White blood cell count decreased	26 (37.1)	2 (2.9)	1 (1.4)	0	23 (32.9)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	25 (35.7)	4 (5.7)	1 (1.4)	6 (8.6)	14 (20.0)
Neutrophil count decreased	22 (31.4)	2 (2.9)	1 (1.4)	1 (1.4)	18 (25.7)
Lymphocyte count decreased	17 (24.3)	1 (1.4)	1 (1.4)	4 (5.7)	11 (15.7)
Neutropenia	15 (21.4)	1 (1.4)	1 (1.4)	2 (2.9)	11 (15.7)
Thrombocytopenia	8 (11.4)	1 (1.4)	0	2 (2.9)	5 (7.1)
Pancytopenia	4 (5.7)	0	1 (1.4)	1 (1.4)	2 (2.9)
Leukopenia	3 (4.3)	0	0	0	3 (4.3)
Lymphopenia	2 (2.9)	0	0	0	2 (2.9)
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Eosinophil count decreased	1 (1.4)	1 (1.4)	0	0	0
Haematocrit decreased	1 (1.4)	1 (1.4)	0	0	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Red blood cell count decreased	1 (1.4)	1 (1.4)	0	0	0
Infections					
-Total	60 (85.7)	3 (4.3)	4 (5.7)	32 (45.7)	21 (30.0)
Nasopharyngitis	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Oral herpes	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	7 (10.0)	1 (1.4)	1 (1.4)	3 (4.3)	2 (2.9)
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	4 (5.7)	1 (1.4)	0
Bacteraemia	6 (8.6)	0	1 (1.4)	4 (5.7)	1 (1.4)
Gastroenteritis	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Rhinovirus infection	5 (7.1)	0	5 (7.1)	0	0
Acute sinusitis	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Candida infection	4 (5.7)	0	3 (4.3)	0	1 (1.4)
Conjunctivitis	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Herpes zoster	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Parainfluenzae virus infection	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)
Paronychia	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Sinusitis	4 (5.7)	0	2 (2.9)	2 (2.9)	0
Staphylococcal bacteraemia	4 (5.7)	0	0	4 (5.7)	0
Urinary tract infection	4 (5.7)	0	2 (2.9)	2 (2.9)	0
Bronchitis	3 (4.3)	0	3 (4.3)	0	0
Device related infection	3 (4.3)	0	0	3 (4.3)	0
Escherichia bacteraemia	3 (4.3)	0	0	2 (2.9)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Nail infection	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Pneumonia fungal	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Respiratory tract infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Sepsis	3 (4.3)	0	0	0	3 (4.3)
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Staphylococcal sepsis	3 (4.3)	0	0	0	3 (4.3)
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0
Bk virus infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Bronchiolitis	2 (2.9)	0	0	2 (2.9)	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Clostridium difficile infection	2 (2.9)	0	0	2 (2.9)	0
Covid-19	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Cytomegalovirus infection reactivation	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Device related sepsis	2 (2.9)	0	0	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Gingivitis	2 (2.9)	2 (2.9)	0	0	0
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Influenza	2 (2.9)	0	2 (2.9)	0	0
Klebsiella bacteraemia	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Otitis externa	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Rhinitis	2 (2.9)	2 (2.9)	0	0	0
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Fungal infection	1 (1.4)	0	1 (1.4)	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Peritonitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	34 (48.6)	4 (5.7)	22 (31.4)	8 (11.4)	0
Hypogammaglobulinaemia	24 (34.3)	1 (1.4)	18 (25.7)	5 (7.1)	0
Blood immunoglobulin a decreased	5 (7.1)	4 (5.7)	0	1 (1.4)	0
Blood immunoglobulin m decreased	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Serious neurological adverse reactions					
-Total	30 (42.9)	9 (12.9)	8 (11.4)	13 (18.6)	0
Delirium	8 (11.4)	2 (2.9)	3 (4.3)	3 (4.3)	0
Agitation	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Encephalopathy	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Mental status changes	7 (10.0)	1 (1.4)	2 (2.9)	4 (5.7)	0
Confusional state	5 (7.1)	5 (7.1)	0	0	0
Somnolence	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Seizure	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Cognitive disorder	2 (2.9)	0	0	2 (2.9)	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	6 (8.6)	0	0	4 (5.7)	2 (2.9)
Tumour lysis syndrome	6 (8.6)	0	0	4 (5.7)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232o
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	0	3 (27.3)	8 (72.7)
Cytokine Release Syndrome					
-Total	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hematological disorders including cytopenias					
-Total	9 (81.8)	0	0	2 (18.2)	7 (63.6)
Febrile neutropenia	4 (36.4)	0	0	4 (36.4)	0
Platelet count decreased	4 (36.4)	0	0	0	4 (36.4)
White blood cell count decreased	3 (27.3)	0	0	0	3 (27.3)
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Leukopenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Thrombocytopenia	1 (9.1)	0	1 (9.1)	0	0
Infections					
-Total	10 (90.9)	0	5 (45.5)	3 (27.3)	2 (18.2)
Sinusitis	3 (27.3)	0	3 (27.3)	0	0
Paronychia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Urinary tract infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Abscess limb	1 (9.1)	0	0	1 (9.1)	0
Catheter site infection	1 (9.1)	0	1 (9.1)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Device related bacteraemia	1 (9.1)	0	1 (9.1)	0	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Fungal infection	1 (9.1)	0	1 (9.1)	0	0
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Post herpetic neuralgia	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Rhinitis	1 (9.1)	1 (9.1)	0	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Tonsillitis	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (63.6)	1 (9.1)	3 (27.3)	3 (27.3)	0
Hypogammaglobulinaemia	7 (63.6)	1 (9.1)	3 (27.3)	3 (27.3)	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Seizure	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0
Dysarthria	1 (9.1)	0	1 (9.1)	0	0
Memory impairment	1 (9.1)	0	1 (9.1)	0	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232o
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	86 (98.9)	0	5 (5.7)	20 (23.0)	61 (70.1)
Cytokine Release Syndrome					
-Total	55 (63.2)	4 (4.6)	14 (16.1)	16 (18.4)	21 (24.1)
Cytokine release syndrome	55 (63.2)	4 (4.6)	15 (17.2)	16 (18.4)	20 (23.0)
Haemophagocytic lymphohistiocytosis	6 (6.9)	1 (1.1)	1 (1.1)	2 (2.3)	2 (2.3)
Hematological disorders including cytopenias					
-Total	68 (78.2)	1 (1.1)	1 (1.1)	22 (25.3)	44 (50.6)
Anaemia	44 (50.6)	6 (6.9)	11 (12.6)	26 (29.9)	1 (1.1)
Febrile neutropenia	41 (47.1)	0	0	38 (43.7)	3 (3.4)
White blood cell count decreased	32 (36.8)	3 (3.4)	3 (3.4)	1 (1.1)	25 (28.7)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	29 (33.3)	2 (2.3)	2 (2.3)	3 (3.4)	22 (25.3)
Platelet count decreased	28 (32.2)	6 (6.9)	2 (2.3)	6 (6.9)	14 (16.1)
Lymphocyte count decreased	22 (25.3)	1 (1.1)	1 (1.1)	9 (10.3)	11 (12.6)
Neutropenia	20 (23.0)	1 (1.1)	2 (2.3)	3 (3.4)	14 (16.1)
Thrombocytopenia	14 (16.1)	1 (1.1)	0	5 (5.7)	8 (9.2)
Leukopenia	5 (5.7)	0	0	1 (1.1)	4 (4.6)
Pancytopenia	5 (5.7)	0	1 (1.1)	2 (2.3)	2 (2.3)
Lymphopenia	2 (2.3)	0	0	0	2 (2.3)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	73 (83.9)	5 (5.7)	8 (9.2)	37 (42.5)	23 (26.4)
Upper respiratory tract infection	13 (14.9)	5 (5.7)	6 (6.9)	2 (2.3)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	9 (10.3)	1 (1.1)	1 (1.1)	4 (4.6)	3 (3.4)
Conjunctivitis	8 (9.2)	3 (3.4)	5 (5.7)	0	0
Nasopharyngitis	8 (9.2)	5 (5.7)	3 (3.4)	0	0
Rhinovirus infection	8 (9.2)	0	7 (8.0)	1 (1.1)	0
Staphylococcal bacteraemia	8 (9.2)	0	0	8 (9.2)	0
Gastroenteritis	7 (8.0)	4 (4.6)	1 (1.1)	2 (2.3)	0
Oral herpes	7 (8.0)	1 (1.1)	3 (3.4)	3 (3.4)	0
Bacteraemia	6 (6.9)	0	1 (1.1)	4 (4.6)	1 (1.1)
Parainfluenzae virus infection	6 (6.9)	1 (1.1)	1 (1.1)	3 (3.4)	1 (1.1)
Sinusitis	6 (6.9)	0	3 (3.4)	3 (3.4)	0
Staphylococcal infection	6 (6.9)	0	2 (2.3)	3 (3.4)	1 (1.1)
Otitis media	5 (5.7)	0	4 (4.6)	1 (1.1)	0
Acute sinusitis	4 (4.6)	0	3 (3.4)	1 (1.1)	0
Candida infection	4 (4.6)	0	3 (3.4)	0	1 (1.1)
Clostridium difficile infection	4 (4.6)	1 (1.1)	0	3 (3.4)	0
Herpes zoster	4 (4.6)	0	1 (1.1)	3 (3.4)	0
Nail infection	4 (4.6)	3 (3.4)	1 (1.1)	0	0
Bronchitis	3 (3.4)	0	3 (3.4)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Device related infection	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Ear infection	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Escherichia bacteraemia	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Gastroenteritis viral	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Gingivitis	3 (3.4)	3 (3.4)	0	0	0
Influenza	3 (3.4)	0	2 (2.3)	0	1 (1.1)
Localised infection	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Metapneumovirus infection	3 (3.4)	0	0	3 (3.4)	0
Oral candidiasis	3 (3.4)	0	3 (3.4)	0	0
Otitis externa	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Paronychia	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Pneumonia fungal	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Respiratory tract infection	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Sepsis	3 (3.4)	0	0	0	3 (3.4)
Septic shock	3 (3.4)	0	0	0	3 (3.4)
Skin infection	3 (3.4)	0	3 (3.4)	0	0
Urinary tract infection	3 (3.4)	0	2 (2.3)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	2 (2.3)	0	0	2 (2.3)	0
Bk virus infection	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.3)	0	0	2 (2.3)	0
Catheter site infection	2 (2.3)	0	0	2 (2.3)	0
Cellulitis	2 (2.3)	0	2 (2.3)	0	0
Clostridium difficile colitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Covid-19	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Device related sepsis	2 (2.3)	0	0	2 (2.3)	0
Encephalitis viral	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Fungal infection	2 (2.3)	0	2 (2.3)	0	0
Herpes simplex	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.3)	0	0	2 (2.3)	0
Klebsiella bacteraemia	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Oral infection	2 (2.3)	0	2 (2.3)	0	0
Pneumocystis jirovecii pneumonia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Respiratory syncytial virus infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Rhinitis	2 (2.3)	1 (1.1)	1 (1.1)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	2 (2.3)	0	0	2 (2.3)	0
Skin papilloma	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Staphylococcal sepsis	2 (2.3)	0	0	0	2 (2.3)
Tinea pedis	2 (2.3)	2 (2.3)	0	0	0
Viral infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	1 (1.1)	0	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	48 (55.2)	4 (4.6)	32 (36.8)	12 (13.8)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	34 (39.1)	1 (1.1)	27 (31.0)	6 (6.9)	0
Blood immunoglobulin a decreased	7 (8.0)	5 (5.7)	1 (1.1)	1 (1.1)	0
Blood immunoglobulin m decreased	7 (8.0)	4 (4.6)	1 (1.1)	2 (2.3)	0
Blood immunoglobulin g decreased	4 (4.6)	1 (1.1)	3 (3.4)	0	0
Immunodeficiency	4 (4.6)	0	0	4 (4.6)	0
Immunoglobulins decreased	2 (2.3)	0	2 (2.3)	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	38 (43.7)	12 (13.8)	10 (11.5)	16 (18.4)	0
Encephalopathy	9 (10.3)	1 (1.1)	3 (3.4)	5 (5.7)	0
Delirium	8 (9.2)	2 (2.3)	3 (3.4)	3 (3.4)	0
Agitation	7 (8.0)	4 (4.6)	3 (3.4)	0	0
Mental status changes	7 (8.0)	1 (1.1)	2 (2.3)	4 (4.6)	0
Confusional state	6 (6.9)	6 (6.9)	0	0	0
Somnolence	6 (6.9)	2 (2.3)	2 (2.3)	2 (2.3)	0
Tremor	6 (6.9)	5 (5.7)	1 (1.1)	0	0
Cognitive disorder	4 (4.6)	0	2 (2.3)	2 (2.3)	0
Irritability	4 (4.6)	3 (3.4)	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	4 (4.6)	3 (3.4)	1 (1.1)	0	0
Seizure	4 (4.6)	0	2 (2.3)	2 (2.3)	0
Hallucination	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Muscular weakness	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	7 (8.0)	0	0	5 (5.7)	2 (2.3)
Tumour lysis syndrome	7 (8.0)	0	0	5 (5.7)	2 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232p
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Cytokine Release Syndrome					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	0	3 (42.9)
Cytokine release syndrome	6 (85.7)	2 (28.6)	1 (14.3)	0	3 (42.9)
Haemophagocytic lymphohistiocytosis	1 (14.3)	0	1 (14.3)	0	0
Hematological disorders including cytopenias					
-Total	6 (85.7)	0	0	2 (28.6)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	0	1 (14.3)	3 (42.9)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Anaemia	3 (42.9)	0	1 (14.3)	2 (28.6)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Febrile neutropenia	3 (42.9)	0	0	3 (42.9)	0
Lymphocyte count decreased	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Platelet count decreased	3 (42.9)	0	1 (14.3)	0	2 (28.6)
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Infections					
-Total	7 (100)	0	2 (28.6)	5 (71.4)	0
Upper respiratory tract infection	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Otitis media	2 (28.6)	0	2 (28.6)	0	0
Bronchiolitis	1 (14.3)	0	0	1 (14.3)	0
Bronchitis	1 (14.3)	0	1 (14.3)	0	0
Cellulitis	1 (14.3)	0	1 (14.3)	0	0
Ear infection	1 (14.3)	0	1 (14.3)	0	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Folliculitis	1 (14.3)	0	1 (14.3)	0	0
Gastroenteritis viral	1 (14.3)	0	1 (14.3)	0	0
Metapneumovirus infection	1 (14.3)	0	0	1 (14.3)	0
Nail infection	1 (14.3)	0	1 (14.3)	0	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Paronychia	1 (14.3)	1 (14.3)	0	0	0
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0
Pneumonia respiratory syncytial viral	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	1 (14.3)	0	0
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Staphylococcal infection	1 (14.3)	0	1 (14.3)	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	4 (57.1)	0	2 (28.6)	2 (28.6)	0
Hypogammaglobulinaemia	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Blood immunoglobulin a decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin g decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	0	0	1 (14.3)	0
Serious neurological adverse reactions					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (14.3)	0	1 (14.3)	0	0
Confusional state	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Encephalopathy	1 (14.3)	0	0	1 (14.3)	0
Generalised tonic-clonic seizure	1 (14.3)	0	1 (14.3)	0	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Somnolence	1 (14.3)	0	0	1 (14.3)	0
Tremor	1 (14.3)	0	1 (14.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232p
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	90 (98.9)	0	5 (5.5)	22 (24.2)	63 (69.2)
Cytokine Release Syndrome					
-Total	55 (60.4)	3 (3.3)	16 (17.6)	17 (18.7)	19 (20.9)
Cytokine release syndrome	55 (60.4)	3 (3.3)	17 (18.7)	17 (18.7)	18 (19.8)
Haemophagocytic lymphohistiocytosis	5 (5.5)	1 (1.1)	0	2 (2.2)	2 (2.2)
Hematological disorders including cytopenias					
-Total	71 (78.0)	1 (1.1)	1 (1.1)	22 (24.2)	47 (51.6)
Anaemia	43 (47.3)	6 (6.6)	11 (12.1)	25 (27.5)	1 (1.1)
Febrile neutropenia	42 (46.2)	0	0	39 (42.9)	3 (3.3)
White blood cell count decreased	31 (34.1)	3 (3.3)	3 (3.3)	1 (1.1)	24 (26.4)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	29 (31.9)	6 (6.6)	1 (1.1)	6 (6.6)	16 (17.6)
Neutrophil count decreased	27 (29.7)	2 (2.2)	2 (2.2)	2 (2.2)	21 (23.1)
Lymphocyte count decreased	21 (23.1)	1 (1.1)	1 (1.1)	7 (7.7)	12 (13.2)
Neutropenia	21 (23.1)	0	2 (2.2)	3 (3.3)	16 (17.6)
Thrombocytopenia	15 (16.5)	1 (1.1)	1 (1.1)	5 (5.5)	8 (8.8)
Leukopenia	6 (6.6)	0	0	1 (1.1)	5 (5.5)
Pancytopenia	6 (6.6)	0	1 (1.1)	3 (3.3)	2 (2.2)
Lymphopenia	2 (2.2)	0	0	0	2 (2.2)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Infections					
-Total	76 (83.5)	5 (5.5)	11 (12.1)	35 (38.5)	25 (27.5)
Upper respiratory tract infection	10 (11.0)	4 (4.4)	4 (4.4)	2 (2.2)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	9 (9.9)	3 (3.3)	6 (6.6)	0	0
Pneumonia	9 (9.9)	1 (1.1)	1 (1.1)	4 (4.4)	3 (3.3)
Rhinovirus infection	8 (8.8)	0	6 (6.6)	2 (2.2)	0
Sinusitis	8 (8.8)	0	5 (5.5)	3 (3.3)	0
Staphylococcal bacteraemia	8 (8.8)	0	0	8 (8.8)	0
Gastroenteritis	7 (7.7)	4 (4.4)	1 (1.1)	2 (2.2)	0
Nasopharyngitis	7 (7.7)	4 (4.4)	3 (3.3)	0	0
Oral herpes	7 (7.7)	1 (1.1)	3 (3.3)	3 (3.3)	0
Parainfluenzae virus infection	7 (7.7)	1 (1.1)	1 (1.1)	4 (4.4)	1 (1.1)
Bacteraemia	6 (6.6)	0	1 (1.1)	4 (4.4)	1 (1.1)
Staphylococcal infection	6 (6.6)	0	2 (2.2)	3 (3.3)	1 (1.1)
Herpes zoster	5 (5.5)	0	1 (1.1)	4 (4.4)	0
Urinary tract infection	5 (5.5)	0	3 (3.3)	2 (2.2)	0
Acute sinusitis	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Candida infection	4 (4.4)	0	3 (3.3)	0	1 (1.1)
Clostridium difficile infection	4 (4.4)	1 (1.1)	0	3 (3.3)	0
Device related infection	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Paronychia	4 (4.4)	0	3 (3.3)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Bronchopulmonary aspergillosis	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Fungal infection	3 (3.3)	0	3 (3.3)	0	0
Gingivitis	3 (3.3)	3 (3.3)	0	0	0
Influenza	3 (3.3)	0	2 (2.2)	0	1 (1.1)
Localised infection	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Nail infection	3 (3.3)	3 (3.3)	0	0	0
Oral candidiasis	3 (3.3)	0	3 (3.3)	0	0
Otitis media	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Pneumonia fungal	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Respiratory syncytial virus infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Rhinitis	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Septic shock	3 (3.3)	0	0	0	3 (3.3)
Staphylococcal sepsis	3 (3.3)	0	0	0	3 (3.3)
Adenovirus infection	2 (2.2)	0	0	2 (2.2)	0
Bk virus infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	2 (2.2)	0	2 (2.2)	0	0
Clostridium difficile colitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Covid-19	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Device related sepsis	2 (2.2)	0	0	2 (2.2)	0
Ear infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Encephalitis	2 (2.2)	0	0	0	2 (2.2)
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Escherichia bacteraemia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fungal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Herpes simplex	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.2)	0	0	2 (2.2)	0
Klebsiella bacteraemia	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Metapneumovirus infection	2 (2.2)	0	0	2 (2.2)	0
Oral infection	2 (2.2)	0	2 (2.2)	0	0
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	2 (2.2)	0	0	2 (2.2)	0
Skin infection	2 (2.2)	0	2 (2.2)	0	0
Skin papilloma	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Staphylococcal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.2)	2 (2.2)	0	0	0
Varicella zoster virus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	51 (56.0)	5 (5.5)	33 (36.3)	13 (14.3)	0
Hypogammaglobulinaemia	38 (41.8)	2 (2.2)	28 (30.8)	8 (8.8)	0
Blood immunoglobulin a decreased	6 (6.6)	5 (5.5)	0	1 (1.1)	0
Blood immunoglobulin m decreased	6 (6.6)	4 (4.4)	1 (1.1)	1 (1.1)	0
Immunodeficiency	4 (4.4)	0	0	4 (4.4)	0
Blood immunoglobulin g decreased	3 (3.3)	0	3 (3.3)	0	0
Immunoglobulins decreased	2 (2.2)	0	2 (2.2)	0	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Serious neurological adverse reactions					
-Total	39 (42.9)	12 (13.2)	11 (12.1)	16 (17.6)	0
Encephalopathy	8 (8.8)	1 (1.1)	3 (3.3)	4 (4.4)	0
Delirium	7 (7.7)	2 (2.2)	2 (2.2)	3 (3.3)	0
Agitation	6 (6.6)	4 (4.4)	2 (2.2)	0	0
Confusional state	6 (6.6)	6 (6.6)	0	0	0
Mental status changes	6 (6.6)	1 (1.1)	2 (2.2)	3 (3.3)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	6 (6.6)	0	3 (3.3)	3 (3.3)	0
Somnolence	5 (5.5)	2 (2.2)	2 (2.2)	1 (1.1)	0
Tremor	5 (5.5)	5 (5.5)	0	0	0
Cognitive disorder	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Lethargy	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Hallucination	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Irritability	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Dysarthria	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	6 (6.6)	0	0	4 (4.4)	2 (2.2)
Tumour lysis syndrome	6 (6.6)	0	0	4 (4.4)	2 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	0	7 (17.5)	33 (82.5)
Cytokine Release Syndrome					
-Total	31 (77.5)	3 (7.5)	7 (17.5)	10 (25.0)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	36 (90.0)	0	0	5 (12.5)	31 (77.5)
Anaemia	21 (52.5)	1 (2.5)	4 (10.0)	16 (40.0)	0
Febrile neutropenia	20 (50.0)	0	0	19 (47.5)	1 (2.5)
White blood cell count decreased	19 (47.5)	0	0	0	19 (47.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	18 (45.0)	0	1 (2.5)	2 (5.0)	15 (37.5)
Platelet count decreased	17 (42.5)	3 (7.5)	0	3 (7.5)	11 (27.5)
Neutrophil count decreased	16 (40.0)	1 (2.5)	0	1 (2.5)	14 (35.0)
Lymphocyte count decreased	12 (30.0)	0	0	2 (5.0)	10 (25.0)
Thrombocytopenia	6 (15.0)	0	0	1 (2.5)	5 (12.5)
Leukopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Pancytopenia	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Lymphopenia	2 (5.0)	0	0	0	2 (5.0)
Eosinophil count decreased	1 (2.5)	1 (2.5)	0	0	0
Haematocrit decreased	1 (2.5)	1 (2.5)	0	0	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Red blood cell count decreased	1 (2.5)	1 (2.5)	0	0	0
Infections					
-Total	39 (97.5)	4 (10.0)	5 (12.5)	19 (47.5)	11 (27.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Gastroenteritis	7 (17.5)	4 (10.0)	1 (2.5)	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Herpes zoster	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Parainfluenzae virus infection	5 (12.5)	1 (2.5)	0	3 (7.5)	1 (2.5)
Pneumonia	5 (12.5)	0	1 (2.5)	2 (5.0)	2 (5.0)
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0
Oral herpes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Respiratory tract infection	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Bacteraemia	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Bronchopulmonary aspergillosis	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Gingivitis	3 (7.5)	3 (7.5)	0	0	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Paronychia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Rhinitis	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Urinary tract infection	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	2 (5.0)	0	0	2 (5.0)	0
Cytomegalovirus infection reactivation	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Device related infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Escherichia bacteraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Fungal infection	2 (5.0)	0	2 (5.0)	0	0
Human herpesvirus 6 infection	2 (5.0)	0	0	2 (5.0)	0
Influenza	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Nail infection	2 (5.0)	2 (5.0)	0	0	0
Oral candidiasis	2 (5.0)	0	2 (5.0)	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal skin infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tinea pedis	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis adenovirus	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Haemophilus bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Stomatococcal infection	1 (2.5)	0	0	0	1 (2.5)
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral skin infection	1 (2.5)	1 (2.5)	0	0	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	29 (72.5)	2 (5.0)	14 (35.0)	13 (32.5)	0
Hypogammaglobulinaemia	22 (55.0)	1 (2.5)	13 (32.5)	8 (20.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	15 (37.5)	3 (7.5)	7 (17.5)	5 (12.5)	0
Agitation	3 (7.5)	3 (7.5)	0	0	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Seizure	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Affect lability	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	1 (2.5)	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0
Sluggishness	1 (2.5)	0	1 (2.5)	0	0
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	4 (10.0)	10 (25.0)	26 (65.0)
Cytokine Release Syndrome					
-Total	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hematological disorders including cytopenias					
-Total	33 (82.5)	1 (2.5)	1 (2.5)	15 (37.5)	16 (40.0)
Anaemia	22 (55.0)	5 (12.5)	8 (20.0)	8 (20.0)	1 (2.5)
Febrile neutropenia	21 (52.5)	0	0	20 (50.0)	1 (2.5)
White blood cell count decreased	15 (37.5)	2 (5.0)	3 (7.5)	1 (2.5)	9 (22.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	14 (35.0)	1 (2.5)	2 (5.0)	2 (5.0)	9 (22.5)
Platelet count decreased	14 (35.0)	3 (7.5)	2 (5.0)	3 (7.5)	6 (15.0)
Lymphocyte count decreased	11 (27.5)	0	1 (2.5)	7 (17.5)	3 (7.5)
Thrombocytopenia	8 (20.0)	1 (2.5)	1 (2.5)	4 (10.0)	2 (5.0)
Neutropenia	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
Agranulocytosis	1 (2.5)	0	0	1 (2.5)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Infections					
-Total	29 (72.5)	1 (2.5)	7 (17.5)	15 (37.5)	6 (15.0)
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0
Staphylococcal bacteraemia	6 (15.0)	0	0	6 (15.0)	0
Upper respiratory tract infection	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Conjunctivitis	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Pneumonia	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	2 (5.0)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	2 (5.0)	0	2 (5.0)	0	0
Bacteraemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bronchiolitis	2 (5.0)	0	0	2 (5.0)	0
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Candida infection	2 (5.0)	0	2 (5.0)	0	0
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gastroenteritis viral	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Metapneumovirus infection	2 (5.0)	0	0	2 (5.0)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oral herpes	2 (5.0)	0	2 (5.0)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Paronychia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Catheter site infection	1 (2.5)	0	1 (2.5)	0	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Epstein-barr virus infection reactivation	1 (2.5)	1 (2.5)	0	0	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes virus infection	1 (2.5)	0	1 (2.5)	0	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Nasopharyngitis	1 (2.5)	1 (2.5)	0	0	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Streptococcal sepsis	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Varicella zoster virus infection	1 (2.5)	0	1 (2.5)	0	0
Viral infection	1 (2.5)	0	1 (2.5)	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Vulval cellulitis	1 (2.5)	0	0	1 (2.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	26 (65.0)	3 (7.5)	21 (52.5)	2 (5.0)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	19 (47.5)	1 (2.5)	17 (42.5)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Blood immunoglobulin g decreased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Serious neurological adverse reactions					
-Total	22 (55.0)	10 (25.0)	4 (10.0)	8 (20.0)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Irritability	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Seizure	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Somnolence	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	2 (5.0)	2 (5.0)	0	0	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Tumour Lysis Syndrome					
-Total	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Tumour lysis syndrome	3 (7.5)	0	0	2 (5.0)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232q
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	0	1 (5.6)	6 (33.3)	10 (55.6)
Hematological disorders including cytopenias					
-Total	8 (44.4)	0	0	4 (22.2)	4 (22.2)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Infections					
-Total	15 (83.3)	0	1 (5.6)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0
Peritonitis	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Serious neurological adverse reactions					
-Total	4 (22.2)	0	0	4 (22.2)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Tumour Lysis Syndrome					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	1 (12.5)	2 (25.0)	5 (62.5)
Cytokine Release Syndrome					
-Total	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Hematological disorders including cytopenias					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Anaemia	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Febrile neutropenia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Infections					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	5 (62.5)	0	4 (50.0)	1 (12.5)	0
Hypogammaglobulinaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Serious neurological adverse reactions					
-Total	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Tremor	1 (12.5)	1 (12.5)	0	0	0

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-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	0	2 (6.7)	8 (26.7)	19 (63.3)
Cytokine Release Syndrome					
-Total	15 (50.0)	1 (3.3)	3 (10.0)	4 (13.3)	7 (23.3)
Cytokine release syndrome	15 (50.0)	1 (3.3)	4 (13.3)	4 (13.3)	6 (20.0)
Haemophagocytic lymphohistiocytosis	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hematological disorders including cytopenias					
-Total	21 (70.0)	1 (3.3)	0	7 (23.3)	13 (43.3)
Anaemia	12 (40.0)	2 (6.7)	3 (10.0)	7 (23.3)	0
Febrile neutropenia	10 (33.3)	0	0	9 (30.0)	1 (3.3)
White blood cell count decreased	10 (33.3)	1 (3.3)	1 (3.3)	1 (3.3)	7 (23.3)

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (26.7)	3 (10.0)	1 (3.3)	1 (3.3)	3 (10.0)
Lymphocyte count decreased	7 (23.3)	0	0	3 (10.0)	4 (13.3)
Neutropenia	6 (20.0)	0	0	1 (3.3)	5 (16.7)
Neutrophil count decreased	6 (20.0)	0	0	1 (3.3)	5 (16.7)
Thrombocytopenia	5 (16.7)	0	0	2 (6.7)	3 (10.0)
Leukopenia	2 (6.7)	0	0	0	2 (6.7)
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0
Infections					
-Total	23 (76.7)	2 (6.7)	4 (13.3)	11 (36.7)	6 (20.0)
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Clostridium difficile infection	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Parainfluenzae virus infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Staphylococcal bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Acute sinusitis	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Influenza	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Klebsiella bacteraemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Pneumonia	2 (6.7)	0	0	0	2 (6.7)
Pneumonia fungal	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Atypical pneumonia	1 (3.3)	1 (3.3)	0	0	0
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Cellulitis	1 (3.3)	0	1 (3.3)	0	0
Cholecystitis infective	1 (3.3)	0	1 (3.3)	0	0
Coronavirus infection	1 (3.3)	0	0	1 (3.3)	0
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Cystitis	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	1 (3.3)	0	0
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Enterovirus infection	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis adenovirus	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis viral	1 (3.3)	1 (3.3)	0	0	0
Haemophilus bacteraemia	1 (3.3)	0	0	0	1 (3.3)
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	0	0	1 (3.3)	0
Molluscum contagiosum	1 (3.3)	1 (3.3)	0	0	0
Oral herpes	1 (3.3)	0	0	1 (3.3)	0
Otitis media	1 (3.3)	0	1 (3.3)	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Pharyngitis streptococcal	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal infection	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Tinea pedis	1 (3.3)	1 (3.3)	0	0	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	14 (46.7)	2 (6.7)	9 (30.0)	3 (10.0)	0
Hypogammaglobulinaemia	10 (33.3)	1 (3.3)	8 (26.7)	1 (3.3)	0
Blood immunoglobulin a decreased	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood immunoglobulin g decreased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Blood immunoglobulin m decreased	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Serious neurological adverse reactions					
-Total	14 (46.7)	7 (23.3)	2 (6.7)	5 (16.7)	0
Delirium	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Encephalopathy	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Agitation	2 (6.7)	0	2 (6.7)	0	0
Cognitive disorder	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Confusional state	2 (6.7)	2 (6.7)	0	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (6.7)	2 (6.7)	0	0	0
Lethargy	2 (6.7)	2 (6.7)	0	0	0
Mental status changes	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Dysarthria	1 (3.3)	0	0	1 (3.3)	0
Muscular weakness	1 (3.3)	1 (3.3)	0	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Somnolence	1 (3.3)	0	0	1 (3.3)	0
Tumour Lysis Syndrome					
-Total	3 (10.0)	0	0	3 (10.0)	0
Tumour lysis syndrome	3 (10.0)	0	0	3 (10.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	3 (16.7)	14 (77.8)
Cytokine Release Syndrome					
-Total	12 (66.7)	0	4 (22.2)	4 (22.2)	4 (22.2)
Cytokine release syndrome	12 (66.7)	0	4 (22.2)	4 (22.2)	4 (22.2)
Haemophagocytic lymphohistiocytosis	1 (5.6)	0	1 (5.6)	0	0
Hematological disorders including cytopenias					
-Total	16 (88.9)	0	1 (5.6)	5 (27.8)	10 (55.6)
Febrile neutropenia	12 (66.7)	0	0	12 (66.7)	0
Anaemia	9 (50.0)	1 (5.6)	4 (22.2)	3 (16.7)	1 (5.6)
Platelet count decreased	6 (33.3)	0	1 (5.6)	2 (11.1)	3 (16.7)

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (33.3)	0	0	0	6 (33.3)
Neutropenia	5 (27.8)	1 (5.6)	1 (5.6)	0	3 (16.7)
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Lymphocyte count decreased	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Thrombocytopenia	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Eosinophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Haematocrit decreased	1 (5.6)	1 (5.6)	0	0	0
Leukopenia	1 (5.6)	0	0	0	1 (5.6)
Lymphopenia	1 (5.6)	0	0	0	1 (5.6)
Pancytopenia	1 (5.6)	0	1 (5.6)	0	0
Red blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Infections					
-Total	15 (83.3)	1 (5.6)	3 (16.7)	10 (55.6)	1 (5.6)
Sinusitis	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Staphylococcal bacteraemia	3 (16.7)	0	0	3 (16.7)	0
Staphylococcal infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Upper respiratory tract infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Bronchitis	2 (11.1)	0	2 (11.1)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	2 (11.1)	0	0	2 (11.1)	0
Nail infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Otitis media	2 (11.1)	0	2 (11.1)	0	0
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0
Adenovirus infection	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	1 (5.6)	0	0
Bk virus infection	1 (5.6)	0	0	1 (5.6)	0
Bronchiolitis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	1 (5.6)	0	0
Conjunctivitis	1 (5.6)	1 (5.6)	0	0	0
Covid-19	1 (5.6)	1 (5.6)	0	0	0
Cytomegalovirus infection reactivation	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (5.6)	0	1 (5.6)	0	0
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Folliculitis	1 (5.6)	0	1 (5.6)	0	0
Fungal skin infection	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis clostridial	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	1 (5.6)	0	0
Herpes simplex	1 (5.6)	0	1 (5.6)	0	0
Human herpesvirus 6 infection	1 (5.6)	0	0	1 (5.6)	0
Metapneumovirus infection	1 (5.6)	0	0	1 (5.6)	0
Nasopharyngitis	1 (5.6)	1 (5.6)	0	0	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pneumocystis jirovecii pneumonia	1 (5.6)	0	0	1 (5.6)	0
Pneumonia respiratory syncytial viral	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Sinusitis fungal	1 (5.6)	0	0	1 (5.6)	0
Syphilis	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection viral	1 (5.6)	1 (5.6)	0	0	0
Varicella zoster virus infection	1 (5.6)	0	1 (5.6)	0	0
Viral infection	1 (5.6)	0	0	1 (5.6)	0
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	9 (50.0)	2 (11.1)	5 (27.8)	2 (11.1)	0
Hypogammaglobulinaemia	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0	0	0
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0	0	0
Immunodeficiency	1 (5.6)	0	0	1 (5.6)	0
Selective igg subclass deficiency	1 (5.6)	0	1 (5.6)	0	0
Serious neurological adverse reactions					
-Total	8 (44.4)	3 (16.7)	2 (11.1)	3 (16.7)	0
Confusional state	3 (16.7)	3 (16.7)	0	0	0
Delirium	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Agitation	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Cognitive disorder	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Generalised tonic-clonic seizure	1 (5.6)	0	1 (5.6)	0	0
Muscular weakness	1 (5.6)	0	0	1 (5.6)	0
Posterior reversible encephalopathy syndrome	1 (5.6)	0	1 (5.6)	0	0
Seizure	1 (5.6)	0	1 (5.6)	0	0
Somnolence	1 (5.6)	0	0	1 (5.6)	0
Tremor	1 (5.6)	0	1 (5.6)	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 232r
Adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (100)	0	1 (2.4)	10 (23.8)	31 (73.8)
Cytokine Release Syndrome					
-Total	29 (69.0)	3 (7.1)	8 (19.0)	9 (21.4)	9 (21.4)
Cytokine release syndrome	29 (69.0)	3 (7.1)	8 (19.0)	9 (21.4)	9 (21.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	1 (2.4)	0	0	0
Hematological disorders including cytopenias					
-Total	34 (81.0)	0	0	9 (21.4)	25 (59.5)
Anaemia	21 (50.0)	2 (4.8)	4 (9.5)	15 (35.7)	0
Febrile neutropenia	19 (45.2)	0	0	18 (42.9)	1 (2.4)
Neutrophil count decreased	18 (42.9)	2 (4.8)	2 (4.8)	1 (2.4)	13 (31.0)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	17 (40.5)	3 (7.1)	0	3 (7.1)	11 (26.2)
White blood cell count decreased	16 (38.1)	1 (2.4)	1 (2.4)	0	14 (33.3)
Lymphocyte count decreased	12 (28.6)	0	1 (2.4)	3 (7.1)	8 (19.0)
Neutropenia	11 (26.2)	0	1 (2.4)	2 (4.8)	8 (19.0)
Thrombocytopenia	6 (14.3)	0	1 (2.4)	2 (4.8)	3 (7.1)
Pancytopenia	4 (9.5)	0	0	2 (4.8)	2 (4.8)
Leukopenia	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Haemoglobin decreased	1 (2.4)	0	0	1 (2.4)	0
Lymphopenia	1 (2.4)	0	0	0	1 (2.4)
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Infections					
-Total	39 (92.9)	2 (4.8)	6 (14.3)	16 (38.1)	15 (35.7)
Upper respiratory tract infection	6 (14.3)	3 (7.1)	1 (2.4)	2 (4.8)	0
Gastroenteritis	5 (11.9)	2 (4.8)	1 (2.4)	2 (4.8)	0
Nasopharyngitis	5 (11.9)	3 (7.1)	2 (4.8)	0	0
Pneumonia	5 (11.9)	1 (2.4)	1 (2.4)	2 (4.8)	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	5 (11.9)	0	3 (7.1)	2 (4.8)	0
Bacteraemia	4 (9.5)	0	0	3 (7.1)	1 (2.4)
Conjunctivitis	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Herpes zoster	4 (9.5)	0	1 (2.4)	3 (7.1)	0
Oral herpes	4 (9.5)	1 (2.4)	2 (4.8)	1 (2.4)	0
Parainfluenzae virus infection	4 (9.5)	0	0	3 (7.1)	1 (2.4)
Paronychia	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Urinary tract infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Candida infection	3 (7.1)	0	2 (4.8)	0	1 (2.4)
Device related infection	3 (7.1)	0	1 (2.4)	2 (4.8)	0
Fungal infection	3 (7.1)	0	3 (7.1)	0	0
Gingivitis	3 (7.1)	3 (7.1)	0	0	0
Oral candidiasis	3 (7.1)	0	3 (7.1)	0	0
Rhinitis	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Septic shock	3 (7.1)	0	0	0	3 (7.1)
Staphylococcal sepsis	3 (7.1)	0	0	0	3 (7.1)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	2 (4.8)	0	0	2 (4.8)	0
Nail infection	2 (4.8)	2 (4.8)	0	0	0
Oral infection	2 (4.8)	0	2 (4.8)	0	0
Otitis externa	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Otitis media	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Respiratory tract infection	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Skin infection	2 (4.8)	0	2 (4.8)	0	0
Skin papilloma	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Staphylococcal infection	2 (4.8)	0	0	2 (4.8)	0
Staphylococcal skin infection	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Abscess limb	1 (2.4)	0	0	1 (2.4)	0
Acute sinusitis	1 (2.4)	0	1 (2.4)	0	0
Adenovirus infection	1 (2.4)	0	0	1 (2.4)	0
Anal abscess	1 (2.4)	0	0	1 (2.4)	0
Bacterial sepsis	1 (2.4)	0	0	0	1 (2.4)
Bk virus infection	1 (2.4)	1 (2.4)	0	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile infection	1 (2.4)	0	0	1 (2.4)	0
Covid-19	1 (2.4)	0	0	1 (2.4)	0
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0
Device related bacteraemia	1 (2.4)	0	1 (2.4)	0	0
Ear infection	1 (2.4)	0	0	1 (2.4)	0
Ear, nose and throat infection	1 (2.4)	0	1 (2.4)	0	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Encephalitis viral	1 (2.4)	0	0	1 (2.4)	0
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection	1 (2.4)	0	1 (2.4)	0	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Escherichia bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Fungaemia	1 (2.4)	0	0	0	1 (2.4)
Fungal pharyngitis	1 (2.4)	0	0	1 (2.4)	0
Fungal sepsis	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.4)	1 (2.4)	0	0	0
Granulicatella infection	1 (2.4)	0	0	1 (2.4)	0
Herpes simplex	1 (2.4)	0	0	1 (2.4)	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Human herpesvirus 6 infection	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	1 (2.4)	0	0
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	0	0	1 (2.4)	0
Myringitis	1 (2.4)	1 (2.4)	0	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	0	0	1 (2.4)
Pneumonia fungal	1 (2.4)	0	0	1 (2.4)	0
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Post herpetic neuralgia	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection viral	1 (2.4)	0	1 (2.4)	0	0
Salmonellosis	1 (2.4)	0	1 (2.4)	0	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Stomatococcal infection	1 (2.4)	0	0	0	1 (2.4)
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Systemic candida	1 (2.4)	0	0	1 (2.4)	0
Tinea pedis	1 (2.4)	1 (2.4)	0	0	0
Tonsillitis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Varicella zoster virus infection	1 (2.4)	0	0	1 (2.4)	0
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0
Viral haemorrhagic cystitis	1 (2.4)	0	0	1 (2.4)	0
Viral infection	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prolonged depletion of normal B cells or Agammaglobulinemia					
-Total	27 (64.3)	1 (2.4)	17 (40.5)	9 (21.4)	0
Hypogammaglobulinaemia	21 (50.0)	0	15 (35.7)	6 (14.3)	0
Blood immunoglobulin a decreased	3 (7.1)	2 (4.8)	0	1 (2.4)	0
Blood immunoglobulin m decreased	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Immunodeficiency	2 (4.8)	0	0	2 (4.8)	0
Immunoglobulins decreased	2 (4.8)	0	2 (4.8)	0	0
B-cell aplasia	1 (2.4)	0	1 (2.4)	0	0
Serious neurological adverse reactions					
-Total	15 (35.7)	2 (4.8)	6 (14.3)	7 (16.7)	0
Encephalopathy	4 (9.5)	0	2 (4.8)	2 (4.8)	0
Seizure	4 (9.5)	0	1 (2.4)	3 (7.1)	0
Tremor	4 (9.5)	4 (9.5)	0	0	0
Agitation	3 (7.1)	3 (7.1)	0	0	0
Hallucination	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Mental status changes	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Lethargy	2 (4.8)	1 (2.4)	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Affect lability	1 (2.4)	0	1 (2.4)	0	0
Amnesia	1 (2.4)	0	1 (2.4)	0	0
Aphasia	1 (2.4)	1 (2.4)	0	0	0
Confusional state	1 (2.4)	1 (2.4)	0	0	0
Delirium	1 (2.4)	0	1 (2.4)	0	0
Depressed level of consciousness	1 (2.4)	0	0	1 (2.4)	0
Disturbance in attention	1 (2.4)	1 (2.4)	0	0	0
Dysarthria	1 (2.4)	0	1 (2.4)	0	0
Hallucination, visual	1 (2.4)	0	1 (2.4)	0	0
Irritability	1 (2.4)	1 (2.4)	0	0	0
Memory impairment	1 (2.4)	0	1 (2.4)	0	0
Mood altered	1 (2.4)	1 (2.4)	0	0	0
Restlessness	1 (2.4)	0	1 (2.4)	0	0
Sluggishness	1 (2.4)	0	1 (2.4)	0	0
Social avoidant behaviour	1 (2.4)	0	1 (2.4)	0	0
Tumour Lysis Syndrome					
-Total	3 (7.1)	0	0	1 (2.4)	2 (4.8)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	3 (7.1)	0	0	1 (2.4)	2 (4.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death within 30 days of CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	1 (3.0)
Nervous system disorders	
-Total	1 (3.0)
Cerebral haemorrhage	1 (3.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death within 30 days of CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (3.0)
Acute lymphocytic leukaemia	1 (3.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	15 (45.5)
General disorders and administration site conditions	
-Total	1 (3.0)
Multiple organ dysfunction syndrome	1 (3.0)
Infections and infestations	
-Total	2 (6.1)
Encephalitis	1 (3.0)
Pneumonia bacterial	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Death >30 days after CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All patients N=33 n (%)
-Total	12 (36.4)
Acute lymphocytic leukaemia	12 (36.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	9 (27.3)
Immune system disorders	
-Total	1 (3.0)
Graft versus host disease	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (24.2)
Acute lymphocytic leukaemia	8 (24.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Death >30 days after CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=14 n (%)
Number of patients with at least one AE	7 (50.0)
General disorders and administration site conditions	
-Total	1 (7.1)
Death	1 (7.1)
Hepatobiliary disorders	
-Total	1 (7.1)
Hepatobiliary disease	1 (7.1)
Infections and infestations	
-Total	1 (7.1)
Systemic mycosis	1 (7.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Death >30 days after CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=14 n (%)
-Total	4 (28.6)
Acute lymphocytic leukaemia	4 (28.6)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	16 (48.5)
General disorders and administration site conditions	
-Total	1 (3.0)
Multiple organ dysfunction syndrome	1 (3.0)
Infections and infestations	
-Total	2 (6.1)
Encephalitis	1 (3.0)
Pneumonia bacterial	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	12 (36.4)

Timing: Any time post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All patients N=33 n (%)
Acute lymphocytic leukaemia	12 (36.4)
Nervous system disorders	
-Total	1 (3.0)
Cerebral haemorrhage	1 (3.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=33 n (%)
Number of patients with at least one AE	10 (30.3)
Immune system disorders	
-Total	1 (3.0)
Graft versus host disease	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	9 (27.3)
Acute lymphocytic leukaemia	9 (27.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233a
Deaths post CTL019 infusion by primary system organ class, preferred term and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=14 n (%)
Number of patients with at least one AE	7 (50.0)
General disorders and administration site conditions	
-Total	1 (7.1)
Death	1 (7.1)
Hepatobiliary disorders	
-Total	1 (7.1)
Hepatobiliary disease	1 (7.1)
Infections and infestations	
-Total	1 (7.1)
Systemic mycosis	1 (7.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Any time post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=14 n (%)
-Total	4 (28.6)
Acute lymphocytic leukaemia	4 (28.6)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death within 30 days of CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 n (%)
Number of patients with at least one AE	1 (2.2)
Nervous system disorders	
-Total	1 (2.2)
Cerebral haemorrhage	1 (2.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death within 30 days of CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 n (%)
Number of patients with at least one AE	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.9)
Acute lymphocytic leukaemia	1 (2.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death >30 days after CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 n (%)
Number of patients with at least one AE	19 (41.3)
General disorders and administration site conditions	
-Total	1 (2.2)
Multiple organ dysfunction syndrome	1 (2.2)
Hepatobiliary disorders	
-Total	1 (2.2)
Hepatobiliary disease	1 (2.2)
Infections and infestations	
-Total	1 (2.2)
Pneumonia bacterial	1 (2.2)

Timing: Death >30 days after CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (34.8)
Acute lymphocytic leukaemia	16 (34.8)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Death >30 days after CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 n (%)
Number of patients with at least one AE	12 (35.3)
General disorders and administration site conditions	
-Total	1 (2.9)
Death	1 (2.9)
Immune system disorders	
-Total	1 (2.9)
Graft versus host disease	1 (2.9)
Infections and infestations	
-Total	2 (5.9)
Encephalitis	1 (2.9)
Systemic mycosis	1 (2.9)

Timing: Death >30 days after CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	8 (23.5)
Acute lymphocytic leukaemia	8 (23.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 n (%)
Number of patients with at least one AE	20 (43.5)
General disorders and administration site conditions	
-Total	1 (2.2)
Multiple organ dysfunction syndrome	1 (2.2)
Hepatobiliary disorders	
-Total	1 (2.2)
Hepatobiliary disease	1 (2.2)
Infections and infestations	
-Total	1 (2.2)
Pneumonia bacterial	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (34.8)
Acute lymphocytic leukaemia	16 (34.8)
Nervous system disorders	
-Total	1 (2.2)
Cerebral haemorrhage	1 (2.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233b
Deaths post CTL019 infusion by primary system organ class, preferred term and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 n (%)
Number of patients with at least one AE	13 (38.2)
General disorders and administration site conditions	
-Total	1 (2.9)
Death	1 (2.9)
Immune system disorders	
-Total	1 (2.9)
Graft versus host disease	1 (2.9)
Infections and infestations	
-Total	2 (5.9)
Encephalitis	1 (2.9)
Systemic mycosis	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	9 (26.5)
Acute lymphocytic leukaemia	9 (26.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death within 30 days of CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 n (%)
Number of patients with at least one AE	1 (1.7)
Nervous system disorders	
-Total	1 (1.7)
Cerebral haemorrhage	1 (1.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death within 30 days of CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 n (%)
Number of patients with at least one AE	1 (10.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (10.0)
Acute lymphocytic leukaemia	1 (10.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 n (%)
Number of patients with at least one AE	20 (33.9)
Immune system disorders	
-Total	1 (1.7)
Graft versus host disease	1 (1.7)
Infections and infestations	
-Total	3 (5.1)
Encephalitis	1 (1.7)
Pneumonia bacterial	1 (1.7)
Systemic mycosis	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (27.1)

Timing: Death >30 days after CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 n (%)
Acute lymphocytic leukaemia	16 (27.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 n (%)
Number of patients with at least one AE	4 (40.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (40.0)
Acute lymphocytic leukaemia	4 (40.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Death >30 days after CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 n (%)
Number of patients with at least one AE	7 (63.6)
General disorders and administration site conditions	
-Total	2 (18.2)
Death	1 (9.1)
Multiple organ dysfunction syndrome	1 (9.1)
Hepatobiliary disorders	
-Total	1 (9.1)
Hepatobiliary disease	1 (9.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (36.4)

Timing: Death >30 days after CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 n (%)
Acute lymphocytic leukaemia	4 (36.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 n (%)
Number of patients with at least one AE	21 (35.6)
Immune system disorders	
-Total	1 (1.7)
Graft versus host disease	1 (1.7)
Infections and infestations	
-Total	3 (5.1)
Encephalitis	1 (1.7)
Pneumonia bacterial	1 (1.7)
Systemic mycosis	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	16 (27.1)

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 n (%)
Acute lymphocytic leukaemia	16 (27.1)
Nervous system disorders	
-Total	1 (1.7)
Cerebral haemorrhage	1 (1.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 n (%)
Number of patients with at least one AE	5 (50.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (50.0)
Acute lymphocytic leukaemia	5 (50.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233c
Deaths post CTL019 infusion by primary system organ class, preferred term and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 n (%)
Number of patients with at least one AE	7 (63.6)
General disorders and administration site conditions	
-Total	2 (18.2)
Death	1 (9.1)
Multiple organ dysfunction syndrome	1 (9.1)
Hepatobiliary disorders	
-Total	1 (9.1)
Hepatobiliary disease	1 (9.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (36.4)

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 n (%)
Acute lymphocytic leukaemia	4 (36.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death within 30 days of CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=15 n (%)
Number of patients with at least one AE	1 (6.7)
Nervous system disorders	
-Total	1 (6.7)
Cerebral haemorrhage	1 (6.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death within 30 days of CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 n (%)
Number of patients with at least one AE	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.5)
Acute lymphocytic leukaemia	1 (1.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death >30 days after CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=15 n (%)
Number of patients with at least one AE	7 (46.7)
General disorders and administration site conditions	
-Total	1 (6.7)
Death	1 (6.7)
Immune system disorders	
-Total	1 (6.7)
Graft versus host disease	1 (6.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (33.3)
Acute lymphocytic leukaemia	5 (33.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Death >30 days after CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 n (%)
Number of patients with at least one AE	24 (36.9)
General disorders and administration site conditions	
-Total	1 (1.5)
Multiple organ dysfunction syndrome	1 (1.5)
Hepatobiliary disorders	
-Total	1 (1.5)
Hepatobiliary disease	1 (1.5)
Infections and infestations	
-Total	3 (4.6)
Encephalitis	1 (1.5)
Pneumonia bacterial	1 (1.5)

Timing: Death >30 days after CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 n (%)
Systemic mycosis	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	19 (29.2)
Acute lymphocytic leukaemia	19 (29.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=15 n (%)
Number of patients with at least one AE	8 (53.3)
General disorders and administration site conditions	
-Total	1 (6.7)
Death	1 (6.7)
Immune system disorders	
-Total	1 (6.7)
Graft versus host disease	1 (6.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (33.3)
Acute lymphocytic leukaemia	5 (33.3)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=15 n (%)
Nervous system disorders	
-Total	1 (6.7)
Cerebral haemorrhage	1 (6.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233d
Deaths post CTL019 infusion by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 n (%)
Number of patients with at least one AE	25 (38.5)
General disorders and administration site conditions	
-Total	1 (1.5)
Multiple organ dysfunction syndrome	1 (1.5)
Hepatobiliary disorders	
-Total	1 (1.5)
Hepatobiliary disease	1 (1.5)
Infections and infestations	
-Total	3 (4.6)
Encephalitis	1 (1.5)
Pneumonia bacterial	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 n (%)
Systemic mycosis	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	20 (30.8)
Acute lymphocytic leukaemia	20 (30.8)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death within 30 days of CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	2 (2.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)
Nervous system disorders	
-Total	1 (1.4)
Cerebral haemorrhage	1 (1.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	2 (33.3)
Immune system disorders	
-Total	1 (16.7)
Graft versus host disease	1 (16.7)
Infections and infestations	
-Total	1 (16.7)
Encephalitis	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	29 (39.2)
General disorders and administration site conditions	
-Total	2 (2.7)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Infections and infestations	
-Total	2 (2.7)
Pneumonia bacterial	1 (1.4)

Timing: Death >30 days after CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=74 n (%)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (32.4)
Acute lymphocytic leukaemia	24 (32.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	2 (33.3)
Immune system disorders	
-Total	1 (16.7)
Graft versus host disease	1 (16.7)
Infections and infestations	
-Total	1 (16.7)
Encephalitis	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233e
Deaths post CTL019 infusion by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	31 (41.9)
General disorders and administration site conditions	
-Total	2 (2.7)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Infections and infestations	
-Total	2 (2.7)
Pneumonia bacterial	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=74 n (%)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (33.8)
Acute lymphocytic leukaemia	25 (33.8)
Nervous system disorders	
-Total	1 (1.4)
Cerebral haemorrhage	1 (1.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Death within 30 days of CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=78 n (%)
Number of patients with at least one AE	2 (2.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Death >30 days after CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=78 n (%)
Number of patients with at least one AE	31 (39.7)
General disorders and administration site conditions	
-Total	2 (2.6)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)

Timing: Death >30 days after CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=78 n (%)
Graft versus host disease	1 (1.3)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (30.8)
Acute lymphocytic leukaemia	24 (30.8)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233f
Deaths post CTL019 infusion by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=78 n (%)
Number of patients with at least one AE	33 (42.3)
General disorders and administration site conditions	
-Total	2 (2.6)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=78 n (%)
Graft versus host disease	1 (1.3)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (32.1)
Acute lymphocytic leukaemia	25 (32.1)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death within 30 days of CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	2 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All patients N=1 n (%)
Number of patients with at least one AE	1 (100)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (100)
Acute lymphocytic leukaemia	1 (100)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	30 (38.0)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Death >30 days after CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	23 (29.1)
Acute lymphocytic leukaemia	23 (29.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All patients N=1 n (%)
Number of patients with at least one AE	1 (100)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (100)
Acute lymphocytic leukaemia	1 (100)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233g
Deaths post CTL019 infusion by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	32 (40.5)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (30.4)
Acute lymphocytic leukaemia	24 (30.4)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Death within 30 days of CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	2 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Death >30 days after CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	31 (39.2)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Death >30 days after CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (30.4)
Acute lymphocytic leukaemia	24 (30.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233h
Deaths post CTL019 infusion by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	33 (41.8)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (31.6)
Acute lymphocytic leukaemia	25 (31.6)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Death within 30 days of CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	2 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Death >30 days after CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	31 (39.2)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Death >30 days after CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	24 (30.4)
Acute lymphocytic leukaemia	24 (30.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233i
Deaths post CTL019 infusion by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 n (%)
Number of patients with at least one AE	33 (41.8)
General disorders and administration site conditions	
-Total	2 (2.5)
Death	1 (1.3)
Multiple organ dysfunction syndrome	1 (1.3)
Hepatobiliary disorders	
-Total	1 (1.3)
Hepatobiliary disease	1 (1.3)
Immune system disorders	
-Total	1 (1.3)
Graft versus host disease	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 n (%)
Infections and infestations	
-Total	3 (3.8)
Encephalitis	1 (1.3)
Pneumonia bacterial	1 (1.3)
Systemic mycosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	25 (31.6)
Acute lymphocytic leukaemia	25 (31.6)
Nervous system disorders	
-Total	1 (1.3)
Cerebral haemorrhage	1 (1.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death within 30 days of CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 n (%)
Number of patients with at least one AE	2 (3.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.9)
Acute lymphocytic leukaemia	1 (1.9)
Nervous system disorders	
-Total	1 (1.9)
Cerebral haemorrhage	1 (1.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=27 n (%)
Number of patients with at least one AE	14 (51.9)
Hepatobiliary disorders	
-Total	1 (3.7)
Hepatobiliary disease	1 (3.7)
Infections and infestations	
-Total	1 (3.7)
Encephalitis	1 (3.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	12 (44.4)
Acute lymphocytic leukaemia	12 (44.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 n (%)
Number of patients with at least one AE	17 (32.1)
General disorders and administration site conditions	
-Total	2 (3.8)
Death	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)
Immune system disorders	
-Total	1 (1.9)
Graft versus host disease	1 (1.9)
Infections and infestations	
-Total	2 (3.8)
Pneumonia bacterial	1 (1.9)

Timing: Death >30 days after CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 n (%)
Systemic mycosis	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	12 (22.6)
Acute lymphocytic leukaemia	12 (22.6)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class **Preferred term**	**All patients** **N=27** **n (%)**
Number of patients with at least one AE	14 (51.9)
Hepatobiliary disorders	
-Total	1 (3.7)
Hepatobiliary disease	1 (3.7)
Infections and infestations	
-Total	1 (3.7)
Encephalitis	1 (3.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	12 (44.4)
Acute lymphocytic leukaemia	12 (44.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233j
Deaths post CTL019 infusion by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 n (%)
Number of patients with at least one AE	19 (35.8)
General disorders and administration site conditions	
-Total	2 (3.8)
Death	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)
Immune system disorders	
-Total	1 (1.9)
Graft versus host disease	1 (1.9)
Infections and infestations	
-Total	2 (3.8)
Pneumonia bacterial	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 n (%)
Systemic mycosis	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	13 (24.5)
Acute lymphocytic leukaemia	13 (24.5)
Nervous system disorders	
-Total	1 (1.9)
Cerebral haemorrhage	1 (1.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death within 30 days of CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 n (%)
Number of patients with at least one AE	2 (4.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.2)
Acute lymphocytic leukaemia	1 (2.2)
Nervous system disorders	
-Total	1 (2.2)
Cerebral haemorrhage	1 (2.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death >30 days after CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All patients N=28 n (%)
Number of patients with at least one AE	9 (32.1)
General disorders and administration site conditions	
-Total	1 (3.6)
Multiple organ dysfunction syndrome	1 (3.6)
Hepatobiliary disorders	
-Total	1 (3.6)
Hepatobiliary disease	1 (3.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	7 (25.0)
Acute lymphocytic leukaemia	7 (25.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death >30 days after CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 n (%)
Number of patients with at least one AE	18 (40.0)
General disorders and administration site conditions	
-Total	1 (2.2)
Death	1 (2.2)
Immune system disorders	
-Total	1 (2.2)
Graft versus host disease	1 (2.2)
Infections and infestations	
-Total	3 (6.7)
Encephalitis	1 (2.2)
Pneumonia bacterial	1 (2.2)
Systemic mycosis	1 (2.2)

Timing: Death >30 days after CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	13 (28.9)
Acute lymphocytic leukaemia	13 (28.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Death >30 days after CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All patients N=7 n (%)
Number of patients with at least one AE	4 (57.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (57.1)
Acute lymphocytic leukaemia	4 (57.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All patients N=28 n (%)
Number of patients with at least one AE	9 (32.1)
General disorders and administration site conditions	
-Total	1 (3.6)
Multiple organ dysfunction syndrome	1 (3.6)
Hepatobiliary disorders	
-Total	1 (3.6)
Hepatobiliary disease	1 (3.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	7 (25.0)
Acute lymphocytic leukaemia	7 (25.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 n (%)
Number of patients with at least one AE	20 (44.4)
General disorders and administration site conditions	
-Total	1 (2.2)
Death	1 (2.2)
Immune system disorders	
-Total	1 (2.2)
Graft versus host disease	1 (2.2)
Infections and infestations	
-Total	3 (6.7)
Encephalitis	1 (2.2)
Pneumonia bacterial	1 (2.2)
Systemic mycosis	1 (2.2)

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	14 (31.1)
Acute lymphocytic leukaemia	14 (31.1)
Nervous system disorders	
-Total	1 (2.2)
Cerebral haemorrhage	1 (2.2)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233k
Deaths post CTL019 infusion by primary system organ class, preferred term and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All patients N=7 n (%)
Number of patients with at least one AE	4 (57.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (57.1)
Acute lymphocytic leukaemia	4 (57.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death within 30 days of CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 n (%)
Number of patients with at least one AE	2 (6.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (3.1)
Acute lymphocytic leukaemia	1 (3.1)
Nervous system disorders	
-Total	1 (3.1)
Cerebral haemorrhage	1 (3.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=48 n (%)
Number of patients with at least one AE	20 (41.7)
Infections and infestations	
-Total	2 (4.2)
Pneumonia bacterial	1 (2.1)
Systemic mycosis	1 (2.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	18 (37.5)
Acute lymphocytic leukaemia	18 (37.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 n (%)
Number of patients with at least one AE	11 (34.4)
General disorders and administration site conditions	
-Total	2 (6.3)
Death	1 (3.1)
Multiple organ dysfunction syndrome	1 (3.1)
Hepatobiliary disorders	
-Total	1 (3.1)
Hepatobiliary disease	1 (3.1)
Immune system disorders	
-Total	1 (3.1)
Graft versus host disease	1 (3.1)

Timing: Death >30 days after CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 n (%)
Infections and infestations	
-Total	1 (3.1)
Encephalitis	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	6 (18.8)
Acute lymphocytic leukaemia	6 (18.8)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=48 n (%)
Number of patients with at least one AE	20 (41.7)
Infections and infestations	
-Total	2 (4.2)
Pneumonia bacterial	1 (2.1)
Systemic mycosis	1 (2.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	18 (37.5)
Acute lymphocytic leukaemia	18 (37.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233l
Deaths post CTL019 infusion by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 n (%)
Number of patients with at least one AE	13 (40.6)
General disorders and administration site conditions	
-Total	2 (6.3)
Death	1 (3.1)
Multiple organ dysfunction syndrome	1 (3.1)
Hepatobiliary disorders	
-Total	1 (3.1)
Hepatobiliary disease	1 (3.1)
Immune system disorders	
-Total	1 (3.1)
Graft versus host disease	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 n (%)
Infections and infestations	
-Total	1 (3.1)
Encephalitis	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	7 (21.9)
Acute lymphocytic leukaemia	7 (21.9)
Nervous system disorders	
-Total	1 (3.1)
Cerebral haemorrhage	1 (3.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death within 30 days of CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=67 n (%)
Number of patients with at least one AE	2 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.5)
Acute lymphocytic leukaemia	1 (1.5)
Nervous system disorders	
-Total	1 (1.5)
Cerebral haemorrhage	1 (1.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=13 n (%)
Number of patients with at least one AE	6 (46.2)
Infections and infestations	
-Total	1 (7.7)
Pneumonia bacterial	1 (7.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (38.5)
Acute lymphocytic leukaemia	5 (38.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=67 n (%)
Number of patients with at least one AE	25 (37.3)
General disorders and administration site conditions	
-Total	2 (3.0)
Death	1 (1.5)
Multiple organ dysfunction syndrome	1 (1.5)
Hepatobiliary disorders	
-Total	1 (1.5)
Hepatobiliary disease	1 (1.5)
Immune system disorders	
-Total	1 (1.5)
Graft versus host disease	1 (1.5)

Timing: Death >30 days after CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=67 n (%)
Infections and infestations	
-Total	2 (3.0)
Encephalitis	1 (1.5)
Systemic mycosis	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	19 (28.4)
Acute lymphocytic leukaemia	19 (28.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=13 n (%)
Number of patients with at least one AE	6 (46.2)
Infections and infestations	
-Total	1 (7.7)
Pneumonia bacterial	1 (7.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (38.5)
Acute lymphocytic leukaemia	5 (38.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233m
Deaths post CTL019 infusion by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=67 n (%)
Number of patients with at least one AE	27 (40.3)
General disorders and administration site conditions	
-Total	2 (3.0)
Death	1 (1.5)
Multiple organ dysfunction syndrome	1 (1.5)
Hepatobiliary disorders	
-Total	1 (1.5)
Hepatobiliary disease	1 (1.5)
Immune system disorders	
-Total	1 (1.5)
Graft versus host disease	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=67 n (%)
Infections and infestations	
-Total	2 (3.0)
Encephalitis	1 (1.5)
Systemic mycosis	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	20 (29.9)
Acute lymphocytic leukaemia	20 (29.9)
Nervous system disorders	
-Total	1 (1.5)
Cerebral haemorrhage	1 (1.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death within 30 days of CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=54 n (%)
Number of patients with at least one AE	2 (3.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.9)
Acute lymphocytic leukaemia	1 (1.9)
Nervous system disorders	
-Total	1 (1.9)
Cerebral haemorrhage	1 (1.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=26 n (%)
Number of patients with at least one AE	6 (23.1)
General disorders and administration site conditions	
-Total	1 (3.8)
Multiple organ dysfunction syndrome	1 (3.8)
Infections and infestations	
-Total	1 (3.8)
Encephalitis	1 (3.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (15.4)

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=26 n (%)
Acute lymphocytic leukaemia	4 (15.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=54 n (%)
Number of patients with at least one AE	25 (46.3)
General disorders and administration site conditions	
-Total	1 (1.9)
Death	1 (1.9)
Hepatobiliary disorders	
-Total	1 (1.9)
Hepatobiliary disease	1 (1.9)
Immune system disorders	
-Total	1 (1.9)
Graft versus host disease	1 (1.9)

Timing: Death >30 days after CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=54 n (%)
Infections and infestations	
-Total	2 (3.7)
Pneumonia bacterial	1 (1.9)
Systemic mycosis	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	20 (37.0)
Acute lymphocytic leukaemia	20 (37.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=26 n (%)
Number of patients with at least one AE	6 (23.1)
General disorders and administration site conditions	
-Total	1 (3.8)
Multiple organ dysfunction syndrome	1 (3.8)
Infections and infestations	
-Total	1 (3.8)
Encephalitis	1 (3.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (15.4)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=26 n (%)
Acute lymphocytic leukaemia	4 (15.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233n
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=54 n (%)
Number of patients with at least one AE	27 (50.0)
General disorders and administration site conditions	
-Total	1 (1.9)
Death	1 (1.9)
Hepatobiliary disorders	
-Total	1 (1.9)
Hepatobiliary disease	1 (1.9)
Immune system disorders	
-Total	1 (1.9)
Graft versus host disease	1 (1.9)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=54 n (%)
Infections and infestations	
-Total	2 (3.7)
Pneumonia bacterial	1 (1.9)
Systemic mycosis	1 (1.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	21 (38.9)
Acute lymphocytic leukaemia	21 (38.9)
Nervous system disorders	
-Total	1 (1.9)
Cerebral haemorrhage	1 (1.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death within 30 days of CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=69 n (%)
Number of patients with at least one AE	2 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)
Nervous system disorders	
-Total	1 (1.4)
Cerebral haemorrhage	1 (1.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 n (%)
Number of patients with at least one AE	3 (27.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	3 (27.3)
Acute lymphocytic leukaemia	3 (27.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=69 n (%)
Number of patients with at least one AE	28 (40.6)
General disorders and administration site conditions	
-Total	2 (2.9)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Immune system disorders	
-Total	1 (1.4)

Timing: Death >30 days after CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=69 n (%)
Graft versus host disease	1 (1.4)
Infections and infestations	
-Total	3 (4.3)
Encephalitis	1 (1.4)
Pneumonia bacterial	1 (1.4)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	21 (30.4)
Acute lymphocytic leukaemia	21 (30.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 n (%)
Number of patients with at least one AE	3 (27.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	3 (27.3)
Acute lymphocytic leukaemia	3 (27.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233o
Deaths post CTL019 infusion by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=69 n (%)
Number of patients with at least one AE	30 (43.5)
General disorders and administration site conditions	
-Total	2 (2.9)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Immune system disorders	
-Total	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=69 n (%)
Graft versus host disease	1 (1.4)
Infections and infestations	
-Total	3 (4.3)
Encephalitis	1 (1.4)
Pneumonia bacterial	1 (1.4)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	22 (31.9)
Acute lymphocytic leukaemia	22 (31.9)
Nervous system disorders	
-Total	1 (1.4)
Cerebral haemorrhage	1 (1.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death within 30 days of CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	1 (16.7)
Nervous system disorders	
-Total	1 (16.7)
Cerebral haemorrhage	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death within 30 days of CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death >30 days after CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	2 (33.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (33.3)
Acute lymphocytic leukaemia	2 (33.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Death >30 days after CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	29 (39.2)
General disorders and administration site conditions	
-Total	2 (2.7)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Immune system disorders	
-Total	1 (1.4)
Graft versus host disease	1 (1.4)

Timing: Death >30 days after CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=74 n (%)
Infections and infestations	
-Total	3 (4.1)
Encephalitis	1 (1.4)
Pneumonia bacterial	1 (1.4)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	22 (29.7)
Acute lymphocytic leukaemia	22 (29.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	3 (50.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	2 (33.3)
Acute lymphocytic leukaemia	2 (33.3)
Nervous system disorders	
-Total	1 (16.7)
Cerebral haemorrhage	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233p
Deaths post CTL019 infusion by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=74 n (%)
Number of patients with at least one AE	30 (40.5)
General disorders and administration site conditions	
-Total	2 (2.7)
Death	1 (1.4)
Multiple organ dysfunction syndrome	1 (1.4)
Hepatobiliary disorders	
-Total	1 (1.4)
Hepatobiliary disease	1 (1.4)
Immune system disorders	
-Total	1 (1.4)
Graft versus host disease	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=74 n (%)
Infections and infestations	
-Total	3 (4.1)
Encephalitis	1 (1.4)
Pneumonia bacterial	1 (1.4)
Systemic mycosis	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	23 (31.1)
Acute lymphocytic leukaemia	23 (31.1)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death within 30 days of CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 n (%)
Number of patients with at least one AE	2 (5.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (2.5)
Acute lymphocytic leukaemia	1 (2.5)
Nervous system disorders	
-Total	1 (2.5)
Cerebral haemorrhage	1 (2.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 n (%)
Number of patients with at least one AE	15 (37.5)
General disorders and administration site conditions	
-Total	1 (2.5)
Multiple organ dysfunction syndrome	1 (2.5)
Hepatobiliary disorders	
-Total	1 (2.5)
Hepatobiliary disease	1 (2.5)
Immune system disorders	
-Total	1 (2.5)
Graft versus host disease	1 (2.5)

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 n (%)
Infections and infestations	
-Total	1 (2.5)
Systemic mycosis	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	11 (27.5)
Acute lymphocytic leukaemia	11 (27.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 n (%)
Number of patients with at least one AE	16 (40.0)
General disorders and administration site conditions	
-Total	1 (2.5)
Death	1 (2.5)
Infections and infestations	
-Total	2 (5.0)
Encephalitis	1 (2.5)
Pneumonia bacterial	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Death >30 days after CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 n (%)
-Total	13 (32.5)
Acute lymphocytic leukaemia	13 (32.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 n (%)
Number of patients with at least one AE	15 (37.5)
General disorders and administration site conditions	
-Total	1 (2.5)
Multiple organ dysfunction syndrome	1 (2.5)
Hepatobiliary disorders	
-Total	1 (2.5)
Hepatobiliary disease	1 (2.5)
Immune system disorders	
-Total	1 (2.5)
Graft versus host disease	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 n (%)
Infections and infestations	
-Total	1 (2.5)
Systemic mycosis	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	11 (27.5)
Acute lymphocytic leukaemia	11 (27.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233q
Deaths post CTL019 infusion by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 n (%)
Number of patients with at least one AE	18 (45.0)
General disorders and administration site conditions	
-Total	1 (2.5)
Death	1 (2.5)
Infections and infestations	
-Total	2 (5.0)
Encephalitis	1 (2.5)
Pneumonia bacterial	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 n (%)
-Total	14 (35.0)
Acute lymphocytic leukaemia	14 (35.0)
Nervous system disorders	
-Total	1 (2.5)
Cerebral haemorrhage	1 (2.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death within 30 days of CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 n (%)
Number of patients with at least one AE	1 (4.5)
Nervous system disorders	
-Total	1 (4.5)
Cerebral haemorrhage	1 (4.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death within 30 days of CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=17 n (%)
Number of patients with at least one AE	1 (5.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	1 (5.9)
Acute lymphocytic leukaemia	1 (5.9)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	2 (33.3)
Immune system disorders	
-Total	1 (16.7)
Graft versus host disease	1 (16.7)
Infections and infestations	
-Total	1 (16.7)
Encephalitis	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 n (%)
Number of patients with at least one AE	9 (40.9)
General disorders and administration site conditions	
-Total	2 (9.1)
Death	1 (4.5)
Multiple organ dysfunction syndrome	1 (4.5)
Infections and infestations	
-Total	1 (4.5)
Pneumonia bacterial	1 (4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 n (%)
-Total	6 (27.3)
Acute lymphocytic leukaemia	6 (27.3)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=17 n (%)
Number of patients with at least one AE	5 (29.4)
Hepatobiliary disorders	
-Total	1 (5.9)
Hepatobiliary disease	1 (5.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	4 (23.5)
Acute lymphocytic leukaemia	4 (23.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Death >30 days after CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=35 n (%)
Number of patients with at least one AE	15 (42.9)
Infections and infestations	
-Total	1 (2.9)
Systemic mycosis	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	14 (40.0)
Acute lymphocytic leukaemia	14 (40.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=6 n (%)
Number of patients with at least one AE	2 (33.3)
Immune system disorders	
-Total	1 (16.7)
Graft versus host disease	1 (16.7)
Infections and infestations	
-Total	1 (16.7)
Encephalitis	1 (16.7)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 n (%)
Number of patients with at least one AE	10 (45.5)
General disorders and administration site conditions	
-Total	2 (9.1)
Death	1 (4.5)
Multiple organ dysfunction syndrome	1 (4.5)
Infections and infestations	
-Total	1 (4.5)
Pneumonia bacterial	1 (4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 n (%)
-Total	6 (27.3)
Acute lymphocytic leukaemia	6 (27.3)
Nervous system disorders	
-Total	1 (4.5)
Cerebral haemorrhage	1 (4.5)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.
-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=17 n (%)
Number of patients with at least one AE	6 (35.3)
Hepatobiliary disorders	
-Total	1 (5.9)
Hepatobiliary disease	1 (5.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	5 (29.4)
Acute lymphocytic leukaemia	5 (29.4)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 233r
Deaths post CTL019 infusion by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=35 n (%)
Number of patients with at least one AE	15 (42.9)
Infections and infestations	
-Total	1 (2.9)
Systemic mycosis	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
-Total	14 (40.0)
Acute lymphocytic leukaemia	14 (40.0)

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency as reported in the All patients column.

-MedDRA version 25.1 has been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (54.5)	0	2 (6.1)	8 (24.2)	8 (24.2)
Cytokine Release Syndrome					
-Total	18 (54.5)	1 (3.0)	6 (18.2)	3 (9.1)	8 (24.2)
Cytokine release syndrome	18 (54.5)	1 (3.0)	6 (18.2)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	1 (3.0)	0	0	0	1 (3.0)
Hematological disorders including cytopenias					
-Total	6 (18.2)	0	0	6 (18.2)	0
Febrile neutropenia	6 (18.2)	0	0	6 (18.2)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (15.2)	0	0	4 (12.1)	1 (3.0)
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Candida infection	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.0)	0	0	1 (3.0)	0
Encephalopathy	1 (3.0)	0	0	1 (3.0)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (69.7)	0	1 (3.0)	11 (33.3)	11 (33.3)
Cytokine Release Syndrome					
-Total	23 (69.7)	0	4 (12.1)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	0	4 (12.1)	10 (30.3)	9 (27.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	7 (21.2)	0	0	5 (15.2)	2 (6.1)
Febrile neutropenia	6 (18.2)	0	0	5 (15.2)	1 (3.0)
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Thrombocytopenia	1 (3.0)	0	0	0	1 (3.0)
Infections					
-Total	2 (6.1)	0	0	1 (3.0)	1 (3.0)

Timing: Within 8 weeks post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0
Rhinovirus infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.0)	0	0	1 (3.0)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	1 (3.0)	0	0	1 (3.0)	0
Dysarthria	1 (3.0)	0	0	1 (3.0)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (3.0)	0	0	1 (3.0)	0
Tumour lysis syndrome	1 (3.0)	0	0	1 (3.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (64.3)	0	1 (7.1)	3 (21.4)	5 (35.7)
Cytokine Release Syndrome					
-Total	9 (64.3)	0	2 (14.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	0	2 (14.3)	3 (21.4)	4 (28.6)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (7.1)	0	0	1 (7.1)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)
Encephalitis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Candida infection	1 (7.1)	0	0	0	1 (7.1)
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Varicella zoster virus infection	1 (7.1)	0	0	1 (7.1)	0
Serious neurological adverse reactions					
-Total	1 (7.1)	0	1 (7.1)	0	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (7.1)	0	1 (7.1)	0	0

Timing: Within 8 weeks post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (33.3)	0	0	6 (20.0)	4 (13.3)
Hematological disorders including cytopenias					
-Total	4 (13.3)	0	0	4 (13.3)	0
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Myelodysplastic syndrome	1 (3.3)	0	0	1 (3.3)	0
Infections					
-Total	8 (26.7)	0	0	4 (13.3)	4 (13.3)
Bronchopulmonary aspergillosis	1 (3.3)	0	0	0	1 (3.3)
Cytomegalovirus infection reactivation	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Enterobacter infection	1 (3.3)	0	0	1 (3.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Human herpesvirus 6 infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella infection	1 (3.3)	0	0	1 (3.3)	0
Mastoiditis	1 (3.3)	0	0	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	0	0	1 (3.3)	0
Otitis externa	1 (3.3)	0	0	1 (3.3)	0
Otitis media	1 (3.3)	0	0	1 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (3.3)	0	0	0	1 (3.3)
Pneumonia	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal sepsis	1 (3.3)	0	0	0	1 (3.3)
Bacteraemia	0	0	0	0	0
Encephalitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (12.9)	0	0	2 (6.5)	2 (6.5)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	4 (12.9)	0	0	2 (6.5)	2 (6.5)
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterobacter infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Encephalitis	1 (3.2)	0	0	0	1 (3.2)
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Respiratory syncytial virus infection	1 (3.2)	0	0	1 (3.2)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	1 (3.2)	0	0	0	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	1 (3.2)	0	0	1 (3.2)	0
Upper respiratory tract infection	1 (3.2)	0	0	1 (3.2)	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	1 (3.2)	0	0	1 (3.2)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.2)	0	1 (3.2)	0	0
Mental status changes	1 (3.2)	0	1 (3.2)	0	0
Tumour Lysis Syndrome					
-Total	1 (3.2)	0	0	0	1 (3.2)
Tumour lysis syndrome	1 (3.2)	0	0	0	1 (3.2)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (28.6)	0	0	3 (21.4)	1 (7.1)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	4 (28.6)	0	0	3 (21.4)	1 (7.1)
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	0	0	0	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Encephalitis	0	0	0	0	0
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (7.1)	0	0	1 (7.1)	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (10.0)	0	0	0	2 (10.0)
Cytokine Release Syndrome					
-Total	1 (5.0)	0	0	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	2 (10.0)	0	0	0	2 (10.0)
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (40.9)	0	0	7 (31.8)	2 (9.1)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	9 (40.9)	0	0	7 (31.8)	2 (9.1)
Candida infection	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Sepsis	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Clostridium difficile colitis	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	1 (4.5)	0	0	1 (4.5)	0
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis escherichia coli	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis salmonella	1 (4.5)	0	0	1 (4.5)	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Meningitis pneumococcal	1 (4.5)	0	0	1 (4.5)	0
Pneumonia	1 (4.5)	0	0	1 (4.5)	0
Pneumonia respiratory syncytial viral	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	1 (4.5)	0	0	0	1 (4.5)
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Upper respiratory tract infection	1 (4.5)	0	0	1 (4.5)	0
Serious neurological adverse reactions					
-Total	1 (4.5)	0	0	1 (4.5)	0
Seizure	1 (4.5)	0	0	1 (4.5)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Candida infection	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Sepsis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	22 (66.7)	0	1 (3.0)	10 (30.3)	11 (33.3)
Cytokine Release Syndrome					
-Total	19 (57.6)	1 (3.0)	6 (18.2)	3 (9.1)	9 (27.3)
Cytokine release syndrome	18 (54.5)	1 (3.0)	6 (18.2)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	0	0	2 (6.1)
Hematological disorders including cytopenias					
-Total	9 (27.3)	0	0	9 (27.3)	0
Febrile neutropenia	8 (24.2)	0	0	8 (24.2)	0
Myelodysplastic syndrome	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	12 (36.4)	0	0	6 (18.2)	6 (18.2)
Bronchopulmonary aspergillosis	1 (3.0)	0	0	0	1 (3.0)
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Covid-19 pneumonia	1 (3.0)	0	0	0	1 (3.0)
Cytomegalovirus infection reactivation	1 (3.0)	0	0	1 (3.0)	0
Device related infection	1 (3.0)	0	0	1 (3.0)	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Enterobacter infection	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis	1 (3.0)	0	0	1 (3.0)	0
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Human herpesvirus 6 infection	1 (3.0)	0	0	1 (3.0)	0
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0
Mastoiditis	1 (3.0)	0	0	1 (3.0)	0
Metapneumovirus infection	1 (3.0)	0	0	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33				
	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis externa	1 (3.0)	0	0	1 (3.0)	0
Otitis media	1 (3.0)	0	0	1 (3.0)	0
Pneumocystis jirovecii pneumonia	1 (3.0)	0	0	0	1 (3.0)
Pneumonia	1 (3.0)	0	0	0	1 (3.0)
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Sepsis	1 (3.0)	0	0	0	1 (3.0)
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal sepsis	1 (3.0)	0	0	0	1 (3.0)
Bacteraemia	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Meningitis pneumococcal	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (6.1)	0	0	2 (6.1)	0

Timing: Any time post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (3.0)	0	0	1 (3.0)	0
Mental status changes	1 (3.0)	0	0	1 (3.0)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	25 (75.8)	0	1 (3.0)	10 (30.3)	14 (42.4)
Cytokine Release Syndrome					
-Total	23 (69.7)	0	4 (12.1)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	0	4 (12.1)	10 (30.3)	9 (27.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	7 (21.2)	0	0	5 (15.2)	2 (6.1)
Febrile neutropenia	6 (18.2)	0	0	5 (15.2)	1 (3.0)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Thrombocytopenia	1 (3.0)	0	0	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	13 (39.4)	0	0	8 (24.2)	5 (15.2)
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	1 (3.0)	0	0	1 (3.0)	0
Pneumonia viral	0	0	0	0	0
Sepsis	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Clostridium difficile colitis	1 (3.0)	0	0	1 (3.0)	0
Covid-19	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Gastroenteritis escherichia coli	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis salmonella	1 (3.0)	0	0	1 (3.0)	0
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0
Pneumonia respiratory syncytial viral	1 (3.0)	0	0	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	0	0	1 (3.0)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	2 (6.1)	0	0	0	2 (6.1)
Sinusitis	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	2 (6.1)	0	0	2 (6.1)	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	1 (3.0)	0	0	1 (3.0)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Encephalopathy	0	0	0	0	0
Mental status changes	1 (3.0)	0	1 (3.0)	0	0
Cognitive disorder	0	0	0	0	0
Delirium	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (3.0)	0	0	1 (3.0)	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Tumour Lysis Syndrome					
-Total	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Tumour lysis syndrome	2 (6.1)	0	0	1 (3.0)	1 (3.0)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245a
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (71.4)	0	1 (7.1)	4 (28.6)	5 (35.7)
Cytokine Release Syndrome					
-Total	9 (64.3)	0	2 (14.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	0	2 (14.3)	3 (21.4)	4 (28.6)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (7.1)	0	0	1 (7.1)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	6 (42.9)	0	0	4 (28.6)	2 (14.3)
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	1 (7.1)	0	0	0	1 (7.1)
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Sepsis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	0	0	0	0	0
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal abscess	1 (7.1)	0	0	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Varicella zoster virus infection	1 (7.1)	0	0	1 (7.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Serious neurological adverse reactions					
-Total	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Cognitive disorder	1 (7.1)	0	1 (7.1)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (50.0)	0	2 (4.3)	9 (19.6)	12 (26.1)
Cytokine Release Syndrome					
-Total	23 (50.0)	0	5 (10.9)	7 (15.2)	11 (23.9)
Cytokine release syndrome	23 (50.0)	0	5 (10.9)	7 (15.2)	11 (23.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	7 (15.2)	0	0	6 (13.0)	1 (2.2)
Febrile neutropenia	6 (13.0)	0	0	6 (13.0)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Infections					

Timing: Within 8 weeks post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (8.7)	0	0	4 (8.7)	0
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.2)	0	0	1 (2.2)	0
Delirium	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Cognitive disorder	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (79.4)	0	2 (5.9)	13 (38.2)	12 (35.3)
Cytokine Release Syndrome					
-Total	27 (79.4)	1 (2.9)	7 (20.6)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	1 (2.9)	7 (20.6)	9 (26.5)	10 (29.4)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	7 (20.6)	0	0	6 (17.6)	1 (2.9)
Febrile neutropenia	7 (20.6)	0	0	6 (17.6)	1 (2.9)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (20.6)	0	1 (2.9)	3 (8.8)	3 (8.8)
Pneumonia fungal	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Serious neurological adverse reactions					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Cognitive disorder	1 (2.9)	0	1 (2.9)	0	0

Timing: Within 8 weeks post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (20.9)	0	0	5 (11.6)	4 (9.3)
Hematological disorders including cytopenias					
-Total	3 (7.0)	0	0	3 (7.0)	0
Febrile neutropenia	3 (7.0)	0	0	3 (7.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	8 (18.6)	0	0	4 (9.3)	4 (9.3)
Cytomegalovirus infection reactivation	1 (2.3)	0	0	1 (2.3)	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Encephalitis	1 (2.3)	0	0	0	1 (2.3)
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (2.3)	0	0	1 (2.3)	0
Metapneumovirus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumocystis jirovecii pneumonia	1 (2.3)	0	0	0	1 (2.3)
Pneumonia	1 (2.3)	0	0	0	1 (2.3)
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal sepsis	1 (2.3)	0	0	0	1 (2.3)
Upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Viral haemorrhagic cystitis	1 (2.3)	0	0	1 (2.3)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (28.1)	0	0	6 (18.8)	3 (9.4)
Hematological disorders including cytopenias					
-Total	1 (3.1)	0	0	1 (3.1)	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0
Infections					
-Total	8 (25.0)	0	0	5 (15.6)	3 (9.4)
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Bronchopulmonary aspergillosis	1 (3.1)	0	0	0	1 (3.1)
Enterobacter infection	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis	2 (6.3)	0	0	2 (6.3)	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Mastoiditis	1 (3.1)	0	0	1 (3.1)	0
Otitis externa	1 (3.1)	0	0	1 (3.1)	0
Otitis media	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	1 (3.1)	0	0	1 (3.1)	0
Septic shock	1 (3.1)	0	0	0	1 (3.1)
Sinusitis	1 (3.1)	0	0	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Mental status changes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (27.6)	0	0	6 (20.7)	2 (6.9)
Cytokine Release Syndrome					
-Total	1 (3.4)	0	0	0	1 (3.4)
Haemophagocytic lymphohistiocytosis	1 (3.4)	0	0	0	1 (3.4)
Infections					
-Total	8 (27.6)	0	0	6 (20.7)	2 (6.9)
Sepsis	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Candida infection	1 (3.4)	0	1 (3.4)	0	0
Clostridium difficile colitis	1 (3.4)	0	0	1 (3.4)	0
Covid-19	1 (3.4)	0	0	1 (3.4)	0

Timing: >1 year post CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (3.4)	0	0	0	1 (3.4)
Gastroenteritis escherichia coli	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis salmonella	1 (3.4)	0	0	1 (3.4)	0
Ophthalmic herpes zoster	1 (3.4)	0	1 (3.4)	0	0
Pneumonia	1 (3.4)	0	0	1 (3.4)	0
Staphylococcal abscess	1 (3.4)	0	0	1 (3.4)	0
Staphylococcal bacteraemia	1 (3.4)	0	0	1 (3.4)	0
Upper respiratory tract infection	1 (3.4)	0	0	1 (3.4)	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (23.8)	0	1 (4.8)	2 (9.5)	2 (9.5)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	5 (23.8)	0	1 (4.8)	2 (9.5)	2 (9.5)
Sepsis	1 (4.8)	0	0	0	1 (4.8)
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Device related sepsis	1 (4.8)	0	0	1 (4.8)	0
Herpes zoster	1 (4.8)	0	0	1 (4.8)	0
Meningitis pneumococcal	1 (4.8)	0	0	1 (4.8)	0
Pneumonia respiratory syncytial viral	1 (4.8)	0	0	1 (4.8)	0
Rhinovirus infection	1 (4.8)	0	1 (4.8)	0	0
Septic shock	1 (4.8)	0	0	0	1 (4.8)
Serious neurological adverse reactions					
-Total	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	0	1 (4.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (63.0)	0	1 (2.2)	12 (26.1)	16 (34.8)
Cytokine Release Syndrome					
-Total	24 (52.2)	0	5 (10.9)	7 (15.2)	12 (26.1)
Cytokine release syndrome	23 (50.0)	0	5 (10.9)	7 (15.2)	11 (23.9)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Hematological disorders including cytopenias					
-Total	9 (19.6)	0	0	8 (17.4)	1 (2.2)
Febrile neutropenia	8 (17.4)	0	0	8 (17.4)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	16 (34.8)	0	0	11 (23.9)	5 (10.9)
Pneumonia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Sepsis	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Staphylococcal bacteraemia	2 (4.3)	0	0	2 (4.3)	0
Upper respiratory tract infection	2 (4.3)	0	0	2 (4.3)	0
Candida infection	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Covid-19	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0
Device related infection	1 (2.2)	0	0	1 (2.2)	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Herpes zoster	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Metapneumovirus infection	1 (2.2)	0	0	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Pneumocystis jirovecii pneumonia	1 (2.2)	0	0	0	1 (2.2)
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Viral haemorrhagic cystitis	1 (2.2)	0	0	1 (2.2)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Cognitive disorder	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245b
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (82.4)	0	2 (5.9)	12 (35.3)	14 (41.2)
Cytokine Release Syndrome					
-Total	27 (79.4)	1 (2.9)	7 (20.6)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	1 (2.9)	7 (20.6)	9 (26.5)	10 (29.4)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	8 (23.5)	0	0	7 (20.6)	1 (2.9)
Febrile neutropenia	7 (20.6)	0	0	6 (17.6)	1 (2.9)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	15 (44.1)	0	0	7 (20.6)	8 (23.5)
Pneumonia	0	0	0	0	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)
Device related sepsis	1 (2.9)	0	0	1 (2.9)	0
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis	2 (5.9)	0	0	2 (5.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia respiratory syncytial viral	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Septic shock	2 (5.9)	0	0	0	2 (5.9)
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	5 (14.7)	0	2 (5.9)	3 (8.8)	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Cognitive disorder	1 (2.9)	0	1 (2.9)	0	0
Encephalopathy	1 (2.9)	0	0	1 (2.9)	0
Mental status changes	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (62.7)	0	4 (6.8)	18 (30.5)	15 (25.4)
Cytokine Release Syndrome					
-Total	37 (62.7)	0	11 (18.6)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	0	11 (18.6)	14 (23.7)	12 (20.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	0	0	1 (1.7)
Hematological disorders including cytopenias					
-Total	11 (18.6)	0	0	9 (15.3)	2 (3.4)
Febrile neutropenia	10 (16.9)	0	0	9 (15.3)	1 (1.7)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Thrombocytopenia	1 (1.7)	0	0	0	1 (1.7)
Infections					

Timing: Within 8 weeks post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (11.9)	0	0	5 (8.5)	2 (3.4)
Candida infection	1 (1.7)	0	0	0	1 (1.7)
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.4)	0	0	2 (3.4)	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Dysarthria	1 (1.7)	0	0	1 (1.7)	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0

Timing: Within 8 weeks post CTL019 infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Cytokine Release Syndrome					
-Total	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Cytokine release syndrome	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	0	0	1 (10.0)
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Rhinovirus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (81.8)	0	0	3 (27.3)	6 (54.5)
Cytokine Release Syndrome					
-Total	9 (81.8)	1 (9.1)	1 (9.1)	1 (9.1)	6 (54.5)
Cytokine release syndrome	9 (81.8)	1 (9.1)	1 (9.1)	1 (9.1)	6 (54.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	3 (27.3)	0	0	3 (27.3)	0
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Meningitis bacterial	0	0	0	0	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	1 (9.1)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (9.1)	0	1 (9.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (9.1)	0	0	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (21.8)	0	0	6 (10.9)	6 (10.9)
Hematological disorders including cytopenias					
-Total	3 (5.5)	0	0	3 (5.5)	0
Febrile neutropenia	2 (3.6)	0	0	2 (3.6)	0
Myelodysplastic syndrome	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	10 (18.2)	0	0	4 (7.3)	6 (10.9)
Gastroenteritis	2 (3.6)	0	0	2 (3.6)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	0	1 (1.8)
Device related infection	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Metapneumovirus infection	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Pneumocystis jirovecii pneumonia	1 (1.8)	0	0	0	1 (1.8)
Pneumonia	1 (1.8)	0	0	0	1 (1.8)
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	0	1 (1.8)	0
Septic shock	1 (1.8)	0	0	0	1 (1.8)
Sinusitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (1.8)	0	1 (1.8)	0	0
Mental status changes	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	0	1 (1.8)
Tumour lysis syndrome	1 (1.8)	0	0	0	1 (1.8)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (11.1)	0	0	1 (11.1)	0
Hematological disorders including cytopenias					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	1 (11.1)	0	0	1 (11.1)	0
Gastroenteritis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (11.1)	0	0	1 (11.1)	0
Enterobacter infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	1 (11.1)	0	0	1 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (45.5)	0	0	4 (36.4)	1 (9.1)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	5 (45.5)	0	0	4 (36.4)	1 (9.1)
Gastroenteritis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Human herpesvirus 6 infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Otitis media	1 (9.1)	0	0	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (28.2)	0	1 (2.6)	7 (17.9)	3 (7.7)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	11 (28.2)	0	1 (2.6)	7 (17.9)	3 (7.7)
Sepsis	3 (7.7)	0	0	1 (2.6)	2 (5.1)
Candida infection	1 (2.6)	0	1 (2.6)	0	0
Clostridium difficile colitis	1 (2.6)	0	0	1 (2.6)	0
Covid-19	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis escherichia coli	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis salmonella	1 (2.6)	0	0	1 (2.6)	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Meningitis pneumococcal	1 (2.6)	0	0	1 (2.6)	0
Ophthalmic herpes zoster	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	0	1 (2.6)	0
Pneumonia respiratory syncytial viral	1 (2.6)	0	0	1 (2.6)	0
Rhinovirus infection	1 (2.6)	0	1 (2.6)	0	0
Septic shock	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal abscess	1 (2.6)	0	0	1 (2.6)	0
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Covid-19 pneumonia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.6)	0	0	1 (2.6)	0
Seizure	1 (2.6)	0	0	1 (2.6)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (16.7)	0	0	1 (16.7)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	1 (16.7)	0	0	1 (16.7)	0
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Upper respiratory tract infection	1 (16.7)	0	0	1 (16.7)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	0	1 (20.0)
Cytokine Release Syndrome					
-Total	1 (20.0)	0	0	0	1 (20.0)
Haemophagocytic lymphohistiocytosis	1 (20.0)	0	0	0	1 (20.0)
Infections					
-Total	1 (20.0)	0	0	0	1 (20.0)
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Covid-19 pneumonia	1 (20.0)	0	0	0	1 (20.0)
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (71.2)	0	3 (5.1)	19 (32.2)	20 (33.9)
Cytokine Release Syndrome					
-Total	37 (62.7)	0	11 (18.6)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	0	11 (18.6)	14 (23.7)	12 (20.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	0	0	1 (1.7)
Hematological disorders including cytopenias					
-Total	13 (22.0)	0	0	11 (18.6)	2 (3.4)
Febrile neutropenia	11 (18.6)	0	0	10 (16.9)	1 (1.7)
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.7)	0	0	0	1 (1.7)
Infections					
-Total	23 (39.0)	0	0	13 (22.0)	10 (16.9)
Sepsis	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Candida infection	2 (3.4)	0	1 (1.7)	0	1 (1.7)
Encephalitis	2 (3.4)	0	0	0	2 (3.4)
Gastroenteritis	2 (3.4)	0	0	2 (3.4)	0
Pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Septic shock	2 (3.4)	0	0	0	2 (3.4)
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	0	1 (1.7)
Clostridium difficile colitis	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis escherichia coli	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis salmonella	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0
Metapneumovirus infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Pneumocystis jirovecii pneumonia	1 (1.7)	0	0	0	1 (1.7)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia respiratory syncytial viral	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0	1 (1.7)	0
Sinusitis	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal sepsis	1 (1.7)	0	0	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0
Bacteraemia	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (6.8)	0	1 (1.7)	3 (5.1)	0

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	1 (1.7)	0	0	1 (1.7)	0
Dysarthria	1 (1.7)	0	0	1 (1.7)	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0
Mental status changes	1 (1.7)	0	1 (1.7)	0	0
Seizure	1 (1.7)	0	0	1 (1.7)	0
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	0	1 (1.7)
Tumour lysis syndrome	1 (1.7)	0	0	0	1 (1.7)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (50.0)	0	0	2 (20.0)	3 (30.0)
Cytokine Release Syndrome					
-Total	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Cytokine release syndrome	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (10.0)	0	0	1 (10.0)	0
Febrile neutropenia	1 (10.0)	0	0	1 (10.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (10.0)	0	0	1 (10.0)	0
Varicella zoster virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (10.0)	0	0	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	1 (10.0)	0	0	1 (10.0)	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245c
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (90.9)	0	0	3 (27.3)	7 (63.6)
Cytokine Release Syndrome					
-Total	10 (90.9)	1 (9.1)	1 (9.1)	1 (9.1)	7 (63.6)
Cytokine release syndrome	9 (81.8)	1 (9.1)	1 (9.1)	1 (9.1)	6 (54.5)
Haemophagocytic lymphohistiocytosis	1 (9.1)	0	0	0	1 (9.1)
Hematological disorders including cytopenias					
-Total	3 (27.3)	0	0	3 (27.3)	0
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	5 (45.5)	0	0	3 (27.3)	2 (18.2)
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Varicella zoster virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Covid-19 pneumonia	1 (9.1)	0	0	0	1 (9.1)
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Meningitis bacterial	0	0	0	0	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Otitis media	1 (9.1)	0	0	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Serious neurological adverse reactions					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0
Seizure	0	0	0	0	0
Cognitive disorder	1 (9.1)	0	1 (9.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (9.1)	0	0	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	0	1 (6.7)	3 (20.0)	9 (60.0)
Cytokine Release Syndrome					
-Total	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	5 (33.3)	0	0	4 (26.7)	1 (6.7)
Febrile neutropenia	5 (33.3)	0	0	4 (26.7)	1 (6.7)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (20.0)	0	1 (6.7)	2 (13.3)	0

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (6.7)	0	1 (6.7)	0	0
Cognitive disorder	1 (6.7)	0	1 (6.7)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	0	0	1 (6.7)	0
Tumour lysis syndrome	1 (6.7)	0	0	1 (6.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (56.9)	0	3 (4.6)	19 (29.2)	15 (23.1)
Cytokine Release Syndrome					
-Total	37 (56.9)	1 (1.5)	8 (12.3)	15 (23.1)	13 (20.0)
Cytokine release syndrome	37 (56.9)	1 (1.5)	8 (12.3)	15 (23.1)	13 (20.0)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	0	0	1 (1.5)
Hematological disorders including cytopenias					
-Total	9 (13.8)	0	0	8 (12.3)	1 (1.5)
Febrile neutropenia	8 (12.3)	0	0	8 (12.3)	0
Pancytopenia	1 (1.5)	0	0	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (12.3)	0	0	5 (7.7)	3 (4.6)
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Rhinovirus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Candida infection	1 (1.5)	0	0	0	1 (1.5)
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Varicella zoster virus infection	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	2 (3.1)	0	0	2 (3.1)	0
Cognitive disorder	0	0	0	0	0
Delirium	1 (1.5)	0	0	1 (1.5)	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0

Timing: Within 8 weeks post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (35.7)	0	0	3 (21.4)	2 (14.3)
Hematological disorders including cytopenias					
-Total	1 (7.1)	0	0	1 (7.1)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	4 (28.6)	0	0	2 (14.3)	2 (14.3)
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Septic shock	1 (7.1)	0	0	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (7.1)	0	1 (7.1)	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (7.1)	0	0	0	1 (7.1)
Tumour lysis syndrome	1 (7.1)	0	0	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (21.3)	0	0	8 (13.1)	5 (8.2)
Hematological disorders including cytopenias					
-Total	3 (4.9)	0	0	3 (4.9)	0
Febrile neutropenia	2 (3.3)	0	0	2 (3.3)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	12 (19.7)	0	0	7 (11.5)	5 (8.2)
Bacteraemia	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Septic shock	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	2 (3.3)	0	0	2 (3.3)	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	0	0	1 (1.6)	0
Otitis externa	1 (1.6)	0	0	1 (1.6)	0
Otitis media	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	0	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (1.6)	0	0	0	1 (1.6)
Rhinovirus infection	1 (1.6)	0	0	1 (1.6)	0
Sinusitis	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	1 (1.6)	0	0	1 (1.6)	0
Mental status changes	1 (1.6)	0	0	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (30.2)	0	1 (2.3)	8 (18.6)	4 (9.3)
Cytokine Release Syndrome					
-Total	1 (2.3)	0	0	0	1 (2.3)
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	13 (30.2)	0	1 (2.3)	8 (18.6)	4 (9.3)
Candida infection	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	0	1 (2.3)	0
Covid-19	1 (2.3)	0	0	1 (2.3)	0
Covid-19 pneumonia	1 (2.3)	0	0	0	1 (2.3)

Timing: >1 year post CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis escherichia coli	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis salmonella	1 (2.3)	0	0	1 (2.3)	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Ophthalmic herpes zoster	1 (2.3)	0	1 (2.3)	0	0
Pneumonia	1 (2.3)	0	0	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0
Rhinovirus infection	1 (2.3)	0	1 (2.3)	0	0
Sepsis	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Septic shock	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal abscess	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Serious neurological adverse reactions					
-Total	1 (2.3)	0	0	1 (2.3)	0
Seizure	1 (2.3)	0	0	1 (2.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (86.7)	0	1 (6.7)	2 (13.3)	10 (66.7)
Cytokine Release Syndrome					
-Total	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	5 (33.3)	0	0	4 (26.7)	1 (6.7)
Febrile neutropenia	5 (33.3)	0	0	4 (26.7)	1 (6.7)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	5 (33.3)	0	0	3 (20.0)	2 (13.3)
Bacteraemia	1 (6.7)	0	0	0	1 (6.7)
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Pharyngitis streptococcal	1 (6.7)	0	0	1 (6.7)	0
Respiratory syncytial virus infection	1 (6.7)	0	0	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Septic shock	1 (6.7)	0	0	0	1 (6.7)
Staphylococcal bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Urinary tract infection	1 (6.7)	0	0	1 (6.7)	0
Viral upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Sepsis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (13.3)	0	2 (13.3)	0	0
Cognitive disorder	1 (6.7)	0	1 (6.7)	0	0
Mental status changes	1 (6.7)	0	1 (6.7)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Tumour lysis syndrome	2 (13.3)	0	0	1 (6.7)	1 (6.7)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245d
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	44 (67.7)	0	2 (3.1)	22 (33.8)	20 (30.8)
Cytokine Release Syndrome					
-Total	38 (58.5)	1 (1.5)	8 (12.3)	15 (23.1)	14 (21.5)
Cytokine release syndrome	37 (56.9)	1 (1.5)	8 (12.3)	15 (23.1)	13 (20.0)
Haemophagocytic lymphohistiocytosis	2 (3.1)	0	0	0	2 (3.1)
Hematological disorders including cytopenias					
-Total	12 (18.5)	0	0	11 (16.9)	1 (1.5)
Febrile neutropenia	10 (15.4)	0	0	10 (15.4)	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Pancytopenia	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	26 (40.0)	0	0	15 (23.1)	11 (16.9)
Bacteraemia	0	0	0	0	0
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Pharyngitis streptococcal	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	0	1 (1.5)	0
Septic shock	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	2 (3.1)	0	0	2 (3.1)	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	0	1 (1.5)
Candida infection	2 (3.1)	0	1 (1.5)	0	1 (1.5)
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Covid-19	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Encephalitis	2 (3.1)	0	0	0	2 (3.1)
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	2 (3.1)	0	0	2 (3.1)	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Herpes zoster	2 (3.1)	0	0	2 (3.1)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.5)	0	0	1 (1.5)	0
Otitis media	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0	1 (1.5)	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	0	1 (1.5)
Pneumonia	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Sepsis	3 (4.6)	0	0	1 (1.5)	2 (3.1)
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Varicella zoster virus infection	1 (1.5)	0	0	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	4 (6.2)	0	0	4 (6.2)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Mental status changes	1 (1.5)	0	0	1 (1.5)	0
Delirium	1 (1.5)	0	0	1 (1.5)	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Seizure	1 (1.5)	0	0	1 (1.5)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (16.7)	0	0	0	1 (16.7)

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Candida infection	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (62.2)	0	4 (5.4)	21 (28.4)	21 (28.4)
Cytokine Release Syndrome					
-Total	46 (62.2)	1 (1.4)	10 (13.5)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	1 (1.4)	10 (13.5)	16 (21.6)	19 (25.7)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	12 (16.2)	0	0	11 (14.9)	1 (1.4)
Febrile neutropenia	11 (14.9)	0	0	11 (14.9)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	10 (13.5)	0	1 (1.4)	7 (9.5)	2 (2.7)

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Candida infection	1 (1.4)	0	0	0	1 (1.4)
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.4)	0	0	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	1 (1.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (25.7)	0	0	11 (15.7)	7 (10.0)
Hematological disorders including cytopenias					
-Total	4 (5.7)	0	0	4 (5.7)	0
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	16 (22.9)	0	0	9 (12.9)	7 (10.0)
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Respiratory syncytial virus infection	2 (2.9)	0	0	2 (2.9)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	0	1 (33.3)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Candida infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (25.5)	0	1 (2.1)	7 (14.9)	4 (8.5)
Cytokine Release Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Infections					
-Total	12 (25.5)	0	1 (2.1)	7 (14.9)	4 (8.5)
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Candida infection	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (2.1)	0	0	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Herpes zoster	1 (2.1)	0	0	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	1 (2.1)	0	0
Sepsis	3 (6.4)	0	0	1 (2.1)	2 (4.3)
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Upper respiratory tract infection	1 (2.1)	0	0	1 (2.1)	0
Serious neurological adverse reactions					
-Total	1 (2.1)	0	0	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	0	0	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245e
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (70.3)	0	3 (4.1)	22 (29.7)	27 (36.5)
Cytokine Release Syndrome					
-Total	47 (63.5)	1 (1.4)	10 (13.5)	16 (21.6)	20 (27.0)
Cytokine release syndrome	46 (62.2)	1 (1.4)	10 (13.5)	16 (21.6)	19 (25.7)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	0	0	1 (1.4)
Hematological disorders including cytopenias					
-Total	15 (20.3)	0	0	14 (18.9)	1 (1.4)
Febrile neutropenia	13 (17.6)	0	0	13 (17.6)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	29 (39.2)	0	0	17 (23.0)	12 (16.2)
Clostridium difficile colitis	0	0	0	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Candida infection	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (2.7)	0	0	2 (2.7)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	0	2 (2.7)	0
Rhinovirus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	3 (4.1)	0	0	3 (4.1)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	5 (6.8)	0	2 (2.7)	3 (4.1)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.7)	0	0	1 (1.4)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (61.5)	0	4 (5.1)	21 (26.9)	23 (29.5)
Cytokine Release Syndrome					
-Total	48 (61.5)	1 (1.3)	12 (15.4)	15 (19.2)	20 (25.6)
Cytokine release syndrome	48 (61.5)	1 (1.3)	12 (15.4)	15 (19.2)	20 (25.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					
-Total	13 (16.7)	0	0	11 (14.1)	2 (2.6)
Pancytopenia	0	0	0	0	0
Febrile neutropenia	13 (16.7)	0	0	12 (15.4)	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	11 (14.1)	0	1 (1.3)	7 (9.0)	3 (3.8)

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (1.3)	0	0	0	1 (1.3)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Group term Preferred term	All patients N=78 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	0	1 (50.0)	1 (50.0)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (21.9)	0	0	10 (13.7)	6 (8.2)
Hematological disorders including cytopenias					
-Total	4 (5.5)	0	0	4 (5.5)	0
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	14 (19.2)	0	0	8 (11.0)	6 (8.2)
Encephalitis	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Group term Preferred term	All patients N=73 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (25.0)	0	1 (2.1)	7 (14.6)	4 (8.3)
Cytokine Release Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Infections					
-Total	12 (25.0)	0	1 (2.1)	7 (14.6)	4 (8.3)
Sepsis	2 (4.2)	0	0	0	2 (4.2)
Candida infection	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile colitis	1 (2.1)	0	0	1 (2.1)	0
Covid-19	1 (2.1)	0	0	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)

Timing: >1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis escherichia coli	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis salmonella	1 (2.1)	0	0	1 (2.1)	0
Herpes zoster	1 (2.1)	0	0	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Pneumonia	1 (2.1)	0	0	1 (2.1)	0
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	1 (2.1)	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Upper respiratory tract infection	1 (2.1)	0	0	1 (2.1)	0
Serious neurological adverse reactions					
-Total	1 (2.1)	0	0	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	0	0	2 (100)
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245f
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	55 (70.5)	0	3 (3.8)	24 (30.8)	28 (35.9)
Cytokine Release Syndrome					
-Total	49 (62.8)	1 (1.3)	12 (15.4)	15 (19.2)	21 (26.9)
Cytokine release syndrome	48 (61.5)	1 (1.3)	12 (15.4)	15 (19.2)	20 (25.6)
Haemophagocytic lymphohistiocytosis	2 (2.6)	0	0	0	2 (2.6)
Hematological disorders including cytopenias					
-Total	16 (20.5)	0	0	14 (17.9)	2 (2.6)
Pancytopenia	0	0	0	0	0
Febrile neutropenia	15 (19.2)	0	0	14 (17.9)	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	29 (37.2)	0	0	17 (21.8)	12 (15.4)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Respiratory syncytial virus infection	1 (1.3)	0	0	1 (1.3)	0
Sepsis	2 (2.6)	0	0	0	2 (2.6)
Upper respiratory tract infection	2 (2.6)	0	0	2 (2.6)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	0	0	1 (1.3)
Candida infection	2 (2.6)	0	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.6)	0	0	2 (2.6)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Herpes zoster	2 (2.6)	0	0	2 (2.6)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	0	1 (1.3)	0
Otitis media	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Septic shock	2 (2.6)	0	0	0	2 (2.6)
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.6)	0	0	2 (2.6)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	6 (7.7)	0	2 (2.6)	4 (5.1)	0
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Group term Preferred term	All patients N=78 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	0	0	1 (1.3)	0
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	0	1 (1.3)
Tumour lysis syndrome	1 (1.3)	0	0	0	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	50 (63.3)	0	4 (5.1)	22 (27.8)	24 (30.4)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	0	0	1 (1.3)
Cytokine Release Syndrome					
-Total	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Febrile neutropenia	13 (16.5)	0	0	12 (15.2)	1 (1.3)
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					
-Total	14 (17.7)	0	0	12 (15.2)	2 (2.5)
Candida infection	1 (1.3)	0	0	0	1 (1.3)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	11 (13.9)	0	1 (1.3)	7 (8.9)	3 (3.8)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Tumour lysis syndrome	1 (1.3)	0	0	1 (1.3)	0

Timing: Within 8 weeks post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	1 (1.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (24.3)	0	0	11 (14.9)	7 (9.5)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Hematological disorders including cytopenias					
-Total	4 (5.4)	0	0	4 (5.4)	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	0	0	2 (2.7)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	2 (2.7)	0	0	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	16 (21.6)	0	0	9 (12.2)	7 (9.5)
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=&sn3_1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (26.0)	0	1 (2.0)	8 (16.0)	4 (8.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Pneumonia	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	1 (2.0)	0	0
Sepsis	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	13 (26.0)	0	1 (2.0)	8 (16.0)	4 (8.0)
Seizure	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	1 (2.0)	0	0	1 (2.0)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245g
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	57 (72.2)	0	3 (3.8)	24 (30.4)	30 (38.0)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	0	0	2 (2.5)
Cytokine Release Syndrome					
-Total	51 (64.6)	1 (1.3)	12 (15.2)	16 (20.3)	22 (27.8)
Febrile neutropenia	15 (19.0)	0	0	14 (17.7)	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					
-Total	17 (21.5)	0	0	15 (19.0)	2 (2.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	0	0	1 (1.3)
Candida infection	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis	2 (2.5)	0	0	2 (2.5)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	0	1 (1.3)	0
Otitis media	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.5)	0	0	2 (2.5)	0
Rhinovirus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Septic shock	2 (2.5)	0	0	0	2 (2.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Upper respiratory tract infection	3 (3.8)	0	0	3 (3.8)	0
Urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	31 (39.2)	0	0	18 (22.8)	13 (16.5)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serious neurological adverse reactions					
-Total	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Tumour lysis syndrome	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Tumour Lysis Syndrome					
-Total	2 (2.5)	0	0	1 (1.3)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	50 (63.3)	0	4 (5.1)	22 (27.8)	24 (30.4)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	0	0	1 (1.3)
Cytokine Release Syndrome					
-Total	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Febrile neutropenia	13 (16.5)	0	0	12 (15.2)	1 (1.3)
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					
-Total	14 (17.7)	0	0	12 (15.2)	2 (2.5)
Candida infection	1 (1.3)	0	0	0	1 (1.3)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	11 (13.9)	0	1 (1.3)	7 (8.9)	3 (3.8)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Tumour lysis syndrome	1 (1.3)	0	0	1 (1.3)	0

Timing: Within 8 weeks post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	1 (1.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (24.3)	0	0	11 (14.9)	7 (9.5)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Hematological disorders including cytopenias					
-Total	4 (5.4)	0	0	4 (5.4)	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	0	0	2 (2.7)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	2 (2.7)	0	0	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	16 (21.6)	0	0	9 (12.2)	7 (9.5)
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (26.5)	0	1 (2.0)	8 (16.3)	4 (8.2)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Pneumonia	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	1 (2.0)	0	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	13 (26.5)	0	1 (2.0)	8 (16.3)	4 (8.2)
Seizure	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	1 (2.0)	0	0	1 (2.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245h
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	57 (72.2)	0	3 (3.8)	24 (30.4)	30 (38.0)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	0	0	2 (2.5)
Cytokine Release Syndrome					
-Total	51 (64.6)	1 (1.3)	12 (15.2)	16 (20.3)	22 (27.8)
Febrile neutropenia	15 (19.0)	0	0	14 (17.7)	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (21.5)	0	0	15 (19.0)	2 (2.5)
Bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	0	0	1 (1.3)
Candida infection	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis	2 (2.5)	0	0	2 (2.5)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	0	1 (1.3)	0
Otitis media	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.5)	0	0	2 (2.5)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Upper respiratory tract infection	3 (3.8)	0	0	3 (3.8)	0
Urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	31 (39.2)	0	0	18 (22.8)	13 (16.5)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Tumour lysis syndrome	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Tumour Lysis Syndrome					
-Total	2 (2.5)	0	0	1 (1.3)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	50 (63.3)	0	4 (5.1)	22 (27.8)	24 (30.4)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	0	0	1 (1.3)
Cytokine Release Syndrome					
-Total	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Febrile neutropenia	13 (16.5)	0	0	12 (15.2)	1 (1.3)
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					
-Total	14 (17.7)	0	0	12 (15.2)	2 (2.5)
Candida infection	1 (1.3)	0	0	0	1 (1.3)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	11 (13.9)	0	1 (1.3)	7 (8.9)	3 (3.8)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Tumour lysis syndrome	1 (1.3)	0	0	1 (1.3)	0

Timing: Within 8 weeks post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	1 (1.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (24.3)	0	0	11 (14.9)	7 (9.5)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Hematological disorders including cytopenias					
-Total	4 (5.4)	0	0	4 (5.4)	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	0	0	2 (2.7)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	2 (2.7)	0	0	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	16 (21.6)	0	0	9 (12.2)	7 (9.5)
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (26.5)	0	1 (2.0)	8 (16.3)	4 (8.2)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Cytokine Release Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Pneumonia	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	1 (2.0)	0	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	13 (26.5)	0	1 (2.0)	8 (16.3)	4 (8.2)
Seizure	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	1 (2.0)	0	0	1 (2.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one Event	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245i
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	57 (72.2)	0	3 (3.8)	24 (30.4)	30 (38.0)
Cytokine release syndrome	50 (63.3)	1 (1.3)	12 (15.2)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	0	0	2 (2.5)
Cytokine Release Syndrome					
-Total	51 (64.6)	1 (1.3)	12 (15.2)	16 (20.3)	22 (27.8)
Febrile neutropenia	15 (19.0)	0	0	14 (17.7)	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Hematological disorders including cytopenias					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (21.5)	0	0	15 (19.0)	2 (2.5)
Bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	0	0	1 (1.3)
Candida infection	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis	2 (2.5)	0	0	2 (2.5)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	0	1 (1.3)	0
Otitis media	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.5)	0	0	2 (2.5)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Upper respiratory tract infection	3 (3.8)	0	0	3 (3.8)	0
Urinary tract infection	1 (1.3)	0	0	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Infections					
-Total	31 (39.2)	0	0	18 (22.8)	13 (16.5)
Cognitive disorder	1 (1.3)	0	1 (1.3)	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Tumour lysis syndrome	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Tumour Lysis Syndrome					
-Total	2 (2.5)	0	0	1 (1.3)	1 (1.3)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (70.4)	0	2 (7.4)	8 (29.6)	9 (33.3)
Cytokine Release Syndrome					
-Total	19 (70.4)	0	3 (11.1)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	0	3 (11.1)	7 (25.9)	9 (33.3)
Haemophagocytic lymphohistiocytosis	1 (3.7)	0	0	0	1 (3.7)
Hematological disorders including cytopenias					
-Total	2 (7.4)	0	0	2 (7.4)	0
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.4)	0	0	0	2 (7.4)
Encephalitis	1 (3.7)	0	0	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Candida infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.7)	0	0	1 (3.7)	0
Encephalopathy	1 (3.7)	0	0	1 (3.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	31 (58.5)	0	2 (3.8)	14 (26.4)	15 (28.3)
Cytokine Release Syndrome					
-Total	31 (58.5)	1 (1.9)	9 (17.0)	9 (17.0)	12 (22.6)
Cytokine release syndrome	31 (58.5)	1 (1.9)	9 (17.0)	9 (17.0)	12 (22.6)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	12 (22.6)	0	0	10 (18.9)	2 (3.8)
Febrile neutropenia	11 (20.8)	0	0	10 (18.9)	1 (1.9)
Pancytopenia	1 (1.9)	0	0	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (17.0)	0	1 (1.9)	7 (13.2)	1 (1.9)
Encephalitis	0	0	0	0	0
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	0	0	0	0	0
Candida infection	1 (1.9)	0	0	0	1 (1.9)
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (1.9)	0	1 (1.9)	0	0
Delirium	1 (1.9)	0	0	1 (1.9)	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0

Timing: Within 8 weeks post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (20.0)	0	0	2 (8.0)	3 (12.0)
Hematological disorders including cytopenias					
-Total	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	5 (20.0)	0	0	2 (8.0)	3 (12.0)
Device related infection	1 (4.0)	0	0	1 (4.0)	0
Gastroenteritis	1 (4.0)	0	0	1 (4.0)	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	0	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (4.0)	0	0	0	1 (4.0)
Sinusitis	1 (4.0)	0	0	1 (4.0)	0
Staphylococcal sepsis	1 (4.0)	0	0	0	1 (4.0)
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (4.0)	0	1 (4.0)	0	0
Mental status changes	1 (4.0)	0	1 (4.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (4.0)	0	0	0	1 (4.0)
Tumour lysis syndrome	1 (4.0)	0	0	0	1 (4.0)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (26.0)	0	0	9 (18.0)	4 (8.0)
Hematological disorders including cytopenias					
-Total	3 (6.0)	0	0	3 (6.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	11 (22.0)	0	0	7 (14.0)	4 (8.0)
Device related infection	0	0	0	0	0
Gastroenteritis	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	1 (2.0)	0	0	0	1 (2.0)
Bronchopulmonary aspergillosis	1 (2.0)	0	0	0	1 (2.0)
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Encephalitis	1 (2.0)	0	0	0	1 (2.0)
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Metapneumovirus infection	1 (2.0)	0	0	1 (2.0)	0
Otitis externa	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	0	1 (2.0)	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumonia	1 (2.0)	0	0	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (4.0)	0	0	2 (4.0)	0
Rhinovirus infection	1 (2.0)	0	0	1 (2.0)	0
Upper respiratory tract infection	2 (4.0)	0	0	2 (4.0)	0
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral haemorrhagic cystitis	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	1 (2.0)	0	0	1 (2.0)	0
Mental status changes	1 (2.0)	0	0	1 (2.0)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (43.8)	0	0	5 (31.3)	2 (12.5)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	7 (43.8)	0	0	5 (31.3)	2 (12.5)
Sepsis	2 (12.5)	0	0	0	2 (12.5)
Candida infection	1 (6.3)	0	1 (6.3)	0	0
Covid-19	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Herpes zoster	1 (6.3)	0	0	1 (6.3)	0

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (6.3)	0	1 (6.3)	0	0
Pneumonia respiratory syncytial viral	1 (6.3)	0	0	1 (6.3)	0
Staphylococcal bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Upper respiratory tract infection	1 (6.3)	0	0	1 (6.3)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Cytokine Release Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Sepsis	1 (2.9)	0	0	1 (2.9)	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Clostridium difficile colitis	1 (2.9)	0	0	1 (2.9)	0
Covid-19 pneumonia	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis escherichia coli	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis salmonella	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	1 (2.9)	0	0	1 (2.9)	0
Seizure	1 (2.9)	0	0	1 (2.9)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	20 (74.1)	0	1 (3.7)	8 (29.6)	11 (40.7)
Cytokine Release Syndrome					
-Total	19 (70.4)	0	3 (11.1)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	0	3 (11.1)	7 (25.9)	9 (33.3)
Haemophagocytic lymphohistiocytosis	1 (3.7)	0	0	0	1 (3.7)
Hematological disorders including cytopenias					
-Total	3 (11.1)	0	0	3 (11.1)	0
Febrile neutropenia	3 (11.1)	0	0	3 (11.1)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	12 (44.4)	0	0	6 (22.2)	6 (22.2)
Sepsis	2 (7.4)	0	0	0	2 (7.4)
Candida infection	1 (3.7)	0	1 (3.7)	0	0
Covid-19	1 (3.7)	0	0	1 (3.7)	0
Device related infection	1 (3.7)	0	0	1 (3.7)	0
Device related sepsis	1 (3.7)	0	0	1 (3.7)	0
Encephalitis	1 (3.7)	0	0	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Gastroenteritis	1 (3.7)	0	0	1 (3.7)	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Ophthalmic herpes zoster	1 (3.7)	0	1 (3.7)	0	0
Pneumocystis jirovecii pneumonia	1 (3.7)	0	0	0	1 (3.7)
Pneumonia respiratory syncytial viral	1 (3.7)	0	0	1 (3.7)	0
Septic shock	1 (3.7)	0	0	0	1 (3.7)
Sinusitis	1 (3.7)	0	0	1 (3.7)	0
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (3.7)	0	0	0	1 (3.7)
Upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Encephalopathy	1 (3.7)	0	0	1 (3.7)	0
Mental status changes	1 (3.7)	0	1 (3.7)	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.7)	0	0	0	1 (3.7)
Tumour lysis syndrome	1 (3.7)	0	0	0	1 (3.7)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245j
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	37 (69.8)	0	2 (3.8)	16 (30.2)	19 (35.8)
Cytokine Release Syndrome					
-Total	32 (60.4)	1 (1.9)	9 (17.0)	9 (17.0)	13 (24.5)
Cytokine release syndrome	31 (58.5)	1 (1.9)	9 (17.0)	9 (17.0)	12 (22.6)
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	0	0	1 (1.9)
Hematological disorders including cytopenias					
-Total	14 (26.4)	0	0	12 (22.6)	2 (3.8)
Febrile neutropenia	12 (22.6)	0	0	11 (20.8)	1 (1.9)
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0
Pancytopenia	1 (1.9)	0	0	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	19 (35.8)	0	0	12 (22.6)	7 (13.2)
Sepsis	1 (1.9)	0	0	1 (1.9)	0
Candida infection	1 (1.9)	0	0	0	1 (1.9)
Covid-19	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	1 (1.9)	0	0	0	1 (1.9)
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis	1 (1.9)	0	0	1 (1.9)	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Septic shock	1 (1.9)	0	0	0	1 (1.9)
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	2 (3.8)	0	0	2 (3.8)	0
Bacteraemia	1 (1.9)	0	0	0	1 (1.9)
Bronchopulmonary aspergillosis	1 (1.9)	0	0	0	1 (1.9)
Clostridium difficile colitis	1 (1.9)	0	0	1 (1.9)	0
Covid-19 pneumonia	1 (1.9)	0	0	0	1 (1.9)
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis escherichia coli	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis salmonella	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	0	1 (1.9)	0
Otitis externa	1 (1.9)	0	0	1 (1.9)	0
Otitis media	1 (1.9)	0	0	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	2 (3.8)	0	0	2 (3.8)	0
Rhinovirus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Viral haemorrhagic cystitis	1 (1.9)	0	0	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Encephalopathy	0	0	0	0	0
Mental status changes	1 (1.9)	0	0	1 (1.9)	0
Cognitive disorder	1 (1.9)	0	1 (1.9)	0	0
Delirium	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Seizure	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (53.6)	0	2 (7.1)	5 (17.9)	8 (28.6)
Cytokine Release Syndrome					
-Total	15 (53.6)	0	2 (7.1)	5 (17.9)	8 (28.6)
Cytokine release syndrome	15 (53.6)	0	2 (7.1)	5 (17.9)	8 (28.6)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (3.6)	0	0	1 (3.6)	0
Pancytopenia	1 (3.6)	0	0	1 (3.6)	0
Febrile neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.7)	0	0	3 (10.7)	0
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	31 (68.9)	0	2 (4.4)	16 (35.6)	13 (28.9)
Cytokine Release Syndrome					
-Total	31 (68.9)	1 (2.2)	10 (22.2)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	1 (2.2)	10 (22.2)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Hematological disorders including cytopenias					
-Total	13 (28.9)	0	0	11 (24.4)	2 (4.4)
Pancytopenia	0	0	0	0	0
Febrile neutropenia	13 (28.9)	0	0	12 (26.7)	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Infections					

Timing: Within 8 weeks post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (15.6)	0	1 (2.2)	4 (8.9)	2 (4.4)
Encephalitis viral	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Candida infection	1 (2.2)	0	0	0	1 (2.2)
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Meningitis bacterial	0	0	0	0	0
Rhinovirus infection	1 (2.2)	0	1 (2.2)	0	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Serious neurological adverse reactions					
-Total	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0
Delirium	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0

Timing: Within 8 weeks post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (2.2)	0	0	1 (2.2)	0
Tumour Lysis Syndrome					
-Total	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Cytokine Release Syndrome					
-Total	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	0	0	1 (14.3)
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (35.7)	0	0	4 (14.3)	6 (21.4)
Hematological disorders including cytopenias					
-Total	2 (7.1)	0	0	2 (7.1)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0
Infections					
-Total	9 (32.1)	0	0	3 (10.7)	6 (21.4)
Gastroenteritis	2 (7.1)	0	0	2 (7.1)	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Device related infection	1 (3.6)	0	0	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)
Pneumonia	1 (3.6)	0	0	0	1 (3.6)
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (17.5)	0	0	6 (15.0)	1 (2.5)
Hematological disorders including cytopenias					
-Total	2 (5.0)	0	0	2 (5.0)	0
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	6 (15.0)	0	0	5 (12.5)	1 (2.5)
Gastroenteritis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Mental status changes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	1 (2.5)	0	0	0	1 (2.5)
Tumour lysis syndrome	1 (2.5)	0	0	0	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	0	0	1 (14.3)	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0
Gastroenteritis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalitis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Pharyngitis streptococcal	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Septic shock	0	0	0	0	0
Upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (27.3)	0	0	3 (13.6)	3 (13.6)
Cytokine Release Syndrome					
-Total	1 (4.5)	0	0	0	1 (4.5)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	6 (27.3)	0	0	3 (13.6)	3 (13.6)
Sepsis	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Covid-19	1 (4.5)	0	0	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)

Timing: >1 year post CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Ophthalmic herpes zoster	1 (4.5)	0	1 (4.5)	0	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (21.7)	0	0	4 (17.4)	1 (4.3)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	5 (21.7)	0	0	4 (17.4)	1 (4.3)
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis escherichia coli	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis salmonella	1 (4.3)	0	0	1 (4.3)	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Pneumonia	1 (4.3)	0	0	1 (4.3)	0
Pneumonia respiratory syncytial viral	1 (4.3)	0	0	1 (4.3)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post CTL019 infusion, Region: Rest of World

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Region: Rest of World

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	1 (20.0)	0	1 (20.0)	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (64.3)	0	1 (3.6)	5 (17.9)	12 (42.9)
Cytokine Release Syndrome					
-Total	16 (57.1)	0	2 (7.1)	5 (17.9)	9 (32.1)
Cytokine release syndrome	15 (53.6)	0	2 (7.1)	5 (17.9)	8 (28.6)
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	0	0	1 (3.6)
Hematological disorders including cytopenias					
-Total	3 (10.7)	0	0	3 (10.7)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0
Pancytopenia	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	13 (46.4)	0	0	5 (17.9)	8 (28.6)
Sepsis	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Gastroenteritis	2 (7.1)	0	0	2 (7.1)	0
Herpes zoster	2 (7.1)	0	0	2 (7.1)	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Candida infection	1 (3.6)	0	1 (3.6)	0	0
Covid-19	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Device related sepsis	1 (3.6)	0	0	1 (3.6)	0
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Ophthalmic herpes zoster	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.6)	0	0	0	1 (3.6)
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile colitis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	34 (75.6)	0	2 (4.4)	17 (37.8)	15 (33.3)
Cytokine Release Syndrome					
-Total	31 (68.9)	1 (2.2)	10 (22.2)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	1 (2.2)	10 (22.2)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Hematological disorders including cytopenias					
-Total	14 (31.1)	0	0	12 (26.7)	2 (4.4)
Febrile neutropenia	14 (31.1)	0	0	13 (28.9)	1 (2.2)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	15 (33.3)	0	0	11 (24.4)	4 (8.9)
Sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	1 (2.2)	0	0	0	1 (2.2)
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Encephalitis viral	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0
Enterobacter infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Mastoiditis	1 (2.2)	0	0	1 (2.2)	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (2.2)	0	0	1 (2.2)	0
Otitis externa	1 (2.2)	0	0	1 (2.2)	0
Otitis media	1 (2.2)	0	0	1 (2.2)	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	1 (2.2)	0	0	1 (2.2)	0
Pneumonia respiratory syncytial viral	1 (2.2)	0	0	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	1 (2.2)	0	0
Septic shock	2 (4.4)	0	0	0	2 (4.4)
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	2 (4.4)	0	0	2 (4.4)	0
Upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Viral upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Serious neurological adverse reactions					
-Total	6 (13.3)	0	2 (4.4)	4 (8.9)	0

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0
Delirium	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Encephalopathy	1 (2.2)	0	0	1 (2.2)	0
Mental status changes	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Tumour Lysis Syndrome					
-Total	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Tumour lysis syndrome	2 (4.4)	0	0	1 (2.2)	1 (2.2)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245k
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Cytokine Release Syndrome					
-Total	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Ophthalmic herpes zoster	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Meningitis pneumococcal	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Septic shock	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	2 (28.6)	0	0	2 (28.6)	0
Varicella zoster virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (60.4)	0	2 (4.2)	15 (31.3)	12 (25.0)
Cytokine Release Syndrome					
-Total	29 (60.4)	1 (2.1)	6 (12.5)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	1 (2.1)	6 (12.5)	11 (22.9)	11 (22.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	6 (12.5)	0	0	6 (12.5)	0
Febrile neutropenia	5 (10.4)	0	0	5 (10.4)	0
Pancytopenia	1 (2.1)	0	0	1 (2.1)	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	8 (16.7)	0	0	7 (14.6)	1 (2.1)

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (2.1)	0	0	0	1 (2.1)
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	0	0	1 (2.1)	0
Encephalitis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=48 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (2.1)	0	0	1 (2.1)	0
Tumour lysis syndrome	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (65.6)	0	2 (6.3)	7 (21.9)	12 (37.5)
Cytokine Release Syndrome					
-Total	21 (65.6)	0	6 (18.8)	5 (15.6)	10 (31.3)
Cytokine release syndrome	21 (65.6)	0	6 (18.8)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	0	0	1 (3.1)
Hematological disorders including cytopenias					
-Total	8 (25.0)	0	0	6 (18.8)	2 (6.3)
Febrile neutropenia	8 (25.0)	0	0	7 (21.9)	1 (3.1)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	3 (9.4)	0	1 (3.1)	0	2 (6.3)

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	0	0	0	0	0
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)
Klebsiella infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Serious neurological adverse reactions					
-Total	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Cognitive disorder	1 (3.1)	0	1 (3.1)	0	0
Delirium	1 (3.1)	0	0	1 (3.1)	0
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (31.3)	0	0	9 (18.8)	6 (12.5)
Hematological disorders including cytopenias					
-Total	4 (8.3)	0	0	4 (8.3)	0
Febrile neutropenia	3 (6.3)	0	0	3 (6.3)	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Infections					
-Total	13 (27.1)	0	0	7 (14.6)	6 (12.5)
Gastroenteritis	2 (4.2)	0	0	2 (4.2)	0
Respiratory syncytial virus infection	2 (4.2)	0	0	2 (4.2)	0
Upper respiratory tract infection	2 (4.2)	0	0	2 (4.2)	0
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (2.1)	0	0	0	1 (2.1)
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Metapneumovirus infection	1 (2.1)	0	0	1 (2.1)	0
Otitis externa	1 (2.1)	0	0	1 (2.1)	0
Otitis media	1 (2.1)	0	0	1 (2.1)	0
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0
Pneumocystis jirovecii pneumonia	1 (2.1)	0	0	0	1 (2.1)
Rhinovirus infection	1 (2.1)	0	0	1 (2.1)	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Sinusitis	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)
Urinary tract infection	1 (2.1)	0	0	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=48 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Herpes zoster	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Tumour Lysis Syndrome					
-Total	1 (2.1)	0	0	0	1 (2.1)
Tumour lysis syndrome	1 (2.1)	0	0	0	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Gastroenteritis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral haemorrhagic cystitis	0	0	0	0	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Pharyngitis streptococcal	1 (3.7)	0	0	1 (3.7)	0
Pneumonia	1 (3.7)	0	0	0	1 (3.7)
Viral upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (27.3)	0	1 (3.0)	5 (15.2)	3 (9.1)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	9 (27.3)	0	1 (3.0)	5 (15.2)	3 (9.1)
Sepsis	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Covid-19	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Septic shock	1 (3.0)	0	0	0	1 (3.0)
Staphylococcal abscess	1 (3.0)	0	0	1 (3.0)	0
Upper respiratory tract infection	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.0)	0	0	1 (3.0)	0
Seizure	1 (3.0)	0	0	1 (3.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Cytokine Release Syndrome					
-Total	1 (5.9)	0	0	0	1 (5.9)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	0	1 (5.9)
Infections					
-Total	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Sepsis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Clostridium difficile colitis	1 (5.9)	0	0	1 (5.9)	0
Covid-19 pneumonia	1 (5.9)	0	0	0	1 (5.9)
Gastroenteritis escherichia coli	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis salmonella	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	33 (68.8)	0	1 (2.1)	16 (33.3)	16 (33.3)
Cytokine Release Syndrome					
-Total	29 (60.4)	1 (2.1)	6 (12.5)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	1 (2.1)	6 (12.5)	11 (22.9)	11 (22.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	9 (18.8)	0	0	9 (18.8)	0
Febrile neutropenia	7 (14.6)	0	0	7 (14.6)	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Pancytopenia	1 (2.1)	0	0	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	23 (47.9)	0	0	14 (29.2)	9 (18.8)
Sepsis	3 (6.3)	0	0	1 (2.1)	2 (4.2)
Upper respiratory tract infection	3 (6.3)	0	0	3 (6.3)	0
Candida infection	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Gastroenteritis	2 (4.2)	0	0	2 (4.2)	0
Respiratory syncytial virus infection	2 (4.2)	0	0	2 (4.2)	0
Septic shock	2 (4.2)	0	0	0	2 (4.2)
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)
Bronchopulmonary aspergillosis	1 (2.1)	0	0	0	1 (2.1)
Covid-19	1 (2.1)	0	0	1 (2.1)	0
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Herpes zoster	1 (2.1)	0	0	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Metapneumovirus infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Otitis externa	1 (2.1)	0	0	1 (2.1)	0
Otitis media	1 (2.1)	0	0	1 (2.1)	0
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0
Pneumocystis jirovecii pneumonia	1 (2.1)	0	0	0	1 (2.1)
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	0	1 (2.1)	0
Sinusitis	1 (2.1)	0	0	1 (2.1)	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)
Urinary tract infection	1 (2.1)	0	0	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	0	0	1 (2.1)	0
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (6.3)	0	1 (2.1)	2 (4.2)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=48 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Tumour lysis syndrome	2 (4.2)	0	0	1 (2.1)	1 (2.1)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245l
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	24 (75.0)	0	2 (6.3)	8 (25.0)	14 (43.8)
Cytokine Release Syndrome					
-Total	22 (68.8)	0	6 (18.8)	5 (15.6)	11 (34.4)
Cytokine release syndrome	21 (65.6)	0	6 (18.8)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	2 (6.3)	0	0	0	2 (6.3)
Hematological disorders including cytopenias					
-Total	8 (25.0)	0	0	6 (18.8)	2 (6.3)
Febrile neutropenia	8 (25.0)	0	0	7 (21.9)	1 (3.1)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	8 (25.0)	0	0	4 (12.5)	4 (12.5)
Sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Candida infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Covid-19	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterobacter infection	0	0	0	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis escherichia coli	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis salmonella	1 (3.1)	0	0	1 (3.1)	0
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Pneumonia respiratory syncytial viral	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Serious neurological adverse reactions					
-Total	3 (9.4)	0	1 (3.1)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Cognitive disorder	1 (3.1)	0	1 (3.1)	0	0
Delirium	1 (3.1)	0	0	1 (3.1)	0
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (76.9)	0	1 (7.7)	8 (61.5)	1 (7.7)
Cytokine Release Syndrome					
-Total	10 (76.9)	0	5 (38.5)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	0	5 (38.5)	4 (30.8)	1 (7.7)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	6 (46.2)	0	0	6 (46.2)	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (7.7)	0	0	1 (7.7)	0

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: Yes

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (59.7)	0	3 (4.5)	14 (20.9)	23 (34.3)
Cytokine Release Syndrome					
-Total	40 (59.7)	1 (1.5)	7 (10.4)	12 (17.9)	20 (29.9)
Cytokine release syndrome	40 (59.7)	1 (1.5)	7 (10.4)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	0	0	1 (1.5)
Hematological disorders including cytopenias					
-Total	8 (11.9)	0	0	6 (9.0)	2 (3.0)
Febrile neutropenia	7 (10.4)	0	0	6 (9.0)	1 (1.5)
Pancytopenia	1 (1.5)	0	0	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	10 (14.9)	0	1 (1.5)	6 (9.0)	3 (4.5)

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	0	0	0	0	0
Candida infection	1 (1.5)	0	0	0	1 (1.5)
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Cognitive disorder	1 (1.5)	0	1 (1.5)	0	0
Delirium	1 (1.5)	0	0	1 (1.5)	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.5)	0	0	1 (1.5)	0
Tumour lysis syndrome	1 (1.5)	0	0	1 (1.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (29.0)	0	0	11 (17.7)	7 (11.3)
Hematological disorders including cytopenias					
-Total	4 (6.5)	0	0	4 (6.5)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	16 (25.8)	0	0	9 (14.5)	7 (11.3)
Bacteraemia	1 (1.6)	0	0	0	1 (1.6)
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	2 (3.2)	0	0	2 (3.2)	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	0	0	1 (1.6)	0
Otitis externa	1 (1.6)	0	0	1 (1.6)	0
Otitis media	1 (1.6)	0	0	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	0	0	1 (1.6)	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	0	0	1 (1.6)
Pneumonia	1 (1.6)	0	0	0	1 (1.6)
Respiratory syncytial virus infection	2 (3.2)	0	0	2 (3.2)	0
Rhinovirus infection	1 (1.6)	0	0	1 (1.6)	0
Septic shock	1 (1.6)	0	0	0	1 (1.6)
Sinusitis	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=62 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract infection	2 (3.2)	0	0	2 (3.2)	0
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Mental status changes	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	0	1 (1.6)
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (25.0)	0	0	2 (25.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (25.0)	0	0	2 (25.0)	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	0	0	1 (12.5)	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (26.2)	0	1 (2.4)	6 (14.3)	4 (9.5)
Cytokine Release Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Infections					
-Total	11 (26.2)	0	1 (2.4)	6 (14.3)	4 (9.5)
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Pneumonia	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Rhinovirus infection	1 (2.4)	0	1 (2.4)	0	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Serious neurological adverse reactions					
-Total	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	0	1 (2.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (76.9)	0	1 (7.7)	8 (61.5)	1 (7.7)
Cytokine Release Syndrome					
-Total	10 (76.9)	0	5 (38.5)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	0	5 (38.5)	4 (30.8)	1 (7.7)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	6 (46.2)	0	0	6 (46.2)	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	2 (15.4)	0	0	2 (15.4)	0
Staphylococcal abscess	1 (7.7)	0	0	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245m
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (70.1)	0	2 (3.0)	16 (23.9)	29 (43.3)
Cytokine Release Syndrome					
-Total	41 (61.2)	1 (1.5)	7 (10.4)	12 (17.9)	21 (31.3)
Cytokine release syndrome	40 (59.7)	1 (1.5)	7 (10.4)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	2 (3.0)	0	0	0	2 (3.0)
Hematological disorders including cytopenias					
-Total	11 (16.4)	0	0	9 (13.4)	2 (3.0)
Febrile neutropenia	9 (13.4)	0	0	8 (11.9)	1 (1.5)
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Pancytopenia	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	29 (43.3)	0	0	16 (23.9)	13 (19.4)
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	2 (3.0)	0	0	2 (3.0)	0
Varicella zoster virus infection	0	0	0	0	0
Bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Bronchopulmonary aspergillosis	1 (1.5)	0	0	0	1 (1.5)
Candida infection	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Covid-19	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Encephalitis	2 (3.0)	0	0	0	2 (3.0)
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	2 (3.0)	0	0	2 (3.0)	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Herpes zoster	2 (3.0)	0	0	2 (3.0)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0
Otitis externa	1 (1.5)	0	0	1 (1.5)	0
Otitis media	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	0	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	2 (3.0)	0	0	2 (3.0)	0
Rhinovirus infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Sepsis	3 (4.5)	0	0	1 (1.5)	2 (3.0)
Septic shock	2 (3.0)	0	0	0	2 (3.0)
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	6 (9.0)	0	2 (3.0)	4 (6.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (1.5)	0	1 (1.5)	0	0
Delirium	1 (1.5)	0	0	1 (1.5)	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Mental status changes	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Seizure	1 (1.5)	0	0	1 (1.5)	0
Tumour Lysis Syndrome					
-Total	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Tumour lysis syndrome	2 (3.0)	0	0	1 (1.5)	1 (1.5)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (46.2)	0	1 (3.8)	7 (26.9)	4 (15.4)
Cytokine Release Syndrome					
-Total	12 (46.2)	0	5 (19.2)	3 (11.5)	4 (15.4)
Cytokine release syndrome	12 (46.2)	0	5 (19.2)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	1 (3.8)	0	0	0	1 (3.8)
Hematological disorders including cytopenias					
-Total	5 (19.2)	0	0	5 (19.2)	0
Febrile neutropenia	4 (15.4)	0	0	4 (15.4)	0
Pancytopenia	1 (3.8)	0	0	1 (3.8)	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	2 (7.7)	0	0	1 (3.8)	1 (3.8)

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (3.8)	0	0	0	1 (3.8)
Staphylococcal bacteraemia	1 (3.8)	0	0	1 (3.8)	0
Candida infection	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.8)	0	0	1 (3.8)	0
Encephalopathy	1 (3.8)	0	0	1 (3.8)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.8)	0	0	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	38 (70.4)	0	3 (5.6)	15 (27.8)	20 (37.0)
Cytokine Release Syndrome					
-Total	38 (70.4)	1 (1.9)	7 (13.0)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	1 (1.9)	7 (13.0)	13 (24.1)	17 (31.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	9 (16.7)	0	0	7 (13.0)	2 (3.7)
Febrile neutropenia	9 (16.7)	0	0	8 (14.8)	1 (1.9)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	9 (16.7)	0	1 (1.9)	6 (11.1)	2 (3.7)

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Candida infection	1 (1.9)	0	0	0	1 (1.9)
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (1.9)	0	1 (1.9)	0	0
Delirium	1 (1.9)	0	0	1 (1.9)	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=54 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (24.0)	0	0	4 (16.0)	2 (8.0)
Hematological disorders including cytopenias					
-Total	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	5 (20.0)	0	0	3 (12.0)	2 (8.0)
Respiratory syncytial virus infection	2 (8.0)	0	0	2 (8.0)	0
Upper respiratory tract infection	2 (8.0)	0	0	2 (8.0)	0
Bronchopulmonary aspergillosis	1 (4.0)	0	0	0	1 (4.0)
Encephalitis	1 (4.0)	0	0	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (4.0)	0	0	1 (4.0)	0
Herpes zoster	1 (4.0)	0	0	1 (4.0)	0
Parainfluenzae virus infection	1 (4.0)	0	0	1 (4.0)	0
Rhinovirus infection	1 (4.0)	0	0	1 (4.0)	0
Viral haemorrhagic cystitis	1 (4.0)	0	0	1 (4.0)	0
Bacteraemia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (24.0)	0	0	7 (14.0)	5 (10.0)
Hematological disorders including cytopenias					
-Total	3 (6.0)	0	0	3 (6.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Infections					
-Total	11 (22.0)	0	0	6 (12.0)	5 (10.0)
Respiratory syncytial virus infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Encephalitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (2.0)	0	0	1 (2.0)	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (2.0)	0	0	0	1 (2.0)
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Device related infection	1 (2.0)	0	0	1 (2.0)	0
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Metapneumovirus infection	1 (2.0)	0	0	1 (2.0)	0
Otitis externa	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	0	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	0	0	1 (2.0)
Pneumonia	1 (2.0)	0	0	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=50 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Sinusitis	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal sepsis	1 (2.0)	0	0	0	1 (2.0)
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Serious neurological adverse reactions					
-Total	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Mental status changes	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Tumour Lysis Syndrome					
-Total	1 (2.0)	0	0	0	1 (2.0)
Tumour lysis syndrome	1 (2.0)	0	0	0	1 (2.0)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (25.0)	0	1 (5.0)	3 (15.0)	1 (5.0)
Cytokine Release Syndrome					
-Total	1 (5.0)	0	0	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)
Infections					
-Total	5 (25.0)	0	1 (5.0)	3 (15.0)	1 (5.0)
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (5.0)	0	1 (5.0)	0	0
Sepsis	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (26.7)	0	0	5 (16.7)	3 (10.0)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	8 (26.7)	0	0	5 (16.7)	3 (10.0)
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	0	0	0	0	0
Sepsis	2 (6.7)	0	0	0	2 (6.7)
Staphylococcal bacteraemia	0	0	0	0	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Covid-19	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Meningitis pneumococcal	1 (3.3)	0	0	1 (3.3)	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Seizure	1 (3.3)	0	0	1 (3.3)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (57.7)	0	1 (3.8)	8 (30.8)	6 (23.1)
Cytokine Release Syndrome					
-Total	13 (50.0)	0	5 (19.2)	3 (11.5)	5 (19.2)
Cytokine release syndrome	12 (46.2)	0	5 (19.2)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	2 (7.7)	0	0	0	2 (7.7)
Hematological disorders including cytopenias					
-Total	5 (19.2)	0	0	5 (19.2)	0
Febrile neutropenia	4 (15.4)	0	0	4 (15.4)	0
Pancytopenia	1 (3.8)	0	0	1 (3.8)	0
Myelodysplastic syndrome	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	9 (34.6)	0	0	5 (19.2)	4 (15.4)
Encephalitis	2 (7.7)	0	0	0	2 (7.7)
Respiratory syncytial virus infection	2 (7.7)	0	0	2 (7.7)	0
Staphylococcal bacteraemia	2 (7.7)	0	0	2 (7.7)	0
Upper respiratory tract infection	2 (7.7)	0	0	2 (7.7)	0
Bronchopulmonary aspergillosis	1 (3.8)	0	0	0	1 (3.8)
Clostridium difficile colitis	1 (3.8)	0	0	1 (3.8)	0
Covid-19 pneumonia	1 (3.8)	0	0	0	1 (3.8)
Gastroenteritis	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis escherichia coli	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis salmonella	1 (3.8)	0	0	1 (3.8)	0
Herpes zoster	1 (3.8)	0	0	1 (3.8)	0
Parainfluenzae virus infection	1 (3.8)	0	0	1 (3.8)	0
Pneumonia	1 (3.8)	0	0	1 (3.8)	0
Rhinovirus infection	1 (3.8)	0	0	1 (3.8)	0
Sepsis	1 (3.8)	0	0	1 (3.8)	0
Viral haemorrhagic cystitis	1 (3.8)	0	0	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.8)	0	0	1 (3.8)	0
Encephalopathy	1 (3.8)	0	0	1 (3.8)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=26 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.8)	0	0	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245n
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	42 (77.8)	0	2 (3.7)	16 (29.6)	24 (44.4)
Cytokine Release Syndrome					
-Total	38 (70.4)	1 (1.9)	7 (13.0)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	1 (1.9)	7 (13.0)	13 (24.1)	17 (31.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	12 (22.2)	0	0	10 (18.5)	2 (3.7)
Febrile neutropenia	11 (20.4)	0	0	10 (18.5)	1 (1.9)
Pancytopenia	0	0	0	0	0
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	22 (40.7)	0	0	13 (24.1)	9 (16.7)
Encephalitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (1.9)	0	0	0	1 (1.9)
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Sepsis	2 (3.7)	0	0	0	2 (3.7)
Viral haemorrhagic cystitis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.9)	0	0	0	1 (1.9)
Candida infection	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Covid-19	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Device related sepsis	1 (1.9)	0	0	1 (1.9)	0
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	0	1 (1.9)	0
Ophthalmic herpes zoster	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	0	1 (1.9)	0
Otitis media	1 (1.9)	0	0	1 (1.9)	0
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (1.9)	0	0	0	1 (1.9)
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia respiratory syncytial viral	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Septic shock	2 (3.7)	0	0	0	2 (3.7)
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Serious neurological adverse reactions					
-Total	5 (9.3)	0	2 (3.7)	3 (5.6)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (1.9)	0	1 (1.9)	0	0
Delirium	1 (1.9)	0	0	1 (1.9)	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=54 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Seizure	1 (1.9)	0	0	1 (1.9)	0
Tumour Lysis Syndrome					
-Total	1 (1.9)	0	0	0	1 (1.9)
Tumour lysis syndrome	1 (1.9)	0	0	0	1 (1.9)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Cytokine Release Syndrome					
-Total	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (9.1)	0	0	1 (9.1)	0
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Febrile neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (66.7)	0	2 (2.9)	21 (30.4)	23 (33.3)
Cytokine Release Syndrome					
-Total	46 (66.7)	1 (1.4)	10 (14.5)	15 (21.7)	20 (29.0)
Cytokine release syndrome	46 (66.7)	1 (1.4)	10 (14.5)	15 (21.7)	20 (29.0)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	0	0	1 (1.4)
Hematological disorders including cytopenias					
-Total	13 (18.8)	0	0	11 (15.9)	2 (2.9)
Pancytopenia	0	0	0	0	0
Febrile neutropenia	13 (18.8)	0	0	12 (17.4)	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	11 (15.9)	0	1 (1.4)	7 (10.1)	3 (4.3)

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (1.4)	0	0	0	1 (1.4)
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=69 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.4)	0	0	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	1 (1.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	16 (25.0)	0	0	10 (15.6)	6 (9.4)
Hematological disorders including cytopenias					
-Total	4 (6.3)	0	0	4 (6.3)	0
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Infections					
-Total	14 (21.9)	0	0	8 (12.5)	6 (9.4)
Encephalitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Rhinovirus infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (1.6)	0	0	0	1 (1.6)
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis	2 (3.1)	0	0	2 (3.1)	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	0	0	1 (1.6)	0
Otitis externa	1 (1.6)	0	0	1 (1.6)	0
Otitis media	1 (1.6)	0	0	1 (1.6)	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	0	0	1 (1.6)
Pneumonia	1 (1.6)	0	0	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	1 (1.6)	0	0	0	1 (1.6)
Sinusitis	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Serious neurological adverse reactions					
-Total	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Mental status changes	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Tumour Lysis Syndrome					
-Total	1 (1.6)	0	0	0	1 (1.6)
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Sepsis	1 (11.1)	0	0	1 (11.1)	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (26.8)	0	0	7 (17.1)	4 (9.8)
Cytokine Release Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Infections					
-Total	11 (26.8)	0	0	7 (17.1)	4 (9.8)
Rhinovirus infection	0	0	0	0	0
Sepsis	2 (4.9)	0	0	0	2 (4.9)
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0
Covid-19	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Pneumonia	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Upper respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Serious neurological adverse reactions					
-Total	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	0	1 (2.4)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (45.5)	0	2 (18.2)	1 (9.1)	2 (18.2)
Cytokine Release Syndrome					
-Total	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (9.1)	0	0	1 (9.1)	0
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245o
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (75.4)	0	1 (1.4)	23 (33.3)	28 (40.6)
Cytokine Release Syndrome					
-Total	47 (68.1)	1 (1.4)	10 (14.5)	15 (21.7)	21 (30.4)
Cytokine release syndrome	46 (66.7)	1 (1.4)	10 (14.5)	15 (21.7)	20 (29.0)
Haemophagocytic lymphohistiocytosis	2 (2.9)	0	0	0	2 (2.9)
Hematological disorders including cytopenias					
-Total	16 (23.2)	0	0	14 (20.3)	2 (2.9)
Pancytopenia	0	0	0	0	0
Febrile neutropenia	15 (21.7)	0	0	14 (20.3)	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	29 (42.0)	0	0	17 (24.6)	12 (17.4)
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Parainfluenzae virus infection	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)
Upper respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Candida infection	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.9)	0	0	2 (2.9)	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	6 (8.7)	0	2 (2.9)	4 (5.8)	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=69 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.4)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	2 (33.3)	0
Febrile neutropenia	2 (33.3)	0	0	2 (33.3)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (62.2)	0	4 (5.4)	21 (28.4)	21 (28.4)
Cytokine Release Syndrome					
-Total	46 (62.2)	1 (1.4)	11 (14.9)	16 (21.6)	18 (24.3)
Cytokine release syndrome	46 (62.2)	1 (1.4)	11 (14.9)	16 (21.6)	18 (24.3)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	0	0	1 (1.4)
Hematological disorders including cytopenias					
-Total	12 (16.2)	0	0	10 (13.5)	2 (2.7)
Febrile neutropenia	11 (14.9)	0	0	10 (13.5)	1 (1.4)
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	11 (14.9)	0	1 (1.4)	7 (9.5)	3 (4.1)

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (1.4)	0	0	0	1 (1.4)
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.4)	0	0	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	0	1 (1.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (20.0)	0	0	1 (20.0)	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	1 (20.0)	0	0	1 (20.0)	0
Metapneumovirus infection	1 (20.0)	0	0	1 (20.0)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	17 (24.3)	0	0	10 (14.3)	7 (10.0)
Hematological disorders including cytopenias					
-Total	4 (5.7)	0	0	4 (5.7)	0
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	15 (21.4)	0	0	8 (11.4)	7 (10.0)
Metapneumovirus infection	0	0	0	0	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	1 (1.4)	0	0	0	1 (1.4)
Respiratory syncytial virus infection	2 (2.9)	0	0	2 (2.9)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (50.0)	0	0	2 (50.0)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (50.0)	0	0	2 (50.0)	0
Pneumonia respiratory syncytial viral	1 (25.0)	0	0	1 (25.0)	0
Upper respiratory tract infection	1 (25.0)	0	0	1 (25.0)	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (23.9)	0	1 (2.2)	6 (13.0)	4 (8.7)
Cytokine Release Syndrome					
-Total	1 (2.2)	0	0	0	1 (2.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	11 (23.9)	0	1 (2.2)	6 (13.0)	4 (8.7)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Candida infection	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0

Timing: >1 year post CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Device related sepsis	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Herpes zoster	1 (2.2)	0	0	1 (2.2)	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	1 (2.2)	0	0
Sepsis	3 (6.5)	0	0	1 (2.2)	2 (4.3)
Septic shock	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Serious neurological adverse reactions					
-Total	1 (2.2)	0	0	1 (2.2)	0
Seizure	1 (2.2)	0	0	1 (2.2)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	0	0	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	2 (33.3)	0
Febrile neutropenia	2 (33.3)	0	0	2 (33.3)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (50.0)	0	0	3 (50.0)	0
Metapneumovirus infection	1 (16.7)	0	0	1 (16.7)	0
Pneumonia respiratory syncytial viral	1 (16.7)	0	0	1 (16.7)	0
Upper respiratory tract infection	1 (16.7)	0	0	1 (16.7)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245p
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	52 (70.3)	0	3 (4.1)	22 (29.7)	27 (36.5)
Cytokine Release Syndrome					
-Total	47 (63.5)	1 (1.4)	11 (14.9)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	1 (1.4)	11 (14.9)	16 (21.6)	18 (24.3)
Haemophagocytic lymphohistiocytosis	2 (2.7)	0	0	0	2 (2.7)
Hematological disorders including cytopenias					
-Total	15 (20.3)	0	0	13 (17.6)	2 (2.7)
Febrile neutropenia	13 (17.6)	0	0	12 (16.2)	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	28 (37.8)	0	0	15 (20.3)	13 (17.6)
Metapneumovirus infection	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Upper respiratory tract infection	2 (2.7)	0	0	2 (2.7)	0
Bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Candida infection	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	2 (2.7)	0	0	0	2 (2.7)
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	2 (2.7)	0	0	2 (2.7)	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Herpes zoster	2 (2.7)	0	0	2 (2.7)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	0	2 (2.7)	0
Rhinovirus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	6 (8.1)	0	2 (2.7)	4 (5.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Tumour Lysis Syndrome					
-Total	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.7)	0	0	1 (1.4)	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (57.5)	0	1 (2.5)	10 (25.0)	12 (30.0)
Cytokine Release Syndrome					
-Total	23 (57.5)	1 (2.5)	3 (7.5)	9 (22.5)	10 (25.0)
Cytokine release syndrome	23 (57.5)	1 (2.5)	3 (7.5)	9 (22.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Febrile neutropenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	8 (20.0)	0	0	6 (15.0)	2 (5.0)

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Candida infection	1 (2.5)	0	0	0	1 (2.5)
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Encephalitis	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (67.5)	0	3 (7.5)	12 (30.0)	12 (30.0)
Cytokine Release Syndrome					
-Total	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Febrile neutropenia	11 (27.5)	0	0	11 (27.5)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	0	0	0	0	0
Candida infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Rhinovirus infection	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Cognitive disorder	1 (2.5)	0	1 (2.5)	0	0
Delirium	1 (2.5)	0	0	1 (2.5)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Encephalopathy	1 (2.5)	0	0	1 (2.5)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (30.0)	0	0	8 (20.0)	4 (10.0)
Hematological disorders including cytopenias					
-Total	2 (5.0)	0	0	2 (5.0)	0
Febrile neutropenia	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Infections					
-Total	11 (27.5)	0	0	7 (17.5)	4 (10.0)
Gastroenteritis	2 (5.0)	0	0	2 (5.0)	0
Bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	0	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	0	0	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (17.1)	0	0	3 (8.6)	3 (8.6)
Hematological disorders including cytopenias					
-Total	2 (5.7)	0	0	2 (5.7)	0
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	5 (14.3)	0	0	2 (5.7)	3 (8.6)
Gastroenteritis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	1 (2.9)	0	1 (2.9)	0	0
Mental status changes	1 (2.9)	0	1 (2.9)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (23.3)	0	1 (3.3)	4 (13.3)	2 (6.7)
Cytokine Release Syndrome					
-Total	1 (3.3)	0	0	0	1 (3.3)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	7 (23.3)	0	1 (3.3)	4 (13.3)	2 (6.7)
Sepsis	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Rhinovirus infection	1 (3.3)	0	1 (3.3)	0	0

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	6 (30.0)	0	0	4 (20.0)	2 (10.0)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	6 (30.0)	0	0	4 (20.0)	2 (10.0)
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Covid-19	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0
Meningitis pneumococcal	1 (5.0)	0	0	1 (5.0)	0
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Pneumonia respiratory syncytial viral	1 (5.0)	0	0	1 (5.0)	0
Septic shock	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Serious neurological adverse reactions					
-Total	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	28 (70.0)	0	1 (2.5)	12 (30.0)	15 (37.5)
Cytokine Release Syndrome					
-Total	24 (60.0)	1 (2.5)	3 (7.5)	9 (22.5)	11 (27.5)
Cytokine release syndrome	23 (57.5)	1 (2.5)	3 (7.5)	9 (22.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	5 (12.5)	0	0	4 (10.0)	1 (2.5)
Febrile neutropenia	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	19 (47.5)	0	0	11 (27.5)	8 (20.0)
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Gastroenteritis	2 (5.0)	0	0	2 (5.0)	0
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	0	0	1 (2.5)
Candida infection	1 (2.5)	0	0	0	1 (2.5)
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	0	0	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245q
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	29 (72.5)	0	2 (5.0)	12 (30.0)	15 (37.5)
Cytokine Release Syndrome					
-Total	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	12 (30.0)	0	0	11 (27.5)	1 (2.5)
Febrile neutropenia	12 (30.0)	0	0	12 (30.0)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	12 (30.0)	0	0	7 (17.5)	5 (12.5)
Encephalitis viral	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	1 (2.5)	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumocystis jirovecii pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Mental status changes	1 (2.5)	0	1 (2.5)	0	0
Cognitive disorder	1 (2.5)	0	1 (2.5)	0	0
Delirium	1 (2.5)	0	0	1 (2.5)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	0	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	0	0	1 (2.5)	1 (2.5)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (16.7)	0	0	0	1 (16.7)

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Candida infection	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	13 (59.1)	0	1 (4.5)	5 (22.7)	7 (31.8)
Cytokine Release Syndrome					
-Total	13 (59.1)	0	3 (13.6)	4 (18.2)	6 (27.3)
Cytokine release syndrome	13 (59.1)	0	3 (13.6)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	4 (18.2)	0	0	3 (13.6)	1 (4.5)
Febrile neutropenia	4 (18.2)	0	0	4 (18.2)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (4.5)	0	0	0	1 (4.5)
Infections					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	1 (4.5)	0	1 (4.5)	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (4.5)	0	1 (4.5)	0	0
Delirium	1 (4.5)	0	0	1 (4.5)	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0
Tumour Lysis Syndrome					

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (58.8)	0	1 (5.9)	5 (29.4)	4 (23.5)
Cytokine Release Syndrome					
-Total	10 (58.8)	0	2 (11.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	0	2 (11.8)	4 (23.5)	4 (23.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	4 (23.5)	0	0	4 (23.5)	0
Febrile neutropenia	4 (23.5)	0	0	4 (23.5)	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	0	0	1 (5.9)	0
Encephalitis	0	0	0	0	0
Candida infection	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Varicella zoster virus infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (65.7)	0	2 (5.7)	11 (31.4)	10 (28.6)
Cytokine Release Syndrome					
-Total	23 (65.7)	1 (2.9)	5 (14.3)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	1 (2.9)	5 (14.3)	8 (22.9)	9 (25.7)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	4 (11.4)	0	0	4 (11.4)	0
Febrile neutropenia	3 (8.6)	0	0	3 (8.6)	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Thrombocytopenia	0	0	0	0	0
Infections					

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (20.0)	0	0	6 (17.1)	1 (2.9)
Encephalitis	0	0	0	0	0
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	0	0	0	0	0
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	0	0	0	0	0
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal bacteraemia	0	0	0	0	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Within 8 weeks post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	1 (5.0)	0	0	1 (5.0)	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (20.0)	0	0	3 (20.0)	0
Hematological disorders including cytopenias					
-Total	2 (13.3)	0	0	2 (13.3)	0
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Myelodysplastic syndrome	0	0	0	0	0
Infections					
-Total	2 (13.3)	0	0	2 (13.3)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Device related infection	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	1 (6.7)	0	0	1 (6.7)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (34.3)	0	0	6 (17.1)	6 (17.1)
Hematological disorders including cytopenias					
-Total	2 (5.7)	0	0	2 (5.7)	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Infections					
-Total	11 (31.4)	0	0	5 (14.3)	6 (17.1)
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis	2 (5.7)	0	0	2 (5.7)	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Pneumonia	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0	1 (2.9)	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Sinusitis	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Mental status changes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (33.3)	0	0	1 (33.3)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Candida infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Cytokine Release Syndrome					
-Total	1 (7.7)	0	0	0	1 (7.7)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Infections					
-Total	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Candida infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	0	0	0	0	0
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Device related sepsis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (18.2)	0	0	2 (18.2)	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	2 (18.2)	0	0	2 (18.2)	0
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Candida infection	0	0	0	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pneumonia respiratory syncytial viral	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Seizure	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	8 (34.8)	0	1 (4.3)	4 (17.4)	3 (13.0)
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Infections					
-Total	8 (34.8)	0	1 (4.3)	4 (17.4)	3 (13.0)
Clostridium difficile colitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Candida infection	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	1 (4.3)	0	0	1 (4.3)	0
Covid-19 pneumonia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Herpes zoster	1 (4.3)	0	0	1 (4.3)	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Ophthalmic herpes zoster	1 (4.3)	0	1 (4.3)	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Sepsis	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	0	0	0	0	0
Upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0
Serious neurological adverse reactions					
-Total	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0

-A patient with multiple adverse events within a group term is counted only once in the

total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	5 (83.3)	0	0	2 (33.3)	3 (50.0)
Cytokine Release Syndrome					
-Total	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Hematological disorders including cytopenias					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (16.7)	0	0	1 (16.7)	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (68.2)	0	1 (4.5)	5 (22.7)	9 (40.9)
Cytokine Release Syndrome					
-Total	14 (63.6)	0	3 (13.6)	4 (18.2)	7 (31.8)
Cytokine release syndrome	13 (59.1)	0	3 (13.6)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	0	0	1 (4.5)
Hematological disorders including cytopenias					
-Total	4 (18.2)	0	0	3 (13.6)	1 (4.5)
Febrile neutropenia	4 (18.2)	0	0	4 (18.2)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	1 (4.5)	0	0	0	1 (4.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	5 (22.7)	0	0	2 (9.1)	3 (13.6)
Clostridium difficile colitis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	1 (4.5)	0	0	0	1 (4.5)
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	1 (4.5)	0	0	1 (4.5)	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (4.5)	0	0	1 (4.5)	0
Serious neurological adverse reactions					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (4.5)	0	1 (4.5)	0	0
Delirium	1 (4.5)	0	0	1 (4.5)	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (64.7)	0	1 (5.9)	6 (35.3)	4 (23.5)
Cytokine Release Syndrome					
-Total	10 (58.8)	0	2 (11.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	0	2 (11.8)	4 (23.5)	4 (23.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	5 (29.4)	0	0	5 (29.4)	0
Febrile neutropenia	5 (29.4)	0	0	5 (29.4)	0
Myelodysplastic syndrome	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	5 (29.4)	0	0	5 (29.4)	0
Clostridium difficile colitis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (5.9)	0	0	1 (5.9)	0
Device related infection	0	0	0	0	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	1 (5.9)	0	0	1 (5.9)	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (5.9)	0	0	1 (5.9)	0
Rhinovirus infection	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.9)	0	0	1 (5.9)	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 245r
Serious adverse events of special interest (AESI) post CTL019 infusion based on identified risks, regardless of study drug relationship, by group term, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	26 (74.3)	0	1 (2.9)	11 (31.4)	14 (40.0)
Cytokine Release Syndrome					
-Total	23 (65.7)	1 (2.9)	5 (14.3)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	1 (2.9)	5 (14.3)	8 (22.9)	9 (25.7)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	6 (17.1)	0	0	6 (17.1)	0
Febrile neutropenia	4 (11.4)	0	0	4 (11.4)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Thrombocytopenia	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections					
-Total	19 (54.3)	0	0	10 (28.6)	9 (25.7)
Clostridium difficile colitis	0	0	0	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Pneumonia	0	0	0	0	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)
Candida infection	2 (5.7)	0	1 (2.9)	0	1 (2.9)
Covid-19	1 (2.9)	0	0	1 (2.9)	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis	2 (5.7)	0	0	2 (5.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Ophthalmic herpes zoster	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Septic shock	2 (5.7)	0	0	0	2 (5.7)
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Upper respiratory tract infection	2 (5.7)	0	0	2 (5.7)	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Tumour Lysis Syndrome					
-Total	1 (2.9)	0	0	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (2.9)	0	0	0	1 (2.9)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	1 (2.9)	0	0	0	1 (2.9)
Fungaemia	1 (2.9)	0	0	0	1 (2.9)
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (6.5)	0	0	1 (3.2)	1 (3.2)
Hematological disorders including cytopenias					
-Total	2 (6.5)	0	0	1 (3.2)	1 (3.2)
Febrile neutropenia	1 (3.2)	0	0	1 (3.2)	0
Neutrophil count decreased	1 (3.2)	0	0	0	1 (3.2)
Infections					
-Total	0	0	0	0	0
Fungaemia	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247a
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Hematological disorders including cytopenias					
-Total	1 (7.7)	0	0	1 (7.7)	0
Febrile neutropenia	1 (7.7)	0	0	1 (7.7)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Fungaemia	0	0	0	0	0
Bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247b
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Hematological disorders including cytopenias					
-Total	1 (2.2)	0	0	1 (2.2)	0
Febrile neutropenia	1 (2.2)	0	0	1 (2.2)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	1 (2.2)	0	0	0	1 (2.2)
Fungaemia	1 (2.2)	0	0	0	1 (2.2)
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247b
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Hematological disorders including cytopenias					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Neutrophil count decreased	1 (3.1)	0	0	0	1 (3.1)
Infections					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Fungaemia	0	0	0	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Hematological disorders including cytopenias					
-Total	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Febrile neutropenia	2 (3.5)	0	0	2 (3.5)	0
Neutrophil count decreased	1 (1.8)	0	0	0	1 (1.8)
Infections					
-Total	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247c
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (18.2)	0	0	0	2 (18.2)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	2 (18.2)	0	0	0	2 (18.2)
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Fungaemia	1 (9.1)	0	0	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247d
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (14.3)	0	0	0	2 (14.3)
Hematological disorders including cytopenias					
-Total	1 (7.1)	0	0	0	1 (7.1)
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Febrile neutropenia	0	0	0	0	0
Infections					
-Total	1 (7.1)	0	0	0	1 (7.1)
Escherichia bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247d
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (4.7)	0	0	2 (3.1)	1 (1.6)
Hematological disorders including cytopenias					
-Total	2 (3.1)	0	0	2 (3.1)	0
Neutrophil count decreased	0	0	0	0	0
Febrile neutropenia	2 (3.1)	0	0	2 (3.1)	0
Infections					
-Total	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Escherichia bacteraemia	0	0	0	0	0
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Fungaemia	1 (1.6)	0	0	0	1 (1.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247e
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247e
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.9)	0	0	2 (2.8)	3 (4.2)
Hematological disorders including cytopenias					
-Total	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Febrile neutropenia	2 (2.8)	0	0	2 (2.8)	0
Neutrophil count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	3 (4.2)	0	0	1 (1.4)	2 (2.8)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247f
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247f
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.5)	0	0	2 (2.6)	3 (3.9)
Hematological disorders including cytopenias					
-Total	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Febrile neutropenia	2 (2.6)	0	0	2 (2.6)	0
Neutrophil count decreased	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	3 (3.9)	0	0	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247g
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247g
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.5)	0	0	2 (2.6)	3 (3.9)
Hematological disorders including cytopenias					
-Total	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Febrile neutropenia	2 (2.6)	0	0	2 (2.6)	0
Neutrophil count decreased	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	3 (3.9)	0	0	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247h
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247h
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.5)	0	0	2 (2.6)	3 (3.9)
Hematological disorders including cytopenias					
-Total	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Febrile neutropenia	2 (2.6)	0	0	2 (2.6)	0
Neutrophil count decreased	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	3 (3.9)	0	0	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247i
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247i
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.5)	0	0	2 (2.6)	3 (3.9)
Hematological disorders including cytopenias					
-Total	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Febrile neutropenia	2 (2.6)	0	0	2 (2.6)	0
Neutrophil count decreased	1 (1.3)	0	0	0	1 (1.3)
Infections					
-Total	3 (3.9)	0	0	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247j
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (14.8)	0	0	2 (7.4)	2 (7.4)
Hematological disorders including cytopenias					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Neutrophil count decreased	1 (3.7)	0	0	0	1 (3.7)
Infections					
-Total	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Fungaemia	1 (3.7)	0	0	0	1 (3.7)
Escherichia bacteraemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247j
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (2.0)	0	0	0	1 (2.0)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	1 (2.0)	0	0	0	1 (2.0)
Bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Escherichia bacteraemia	1 (2.0)	0	0	0	1 (2.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247k
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Hematological disorders including cytopenias					
-Total	1 (3.7)	0	0	1 (3.7)	0
Febrile neutropenia	1 (3.7)	0	0	1 (3.7)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Escherichia bacteraemia	1 (3.7)	0	0	0	1 (3.7)
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247k
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (6.8)	0	0	1 (2.3)	2 (4.5)
Hematological disorders including cytopenias					
-Total	2 (4.5)	0	0	1 (2.3)	1 (2.3)
Febrile neutropenia	1 (2.3)	0	0	1 (2.3)	0
Neutrophil count decreased	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	1 (2.3)	0	0	0	1 (2.3)
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	1 (2.3)	0	0	0	1 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247k
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247l
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (8.7)	0	0	1 (2.2)	3 (6.5)
Hematological disorders including cytopenias					
-Total	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Febrile neutropenia	1 (2.2)	0	0	1 (2.2)	0
Neutrophil count decreased	1 (2.2)	0	0	0	1 (2.2)
Infections					
-Total	3 (6.5)	0	0	1 (2.2)	2 (4.3)
Bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia bacteraemia	1 (2.2)	0	0	0	1 (2.2)
Fungaemia	1 (2.2)	0	0	0	1 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247l
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (3.1)	0	0	1 (3.1)	0
Hematological disorders including cytopenias					
-Total	1 (3.1)	0	0	1 (3.1)	0
Febrile neutropenia	1 (3.1)	0	0	1 (3.1)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247m
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247m
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (7.7)	0	0	2 (3.1)	3 (4.6)
Hematological disorders including cytopenias					
-Total	3 (4.6)	0	0	2 (3.1)	1 (1.5)
Febrile neutropenia	2 (3.1)	0	0	2 (3.1)	0
Neutrophil count decreased	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	3 (4.6)	0	0	1 (1.5)	2 (3.1)
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247n
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (4.0)	0	0	1 (4.0)	0
Hematological disorders including cytopenias					
-Total	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247n
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (7.5)	0	0	1 (1.9)	3 (5.7)
Hematological disorders including cytopenias					
-Total	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Febrile neutropenia	1 (1.9)	0	0	1 (1.9)	0
Neutrophil count decreased	1 (1.9)	0	0	0	1 (1.9)
Infections					
-Total	3 (5.7)	0	0	1 (1.9)	2 (3.8)
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	0	1 (1.9)
Fungaemia	1 (1.9)	0	0	0	1 (1.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247o
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247o
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (7.5)	0	0	2 (3.0)	3 (4.5)
Hematological disorders including cytopenias					
-Total	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Febrile neutropenia	2 (3.0)	0	0	2 (3.0)	0
Neutrophil count decreased	1 (1.5)	0	0	0	1 (1.5)
Infections					
-Total	3 (4.5)	0	0	1 (1.5)	2 (3.0)
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247p
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247p
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (6.9)	0	0	2 (2.8)	3 (4.2)
Hematological disorders including cytopenias					
-Total	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Febrile neutropenia	2 (2.8)	0	0	2 (2.8)	0
Neutrophil count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	3 (4.2)	0	0	1 (1.4)	2 (2.8)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (5.3)	0	0	1 (2.6)	1 (2.6)
Hematological disorders including cytopenias					
-Total	1 (2.6)	0	0	1 (2.6)	0
Febrile neutropenia	1 (2.6)	0	0	1 (2.6)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	2 (5.3)	0	0	1 (2.6)	1 (2.6)
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Escherichia bacteraemia	1 (2.6)	0	0	0	1 (2.6)
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Hematological disorders including cytopenias					
-Total	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Febrile neutropenia	1 (2.6)	0	0	1 (2.6)	0
Neutrophil count decreased	1 (2.6)	0	0	0	1 (2.6)
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247q
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	1 (100)	0	0	0	1 (100)
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (4.5)	0	0	1 (4.5)	0
Hematological disorders including cytopenias					
-Total	1 (4.5)	0	0	1 (4.5)	0
Febrile neutropenia	1 (4.5)	0	0	1 (4.5)	0
Neutrophil count decreased	0	0	0	0	0
Infections					
-Total	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 247r
Serious adverse events of special interest (AESI) during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (11.4)	0	0	1 (2.9)	3 (8.6)
Hematological disorders including cytopenias					
-Total	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Neutrophil count decreased	1 (2.9)	0	0	0	1 (2.9)
Infections					
-Total	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Fungaemia	1 (2.9)	0	0	0	1 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (75.6)	0	1 (2.4)	14 (34.1)	16 (39.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	19 (46.3)	1 (2.4)	6 (14.6)	3 (7.3)	9 (22.0)
Cytokine release syndrome	18 (43.9)	1 (2.4)	6 (14.6)	3 (7.3)	8 (19.5)
Haemophagocytic lymphohistiocytosis	2 (4.9)	0	0	0	2 (4.9)
Hematological disorders including cytopenias					
-Total	19 (46.3)	0	0	17 (41.5)	2 (4.9)
Febrile neutropenia	16 (39.0)	0	0	16 (39.0)	0
Neutrophil count decreased	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	0	1 (2.4)	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	20 (48.8)	0	0	10 (24.4)	10 (24.4)
Bronchopulmonary aspergillosis	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Device related infection	2 (4.9)	0	0	2 (4.9)	0
Pneumonia	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Cytomegalovirus infection reactivation	1 (2.4)	0	0	1 (2.4)	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Escherichia bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Fungaemia	1 (2.4)	0	0	0	1 (2.4)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	0	0	1 (2.4)	0
Haemophilus bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Human herpesvirus 6 infection	1 (2.4)	0	0	1 (2.4)	0
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Otitis externa	1 (2.4)	0	0	1 (2.4)	0
Otitis media	1 (2.4)	0	0	1 (2.4)	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	0	0	1 (2.4)
Pneumonia fungal	1 (2.4)	0	0	0	1 (2.4)
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sepsis	1 (2.4)	0	0	0	1 (2.4)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	0	0	1 (2.4)
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (9.8)	0	0	4 (9.8)	0
Encephalopathy	2 (4.9)	0	0	2 (4.9)	0
Mental status changes	2 (4.9)	0	0	2 (4.9)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (82.5)	0	1 (2.5)	12 (30.0)	20 (50.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	23 (57.5)	0	4 (10.0)	10 (25.0)	9 (22.5)
Cytokine release syndrome	23 (57.5)	0	4 (10.0)	10 (25.0)	9 (22.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	10 (25.0)	0	0	6 (15.0)	4 (10.0)
Febrile neutropenia	7 (17.5)	0	0	6 (15.0)	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Anaemia	1 (2.5)	0	0	0	1 (2.5)
Myelodysplastic syndrome	0	0	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Platelet count decreased	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	25 (62.5)	0	0	15 (37.5)	10 (25.0)
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	3 (7.5)	0	0	3 (7.5)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	3 (7.5)	0	0	1 (2.5)	2 (5.0)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Systemic mycosis	0	0	0	0	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Bacterial sepsis	0	0	0	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Fungal sepsis	0	0	0	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	0	0	0	0	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal abscess	0	0	0	0	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Staphylococcal skin infection	0	0	0	0	0
Upper respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Encephalopathy	0	0	0	0	0
Mental status changes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	1 (2.5)	0	0	1 (2.5)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Seizure	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	0	0	1 (2.5)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249a
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (82.4)	0	0	7 (41.2)	7 (41.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	9 (52.9)	0	2 (11.8)	3 (17.6)	4 (23.5)
Cytokine release syndrome	9 (52.9)	0	2 (11.8)	3 (17.6)	4 (23.5)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	6 (35.3)	0	0	4 (23.5)	2 (11.8)
Febrile neutropenia	5 (29.4)	0	0	4 (23.5)	1 (5.9)
Neutrophil count decreased	0	0	0	0	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Platelet count decreased	0	0	0	0	0
Infections					
-Total	11 (64.7)	0	0	7 (41.2)	4 (23.5)
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Aspergillus infection	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Candida infection	1 (5.9)	0	0	0	1 (5.9)
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	1 (5.9)	0	0	0	1 (5.9)
Fungaemia	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	0	0	0	0	0
Gastroenteritis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	1 (5.9)	0	0	1 (5.9)	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Sepsis	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis viral	1 (5.9)	0	0	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (5.9)	0	0	1 (5.9)	0
Rhinovirus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)
Serratia sepsis	0	0	0	0	0
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	2 (11.8)	0	0	2 (11.8)	0
Varicella zoster virus infection	1 (5.9)	0	0	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Serious neurological adverse reactions					
-Total	1 (5.9)	0	1 (5.9)	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Cognitive disorder	1 (5.9)	0	1 (5.9)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249b
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (76.4)	0	2 (3.6)	16 (29.1)	24 (43.6)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	24 (43.6)	0	5 (9.1)	7 (12.7)	12 (21.8)
Cytokine release syndrome	23 (41.8)	0	5 (9.1)	7 (12.7)	11 (20.0)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	0	0	1 (1.8)
Hematological disorders including cytopenias					
-Total	18 (32.7)	0	0	14 (25.5)	4 (7.3)
Febrile neutropenia	14 (25.5)	0	0	14 (25.5)	0
Anaemia	2 (3.6)	0	1 (1.8)	0	1 (1.8)
Neutropenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Thrombocytopenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Myelodysplastic syndrome	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	28 (50.9)	0	0	17 (30.9)	11 (20.0)
Pneumonia	3 (5.5)	0	0	2 (3.6)	1 (1.8)
Sepsis	3 (5.5)	0	0	1 (1.8)	2 (3.6)
Staphylococcal sepsis	3 (5.5)	0	0	0	3 (5.5)
Device related infection	2 (3.6)	0	0	2 (3.6)	0
Herpes zoster	2 (3.6)	0	0	2 (3.6)	0
Respiratory tract infection	2 (3.6)	0	0	2 (3.6)	0
Staphylococcal bacteraemia	2 (3.6)	0	0	2 (3.6)	0
Upper respiratory tract infection	2 (3.6)	0	0	2 (3.6)	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Candida infection	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Covid-19	1 (1.8)	0	0	1 (1.8)	0
Covid-19 pneumonia	1 (1.8)	0	0	0	1 (1.8)
Cytomegalovirus infection reactivation	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	0	0	1 (1.8)	0
Ophthalmic herpes zoster	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Paronychia	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumocystis jirovecii pneumonia	1 (1.8)	0	0	0	1 (1.8)
Pneumonia fungal	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Sinusitis	1 (1.8)	0	0	1 (1.8)	0
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Varicella zoster virus infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (7.3)	0	1 (1.8)	3 (5.5)	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Dysarthria	1 (1.8)	0	0	1 (1.8)	0
Encephalopathy	1 (1.8)	0	0	1 (1.8)	0
Mental status changes	1 (1.8)	0	0	1 (1.8)	0
Seizure	1 (1.8)	0	1 (1.8)	0	0
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Tumour lysis syndrome	2 (3.6)	0	0	1 (1.8)	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249b
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (83.7)	0	0	17 (39.5)	19 (44.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	27 (62.8)	1 (2.3)	7 (16.3)	9 (20.9)	10 (23.3)
Cytokine release syndrome	27 (62.8)	1 (2.3)	7 (16.3)	9 (20.9)	10 (23.3)
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	0	0	1 (2.3)
Hematological disorders including cytopenias					
-Total	17 (39.5)	0	0	13 (30.2)	4 (9.3)
Febrile neutropenia	14 (32.6)	0	0	12 (27.9)	2 (4.7)
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Pancytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Myelodysplastic syndrome	1 (2.3)	0	0	1 (2.3)	0
Platelet count decreased	1 (2.3)	0	0	0	1 (2.3)
Infections					
-Total	28 (65.1)	0	0	15 (34.9)	13 (30.2)
Pneumonia	1 (2.3)	0	0	0	1 (2.3)
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal sepsis	0	0	0	0	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Herpes zoster	2 (4.7)	0	0	2 (4.7)	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal bacteraemia	2 (4.7)	0	0	2 (4.7)	0
Upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (2.3)	0	0	0	1 (2.3)
Candida infection	1 (2.3)	0	0	0	1 (2.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	1 (2.3)	0	0	0	1 (2.3)
Escherichia bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Fungaemia	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	1 (2.3)	0	0	0	1 (2.3)
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (2.3)	0	0	1 (2.3)	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bacteraemia	3 (7.0)	0	0	2 (4.7)	1 (2.3)
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Device related sepsis	2 (4.7)	0	0	2 (4.7)	0
Encephalitis viral	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Enterobacter infection	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	1 (2.3)	0	0	0	1 (2.3)
Fungal skin infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Gastroenteritis adenovirus	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	0	1 (2.3)	0
Haemophilus bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Klebsiella infection	1 (2.3)	0	0	1 (2.3)	0
Mastoiditis	1 (2.3)	0	0	1 (2.3)	0
Meningitis bacterial	1 (2.3)	0	0	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Otitis externa	1 (2.3)	0	0	1 (2.3)	0
Otitis media	1 (2.3)	0	0	1 (2.3)	0
Pharyngitis streptococcal	1 (2.3)	0	0	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0
Pneumonia viral	1 (2.3)	0	0	1 (2.3)	0
Rhinovirus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Septic shock	3 (7.0)	0	0	0	3 (7.0)
Staphylococcal skin infection	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection	2 (4.7)	0	0	2 (4.7)	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Serious neurological adverse reactions					
-Total	6 (14.0)	0	2 (4.7)	4 (9.3)	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Mental status changes	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Seizure	1 (2.3)	0	0	1 (2.3)	0
Cognitive disorder	1 (2.3)	0	1 (2.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (2.3)	0	0	0	1 (2.3)
Tumour lysis syndrome	1 (2.3)	0	0	0	1 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (82.9)	0	2 (2.9)	26 (37.1)	30 (42.9)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	37 (52.9)	0	11 (15.7)	14 (20.0)	12 (17.1)
Cytokine release syndrome	37 (52.9)	0	11 (15.7)	14 (20.0)	12 (17.1)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	0	0	1 (1.4)
Hematological disorders including cytopenias					
-Total	27 (38.6)	0	0	21 (30.0)	6 (8.6)
Febrile neutropenia	21 (30.0)	0	0	20 (28.6)	1 (1.4)
Pancytopenia	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Anaemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Neutropenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Platelet count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	43 (61.4)	0	0	25 (35.7)	18 (25.7)
Sepsis	4 (5.7)	0	0	1 (1.4)	3 (4.3)
Staphylococcal bacteraemia	4 (5.7)	0	0	4 (5.7)	0
Device related infection	3 (4.3)	0	0	3 (4.3)	0
Herpes zoster	3 (4.3)	0	0	3 (4.3)	0
Pneumonia	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Staphylococcal sepsis	3 (4.3)	0	0	0	3 (4.3)
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Candida infection	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Device related sepsis	2 (2.9)	0	0	2 (2.9)	0
Encephalitis	2 (2.9)	0	0	0	2 (2.9)
Gastroenteritis	2 (2.9)	0	0	2 (2.9)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	2 (2.9)	0	0	2 (2.9)	0
Sinusitis	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Localised infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0	1 (1.4)	0
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Fungaemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Otitis externa	0	0	0	0	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	8 (11.4)	0	2 (2.9)	6 (8.6)	0
Mental status changes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Encephalopathy	2 (2.9)	0	0	2 (2.9)	0
Seizure	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	0	2 (2.9)
Tumour lysis syndrome	2 (2.9)	0	0	0	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (46.7)	0	0	3 (20.0)	4 (26.7)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (26.7)	0	0	1 (6.7)	3 (20.0)
Cytokine release syndrome	4 (26.7)	0	0	1 (6.7)	3 (20.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	2 (13.3)	0	0	2 (13.3)	0
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Pancytopenia	0	0	0	0	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	5 (33.3)	0	0	3 (20.0)	2 (13.3)
Sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Candida infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Encephalitis viral	1 (6.7)	0	0	0	1 (6.7)
Enterobacter infection	0	0	0	0	0
Fungaemia	0	0	0	0	0
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (6.7)	0	0	1 (6.7)	0
Otitis externa	0	0	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249c
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	0	4 (30.8)	9 (69.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	10 (76.9)	1 (7.7)	1 (7.7)	1 (7.7)	7 (53.8)
Cytokine release syndrome	9 (69.2)	1 (7.7)	1 (7.7)	1 (7.7)	6 (46.2)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Hematological disorders including cytopenias					
-Total	6 (46.2)	0	0	4 (30.8)	2 (15.4)
Febrile neutropenia	5 (38.5)	0	0	4 (30.8)	1 (7.7)
Pancytopenia	0	0	0	0	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (7.7)	0	0	0	1 (7.7)
Thrombocytopenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	8 (61.5)	0	0	4 (30.8)	4 (30.8)
Sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Herpes zoster	1 (7.7)	0	0	1 (7.7)	0
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Septic shock	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Candida infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (7.7)	0	0	1 (7.7)	0
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Rhinovirus infection	1 (7.7)	0	1 (7.7)	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Urinary tract infection	1 (7.7)	0	0	1 (7.7)	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis viral	1 (7.7)	0	0	1 (7.7)	0
Enterobacter infection	1 (7.7)	0	0	1 (7.7)	0
Fungaemia	1 (7.7)	0	0	0	1 (7.7)
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	1 (7.7)	0	0	1 (7.7)	0
Mastoiditis	1 (7.7)	0	0	1 (7.7)	0
Meningitis bacterial	0	0	0	0	0
Otitis externa	1 (7.7)	0	0	1 (7.7)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	1 (7.7)	0	0	1 (7.7)	0
Pharyngitis streptococcal	1 (7.7)	0	0	1 (7.7)	0
Viral upper respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Serious neurological adverse reactions					
-Total	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Mental status changes	1 (7.7)	0	0	1 (7.7)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Cognitive disorder	1 (7.7)	0	1 (7.7)	0	0
Tumour Lysis Syndrome					
-Total	1 (7.7)	0	0	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249d
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	0	0	4 (22.2)	13 (72.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Cytokine release syndrome	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	7 (38.9)	0	0	4 (22.2)	3 (16.7)
Febrile neutropenia	5 (27.8)	0	0	4 (22.2)	1 (5.6)
Anaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (5.6)	0	0	1 (5.6)	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	12 (66.7)	0	0	8 (44.4)	4 (22.2)
Bacteraemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Escherichia bacteraemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Urinary tract infection	2 (11.1)	0	0	2 (11.1)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Encephalitis viral	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis streptococcal	1 (5.6)	0	0	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (5.6)	0	0	0	1 (5.6)
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Viral upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Abscess limb	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Mental status changes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Cognitive disorder	1 (5.6)	0	1 (5.6)	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249d
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (76.3)	0	2 (2.5)	29 (36.3)	30 (37.5)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	38 (47.5)	1 (1.3)	8 (10.0)	15 (18.8)	14 (17.5)
Cytokine release syndrome	37 (46.3)	1 (1.3)	8 (10.0)	15 (18.8)	13 (16.3)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	0	0	2 (2.5)
Hematological disorders including cytopenias					
-Total	28 (35.0)	0	0	23 (28.8)	5 (6.3)
Febrile neutropenia	23 (28.8)	0	0	22 (27.5)	1 (1.3)
Anaemia	0	0	0	0	0
Neutrophil count decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Platelet count decreased	0	0	0	0	0

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Neutropenia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pancytopenia	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Infections					
-Total	44 (55.0)	0	0	24 (30.0)	20 (25.0)
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Escherichia bacteraemia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis viral	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	2 (2.5)	0	0	2 (2.5)	0
Gastroenteritis viral	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.3)	0	0	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Upper respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Viral upper respiratory tract infection	0	0	0	0	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Candida infection	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	3 (3.8)	0	0	3 (3.8)	0
Device related sepsis	2 (2.5)	0	0	2 (2.5)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Fungal sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis adenovirus	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Haemophilus bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Herpes zoster	4 (5.0)	0	0	4 (5.0)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0
Paronychia	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia	4 (5.0)	0	0	2 (2.5)	2 (2.5)
Pneumonia fungal	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Sepsis	4 (5.0)	0	0	1 (1.3)	3 (3.8)
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Sialoadenitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal infection	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Staphylococcal sepsis	3 (3.8)	0	0	0	3 (3.8)
Staphylococcal skin infection	1 (1.3)	0	0	1 (1.3)	0
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Serious neurological adverse reactions					
-Total	7 (8.8)	0	1 (1.3)	6 (7.5)	0
Mental status changes	2 (2.5)	0	0	2 (2.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	1 (1.3)	0	0	1 (1.3)	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	2 (2.5)	0	0	2 (2.5)	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	0	1 (1.3)
Tumour lysis syndrome	1 (1.3)	0	0	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249e
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	0	0	2 (25.0)	5 (62.5)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (50.0)	0	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Hematological disorders including cytopenias					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249e
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (78.9)	0	2 (2.2)	31 (34.4)	38 (42.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	47 (52.2)	1 (1.1)	10 (11.1)	16 (17.8)	20 (22.2)
Cytokine release syndrome	46 (51.1)	1 (1.1)	10 (11.1)	16 (17.8)	19 (21.1)
Haemophagocytic lymphohistiocytosis	1 (1.1)	0	0	0	1 (1.1)
Hematological disorders including cytopenias					
-Total	33 (36.7)	0	0	26 (28.9)	7 (7.8)
Febrile neutropenia	26 (28.9)	0	0	25 (27.8)	1 (1.1)
Anaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Pancytopenia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Infections					
-Total	50 (55.6)	0	0	29 (32.2)	21 (23.3)
Clostridium difficile colitis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Pneumonia	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	3 (3.3)	0	0	3 (3.3)	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Candida infection	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Covid-19	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	0	0	1 (1.1)	0
Device related infection	3 (3.3)	0	0	3 (3.3)	0
Device related sepsis	2 (2.2)	0	0	2 (2.2)	0
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Escherichia bacteraemia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes zoster	4 (4.4)	0	0	4 (4.4)	0
Human herpesvirus 6 infection	1 (1.1)	0	0	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis externa	1 (1.1)	0	0	1 (1.1)	0
Otitis media	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory syncytial virus infection	2 (2.2)	0	0	2 (2.2)	0
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Rhinovirus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Septic shock	3 (3.3)	0	0	0	3 (3.3)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	2 (2.2)	0	0	2 (2.2)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	3 (3.3)	0	0	0	3 (3.3)
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Upper respiratory tract infection	3 (3.3)	0	0	3 (3.3)	0
Urinary tract infection	2 (2.2)	0	0	2 (2.2)	0
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Serious neurological adverse reactions					
-Total	9 (10.0)	0	3 (3.3)	6 (6.7)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Cognitive disorder	1 (1.1)	0	1 (1.1)	0	0
Delirium	1 (1.1)	0	0	1 (1.1)	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Mental status changes	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Seizure	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tumour Lysis Syndrome					
-Total	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Tumour lysis syndrome	3 (3.3)	0	0	1 (1.1)	2 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249f
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Anaemia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249f
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	76 (79.2)	0	2 (2.1)	33 (34.4)	41 (42.7)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	49 (51.0)	1 (1.0)	12 (12.5)	15 (15.6)	21 (21.9)
Cytokine release syndrome	48 (50.0)	1 (1.0)	12 (12.5)	15 (15.6)	20 (20.8)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	0	0	2 (2.1)
Hematological disorders including cytopenias					
-Total	34 (35.4)	0	0	26 (27.1)	8 (8.3)
Pancytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Febrile neutropenia	28 (29.2)	0	0	26 (27.1)	2 (2.1)
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Thrombocytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Infections					
-Total	54 (56.3)	0	0	31 (32.3)	23 (24.0)
Abscess limb	0	0	0	0	0
Encephalitis	1 (1.0)	0	0	0	1 (1.0)
Respiratory syncytial virus infection	1 (1.0)	0	0	1 (1.0)	0
Sepsis	3 (3.1)	0	0	0	3 (3.1)
Upper respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchopulmonary aspergillosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Covid-19	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cytomegalovirus infection reactivation	1 (1.0)	0	0	1 (1.0)	0
Device related infection	3 (3.1)	0	0	3 (3.1)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Escherichia bacteraemia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes zoster	4 (4.2)	0	0	4 (4.2)	0
Human herpesvirus 6 infection	1 (1.0)	0	0	1 (1.0)	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis externa	1 (1.0)	0	0	1 (1.0)	0
Otitis media	1 (1.0)	0	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	0	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Rhinovirus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis	2 (2.1)	0	0	2 (2.1)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal bacteraemia	4 (4.2)	0	0	4 (4.2)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection	2 (2.1)	0	0	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.0)	0	0	1 (1.0)	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Serious neurological adverse reactions					
-Total	10 (10.4)	0	3 (3.1)	7 (7.3)	0
Cognitive disorder	1 (1.0)	0	1 (1.0)	0	0
Delirium	1 (1.0)	0	0	1 (1.0)	0
Dysarthria	1 (1.0)	0	0	1 (1.0)	0
Encephalopathy	2 (2.1)	0	0	2 (2.1)	0
Mental status changes	4 (4.2)	0	1 (1.0)	3 (3.1)	0
Seizure	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tumour Lysis Syndrome					
-Total	2 (2.1)	0	0	0	2 (2.1)
Tumour lysis syndrome	2 (2.1)	0	0	0	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249g
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249g
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (80.4)	0	2 (2.1)	33 (34.0)	43 (44.3)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	51 (52.6)	1 (1.0)	12 (12.4)	16 (16.5)	22 (22.7)
Cytokine release syndrome	50 (51.5)	1 (1.0)	12 (12.4)	16 (16.5)	21 (21.6)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	0	0	2 (2.1)
Hematological disorders including cytopenias					
-Total	35 (36.1)	0	0	27 (27.8)	8 (8.2)
Febrile neutropenia	28 (28.9)	0	0	26 (26.8)	2 (2.1)
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Pancytopenia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Thrombocytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Infections					
-Total	56 (57.7)	0	0	32 (33.0)	24 (24.7)
Herpes zoster	4 (4.1)	0	0	4 (4.1)	0
Pneumonia	4 (4.1)	0	0	2 (2.1)	2 (2.1)
Sepsis	4 (4.1)	0	0	1 (1.0)	3 (3.1)
Staphylococcal bacteraemia	4 (4.1)	0	0	4 (4.1)	0
Bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Device related infection	3 (3.1)	0	0	3 (3.1)	0
Gastroenteritis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Upper respiratory tract infection	3 (3.1)	0	0	3 (3.1)	0
Bronchopulmonary aspergillosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)	0	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Escherichia bacteraemia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory syncytial virus infection	2 (2.1)	0	0	2 (2.1)	0
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Rhinovirus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Sinusitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Urinary tract infection	2 (2.1)	0	0	2 (2.1)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Covid-19	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cytomegalovirus infection reactivation	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Human herpesvirus 6 infection	1 (1.0)	0	0	1 (1.0)	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis externa	1 (1.0)	0	0	1 (1.0)	0
Otitis media	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	0	0	1 (1.0)
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Varicella zoster virus infection	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Serious neurological adverse reactions					
-Total	10 (10.3)	0	3 (3.1)	7 (7.2)	0
Mental status changes	4 (4.1)	0	1 (1.0)	3 (3.1)	0
Encephalopathy	2 (2.1)	0	0	2 (2.1)	0
Seizure	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Cognitive disorder	1 (1.0)	0	1 (1.0)	0	0
Delirium	1 (1.0)	0	0	1 (1.0)	0
Dysarthria	1 (1.0)	0	0	1 (1.0)	0
Tumour Lysis Syndrome					
-Total	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Tumour lysis syndrome	3 (3.1)	0	0	1 (1.0)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249h
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (33.3)	0	0	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Anaemia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249h
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	75 (78.9)	0	2 (2.1)	32 (33.7)	41 (43.2)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	51 (53.7)	1 (1.1)	12 (12.6)	16 (16.8)	22 (23.2)
Cytokine release syndrome	50 (52.6)	1 (1.1)	12 (12.6)	16 (16.8)	21 (22.1)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	0	0	2 (2.1)
Hematological disorders including cytopenias					
-Total	34 (35.8)	0	0	26 (27.4)	8 (8.4)
Neutrophil count decreased	2 (2.1)	0	0	0	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.1)	0	1 (1.1)
Febrile neutropenia	28 (29.5)	0	0	26 (27.4)	2 (2.1)
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Pancytopenia	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Infections					
-Total	53 (55.8)	0	0	31 (32.6)	22 (23.2)
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Candida infection	2 (2.1)	0	1 (1.1)	0	1 (1.1)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0
Covid-19	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	0	0	1 (1.1)	0
Device related infection	3 (3.2)	0	0	3 (3.2)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	4 (4.2)	0	0	4 (4.2)	0
Human herpesvirus 6 infection	1 (1.1)	0	0	1 (1.1)	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis externa	1 (1.1)	0	0	1 (1.1)	0
Otitis media	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	0	0	1 (1.1)
Pneumonia	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Pneumonia fungal	2 (2.1)	0	0	1 (1.1)	1 (1.1)

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory syncytial virus infection	2 (2.1)	0	0	2 (2.1)	0
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Rhinovirus infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Sepsis	4 (4.2)	0	0	1 (1.1)	3 (3.2)
Septic shock	3 (3.2)	0	0	0	3 (3.2)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	2 (2.1)	0	0	2 (2.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal bacteraemia	4 (4.2)	0	0	4 (4.2)	0
Staphylococcal sepsis	3 (3.2)	0	0	0	3 (3.2)
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Upper respiratory tract infection	3 (3.2)	0	0	3 (3.2)	0
Urinary tract infection	2 (2.1)	0	0	2 (2.1)	0
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Serious neurological adverse reactions					
-Total	10 (10.5)	0	3 (3.2)	7 (7.4)	0
Cognitive disorder	1 (1.1)	0	1 (1.1)	0	0
Delirium	1 (1.1)	0	0	1 (1.1)	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	2 (2.1)	0	0	2 (2.1)	0
Mental status changes	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Seizure	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Tumour Lysis Syndrome					
-Total	3 (3.2)	0	0	1 (1.1)	2 (2.1)
Tumour lysis syndrome	3 (3.2)	0	0	1 (1.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249i
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	2 (100)	0
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	2 (100)	0	0	2 (100)	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249i
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	76 (79.2)	0	2 (2.1)	31 (32.3)	43 (44.8)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	51 (53.1)	1 (1.0)	12 (12.5)	16 (16.7)	22 (22.9)
Cytokine release syndrome	50 (52.1)	1 (1.0)	12 (12.5)	16 (16.7)	21 (21.9)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	0	0	2 (2.1)
Hematological disorders including cytopenias					
-Total	33 (34.4)	0	0	25 (26.0)	8 (8.3)
Febrile neutropenia	26 (27.1)	0	0	24 (25.0)	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Pancytopenia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Thrombocytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Infections					
-Total	55 (57.3)	0	0	31 (32.3)	24 (25.0)
Fungal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchopulmonary aspergillosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Covid-19	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytomegalovirus infection reactivation	1 (1.0)	0	0	1 (1.0)	0
Device related infection	3 (3.1)	0	0	3 (3.1)	0
Device related sepsis	2 (2.1)	0	0	2 (2.1)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Escherichia bacteraemia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes zoster	4 (4.2)	0	0	4 (4.2)	0
Human herpesvirus 6 infection	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis externa	1 (1.0)	0	0	1 (1.0)	0
Otitis media	1 (1.0)	0	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	0	0	1 (1.0)
Pneumonia	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Respiratory syncytial virus infection	2 (2.1)	0	0	2 (2.1)	0
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Rhinovirus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Sepsis	4 (4.2)	0	0	1 (1.0)	3 (3.1)
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis	2 (2.1)	0	0	2 (2.1)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal bacteraemia	4 (4.2)	0	0	4 (4.2)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	3 (3.1)	0	0	0	3 (3.1)
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Upper respiratory tract infection	3 (3.1)	0	0	3 (3.1)	0
Urinary tract infection	2 (2.1)	0	0	2 (2.1)	0
Varicella zoster virus infection	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Serious neurological adverse reactions					
-Total	10 (10.4)	0	3 (3.1)	7 (7.3)	0
Cognitive disorder	1 (1.0)	0	1 (1.0)	0	0
Delirium	1 (1.0)	0	0	1 (1.0)	0
Dysarthria	1 (1.0)	0	0	1 (1.0)	0
Encephalopathy	2 (2.1)	0	0	2 (2.1)	0
Mental status changes	4 (4.2)	0	1 (1.0)	3 (3.1)	0
Seizure	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tumour Lysis Syndrome					
-Total	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Tumour lysis syndrome	3 (3.1)	0	0	1 (1.0)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249j
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (83.3)	0	0	9 (30.0)	16 (53.3)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	19 (63.3)	0	3 (10.0)	7 (23.3)	9 (30.0)
Cytokine release syndrome	19 (63.3)	0	3 (10.0)	7 (23.3)	9 (30.0)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Hematological disorders including cytopenias					
-Total	9 (30.0)	0	0	7 (23.3)	2 (6.7)
Febrile neutropenia	7 (23.3)	0	0	7 (23.3)	0
Neutrophil count decreased	2 (6.7)	0	0	0	2 (6.7)
Platelet count decreased	1 (3.3)	0	0	0	1 (3.3)
Anaemia	0	0	0	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	19 (63.3)	0	0	8 (26.7)	11 (36.7)
Staphylococcal sepsis	3 (10.0)	0	0	0	3 (10.0)
Sepsis	2 (6.7)	0	0	0	2 (6.7)
Staphylococcal bacteraemia	2 (6.7)	0	0	2 (6.7)	0
Staphylococcal infection	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Covid-19	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Encephalitis	1 (3.3)	0	0	0	1 (3.3)

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Fungaemia	1 (3.3)	0	0	0	1 (3.3)
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Paronychia	1 (3.3)	0	0	1 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (3.3)	0	0	0	1 (3.3)
Pneumonia	1 (3.3)	0	0	1 (3.3)	0
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Sinusitis	1 (3.3)	0	0	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Abscess limb	0	0	0	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

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

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Mental status changes	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Encephalopathy	1 (3.3)	0	0	1 (3.3)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.3)	0	0	0	1 (3.3)
Tumour lysis syndrome	1 (3.3)	0	0	0	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249j
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (77.9)	0	2 (2.9)	24 (35.3)	27 (39.7)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	32 (47.1)	1 (1.5)	9 (13.2)	9 (13.2)	13 (19.1)
Cytokine release syndrome	31 (45.6)	1 (1.5)	9 (13.2)	9 (13.2)	12 (17.6)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	0	0	1 (1.5)
Hematological disorders including cytopenias					
-Total	26 (38.2)	0	0	20 (29.4)	6 (8.8)
Febrile neutropenia	21 (30.9)	0	0	19 (27.9)	2 (2.9)
Neutrophil count decreased	1 (1.5)	0	0	1 (1.5)	0
Platelet count decreased	0	0	0	0	0
Anaemia	2 (2.9)	0	1 (1.5)	0	1 (1.5)

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Neutropenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Pancytopenia	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Thrombocytopenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Infections					
-Total	37 (54.4)	0	0	24 (35.3)	13 (19.1)
Staphylococcal sepsis	0	0	0	0	0
Sepsis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Bronchiolitis	0	0	0	0	0
Candida infection	1 (1.5)	0	0	0	1 (1.5)
Covid-19	0	0	0	0	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (1.5)	0	0	1 (1.5)	0
Fungaemia	0	0	0	0	0
Gastroenteritis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Herpes zoster	3 (4.4)	0	0	3 (4.4)	0
Meningitis bacterial	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	1 (1.5)	0	0	1 (1.5)	0
Paronychia	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	3 (4.4)	0	0	1 (1.5)	2 (2.9)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Serratia sepsis	0	0	0	0	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Urinary tract infection	1 (1.5)	0	0	1 (1.5)	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Fungal sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis adenovirus	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Haemophilus bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	1 (1.5)	0	0	1 (1.5)	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	0	1 (1.5)	0
Otitis externa	1 (1.5)	0	0	1 (1.5)	0
Otitis media	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	2 (2.9)	0	0	2 (2.9)	0
Rhinovirus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal skin infection	1 (1.5)	0	0	1 (1.5)	0
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Varicella zoster virus infection	1 (1.5)	0	0	1 (1.5)	0

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

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Serious neurological adverse reactions					
-Total	7 (10.3)	0	2 (2.9)	5 (7.4)	0
Mental status changes	2 (2.9)	0	0	2 (2.9)	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Cognitive disorder	1 (1.5)	0	1 (1.5)	0	0
Delirium	1 (1.5)	0	0	1 (1.5)	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Seizure	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.5)	1 (1.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249k
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (84.4)	0	0	10 (31.3)	17 (53.1)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	16 (50.0)	0	2 (6.3)	5 (15.6)	9 (28.1)
Cytokine release syndrome	15 (46.9)	0	2 (6.3)	5 (15.6)	8 (25.0)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	0	0	1 (3.1)
Hematological disorders including cytopenias					
-Total	13 (40.6)	0	0	11 (34.4)	2 (6.3)
Febrile neutropenia	9 (28.1)	0	0	8 (25.0)	1 (3.1)
Pancytopenia	2 (6.3)	0	0	2 (6.3)	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0
Neutropenia	1 (3.1)	0	0	0	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (3.1)	0	0	1 (3.1)	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	22 (68.8)	0	0	10 (31.3)	12 (37.5)
Herpes zoster	4 (12.5)	0	0	4 (12.5)	0
Device related infection	3 (9.4)	0	0	3 (9.4)	0
Gastroenteritis	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Pneumonia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Sepsis	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Staphylococcal sepsis	3 (9.4)	0	0	0	3 (9.4)
Bacteraemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Device related sepsis	2 (6.3)	0	0	2 (6.3)	0
Respiratory tract infection	2 (6.3)	0	0	2 (6.3)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	0	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Covid-19	1 (3.1)	0	0	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis adenovirus	1 (3.1)	0	0	1 (3.1)	0
Haemophilus bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Ophthalmic herpes zoster	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Paronychia	1 (3.1)	0	0	1 (3.1)	0
Pneumocystis jirovecii pneumonia	1 (3.1)	0	0	0	1 (3.1)
Pneumonia fungal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia viral	1 (3.1)	0	0	1 (3.1)	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0
Sinusitis	1 (3.1)	0	0	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral haemorrhagic cystitis	1 (3.1)	0	0	1 (3.1)	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.1)	0	0	1 (3.1)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249k
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (80.7)	0	2 (3.5)	21 (36.8)	23 (40.4)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	31 (54.4)	1 (1.8)	10 (17.5)	10 (17.5)	10 (17.5)
Cytokine release syndrome	31 (54.4)	1 (1.8)	10 (17.5)	10 (17.5)	10 (17.5)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	0	0	1 (1.8)
Hematological disorders including cytopenias					
-Total	21 (36.8)	0	0	15 (26.3)	6 (10.5)
Febrile neutropenia	18 (31.6)	0	0	17 (29.8)	1 (1.8)
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	2 (3.5)	0	0	0	2 (3.5)
Anaemia	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Platelet count decreased	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Infections					
-Total	31 (54.4)	0	0	20 (35.1)	11 (19.3)
Herpes zoster	0	0	0	0	0
Device related infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Device related sepsis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida infection	1 (1.8)	0	0	0	1 (1.8)
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Encephalitis viral	0	0	0	0	0
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	1 (1.8)	0	0	0	1 (1.8)
Pneumonia viral	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection reactivation	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Enterobacter infection	1 (1.8)	0	0	1 (1.8)	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Fungal sepsis	1 (1.8)	0	0	0	1 (1.8)
Fungal skin infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	0	0	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Mastoiditis	1 (1.8)	0	0	1 (1.8)	0
Meningitis bacterial	0	0	0	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Meningitis pneumococcal	1 (1.8)	0	0	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	0	0	1 (1.8)	0
Otitis externa	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis streptococcal	1 (1.8)	0	0	1 (1.8)	0
Pneumonia respiratory syncytial viral	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	1 (1.8)	0	0
Septic shock	3 (5.3)	0	0	0	3 (5.3)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal bacteraemia	4 (7.0)	0	0	4 (7.0)	0
Staphylococcal infection	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Serious neurological adverse reactions					
-Total	9 (15.8)	0	3 (5.3)	6 (10.5)	0
Encephalopathy	1 (1.8)	0	0	1 (1.8)	0
Cognitive disorder	1 (1.8)	0	1 (1.8)	0	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Dysarthria	1 (1.8)	0	0	1 (1.8)	0
Mental status changes	4 (7.0)	0	1 (1.8)	3 (5.3)	0
Seizure	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Tumour Lysis Syndrome					
-Total	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Tumour lysis syndrome	2 (3.5)	0	0	1 (1.8)	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249k
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (55.6)	0	0	2 (22.2)	3 (33.3)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Cytokine release syndrome	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Pancytopenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (33.3)	0	0	2 (22.2)	1 (11.1)
Herpes zoster	0	0	0	0	0
Device related infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Sepsis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	1 (11.1)	0	0	0	1 (11.1)
Escherichia bacteraemia	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	1 (11.1)	0	0	1 (11.1)	0
Paronychia	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (11.1)	0	0	1 (11.1)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (11.1)	0	0	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	0	1 (11.1)	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	2 (22.2)	0	0	2 (22.2)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249l
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (77.6)	0	1 (1.7)	21 (36.2)	23 (39.7)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	29 (50.0)	1 (1.7)	6 (10.3)	11 (19.0)	11 (19.0)
Cytokine release syndrome	29 (50.0)	1 (1.7)	6 (10.3)	11 (19.0)	11 (19.0)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	22 (37.9)	0	0	17 (29.3)	5 (8.6)
Febrile neutropenia	16 (27.6)	0	0	15 (25.9)	1 (1.7)
Neutrophil count decreased	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Pancytopenia	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Anaemia	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Neutropenia	1 (1.7)	0	0	0	1 (1.7)
Platelet count decreased	1 (1.7)	0	0	0	1 (1.7)
Thrombocytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	34 (58.6)	0	0	19 (32.8)	15 (25.9)
Bacteraemia	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Device related infection	3 (5.2)	0	0	3 (5.2)	0
Gastroenteritis	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Herpes zoster	3 (5.2)	0	0	3 (5.2)	0
Sepsis	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Septic shock	3 (5.2)	0	0	0	3 (5.2)
Staphylococcal sepsis	3 (5.2)	0	0	0	3 (5.2)
Upper respiratory tract infection	3 (5.2)	0	0	3 (5.2)	0
Bronchopulmonary aspergillosis	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Candida infection	2 (3.4)	0	1 (1.7)	0	1 (1.7)
Device related sepsis	2 (3.4)	0	0	2 (3.4)	0
Parainfluenzae virus infection	2 (3.4)	0	0	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Respiratory syncytial virus infection	2 (3.4)	0	0	2 (3.4)	0
Sinusitis	2 (3.4)	0	0	2 (3.4)	0
Abscess limb	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection reactivation	1 (1.7)	0	0	1 (1.7)	0
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Encephalitis viral	1 (1.7)	0	0	1 (1.7)	0
Enterobacter infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Fungaemia	1 (1.7)	0	0	0	1 (1.7)
Fungal sepsis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis adenovirus	1 (1.7)	0	0	1 (1.7)	0
Haemophilus bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Mastoiditis	1 (1.7)	0	0	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0
Metapneumovirus infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Otitis externa	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	0	1 (1.7)	0
Paronychia	1 (1.7)	0	0	1 (1.7)	0
Pneumocystis jirovecii pneumonia	1 (1.7)	0	0	0	1 (1.7)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal skin infection	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0
Aspergillus infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Localised infection	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (8.6)	0	2 (3.4)	3 (5.2)	0
Mental status changes	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Seizure	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Tumour lysis syndrome	3 (5.2)	0	0	1 (1.7)	2 (3.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249l
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (82.5)	0	1 (2.5)	12 (30.0)	20 (50.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	22 (55.0)	0	6 (15.0)	5 (12.5)	11 (27.5)
Cytokine release syndrome	21 (52.5)	0	6 (15.0)	5 (12.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	2 (5.0)	0	0	0	2 (5.0)
Hematological disorders including cytopenias					
-Total	13 (32.5)	0	0	10 (25.0)	3 (7.5)
Febrile neutropenia	12 (30.0)	0	0	11 (27.5)	1 (2.5)
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Anaemia	1 (2.5)	0	0	0	1 (2.5)

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	1 (2.5)	0	0	1 (2.5)	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Infections					
-Total	22 (55.0)	0	0	13 (32.5)	9 (22.5)
Bacteraemia	0	0	0	0	0
Device related infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Septic shock	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Respiratory syncytial virus infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Paronychia	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	1 (2.5)	0	0	0	1 (2.5)
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	1 (2.5)	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Mental status changes	2 (5.0)	0	0	2 (5.0)	0
Seizure	0	0	0	0	0
Encephalopathy	1 (2.5)	0	0	1 (2.5)	0
Cognitive disorder	1 (2.5)	0	1 (2.5)	0	0
Delirium	1 (2.5)	0	0	1 (2.5)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249m
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (70.6)	0	1 (5.9)	9 (52.9)	2 (11.8)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	10 (58.8)	0	5 (29.4)	4 (23.5)	1 (5.9)
Cytokine release syndrome	10 (58.8)	0	5 (29.4)	4 (23.5)	1 (5.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	8 (47.1)	0	0	8 (47.1)	0
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	5 (29.4)	0	0	4 (23.5)	1 (5.9)
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Varicella zoster virus infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.9)	0	0	1 (5.9)	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249m
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (81.5)	0	1 (1.2)	24 (29.6)	41 (50.6)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	41 (50.6)	1 (1.2)	7 (8.6)	12 (14.8)	21 (25.9)
Cytokine release syndrome	40 (49.4)	1 (1.2)	7 (8.6)	12 (14.8)	20 (24.7)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	0	0	2 (2.5)
Hematological disorders including cytopenias					
-Total	27 (33.3)	0	0	19 (23.5)	8 (9.9)
Febrile neutropenia	20 (24.7)	0	0	18 (22.2)	2 (2.5)
Anaemia	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Myelodysplastic syndrome	1 (1.2)	0	0	1 (1.2)	0
Neutropenia	2 (2.5)	0	0	1 (1.2)	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (3.7)	0	0	1 (1.2)	2 (2.5)
Pancytopenia	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Platelet count decreased	1 (1.2)	0	0	0	1 (1.2)
Thrombocytopenia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Infections					
-Total	51 (63.0)	0	0	28 (34.6)	23 (28.4)
Aspergillus infection	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	3 (3.7)	0	0	3 (3.7)	0
Staphylococcal infection	1 (1.2)	0	0	0	1 (1.2)
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Abscess limb	1 (1.2)	0	0	1 (1.2)	0
Bacteraemia	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Bacterial sepsis	1 (1.2)	0	0	0	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (1.2)	0	0	1 (1.2)	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Candida infection	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Clostridium difficile colitis	1 (1.2)	0	0	1 (1.2)	0
Covid-19	1 (1.2)	0	0	1 (1.2)	0
Covid-19 pneumonia	1 (1.2)	0	0	0	1 (1.2)
Cytomegalovirus infection reactivation	1 (1.2)	0	0	1 (1.2)	0
Device related infection	3 (3.7)	0	0	3 (3.7)	0
Device related sepsis	2 (2.5)	0	0	2 (2.5)	0
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Enterobacter infection	1 (1.2)	0	0	1 (1.2)	0
Escherichia bacteraemia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Fungaemia	1 (1.2)	0	0	0	1 (1.2)
Fungal sepsis	1 (1.2)	0	0	0	1 (1.2)
Gastroenteritis	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Gastroenteritis adenovirus	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis escherichia coli	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis salmonella	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis viral	1 (1.2)	0	0	1 (1.2)	0
Haemophilus bacteraemia	1 (1.2)	0	0	0	1 (1.2)
Herpes zoster	4 (4.9)	0	0	4 (4.9)	0
Human herpesvirus 6 infection	1 (1.2)	0	0	1 (1.2)	0
Klebsiella bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Klebsiella infection	1 (1.2)	0	0	1 (1.2)	0
Localised infection	1 (1.2)	0	0	1 (1.2)	0
Mastoiditis	1 (1.2)	0	0	1 (1.2)	0
Meningitis bacterial	1 (1.2)	0	0	1 (1.2)	0
Meningitis pneumococcal	1 (1.2)	0	0	1 (1.2)	0
Metapneumovirus infection	1 (1.2)	0	0	1 (1.2)	0
Ophthalmic herpes zoster	1 (1.2)	0	1 (1.2)	0	0
Otitis externa	1 (1.2)	0	0	1 (1.2)	0
Otitis media	1 (1.2)	0	0	1 (1.2)	0
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0
Paronychia	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis streptococcal	1 (1.2)	0	0	1 (1.2)	0
Pneumocystis jirovecii pneumonia	1 (1.2)	0	0	0	1 (1.2)
Pneumonia	4 (4.9)	0	0	2 (2.5)	2 (2.5)
Pneumonia fungal	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Pneumonia respiratory syncytial viral	1 (1.2)	0	0	1 (1.2)	0
Pneumonia viral	1 (1.2)	0	0	1 (1.2)	0
Respiratory syncytial virus infection	2 (2.5)	0	0	2 (2.5)	0
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Rhinovirus infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Sepsis	4 (4.9)	0	0	1 (1.2)	3 (3.7)
Septic shock	3 (3.7)	0	0	0	3 (3.7)
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Sialoadenitis	1 (1.2)	0	0	1 (1.2)	0
Sinusitis	2 (2.5)	0	0	2 (2.5)	0
Soft tissue infection	1 (1.2)	0	0	1 (1.2)	0
Staphylococcal sepsis	3 (3.7)	0	0	0	3 (3.7)
Staphylococcal skin infection	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	2 (2.5)	0	0	2 (2.5)	0
Viral haemorrhagic cystitis	1 (1.2)	0	0	1 (1.2)	0
Viral upper respiratory tract infection	1 (1.2)	0	0	1 (1.2)	0
Serious neurological adverse reactions					
-Total	9 (11.1)	0	3 (3.7)	6 (7.4)	0
Mental status changes	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Cognitive disorder	1 (1.2)	0	1 (1.2)	0	0
Delirium	1 (1.2)	0	0	1 (1.2)	0
Dysarthria	1 (1.2)	0	0	1 (1.2)	0
Encephalopathy	2 (2.5)	0	0	2 (2.5)	0
Seizure	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Tumour Lysis Syndrome					
-Total	3 (3.7)	0	0	1 (1.2)	2 (2.5)
Tumour lysis syndrome	3 (3.7)	0	0	1 (1.2)	2 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249n
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (60.7)	0	2 (7.1)	9 (32.1)	6 (21.4)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	13 (46.4)	0	5 (17.9)	3 (10.7)	5 (17.9)
Cytokine release syndrome	12 (42.9)	0	5 (17.9)	3 (10.7)	4 (14.3)
Haemophagocytic lymphohistiocytosis	2 (7.1)	0	0	0	2 (7.1)
Hematological disorders including cytopenias					
-Total	8 (28.6)	0	0	8 (28.6)	0
Febrile neutropenia	7 (25.0)	0	0	7 (25.0)	0
Anaemia	1 (3.6)	0	1 (3.6)	0	0
Pancytopenia	1 (3.6)	0	0	1 (3.6)	0
Thrombocytopenia	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	11 (39.3)	0	0	7 (25.0)	4 (14.3)
Staphylococcal bacteraemia	3 (10.7)	0	0	3 (10.7)	0
Encephalitis	2 (7.1)	0	0	0	2 (7.1)
Respiratory syncytial virus infection	2 (7.1)	0	0	2 (7.1)	0
Upper respiratory tract infection	2 (7.1)	0	0	2 (7.1)	0
Abscess limb	1 (3.6)	0	0	1 (3.6)	0
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Clostridium difficile colitis	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)
Gastroenteritis	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis escherichia coli	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis salmonella	1 (3.6)	0	0	1 (3.6)	0
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Localised infection	1 (3.6)	0	0	1 (3.6)	0
Parainfluenzae virus infection	1 (3.6)	0	0	1 (3.6)	0
Pneumonia	1 (3.6)	0	0	1 (3.6)	0
Rhinovirus infection	1 (3.6)	0	0	1 (3.6)	0
Sepsis	1 (3.6)	0	0	1 (3.6)	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Encephalopathy	1 (3.6)	0	0	1 (3.6)	0
Seizure	1 (3.6)	0	1 (3.6)	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.6)	0	0	1 (3.6)	0
Tumour lysis syndrome	1 (3.6)	0	0	1 (3.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249n
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (87.1)	0	0	24 (34.3)	37 (52.9)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	38 (54.3)	1 (1.4)	7 (10.0)	13 (18.6)	17 (24.3)
Cytokine release syndrome	38 (54.3)	1 (1.4)	7 (10.0)	13 (18.6)	17 (24.3)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	27 (38.6)	0	0	19 (27.1)	8 (11.4)
Febrile neutropenia	21 (30.0)	0	0	19 (27.1)	2 (2.9)
Anaemia	1 (1.4)	0	0	0	1 (1.4)
Pancytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Neutropenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Neutrophil count decreased	3 (4.3)	0	0	1 (1.4)	2 (2.9)
Platelet count decreased	1 (1.4)	0	0	0	1 (1.4)
Infections					
-Total	45 (64.3)	0	0	25 (35.7)	20 (28.6)
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Encephalitis	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Abscess limb	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Gastroenteritis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Herpes zoster	3 (4.3)	0	0	3 (4.3)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Pneumonia	3 (4.3)	0	0	1 (1.4)	2 (2.9)
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	3 (4.3)	0	0	0	3 (4.3)
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal skin infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacteraemia	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Candida infection	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	3 (4.3)	0	0	3 (4.3)	0
Device related sepsis	2 (2.9)	0	0	2 (2.9)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia fungal	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	3 (4.3)	0	0	0	3 (4.3)
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	2 (2.9)	0	0	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Serious neurological adverse reactions					
-Total	8 (11.4)	0	2 (2.9)	6 (8.6)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Cognitive disorder	1 (1.4)	0	1 (1.4)	0	0
Delirium	1 (1.4)	0	0	1 (1.4)	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Mental status changes	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Tumour Lysis Syndrome					
-Total	2 (2.9)	0	0	0	2 (2.9)
Tumour lysis syndrome	2 (2.9)	0	0	0	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249o
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	5 (45.5)	3 (27.3)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	0	2 (18.2)	1 (9.1)	1 (9.1)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	4 (36.4)	0	0	4 (36.4)	0
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	5 (45.5)	0	0	3 (27.3)	2 (18.2)
Abscess limb	1 (9.1)	0	0	1 (9.1)	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	1 (9.1)	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249o
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (79.3)	0	1 (1.1)	28 (32.2)	40 (46.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	47 (54.0)	1 (1.1)	10 (11.5)	15 (17.2)	21 (24.1)
Cytokine release syndrome	46 (52.9)	1 (1.1)	10 (11.5)	15 (17.2)	20 (23.0)
Haemophagocytic lymphohistiocytosis	2 (2.3)	0	0	0	2 (2.3)
Hematological disorders including cytopenias					
-Total	31 (35.6)	0	0	23 (26.4)	8 (9.2)
Febrile neutropenia	25 (28.7)	0	0	23 (26.4)	2 (2.3)
Pancytopenia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Anaemia	2 (2.3)	0	1 (1.1)	0	1 (1.1)
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Neutrophil count decreased	3 (3.4)	0	0	1 (1.1)	2 (2.3)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Infections					
-Total	51 (58.6)	0	0	29 (33.3)	22 (25.3)
Abscess limb	0	0	0	0	0
Device related infection	2 (2.3)	0	0	2 (2.3)	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Herpes zoster	3 (3.4)	0	0	3 (3.4)	0
Parainfluenzae virus infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	0	0	0	0	0
Respiratory syncytial virus infection	1 (1.1)	0	0	1 (1.1)	0
Rhinovirus infection	1 (1.1)	0	1 (1.1)	0	0
Sepsis	3 (3.4)	0	0	0	3 (3.4)
Staphylococcal sepsis	2 (2.3)	0	0	0	2 (2.3)
Staphylococcal skin infection	0	0	0	0	0
Upper respiratory tract infection	2 (2.3)	0	0	2 (2.3)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Candida infection	2 (2.3)	0	1 (1.1)	0	1 (1.1)
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0
Covid-19	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	2 (2.3)	0	0	2 (2.3)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Encephalitis viral	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Escherichia bacteraemia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Fungaemia	1 (1.1)	0	0	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Human herpesvirus 6 infection	1 (1.1)	0	0	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis externa	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	0	0	1 (1.1)
Pneumonia	4 (4.6)	0	0	2 (2.3)	2 (2.3)
Pneumonia fungal	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection	2 (2.3)	0	0	2 (2.3)	0
Septic shock	3 (3.4)	0	0	0	3 (3.4)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	2 (2.3)	0	0	2 (2.3)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal bacteraemia	4 (4.6)	0	0	4 (4.6)	0
Staphylococcal infection	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Serious neurological adverse reactions					
-Total	9 (10.3)	0	2 (2.3)	7 (8.0)	0
Seizure	1 (1.1)	0	0	1 (1.1)	0
Cognitive disorder	1 (1.1)	0	1 (1.1)	0	0
Delirium	1 (1.1)	0	0	1 (1.1)	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	2 (2.3)	0	0	2 (2.3)	0
Mental status changes	4 (4.6)	0	1 (1.1)	3 (3.4)	0
Tumour Lysis Syndrome					
-Total	3 (3.4)	0	0	1 (1.1)	2 (2.3)
Tumour lysis syndrome	3 (3.4)	0	0	1 (1.1)	2 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249p
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	2 (28.6)	3 (42.9)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (57.1)	0	1 (14.3)	0	3 (42.9)
Cytokine release syndrome	4 (57.1)	0	1 (14.3)	0	3 (42.9)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	2 (28.6)	0	0	2 (28.6)	0
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	4 (57.1)	0	0	4 (57.1)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Metapneumovirus infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia respiratory syncytial viral	1 (14.3)	0	0	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249p
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	73 (80.2)	0	2 (2.2)	31 (34.1)	40 (44.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	47 (51.6)	1 (1.1)	11 (12.1)	16 (17.6)	19 (20.9)
Cytokine release syndrome	46 (50.5)	1 (1.1)	11 (12.1)	16 (17.6)	18 (19.8)
Haemophagocytic lymphohistiocytosis	2 (2.2)	0	0	0	2 (2.2)
Hematological disorders including cytopenias					
-Total	33 (36.3)	0	0	25 (27.5)	8 (8.8)
Febrile neutropenia	26 (28.6)	0	0	24 (26.4)	2 (2.2)
Anaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Neutropenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Pancytopenia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Infections					
-Total	52 (57.1)	0	0	28 (30.8)	24 (26.4)
Escherichia bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Metapneumovirus infection	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Upper respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Candida infection	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Covid-19	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	0	0	1 (1.1)	0
Device related infection	3 (3.3)	0	0	3 (3.3)	0
Device related sepsis	2 (2.2)	0	0	2 (2.2)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Encephalitis	2 (2.2)	0	0	0	2 (2.2)
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	4 (4.4)	0	0	4 (4.4)	0
Human herpesvirus 6 infection	1 (1.1)	0	0	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis externa	1 (1.1)	0	0	1 (1.1)	0
Otitis media	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	0	0	1 (1.1)
Pneumonia	4 (4.4)	0	0	2 (2.2)	2 (2.2)
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory syncytial virus infection	2 (2.2)	0	0	2 (2.2)	0
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Rhinovirus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Septic shock	3 (3.3)	0	0	0	3 (3.3)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	2 (2.2)	0	0	2 (2.2)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal bacteraemia	4 (4.4)	0	0	4 (4.4)	0
Staphylococcal infection	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Staphylococcal sepsis	3 (3.3)	0	0	0	3 (3.3)
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection	2 (2.2)	0	0	2 (2.2)	0
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Serious neurological adverse reactions					
-Total	10 (11.0)	0	3 (3.3)	7 (7.7)	0
Cognitive disorder	1 (1.1)	0	1 (1.1)	0	0
Delirium	1 (1.1)	0	0	1 (1.1)	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	2 (2.2)	0	0	2 (2.2)	0
Mental status changes	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Seizure	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tumour Lysis Syndrome					
-Total	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Tumour lysis syndrome	3 (3.3)	0	0	1 (1.1)	2 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (82.5)	0	0	16 (40.0)	17 (42.5)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	24 (60.0)	1 (2.5)	3 (7.5)	9 (22.5)	11 (27.5)
Cytokine release syndrome	23 (57.5)	1 (2.5)	3 (7.5)	9 (22.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	14 (35.0)	0	0	11 (27.5)	3 (7.5)
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Pancytopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Neutropenia	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (2.5)	0	0	1 (2.5)	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	26 (65.0)	0	0	16 (40.0)	10 (25.0)
Herpes zoster	4 (10.0)	0	0	4 (10.0)	0
Gastroenteritis	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Bacteraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Bronchopulmonary aspergillosis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Candida infection	1 (2.5)	0	0	0	1 (2.5)
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Gastroenteritis adenovirus	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Haemophilus bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0	1 (2.5)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal skin infection	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchiolitis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	0	0	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (77.5)	0	2 (5.0)	12 (30.0)	17 (42.5)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	0	9 (22.5)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	0	0	1 (2.5)
Hematological disorders including cytopenias					
-Total	17 (42.5)	0	0	14 (35.0)	3 (7.5)
Febrile neutropenia	15 (37.5)	0	0	15 (37.5)	0
Pancytopenia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Anaemia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Platelet count decreased	1 (2.5)	0	0	0	1 (2.5)
Thrombocytopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Infections					
-Total	17 (42.5)	0	0	11 (27.5)	6 (15.0)
Herpes zoster	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Abscess limb	0	0	0	0	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	0	0	0	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (5.0)	0	0	2 (5.0)	0
Pneumonia fungal	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	1 (2.5)	0	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Klebsiella bacteraemia	0	0	0	0	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumocystis jirovecii pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (2.5)	0	0	1 (2.5)	0
Systemic mycosis	0	0	0	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Serious neurological adverse reactions					
-Total	6 (15.0)	0	3 (7.5)	3 (7.5)	0
Mental status changes	1 (2.5)	0	1 (2.5)	0	0
Cognitive disorder	1 (2.5)	0	1 (2.5)	0	0
Delirium	1 (2.5)	0	0	1 (2.5)	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Encephalopathy	1 (2.5)	0	0	1 (2.5)	0
Seizure	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tumour Lysis Syndrome					
-Total	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	0	0	1 (2.5)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249q
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	0	0	5 (27.8)	9 (50.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	0	0	0	0	0
Cytokine release syndrome	0	0	0	0	0
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	4 (22.2)	0	0	2 (11.1)	2 (11.1)
Febrile neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Pancytopenia	1 (5.6)	0	0	1 (5.6)	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	13 (72.2)	0	0	5 (27.8)	8 (44.4)
Herpes zoster	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Upper respiratory tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Encephalitis	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	0	0	0	0	0
Clostridium difficile colitis	0	0	0	0	0
Covid-19	0	0	0	0	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Meningitis pneumococcal	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal bacteraemia	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (16.7)	0	0	3 (16.7)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	0	0	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	0	0	2 (25.0)	5 (62.5)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	4 (50.0)	0	2 (25.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Hematological disorders including cytopenias					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (76.7)	0	1 (3.3)	10 (33.3)	12 (40.0)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	14 (46.7)	0	3 (10.0)	4 (13.3)	7 (23.3)
Cytokine release syndrome	13 (43.3)	0	3 (10.0)	4 (13.3)	6 (20.0)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Hematological disorders including cytopenias					
-Total	9 (30.0)	0	0	8 (26.7)	1 (3.3)
Febrile neutropenia	7 (23.3)	0	0	7 (23.3)	0
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (3.3)	0	0	1 (3.3)	0
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	1 (3.3)	0	0	0	1 (3.3)
Infections					
-Total	14 (46.7)	0	0	8 (26.7)	6 (20.0)
Clostridium difficile colitis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Pneumonia	1 (3.3)	0	0	0	1 (3.3)
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	1 (3.3)	0	0	0	1 (3.3)
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Klebsiella infection	0	0	0	0	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	1 (3.3)	0	0	1 (3.3)	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (3.3)	0	0	0	1 (3.3)
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Rhinovirus infection	1 (3.3)	0	1 (3.3)	0	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Septic shock	0	0	0	0	0
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Sinusitis	0	0	0	0	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Upper respiratory tract infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Varicella zoster virus infection	0	0	0	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Serious neurological adverse reactions					
-Total	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	1 (3.3)	0	1 (3.3)	0	0
Delirium	1 (3.3)	0	0	1 (3.3)	0
Dysarthria	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	0	9 (50.0)	6 (33.3)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	10 (55.6)	0	2 (11.1)	4 (22.2)	4 (22.2)
Cytokine release syndrome	10 (55.6)	0	2 (11.1)	4 (22.2)	4 (22.2)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	9 (50.0)	0	0	8 (44.4)	1 (5.6)
Febrile neutropenia	8 (44.4)	0	0	8 (44.4)	0
Anaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Myelodysplastic syndrome	0	0	0	0	0
Neutropenia	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	1 (5.6)	0	0	1 (5.6)	0
Infections					
-Total	10 (55.6)	0	0	9 (50.0)	1 (5.6)
Clostridium difficile colitis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	0	0	0	0	0
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Pneumonia	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Staphylococcal infection	1 (5.6)	0	0	1 (5.6)	0
Abscess limb	0	0	0	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Candida infection	0	0	0	0	0
Covid-19	0	0	0	0	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	1 (5.6)	0	0	1 (5.6)	0
Device related infection	0	0	0	0	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Encephalitis viral	0	0	0	0	0
Enterobacter infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungaemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Human herpesvirus 6 infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	0	0	0	0	0
Localised infection	0	0	0	0	0
Mastoiditis	0	0	0	0	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	0	0	0	0	0
Metapneumovirus infection	0	0	0	0	0
Ophthalmic herpes zoster	0	0	0	0	0
Otitis externa	0	0	0	0	0
Otitis media	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	0	0	0	0	0
Pneumonia respiratory syncytial viral	1 (5.6)	0	0	1 (5.6)	0
Pneumonia viral	0	0	0	0	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Soft tissue infection	0	0	0	0	0
Staphylococcal abscess	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Varicella zoster virus infection	0	0	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Viral haemorrhagic cystitis	0	0	0	0	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	0	0	0	0	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 249r
Serious adverse events of special interest (AESI) at anytime during the study by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (78.6)	0	1 (2.4)	12 (28.6)	20 (47.6)
	0	0	0	0	0
Cytokine Release Syndrome					
-Total	23 (54.8)	1 (2.4)	5 (11.9)	8 (19.0)	9 (21.4)
Cytokine release syndrome	23 (54.8)	1 (2.4)	5 (11.9)	8 (19.0)	9 (21.4)
Haemophagocytic lymphohistiocytosis	0	0	0	0	0
Hematological disorders including cytopenias					
-Total	15 (35.7)	0	0	10 (23.8)	5 (11.9)
Febrile neutropenia	11 (26.2)	0	0	10 (23.8)	1 (2.4)
Anaemia	0	0	0	0	0
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (4.8)	0	0	0	2 (4.8)
Pancytopenia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Platelet count decreased	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	26 (61.9)	0	0	12 (28.6)	14 (33.3)
Clostridium difficile colitis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Gastroenteritis escherichia coli	0	0	0	0	0
Gastroenteritis salmonella	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Abscess limb	1 (2.4)	0	0	1 (2.4)	0
Aspergillus infection	0	0	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	3 (7.1)	0	0	2 (4.8)	1 (2.4)
Bacterial sepsis	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	0	1 (2.4)
Candida infection	2 (4.8)	0	1 (2.4)	0	1 (2.4)
Covid-19	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	0	0	0	0	0
Cytomegalovirus infection reactivation	0	0	0	0	0
Device related infection	2 (4.8)	0	0	2 (4.8)	0
Device related sepsis	0	0	0	0	0
Encephalitis viral	1 (2.4)	0	0	1 (2.4)	0
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Escherichia bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Fungaemia	1 (2.4)	0	0	0	1 (2.4)
Fungal sepsis	1 (2.4)	0	0	0	1 (2.4)
Fungal skin infection	0	0	0	0	0
Gastroenteritis	3 (7.1)	0	1 (2.4)	2 (4.8)	0
Gastroenteritis adenovirus	0	0	0	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	3 (7.1)	0	0	3 (7.1)	0
Human herpesvirus 6 infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Localised infection	0	0	0	0	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0
Meningitis bacterial	0	0	0	0	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Otitis externa	1 (2.4)	0	0	1 (2.4)	0
Otitis media	1 (2.4)	0	0	1 (2.4)	0
Parainfluenzae virus infection	2 (4.8)	0	0	2 (4.8)	0
Paronychia	1 (2.4)	0	0	1 (2.4)	0
Pharyngitis	0	0	0	0	0
Pharyngitis streptococcal	0	0	0	0	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	0	0	0	0	0
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Respiratory syncytial virus infection	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Rhinovirus infection	1 (2.4)	0	0	1 (2.4)	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Septic shock	3 (7.1)	0	0	0	3 (7.1)
Sialoadenitis	0	0	0	0	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal sepsis	3 (7.1)	0	0	0	3 (7.1)
Staphylococcal skin infection	1 (2.4)	0	0	1 (2.4)	0
Systemic mycosis	0	0	0	0	0
Upper respiratory tract infection	2 (4.8)	0	0	2 (4.8)	0
Urinary tract infection	1 (2.4)	0	0	1 (2.4)	0
Varicella zoster virus infection	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0
Viral haemorrhagic cystitis	1 (2.4)	0	0	1 (2.4)	0
Viral upper respiratory tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	5 (11.9)	0	2 (4.8)	3 (7.1)	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Cognitive disorder	0	0	0	0	0
Delirium	0	0	0	0	0
Dysarthria	0	0	0	0	0
Mental status changes	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Seizure	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Tumour Lysis Syndrome					
-Total	2 (4.8)	0	0	0	2 (4.8)
Tumour lysis syndrome	2 (4.8)	0	0	0	2 (4.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -A patient with multiple adverse events within a group term is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum

toxicity grade. -Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	795	33 (100.00)	285	27 (81.82)
Blood and lymphatic system disorders				
- Total	65	21 (63.64)	40	16 (48.48)
Anaemia	34	13 (39.39)	16	7 (21.21)
Febrile neutropenia	13	12 (36.36)	13	12 (36.36)
Disseminated intravascular coagulation	4	4 (12.12)	1	1 (3.03)
Thrombocytopenia	4	4 (12.12)	4	4 (12.12)
Neutropenia	3	3 (9.09)	2	2 (6.06)
Eosinophilia	2	1 (3.03)	0	0 (0.00)
Coagulopathy	1	1 (3.03)	1	1 (3.03)
Leukopenia	1	1 (3.03)	1	1 (3.03)
Lymphopenia	1	1 (3.03)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Pancytopenia	1	1 (3.03)	1	1 (3.03)
Splenomegaly	1	1 (3.03)	0	0 (0.00)
Cardiac disorders				
- Total	19	10 (30.30)	4	4 (12.12)
Tachycardia	13	9 (27.27)	2	2 (6.06)
Left ventricular dysfunction	2	2 (6.06)	2	2 (6.06)
Cardiac dysfunction	1	1 (3.03)	0	0 (0.00)
Cardiac failure congestive	1	1 (3.03)	0	0 (0.00)
Mitral valve incompetence	1	1 (3.03)	0	0 (0.00)
Right ventricular dysfunction	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Ear pain	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (6.06)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.03)	0	0 (0.00)
Hypothyroidism	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Eye disorders				
- Total	8	5 (15.15)	0	0 (0.00)
Eyelid oedema	3	2 (6.06)	0	0 (0.00)
Ocular hyperaemia	2	2 (6.06)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.03)	0	0 (0.00)
Eye pain	1	1 (3.03)	0	0 (0.00)
Visual impairment	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	77	23 (69.70)	9	7 (21.21)
Vomiting	20	12 (36.36)	0	0 (0.00)
Nausea	13	11 (33.33)	1	1 (3.03)
Diarrhoea	9	8 (24.24)	1	1 (3.03)
Abdominal pain	8	6 (18.18)	2	2 (6.06)
Constipation	6	6 (18.18)	0	0 (0.00)
Abdominal distension	3	3 (9.09)	0	0 (0.00)
Ascites	3	3 (9.09)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (6.06)	0	0 (0.00)
Mouth haemorrhage	2	2 (6.06)	1	1 (3.03)
Abdominal compartment syndrome	1	1 (3.03)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Abdominal pain upper	1	1 (3.03)	0	0 (0.00)
Anal fissure	1	1 (3.03)	0	0 (0.00)
Anal haemorrhage	1	1 (3.03)	0	0 (0.00)
Haematemesis	1	1 (3.03)	0	0 (0.00)
Lip oedema	1	1 (3.03)	0	0 (0.00)
Melaena	1	1 (3.03)	1	1 (3.03)
Neutropenic colitis	1	1 (3.03)	1	1 (3.03)
Pancreatitis	1	1 (3.03)	0	0 (0.00)
Stomatitis	1	1 (3.03)	1	1 (3.03)
Upper gastrointestinal haemorrhage	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	46	15 (45.45)	7	3 (9.09)
Pyrexia	21	8 (24.24)	3	2 (6.06)
Fatigue	8	8 (24.24)	0	0 (0.00)
Chills	3	3 (9.09)	0	0 (0.00)
Face oedema	3	3 (9.09)	0	0 (0.00)
Generalised oedema	3	3 (9.09)	0	0 (0.00)
Catheter site erythema	2	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Asthenia	1	1 (3.03)	0	0 (0.00)
Chest discomfort	1	1 (3.03)	1	1 (3.03)
Influenza like illness	1	1 (3.03)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.03)	1	1 (3.03)
Pain	1	1 (3.03)	1	1 (3.03)
Systemic inflammatory response syndrome	1	1 (3.03)	1	1 (3.03)
Hepatobiliary disorders				
- Total	10	7 (21.21)	2	2 (6.06)
Cholelithiasis	2	2 (6.06)	0	0 (0.00)
Hepatic function abnormal	2	1 (3.03)	1	1 (3.03)
Hyperbilirubinaemia	2	2 (6.06)	0	0 (0.00)
Cholestasis	1	1 (3.03)	1	1 (3.03)
Gallbladder enlargement	1	1 (3.03)	0	0 (0.00)
Hepatomegaly	1	1 (3.03)	0	0 (0.00)
Ocular icterus	1	1 (3.03)	0	0 (0.00)
Immune system disorders				
- Total	54	27 (81.82)	19	14 (42.42)
Cytokine release syndrome	39	24 (72.73)	14	11 (33.33)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hypogammaglobulinaemia	11	10 (30.30)	2	2 (6.06)
Haemophagocytic lymphohistiocytosis	2	2 (6.06)	1	1 (3.03)
Immunodeficiency	2	2 (6.06)	2	2 (6.06)
Infections and infestations				
- Total	21	14 (42.42)	8	7 (21.21)
Conjunctivitis	5	4 (12.12)	0	0 (0.00)
Clostridium difficile infection	2	2 (6.06)	1	1 (3.03)
Oral infection	2	2 (6.06)	0	0 (0.00)
Staphylococcal infection	2	2 (6.06)	1	1 (3.03)
BK virus infection	1	1 (3.03)	0	0 (0.00)
Candida infection	1	1 (3.03)	0	0 (0.00)
Encephalitis	1	1 (3.03)	1	1 (3.03)
Klebsiella infection	1	1 (3.03)	1	1 (3.03)
Localised infection	1	1 (3.03)	0	0 (0.00)
Nail infection	1	1 (3.03)	0	0 (0.00)
Oral herpes	1	1 (3.03)	1	1 (3.03)
Pneumonia viral	1	1 (3.03)	1	1 (3.03)
Soft tissue infection	1	1 (3.03)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Staphylococcal bacteraemia	1	1 (3.03)	1	1 (3.03)
Injury, poisoning and procedural complications				
- Total	11	6 (18.18)	2	1 (3.03)
Infusion related reaction	2	1 (3.03)	0	0 (0.00)
Transfusion reaction	2	2 (6.06)	0	0 (0.00)
Wound	2	1 (3.03)	1	1 (3.03)
Fall	1	1 (3.03)	0	0 (0.00)
Scratch	1	1 (3.03)	0	0 (0.00)
Skin injury	1	1 (3.03)	0	0 (0.00)
Skin wound	1	1 (3.03)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.03)	1	1 (3.03)
Investigations				
- Total	204	27 (81.82)	117	22 (66.67)
Platelet count decreased	45	11 (33.33)	29	8 (24.24)
White blood cell count decreased	34	16 (48.48)	27	13 (39.39)
Neutrophil count decreased	28	13 (39.39)	23	11 (33.33)
Lymphocyte count decreased	18	8 (24.24)	16	8 (24.24)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Aspartate aminotransferase increased	14	8 (24.24)	6	4 (12.12)
Alanine aminotransferase increased	12	9 (27.27)	1	1 (3.03)
Blood bilirubin increased	6	5 (15.15)	4	4 (12.12)
Blood immunoglobulin M decreased	6	6 (18.18)	1	1 (3.03)
International normalised ratio increased	5	4 (12.12)	0	0 (0.00)
Activated partial thromboplastin time prolonged	4	3 (9.09)	0	0 (0.00)
Blood immunoglobulin A decreased	4	4 (12.12)	0	0 (0.00)
Blood fibrinogen decreased	3	3 (9.09)	1	1 (3.03)
Lipase increased	3	1 (3.03)	2	1 (3.03)
Serum ferritin increased	3	3 (9.09)	0	0 (0.00)
Blood immunoglobulin G decreased	2	2 (6.06)	0	0 (0.00)
Blood lactate dehydrogenase increased	2	2 (6.06)	0	0 (0.00)
Blood uric acid increased	2	2 (6.06)	0	0 (0.00)
Fibrin D dimer increased	2	2 (6.06)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (6.06)	2	2 (6.06)
Weight increased	2	2 (6.06)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Blood creatine phosphokinase increased	1	1 (3.03)	1	1 (3.03)
Blood creatinine increased	1	1 (3.03)	1	1 (3.03)
C-reactive protein increased	1	1 (3.03)	1	1 (3.03)
Electrocardiogram QT prolonged	1	1 (3.03)	0	0 (0.00)
Immunoglobulins decreased	1	1 (3.03)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.03)	0	0 (0.00)
Urine output decreased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	104	19 (57.58)	34	10 (30.30)
Hypokalaemia	27	7 (21.21)	13	4 (12.12)
Hypophosphataemia	22	10 (30.30)	4	4 (12.12)
Hypocalcaemia	13	7 (21.21)	3	2 (6.06)
Hypoalbuminaemia	10	4 (12.12)	0	0 (0.00)
Decreased appetite	8	8 (24.24)	5	5 (15.15)
Hyperglycaemia	3	3 (9.09)	3	3 (9.09)
Hyperuricaemia	3	2 (6.06)	0	0 (0.00)
Hypermagnesaemia	2	1 (3.03)	0	0 (0.00)
Hypernatraemia	2	2 (6.06)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hyperphosphataemia	2	2 (6.06)	0	0 (0.00)
Metabolic acidosis	2	2 (6.06)	1	1 (3.03)
Dehydration	1	1 (3.03)	0	0 (0.00)
Haemosiderosis	1	1 (3.03)	0	0 (0.00)
Hypercalcaemia	1	1 (3.03)	1	1 (3.03)
Hyperkalaemia	1	1 (3.03)	1	1 (3.03)
Hyperlactacidaemia	1	1 (3.03)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.03)	1	1 (3.03)
Hypervolaemia	1	1 (3.03)	0	0 (0.00)
Hypomagnesaemia	1	1 (3.03)	0	0 (0.00)
Hyponatraemia	1	1 (3.03)	0	0 (0.00)
Malnutrition	1	1 (3.03)	1	1 (3.03)
Musculoskeletal and connective tissue disorders				
- Total	24	16 (48.48)	2	2 (6.06)
Pain in extremity	8	8 (24.24)	0	0 (0.00)
Back pain	4	4 (12.12)	1	1 (3.03)
Arthralgia	3	3 (9.09)	0	0 (0.00)
Bone pain	3	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Myalgia	3	3 (9.09)	0	0 (0.00)
Muscular weakness	1	1 (3.03)	0	0 (0.00)
Myositis	1	1 (3.03)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.03)	1	1 (3.03)
Nervous system disorders				
- Total	23	16 (48.48)	6	5 (15.15)
Headache	7	7 (21.21)	1	1 (3.03)
Encephalopathy	4	4 (12.12)	2	2 (6.06)
Dysgeusia	2	2 (6.06)	0	0 (0.00)
Lethargy	2	2 (6.06)	0	0 (0.00)
Tremor	2	2 (6.06)	0	0 (0.00)
Cerebral haemorrhage	1	1 (3.03)	1	1 (3.03)
Depressed level of consciousness	1	1 (3.03)	1	1 (3.03)
Monoparesis	1	1 (3.03)	0	0 (0.00)
Neuralgia	1	1 (3.03)	0	0 (0.00)
Seizure	1	1 (3.03)	1	1 (3.03)
Somnolence	1	1 (3.03)	0	0 (0.00)
Psychiatric disorders				

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	19	14 (42.42)	0	0 (0.00)
Confusional state	4	4 (12.12)	0	0 (0.00)
Anxiety	3	3 (9.09)	0	0 (0.00)
Insomnia	3	3 (9.09)	0	0 (0.00)
Delirium	2	2 (6.06)	0	0 (0.00)
Hallucination	2	2 (6.06)	0	0 (0.00)
Irritability	2	2 (6.06)	0	0 (0.00)
Agitation	1	1 (3.03)	0	0 (0.00)
Restlessness	1	1 (3.03)	0	0 (0.00)
Sleep disorder	1	1 (3.03)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	9 (27.27)	4	3 (9.09)
Acute kidney injury	3	3 (9.09)	2	2 (6.06)
Dysuria	2	2 (6.06)	0	0 (0.00)
Haematuria	2	2 (6.06)	0	0 (0.00)
Anuria	1	1 (3.03)	1	1 (3.03)
Bladder dilatation	1	1 (3.03)	0	0 (0.00)
Incontinence	1	1 (3.03)	0	0 (0.00)
Proteinuria	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Renal failure	1	1 (3.03)	0	0 (0.00)
Renal tubular dysfunction	1	1 (3.03)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.03)	1	1 (3.03)
Urinary retention	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)
Vaginal ulceration	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	42	17 (51.52)	18	7 (21.21)
Cough	7	6 (18.18)	0	0 (0.00)
Hypoxia	7	6 (18.18)	5	4 (12.12)
Pulmonary oedema	4	4 (12.12)	3	3 (9.09)
Tachypnoea	4	4 (12.12)	2	2 (6.06)
Atelectasis	3	1 (3.03)	1	1 (3.03)
Dyspnoea	2	2 (6.06)	2	2 (6.06)
Epistaxis	2	2 (6.06)	1	1 (3.03)
Lung infiltration	2	1 (3.03)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Oropharyngeal pain	2	1 (3.03)	0	0 (0.00)
Pleural effusion	2	2 (6.06)	1	1 (3.03)
Rhinorrhoea	2	2 (6.06)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (3.03)	1	1 (3.03)
Nasal congestion	1	1 (3.03)	0	0 (0.00)
Productive cough	1	1 (3.03)	0	0 (0.00)
Respiratory acidosis	1	1 (3.03)	1	1 (3.03)
Respiratory distress	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	31	12 (36.36)	3	2 (6.06)
Pruritus	4	3 (9.09)	0	0 (0.00)
Rash maculo-papular	3	2 (6.06)	1	1 (3.03)
Blister	2	2 (6.06)	0	0 (0.00)
Dermatitis atopic	2	2 (6.06)	0	0 (0.00)
Erythema	2	2 (6.06)	0	0 (0.00)
Rash papular	2	2 (6.06)	0	0 (0.00)
Rash vesicular	2	1 (3.03)	0	0 (0.00)
Decubitus ulcer	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Dermatitis	1	1 (3.03)	0	0 (0.00)
Dry skin	1	1 (3.03)	0	0 (0.00)
Eczema	1	1 (3.03)	0	0 (0.00)
Petechiae	1	1 (3.03)	1	1 (3.03)
Pruritus allergic	1	1 (3.03)	0	0 (0.00)
Purpura	1	1 (3.03)	0	0 (0.00)
Rash	1	1 (3.03)	0	0 (0.00)
Rash pruritic	1	1 (3.03)	0	0 (0.00)
Scab	1	1 (3.03)	0	0 (0.00)
Skin discolouration	1	1 (3.03)	0	0 (0.00)
Skin necrosis	1	1 (3.03)	1	1 (3.03)
Skin ulcer	1	1 (3.03)	0	0 (0.00)
Urticaria	1	1 (3.03)	0	0 (0.00)
Vascular disorders				
- Total	18	13 (39.39)	9	7 (21.21)
Hypotension	12	10 (30.30)	7	6 (18.18)
Hypertension	6	5 (15.15)	2	2 (6.06)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

/vob/CCTL019/haq/haq_eu_7/pgm/saf/t250_gd_b2202.sas@@/main/1 15AUG23:06:00 **Final**

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	636	33 (100.00)	230	28 (84.85)
Blood and lymphatic system disorders				
- Total	44	21 (63.64)	27	18 (54.55)
Febrile neutropenia	14	12 (36.36)	14	12 (36.36)
Anaemia	10	5 (15.15)	0	0 (0.00)
Neutropenia	5	4 (12.12)	5	4 (12.12)
Disseminated intravascular coagulation	3	3 (9.09)	1	1 (3.03)
Leukopenia	3	2 (6.06)	2	1 (3.03)
Splenomegaly	3	3 (9.09)	0	0 (0.00)
Thrombocytopenia	3	3 (9.09)	3	3 (9.09)
Coagulopathy	2	2 (6.06)	1	1 (3.03)
Pancytopenia	1	1 (3.03)	1	1 (3.03)
Cardiac disorders				

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	16	9 (27.27)	4	3 (9.09)
Tachycardia	7	6 (18.18)	1	1 (3.03)
Bradycardia	3	3 (9.09)	0	0 (0.00)
Atrioventricular block first degree	1	1 (3.03)	0	0 (0.00)
Cardiac arrest	1	1 (3.03)	1	1 (3.03)
Left ventricular dysfunction	1	1 (3.03)	1	1 (3.03)
Pericardial effusion	1	1 (3.03)	0	0 (0.00)
Sinus bradycardia	1	1 (3.03)	1	1 (3.03)
Sinus tachycardia	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Ear pruritus	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.03)	0	0 (0.00)
Eye disorders				
- Total	6	3 (9.09)	0	0 (0.00)
Retinal haemorrhage	2	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Conjunctival haemorrhage	1	1 (3.03)	0	0 (0.00)
Eye oedema	1	1 (3.03)	0	0 (0.00)
Periorbital oedema	1	1 (3.03)	0	0 (0.00)
Visual field defect	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	32	16 (48.48)	5	5 (15.15)
Diarrhoea	7	5 (15.15)	0	0 (0.00)
Vomiting	5	4 (12.12)	1	1 (3.03)
Nausea	4	4 (12.12)	1	1 (3.03)
Abdominal pain	3	3 (9.09)	0	0 (0.00)
Pancreatitis	3	3 (9.09)	1	1 (3.03)
Abdominal pain upper	1	1 (3.03)	0	0 (0.00)
Constipation	1	1 (3.03)	0	0 (0.00)
Dysphagia	1	1 (3.03)	1	1 (3.03)
Enterocolitis	1	1 (3.03)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.03)	0	0 (0.00)
Gingival erythema	1	1 (3.03)	0	0 (0.00)
Mouth swelling	1	1 (3.03)	0	0 (0.00)
Odynophagia	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Proctalgia	1	1 (3.03)	1	1 (3.03)
Trichoglossia	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	35	16 (48.48)	7	5 (15.15)
Pyrexia	14	10 (30.30)	4	4 (12.12)
Face oedema	5	4 (12.12)	1	1 (3.03)
Oedema peripheral	5	4 (12.12)	2	1 (3.03)
Fatigue	2	2 (6.06)	0	0 (0.00)
Generalised oedema	2	2 (6.06)	0	0 (0.00)
Localised oedema	2	2 (6.06)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.03)	0	0 (0.00)
Catheter site pain	1	1 (3.03)	0	0 (0.00)
Chills	1	1 (3.03)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (3.03)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (3.03)	0	0 (0.00)
Hepatobiliary disorders				
- Total	13	6 (18.18)	4	3 (9.09)
Hepatic function abnormal	7	2 (6.06)	3	2 (6.06)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hyperbilirubinaemia	3	2 (6.06)	0	0 (0.00)
Hepatomegaly	2	2 (6.06)	1	1 (3.03)
Hypertransaminasaemia	1	1 (3.03)	0	0 (0.00)
Immune system disorders				
- Total	78	28 (84.85)	37	21 (63.64)
Cytokine release syndrome	61	25 (75.76)	30	19 (57.58)
Hypogammaglobulinaemia	11	10 (30.30)	5	5 (15.15)
Haemophagocytic lymphohistiocytosis	2	2 (6.06)	1	1 (3.03)
Hypersensitivity	1	1 (3.03)	0	0 (0.00)
Immunodeficiency	1	1 (3.03)	1	1 (3.03)
Seasonal allergy	1	1 (3.03)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	16	12 (36.36)	8	6 (18.18)
Anal abscess	1	1 (3.03)	1	1 (3.03)
Bacteraemia	1	1 (3.03)	1	1 (3.03)
Bronchopulmonary aspergillosis	1	1 (3.03)	1	1 (3.03)
Cholecystitis infective	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Clostridium difficile infection	1	1 (3.03)	1	1 (3.03)
Encephalitis viral	1	1 (3.03)	1	1 (3.03)
Gastroenteritis norovirus	1	1 (3.03)	0	0 (0.00)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Meningitis bacterial	1	1 (3.03)	1	1 (3.03)
Nail infection	1	1 (3.03)	0	0 (0.00)
Otitis externa	1	1 (3.03)	0	0 (0.00)
Paronychia	1	1 (3.03)	0	0 (0.00)
Pneumonia fungal	1	1 (3.03)	1	1 (3.03)
Rhinovirus infection	1	1 (3.03)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (3.03)	1	1 (3.03)
Staphylococcal infection	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	4 (12.12)	0	0 (0.00)
Contusion	2	1 (3.03)	0	0 (0.00)
Procedural pain	2	2 (6.06)	0	0 (0.00)
Infusion related reaction	1	1 (3.03)	0	0 (0.00)
Skin abrasion	1	1 (3.03)	0	0 (0.00)
Wound	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Investigations				
- Total	158	21 (63.64)	68	17 (51.52)
Neutrophil count decreased	19	6 (18.18)	14	5 (15.15)
Platelet count decreased	17	7 (21.21)	7	4 (12.12)
Aspartate aminotransferase increased	14	7 (21.21)	4	4 (12.12)
White blood cell count decreased	14	7 (21.21)	7	4 (12.12)
Blood bilirubin increased	11	6 (18.18)	4	4 (12.12)
Lymphocyte count decreased	11	6 (18.18)	8	5 (15.15)
Alanine aminotransferase increased	10	7 (21.21)	4	4 (12.12)
Blood creatinine increased	5	3 (9.09)	4	2 (6.06)
Electrocardiogram QT prolonged	5	4 (12.12)	2	2 (6.06)
International normalised ratio increased	5	3 (9.09)	0	0 (0.00)
Serum ferritin increased	5	5 (15.15)	2	2 (6.06)
Activated partial thromboplastin time prolonged	4	3 (9.09)	1	1 (3.03)
Blood fibrinogen decreased	4	4 (12.12)	1	1 (3.03)
Immunoglobulins decreased	4	1 (3.03)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (3.03)	1	1 (3.03)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
C-reactive protein increased	3	3 (9.09)	2	2 (6.06)
Blood lactate dehydrogenase increased	2	2 (6.06)	1	1 (3.03)
Haemoglobin decreased	2	1 (3.03)	1	1 (3.03)
Urine output decreased	2	1 (3.03)	2	1 (3.03)
Weight increased	2	2 (6.06)	0	0 (0.00)
Amylase increased	1	1 (3.03)	0	0 (0.00)
Bacterial test positive	1	1 (3.03)	1	1 (3.03)
Blood alkaline phosphatase increased	1	1 (3.03)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.03)	0	0 (0.00)
Blood phosphorus increased	1	1 (3.03)	0	0 (0.00)
Blood testosterone decreased	1	1 (3.03)	0	0 (0.00)
Cardiac murmur	1	1 (3.03)	0	0 (0.00)
Coagulation test abnormal	1	1 (3.03)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (3.03)	0	0 (0.00)
Enterovirus test positive	1	1 (3.03)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.03)	1	1 (3.03)
Haptoglobin decreased	1	1 (3.03)	0	0 (0.00)
Lipase increased	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Prothrombin time prolonged	1	1 (3.03)	0	0 (0.00)
Troponin increased	1	1 (3.03)	1	1 (3.03)
Weight decreased	1	1 (3.03)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	71	20 (60.61)	25	13 (39.39)
Decreased appetite	11	11 (33.33)	4	4 (12.12)
Hypocalcaemia	8	6 (18.18)	1	1 (3.03)
Hypoalbuminaemia	7	5 (15.15)	0	0 (0.00)
Hypokalaemia	7	6 (18.18)	5	5 (15.15)
Hyperuricaemia	5	4 (12.12)	1	1 (3.03)
Hypophosphataemia	5	5 (15.15)	3	3 (9.09)
Hyperglycaemia	4	2 (6.06)	1	1 (3.03)
Hypercalcaemia	3	2 (6.06)	1	1 (3.03)
Hyperphosphataemia	3	3 (9.09)	1	1 (3.03)
Hypomagnesaemia	3	3 (9.09)	0	0 (0.00)
Tumour lysis syndrome	3	3 (9.09)	3	3 (9.09)
Acidosis	2	1 (3.03)	1	1 (3.03)
Hypervolaemia	2	2 (6.06)	1	1 (3.03)
Hyponatraemia	2	2 (6.06)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Calcium deficiency	1	1 (3.03)	0	0 (0.00)
Hyperchloraemia	1	1 (3.03)	0	0 (0.00)
Hyperkalaemia	1	1 (3.03)	1	1 (3.03)
Hypermagnesaemia	1	1 (3.03)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.03)	1	1 (3.03)
Metabolic acidosis	1	1 (3.03)	1	1 (3.03)
Musculoskeletal and connective tissue disorders				
- Total	16	11 (33.33)	3	2 (6.06)
Arthralgia	4	4 (12.12)	1	1 (3.03)
Myalgia	4	4 (12.12)	0	0 (0.00)
Pain in extremity	2	2 (6.06)	0	0 (0.00)
Back pain	1	1 (3.03)	0	0 (0.00)
Bone pain	1	1 (3.03)	0	0 (0.00)
Haemarthrosis	1	1 (3.03)	1	1 (3.03)
Muscle rigidity	1	1 (3.03)	0	0 (0.00)
Muscular weakness	1	1 (3.03)	1	1 (3.03)
Pain in jaw	1	1 (3.03)	0	0 (0.00)
Nervous system disorders				

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	31	19 (57.58)	4	3 (9.09)
Headache	15	13 (39.39)	1	1 (3.03)
Encephalopathy	3	3 (9.09)	1	1 (3.03)
Cognitive disorder	2	2 (6.06)	0	0 (0.00)
Dizziness	2	2 (6.06)	0	0 (0.00)
Seizure	2	1 (3.03)	0	0 (0.00)
Somnolence	2	2 (6.06)	1	1 (3.03)
Tremor	2	2 (6.06)	0	0 (0.00)
Dysarthria	1	1 (3.03)	1	1 (3.03)
Generalised tonic-clonic seizure	1	1 (3.03)	0	0 (0.00)
Hypoaesthesia	1	1 (3.03)	0	0 (0.00)
Psychiatric disorders				
- Total	18	10 (30.30)	4	4 (12.12)
Agitation	3	2 (6.06)	0	0 (0.00)
Anxiety	3	3 (9.09)	2	2 (6.06)
Confusional state	3	3 (9.09)	0	0 (0.00)
Delirium	3	3 (9.09)	1	1 (3.03)
Mental status changes	2	2 (6.06)	1	1 (3.03)
Sleep disorder	2	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Automatism	1	1 (3.03)	0	0 (0.00)
Insomnia	1	1 (3.03)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	7 (21.21)	5	4 (12.12)
Acute kidney injury	9	4 (12.12)	5	4 (12.12)
Anuria	1	1 (3.03)	0	0 (0.00)
Azotaemia	1	1 (3.03)	0	0 (0.00)
Dysuria	1	1 (3.03)	0	0 (0.00)
Micturition urgency	1	1 (3.03)	0	0 (0.00)
Pollakiuria	1	1 (3.03)	0	0 (0.00)
Urinary tract disorder	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Perineal rash	1	1 (3.03)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	46	14 (42.42)	20	11 (33.33)
Hypoxia	12	8 (24.24)	9	5 (15.15)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Pleural effusion	5	5 (15.15)	2	2 (6.06)
Cough	4	4 (12.12)	0	0 (0.00)
Pulmonary oedema	4	4 (12.12)	1	1 (3.03)
Tachypnoea	4	3 (9.09)	2	2 (6.06)
Oropharyngeal pain	2	2 (6.06)	0	0 (0.00)
Respiratory failure	2	2 (6.06)	2	2 (6.06)
Acute respiratory distress syndrome	1	1 (3.03)	1	1 (3.03)
Acute respiratory failure	1	1 (3.03)	1	1 (3.03)
Atelectasis	1	1 (3.03)	1	1 (3.03)
Bradypnoea	1	1 (3.03)	1	1 (3.03)
Epistaxis	1	1 (3.03)	0	0 (0.00)
Haemoptysis	1	1 (3.03)	0	0 (0.00)
Nasal congestion	1	1 (3.03)	0	0 (0.00)
Nasal discomfort	1	1 (3.03)	0	0 (0.00)
Painful respiration	1	1 (3.03)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (3.03)	0	0 (0.00)
Respiratory disorder	1	1 (3.03)	0	0 (0.00)
Respiratory distress	1	1 (3.03)	0	0 (0.00)
Wheezing	1	1 (3.03)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	15	9 (27.27)	1	1 (3.03)
Blister	4	1 (3.03)	0	0 (0.00)
Rash	4	4 (12.12)	0	0 (0.00)
Dermatitis diaper	1	1 (3.03)	0	0 (0.00)
Erythema	1	1 (3.03)	0	0 (0.00)
Hyperhidrosis	1	1 (3.03)	0	0 (0.00)
Petechiae	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)
Skin ulcer	1	1 (3.03)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (3.03)	1	1 (3.03)
Vascular disorders				
- Total	16	10 (30.30)	8	7 (21.21)
Hypotension	9	7 (21.21)	6	5 (15.15)
Hypertension	4	4 (12.12)	1	1 (3.03)
Capillary leak syndrome	2	2 (6.06)	1	1 (3.03)
Thrombosis	1	1 (3.03)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	320	13 (92.86)	104	12 (85.71)
Blood and lymphatic system disorders				
- Total	16	8 (57.14)	9	5 (35.71)
Anaemia	6	3 (21.43)	4	1 (7.14)
Neutropenia	3	2 (14.29)	2	1 (7.14)
Coagulopathy	2	2 (14.29)	0	0 (0.00)
Febrile neutropenia	2	2 (14.29)	2	2 (14.29)
B-cell aplasia	1	1 (7.14)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (7.14)	0	0 (0.00)
Thrombocytopenia	1	1 (7.14)	1	1 (7.14)
Cardiac disorders				
- Total	10	5 (35.71)	2	1 (7.14)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Cardiac failure	4	1 (7.14)	2	1 (7.14)
Sinus tachycardia	3	2 (14.29)	0	0 (0.00)
Tachycardia	2	2 (14.29)	0	0 (0.00)
Cardiac dysfunction	1	1 (7.14)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (14.29)	0	0 (0.00)
Adrenal insufficiency	2	2 (14.29)	0	0 (0.00)
Eye disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Periorbital swelling	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	26	12 (85.71)	2	2 (14.29)
Vomiting	5	5 (35.71)	0	0 (0.00)
Constipation	4	4 (28.57)	0	0 (0.00)
Nausea	4	3 (21.43)	0	0 (0.00)
Abdominal pain	2	2 (14.29)	0	0 (0.00)
Diarrhoea	2	2 (14.29)	0	0 (0.00)
Mouth haemorrhage	2	2 (14.29)	1	1 (7.14)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Abdominal pain upper	1	1 (7.14)	0	0 (0.00)
Dry mouth	1	1 (7.14)	0	0 (0.00)
Gingival bleeding	1	1 (7.14)	0	0 (0.00)
Gingivitis ulcerative	1	1 (7.14)	1	1 (7.14)
Ileus	1	1 (7.14)	0	0 (0.00)
Lip dry	1	1 (7.14)	0	0 (0.00)
Stomatitis	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	31	9 (64.29)	5	3 (21.43)
Pyrexia	9	6 (42.86)	2	2 (14.29)
Chills	5	2 (14.29)	0	0 (0.00)
Catheter site pain	3	1 (7.14)	2	1 (7.14)
Oedema peripheral	2	2 (14.29)	0	0 (0.00)
Asthenia	1	1 (7.14)	0	0 (0.00)
Crying	1	1 (7.14)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (7.14)	0	0 (0.00)
Face oedema	1	1 (7.14)	0	0 (0.00)
Facial pain	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Fatigue	1	1 (7.14)	0	0 (0.00)
Influenza like illness	1	1 (7.14)	0	0 (0.00)
Malaise	1	1 (7.14)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (7.14)	1	1 (7.14)
Sluggishness	1	1 (7.14)	0	0 (0.00)
Swelling face	1	1 (7.14)	0	0 (0.00)
Vascular device occlusion	1	1 (7.14)	0	0 (0.00)
Hepatobiliary disorders				
- Total	6	4 (28.57)	1	1 (7.14)
Hepatic function abnormal	2	2 (14.29)	0	0 (0.00)
Biliary tract disorder	1	1 (7.14)	0	0 (0.00)
Gallbladder enlargement	1	1 (7.14)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (7.14)	1	1 (7.14)
Hypertransaminasaemia	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	32	12 (85.71)	12	8 (57.14)
Cytokine release syndrome	28	12 (85.71)	11	8 (57.14)
Hypogammaglobulinaemia	3	3 (21.43)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (7.14)	1	1 (7.14)
Infections and infestations				
- Total	27	9 (64.29)	15	6 (42.86)
Candida infection	3	2 (14.29)	2	1 (7.14)
Oral candidiasis	2	1 (7.14)	0	0 (0.00)
Staphylococcal bacteraemia	2	1 (7.14)	2	1 (7.14)
Staphylococcal infection	2	2 (14.29)	1	1 (7.14)
Adenovirus infection	1	1 (7.14)	1	1 (7.14)
Atypical pneumonia	1	1 (7.14)	0	0 (0.00)
Clostridium difficile infection	1	1 (7.14)	1	1 (7.14)
Conjunctivitis	1	1 (7.14)	0	0 (0.00)
Encephalitis viral	1	1 (7.14)	1	1 (7.14)
Granulicatella infection	1	1 (7.14)	1	1 (7.14)
Herpes simplex	1	1 (7.14)	1	1 (7.14)
Human herpesvirus 6 infection	1	1 (7.14)	1	1 (7.14)
Klebsiella bacteraemia	1	1 (7.14)	0	0 (0.00)
Myringitis	1	1 (7.14)	0	0 (0.00)
Oral herpes	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Pneumonia	1	1 (7.14)	1	1 (7.14)
Rhinovirus infection	1	1 (7.14)	0	0 (0.00)
Sinusitis	1	1 (7.14)	1	1 (7.14)
Stomatococcal infection	1	1 (7.14)	0	0 (0.00)
Systemic candida	1	1 (7.14)	1	1 (7.14)
Urinary tract infection viral	1	1 (7.14)	0	0 (0.00)
Varicella zoster virus infection	1	1 (7.14)	1	1 (7.14)
Injury, poisoning and procedural complications				
- Total	2	1 (7.14)	1	1 (7.14)
Fall	1	1 (7.14)	0	0 (0.00)
Transplant failure	1	1 (7.14)	1	1 (7.14)
Investigations				
- Total	24	9 (64.29)	12	6 (42.86)
Aspartate aminotransferase increased	5	4 (28.57)	3	3 (21.43)
Alanine aminotransferase increased	4	2 (14.29)	1	1 (7.14)
Platelet count decreased	3	3 (21.43)	2	2 (14.29)
Blood glucose increased	2	1 (7.14)	2	1 (7.14)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
International normalised ratio increased	2	2 (14.29)	0	0 (0.00)
White blood cell count decreased	2	1 (7.14)	2	1 (7.14)
Blood bilirubin increased	1	1 (7.14)	1	1 (7.14)
Blood immunoglobulin A decreased	1	1 (7.14)	0	0 (0.00)
Breath sounds abnormal	1	1 (7.14)	0	0 (0.00)
Lymphocyte count decreased	1	1 (7.14)	0	0 (0.00)
Neutrophil count decreased	1	1 (7.14)	1	1 (7.14)
Staphylococcus test positive	1	1 (7.14)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	35	7 (50.00)	17	6 (42.86)
Hypokalaemia	6	6 (42.86)	2	2 (14.29)
Decreased appetite	5	5 (35.71)	2	2 (14.29)
Hyperglycaemia	4	3 (21.43)	0	0 (0.00)
Hypophosphataemia	4	2 (14.29)	4	2 (14.29)
Hypervolaemia	3	3 (21.43)	3	3 (21.43)
Hypocalcaemia	3	3 (21.43)	2	2 (14.29)
Hypomagnesaemia	3	2 (14.29)	0	0 (0.00)
Hypoalbuminaemia	2	2 (14.29)	1	1 (7.14)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Acidosis	1	1 (7.14)	1	1 (7.14)
Hyperuricaemia	1	1 (7.14)	0	0 (0.00)
Hypoglycaemia	1	1 (7.14)	0	0 (0.00)
Polydipsia	1	1 (7.14)	1	1 (7.14)
Tumour lysis syndrome	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	13	6 (42.86)	1	1 (7.14)
Arthralgia	3	3 (21.43)	0	0 (0.00)
Myalgia	3	2 (14.29)	0	0 (0.00)
Back pain	2	1 (7.14)	0	0 (0.00)
Muscle spasms	1	1 (7.14)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (7.14)	0	0 (0.00)
Neck pain	1	1 (7.14)	0	0 (0.00)
Pain in extremity	1	1 (7.14)	0	0 (0.00)
Pain in jaw	1	1 (7.14)	1	1 (7.14)
Nervous system disorders				
- Total	23	5 (35.71)	4	2 (14.29)
Headache	4	3 (21.43)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Cognitive disorder	3	1 (7.14)	1	1 (7.14)
Tremor	3	2 (14.29)	0	0 (0.00)
Hyperaesthesia	2	1 (7.14)	0	0 (0.00)
Somnolence	2	2 (14.29)	1	1 (7.14)
Amnesia	1	1 (7.14)	0	0 (0.00)
Aphasia	1	1 (7.14)	0	0 (0.00)
Disturbance in attention	1	1 (7.14)	0	0 (0.00)
Dizziness	1	1 (7.14)	0	0 (0.00)
Dysgeusia	1	1 (7.14)	0	0 (0.00)
Encephalopathy	1	1 (7.14)	1	1 (7.14)
Lethargy	1	1 (7.14)	0	0 (0.00)
Neurological decompensation	1	1 (7.14)	1	1 (7.14)
Paraesthesia	1	1 (7.14)	0	0 (0.00)
Psychiatric disorders				
- Total	10	4 (28.57)	2	2 (14.29)
Agitation	2	2 (14.29)	0	0 (0.00)
Delirium	2	2 (14.29)	2	2 (14.29)
Affect lability	1	1 (7.14)	0	0 (0.00)
Hallucination	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hallucination, visual	1	1 (7.14)	0	0 (0.00)
Irritability	1	1 (7.14)	0	0 (0.00)
Mental status changes	1	1 (7.14)	0	0 (0.00)
Social avoidant behaviour	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	4 (28.57)	4	2 (14.29)
Renal failure	3	1 (7.14)	3	1 (7.14)
Acute kidney injury	2	2 (14.29)	1	1 (7.14)
Urinary incontinence	2	1 (7.14)	0	0 (0.00)
Pollakiuria	1	1 (7.14)	0	0 (0.00)
Urinary retention	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (21.43)	0	0 (0.00)
Vaginal haemorrhage	2	1 (7.14)	0	0 (0.00)
Female genital tract fistula	1	1 (7.14)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	26	10 (71.43)	12	5 (35.71)
Hypoxia	4	3 (21.43)	4	3 (21.43)
Pulmonary oedema	4	4 (28.57)	3	3 (21.43)
Oropharyngeal pain	2	2 (14.29)	0	0 (0.00)
Respiratory distress	2	1 (7.14)	2	1 (7.14)
Respiratory failure	2	2 (14.29)	2	2 (14.29)
Atelectasis	1	1 (7.14)	0	0 (0.00)
Dyspnoea	1	1 (7.14)	1	1 (7.14)
Epistaxis	1	1 (7.14)	0	0 (0.00)
Nasal congestion	1	1 (7.14)	0	0 (0.00)
Nasal dryness	1	1 (7.14)	0	0 (0.00)
Oropharyngeal plaque	1	1 (7.14)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (7.14)	0	0 (0.00)
Pharyngeal erythema	1	1 (7.14)	0	0 (0.00)
Pharyngeal exudate	1	1 (7.14)	0	0 (0.00)
Pharyngeal oedema	1	1 (7.14)	0	0 (0.00)
Pulmonary mass	1	1 (7.14)	0	0 (0.00)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Tachypnoea	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	6 (42.86)	0	0 (0.00)
Hyperhidrosis	2	2 (14.29)	0	0 (0.00)
Pruritus	2	2 (14.29)	0	0 (0.00)
Rash papular	2	1 (7.14)	0	0 (0.00)
Erythema	1	1 (7.14)	0	0 (0.00)
Erythema nodosum	1	1 (7.14)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (7.14)	0	0 (0.00)
Skin lesion	1	1 (7.14)	0	0 (0.00)
Social circumstances				
- Total	1	1 (7.14)	0	0 (0.00)
Patient uncooperative	1	1 (7.14)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (7.14)	1	1 (7.14)
Thrombolysis	1	1 (7.14)	1	1 (7.14)

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Vascular disorders				
- Total	11	5 (35.71)	4	3 (21.43)
Hypertension	4	4 (28.57)	1	1 (7.14)
Hypotension	4	4 (28.57)	3	3 (21.43)
Flushing	1	1 (7.14)	0	0 (0.00)
Hot flush	1	1 (7.14)	0	0 (0.00)
Peripheral ischaemia	1	1 (7.14)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Total number of AE per patient	238	28 (93.33)	73	17 (56.67)
Blood and lymphatic system disorders				
- Total	17	6 (20.00)	10	3 (10.00)
Anaemia	7	2 (6.67)	3	1 (3.33)
Febrile neutropenia	4	3 (10.00)	4	3 (10.00)
Thrombocytopenia	2	2 (6.67)	2	2 (6.67)
Eosinophilia	1	1 (3.33)	0	0 (0.00)
Leukocytosis	1	1 (3.33)	0	0 (0.00)
Lymphadenopathy	1	1 (3.33)	0	0 (0.00)
Lymphopenia	1	1 (3.33)	1	1 (3.33)
Cardiac disorders				
- Total	3	3 (10.00)	1	1 (3.33)
Cardiac arrest	1	1 (3.33)	1	1 (3.33)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Tachycardia	1	1 (3.33)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (3.33)	0	0 (0.00)
Eye disorders				
- Total	3	2 (6.67)	0	0 (0.00)
Cataract	1	1 (3.33)	0	0 (0.00)
Hypermetropia	1	1 (3.33)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	22	8 (26.67)	1	1 (3.33)
Vomiting	7	6 (20.00)	0	0 (0.00)
Diarrhoea	5	5 (16.67)	0	0 (0.00)
Nausea	3	3 (10.00)	0	0 (0.00)
Constipation	2	1 (3.33)	0	0 (0.00)
Abdominal pain	1	1 (3.33)	0	0 (0.00)
Abdominal pain upper	1	1 (3.33)	0	0 (0.00)
Dyspepsia	1	1 (3.33)	0	0 (0.00)
Pancreatitis	1	1 (3.33)	1	1 (3.33)
Proctalgia	1	1 (3.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
General disorders and administration site conditions				
- Total	12	10 (33.33)	1	1 (3.33)
Pyrexia	7	6 (20.00)	0	0 (0.00)
Fatigue	4	4 (13.33)	0	0 (0.00)
Pain	1	1 (3.33)	1	1 (3.33)
Hepatobiliary disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Liver disorder	1	1 (3.33)	0	0 (0.00)
Immune system disorders				
- Total	6	6 (20.00)	1	1 (3.33)
Hypogammaglobulinaemia	3	3 (10.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (3.33)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.33)	0	0 (0.00)
Graft versus host disease	1	1 (3.33)	1	1 (3.33)
Infections and infestations				
- Total	54	17 (56.67)	23	10 (33.33)
Bronchopulmonary aspergillosis	5	1 (3.33)	3	1 (3.33)
Nasopharyngitis	4	3 (10.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Upper respiratory tract infection	4	4 (13.33)	0	0 (0.00)
Otitis media	3	3 (10.00)	1	1 (3.33)
Ear infection	2	1 (3.33)	0	0 (0.00)
Gastroenteritis	2	2 (6.67)	1	1 (3.33)
Klebsiella infection	2	1 (3.33)	2	1 (3.33)
Metapneumovirus infection	2	2 (6.67)	2	2 (6.67)
Parainfluenzae virus infection	2	1 (3.33)	1	1 (3.33)
Pneumocystis jirovecii pneumonia	2	2 (6.67)	2	2 (6.67)
Pneumonia	2	2 (6.67)	1	1 (3.33)
Rhinovirus infection	2	2 (6.67)	0	0 (0.00)
Viral infection	2	2 (6.67)	1	1 (3.33)
Cellulitis	1	1 (3.33)	0	0 (0.00)
Conjunctivitis	1	1 (3.33)	0	0 (0.00)
Cystitis	1	1 (3.33)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (3.33)	1	1 (3.33)
Device related infection	1	1 (3.33)	1	1 (3.33)
Enterobacter infection	1	1 (3.33)	1	1 (3.33)
Gingivitis	1	1 (3.33)	0	0 (0.00)
Herpes zoster	1	1 (3.33)	1	1 (3.33)
Human herpesvirus 6 infection	1	1 (3.33)	1	1 (3.33)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Mastoiditis	1	1 (3.33)	1	1 (3.33)
Oral candidiasis	1	1 (3.33)	0	0 (0.00)
Oral herpes	1	1 (3.33)	0	0 (0.00)
Otitis externa	1	1 (3.33)	1	1 (3.33)
Respiratory syncytial virus infection	1	1 (3.33)	0	0 (0.00)
Respiratory tract infection viral	1	1 (3.33)	0	0 (0.00)
Rhinitis	1	1 (3.33)	0	0 (0.00)
Salmonellosis	1	1 (3.33)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (3.33)	1	1 (3.33)
Staphylococcal sepsis	1	1 (3.33)	1	1 (3.33)
Staphylococcal skin infection	1	1 (3.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	5 (16.67)	0	0 (0.00)
Infusion related reaction	3	2 (6.67)	0	0 (0.00)
Contusion	1	1 (3.33)	0	0 (0.00)
Ligament sprain	1	1 (3.33)	0	0 (0.00)
Skin abrasion	1	1 (3.33)	0	0 (0.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
- Total	50	14 (46.67)	22	8 (26.67)
Platelet count decreased	16	5 (16.67)	9	2 (6.67)
Neutrophil count decreased	11	7 (23.33)	7	5 (16.67)
White blood cell count decreased	11	7 (23.33)	2	2 (6.67)
Lymphocyte count decreased	5	3 (10.00)	2	2 (6.67)
Alanine aminotransferase increased	2	1 (3.33)	1	1 (3.33)
Blood immunoglobulin A decreased	1	1 (3.33)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.33)	0	0 (0.00)
Blood uric acid increased	1	1 (3.33)	1	1 (3.33)
C-reactive protein increased	1	1 (3.33)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (3.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	11	5 (16.67)	4	2 (6.67)
Hypokalaemia	5	2 (6.67)	4	2 (6.67)
Decreased appetite	3	3 (10.00)	0	0 (0.00)
Hyperkalaemia	1	1 (3.33)	0	0 (0.00)
Hypophagia	1	1 (3.33)	0	0 (0.00)
Iron overload	1	1 (3.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	7	5 (16.67)	2	2 (6.67)
Pain in extremity	3	3 (10.00)	1	1 (3.33)
Arthralgia	1	1 (3.33)	0	0 (0.00)
Back pain	1	1 (3.33)	1	1 (3.33)
Bone pain	1	1 (3.33)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.33)	1	1 (3.33)
Myelodysplastic syndrome	1	1 (3.33)	1	1 (3.33)
Nervous system disorders				
- Total	6	3 (10.00)	3	1 (3.33)
Hydrocephalus	3	1 (3.33)	3	1 (3.33)
Dizziness	2	1 (3.33)	0	0 (0.00)
Headache	1	1 (3.33)	0	0 (0.00)
Psychiatric disorders				
- Total	8	3 (10.00)	1	1 (3.33)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Anxiety	2	2 (6.67)	0	0 (0.00)
Agitation	1	1 (3.33)	0	0 (0.00)
Delirium	1	1 (3.33)	0	0 (0.00)
Mental status changes	1	1 (3.33)	1	1 (3.33)
Mood altered	1	1 (3.33)	0	0 (0.00)
Nightmare	1	1 (3.33)	0	0 (0.00)
Tearfulness	1	1 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	22	12 (40.00)	3	3 (10.00)
Cough	8	6 (20.00)	0	0 (0.00)
Nasal congestion	3	3 (10.00)	0	0 (0.00)
Rhinorrhoea	3	3 (10.00)	0	0 (0.00)
Epistaxis	2	2 (6.67)	0	0 (0.00)
Hypoxia	2	2 (6.67)	2	2 (6.67)
Rhinitis allergic	2	2 (6.67)	0	0 (0.00)
Bronchospasm	1	1 (3.33)	0	0 (0.00)
Respiratory failure	1	1 (3.33)	1	1 (3.33)
Skin and subcutaneous tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
- Total	9	7 (23.33)	0	0 (0.00)
Dry skin	2	1 (3.33)	0	0 (0.00)
Dermatitis allergic	1	1 (3.33)	0	0 (0.00)
Dermatitis atopic	1	1 (3.33)	0	0 (0.00)
Erythema	1	1 (3.33)	0	0 (0.00)
Miliaria	1	1 (3.33)	0	0 (0.00)
Night sweats	1	1 (3.33)	0	0 (0.00)
Photosensitivity reaction	1	1 (3.33)	0	0 (0.00)
Rash	1	1 (3.33)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Total number of AE per patient	219	29 (93.55)	53	13 (41.94)
Blood and lymphatic system disorders				
- Total	7	7 (22.58)	4	4 (12.90)
Neutropenia	3	3 (9.68)	3	3 (9.68)
Anaemia	1	1 (3.23)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (3.23)	1	1 (3.23)
Leukopenia	1	1 (3.23)	0	0 (0.00)
Lymphocytosis	1	1 (3.23)	0	0 (0.00)
Cardiac disorders				
- Total	5	4 (12.90)	3	2 (6.45)
Cardiac failure	2	2 (6.45)	2	2 (6.45)
Cardiac arrest	1	1 (3.23)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Left ventricular dysfunction	1	1 (3.23)	0	0 (0.00)
Tachycardia	1	1 (3.23)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Hypothyroidism	1	1 (3.23)	0	0 (0.00)
Eye disorders				
- Total	1	1 (3.23)	0	0 (0.00)
Visual impairment	1	1 (3.23)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	7 (22.58)	0	0 (0.00)
Constipation	2	2 (6.45)	0	0 (0.00)
Diarrhoea	2	2 (6.45)	0	0 (0.00)
Abdominal rigidity	1	1 (3.23)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (3.23)	0	0 (0.00)
Mouth haemorrhage	1	1 (3.23)	0	0 (0.00)
Nausea	1	1 (3.23)	0	0 (0.00)
Peritoneal haematoma	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
General disorders and administration site conditions				
- Total	14	9 (29.03)	2	2 (6.45)
Pyrexia	6	6 (19.35)	2	2 (6.45)
Fatigue	3	2 (6.45)	0	0 (0.00)
Oedema peripheral	2	1 (3.23)	0	0 (0.00)
Asthenia	1	1 (3.23)	0	0 (0.00)
Chills	1	1 (3.23)	0	0 (0.00)
Malaise	1	1 (3.23)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (6.45)	0	0 (0.00)
Hepatic cytolysis	1	1 (3.23)	0	0 (0.00)
Hypertransaminasaemia	1	1 (3.23)	0	0 (0.00)
Immune system disorders				
- Total	9	6 (19.35)	2	1 (3.23)
Hypogammaglobulinaemia	7	5 (16.13)	0	0 (0.00)
Engraftment syndrome	1	1 (3.23)	1	1 (3.23)
Graft versus host disease	1	1 (3.23)	1	1 (3.23)
Infections and infestations				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	39	15 (48.39)	11	6 (19.35)
Sinusitis	4	3 (9.68)	1	1 (3.23)
Upper respiratory tract infection	4	3 (9.68)	1	1 (3.23)
Nasopharyngitis	3	2 (6.45)	0	0 (0.00)
Gastroenteritis	2	2 (6.45)	0	0 (0.00)
Respiratory tract infection	2	2 (6.45)	0	0 (0.00)
Adenovirus infection	1	1 (3.23)	1	1 (3.23)
BK virus infection	1	1 (3.23)	1	1 (3.23)
Bacteraemia	1	1 (3.23)	0	0 (0.00)
Coronavirus infection	1	1 (3.23)	1	1 (3.23)
Ear infection	1	1 (3.23)	0	0 (0.00)
Encephalitis	1	1 (3.23)	1	1 (3.23)
Gastroenteritis clostridial	1	1 (3.23)	0	0 (0.00)
Gastroenteritis viral	1	1 (3.23)	0	0 (0.00)
Gastrointestinal infection	1	1 (3.23)	0	0 (0.00)
Herpes simplex	1	1 (3.23)	0	0 (0.00)
Influenza	1	1 (3.23)	0	0 (0.00)
Metapneumovirus infection	1	1 (3.23)	1	1 (3.23)
Molluscum contagiosum	1	1 (3.23)	0	0 (0.00)
Otitis externa	1	1 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Parainfluenzae virus infection	1	1 (3.23)	0	0 (0.00)
Paronychia	1	1 (3.23)	0	0 (0.00)
Pneumonia	1	1 (3.23)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (3.23)	1	1 (3.23)
Rhinitis	1	1 (3.23)	0	0 (0.00)
Rhinovirus infection	1	1 (3.23)	0	0 (0.00)
Septic shock	1	1 (3.23)	1	1 (3.23)
Sinusitis fungal	1	1 (3.23)	1	1 (3.23)
Tinea pedis	1	1 (3.23)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (3.23)	1	1 (3.23)
Injury, poisoning and procedural complications				
- Total	3	3 (9.68)	0	0 (0.00)
Fibula fracture	1	1 (3.23)	0	0 (0.00)
Infusion related reaction	1	1 (3.23)	0	0 (0.00)
Limb injury	1	1 (3.23)	0	0 (0.00)
Investigations				
- Total	36	12 (38.71)	12	7 (22.58)
Neutrophil count decreased	8	3 (9.68)	4	2 (6.45)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
White blood cell count decreased	6	2 (6.45)	1	1 (3.23)
Immunoglobulins decreased	5	1 (3.23)	0	0 (0.00)
Weight increased	3	1 (3.23)	1	1 (3.23)
Blood bilirubin increased	2	1 (3.23)	1	1 (3.23)
Alanine aminotransferase increased	1	1 (3.23)	0	0 (0.00)
Blood creatinine increased	1	1 (3.23)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.23)	1	1 (3.23)
Blood immunoglobulin M decreased	1	1 (3.23)	1	1 (3.23)
Blood thyroid stimulating hormone increased	1	1 (3.23)	0	0 (0.00)
Blood urea increased	1	1 (3.23)	1	1 (3.23)
Blood uric acid increased	1	1 (3.23)	1	1 (3.23)
Bone density decreased	1	1 (3.23)	0	0 (0.00)
Ejection fraction decreased	1	1 (3.23)	0	0 (0.00)
Lymphocyte count decreased	1	1 (3.23)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.23)	0	0 (0.00)
Weight decreased	1	1 (3.23)	1	1 (3.23)
Metabolism and nutrition disorders				
- Total	14	9 (29.03)	5	4 (12.90)
Decreased appetite	3	3 (9.68)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Hyperuricaemia	3	3 (9.68)	0	0 (0.00)
Haemochromatosis	1	1 (3.23)	1	1 (3.23)
Hyperchloraemia	1	1 (3.23)	0	0 (0.00)
Hypervolaemia	1	1 (3.23)	1	1 (3.23)
Hypokalaemia	1	1 (3.23)	0	0 (0.00)
Hypophosphataemia	1	1 (3.23)	0	0 (0.00)
Metabolic acidosis	1	1 (3.23)	1	1 (3.23)
Metabolic syndrome	1	1 (3.23)	0	0 (0.00)
Tumour lysis syndrome	1	1 (3.23)	1	1 (3.23)
Musculoskeletal and connective tissue disorders				
- Total	10	7 (22.58)	1	1 (3.23)
Back pain	4	4 (12.90)	1	1 (3.23)
Pain in extremity	2	2 (6.45)	0	0 (0.00)
Arthralgia	1	1 (3.23)	0	0 (0.00)
Growth retardation	1	1 (3.23)	0	0 (0.00)
Musculoskeletal pain	1	1 (3.23)	0	0 (0.00)
Myalgia	1	1 (3.23)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
- Total	3	3 (9.68)	0	0 (0.00)
Skin papilloma	2	2 (6.45)	0	0 (0.00)
Cancer pain	1	1 (3.23)	0	0 (0.00)
Nervous system disorders				
- Total	10	7 (22.58)	3	1 (3.23)
Headache	6	6 (19.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (3.23)	1	1 (3.23)
Cerebral haemorrhage	1	1 (3.23)	1	1 (3.23)
Memory impairment	1	1 (3.23)	0	0 (0.00)
Seizure	1	1 (3.23)	1	1 (3.23)
Psychiatric disorders				
- Total	4	4 (12.90)	0	0 (0.00)
Anxiety	1	1 (3.23)	0	0 (0.00)
Mental status changes	1	1 (3.23)	0	0 (0.00)
Persistent depressive disorder	1	1 (3.23)	0	0 (0.00)
Sleep disorder	1	1 (3.23)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (12.90)	3	3 (9.68)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Acute kidney injury	3	3 (9.68)	1	1 (3.23)
Dysuria	1	1 (3.23)	0	0 (0.00)
Haematuria	1	1 (3.23)	1	1 (3.23)
Kidney enlargement	1	1 (3.23)	0	0 (0.00)
Renal mass	1	1 (3.23)	0	0 (0.00)
Renal tubular disorder	1	1 (3.23)	1	1 (3.23)
Reproductive system and breast disorders				
- Total	2	1 (3.23)	0	0 (0.00)
Dysmenorrhoea	2	1 (3.23)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	21	9 (29.03)	3	3 (9.68)
Cough	6	5 (16.13)	0	0 (0.00)
Nasal congestion	4	3 (9.68)	0	0 (0.00)
Dyspnoea	2	1 (3.23)	0	0 (0.00)
Oropharyngeal pain	2	2 (6.45)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (3.23)	1	1 (3.23)
Epistaxis	1	1 (3.23)	0	0 (0.00)
Hypoxia	1	1 (3.23)	1	1 (3.23)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=31 n (%)[1]	Grade >= 3 Total events	All patients N=31 n (%)[2]
Lung disorder	1	1 (3.23)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (3.23)	0	0 (0.00)
Pleural effusion	1	1 (3.23)	0	0 (0.00)
Respiratory distress	1	1 (3.23)	1	1 (3.23)
Skin and subcutaneous tissue disorders				
- Total	15	9 (29.03)	0	0 (0.00)
Rash	5	3 (9.68)	0	0 (0.00)
Dry skin	4	4 (12.90)	0	0 (0.00)
Ingrowing nail	2	2 (6.45)	0	0 (0.00)
Eczema	1	1 (3.23)	0	0 (0.00)
Skin discolouration	1	1 (3.23)	0	0 (0.00)
Skin hypopigmentation	1	1 (3.23)	0	0 (0.00)
Skin swelling	1	1 (3.23)	0	0 (0.00)
Vascular disorders				
- Total	6	5 (16.13)	4	4 (12.90)
Hypotension	4	4 (12.90)	3	3 (9.68)
Hypertension	1	1 (3.23)	0	0 (0.00)
Venoocclusive disease	1	1 (3.23)	1	1 (3.23)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	77	12 (85.71)	20	6 (42.86)
Blood and lymphatic system disorders				
- Total	8	4 (28.57)	3	3 (21.43)
Anaemia	4	3 (21.43)	1	1 (7.14)
B-cell aplasia	2	1 (7.14)	0	0 (0.00)
Neutropenia	2	2 (14.29)	2	2 (14.29)
Eye disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Cataract	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	7	5 (35.71)	0	0 (0.00)
Abdominal pain	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Enteritis	1	1 (7.14)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (7.14)	0	0 (0.00)
Nausea	1	1 (7.14)	0	0 (0.00)
Pancreatitis	1	1 (7.14)	0	0 (0.00)
Stomatitis	1	1 (7.14)	0	0 (0.00)
Trichoglossia	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	5 (35.71)	0	0 (0.00)
Pyrexia	3	3 (21.43)	0	0 (0.00)
Non-cardiac chest pain	1	1 (7.14)	0	0 (0.00)
Pain	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (28.57)	2	2 (14.29)
Hypogammaglobulinaemia	2	2 (14.29)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (7.14)	1	1 (7.14)
Immunodeficiency	1	1 (7.14)	1	1 (7.14)
Infections and infestations				
- Total	20	7 (50.00)	11	4 (28.57)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Bacteraemia	2	1 (7.14)	2	1 (7.14)
Nasopharyngitis	2	2 (14.29)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (14.29)	1	1 (7.14)
Rhinovirus infection	2	2 (14.29)	1	1 (7.14)
Upper respiratory tract infection	2	1 (7.14)	1	1 (7.14)
Urinary tract infection	2	1 (7.14)	2	1 (7.14)
Acute sinusitis	1	1 (7.14)	0	0 (0.00)
Ear, nose and throat infection	1	1 (7.14)	0	0 (0.00)
Gastroenteritis	1	1 (7.14)	1	1 (7.14)
Nail infection	1	1 (7.14)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (7.14)	1	1 (7.14)
Respiratory syncytial virus infection	1	1 (7.14)	1	1 (7.14)
Respiratory tract infection	1	1 (7.14)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (7.14)	1	1 (7.14)
Injury, poisoning and procedural complications				
- Total	1	1 (7.14)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (7.14)	0	0 (0.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	5	4 (28.57)	1	1 (7.14)
Blood bilirubin increased	2	1 (7.14)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (7.14)	0	0 (0.00)
Heart sounds abnormal	1	1 (7.14)	0	0 (0.00)
White blood cell count decreased	1	1 (7.14)	1	1 (7.14)
Metabolism and nutrition disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Malnutrition	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	5	3 (21.43)	0	0 (0.00)
Back pain	2	1 (7.14)	0	0 (0.00)
Arthralgia	1	1 (7.14)	0	0 (0.00)
Bone pain	1	1 (7.14)	0	0 (0.00)
Neck pain	1	1 (7.14)	0	0 (0.00)
Nervous system disorders				
- Total	7	4 (28.57)	0	0 (0.00)
Headache	4	3 (21.43)	0	0 (0.00)
Migraine	2	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Extrapyramidal disorder	1	1 (7.14)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (21.43)	0	0 (0.00)
Anxiety	3	3 (21.43)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	3	3 (21.43)	0	0 (0.00)
Bronchial oedema	1	1 (7.14)	0	0 (0.00)
Pleural effusion	1	1 (7.14)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	4 (28.57)	1	1 (7.14)
Pruritus	2	1 (7.14)	0	0 (0.00)
Decubitus ulcer	1	1 (7.14)	1	1 (7.14)
Dry skin	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hangnail	1	1 (7.14)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (7.14)	1	1 (7.14)
Venoocclusive disease	1	1 (7.14)	1	1 (7.14)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	68	12 (60.00)	24	5 (25.00)
Blood and lymphatic system disorders				
- Total	5	3 (15.00)	1	1 (5.00)
Agranulocytosis	1	1 (5.00)	1	1 (5.00)
Anaemia	1	1 (5.00)	0	0 (0.00)
Hypercoagulation	1	1 (5.00)	0	0 (0.00)
Lymphadenopathy	1	1 (5.00)	0	0 (0.00)
Thrombocytopenia	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	3	2 (10.00)	1	1 (5.00)
Eye pain	1	1 (5.00)	1	1 (5.00)
Eyelid oedema	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Mydriasis	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	3 (15.00)	1	1 (5.00)
Diarrhoea	2	2 (10.00)	1	1 (5.00)
Constipation	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	2 (10.00)	2	2 (10.00)
Pyrexia	2	2 (10.00)	1	1 (5.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	4	3 (15.00)	2	1 (5.00)
Chronic graft versus host disease	2	2 (10.00)	1	1 (5.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.00)	1	1 (5.00)
Hypogammaglobulinaemia	1	1 (5.00)	0	0 (0.00)
Infections and infestations				
- Total	24	8 (40.00)	8	3 (15.00)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Conjunctivitis	2	2 (10.00)	0	0 (0.00)
Fungal infection	2	1 (5.00)	0	0 (0.00)
Upper respiratory tract infection	2	2 (10.00)	0	0 (0.00)
Bronchitis	1	1 (5.00)	0	0 (0.00)
COVID-19 pneumonia	1	1 (5.00)	1	1 (5.00)
Candida infection	1	1 (5.00)	0	0 (0.00)
Enterovirus infection	1	1 (5.00)	1	1 (5.00)
Gastroenteritis	1	1 (5.00)	0	0 (0.00)
Herpes virus infection	1	1 (5.00)	0	0 (0.00)
Influenza	1	1 (5.00)	1	1 (5.00)
Neutropenic infection	1	1 (5.00)	1	1 (5.00)
Ophthalmic herpes zoster	1	1 (5.00)	0	0 (0.00)
Oral herpes	1	1 (5.00)	0	0 (0.00)
Otitis media acute	1	1 (5.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.00)	1	1 (5.00)
Pneumonia	1	1 (5.00)	1	1 (5.00)
Rhinovirus infection	1	1 (5.00)	1	1 (5.00)
Sepsis	1	1 (5.00)	1	1 (5.00)
Skin infection	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Streptococcal sepsis	1	1 (5.00)	0	0 (0.00)
Viral skin infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (5.00)	0	0 (0.00)
Abdominal injury	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	4	3 (15.00)	1	1 (5.00)
Neutrophil count decreased	1	1 (5.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.00)	1	1 (5.00)
Platelet count decreased	1	1 (5.00)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (10.00)	2	2 (10.00)
Hyperglycaemia	1	1 (5.00)	1	1 (5.00)
Obesity	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	3	3 (15.00)	0	0 (0.00)
Pain in extremity	2	2 (10.00)	0	0 (0.00)
Growth retardation	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (5.00)	1	1 (5.00)
Bone giant cell tumour benign	2	1 (5.00)	1	1 (5.00)
Nervous system disorders				
- Total	2	1 (5.00)	1	1 (5.00)
Headache	2	1 (5.00)	1	1 (5.00)
Respiratory, thoracic and mediastinal disorders				
- Total	8	3 (15.00)	3	1 (5.00)
Tachypnoea	2	1 (5.00)	2	1 (5.00)
Cough	1	1 (5.00)	0	0 (0.00)
Dyspnoea	1	1 (5.00)	1	1 (5.00)
Dyspnoea exertional	1	1 (5.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Pleural effusion	1	1 (5.00)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (10.00)	0	0 (0.00)
Dry skin	1	1 (5.00)	0	0 (0.00)
Rash	1	1 (5.00)	0	0 (0.00)
Rash maculo-papular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (5.00)	1	1 (5.00)
Hypertension	1	1 (5.00)	1	1 (5.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Total number of AE per patient	109	17 (77.27)	31	11 (50.00)
Blood and lymphatic system disorders				
- Total	1	1 (4.55)	1	1 (4.55)
Neutropenia	1	1 (4.55)	1	1 (4.55)
Endocrine disorders				
- Total	2	1 (4.55)	0	0 (0.00)
Delayed puberty	1	1 (4.55)	0	0 (0.00)
Hypothyroidism	1	1 (4.55)	0	0 (0.00)
Eye disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Dry eye	1	1 (4.55)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	5	3 (13.64)	0	0 (0.00)
Diarrhoea	2	2 (9.09)	0	0 (0.00)
Irritable bowel syndrome	1	1 (4.55)	0	0 (0.00)
Nausea	1	1 (4.55)	0	0 (0.00)
Vomiting	1	1 (4.55)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	5 (22.73)	0	0 (0.00)
Pyrexia	2	2 (9.09)	0	0 (0.00)
Fatigue	1	1 (4.55)	0	0 (0.00)
Pain	1	1 (4.55)	0	0 (0.00)
Xerosis	1	1 (4.55)	0	0 (0.00)
Immune system disorders				
- Total	6	6 (27.27)	1	1 (4.55)
Seasonal allergy	3	3 (13.64)	0	0 (0.00)
Hypogammaglobulinaemia	2	2 (9.09)	0	0 (0.00)
Drug hypersensitivity	1	1 (4.55)	1	1 (4.55)
Infections and infestations				
- Total	52	12 (54.55)	17	10 (45.45)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Sinusitis	7	4 (18.18)	0	0 (0.00)
Upper respiratory tract infection	4	2 (9.09)	1	1 (4.55)
COVID-19	3	2 (9.09)	1	1 (4.55)
Conjunctivitis	3	2 (9.09)	0	0 (0.00)
Otitis media	3	2 (9.09)	0	0 (0.00)
Device related sepsis	2	1 (4.55)	2	1 (4.55)
Gastroenteritis viral	2	1 (4.55)	0	0 (0.00)
Herpes zoster	2	2 (9.09)	1	1 (4.55)
Rhinovirus infection	2	2 (9.09)	0	0 (0.00)
Sepsis	2	2 (9.09)	2	2 (9.09)
Skin infection	2	2 (9.09)	0	0 (0.00)
Bronchiolitis	1	1 (4.55)	1	1 (4.55)
Bronchitis	1	1 (4.55)	0	0 (0.00)
Clostridium difficile colitis	1	1 (4.55)	1	1 (4.55)
Ear infection	1	1 (4.55)	1	1 (4.55)
Folliculitis	1	1 (4.55)	0	0 (0.00)
Fungal infection	1	1 (4.55)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (4.55)	1	1 (4.55)
Gastroenteritis salmonella	1	1 (4.55)	1	1 (4.55)
Meningitis pneumococcal	1	1 (4.55)	1	1 (4.55)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Nail infection	1	1 (4.55)	0	0 (0.00)
Oral candidiasis	1	1 (4.55)	0	0 (0.00)
Oral herpes	1	1 (4.55)	0	0 (0.00)
Pneumonia	1	1 (4.55)	1	1 (4.55)
Pneumonia respiratory syncytial viral	1	1 (4.55)	1	1 (4.55)
Rhinitis	1	1 (4.55)	0	0 (0.00)
Septic shock	1	1 (4.55)	1	1 (4.55)
Staphylococcal bacteraemia	1	1 (4.55)	1	1 (4.55)
Syphilis	1	1 (4.55)	0	0 (0.00)
Urinary tract infection	1	1 (4.55)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (4.55)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (9.09)	1	1 (4.55)
Infusion related reaction	1	1 (4.55)	1	1 (4.55)
Ligament sprain	1	1 (4.55)	0	0 (0.00)
Investigations				
- Total	1	1 (4.55)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (4.55)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Metabolism and nutrition disorders				
- Total	4	3 (13.64)	3	2 (9.09)
Decreased appetite	2	1 (4.55)	2	1 (4.55)
Hyperlipidaemia	1	1 (4.55)	0	0 (0.00)
Hypernatraemia	1	1 (4.55)	1	1 (4.55)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (13.64)	0	0 (0.00)
Arthralgia	1	1 (4.55)	0	0 (0.00)
Osteonecrosis	1	1 (4.55)	0	0 (0.00)
Osteopenia	1	1 (4.55)	0	0 (0.00)
Nervous system disorders				
- Total	7	3 (13.64)	2	1 (4.55)
Seizure	3	1 (4.55)	1	1 (4.55)
Nervous system disorder	2	1 (4.55)	1	1 (4.55)
Dysarthria	1	1 (4.55)	0	0 (0.00)
Headache	1	1 (4.55)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Anxiety	1	1 (4.55)	0	0 (0.00)
Tic	1	1 (4.55)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	11	6 (27.27)	2	2 (9.09)
Cough	2	2 (9.09)	0	0 (0.00)
Rhinorrhoea	2	2 (9.09)	0	0 (0.00)
Dyspnoea	1	1 (4.55)	0	0 (0.00)
Epistaxis	1	1 (4.55)	0	0 (0.00)
Hypoxia	1	1 (4.55)	1	1 (4.55)
Oropharyngeal pain	1	1 (4.55)	0	0 (0.00)
Respiratory failure	1	1 (4.55)	1	1 (4.55)
Sleep apnoea syndrome	1	1 (4.55)	0	0 (0.00)
Wheezing	1	1 (4.55)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	5 (22.73)	4	3 (13.64)
Rash macular	2	1 (4.55)	2	1 (4.55)
Dermatitis atopic	1	1 (4.55)	1	1 (4.55)
Eczema	1	1 (4.55)	1	1 (4.55)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Papule	1	1 (4.55)	0	0 (0.00)
Rash	1	1 (4.55)	0	0 (0.00)
Rash erythematous	1	1 (4.55)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Total number of AE per patient	43	3 (37.50)	8	3 (37.50)
Congenital, familial and genetic disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (12.50)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Deafness unilateral	1	1 (12.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Diarrhoea	1	1 (12.50)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
General disorders and administration site conditions				
- Total	5	2 (25.00)	0	0 (0.00)
Pyrexia	3	1 (12.50)	0	0 (0.00)
Non-cardiac chest pain	1	1 (12.50)	0	0 (0.00)
Pain	1	1 (12.50)	0	0 (0.00)
Infections and infestations				
- Total	10	3 (37.50)	1	1 (12.50)
Sinusitis	2	2 (25.00)	0	0 (0.00)
Acute sinusitis	1	1 (12.50)	0	0 (0.00)
Fungal skin infection	1	1 (12.50)	0	0 (0.00)
Influenza	1	1 (12.50)	0	0 (0.00)
Rhinovirus infection	1	1 (12.50)	0	0 (0.00)
Staphylococcal abscess	1	1 (12.50)	1	1 (12.50)
Upper respiratory tract infection	1	1 (12.50)	0	0 (0.00)
Urinary tract infection	1	1 (12.50)	0	0 (0.00)
Varicella zoster virus infection	1	1 (12.50)	0	0 (0.00)
Investigations				
- Total	11	2 (25.00)	5	1 (12.50)

Timing: >1 year post-CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Neutrophil count decreased	7	2 (25.00)	5	1 (12.50)
Blood bilirubin increased	3	1 (12.50)	0	0 (0.00)
Platelet count decreased	1	1 (12.50)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	1 (12.50)	0	0 (0.00)
Iron overload	2	1 (12.50)	0	0 (0.00)
Hypercholesterolaemia	1	1 (12.50)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (12.50)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	1 (12.50)	0	0 (0.00)
Joint effusion	1	1 (12.50)	0	0 (0.00)
Synovitis	1	1 (12.50)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Anxiety	1	1 (12.50)	0	0 (0.00)
Reproductive system and breast disorders				

Timing: >1 year post-CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
- Total	2	1 (12.50)	1	1 (12.50)
Endometriosis	2	1 (12.50)	1	1 (12.50)
Respiratory, thoracic and mediastinal disorders				
- Total	4	1 (12.50)	1	1 (12.50)
Cough	1	1 (12.50)	0	0 (0.00)
Dyspnoea	1	1 (12.50)	0	0 (0.00)
Laryngeal oedema	1	1 (12.50)	1	1 (12.50)
Rhinorrhoea	1	1 (12.50)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Hypertension	1	1 (12.50)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	1101	33 (100.00)	382	29 (87.88)
Blood and lymphatic system disorders				
- Total	87	23 (69.70)	51	17 (51.52)
Anaemia	42	14 (42.42)	19	7 (21.21)
Febrile neutropenia	17	13 (39.39)	17	13 (39.39)
Thrombocytopenia	7	5 (15.15)	6	5 (15.15)
Disseminated intravascular coagulation	4	4 (12.12)	1	1 (3.03)
Eosinophilia	3	1 (3.03)	0	0 (0.00)
Neutropenia	3	3 (9.09)	2	2 (6.06)
Lymphadenopathy	2	2 (6.06)	0	0 (0.00)
Lymphopenia	2	2 (6.06)	2	2 (6.06)
Agranulocytosis	1	1 (3.03)	1	1 (3.03)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Coagulopathy	1	1 (3.03)	1	1 (3.03)
Hypercoagulation	1	1 (3.03)	0	0 (0.00)
Leukocytosis	1	1 (3.03)	0	0 (0.00)
Leukopenia	1	1 (3.03)	1	1 (3.03)
Pancytopenia	1	1 (3.03)	1	1 (3.03)
Splenomegaly	1	1 (3.03)	0	0 (0.00)
Cardiac disorders				
- Total	22	11 (33.33)	5	5 (15.15)
Tachycardia	14	9 (27.27)	2	2 (6.06)
Left ventricular dysfunction	2	2 (6.06)	2	2 (6.06)
Cardiac arrest	1	1 (3.03)	1	1 (3.03)
Cardiac dysfunction	1	1 (3.03)	0	0 (0.00)
Cardiac failure congestive	1	1 (3.03)	0	0 (0.00)
Mitral valve incompetence	1	1 (3.03)	0	0 (0.00)
Right ventricular dysfunction	1	1 (3.03)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Ear pain	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (6.06)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.03)	0	0 (0.00)
Hypothyroidism	1	1 (3.03)	0	0 (0.00)
Eye disorders				
- Total	14	8 (24.24)	1	1 (3.03)
Eyelid oedema	4	3 (9.09)	0	0 (0.00)
Ocular hyperaemia	3	3 (9.09)	0	0 (0.00)
Eye pain	2	2 (6.06)	1	1 (3.03)
Cataract	1	1 (3.03)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.03)	0	0 (0.00)
Hypermetropia	1	1 (3.03)	0	0 (0.00)
Mydriasis	1	1 (3.03)	0	0 (0.00)
Visual impairment	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	102	27 (81.82)	11	9 (27.27)
Vomiting	27	16 (48.48)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Diarrhoea	16	14 (42.42)	2	2 (6.06)
Nausea	16	13 (39.39)	1	1 (3.03)
Abdominal pain	9	6 (18.18)	2	2 (6.06)
Constipation	9	7 (21.21)	0	0 (0.00)
Abdominal distension	3	3 (9.09)	0	0 (0.00)
Ascites	3	3 (9.09)	0	0 (0.00)
Abdominal pain upper	2	2 (6.06)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (6.06)	0	0 (0.00)
Mouth haemorrhage	2	2 (6.06)	1	1 (3.03)
Pancreatitis	2	2 (6.06)	1	1 (3.03)
Abdominal compartment syndrome	1	1 (3.03)	1	1 (3.03)
Anal fissure	1	1 (3.03)	0	0 (0.00)
Anal haemorrhage	1	1 (3.03)	0	0 (0.00)
Dyspepsia	1	1 (3.03)	0	0 (0.00)
Haematemesis	1	1 (3.03)	0	0 (0.00)
Lip oedema	1	1 (3.03)	0	0 (0.00)
Melaena	1	1 (3.03)	1	1 (3.03)
Neutropenic colitis	1	1 (3.03)	1	1 (3.03)
Proctalgia	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Stomatitis	1	1 (3.03)	1	1 (3.03)
Upper gastrointestinal haemorrhage	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	61	20 (60.61)	10	5 (15.15)
Pyrexia	30	13 (39.39)	4	3 (9.09)
Fatigue	12	11 (33.33)	0	0 (0.00)
Chills	3	3 (9.09)	0	0 (0.00)
Face oedema	3	3 (9.09)	0	0 (0.00)
Generalised oedema	3	3 (9.09)	0	0 (0.00)
Catheter site erythema	2	1 (3.03)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (6.06)	2	2 (6.06)
Pain	2	2 (6.06)	2	2 (6.06)
Asthenia	1	1 (3.03)	0	0 (0.00)
Chest discomfort	1	1 (3.03)	1	1 (3.03)
Influenza like illness	1	1 (3.03)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.03)	1	1 (3.03)
Hepatobiliary disorders				

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	11	8 (24.24)	2	2 (6.06)
Cholelithiasis	2	2 (6.06)	0	0 (0.00)
Hepatic function abnormal	2	1 (3.03)	1	1 (3.03)
Hyperbilirubinaemia	2	2 (6.06)	0	0 (0.00)
Cholestasis	1	1 (3.03)	1	1 (3.03)
Gallbladder enlargement	1	1 (3.03)	0	0 (0.00)
Hepatomegaly	1	1 (3.03)	0	0 (0.00)
Liver disorder	1	1 (3.03)	0	0 (0.00)
Ocular icterus	1	1 (3.03)	0	0 (0.00)
Immune system disorders				
- Total	64	29 (87.88)	22	16 (48.48)
Cytokine release syndrome	39	24 (72.73)	14	11 (33.33)
Hypogammaglobulinaemia	15	13 (39.39)	2	2 (6.06)
Haemophagocytic lymphohistiocytosis	3	3 (9.09)	2	2 (6.06)
Chronic graft versus host disease	2	2 (6.06)	1	1 (3.03)
Immunodeficiency	2	2 (6.06)	2	2 (6.06)
Allergy to immunoglobulin therapy	1	1 (3.03)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Graft versus host disease	1	1 (3.03)	1	1 (3.03)
Infections and infestations				
- Total	99	25 (75.76)	39	14 (42.42)
Conjunctivitis	8	5 (15.15)	0	0 (0.00)
Upper respiratory tract infection	6	6 (18.18)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (3.03)	3	1 (3.03)
Nasopharyngitis	4	3 (9.09)	0	0 (0.00)
Gastroenteritis	3	3 (9.09)	1	1 (3.03)
Klebsiella infection	3	1 (3.03)	3	1 (3.03)
Oral herpes	3	2 (6.06)	1	1 (3.03)
Otitis media	3	3 (9.09)	1	1 (3.03)
Parainfluenzae virus infection	3	2 (6.06)	2	2 (6.06)
Pneumonia	3	3 (9.09)	2	2 (6.06)
Rhinovirus infection	3	3 (9.09)	1	1 (3.03)
Candida infection	2	2 (6.06)	0	0 (0.00)
Clostridium difficile infection	2	2 (6.06)	1	1 (3.03)
Ear infection	2	1 (3.03)	0	0 (0.00)
Fungal infection	2	1 (3.03)	0	0 (0.00)
Metapneumovirus infection	2	2 (6.06)	2	2 (6.06)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Oral infection	2	2 (6.06)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (6.06)	2	2 (6.06)
Staphylococcal bacteraemia	2	2 (6.06)	2	2 (6.06)
Staphylococcal infection	2	2 (6.06)	1	1 (3.03)
Viral infection	2	2 (6.06)	1	1 (3.03)
BK virus infection	1	1 (3.03)	0	0 (0.00)
Bronchitis	1	1 (3.03)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.03)	1	1 (3.03)
Cellulitis	1	1 (3.03)	0	0 (0.00)
Cystitis	1	1 (3.03)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (3.03)	1	1 (3.03)
Device related infection	1	1 (3.03)	1	1 (3.03)
Encephalitis	1	1 (3.03)	1	1 (3.03)
Enterobacter infection	1	1 (3.03)	1	1 (3.03)
Enterovirus infection	1	1 (3.03)	1	1 (3.03)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Herpes virus infection	1	1 (3.03)	0	0 (0.00)
Herpes zoster	1	1 (3.03)	1	1 (3.03)
Human herpesvirus 6 infection	1	1 (3.03)	1	1 (3.03)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Influenza	1	1 (3.03)	1	1 (3.03)
Localised infection	1	1 (3.03)	0	0 (0.00)
Mastoiditis	1	1 (3.03)	1	1 (3.03)
Nail infection	1	1 (3.03)	0	0 (0.00)
Neutropenic infection	1	1 (3.03)	1	1 (3.03)
Ophthalmic herpes zoster	1	1 (3.03)	0	0 (0.00)
Oral candidiasis	1	1 (3.03)	0	0 (0.00)
Otitis externa	1	1 (3.03)	1	1 (3.03)
Otitis media acute	1	1 (3.03)	0	0 (0.00)
Pneumonia viral	1	1 (3.03)	1	1 (3.03)
Respiratory syncytial virus infection	1	1 (3.03)	0	0 (0.00)
Respiratory tract infection viral	1	1 (3.03)	0	0 (0.00)
Rhinitis	1	1 (3.03)	0	0 (0.00)
Salmonellosis	1	1 (3.03)	0	0 (0.00)
Sepsis	1	1 (3.03)	1	1 (3.03)
Skin infection	1	1 (3.03)	0	0 (0.00)
Soft tissue infection	1	1 (3.03)	1	1 (3.03)
Staphylococcal sepsis	1	1 (3.03)	1	1 (3.03)
Staphylococcal skin infection	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Streptococcal sepsis	1	1 (3.03)	0	0 (0.00)
Viral skin infection	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	18	10 (30.30)	2	1 (3.03)
Infusion related reaction	5	2 (6.06)	0	0 (0.00)
Transfusion reaction	2	2 (6.06)	0	0 (0.00)
Wound	2	1 (3.03)	1	1 (3.03)
Abdominal injury	1	1 (3.03)	0	0 (0.00)
Contusion	1	1 (3.03)	0	0 (0.00)
Fall	1	1 (3.03)	0	0 (0.00)
Ligament sprain	1	1 (3.03)	0	0 (0.00)
Scratch	1	1 (3.03)	0	0 (0.00)
Skin abrasion	1	1 (3.03)	0	0 (0.00)
Skin injury	1	1 (3.03)	0	0 (0.00)
Skin wound	1	1 (3.03)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.03)	1	1 (3.03)
Investigations				
- Total	258	27 (81.82)	140	23 (69.70)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Platelet count decreased	62	14 (42.42)	38	9 (27.27)
White blood cell count decreased	45	17 (51.52)	29	13 (39.39)
Neutrophil count decreased	40	16 (48.48)	30	15 (45.45)
Lymphocyte count decreased	23	10 (30.30)	18	10 (30.30)
Alanine aminotransferase increased	14	9 (27.27)	2	2 (6.06)
Aspartate aminotransferase increased	14	8 (24.24)	6	4 (12.12)
Blood bilirubin increased	6	5 (15.15)	4	4 (12.12)
Blood immunoglobulin M decreased	6	6 (18.18)	1	1 (3.03)
Blood immunoglobulin A decreased	5	5 (15.15)	0	0 (0.00)
International normalised ratio increased	5	4 (12.12)	0	0 (0.00)
Activated partial thromboplastin time prolonged	4	3 (9.09)	0	0 (0.00)
Blood fibrinogen decreased	3	3 (9.09)	1	1 (3.03)
Blood lactate dehydrogenase increased	3	3 (9.09)	0	0 (0.00)
Blood uric acid increased	3	3 (9.09)	1	1 (3.03)
Lipase increased	3	1 (3.03)	2	1 (3.03)
Serum ferritin increased	3	3 (9.09)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Blood immunoglobulin G decreased	2	2 (6.06)	0	0 (0.00)
C-reactive protein increased	2	2 (6.06)	1	1 (3.03)
Fibrin D dimer increased	2	2 (6.06)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (6.06)	2	2 (6.06)
Oxygen saturation decreased	2	2 (6.06)	1	1 (3.03)
Weight increased	2	2 (6.06)	1	1 (3.03)
Blood creatine phosphokinase increased	1	1 (3.03)	1	1 (3.03)
Blood creatinine increased	1	1 (3.03)	1	1 (3.03)
Electrocardiogram QT prolonged	1	1 (3.03)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (3.03)	0	0 (0.00)
Immunoglobulins decreased	1	1 (3.03)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (3.03)	0	0 (0.00)
Urine output decreased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	117	21 (63.64)	40	12 (36.36)
Hypokalaemia	32	7 (21.21)	17	4 (12.12)
Hypophosphataemia	22	10 (30.30)	4	4 (12.12)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hypocalcaemia	13	7 (21.21)	3	2 (6.06)
Decreased appetite	11	11 (33.33)	5	5 (15.15)
Hypoalbuminaemia	10	4 (12.12)	0	0 (0.00)
Hyperglycaemia	4	4 (12.12)	4	4 (12.12)
Hyperuricaemia	3	2 (6.06)	0	0 (0.00)
Hyperkalaemia	2	2 (6.06)	1	1 (3.03)
Hypermagnesaemia	2	1 (3.03)	0	0 (0.00)
Hypernatraemia	2	2 (6.06)	1	1 (3.03)
Hyperphosphataemia	2	2 (6.06)	0	0 (0.00)
Metabolic acidosis	2	2 (6.06)	1	1 (3.03)
Dehydration	1	1 (3.03)	0	0 (0.00)
Haemosiderosis	1	1 (3.03)	0	0 (0.00)
Hypercalcaemia	1	1 (3.03)	1	1 (3.03)
Hyperlactacidaemia	1	1 (3.03)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.03)	1	1 (3.03)
Hypervolaemia	1	1 (3.03)	0	0 (0.00)
Hypomagnesaemia	1	1 (3.03)	0	0 (0.00)
Hyponatraemia	1	1 (3.03)	0	0 (0.00)
Hypophagia	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Iron overload	1	1 (3.03)	0	0 (0.00)
Malnutrition	1	1 (3.03)	1	1 (3.03)
Obesity	1	1 (3.03)	1	1 (3.03)
Musculoskeletal and connective tissue disorders				
- Total	34	19 (57.58)	4	4 (12.12)
Pain in extremity	13	12 (36.36)	1	1 (3.03)
Back pain	5	5 (15.15)	2	2 (6.06)
Arthralgia	4	4 (12.12)	0	0 (0.00)
Bone pain	4	2 (6.06)	0	0 (0.00)
Myalgia	3	3 (9.09)	0	0 (0.00)
Growth retardation	1	1 (3.03)	0	0 (0.00)
Muscular weakness	1	1 (3.03)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.03)	0	0 (0.00)
Myositis	1	1 (3.03)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.03)	1	1 (3.03)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	2 (6.06)	2	2 (6.06)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Bone giant cell tumour benign	2	1 (3.03)	1	1 (3.03)
Myelodysplastic syndrome	1	1 (3.03)	1	1 (3.03)
Nervous system disorders				
- Total	31	18 (54.55)	10	7 (21.21)
Headache	10	8 (24.24)	2	2 (6.06)
Encephalopathy	4	4 (12.12)	2	2 (6.06)
Hydrocephalus	3	1 (3.03)	3	1 (3.03)
Dizziness	2	1 (3.03)	0	0 (0.00)
Dysgeusia	2	2 (6.06)	0	0 (0.00)
Lethargy	2	2 (6.06)	0	0 (0.00)
Tremor	2	2 (6.06)	0	0 (0.00)
Cerebral haemorrhage	1	1 (3.03)	1	1 (3.03)
Depressed level of consciousness	1	1 (3.03)	1	1 (3.03)
Monoparesis	1	1 (3.03)	0	0 (0.00)
Neuralgia	1	1 (3.03)	0	0 (0.00)
Seizure	1	1 (3.03)	1	1 (3.03)
Somnolence	1	1 (3.03)	0	0 (0.00)
Psychiatric disorders				

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	27	16 (48.48)	1	1 (3.03)
Anxiety	5	5 (15.15)	0	0 (0.00)
Confusional state	4	4 (12.12)	0	0 (0.00)
Delirium	3	3 (9.09)	0	0 (0.00)
Insomnia	3	3 (9.09)	0	0 (0.00)
Agitation	2	2 (6.06)	0	0 (0.00)
Hallucination	2	2 (6.06)	0	0 (0.00)
Irritability	2	2 (6.06)	0	0 (0.00)
Mental status changes	1	1 (3.03)	1	1 (3.03)
Mood altered	1	1 (3.03)	0	0 (0.00)
Nightmare	1	1 (3.03)	0	0 (0.00)
Restlessness	1	1 (3.03)	0	0 (0.00)
Sleep disorder	1	1 (3.03)	0	0 (0.00)
Tearfulness	1	1 (3.03)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	9 (27.27)	4	3 (9.09)
Acute kidney injury	3	3 (9.09)	2	2 (6.06)
Dysuria	2	2 (6.06)	0	0 (0.00)
Haematuria	2	2 (6.06)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Anuria	1	1 (3.03)	1	1 (3.03)
Bladder dilatation	1	1 (3.03)	0	0 (0.00)
Incontinence	1	1 (3.03)	0	0 (0.00)
Proteinuria	1	1 (3.03)	0	0 (0.00)
Renal failure	1	1 (3.03)	0	0 (0.00)
Renal tubular dysfunction	1	1 (3.03)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.03)	1	1 (3.03)
Urinary retention	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.03)	1	1 (3.03)
Vaginal ulceration	1	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	72	23 (69.70)	24	10 (30.30)
Cough	16	11 (33.33)	0	0 (0.00)
Hypoxia	9	8 (24.24)	7	6 (18.18)
Tachypnoea	6	5 (15.15)	4	3 (9.09)
Rhinorrhoea	5	3 (9.09)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Epistaxis	4	3 (9.09)	1	1 (3.03)
Nasal congestion	4	4 (12.12)	0	0 (0.00)
Pulmonary oedema	4	4 (12.12)	3	3 (9.09)
Atelectasis	3	1 (3.03)	1	1 (3.03)
Dyspnoea	3	3 (9.09)	3	3 (9.09)
Pleural effusion	3	3 (9.09)	1	1 (3.03)
Lung infiltration	2	1 (3.03)	1	1 (3.03)
Oropharyngeal pain	2	1 (3.03)	0	0 (0.00)
Rhinitis allergic	2	2 (6.06)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (3.03)	1	1 (3.03)
Bronchospasm	1	1 (3.03)	0	0 (0.00)
Dyspnoea exertional	1	1 (3.03)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.03)	0	0 (0.00)
Productive cough	1	1 (3.03)	0	0 (0.00)
Respiratory acidosis	1	1 (3.03)	1	1 (3.03)
Respiratory distress	1	1 (3.03)	0	0 (0.00)
Respiratory failure	1	1 (3.03)	1	1 (3.03)
Sleep apnoea syndrome	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	43	17 (51.52)	3	2 (6.06)
Dry skin	4	3 (9.09)	0	0 (0.00)
Pruritus	4	3 (9.09)	0	0 (0.00)
Rash maculo-papular	4	3 (9.09)	1	1 (3.03)
Dermatitis atopic	3	2 (6.06)	0	0 (0.00)
Erythema	3	3 (9.09)	0	0 (0.00)
Rash	3	3 (9.09)	0	0 (0.00)
Blister	2	2 (6.06)	0	0 (0.00)
Rash papular	2	2 (6.06)	0	0 (0.00)
Rash vesicular	2	1 (3.03)	0	0 (0.00)
Decubitus ulcer	1	1 (3.03)	0	0 (0.00)
Dermatitis	1	1 (3.03)	0	0 (0.00)
Dermatitis allergic	1	1 (3.03)	0	0 (0.00)
Eczema	1	1 (3.03)	0	0 (0.00)
Miliaria	1	1 (3.03)	0	0 (0.00)
Night sweats	1	1 (3.03)	0	0 (0.00)
Petechiae	1	1 (3.03)	1	1 (3.03)

Timing: At anytime, Age: <10 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Photosensitivity reaction	1	1 (3.03)	0	0 (0.00)
Pruritus allergic	1	1 (3.03)	0	0 (0.00)
Purpura	1	1 (3.03)	0	0 (0.00)
Rash pruritic	1	1 (3.03)	0	0 (0.00)
Scab	1	1 (3.03)	0	0 (0.00)
Skin discolouration	1	1 (3.03)	0	0 (0.00)
Skin necrosis	1	1 (3.03)	1	1 (3.03)
Skin ulcer	1	1 (3.03)	0	0 (0.00)
Urticaria	1	1 (3.03)	0	0 (0.00)
Vascular disorders				
- Total	19	14 (42.42)	10	8 (24.24)
Hypotension	12	10 (30.30)	7	6 (18.18)
Hypertension	7	6 (18.18)	3	3 (9.09)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	964	33 (100.00)	314	31 (93.94)
Blood and lymphatic system disorders				
- Total	52	23 (69.70)	32	19 (57.58)
Febrile neutropenia	14	12 (36.36)	14	12 (36.36)
Anaemia	11	6 (18.18)	0	0 (0.00)
Neutropenia	9	5 (15.15)	9	5 (15.15)
Disseminated intravascular coagulation	4	4 (12.12)	2	2 (6.06)
Leukopenia	4	2 (6.06)	2	1 (3.03)
Splenomegaly	3	3 (9.09)	0	0 (0.00)
Thrombocytopenia	3	3 (9.09)	3	3 (9.09)
Coagulopathy	2	2 (6.06)	1	1 (3.03)
Lymphocytosis	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Pancytopenia	1	1 (3.03)	1	1 (3.03)
Cardiac disorders				
- Total	21	12 (36.36)	7	5 (15.15)
Tachycardia	8	6 (18.18)	1	1 (3.03)
Bradycardia	3	3 (9.09)	0	0 (0.00)
Cardiac arrest	2	2 (6.06)	2	2 (6.06)
Cardiac failure	2	2 (6.06)	2	2 (6.06)
Left ventricular dysfunction	2	2 (6.06)	1	1 (3.03)
Atrioventricular block first degree	1	1 (3.03)	0	0 (0.00)
Pericardial effusion	1	1 (3.03)	0	0 (0.00)
Sinus bradycardia	1	1 (3.03)	1	1 (3.03)
Sinus tachycardia	1	1 (3.03)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Ear pruritus	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	4	3 (9.09)	0	0 (0.00)
Hypothyroidism	2	2 (6.06)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Adrenal insufficiency	1	1 (3.03)	0	0 (0.00)
Delayed puberty	1	1 (3.03)	0	0 (0.00)
Eye disorders				
- Total	8	5 (15.15)	0	0 (0.00)
Retinal haemorrhage	2	1 (3.03)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.03)	0	0 (0.00)
Dry eye	1	1 (3.03)	0	0 (0.00)
Eye oedema	1	1 (3.03)	0	0 (0.00)
Periorbital oedema	1	1 (3.03)	0	0 (0.00)
Visual field defect	1	1 (3.03)	0	0 (0.00)
Visual impairment	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	46	20 (60.61)	5	5 (15.15)
Diarrhoea	11	9 (27.27)	0	0 (0.00)
Nausea	6	5 (15.15)	1	1 (3.03)
Vomiting	6	5 (15.15)	1	1 (3.03)
Abdominal pain	3	3 (9.09)	0	0 (0.00)
Constipation	3	3 (9.09)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Pancreatitis	3	3 (9.09)	1	1 (3.03)
Abdominal pain upper	1	1 (3.03)	0	0 (0.00)
Abdominal rigidity	1	1 (3.03)	0	0 (0.00)
Dysphagia	1	1 (3.03)	1	1 (3.03)
Enterocolitis	1	1 (3.03)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (3.03)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.03)	0	0 (0.00)
Gingival erythema	1	1 (3.03)	0	0 (0.00)
Irritable bowel syndrome	1	1 (3.03)	0	0 (0.00)
Mouth haemorrhage	1	1 (3.03)	0	0 (0.00)
Mouth swelling	1	1 (3.03)	0	0 (0.00)
Odynophagia	1	1 (3.03)	0	0 (0.00)
Peritoneal haematoma	1	1 (3.03)	0	0 (0.00)
Proctalgia	1	1 (3.03)	1	1 (3.03)
Trichoglossia	1	1 (3.03)	0	0 (0.00)
General disorders and administration site conditions				
- Total	54	22 (66.67)	9	7 (21.21)
Pyrexia	22	15 (45.45)	6	6 (18.18)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Oedema peripheral	7	5 (15.15)	2	1 (3.03)
Fatigue	6	5 (15.15)	0	0 (0.00)
Face oedema	5	4 (12.12)	1	1 (3.03)
Chills	2	2 (6.06)	0	0 (0.00)
Generalised oedema	2	2 (6.06)	0	0 (0.00)
Localised oedema	2	2 (6.06)	0	0 (0.00)
Asthenia	1	1 (3.03)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.03)	0	0 (0.00)
Catheter site pain	1	1 (3.03)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (3.03)	0	0 (0.00)
Malaise	1	1 (3.03)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (3.03)	0	0 (0.00)
Pain	1	1 (3.03)	0	0 (0.00)
Xerosis	1	1 (3.03)	0	0 (0.00)
Hepatobiliary disorders				
- Total	15	7 (21.21)	4	3 (9.09)
Hepatic function abnormal	7	2 (6.06)	3	2 (6.06)
Hyperbilirubinaemia	3	2 (6.06)	0	0 (0.00)
Hepatomegaly	2	2 (6.06)	1	1 (3.03)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hypertransaminasaemia	2	1 (3.03)	0	0 (0.00)
Hepatic cytolysis	1	1 (3.03)	0	0 (0.00)
Immune system disorders				
- Total	93	29 (87.88)	40	21 (63.64)
Cytokine release syndrome	61	25 (75.76)	30	19 (57.58)
Hypogammaglobulinaemia	20	15 (45.45)	5	5 (15.15)
Seasonal allergy	4	4 (12.12)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	2	2 (6.06)	1	1 (3.03)
Drug hypersensitivity	1	1 (3.03)	1	1 (3.03)
Engraftment syndrome	1	1 (3.03)	1	1 (3.03)
Graft versus host disease	1	1 (3.03)	1	1 (3.03)
Hypersensitivity	1	1 (3.03)	0	0 (0.00)
Immunodeficiency	1	1 (3.03)	1	1 (3.03)
Selective IgG subclass deficiency	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	107	22 (66.67)	36	17 (51.52)
Sinusitis	11	4 (12.12)	1	1 (3.03)
Upper respiratory tract infection	8	5 (15.15)	2	2 (6.06)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Rhinovirus infection	4	4 (12.12)	0	0 (0.00)
COVID-19	3	2 (6.06)	1	1 (3.03)
Conjunctivitis	3	2 (6.06)	0	0 (0.00)
Gastroenteritis viral	3	2 (6.06)	0	0 (0.00)
Nasopharyngitis	3	2 (6.06)	0	0 (0.00)
Otitis media	3	2 (6.06)	0	0 (0.00)
Bacteraemia	2	2 (6.06)	1	1 (3.03)
Device related sepsis	2	1 (3.03)	2	1 (3.03)
Ear infection	2	2 (6.06)	1	1 (3.03)
Gastroenteritis	2	2 (6.06)	0	0 (0.00)
Herpes zoster	2	2 (6.06)	1	1 (3.03)
Nail infection	2	2 (6.06)	0	0 (0.00)
Otitis externa	2	2 (6.06)	0	0 (0.00)
Paronychia	2	2 (6.06)	0	0 (0.00)
Pneumonia	2	2 (6.06)	1	1 (3.03)
Respiratory tract infection	2	2 (6.06)	0	0 (0.00)
Rhinitis	2	2 (6.06)	0	0 (0.00)
Sepsis	2	2 (6.06)	2	2 (6.06)
Septic shock	2	2 (6.06)	2	2 (6.06)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Skin infection	2	2 (6.06)	0	0 (0.00)
Staphylococcal bacteraemia	2	2 (6.06)	2	2 (6.06)
Adenovirus infection	1	1 (3.03)	1	1 (3.03)
Anal abscess	1	1 (3.03)	1	1 (3.03)
BK virus infection	1	1 (3.03)	1	1 (3.03)
Bronchiolitis	1	1 (3.03)	1	1 (3.03)
Bronchitis	1	1 (3.03)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (3.03)	1	1 (3.03)
Cholecystitis infective	1	1 (3.03)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.03)	1	1 (3.03)
Clostridium difficile infection	1	1 (3.03)	1	1 (3.03)
Coronavirus infection	1	1 (3.03)	1	1 (3.03)
Encephalitis	1	1 (3.03)	1	1 (3.03)
Encephalitis viral	1	1 (3.03)	1	1 (3.03)
Folliculitis	1	1 (3.03)	0	0 (0.00)
Fungal infection	1	1 (3.03)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (3.03)	1	1 (3.03)
Gastroenteritis clostridial	1	1 (3.03)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Gastroenteritis salmonella	1	1 (3.03)	1	1 (3.03)
Gastrointestinal infection	1	1 (3.03)	0	0 (0.00)
Gingivitis	1	1 (3.03)	0	0 (0.00)
Herpes simplex	1	1 (3.03)	0	0 (0.00)
Influenza	1	1 (3.03)	0	0 (0.00)
Meningitis bacterial	1	1 (3.03)	1	1 (3.03)
Meningitis pneumococcal	1	1 (3.03)	1	1 (3.03)
Metapneumovirus infection	1	1 (3.03)	1	1 (3.03)
Molluscum contagiosum	1	1 (3.03)	0	0 (0.00)
Oral candidiasis	1	1 (3.03)	0	0 (0.00)
Oral herpes	1	1 (3.03)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.03)	0	0 (0.00)
Pneumonia fungal	1	1 (3.03)	1	1 (3.03)
Pneumonia respiratory syncytial viral	1	1 (3.03)	1	1 (3.03)
Respiratory syncytial virus infection	1	1 (3.03)	1	1 (3.03)
Sinusitis fungal	1	1 (3.03)	1	1 (3.03)
Staphylococcal infection	1	1 (3.03)	0	0 (0.00)
Syphilis	1	1 (3.03)	0	0 (0.00)
Tinea pedis	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Urinary tract infection	1	1 (3.03)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (3.03)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (3.03)	1	1 (3.03)
Injury, poisoning and procedural complications				
- Total	12	9 (27.27)	1	1 (3.03)
Infusion related reaction	3	3 (9.09)	1	1 (3.03)
Contusion	2	1 (3.03)	0	0 (0.00)
Procedural pain	2	2 (6.06)	0	0 (0.00)
Fibula fracture	1	1 (3.03)	0	0 (0.00)
Ligament sprain	1	1 (3.03)	0	0 (0.00)
Limb injury	1	1 (3.03)	0	0 (0.00)
Skin abrasion	1	1 (3.03)	0	0 (0.00)
Wound	1	1 (3.03)	0	0 (0.00)
Investigations				
- Total	195	24 (72.73)	80	19 (57.58)
Neutrophil count decreased	27	6 (18.18)	18	5 (15.15)
White blood cell count decreased	20	7 (21.21)	8	4 (12.12)
Platelet count decreased	17	7 (21.21)	7	4 (12.12)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Aspartate aminotransferase increased	14	7 (21.21)	4	4 (12.12)
Blood bilirubin increased	13	6 (18.18)	5	4 (12.12)
Lymphocyte count decreased	12	6 (18.18)	8	5 (15.15)
Alanine aminotransferase increased	11	7 (21.21)	4	4 (12.12)
Immunoglobulins decreased	9	1 (3.03)	0	0 (0.00)
Blood creatinine increased	6	4 (12.12)	4	2 (6.06)
Electrocardiogram QT prolonged	5	4 (12.12)	2	2 (6.06)
International normalised ratio increased	5	3 (9.09)	0	0 (0.00)
Serum ferritin increased	5	5 (15.15)	2	2 (6.06)
Weight increased	5	2 (6.06)	1	1 (3.03)
Activated partial thromboplastin time prolonged	4	3 (9.09)	1	1 (3.03)
Blood fibrinogen decreased	4	4 (12.12)	1	1 (3.03)
Blood creatine phosphokinase increased	3	1 (3.03)	1	1 (3.03)
C-reactive protein increased	3	3 (9.09)	2	2 (6.06)
Blood lactate dehydrogenase increased	2	2 (6.06)	1	1 (3.03)
Haemoglobin decreased	2	1 (3.03)	1	1 (3.03)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Urine output decreased	2	1 (3.03)	2	1 (3.03)
Weight decreased	2	2 (6.06)	1	1 (3.03)
Amylase increased	1	1 (3.03)	0	0 (0.00)
Bacterial test positive	1	1 (3.03)	1	1 (3.03)
Blood alkaline phosphatase increased	1	1 (3.03)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.03)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.03)	1	1 (3.03)
Blood immunoglobulin G decreased	1	1 (3.03)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (3.03)	1	1 (3.03)
Blood phosphorus increased	1	1 (3.03)	0	0 (0.00)
Blood testosterone decreased	1	1 (3.03)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (3.03)	0	0 (0.00)
Blood urea increased	1	1 (3.03)	1	1 (3.03)
Blood uric acid increased	1	1 (3.03)	1	1 (3.03)
Bone density decreased	1	1 (3.03)	0	0 (0.00)
Cardiac murmur	1	1 (3.03)	0	0 (0.00)
Coagulation test abnormal	1	1 (3.03)	0	0 (0.00)
Ejection fraction decreased	1	1 (3.03)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Electrocardiogram T wave abnormal	1	1 (3.03)	0	0 (0.00)
Enterovirus test positive	1	1 (3.03)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.03)	1	1 (3.03)
Haptoglobin decreased	1	1 (3.03)	0	0 (0.00)
Lipase increased	1	1 (3.03)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.03)	0	0 (0.00)
Prothrombin time prolonged	1	1 (3.03)	0	0 (0.00)
Troponin increased	1	1 (3.03)	1	1 (3.03)
Metabolism and nutrition disorders				
- Total	89	23 (69.70)	33	15 (45.45)
Decreased appetite	16	14 (42.42)	7	5 (15.15)
Hyperuricaemia	8	6 (18.18)	1	1 (3.03)
Hypocalcaemia	8	6 (18.18)	1	1 (3.03)
Hypokalaemia	8	7 (21.21)	5	5 (15.15)
Hypoalbuminaemia	7	5 (15.15)	0	0 (0.00)
Hypophosphataemia	6	6 (18.18)	3	3 (9.09)
Hyperglycaemia	4	2 (6.06)	1	1 (3.03)
Tumour lysis syndrome	4	4 (12.12)	4	4 (12.12)
Hypercalcaemia	3	2 (6.06)	1	1 (3.03)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Hyperphosphataemia	3	3 (9.09)	1	1 (3.03)
Hypervolaemia	3	3 (9.09)	2	2 (6.06)
Hypomagnesaemia	3	3 (9.09)	0	0 (0.00)
Acidosis	2	1 (3.03)	1	1 (3.03)
Hyperchloraemia	2	2 (6.06)	0	0 (0.00)
Hyponatraemia	2	2 (6.06)	0	0 (0.00)
Metabolic acidosis	2	2 (6.06)	2	2 (6.06)
Calcium deficiency	1	1 (3.03)	0	0 (0.00)
Haemochromatosis	1	1 (3.03)	1	1 (3.03)
Hyperkalaemia	1	1 (3.03)	1	1 (3.03)
Hyperlipidaemia	1	1 (3.03)	0	0 (0.00)
Hypermagnesaemia	1	1 (3.03)	0	0 (0.00)
Hypernatraemia	1	1 (3.03)	1	1 (3.03)
Hypertriglyceridaemia	1	1 (3.03)	1	1 (3.03)
Metabolic syndrome	1	1 (3.03)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	29	18 (54.55)	4	3 (9.09)
Arthralgia	6	5 (15.15)	1	1 (3.03)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Back pain	5	4 (12.12)	1	1 (3.03)
Myalgia	5	5 (15.15)	0	0 (0.00)
Pain in extremity	4	4 (12.12)	0	0 (0.00)
Bone pain	1	1 (3.03)	0	0 (0.00)
Growth retardation	1	1 (3.03)	0	0 (0.00)
Haemarthrosis	1	1 (3.03)	1	1 (3.03)
Muscle rigidity	1	1 (3.03)	0	0 (0.00)
Muscular weakness	1	1 (3.03)	1	1 (3.03)
Musculoskeletal pain	1	1 (3.03)	0	0 (0.00)
Osteonecrosis	1	1 (3.03)	0	0 (0.00)
Osteopenia	1	1 (3.03)	0	0 (0.00)
Pain in jaw	1	1 (3.03)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (9.09)	0	0 (0.00)
Skin papilloma	2	2 (6.06)	0	0 (0.00)
Cancer pain	1	1 (3.03)	0	0 (0.00)
Nervous system disorders				
- Total	48	22 (66.67)	9	5 (15.15)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Headache	22	15 (45.45)	1	1 (3.03)
Seizure	6	3 (9.09)	2	2 (6.06)
Encephalopathy	3	3 (9.09)	1	1 (3.03)
Cognitive disorder	2	2 (6.06)	0	0 (0.00)
Dizziness	2	2 (6.06)	0	0 (0.00)
Dysarthria	2	2 (6.06)	1	1 (3.03)
Nervous system disorder	2	1 (3.03)	1	1 (3.03)
Somnolence	2	2 (6.06)	1	1 (3.03)
Tremor	2	2 (6.06)	0	0 (0.00)
Autonomic neuropathy	1	1 (3.03)	1	1 (3.03)
Cerebral haemorrhage	1	1 (3.03)	1	1 (3.03)
Generalised tonic-clonic seizure	1	1 (3.03)	0	0 (0.00)
Hypoaesthesia	1	1 (3.03)	0	0 (0.00)
Memory impairment	1	1 (3.03)	0	0 (0.00)
Psychiatric disorders				
- Total	24	16 (48.48)	4	4 (12.12)
Anxiety	5	5 (15.15)	2	2 (6.06)
Agitation	3	2 (6.06)	0	0 (0.00)
Confusional state	3	3 (9.09)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Delirium	3	3 (9.09)	1	1 (3.03)
Mental status changes	3	3 (9.09)	1	1 (3.03)
Sleep disorder	3	2 (6.06)	0	0 (0.00)
Automatism	1	1 (3.03)	0	0 (0.00)
Insomnia	1	1 (3.03)	0	0 (0.00)
Persistent depressive disorder	1	1 (3.03)	0	0 (0.00)
Tic	1	1 (3.03)	0	0 (0.00)
Renal and urinary disorders				
- Total	23	11 (33.33)	8	7 (21.21)
Acute kidney injury	12	7 (21.21)	6	5 (15.15)
Dysuria	2	2 (6.06)	0	0 (0.00)
Anuria	1	1 (3.03)	0	0 (0.00)
Azotaemia	1	1 (3.03)	0	0 (0.00)
Haematuria	1	1 (3.03)	1	1 (3.03)
Kidney enlargement	1	1 (3.03)	0	0 (0.00)
Micturition urgency	1	1 (3.03)	0	0 (0.00)
Pollakiuria	1	1 (3.03)	0	0 (0.00)
Renal mass	1	1 (3.03)	0	0 (0.00)
Renal tubular disorder	1	1 (3.03)	1	1 (3.03)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Urinary tract disorder	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	3	1 (3.03)	0	0 (0.00)
Dysmenorrhoea	2	1 (3.03)	0	0 (0.00)
Perineal rash	1	1 (3.03)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	78	21 (63.64)	25	13 (39.39)
Hypoxia	14	9 (27.27)	11	7 (21.21)
Cough	12	11 (33.33)	0	0 (0.00)
Pleural effusion	6	5 (15.15)	2	2 (6.06)
Nasal congestion	5	4 (12.12)	0	0 (0.00)
Oropharyngeal pain	5	5 (15.15)	0	0 (0.00)
Pulmonary oedema	4	4 (12.12)	1	1 (3.03)
Tachypnoea	4	3 (9.09)	2	2 (6.06)
Dyspnoea	3	2 (6.06)	0	0 (0.00)
Epistaxis	3	3 (9.09)	0	0 (0.00)
Respiratory failure	3	3 (9.09)	3	3 (9.09)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Acute respiratory distress syndrome	2	2 (6.06)	2	2 (6.06)
Respiratory distress	2	2 (6.06)	1	1 (3.03)
Rhinorrhoea	2	2 (6.06)	0	0 (0.00)
Wheezing	2	2 (6.06)	0	0 (0.00)
Acute respiratory failure	1	1 (3.03)	1	1 (3.03)
Atelectasis	1	1 (3.03)	1	1 (3.03)
Bradypnoea	1	1 (3.03)	1	1 (3.03)
Haemoptysis	1	1 (3.03)	0	0 (0.00)
Lung disorder	1	1 (3.03)	0	0 (0.00)
Nasal discomfort	1	1 (3.03)	0	0 (0.00)
Painful respiration	1	1 (3.03)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (3.03)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (3.03)	0	0 (0.00)
Respiratory disorder	1	1 (3.03)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	37	14 (42.42)	5	4 (12.12)
Rash	10	5 (15.15)	0	0 (0.00)

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Blister	4	1 (3.03)	0	0 (0.00)
Dry skin	4	4 (12.12)	0	0 (0.00)
Eczema	2	2 (6.06)	1	1 (3.03)
Ingrowing nail	2	2 (6.06)	0	0 (0.00)
Rash macular	2	1 (3.03)	2	1 (3.03)
Dermatitis atopic	1	1 (3.03)	1	1 (3.03)
Dermatitis diaper	1	1 (3.03)	0	0 (0.00)
Erythema	1	1 (3.03)	0	0 (0.00)
Hyperhidrosis	1	1 (3.03)	0	0 (0.00)
Papule	1	1 (3.03)	0	0 (0.00)
Petechiae	1	1 (3.03)	0	0 (0.00)
Pruritus	1	1 (3.03)	0	0 (0.00)
Rash erythematous	1	1 (3.03)	0	0 (0.00)
Skin discolouration	1	1 (3.03)	0	0 (0.00)
Skin hypopigmentation	1	1 (3.03)	0	0 (0.00)
Skin swelling	1	1 (3.03)	0	0 (0.00)
Skin ulcer	1	1 (3.03)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (3.03)	1	1 (3.03)
Vascular disorders				

Timing: At anytime, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
- Total	22	13 (39.39)	12	9 (27.27)
Hypotension	13	10 (30.30)	9	7 (21.21)
Hypertension	5	5 (15.15)	1	1 (3.03)
Capillary leak syndrome	2	2 (6.06)	1	1 (3.03)
Thrombosis	1	1 (3.03)	0	0 (0.00)
Venoocclusive disease	1	1 (3.03)	1	1 (3.03)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250a
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Age
Safety Set

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	440	14 (100.00)	132	13 (92.86)
Blood and lymphatic system disorders				
- Total	24	9 (64.29)	12	7 (50.00)
Anaemia	10	5 (35.71)	5	2 (14.29)
Neutropenia	5	3 (21.43)	4	2 (14.29)
B-cell aplasia	3	1 (7.14)	0	0 (0.00)
Coagulopathy	2	2 (14.29)	0	0 (0.00)
Febrile neutropenia	2	2 (14.29)	2	2 (14.29)
Hypofibrinogenaemia	1	1 (7.14)	0	0 (0.00)
Thrombocytopenia	1	1 (7.14)	1	1 (7.14)
Cardiac disorders				
- Total	10	5 (35.71)	2	1 (7.14)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Cardiac failure	4	1 (7.14)	2	1 (7.14)
Sinus tachycardia	3	2 (14.29)	0	0 (0.00)
Tachycardia	2	2 (14.29)	0	0 (0.00)
Cardiac dysfunction	1	1 (7.14)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (7.14)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (7.14)	0	0 (0.00)
Deafness unilateral	1	1 (7.14)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (14.29)	0	0 (0.00)
Adrenal insufficiency	2	2 (14.29)	0	0 (0.00)
Eye disorders				
- Total	2	2 (14.29)	0	0 (0.00)
Cataract	1	1 (7.14)	0	0 (0.00)
Periorbital swelling	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Gastrointestinal disorders				
- Total	34	13 (92.86)	2	2 (14.29)
Nausea	5	4 (28.57)	0	0 (0.00)
Vomiting	5	5 (35.71)	0	0 (0.00)
Constipation	4	4 (28.57)	0	0 (0.00)
Abdominal pain	3	2 (14.29)	0	0 (0.00)
Diarrhoea	3	3 (21.43)	0	0 (0.00)
Mouth haemorrhage	2	2 (14.29)	1	1 (7.14)
Stomatitis	2	2 (14.29)	0	0 (0.00)
Abdominal pain upper	1	1 (7.14)	0	0 (0.00)
Dry mouth	1	1 (7.14)	0	0 (0.00)
Enteritis	1	1 (7.14)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (7.14)	0	0 (0.00)
Gingival bleeding	1	1 (7.14)	0	0 (0.00)
Gingivitis ulcerative	1	1 (7.14)	1	1 (7.14)
Ileus	1	1 (7.14)	0	0 (0.00)
Lip dry	1	1 (7.14)	0	0 (0.00)
Pancreatitis	1	1 (7.14)	0	0 (0.00)
Trichoglossia	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
General disorders and administration site conditions				
- Total	41	11 (78.57)	5	3 (21.43)
Pyrexia	15	7 (50.00)	2	2 (14.29)
Chills	5	2 (14.29)	0	0 (0.00)
Catheter site pain	3	1 (7.14)	2	1 (7.14)
Non-cardiac chest pain	2	2 (14.29)	0	0 (0.00)
Oedema peripheral	2	2 (14.29)	0	0 (0.00)
Pain	2	2 (14.29)	0	0 (0.00)
Asthenia	1	1 (7.14)	0	0 (0.00)
Crying	1	1 (7.14)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (7.14)	0	0 (0.00)
Face oedema	1	1 (7.14)	0	0 (0.00)
Facial pain	1	1 (7.14)	0	0 (0.00)
Fatigue	1	1 (7.14)	0	0 (0.00)
Influenza like illness	1	1 (7.14)	0	0 (0.00)
Malaise	1	1 (7.14)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (7.14)	1	1 (7.14)
Sluggishness	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Swelling face	1	1 (7.14)	0	0 (0.00)
Vascular device occlusion	1	1 (7.14)	0	0 (0.00)
Hepatobiliary disorders				
- Total	6	4 (28.57)	1	1 (7.14)
Hepatic function abnormal	2	2 (14.29)	0	0 (0.00)
Biliary tract disorder	1	1 (7.14)	0	0 (0.00)
Gallbladder enlargement	1	1 (7.14)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (7.14)	1	1 (7.14)
Hypertransaminasaemia	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	36	13 (92.86)	14	9 (64.29)
Cytokine release syndrome	28	12 (85.71)	11	8 (57.14)
Hypogammaglobulinaemia	5	5 (35.71)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (7.14)	1	1 (7.14)
Haemophagocytic lymphohistiocytosis	1	1 (7.14)	1	1 (7.14)
Immunodeficiency	1	1 (7.14)	1	1 (7.14)
Infections and infestations				

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	57	13 (92.86)	27	8 (57.14)
Rhinovirus infection	4	2 (14.29)	1	1 (7.14)
Candida infection	3	2 (14.29)	2	1 (7.14)
Sinusitis	3	3 (21.43)	1	1 (7.14)
Upper respiratory tract infection	3	2 (14.29)	1	1 (7.14)
Urinary tract infection	3	2 (14.29)	2	1 (7.14)
Acute sinusitis	2	2 (14.29)	0	0 (0.00)
Bacteraemia	2	1 (7.14)	2	1 (7.14)
Nasopharyngitis	2	2 (14.29)	0	0 (0.00)
Oral candidiasis	2	1 (7.14)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (14.29)	1	1 (7.14)
Staphylococcal bacteraemia	2	1 (7.14)	2	1 (7.14)
Staphylococcal infection	2	2 (14.29)	1	1 (7.14)
Varicella zoster virus infection	2	2 (14.29)	1	1 (7.14)
Adenovirus infection	1	1 (7.14)	1	1 (7.14)
Atypical pneumonia	1	1 (7.14)	0	0 (0.00)
Clostridium difficile infection	1	1 (7.14)	1	1 (7.14)
Conjunctivitis	1	1 (7.14)	0	0 (0.00)
Ear, nose and throat infection	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Encephalitis viral	1	1 (7.14)	1	1 (7.14)
Fungal skin infection	1	1 (7.14)	0	0 (0.00)
Gastroenteritis	1	1 (7.14)	1	1 (7.14)
Granulicatella infection	1	1 (7.14)	1	1 (7.14)
Herpes simplex	1	1 (7.14)	1	1 (7.14)
Human herpesvirus 6 infection	1	1 (7.14)	1	1 (7.14)
Influenza	1	1 (7.14)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (7.14)	0	0 (0.00)
Myringitis	1	1 (7.14)	0	0 (0.00)
Nail infection	1	1 (7.14)	0	0 (0.00)
Oral herpes	1	1 (7.14)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (7.14)	1	1 (7.14)
Pneumonia	1	1 (7.14)	1	1 (7.14)
Respiratory syncytial virus infection	1	1 (7.14)	1	1 (7.14)
Respiratory tract infection	1	1 (7.14)	0	0 (0.00)
Staphylococcal abscess	1	1 (7.14)	1	1 (7.14)
Stomatococcal infection	1	1 (7.14)	0	0 (0.00)
Systemic candida	1	1 (7.14)	1	1 (7.14)
Urinary tract infection viral	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Viral upper respiratory tract infection	1	1 (7.14)	1	1 (7.14)
Injury, poisoning and procedural complications				
- Total	3	2 (14.29)	1	1 (7.14)
Fall	1	1 (7.14)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (7.14)	0	0 (0.00)
Transplant failure	1	1 (7.14)	1	1 (7.14)
Investigations				
- Total	40	9 (64.29)	18	6 (42.86)
Neutrophil count decreased	8	2 (14.29)	6	1 (7.14)
Blood bilirubin increased	6	2 (14.29)	1	1 (7.14)
Aspartate aminotransferase increased	5	4 (28.57)	3	3 (21.43)
Alanine aminotransferase increased	4	2 (14.29)	1	1 (7.14)
Platelet count decreased	4	3 (21.43)	2	2 (14.29)
White blood cell count decreased	3	1 (7.14)	3	1 (7.14)
Blood glucose increased	2	1 (7.14)	2	1 (7.14)
International normalised ratio increased	2	2 (14.29)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Blood immunoglobulin A decreased	1	1 (7.14)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (7.14)	0	0 (0.00)
Breath sounds abnormal	1	1 (7.14)	0	0 (0.00)
Heart sounds abnormal	1	1 (7.14)	0	0 (0.00)
Lymphocyte count decreased	1	1 (7.14)	0	0 (0.00)
Staphylococcus test positive	1	1 (7.14)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	40	8 (57.14)	18	6 (42.86)
Hypokalaemia	6	6 (42.86)	2	2 (14.29)
Decreased appetite	5	5 (35.71)	2	2 (14.29)
Hyperglycaemia	4	3 (21.43)	0	0 (0.00)
Hypophosphataemia	4	2 (14.29)	4	2 (14.29)
Hypervolaemia	3	3 (21.43)	3	3 (21.43)
Hypocalcaemia	3	3 (21.43)	2	2 (14.29)
Hypomagnesaemia	3	2 (14.29)	0	0 (0.00)
Hypoalbuminaemia	2	2 (14.29)	1	1 (7.14)
Iron overload	2	1 (7.14)	0	0 (0.00)
Acidosis	1	1 (7.14)	1	1 (7.14)
Hypercholesterolaemia	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hypertriglyceridaemia	1	1 (7.14)	0	0 (0.00)
Hyperuricaemia	1	1 (7.14)	0	0 (0.00)
Hypoglycaemia	1	1 (7.14)	0	0 (0.00)
Malnutrition	1	1 (7.14)	1	1 (7.14)
Polydipsia	1	1 (7.14)	1	1 (7.14)
Tumour lysis syndrome	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	20	7 (50.00)	1	1 (7.14)
Arthralgia	4	3 (21.43)	0	0 (0.00)
Back pain	4	1 (7.14)	0	0 (0.00)
Myalgia	3	2 (14.29)	0	0 (0.00)
Neck pain	2	2 (14.29)	0	0 (0.00)
Bone pain	1	1 (7.14)	0	0 (0.00)
Joint effusion	1	1 (7.14)	0	0 (0.00)
Muscle spasms	1	1 (7.14)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (7.14)	0	0 (0.00)
Pain in extremity	1	1 (7.14)	0	0 (0.00)
Pain in jaw	1	1 (7.14)	1	1 (7.14)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Synovitis	1	1 (7.14)	0	0 (0.00)
Nervous system disorders				
- Total	30	7 (50.00)	4	2 (14.29)
Headache	8	4 (28.57)	0	0 (0.00)
Cognitive disorder	3	1 (7.14)	1	1 (7.14)
Tremor	3	2 (14.29)	0	0 (0.00)
Hyperaesthesia	2	1 (7.14)	0	0 (0.00)
Migraine	2	1 (7.14)	0	0 (0.00)
Somnolence	2	2 (14.29)	1	1 (7.14)
Amnesia	1	1 (7.14)	0	0 (0.00)
Aphasia	1	1 (7.14)	0	0 (0.00)
Disturbance in attention	1	1 (7.14)	0	0 (0.00)
Dizziness	1	1 (7.14)	0	0 (0.00)
Dysgeusia	1	1 (7.14)	0	0 (0.00)
Encephalopathy	1	1 (7.14)	1	1 (7.14)
Extrapyramidal disorder	1	1 (7.14)	0	0 (0.00)
Lethargy	1	1 (7.14)	0	0 (0.00)
Neurological decompensation	1	1 (7.14)	1	1 (7.14)
Paraesthesia	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Psychiatric disorders				
- Total	14	7 (50.00)	2	2 (14.29)
Anxiety	4	4 (28.57)	0	0 (0.00)
Agitation	2	2 (14.29)	0	0 (0.00)
Delirium	2	2 (14.29)	2	2 (14.29)
Affect lability	1	1 (7.14)	0	0 (0.00)
Hallucination	1	1 (7.14)	0	0 (0.00)
Hallucination, visual	1	1 (7.14)	0	0 (0.00)
Irritability	1	1 (7.14)	0	0 (0.00)
Mental status changes	1	1 (7.14)	0	0 (0.00)
Social avoidant behaviour	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	10	5 (35.71)	4	2 (14.29)
Renal failure	3	1 (7.14)	3	1 (7.14)
Acute kidney injury	2	2 (14.29)	1	1 (7.14)
Urinary incontinence	2	1 (7.14)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (7.14)	0	0 (0.00)
Pollakiuria	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Urinary retention	1	1 (7.14)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	4 (28.57)	1	1 (7.14)
Endometriosis	2	1 (7.14)	1	1 (7.14)
Vaginal haemorrhage	2	1 (7.14)	0	0 (0.00)
Female genital tract fistula	1	1 (7.14)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	33	11 (78.57)	13	6 (42.86)
Hypoxia	4	3 (21.43)	4	3 (21.43)
Pulmonary oedema	4	4 (28.57)	3	3 (21.43)
Dyspnoea	2	2 (14.29)	1	1 (7.14)
Oropharyngeal pain	2	2 (14.29)	0	0 (0.00)
Respiratory distress	2	1 (7.14)	2	1 (7.14)
Respiratory failure	2	2 (14.29)	2	2 (14.29)
Atelectasis	1	1 (7.14)	0	0 (0.00)
Bronchial oedema	1	1 (7.14)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Cough	1	1 (7.14)	0	0 (0.00)
Epistaxis	1	1 (7.14)	0	0 (0.00)
Laryngeal oedema	1	1 (7.14)	1	1 (7.14)
Nasal congestion	1	1 (7.14)	0	0 (0.00)
Nasal dryness	1	1 (7.14)	0	0 (0.00)
Oropharyngeal plaque	1	1 (7.14)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (7.14)	0	0 (0.00)
Pharyngeal erythema	1	1 (7.14)	0	0 (0.00)
Pharyngeal exudate	1	1 (7.14)	0	0 (0.00)
Pharyngeal oedema	1	1 (7.14)	0	0 (0.00)
Pleural effusion	1	1 (7.14)	0	0 (0.00)
Pulmonary mass	1	1 (7.14)	0	0 (0.00)
Rhinorrhoea	1	1 (7.14)	0	0 (0.00)
Tachypnoea	1	1 (7.14)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	15	9 (64.29)	1	1 (7.14)
Pruritus	4	3 (21.43)	0	0 (0.00)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hyperhidrosis	2	2 (14.29)	0	0 (0.00)
Rash papular	2	1 (7.14)	0	0 (0.00)
Decubitus ulcer	1	1 (7.14)	1	1 (7.14)
Dry skin	1	1 (7.14)	0	0 (0.00)
Erythema	1	1 (7.14)	0	0 (0.00)
Erythema nodosum	1	1 (7.14)	0	0 (0.00)
Hangnail	1	1 (7.14)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (7.14)	0	0 (0.00)
Skin lesion	1	1 (7.14)	0	0 (0.00)
Social circumstances				
- Total	1	1 (7.14)	0	0 (0.00)
Patient uncooperative	1	1 (7.14)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (7.14)	1	1 (7.14)
Thrombolysis	1	1 (7.14)	1	1 (7.14)
Vascular disorders				
- Total	13	7 (50.00)	5	4 (28.57)

Timing: At anytime, Age: >=18

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hypertension	5	5 (35.71)	1	1 (7.14)
Hypotension	4	4 (28.57)	3	3 (21.43)
Flushing	1	1 (7.14)	0	0 (0.00)
Hot flush	1	1 (7.14)	0	0 (0.00)
Peripheral ischaemia	1	1 (7.14)	0	0 (0.00)
Venoocclusive disease	1	1 (7.14)	1	1 (7.14)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Total number of AE per patient	771	45 (97.83)	260	35 (76.09)
Blood and lymphatic system disorders				
- Total	49	25 (54.35)	29	17 (36.96)
Anaemia	12	7 (15.22)	5	3 (6.52)
Febrile neutropenia	11	11 (23.91)	11	11 (23.91)
Disseminated intravascular coagulation	5	5 (10.87)	0	0 (0.00)
Neutropenia	5	4 (8.70)	4	3 (6.52)
Thrombocytopenia	5	5 (10.87)	5	5 (10.87)
Leukopenia	3	2 (4.35)	2	1 (2.17)
Coagulopathy	2	2 (4.35)	0	0 (0.00)
Eosinophilia	2	1 (2.17)	0	0 (0.00)
Splenomegaly	2	2 (4.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Lymphopenia	1	1 (2.17)	1	1 (2.17)
Pancytopenia	1	1 (2.17)	1	1 (2.17)
Cardiac disorders				
- Total	21	11 (23.91)	4	4 (8.70)
Tachycardia	11	9 (19.57)	2	2 (4.35)
Bradycardia	2	2 (4.35)	0	0 (0.00)
Left ventricular dysfunction	2	2 (4.35)	2	2 (4.35)
Atrioventricular block first degree	1	1 (2.17)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.17)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.17)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.17)	0	0 (0.00)
Pericardial effusion	1	1 (2.17)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.17)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.17)	0	0 (0.00)
Ear pain	1	1 (2.17)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (4.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Adrenal insufficiency	1	1 (2.17)	0	0 (0.00)
Hypothyroidism	1	1 (2.17)	0	0 (0.00)
Eye disorders				
- Total	8	5 (10.87)	0	0 (0.00)
Eyelid oedema	2	1 (2.17)	0	0 (0.00)
Ocular hyperaemia	2	2 (4.35)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.17)	0	0 (0.00)
Eye oedema	1	1 (2.17)	0	0 (0.00)
Eye pain	1	1 (2.17)	0	0 (0.00)
Visual impairment	1	1 (2.17)	0	0 (0.00)
Gastrointestinal disorders				
- Total	71	28 (60.87)	9	8 (17.39)
Vomiting	16	12 (26.09)	0	0 (0.00)
Nausea	14	12 (26.09)	1	1 (2.17)
Abdominal pain	7	6 (13.04)	2	2 (4.35)
Diarrhoea	7	7 (15.22)	1	1 (2.17)
Constipation	5	5 (10.87)	0	0 (0.00)
Pancreatitis	3	3 (6.52)	1	1 (2.17)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Abdominal pain upper	2	2 (4.35)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.35)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (2.17)	1	1 (2.17)
Abdominal distension	1	1 (2.17)	0	0 (0.00)
Anal fissure	1	1 (2.17)	0	0 (0.00)
Ascites	1	1 (2.17)	0	0 (0.00)
Dry mouth	1	1 (2.17)	0	0 (0.00)
Enterocolitis	1	1 (2.17)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.17)	0	0 (0.00)
Haematemesis	1	1 (2.17)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.17)	1	1 (2.17)
Mouth swelling	1	1 (2.17)	0	0 (0.00)
Neutropenic colitis	1	1 (2.17)	1	1 (2.17)
Odynophagia	1	1 (2.17)	0	0 (0.00)
Proctalgia	1	1 (2.17)	1	1 (2.17)
Trichoglossia	1	1 (2.17)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.17)	0	0 (0.00)
General disorders and administration site conditions				

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
- Total	44	19 (41.30)	8	4 (8.70)
Pyrexia	14	11 (23.91)	3	3 (6.52)
Fatigue	7	7 (15.22)	0	0 (0.00)
Face oedema	5	4 (8.70)	1	1 (2.17)
Chills	4	3 (6.52)	0	0 (0.00)
Oedema peripheral	4	3 (6.52)	2	1 (2.17)
Catheter site erythema	2	1 (2.17)	0	0 (0.00)
Asthenia	1	1 (2.17)	0	0 (0.00)
Catheter site pain	1	1 (2.17)	0	0 (0.00)
Chest discomfort	1	1 (2.17)	1	1 (2.17)
Generalised oedema	1	1 (2.17)	0	0 (0.00)
Localised oedema	1	1 (2.17)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.17)	0	0 (0.00)
Pain	1	1 (2.17)	1	1 (2.17)
Vascular device occlusion	1	1 (2.17)	0	0 (0.00)
Hepatobiliary disorders				
- Total	14	8 (17.39)	3	2 (4.35)
Hepatic function abnormal	6	2 (4.35)	3	2 (4.35)
Hepatomegaly	2	2 (4.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Hyperbilirubinaemia	2	2 (4.35)	0	0 (0.00)
Biliary tract disorder	1	1 (2.17)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.17)	0	0 (0.00)
Hypertransaminasaemia	1	1 (2.17)	0	0 (0.00)
Ocular icterus	1	1 (2.17)	0	0 (0.00)
Immune system disorders				
- Total	84	36 (78.26)	34	22 (47.83)
Cytokine release syndrome	63	31 (67.39)	27	19 (41.30)
Hypogammaglobulinaemia	14	12 (26.09)	3	3 (6.52)
Haemophagocytic lymphohistiocytosis	3	3 (6.52)	2	2 (4.35)
Immunodeficiency	2	2 (4.35)	2	2 (4.35)
Hypersensitivity	1	1 (2.17)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (2.17)	0	0 (0.00)
Infections and infestations				
- Total	29	19 (41.30)	10	9 (19.57)
Conjunctivitis	4	3 (6.52)	0	0 (0.00)
Clostridium difficile infection	3	3 (6.52)	2	2 (4.35)
Staphylococcal infection	3	3 (6.52)	1	1 (2.17)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Candida infection	2	2 (4.35)	0	0 (0.00)
Oral infection	2	2 (4.35)	0	0 (0.00)
Anal abscess	1	1 (2.17)	1	1 (2.17)
Atypical pneumonia	1	1 (2.17)	0	0 (0.00)
BK virus infection	1	1 (2.17)	0	0 (0.00)
Cholecystitis infective	1	1 (2.17)	0	0 (0.00)
Gingivitis	1	1 (2.17)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (2.17)	0	0 (0.00)
Nail infection	1	1 (2.17)	0	0 (0.00)
Oral herpes	1	1 (2.17)	1	1 (2.17)
Otitis externa	1	1 (2.17)	0	0 (0.00)
Paronychia	1	1 (2.17)	0	0 (0.00)
Pneumonia	1	1 (2.17)	1	1 (2.17)
Pneumonia fungal	1	1 (2.17)	1	1 (2.17)
Soft tissue infection	1	1 (2.17)	1	1 (2.17)
Staphylococcal bacteraemia	1	1 (2.17)	1	1 (2.17)
Varicella zoster virus infection	1	1 (2.17)	1	1 (2.17)
Injury, poisoning and procedural complications				

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
- Total	4	4 (8.70)	0	0 (0.00)
Transfusion reaction	2	2 (4.35)	0	0 (0.00)
Fall	1	1 (2.17)	0	0 (0.00)
Scratch	1	1 (2.17)	0	0 (0.00)
Investigations				
- Total	178	29 (63.04)	86	22 (47.83)
Platelet count decreased	30	11 (23.91)	15	7 (15.22)
White blood cell count decreased	25	12 (26.09)	17	9 (19.57)
Neutrophil count decreased	17	8 (17.39)	16	8 (17.39)
Alanine aminotransferase increased	16	13 (28.26)	3	3 (6.52)
Aspartate aminotransferase increased	14	12 (26.09)	6	6 (13.04)
Blood bilirubin increased	9	8 (17.39)	7	7 (15.22)
Lymphocyte count decreased	9	5 (10.87)	7	5 (10.87)
Serum ferritin increased	6	6 (13.04)	1	1 (2.17)
Activated partial thromboplastin time prolonged	5	4 (8.70)	1	1 (2.17)
Immunoglobulins decreased	5	2 (4.35)	0	0 (0.00)
Blood fibrinogen decreased	4	4 (8.70)	1	1 (2.17)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Blood creatine phosphokinase increased	3	1 (2.17)	1	1 (2.17)
Blood lactate dehydrogenase increased	3	3 (6.52)	0	0 (0.00)
International normalised ratio increased	3	3 (6.52)	0	0 (0.00)
Blood creatinine increased	2	2 (4.35)	2	2 (4.35)
Blood immunoglobulin A decreased	2	2 (4.35)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (4.35)	1	1 (2.17)
C-reactive protein increased	2	2 (4.35)	1	1 (2.17)
Electrocardiogram QT prolonged	2	2 (4.35)	1	1 (2.17)
Fibrin D dimer increased	2	2 (4.35)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (4.35)	2	2 (4.35)
Haemoglobin decreased	2	1 (2.17)	1	1 (2.17)
Weight increased	2	2 (4.35)	1	1 (2.17)
Amylase increased	1	1 (2.17)	0	0 (0.00)
Bacterial test positive	1	1 (2.17)	1	1 (2.17)
Blood immunoglobulin G decreased	1	1 (2.17)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Blood uric acid increased	1	1 (2.17)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.17)	0	0 (0.00)
Lipase increased	1	1 (2.17)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.17)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.17)	0	0 (0.00)
Staphylococcus test positive	1	1 (2.17)	0	0 (0.00)
Urine output decreased	1	1 (2.17)	1	1 (2.17)
Metabolism and nutrition disorders				
- Total	85	25 (54.35)	30	13 (28.26)
Hypokalaemia	14	9 (19.57)	7	5 (10.87)
Hypocalcaemia	12	9 (19.57)	3	3 (6.52)
Hypophosphataemia	12	7 (15.22)	3	3 (6.52)
Decreased appetite	10	10 (21.74)	4	4 (8.70)
Hypoalbuminaemia	8	4 (8.70)	0	0 (0.00)
Hyperuricaemia	5	4 (8.70)	0	0 (0.00)
Hyperglycaemia	3	3 (6.52)	3	3 (6.52)
Hypomagnesaemia	3	3 (6.52)	0	0 (0.00)
Tumour lysis syndrome	3	3 (6.52)	3	3 (6.52)
Hypermagnesaemia	2	1 (2.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Hyperphosphataemia	2	2 (4.35)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (4.35)	2	2 (4.35)
Hypervolaemia	2	2 (4.35)	1	1 (2.17)
Metabolic acidosis	2	2 (4.35)	1	1 (2.17)
Dehydration	1	1 (2.17)	0	0 (0.00)
Hypercalcaemia	1	1 (2.17)	1	1 (2.17)
Hyperkalaemia	1	1 (2.17)	1	1 (2.17)
Hypernatraemia	1	1 (2.17)	0	0 (0.00)
Malnutrition	1	1 (2.17)	1	1 (2.17)
Musculoskeletal and connective tissue disorders				
- Total	23	15 (32.61)	0	0 (0.00)
Arthralgia	7	7 (15.22)	0	0 (0.00)
Pain in extremity	7	7 (15.22)	0	0 (0.00)
Myalgia	3	2 (4.35)	0	0 (0.00)
Back pain	2	2 (4.35)	0	0 (0.00)
Bone pain	1	1 (2.17)	0	0 (0.00)
Muscle spasms	1	1 (2.17)	0	0 (0.00)
Muscular weakness	1	1 (2.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Pain in jaw	1	1 (2.17)	0	0 (0.00)
Nervous system disorders				
- Total	29	21 (45.65)	8	5 (10.87)
Headache	11	11 (23.91)	2	2 (4.35)
Encephalopathy	4	4 (8.70)	1	1 (2.17)
Dizziness	2	2 (4.35)	0	0 (0.00)
Dysgeusia	2	2 (4.35)	0	0 (0.00)
Somnolence	2	2 (4.35)	1	1 (2.17)
Cerebral haemorrhage	1	1 (2.17)	1	1 (2.17)
Cognitive disorder	1	1 (2.17)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.17)	1	1 (2.17)
Dysarthria	1	1 (2.17)	1	1 (2.17)
Hypoaesthesia	1	1 (2.17)	0	0 (0.00)
Lethargy	1	1 (2.17)	0	0 (0.00)
Neuralgia	1	1 (2.17)	0	0 (0.00)
Neurological decompensation	1	1 (2.17)	1	1 (2.17)
Psychiatric disorders				
- Total	23	15 (32.61)	2	2 (4.35)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Delirium	5	5 (10.87)	2	2 (4.35)
Confusional state	4	4 (8.70)	0	0 (0.00)
Anxiety	3	3 (6.52)	0	0 (0.00)
Insomnia	3	3 (6.52)	0	0 (0.00)
Agitation	2	2 (4.35)	0	0 (0.00)
Sleep disorder	2	1 (2.17)	0	0 (0.00)
Hallucination	1	1 (2.17)	0	0 (0.00)
Irritability	1	1 (2.17)	0	0 (0.00)
Mental status changes	1	1 (2.17)	0	0 (0.00)
Restlessness	1	1 (2.17)	0	0 (0.00)
Renal and urinary disorders				
- Total	15	10 (21.74)	5	3 (6.52)
Renal failure	4	2 (4.35)	3	1 (2.17)
Acute kidney injury	3	3 (6.52)	2	2 (4.35)
Dysuria	2	2 (4.35)	0	0 (0.00)
Haematuria	2	2 (4.35)	0	0 (0.00)
Incontinence	1	1 (2.17)	0	0 (0.00)
Proteinuria	1	1 (2.17)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Urinary tract disorder	1	1 (2.17)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	51	19 (41.30)	23	9 (19.57)
Hypoxia	11	9 (19.57)	8	6 (13.04)
Pleural effusion	6	6 (13.04)	3	3 (6.52)
Pulmonary oedema	6	6 (13.04)	3	3 (6.52)
Cough	4	4 (8.70)	0	0 (0.00)
Oropharyngeal pain	4	3 (6.52)	0	0 (0.00)
Respiratory distress	3	2 (4.35)	2	1 (2.17)
Tachypnoea	3	3 (6.52)	1	1 (2.17)
Lung infiltration	2	1 (2.17)	1	1 (2.17)
Nasal congestion	2	2 (4.35)	0	0 (0.00)
Respiratory failure	2	2 (4.35)	2	2 (4.35)
Atelectasis	1	1 (2.17)	1	1 (2.17)
Bradypnoea	1	1 (2.17)	1	1 (2.17)
Dyspnoea	1	1 (2.17)	1	1 (2.17)
Epistaxis	1	1 (2.17)	0	0 (0.00)
Painful respiration	1	1 (2.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Productive cough	1	1 (2.17)	0	0 (0.00)
Respiratory disorder	1	1 (2.17)	0	0 (0.00)
Wheezing	1	1 (2.17)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	21	14 (30.43)	1	1 (2.17)
Pruritus	5	4 (8.70)	0	0 (0.00)
Rash	3	3 (6.52)	0	0 (0.00)
Blister	2	2 (4.35)	0	0 (0.00)
Erythema	2	2 (4.35)	0	0 (0.00)
Dermatitis	1	1 (2.17)	0	0 (0.00)
Dermatitis atopic	1	1 (2.17)	0	0 (0.00)
Erythema nodosum	1	1 (2.17)	0	0 (0.00)
Pruritus allergic	1	1 (2.17)	0	0 (0.00)
Scab	1	1 (2.17)	0	0 (0.00)
Skin discolouration	1	1 (2.17)	0	0 (0.00)
Skin ulcer	1	1 (2.17)	0	0 (0.00)
Urticaria	1	1 (2.17)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.17)	1	1 (2.17)

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Vascular disorders				
- Total	19	16 (34.78)	8	8 (17.39)
Hypotension	10	10 (21.74)	5	5 (10.87)
Hypertension	7	7 (15.22)	2	2 (4.35)
Capillary leak syndrome	2	2 (4.35)	1	1 (2.17)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	980	34 (100.00)	359	32 (94.12)
Blood and lymphatic system disorders				
- Total	76	25 (73.53)	47	22 (64.71)
Anaemia	38	14 (41.18)	15	5 (14.71)
Febrile neutropenia	18	15 (44.12)	18	15 (44.12)
Neutropenia	6	5 (14.71)	5	4 (11.76)
Coagulopathy	3	3 (8.82)	2	2 (5.88)
Thrombocytopenia	3	3 (8.82)	3	3 (8.82)
Disseminated intravascular coagulation	2	2 (5.88)	2	2 (5.88)
Splenomegaly	2	2 (5.88)	0	0 (0.00)
B-cell aplasia	1	1 (2.94)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Leukopenia	1	1 (2.94)	1	1 (2.94)
Pancytopenia	1	1 (2.94)	1	1 (2.94)
Cardiac disorders				
- Total	24	13 (38.24)	6	4 (11.76)
Tachycardia	11	8 (23.53)	1	1 (2.94)
Cardiac failure	4	1 (2.94)	2	1 (2.94)
Sinus tachycardia	4	3 (8.82)	0	0 (0.00)
Bradycardia	1	1 (2.94)	0	0 (0.00)
Cardiac arrest	1	1 (2.94)	1	1 (2.94)
Cardiac dysfunction	1	1 (2.94)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.94)	1	1 (2.94)
Sinus bradycardia	1	1 (2.94)	1	1 (2.94)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Ear pruritus	1	1 (2.94)	0	0 (0.00)
Endocrine disorders				
- Total	3	3 (8.82)	0	0 (0.00)
Adrenal insufficiency	3	3 (8.82)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Eye disorders				
- Total	7	4 (11.76)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.94)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.94)	0	0 (0.00)
Eyelid oedema	1	1 (2.94)	0	0 (0.00)
Periorbital oedema	1	1 (2.94)	0	0 (0.00)
Periorbital swelling	1	1 (2.94)	0	0 (0.00)
Visual field defect	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	64	23 (67.65)	7	6 (17.65)
Vomiting	14	9 (26.47)	1	1 (2.94)
Diarrhoea	11	8 (23.53)	0	0 (0.00)
Nausea	7	6 (17.65)	1	1 (2.94)
Abdominal pain	6	5 (14.71)	0	0 (0.00)
Constipation	6	6 (17.65)	0	0 (0.00)
Mouth haemorrhage	3	3 (8.82)	1	1 (2.94)
Abdominal distension	2	2 (5.88)	0	0 (0.00)
Ascites	2	2 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Stomatitis	2	2 (5.88)	1	1 (2.94)
Abdominal pain upper	1	1 (2.94)	0	0 (0.00)
Anal haemorrhage	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	1	1 (2.94)
Gingival bleeding	1	1 (2.94)	0	0 (0.00)
Gingival erythema	1	1 (2.94)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.94)	1	1 (2.94)
Ileus	1	1 (2.94)	0	0 (0.00)
Lip dry	1	1 (2.94)	0	0 (0.00)
Lip oedema	1	1 (2.94)	0	0 (0.00)
Melaena	1	1 (2.94)	1	1 (2.94)
Pancreatitis	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	68	21 (61.76)	11	7 (20.59)
Pyrexia	30	13 (38.24)	6	5 (14.71)
Chills	5	3 (8.82)	0	0 (0.00)
Face oedema	4	4 (11.76)	0	0 (0.00)
Fatigue	4	4 (11.76)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Generalised oedema	4	4 (11.76)	0	0 (0.00)
Catheter site pain	3	1 (2.94)	2	1 (2.94)
Oedema peripheral	3	3 (8.82)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (5.88)	0	0 (0.00)
Influenza like illness	2	2 (5.88)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (5.88)	2	2 (5.88)
Asthenia	1	1 (2.94)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Crying	1	1 (2.94)	0	0 (0.00)
Facial pain	1	1 (2.94)	0	0 (0.00)
Localised oedema	1	1 (2.94)	0	0 (0.00)
Malaise	1	1 (2.94)	0	0 (0.00)
Sluggishness	1	1 (2.94)	0	0 (0.00)
Swelling face	1	1 (2.94)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (2.94)	1	1 (2.94)
Hepatobiliary disorders				
- Total	15	9 (26.47)	4	4 (11.76)
Hepatic function abnormal	5	3 (8.82)	1	1 (2.94)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hyperbilirubinaemia	4	3 (8.82)	1	1 (2.94)
Cholelithiasis	2	2 (5.88)	0	0 (0.00)
Cholestasis	1	1 (2.94)	1	1 (2.94)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Hepatomegaly	1	1 (2.94)	1	1 (2.94)
Hypertransaminasaemia	1	1 (2.94)	0	0 (0.00)
Immune system disorders				
- Total	80	31 (91.18)	34	21 (61.76)
Cytokine release syndrome	65	30 (88.24)	28	19 (55.88)
Hypogammaglobulinaemia	11	11 (32.35)	4	4 (11.76)
Haemophagocytic lymphohistiocytosis	2	2 (5.88)	1	1 (2.94)
Immunodeficiency	1	1 (2.94)	1	1 (2.94)
Seasonal allergy	1	1 (2.94)	0	0 (0.00)
Infections and infestations				
- Total	35	16 (47.06)	21	10 (29.41)
Staphylococcal bacteraemia	3	2 (5.88)	3	2 (5.88)
Candida infection	2	1 (2.94)	2	1 (2.94)
Conjunctivitis	2	2 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Encephalitis viral	2	2 (5.88)	2	2 (5.88)
Oral candidiasis	2	1 (2.94)	0	0 (0.00)
Rhinovirus infection	2	2 (5.88)	0	0 (0.00)
Staphylococcal infection	2	2 (5.88)	1	1 (2.94)
Adenovirus infection	1	1 (2.94)	1	1 (2.94)
Bacteraemia	1	1 (2.94)	1	1 (2.94)
Bronchopulmonary aspergillosis	1	1 (2.94)	1	1 (2.94)
Clostridium difficile infection	1	1 (2.94)	1	1 (2.94)
Encephalitis	1	1 (2.94)	1	1 (2.94)
Gastroenteritis norovirus	1	1 (2.94)	0	0 (0.00)
Granulicatella infection	1	1 (2.94)	1	1 (2.94)
Herpes simplex	1	1 (2.94)	1	1 (2.94)
Human herpesvirus 6 infection	1	1 (2.94)	1	1 (2.94)
Klebsiella infection	1	1 (2.94)	1	1 (2.94)
Localised infection	1	1 (2.94)	0	0 (0.00)
Meningitis bacterial	1	1 (2.94)	1	1 (2.94)
Myringitis	1	1 (2.94)	0	0 (0.00)
Nail infection	1	1 (2.94)	0	0 (0.00)
Oral herpes	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pneumonia viral	1	1 (2.94)	1	1 (2.94)
Sinusitis	1	1 (2.94)	1	1 (2.94)
Stomatococcal infection	1	1 (2.94)	0	0 (0.00)
Systemic candida	1	1 (2.94)	1	1 (2.94)
Urinary tract infection viral	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	16	7 (20.59)	3	2 (5.88)
Infusion related reaction	3	2 (5.88)	0	0 (0.00)
Wound	3	2 (5.88)	1	1 (2.94)
Contusion	2	1 (2.94)	0	0 (0.00)
Procedural pain	2	2 (5.88)	0	0 (0.00)
Fall	1	1 (2.94)	0	0 (0.00)
Skin abrasion	1	1 (2.94)	0	0 (0.00)
Skin injury	1	1 (2.94)	0	0 (0.00)
Skin wound	1	1 (2.94)	0	0 (0.00)
Transplant failure	1	1 (2.94)	1	1 (2.94)
Vasoplegia syndrome	1	1 (2.94)	1	1 (2.94)
Investigations				

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	208	28 (82.35)	111	23 (67.65)
Platelet count decreased	35	10 (29.41)	23	7 (20.59)
Neutrophil count decreased	31	12 (35.29)	22	9 (26.47)
White blood cell count decreased	25	12 (35.29)	19	9 (26.47)
Lymphocyte count decreased	21	10 (29.41)	17	8 (23.53)
Aspartate aminotransferase increased	19	7 (20.59)	7	5 (14.71)
Alanine aminotransferase increased	10	5 (14.71)	3	3 (8.82)
Blood bilirubin increased	9	4 (11.76)	2	2 (5.88)
International normalised ratio increased	9	6 (17.65)	0	0 (0.00)
Blood creatinine increased	4	2 (5.88)	3	1 (2.94)
Blood immunoglobulin M decreased	4	4 (11.76)	0	0 (0.00)
Electrocardiogram QT prolonged	4	3 (8.82)	1	1 (2.94)
Activated partial thromboplastin time prolonged	3	2 (5.88)	0	0 (0.00)
Blood fibrinogen decreased	3	3 (8.82)	1	1 (2.94)
Blood immunoglobulin A decreased	3	3 (8.82)	0	0 (0.00)
Lipase increased	3	1 (2.94)	2	1 (2.94)
Blood glucose increased	2	1 (2.94)	2	1 (2.94)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
C-reactive protein increased	2	2 (5.88)	2	2 (5.88)
Serum ferritin increased	2	2 (5.88)	1	1 (2.94)
Urine output decreased	2	1 (2.94)	2	1 (2.94)
Weight increased	2	2 (5.88)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.94)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.94)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.94)	1	1 (2.94)
Blood immunoglobulin G decreased	1	1 (2.94)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.94)	1	1 (2.94)
Blood phosphorus increased	1	1 (2.94)	0	0 (0.00)
Blood uric acid increased	1	1 (2.94)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.94)	0	0 (0.00)
Cardiac murmur	1	1 (2.94)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.94)	0	0 (0.00)
Enterovirus test positive	1	1 (2.94)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.94)	1	1 (2.94)
Haptoglobin decreased	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Troponin increased	1	1 (2.94)	1	1 (2.94)
Weight decreased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	125	21 (61.76)	46	16 (47.06)
Hypokalaemia	26	10 (29.41)	13	6 (17.65)
Hypophosphataemia	19	10 (29.41)	8	6 (17.65)
Decreased appetite	14	14 (41.18)	7	7 (20.59)
Hypocalcaemia	12	7 (20.59)	3	2 (5.88)
Hypoalbuminaemia	11	7 (20.59)	1	1 (2.94)
Hyperglycaemia	8	5 (14.71)	1	1 (2.94)
Hyperuricaemia	4	3 (8.82)	1	1 (2.94)
Hypervolaemia	4	4 (11.76)	3	3 (8.82)
Hypomagnesaemia	4	3 (8.82)	0	0 (0.00)
Acidosis	3	2 (5.88)	2	2 (5.88)
Hypercalcaemia	3	2 (5.88)	1	1 (2.94)
Hyperphosphataemia	3	3 (8.82)	1	1 (2.94)
Hyponatraemia	3	3 (8.82)	0	0 (0.00)
Calcium deficiency	1	1 (2.94)	0	0 (0.00)
Haemosiderosis	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hyperchloraemia	1	1 (2.94)	0	0 (0.00)
Hyperkalaemia	1	1 (2.94)	1	1 (2.94)
Hyperlactacidaemia	1	1 (2.94)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.94)	0	0 (0.00)
Hypernatraemia	1	1 (2.94)	1	1 (2.94)
Hypoglycaemia	1	1 (2.94)	0	0 (0.00)
Metabolic acidosis	1	1 (2.94)	1	1 (2.94)
Polydipsia	1	1 (2.94)	1	1 (2.94)
Tumour lysis syndrome	1	1 (2.94)	1	1 (2.94)
Musculoskeletal and connective tissue disorders				
- Total	30	18 (52.94)	6	5 (14.71)
Myalgia	7	7 (20.59)	0	0 (0.00)
Back pain	5	4 (11.76)	1	1 (2.94)
Pain in extremity	4	4 (11.76)	0	0 (0.00)
Arthralgia	3	3 (8.82)	1	1 (2.94)
Bone pain	3	1 (2.94)	0	0 (0.00)
Haemarthrosis	1	1 (2.94)	1	1 (2.94)
Muscle rigidity	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Muscular weakness	1	1 (2.94)	1	1 (2.94)
Musculoskeletal chest pain	1	1 (2.94)	0	0 (0.00)
Myositis	1	1 (2.94)	0	0 (0.00)
Neck pain	1	1 (2.94)	0	0 (0.00)
Pain in jaw	1	1 (2.94)	1	1 (2.94)
Rhabdomyolysis	1	1 (2.94)	1	1 (2.94)
Nervous system disorders				
- Total	48	19 (55.88)	6	5 (14.71)
Headache	15	12 (35.29)	0	0 (0.00)
Tremor	7	6 (17.65)	0	0 (0.00)
Cognitive disorder	4	2 (5.88)	1	1 (2.94)
Encephalopathy	4	4 (11.76)	3	3 (8.82)
Seizure	3	2 (5.88)	1	1 (2.94)
Somnolence	3	3 (8.82)	1	1 (2.94)
Hyperaesthesia	2	1 (2.94)	0	0 (0.00)
Lethargy	2	2 (5.88)	0	0 (0.00)
Amnesia	1	1 (2.94)	0	0 (0.00)
Aphasia	1	1 (2.94)	0	0 (0.00)
Disturbance in attention	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Dizziness	1	1 (2.94)	0	0 (0.00)
Dysgeusia	1	1 (2.94)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (2.94)	0	0 (0.00)
Monoparesis	1	1 (2.94)	0	0 (0.00)
Paraesthesia	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	24	13 (38.24)	4	4 (11.76)
Agitation	4	3 (8.82)	0	0 (0.00)
Anxiety	3	3 (8.82)	2	2 (5.88)
Confusional state	3	3 (8.82)	0	0 (0.00)
Delirium	2	2 (5.88)	1	1 (2.94)
Hallucination	2	2 (5.88)	0	0 (0.00)
Irritability	2	2 (5.88)	0	0 (0.00)
Mental status changes	2	2 (5.88)	1	1 (2.94)
Affect lability	1	1 (2.94)	0	0 (0.00)
Automatism	1	1 (2.94)	0	0 (0.00)
Hallucination, visual	1	1 (2.94)	0	0 (0.00)
Insomnia	1	1 (2.94)	0	0 (0.00)
Sleep disorder	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Social avoidant behaviour	1	1 (2.94)	0	0 (0.00)
Renal and urinary disorders				
- Total	24	10 (29.41)	8	6 (17.65)
Acute kidney injury	11	6 (17.65)	6	5 (14.71)
Anuria	2	2 (5.88)	1	1 (2.94)
Pollakiuria	2	2 (5.88)	0	0 (0.00)
Urinary incontinence	2	1 (2.94)	0	0 (0.00)
Urinary retention	2	2 (5.88)	0	0 (0.00)
Azotaemia	1	1 (2.94)	0	0 (0.00)
Bladder dilatation	1	1 (2.94)	0	0 (0.00)
Dysuria	1	1 (2.94)	0	0 (0.00)
Micturition urgency	1	1 (2.94)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.94)	1	1 (2.94)
Reproductive system and breast disorders				
- Total	6	5 (14.71)	1	1 (2.94)
Vaginal haemorrhage	2	1 (2.94)	0	0 (0.00)
Female genital tract fistula	1	1 (2.94)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Perineal rash	1	1 (2.94)	0	0 (0.00)
Vaginal ulceration	1	1 (2.94)	1	1 (2.94)
Respiratory, thoracic and mediastinal disorders				
- Total	63	22 (64.71)	27	14 (41.18)
Hypoxia	12	8 (23.53)	10	6 (17.65)
Cough	7	6 (17.65)	0	0 (0.00)
Pulmonary oedema	6	6 (17.65)	4	4 (11.76)
Tachypnoea	6	5 (14.71)	3	3 (8.82)
Atelectasis	4	2 (5.88)	1	1 (2.94)
Epistaxis	3	3 (8.82)	1	1 (2.94)
Acute respiratory distress syndrome	2	2 (5.88)	2	2 (5.88)
Dyspnoea	2	2 (5.88)	2	2 (5.88)
Oropharyngeal pain	2	2 (5.88)	0	0 (0.00)
Respiratory failure	2	2 (5.88)	2	2 (5.88)
Rhinorrhoea	2	2 (5.88)	0	0 (0.00)
Acute respiratory failure	1	1 (2.94)	1	1 (2.94)
Haemoptysis	1	1 (2.94)	0	0 (0.00)
Nasal congestion	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Nasal discomfort	1	1 (2.94)	0	0 (0.00)
Nasal dryness	1	1 (2.94)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.94)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.94)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.94)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.94)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.94)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.94)	0	0 (0.00)
Pleural effusion	1	1 (2.94)	0	0 (0.00)
Pulmonary mass	1	1 (2.94)	0	0 (0.00)
Respiratory acidosis	1	1 (2.94)	1	1 (2.94)
Respiratory distress	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	35	13 (38.24)	3	2 (5.88)
Blister	4	1 (2.94)	0	0 (0.00)
Rash papular	4	3 (8.82)	0	0 (0.00)
Hyperhidrosis	3	3 (8.82)	0	0 (0.00)
Rash maculo-papular	3	2 (5.88)	1	1 (2.94)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Erythema	2	2 (5.88)	0	0 (0.00)
Petechiae	2	2 (5.88)	1	1 (2.94)
Pruritus	2	2 (5.88)	0	0 (0.00)
Rash	2	2 (5.88)	0	0 (0.00)
Rash vesicular	2	1 (2.94)	0	0 (0.00)
Decubitus ulcer	1	1 (2.94)	0	0 (0.00)
Dermatitis atopic	1	1 (2.94)	0	0 (0.00)
Dermatitis diaper	1	1 (2.94)	0	0 (0.00)
Dry skin	1	1 (2.94)	0	0 (0.00)
Eczema	1	1 (2.94)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.94)	0	0 (0.00)
Purpura	1	1 (2.94)	0	0 (0.00)
Rash pruritic	1	1 (2.94)	0	0 (0.00)
Skin lesion	1	1 (2.94)	0	0 (0.00)
Skin necrosis	1	1 (2.94)	1	1 (2.94)
Skin ulcer	1	1 (2.94)	0	0 (0.00)
Social circumstances				
- Total	1	1 (2.94)	0	0 (0.00)

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Patient uncooperative	1	1 (2.94)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (2.94)	1	1 (2.94)
Thrombolysis	1	1 (2.94)	1	1 (2.94)
Vascular disorders				
- Total	26	12 (35.29)	13	9 (26.47)
Hypotension	15	11 (32.35)	11	9 (26.47)
Hypertension	7	6 (17.65)	2	2 (5.88)
Flushing	1	1 (2.94)	0	0 (0.00)
Hot flush	1	1 (2.94)	0	0 (0.00)
Peripheral ischaemia	1	1 (2.94)	0	0 (0.00)
Thrombosis	1	1 (2.94)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Total number of AE per patient	316	40 (93.02)	91	22 (51.16)
Blood and lymphatic system disorders				
- Total	21	10 (23.26)	12	5 (11.63)
Anaemia	7	2 (4.65)	3	1 (2.33)
Febrile neutropenia	4	3 (6.98)	4	3 (6.98)
Thrombocytopenia	2	2 (4.65)	2	2 (4.65)
Disseminated intravascular coagulation	1	1 (2.33)	1	1 (2.33)
Eosinophilia	1	1 (2.33)	0	0 (0.00)
Leukocytosis	1	1 (2.33)	0	0 (0.00)
Leukopenia	1	1 (2.33)	0	0 (0.00)
Lymphadenopathy	1	1 (2.33)	0	0 (0.00)
Lymphocytosis	1	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Lymphopenia	1	1 (2.33)	1	1 (2.33)
Neutropenia	1	1 (2.33)	1	1 (2.33)
Cardiac disorders				
- Total	6	5 (11.63)	2	1 (2.33)
Tachycardia	2	2 (4.65)	0	0 (0.00)
Cardiac arrest	1	1 (2.33)	1	1 (2.33)
Cardiac failure	1	1 (2.33)	1	1 (2.33)
Left ventricular dysfunction	1	1 (2.33)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.33)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.98)	0	0 (0.00)
Cataract	2	2 (4.65)	0	0 (0.00)
Hypermetropia	1	1 (2.33)	0	0 (0.00)
Visual impairment	1	1 (2.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	21	13 (30.23)	1	1 (2.33)
Diarrhoea	5	5 (11.63)	0	0 (0.00)
Constipation	3	2 (4.65)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Vomiting	3	3 (6.98)	0	0 (0.00)
Nausea	2	2 (4.65)	0	0 (0.00)
Abdominal pain	1	1 (2.33)	0	0 (0.00)
Enteritis	1	1 (2.33)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.33)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.33)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.33)	0	0 (0.00)
Pancreatitis	1	1 (2.33)	1	1 (2.33)
Peritoneal haematoma	1	1 (2.33)	0	0 (0.00)
Trichoglossia	1	1 (2.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	15	13 (30.23)	2	2 (4.65)
Pyrexia	10	10 (23.26)	2	2 (4.65)
Fatigue	3	3 (6.98)	0	0 (0.00)
Asthenia	1	1 (2.33)	0	0 (0.00)
Malaise	1	1 (2.33)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (4.65)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Hepatic cytolysis	1	1 (2.33)	0	0 (0.00)
Liver disorder	1	1 (2.33)	0	0 (0.00)
Immune system disorders				
- Total	11	10 (23.26)	4	3 (6.98)
Hypogammaglobulinaemia	5	5 (11.63)	0	0 (0.00)
Graft versus host disease	2	2 (4.65)	2	2 (4.65)
Allergy to immunoglobulin therapy	1	1 (2.33)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.33)	0	0 (0.00)
Engraftment syndrome	1	1 (2.33)	1	1 (2.33)
Immunodeficiency	1	1 (2.33)	1	1 (2.33)
Infections and infestations				
- Total	68	23 (53.49)	22	12 (27.91)
Nasopharyngitis	7	5 (11.63)	0	0 (0.00)
Upper respiratory tract infection	6	6 (13.95)	1	1 (2.33)
Metapneumovirus infection	3	3 (6.98)	3	3 (6.98)
Parainfluenzae virus infection	3	2 (4.65)	1	1 (2.33)
Pneumonia	3	3 (6.98)	1	1 (2.33)
Ear infection	2	1 (2.33)	0	0 (0.00)
Gastroenteritis	2	2 (4.65)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Otitis media	2	2 (4.65)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (4.65)	2	2 (4.65)
Respiratory syncytial virus infection	2	2 (4.65)	1	1 (2.33)
Respiratory tract infection	2	2 (4.65)	0	0 (0.00)
Rhinovirus infection	2	2 (4.65)	0	0 (0.00)
Viral infection	2	2 (4.65)	1	1 (2.33)
Adenovirus infection	1	1 (2.33)	1	1 (2.33)
BK virus infection	1	1 (2.33)	1	1 (2.33)
Bacteraemia	1	1 (2.33)	0	0 (0.00)
Cellulitis	1	1 (2.33)	0	0 (0.00)
Conjunctivitis	1	1 (2.33)	0	0 (0.00)
Coronavirus infection	1	1 (2.33)	1	1 (2.33)
Cytomegalovirus infection reactivation	1	1 (2.33)	1	1 (2.33)
Device related infection	1	1 (2.33)	1	1 (2.33)
Encephalitis	1	1 (2.33)	1	1 (2.33)
Gastroenteritis clostridial	1	1 (2.33)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.33)	0	0 (0.00)
Gastrointestinal infection	1	1 (2.33)	0	0 (0.00)
Gingivitis	1	1 (2.33)	0	0 (0.00)
Herpes simplex	1	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Herpes zoster	1	1 (2.33)	1	1 (2.33)
Human herpesvirus 6 infection	1	1 (2.33)	1	1 (2.33)
Influenza	1	1 (2.33)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.33)	0	0 (0.00)
Nail infection	1	1 (2.33)	0	0 (0.00)
Oral herpes	1	1 (2.33)	0	0 (0.00)
Otitis externa	1	1 (2.33)	0	0 (0.00)
Paronychia	1	1 (2.33)	0	0 (0.00)
Rhinitis	1	1 (2.33)	0	0 (0.00)
Salmonellosis	1	1 (2.33)	0	0 (0.00)
Sinusitis	1	1 (2.33)	0	0 (0.00)
Sinusitis fungal	1	1 (2.33)	1	1 (2.33)
Staphylococcal bacteraemia	1	1 (2.33)	1	1 (2.33)
Staphylococcal sepsis	1	1 (2.33)	1	1 (2.33)
Tinea pedis	1	1 (2.33)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (2.33)	1	1 (2.33)
Injury, poisoning and procedural complications				
- Total	5	5 (11.63)	0	0 (0.00)
Contusion	1	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Fibula fracture	1	1 (2.33)	0	0 (0.00)
Infusion related reaction	1	1 (2.33)	0	0 (0.00)
Ligament sprain	1	1 (2.33)	0	0 (0.00)
Skin abrasion	1	1 (2.33)	0	0 (0.00)
Investigations				
- Total	57	18 (41.86)	25	10 (23.26)
Platelet count decreased	13	3 (6.98)	9	2 (4.65)
Neutrophil count decreased	7	4 (9.30)	6	4 (9.30)
White blood cell count decreased	7	5 (11.63)	1	1 (2.33)
Immunoglobulins decreased	5	1 (2.33)	0	0 (0.00)
Blood bilirubin increased	4	2 (4.65)	1	1 (2.33)
Lymphocyte count decreased	4	2 (4.65)	2	2 (4.65)
Alanine aminotransferase increased	3	2 (4.65)	1	1 (2.33)
Blood immunoglobulin A decreased	2	2 (4.65)	1	1 (2.33)
Blood creatinine increased	1	1 (2.33)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.33)	1	1 (2.33)
Blood lactate dehydrogenase increased	1	1 (2.33)	0	0 (0.00)
Blood urea increased	1	1 (2.33)	1	1 (2.33)
Blood uric acid increased	1	1 (2.33)	1	1 (2.33)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Bone density decreased	1	1 (2.33)	0	0 (0.00)
C-reactive protein increased	1	1 (2.33)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.33)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.33)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.33)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.33)	0	0 (0.00)
Weight decreased	1	1 (2.33)	1	1 (2.33)
Metabolism and nutrition disorders				
- Total	15	8 (18.60)	6	3 (6.98)
Decreased appetite	5	5 (11.63)	1	1 (2.33)
Hypokalaemia	4	1 (2.33)	3	1 (2.33)
Haemochromatosis	1	1 (2.33)	1	1 (2.33)
Hyperkalaemia	1	1 (2.33)	0	0 (0.00)
Hyperuricaemia	1	1 (2.33)	0	0 (0.00)
Hypervolaemia	1	1 (2.33)	1	1 (2.33)
Hypophosphataemia	1	1 (2.33)	0	0 (0.00)
Iron overload	1	1 (2.33)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
- Total	15	9 (20.93)	2	2 (4.65)
Back pain	4	4 (9.30)	2	2 (4.65)
Arthralgia	3	3 (6.98)	0	0 (0.00)
Pain in extremity	3	3 (6.98)	0	0 (0.00)
Bone pain	1	1 (2.33)	0	0 (0.00)
Growth retardation	1	1 (2.33)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.33)	0	0 (0.00)
Myalgia	1	1 (2.33)	0	0 (0.00)
Neck pain	1	1 (2.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (6.98)	0	0 (0.00)
Skin papilloma	2	2 (4.65)	0	0 (0.00)
Cancer pain	1	1 (2.33)	0	0 (0.00)
Nervous system disorders				
- Total	12	6 (13.95)	6	2 (4.65)
Headache	3	3 (6.98)	0	0 (0.00)
Hydrocephalus	3	1 (2.33)	3	1 (2.33)
Dizziness	2	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Autonomic neuropathy	1	1 (2.33)	1	1 (2.33)
Cerebral haemorrhage	1	1 (2.33)	1	1 (2.33)
Memory impairment	1	1 (2.33)	0	0 (0.00)
Seizure	1	1 (2.33)	1	1 (2.33)
Psychiatric disorders				
- Total	11	6 (13.95)	0	0 (0.00)
Anxiety	4	4 (9.30)	0	0 (0.00)
Agitation	1	1 (2.33)	0	0 (0.00)
Delirium	1	1 (2.33)	0	0 (0.00)
Mood altered	1	1 (2.33)	0	0 (0.00)
Nightmare	1	1 (2.33)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.33)	0	0 (0.00)
Sleep disorder	1	1 (2.33)	0	0 (0.00)
Tearfulness	1	1 (2.33)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (9.30)	2	2 (4.65)
Acute kidney injury	2	2 (4.65)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (2.33)	0	0 (0.00)
Dysuria	1	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Haematuria	1	1 (2.33)	1	1 (2.33)
Kidney enlargement	1	1 (2.33)	0	0 (0.00)
Renal mass	1	1 (2.33)	0	0 (0.00)
Renal tubular disorder	1	1 (2.33)	1	1 (2.33)
Respiratory, thoracic and mediastinal disorders				
- Total	22	12 (27.91)	4	4 (9.30)
Cough	7	5 (11.63)	0	0 (0.00)
Nasal congestion	3	3 (6.98)	0	0 (0.00)
Hypoxia	2	2 (4.65)	2	2 (4.65)
Pleural effusion	2	2 (4.65)	0	0 (0.00)
Bronchospasm	1	1 (2.33)	0	0 (0.00)
Epistaxis	1	1 (2.33)	0	0 (0.00)
Lung disorder	1	1 (2.33)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.33)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.33)	0	0 (0.00)
Respiratory distress	1	1 (2.33)	1	1 (2.33)
Respiratory failure	1	1 (2.33)	1	1 (2.33)
Rhinitis allergic	1	1 (2.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	15	10 (23.26)	0	0 (0.00)
Rash	5	3 (6.98)	0	0 (0.00)
Dry skin	2	2 (4.65)	0	0 (0.00)
Dermatitis allergic	1	1 (2.33)	0	0 (0.00)
Erythema	1	1 (2.33)	0	0 (0.00)
Ingrowing nail	1	1 (2.33)	0	0 (0.00)
Miliaria	1	1 (2.33)	0	0 (0.00)
Night sweats	1	1 (2.33)	0	0 (0.00)
Photosensitivity reaction	1	1 (2.33)	0	0 (0.00)
Skin discolouration	1	1 (2.33)	0	0 (0.00)
Skin swelling	1	1 (2.33)	0	0 (0.00)
Vascular disorders				
- Total	5	4 (9.30)	3	3 (6.98)
Hypotension	2	2 (4.65)	1	1 (2.33)
Venoocclusive disease	2	2 (4.65)	2	2 (4.65)
Hypertension	1	1 (2.33)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	218	29 (90.63)	55	14 (43.75)
Blood and lymphatic system disorders				
- Total	11	7 (21.88)	5	5 (15.63)
Anaemia	5	4 (12.50)	1	1 (3.13)
Neutropenia	4	4 (12.50)	4	4 (12.50)
B-cell aplasia	2	1 (3.13)	0	0 (0.00)
Cardiac disorders				
- Total	2	2 (6.25)	2	2 (6.25)
Cardiac arrest	1	1 (3.13)	1	1 (3.13)
Cardiac failure	1	1 (3.13)	1	1 (3.13)
Endocrine disorders				
- Total	1	1 (3.13)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hypothyroidism	1	1 (3.13)	0	0 (0.00)
Eye disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Ocular hyperaemia	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	17	7 (21.88)	0	0 (0.00)
Vomiting	4	3 (9.38)	0	0 (0.00)
Nausea	3	3 (9.38)	0	0 (0.00)
Diarrhoea	2	2 (6.25)	0	0 (0.00)
Abdominal pain	1	1 (3.13)	0	0 (0.00)
Abdominal pain upper	1	1 (3.13)	0	0 (0.00)
Abdominal rigidity	1	1 (3.13)	0	0 (0.00)
Constipation	1	1 (3.13)	0	0 (0.00)
Dyspepsia	1	1 (3.13)	0	0 (0.00)
Pancreatitis	1	1 (3.13)	0	0 (0.00)
Proctalgia	1	1 (3.13)	0	0 (0.00)
Stomatitis	1	1 (3.13)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	16	11 (34.38)	1	1 (3.13)
Pyrexia	6	5 (15.63)	0	0 (0.00)
Fatigue	4	3 (9.38)	0	0 (0.00)
Oedema peripheral	2	1 (3.13)	0	0 (0.00)
Pain	2	2 (6.25)	1	1 (3.13)
Chills	1	1 (3.13)	0	0 (0.00)
Non-cardiac chest pain	1	1 (3.13)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Hypertransaminasaemia	1	1 (3.13)	0	0 (0.00)
Immune system disorders				
- Total	8	6 (18.75)	1	1 (3.13)
Hypogammaglobulinaemia	7	5 (15.63)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (3.13)	1	1 (3.13)
Infections and infestations				
- Total	45	16 (50.00)	23	8 (25.00)
Bronchopulmonary aspergillosis	5	1 (3.13)	3	1 (3.13)
Upper respiratory tract infection	4	2 (6.25)	1	1 (3.13)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Gastroenteritis	3	3 (9.38)	2	2 (6.25)
Rhinovirus infection	3	3 (9.38)	1	1 (3.13)
Sinusitis	3	2 (6.25)	1	1 (3.13)
Bacteraemia	2	1 (3.13)	2	1 (3.13)
Klebsiella infection	2	1 (3.13)	2	1 (3.13)
Nasopharyngitis	2	2 (6.25)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (6.25)	1	1 (3.13)
Urinary tract infection	2	1 (3.13)	2	1 (3.13)
Acute sinusitis	1	1 (3.13)	0	0 (0.00)
Cystitis	1	1 (3.13)	0	0 (0.00)
Ear infection	1	1 (3.13)	0	0 (0.00)
Ear, nose and throat infection	1	1 (3.13)	0	0 (0.00)
Enterobacter infection	1	1 (3.13)	1	1 (3.13)
Mastoiditis	1	1 (3.13)	1	1 (3.13)
Oral candidiasis	1	1 (3.13)	0	0 (0.00)
Otitis externa	1	1 (3.13)	1	1 (3.13)
Otitis media	1	1 (3.13)	1	1 (3.13)
Pharyngitis streptococcal	1	1 (3.13)	1	1 (3.13)
Respiratory syncytial virus infection	1	1 (3.13)	1	1 (3.13)
Respiratory tract infection	1	1 (3.13)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Respiratory tract infection viral	1	1 (3.13)	0	0 (0.00)
Rhinitis	1	1 (3.13)	0	0 (0.00)
Septic shock	1	1 (3.13)	1	1 (3.13)
Staphylococcal skin infection	1	1 (3.13)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.13)	1	1 (3.13)
Injury, poisoning and procedural complications				
- Total	5	4 (12.50)	0	0 (0.00)
Infusion related reaction	3	2 (6.25)	0	0 (0.00)
Limb injury	1	1 (3.13)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (3.13)	0	0 (0.00)
Investigations				
- Total	34	12 (37.50)	10	6 (18.75)
Neutrophil count decreased	12	6 (18.75)	5	3 (9.38)
White blood cell count decreased	11	5 (15.63)	3	3 (9.38)
Platelet count decreased	3	2 (6.25)	0	0 (0.00)
Weight increased	3	1 (3.13)	1	1 (3.13)
Lymphocyte count decreased	2	2 (6.25)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.13)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood thyroid stimulating hormone increased	1	1 (3.13)	0	0 (0.00)
Blood uric acid increased	1	1 (3.13)	1	1 (3.13)
Metabolism and nutrition disorders				
- Total	11	7 (21.88)	4	4 (12.50)
Hyperuricaemia	2	2 (6.25)	0	0 (0.00)
Hypokalaemia	2	2 (6.25)	1	1 (3.13)
Decreased appetite	1	1 (3.13)	0	0 (0.00)
Hyperchloraemia	1	1 (3.13)	0	0 (0.00)
Hypophagia	1	1 (3.13)	0	0 (0.00)
Malnutrition	1	1 (3.13)	1	1 (3.13)
Metabolic acidosis	1	1 (3.13)	1	1 (3.13)
Metabolic syndrome	1	1 (3.13)	0	0 (0.00)
Tumour lysis syndrome	1	1 (3.13)	1	1 (3.13)
Musculoskeletal and connective tissue disorders				
- Total	7	6 (18.75)	1	1 (3.13)
Back pain	3	2 (6.25)	0	0 (0.00)
Pain in extremity	2	2 (6.25)	1	1 (3.13)
Bone pain	1	1 (3.13)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Musculoskeletal pain	1	1 (3.13)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.13)	1	1 (3.13)
Myelodysplastic syndrome	1	1 (3.13)	1	1 (3.13)
Nervous system disorders				
- Total	11	8 (25.00)	0	0 (0.00)
Headache	8	7 (21.88)	0	0 (0.00)
Migraine	2	1 (3.13)	0	0 (0.00)
Extrapyramidal disorder	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (12.50)	1	1 (3.13)
Anxiety	2	2 (6.25)	0	0 (0.00)
Mental status changes	2	2 (6.25)	1	1 (3.13)
Renal and urinary disorders				
- Total	1	1 (3.13)	1	1 (3.13)
Acute kidney injury	1	1 (3.13)	1	1 (3.13)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (3.13)	0	0 (0.00)
Dysmenorrhoea	2	1 (3.13)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	24	12 (37.50)	2	2 (6.25)
Cough	7	6 (18.75)	0	0 (0.00)
Nasal congestion	4	3 (9.38)	0	0 (0.00)
Rhinorrhoea	3	3 (9.38)	0	0 (0.00)
Dyspnoea	2	1 (3.13)	0	0 (0.00)
Epistaxis	2	2 (6.25)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (3.13)	1	1 (3.13)
Bronchial oedema	1	1 (3.13)	0	0 (0.00)
Hypoxia	1	1 (3.13)	1	1 (3.13)
Oropharyngeal pain	1	1 (3.13)	0	0 (0.00)
Rhinitis allergic	1	1 (3.13)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (3.13)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	14	10 (31.25)	1	1 (3.13)
Dry skin	5	4 (12.50)	0	0 (0.00)
Pruritus	2	1 (3.13)	0	0 (0.00)
Decubitus ulcer	1	1 (3.13)	1	1 (3.13)
Dermatitis atopic	1	1 (3.13)	0	0 (0.00)
Eczema	1	1 (3.13)	0	0 (0.00)
Hangnail	1	1 (3.13)	0	0 (0.00)
Ingrowing nail	1	1 (3.13)	0	0 (0.00)
Rash	1	1 (3.13)	0	0 (0.00)
Skin hypopigmentation	1	1 (3.13)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (6.25)	2	2 (6.25)
Hypotension	2	2 (6.25)	2	2 (6.25)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Total number of AE per patient	119	19 (65.52)	37	10 (34.48)
Blood and lymphatic system disorders				
- Total	4	2 (6.90)	1	1 (3.45)
Agranulocytosis	1	1 (3.45)	1	1 (3.45)
Anaemia	1	1 (3.45)	0	0 (0.00)
Hypercoagulation	1	1 (3.45)	0	0 (0.00)
Thrombocytopenia	1	1 (3.45)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (3.45)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (3.45)	0	0 (0.00)
Ear and labyrinth disorders				

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
- Total	1	1 (3.45)	0	0 (0.00)
Deafness unilateral	1	1 (3.45)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (3.45)	0	0 (0.00)
Delayed puberty	1	1 (3.45)	0	0 (0.00)
Hypothyroidism	1	1 (3.45)	0	0 (0.00)
Eye disorders				
- Total	4	3 (10.34)	1	1 (3.45)
Dry eye	1	1 (3.45)	0	0 (0.00)
Eye pain	1	1 (3.45)	1	1 (3.45)
Eyelid oedema	1	1 (3.45)	0	0 (0.00)
Mydriasis	1	1 (3.45)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	4 (13.79)	1	1 (3.45)
Diarrhoea	3	3 (10.34)	1	1 (3.45)
Irritable bowel syndrome	1	1 (3.45)	0	0 (0.00)
Nausea	1	1 (3.45)	0	0 (0.00)
Vomiting	1	1 (3.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
General disorders and administration site conditions				
- Total	8	7 (24.14)	2	2 (6.90)
Pyrexia	3	3 (10.34)	1	1 (3.45)
Fatigue	1	1 (3.45)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.45)	1	1 (3.45)
Non-cardiac chest pain	1	1 (3.45)	0	0 (0.00)
Pain	1	1 (3.45)	0	0 (0.00)
Xerosis	1	1 (3.45)	0	0 (0.00)
Immune system disorders				
- Total	5	4 (13.79)	2	1 (3.45)
Chronic graft versus host disease	2	2 (6.90)	1	1 (3.45)
Seasonal allergy	2	2 (6.90)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (3.45)	1	1 (3.45)
Infections and infestations				
- Total	50	13 (44.83)	17	9 (31.03)
Conjunctivitis	5	4 (13.79)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Sinusitis	5	2 (6.90)	0	0 (0.00)
Upper respiratory tract infection	4	2 (6.90)	1	1 (3.45)
COVID-19	3	2 (6.90)	1	1 (3.45)
Influenza	2	2 (6.90)	1	1 (3.45)
Oral herpes	2	2 (6.90)	0	0 (0.00)
Otitis media	2	1 (3.45)	0	0 (0.00)
Pneumonia	2	2 (6.90)	2	2 (6.90)
Rhinovirus infection	2	2 (6.90)	1	1 (3.45)
Sepsis	2	2 (6.90)	2	2 (6.90)
Skin infection	2	2 (6.90)	0	0 (0.00)
Acute sinusitis	1	1 (3.45)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.45)	1	1 (3.45)
Candida infection	1	1 (3.45)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.45)	1	1 (3.45)
Ear infection	1	1 (3.45)	1	1 (3.45)
Enterovirus infection	1	1 (3.45)	1	1 (3.45)
Gastroenteritis Escherichia coli	1	1 (3.45)	1	1 (3.45)
Gastroenteritis salmonella	1	1 (3.45)	1	1 (3.45)
Herpes virus infection	1	1 (3.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Herpes zoster	1	1 (3.45)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (3.45)	0	0 (0.00)
Otitis media acute	1	1 (3.45)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.45)	1	1 (3.45)
Rhinitis	1	1 (3.45)	0	0 (0.00)
Staphylococcal abscess	1	1 (3.45)	1	1 (3.45)
Staphylococcal bacteraemia	1	1 (3.45)	1	1 (3.45)
Streptococcal sepsis	1	1 (3.45)	0	0 (0.00)
Syphilis	1	1 (3.45)	0	0 (0.00)
Viral skin infection	1	1 (3.45)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.45)	1	1 (3.45)
Infusion related reaction	1	1 (3.45)	1	1 (3.45)
Investigations				
- Total	8	3 (10.34)	1	1 (3.45)
Blood bilirubin increased	3	1 (3.45)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.45)	0	0 (0.00)
Neutrophil count decreased	1	1 (3.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Oxygen saturation decreased	1	1 (3.45)	1	1 (3.45)
Platelet count decreased	1	1 (3.45)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (3.45)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (6.90)	3	2 (6.90)
Decreased appetite	2	1 (3.45)	2	1 (3.45)
Hyperglycaemia	1	1 (3.45)	1	1 (3.45)
Musculoskeletal and connective tissue disorders				
- Total	4	4 (13.79)	0	0 (0.00)
Arthralgia	1	1 (3.45)	0	0 (0.00)
Osteonecrosis	1	1 (3.45)	0	0 (0.00)
Osteopenia	1	1 (3.45)	0	0 (0.00)
Pain in extremity	1	1 (3.45)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (6.90)	1	1 (3.45)
Headache	2	1 (3.45)	1	1 (3.45)
Dysarthria	1	1 (3.45)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Psychiatric disorders				
- Total	1	1 (3.45)	0	0 (0.00)
Anxiety	1	1 (3.45)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	14	5 (17.24)	4	2 (6.90)
Cough	4	4 (13.79)	0	0 (0.00)
Dyspnoea	2	2 (6.90)	1	1 (3.45)
Rhinorrhoea	2	2 (6.90)	0	0 (0.00)
Tachypnoea	2	1 (3.45)	2	1 (3.45)
Laryngeal oedema	1	1 (3.45)	1	1 (3.45)
Oropharyngeal pain	1	1 (3.45)	0	0 (0.00)
Pleural effusion	1	1 (3.45)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (3.45)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (10.34)	2	2 (6.90)
Dermatitis atopic	1	1 (3.45)	1	1 (3.45)
Eczema	1	1 (3.45)	1	1 (3.45)

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=29 n (%)[1]	Grade >= 3 Total events	All patients N=29 n (%)[2]
Papule	1	1 (3.45)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (3.45)	1	1 (3.45)
Hypertension	1	1 (3.45)	1	1 (3.45)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Total number of AE per patient	101	13 (61.90)	26	9 (42.86)
Blood and lymphatic system disorders				
- Total	2	2 (9.52)	1	1 (4.76)
Lymphadenopathy	1	1 (4.76)	0	0 (0.00)
Neutropenia	1	1 (4.76)	1	1 (4.76)
Gastrointestinal disorders				
- Total	3	3 (14.29)	0	0 (0.00)
Diarrhoea	2	2 (9.52)	0	0 (0.00)
Constipation	1	1 (4.76)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	2 (9.52)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Pyrexia	4	2 (9.52)	0	0 (0.00)
Pain	1	1 (4.76)	0	0 (0.00)
Immune system disorders				
- Total	5	5 (23.81)	1	1 (4.76)
Hypogammaglobulinaemia	3	3 (14.29)	0	0 (0.00)
Drug hypersensitivity	1	1 (4.76)	1	1 (4.76)
Seasonal allergy	1	1 (4.76)	0	0 (0.00)
Infections and infestations				
- Total	36	10 (47.62)	9	5 (23.81)
Sinusitis	4	4 (19.05)	0	0 (0.00)
Fungal infection	3	2 (9.52)	0	0 (0.00)
Upper respiratory tract infection	3	3 (14.29)	0	0 (0.00)
Bronchitis	2	2 (9.52)	0	0 (0.00)
Device related sepsis	2	1 (4.76)	2	1 (4.76)
Gastroenteritis viral	2	1 (4.76)	0	0 (0.00)
Rhinovirus infection	2	2 (9.52)	0	0 (0.00)
Urinary tract infection	2	2 (9.52)	0	0 (0.00)
Bronchiolitis	1	1 (4.76)	1	1 (4.76)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Folliculitis	1	1 (4.76)	0	0 (0.00)
Fungal skin infection	1	1 (4.76)	0	0 (0.00)
Gastroenteritis	1	1 (4.76)	0	0 (0.00)
Herpes zoster	1	1 (4.76)	1	1 (4.76)
Meningitis pneumococcal	1	1 (4.76)	1	1 (4.76)
Nail infection	1	1 (4.76)	0	0 (0.00)
Neutropenic infection	1	1 (4.76)	1	1 (4.76)
Oral candidiasis	1	1 (4.76)	0	0 (0.00)
Otitis media	1	1 (4.76)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (4.76)	1	1 (4.76)
Sepsis	1	1 (4.76)	1	1 (4.76)
Septic shock	1	1 (4.76)	1	1 (4.76)
Skin infection	1	1 (4.76)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (4.76)	0	0 (0.00)
Varicella zoster virus infection	1	1 (4.76)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (9.52)	0	0 (0.00)
Abdominal injury	1	1 (4.76)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Ligament sprain	1	1 (4.76)	0	0 (0.00)
Investigations				
- Total	8	3 (14.29)	5	1 (4.76)
Neutrophil count decreased	7	2 (9.52)	5	1 (4.76)
Platelet count decreased	1	1 (4.76)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	7	4 (19.05)	2	2 (9.52)
Iron overload	2	1 (4.76)	0	0 (0.00)
Hypercholesterolaemia	1	1 (4.76)	0	0 (0.00)
Hyperlipidaemia	1	1 (4.76)	0	0 (0.00)
Hypernatraemia	1	1 (4.76)	1	1 (4.76)
Hypertriglyceridaemia	1	1 (4.76)	0	0 (0.00)
Obesity	1	1 (4.76)	1	1 (4.76)
Musculoskeletal and connective tissue disorders				
- Total	4	3 (14.29)	0	0 (0.00)
Growth retardation	1	1 (4.76)	0	0 (0.00)
Joint effusion	1	1 (4.76)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Pain in extremity	1	1 (4.76)	0	0 (0.00)
Synovitis	1	1 (4.76)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (4.76)	1	1 (4.76)
Bone giant cell tumour benign	2	1 (4.76)	1	1 (4.76)
Nervous system disorders				
- Total	6	2 (9.52)	2	1 (4.76)
Seizure	3	1 (4.76)	1	1 (4.76)
Nervous system disorder	2	1 (4.76)	1	1 (4.76)
Headache	1	1 (4.76)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (9.52)	0	0 (0.00)
Anxiety	1	1 (4.76)	0	0 (0.00)
Tic	1	1 (4.76)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (4.76)	1	1 (4.76)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Endometriosis	2	1 (4.76)	1	1 (4.76)
Respiratory, thoracic and mediastinal disorders				
- Total	9	5 (23.81)	2	2 (9.52)
Dyspnoea	1	1 (4.76)	0	0 (0.00)
Dyspnoea exertional	1	1 (4.76)	0	0 (0.00)
Epistaxis	1	1 (4.76)	0	0 (0.00)
Hypoxia	1	1 (4.76)	1	1 (4.76)
Pharyngeal erythema	1	1 (4.76)	0	0 (0.00)
Respiratory failure	1	1 (4.76)	1	1 (4.76)
Rhinorrhoea	1	1 (4.76)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (4.76)	0	0 (0.00)
Wheezing	1	1 (4.76)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	4 (19.05)	2	1 (4.76)
Rash	2	2 (9.52)	0	0 (0.00)
Rash macular	2	1 (4.76)	2	1 (4.76)
Dry skin	1	1 (4.76)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=21 n (%)[1]	Grade >= 3 Total events	All patients N=21 n (%)[2]
Rash erythematous	1	1 (4.76)	0	0 (0.00)
Rash maculo-papular	1	1 (4.76)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (4.76)	0	0 (0.00)
Hypertension	1	1 (4.76)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Total number of AE per patient	1206	46 (100.00)	388	41 (89.13)
Blood and lymphatic system disorders				
- Total	74	27 (58.70)	42	18 (39.13)
Anaemia	20	9 (19.57)	8	3 (6.52)
Febrile neutropenia	15	12 (26.09)	15	12 (26.09)
Thrombocytopenia	8	6 (13.04)	7	6 (13.04)
Disseminated intravascular coagulation	6	6 (13.04)	1	1 (2.17)
Neutropenia	6	4 (8.70)	5	3 (6.52)
Leukopenia	4	2 (4.35)	2	1 (2.17)
Eosinophilia	3	1 (2.17)	0	0 (0.00)
Coagulopathy	2	2 (4.35)	0	0 (0.00)
Lymphopenia	2	2 (4.35)	2	2 (4.35)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Splenomegaly	2	2 (4.35)	0	0 (0.00)
Agranulocytosis	1	1 (2.17)	1	1 (2.17)
Hypercoagulation	1	1 (2.17)	0	0 (0.00)
Leukocytosis	1	1 (2.17)	0	0 (0.00)
Lymphadenopathy	1	1 (2.17)	0	0 (0.00)
Lymphocytosis	1	1 (2.17)	0	0 (0.00)
Pancytopenia	1	1 (2.17)	1	1 (2.17)
Cardiac disorders				
- Total	27	13 (28.26)	6	5 (10.87)
Tachycardia	13	9 (19.57)	2	2 (4.35)
Left ventricular dysfunction	3	3 (6.52)	2	2 (4.35)
Bradycardia	2	2 (4.35)	0	0 (0.00)
Atrioventricular block first degree	1	1 (2.17)	0	0 (0.00)
Cardiac arrest	1	1 (2.17)	1	1 (2.17)
Cardiac dysfunction	1	1 (2.17)	0	0 (0.00)
Cardiac failure	1	1 (2.17)	1	1 (2.17)
Cardiac failure congestive	1	1 (2.17)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.17)	0	0 (0.00)
Pericardial effusion	1	1 (2.17)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Right ventricular dysfunction	1	1 (2.17)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.17)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.17)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.17)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (4.35)	0	0 (0.00)
Deafness unilateral	1	1 (2.17)	0	0 (0.00)
Ear pain	1	1 (2.17)	0	0 (0.00)
Endocrine disorders				
- Total	4	3 (6.52)	0	0 (0.00)
Hypothyroidism	2	2 (4.35)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.17)	0	0 (0.00)
Delayed puberty	1	1 (2.17)	0	0 (0.00)
Eye disorders				
- Total	16	10 (21.74)	1	1 (2.17)
Eyelid oedema	3	2 (4.35)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Cataract	2	2 (4.35)	0	0 (0.00)
Eye pain	2	2 (4.35)	1	1 (2.17)
Ocular hyperaemia	2	2 (4.35)	0	0 (0.00)
Visual impairment	2	2 (4.35)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.17)	0	0 (0.00)
Dry eye	1	1 (2.17)	0	0 (0.00)
Eye oedema	1	1 (2.17)	0	0 (0.00)
Hypermetropia	1	1 (2.17)	0	0 (0.00)
Mydriasis	1	1 (2.17)	0	0 (0.00)
Gastrointestinal disorders				
- Total	98	35 (76.09)	11	10 (21.74)
Vomiting	20	15 (32.61)	0	0 (0.00)
Nausea	17	14 (30.43)	1	1 (2.17)
Diarrhoea	15	14 (30.43)	2	2 (4.35)
Abdominal pain	8	6 (13.04)	2	2 (4.35)
Constipation	8	7 (15.22)	0	0 (0.00)
Pancreatitis	4	4 (8.70)	2	2 (4.35)
Abdominal pain upper	2	2 (4.35)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.35)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Mouth haemorrhage	2	2 (4.35)	1	1 (2.17)
Trichoglossia	2	2 (4.35)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (2.17)	1	1 (2.17)
Abdominal distension	1	1 (2.17)	0	0 (0.00)
Anal fissure	1	1 (2.17)	0	0 (0.00)
Ascites	1	1 (2.17)	0	0 (0.00)
Dry mouth	1	1 (2.17)	0	0 (0.00)
Enteritis	1	1 (2.17)	0	0 (0.00)
Enterocolitis	1	1 (2.17)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.17)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.17)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.17)	0	0 (0.00)
Haematemesis	1	1 (2.17)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.17)	0	0 (0.00)
Mouth swelling	1	1 (2.17)	0	0 (0.00)
Neutropenic colitis	1	1 (2.17)	1	1 (2.17)
Odynophagia	1	1 (2.17)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.17)	0	0 (0.00)
Proctalgia	1	1 (2.17)	1	1 (2.17)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Upper gastrointestinal haemorrhage	1	1 (2.17)	0	0 (0.00)
General disorders and administration site conditions				
- Total	67	28 (60.87)	12	8 (17.39)
Pyrexia	27	19 (41.30)	6	6 (13.04)
Fatigue	11	11 (23.91)	0	0 (0.00)
Face oedema	5	4 (8.70)	1	1 (2.17)
Chills	4	3 (6.52)	0	0 (0.00)
Oedema peripheral	4	3 (6.52)	2	1 (2.17)
Asthenia	2	2 (4.35)	0	0 (0.00)
Catheter site erythema	2	1 (2.17)	0	0 (0.00)
Pain	2	2 (4.35)	1	1 (2.17)
Catheter site pain	1	1 (2.17)	0	0 (0.00)
Chest discomfort	1	1 (2.17)	1	1 (2.17)
Generalised oedema	1	1 (2.17)	0	0 (0.00)
Localised oedema	1	1 (2.17)	0	0 (0.00)
Malaise	1	1 (2.17)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.17)	1	1 (2.17)
Non-cardiac chest pain	1	1 (2.17)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Oedema due to hepatic disease	1	1 (2.17)	0	0 (0.00)
Vascular device occlusion	1	1 (2.17)	0	0 (0.00)
Xerosis	1	1 (2.17)	0	0 (0.00)
Hepatobiliary disorders				
- Total	16	10 (21.74)	3	2 (4.35)
Hepatic function abnormal	6	2 (4.35)	3	2 (4.35)
Hepatomegaly	2	2 (4.35)	0	0 (0.00)
Hyperbilirubinaemia	2	2 (4.35)	0	0 (0.00)
Biliary tract disorder	1	1 (2.17)	0	0 (0.00)
Gallbladder enlargement	1	1 (2.17)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.17)	0	0 (0.00)
Hypertransaminasaemia	1	1 (2.17)	0	0 (0.00)
Liver disorder	1	1 (2.17)	0	0 (0.00)
Ocular icterus	1	1 (2.17)	0	0 (0.00)
Immune system disorders				
- Total	100	39 (84.78)	40	25 (54.35)
Cytokine release syndrome	63	31 (67.39)	27	19 (41.30)
Hypogammaglobulinaemia	19	17 (36.96)	3	3 (6.52)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Haemophagocytic lymphohistiocytosis	4	4 (8.70)	3	3 (6.52)
Immunodeficiency	3	3 (6.52)	3	3 (6.52)
Chronic graft versus host disease	2	2 (4.35)	1	1 (2.17)
Graft versus host disease	2	2 (4.35)	2	2 (4.35)
Seasonal allergy	2	2 (4.35)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (2.17)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.17)	0	0 (0.00)
Engraftment syndrome	1	1 (2.17)	1	1 (2.17)
Hypersensitivity	1	1 (2.17)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (2.17)	0	0 (0.00)
Infections and infestations				
- Total	147	36 (78.26)	49	21 (45.65)
Conjunctivitis	10	6 (13.04)	0	0 (0.00)
Upper respiratory tract infection	10	8 (17.39)	2	2 (4.35)
Nasopharyngitis	7	5 (10.87)	0	0 (0.00)
Pneumonia	6	6 (13.04)	4	4 (8.70)
Sinusitis	6	2 (4.35)	0	0 (0.00)
Oral herpes	4	3 (6.52)	1	1 (2.17)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Otitis media	4	3 (6.52)	0	0 (0.00)
Parainfluenzae virus infection	4	3 (6.52)	2	2 (4.35)
Rhinovirus infection	4	4 (8.70)	1	1 (2.17)
COVID-19	3	2 (4.35)	1	1 (2.17)
Candida infection	3	3 (6.52)	0	0 (0.00)
Clostridium difficile infection	3	3 (6.52)	2	2 (4.35)
Ear infection	3	2 (4.35)	1	1 (2.17)
Influenza	3	3 (6.52)	1	1 (2.17)
Metapneumovirus infection	3	3 (6.52)	3	3 (6.52)
Staphylococcal bacteraemia	3	3 (6.52)	3	3 (6.52)
Staphylococcal infection	3	3 (6.52)	1	1 (2.17)
BK virus infection	2	2 (4.35)	1	1 (2.17)
Gastroenteritis	2	2 (4.35)	0	0 (0.00)
Gingivitis	2	2 (4.35)	0	0 (0.00)
Herpes zoster	2	2 (4.35)	1	1 (2.17)
Nail infection	2	2 (4.35)	0	0 (0.00)
Oral infection	2	2 (4.35)	0	0 (0.00)
Otitis externa	2	2 (4.35)	0	0 (0.00)
Paronychia	2	2 (4.35)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Pneumocystis jirovecii pneumonia	2	2 (4.35)	2	2 (4.35)
Respiratory syncytial virus infection	2	2 (4.35)	1	1 (2.17)
Respiratory tract infection	2	2 (4.35)	0	0 (0.00)
Rhinitis	2	2 (4.35)	0	0 (0.00)
Sepsis	2	2 (4.35)	2	2 (4.35)
Skin infection	2	2 (4.35)	0	0 (0.00)
Viral infection	2	2 (4.35)	1	1 (2.17)
Acute sinusitis	1	1 (2.17)	0	0 (0.00)
Adenovirus infection	1	1 (2.17)	1	1 (2.17)
Anal abscess	1	1 (2.17)	1	1 (2.17)
Atypical pneumonia	1	1 (2.17)	0	0 (0.00)
Bacteraemia	1	1 (2.17)	0	0 (0.00)
COVID-19 pneumonia	1	1 (2.17)	1	1 (2.17)
Cellulitis	1	1 (2.17)	0	0 (0.00)
Cholecystitis infective	1	1 (2.17)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.17)	1	1 (2.17)
Coronavirus infection	1	1 (2.17)	1	1 (2.17)
Cytomegalovirus infection reactivation	1	1 (2.17)	1	1 (2.17)
Device related infection	1	1 (2.17)	1	1 (2.17)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Encephalitis	1	1 (2.17)	1	1 (2.17)
Enterovirus infection	1	1 (2.17)	1	1 (2.17)
Gastroenteritis Escherichia coli	1	1 (2.17)	1	1 (2.17)
Gastroenteritis clostridial	1	1 (2.17)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (2.17)	1	1 (2.17)
Gastroenteritis viral	1	1 (2.17)	0	0 (0.00)
Gastrointestinal infection	1	1 (2.17)	0	0 (0.00)
Herpes simplex	1	1 (2.17)	0	0 (0.00)
Herpes virus infection	1	1 (2.17)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.17)	1	1 (2.17)
Klebsiella bacteraemia	1	1 (2.17)	0	0 (0.00)
Molluscum contagiosum	1	1 (2.17)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (2.17)	0	0 (0.00)
Otitis media acute	1	1 (2.17)	0	0 (0.00)
Pneumonia fungal	1	1 (2.17)	1	1 (2.17)
Salmonellosis	1	1 (2.17)	0	0 (0.00)
Sinusitis fungal	1	1 (2.17)	1	1 (2.17)
Soft tissue infection	1	1 (2.17)	1	1 (2.17)
Staphylococcal abscess	1	1 (2.17)	1	1 (2.17)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Staphylococcal sepsis	1	1 (2.17)	1	1 (2.17)
Streptococcal sepsis	1	1 (2.17)	0	0 (0.00)
Syphilis	1	1 (2.17)	0	0 (0.00)
Tinea pedis	1	1 (2.17)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.17)	1	1 (2.17)
Viral haemorrhagic cystitis	1	1 (2.17)	1	1 (2.17)
Viral skin infection	1	1 (2.17)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	10	9 (19.57)	1	1 (2.17)
Infusion related reaction	2	2 (4.35)	1	1 (2.17)
Transfusion reaction	2	2 (4.35)	0	0 (0.00)
Contusion	1	1 (2.17)	0	0 (0.00)
Fall	1	1 (2.17)	0	0 (0.00)
Fibula fracture	1	1 (2.17)	0	0 (0.00)
Ligament sprain	1	1 (2.17)	0	0 (0.00)
Scratch	1	1 (2.17)	0	0 (0.00)
Skin abrasion	1	1 (2.17)	0	0 (0.00)
Investigations				

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
- Total	243	32 (69.57)	112	24 (52.17)
Platelet count decreased	44	12 (26.09)	24	8 (17.39)
White blood cell count decreased	32	12 (26.09)	18	9 (19.57)
Neutrophil count decreased	25	12 (26.09)	22	11 (23.91)
Alanine aminotransferase increased	19	13 (28.26)	4	4 (8.70)
Blood bilirubin increased	16	9 (19.57)	8	7 (15.22)
Aspartate aminotransferase increased	14	12 (26.09)	6	6 (13.04)
Lymphocyte count decreased	13	7 (15.22)	9	7 (15.22)
Immunoglobulins decreased	10	2 (4.35)	0	0 (0.00)
Serum ferritin increased	6	6 (13.04)	1	1 (2.17)
Activated partial thromboplastin time prolonged	5	4 (8.70)	1	1 (2.17)
Blood fibrinogen decreased	4	4 (8.70)	1	1 (2.17)
Blood immunoglobulin A decreased	4	4 (8.70)	1	1 (2.17)
Blood lactate dehydrogenase increased	4	4 (8.70)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (2.17)	1	1 (2.17)
Blood creatinine increased	3	3 (6.52)	2	2 (4.35)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Blood immunoglobulin M decreased	3	3 (6.52)	2	2 (4.35)
C-reactive protein increased	3	3 (6.52)	1	1 (2.17)
International normalised ratio increased	3	3 (6.52)	0	0 (0.00)
Oxygen saturation decreased	3	3 (6.52)	1	1 (2.17)
Blood immunoglobulin G decreased	2	2 (4.35)	0	0 (0.00)
Blood uric acid increased	2	2 (4.35)	1	1 (2.17)
Electrocardiogram QT prolonged	2	2 (4.35)	1	1 (2.17)
Fibrin D dimer increased	2	2 (4.35)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (4.35)	2	2 (4.35)
Haemoglobin decreased	2	1 (2.17)	1	1 (2.17)
Weight increased	2	2 (4.35)	1	1 (2.17)
Amylase increased	1	1 (2.17)	0	0 (0.00)
Bacterial test positive	1	1 (2.17)	1	1 (2.17)
Blood testosterone decreased	1	1 (2.17)	0	0 (0.00)
Blood urea increased	1	1 (2.17)	1	1 (2.17)
Bone density decreased	1	1 (2.17)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.17)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.17)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Heart sounds abnormal	1	1 (2.17)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.17)	0	0 (0.00)
Lipase increased	1	1 (2.17)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.17)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (2.17)	0	0 (0.00)
Staphylococcus test positive	1	1 (2.17)	0	0 (0.00)
Urine output decreased	1	1 (2.17)	1	1 (2.17)
Weight decreased	1	1 (2.17)	1	1 (2.17)
Metabolism and nutrition disorders				
- Total	103	28 (60.87)	39	15 (32.61)
Hypokalaemia	18	9 (19.57)	10	5 (10.87)
Decreased appetite	17	15 (32.61)	7	5 (10.87)
Hypophosphataemia	13	8 (17.39)	3	3 (6.52)
Hypocalcaemia	12	9 (19.57)	3	3 (6.52)
Hypoalbuminaemia	8	4 (8.70)	0	0 (0.00)
Hyperuricaemia	6	5 (10.87)	0	0 (0.00)
Hyperglycaemia	4	4 (8.70)	4	4 (8.70)
Hypervolaemia	3	3 (6.52)	2	2 (4.35)
Hypomagnesaemia	3	3 (6.52)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Tumour lysis syndrome	3	3 (6.52)	3	3 (6.52)
Hyperkalaemia	2	2 (4.35)	1	1 (2.17)
Hypermagnesaemia	2	1 (2.17)	0	0 (0.00)
Hyperphosphataemia	2	2 (4.35)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (4.35)	2	2 (4.35)
Metabolic acidosis	2	2 (4.35)	1	1 (2.17)
Dehydration	1	1 (2.17)	0	0 (0.00)
Haemochromatosis	1	1 (2.17)	1	1 (2.17)
Hypercalcaemia	1	1 (2.17)	1	1 (2.17)
Hypernatraemia	1	1 (2.17)	0	0 (0.00)
Iron overload	1	1 (2.17)	0	0 (0.00)
Malnutrition	1	1 (2.17)	1	1 (2.17)
Musculoskeletal and connective tissue disorders				
- Total	42	23 (50.00)	2	2 (4.35)
Arthralgia	11	9 (19.57)	0	0 (0.00)
Pain in extremity	11	10 (21.74)	0	0 (0.00)
Back pain	6	5 (10.87)	2	2 (4.35)
Myalgia	4	3 (6.52)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Bone pain	2	2 (4.35)	0	0 (0.00)
Growth retardation	1	1 (2.17)	0	0 (0.00)
Muscle spasms	1	1 (2.17)	0	0 (0.00)
Muscular weakness	1	1 (2.17)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.17)	0	0 (0.00)
Neck pain	1	1 (2.17)	0	0 (0.00)
Osteonecrosis	1	1 (2.17)	0	0 (0.00)
Osteopenia	1	1 (2.17)	0	0 (0.00)
Pain in jaw	1	1 (2.17)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (6.52)	0	0 (0.00)
Skin papilloma	2	2 (4.35)	0	0 (0.00)
Cancer pain	1	1 (2.17)	0	0 (0.00)
Nervous system disorders				
- Total	44	24 (52.17)	15	8 (17.39)
Headache	16	12 (26.09)	3	3 (6.52)
Dizziness	4	3 (6.52)	0	0 (0.00)
Encephalopathy	4	4 (8.70)	1	1 (2.17)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Hydrocephalus	3	1 (2.17)	3	1 (2.17)
Cerebral haemorrhage	2	2 (4.35)	2	2 (4.35)
Dysarthria	2	2 (4.35)	1	1 (2.17)
Dysgeusia	2	2 (4.35)	0	0 (0.00)
Somnolence	2	2 (4.35)	1	1 (2.17)
Autonomic neuropathy	1	1 (2.17)	1	1 (2.17)
Cognitive disorder	1	1 (2.17)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.17)	1	1 (2.17)
Hypoaesthesia	1	1 (2.17)	0	0 (0.00)
Lethargy	1	1 (2.17)	0	0 (0.00)
Memory impairment	1	1 (2.17)	0	0 (0.00)
Neuralgia	1	1 (2.17)	0	0 (0.00)
Neurological decompensation	1	1 (2.17)	1	1 (2.17)
Seizure	1	1 (2.17)	1	1 (2.17)
Psychiatric disorders				
- Total	35	21 (45.65)	2	2 (4.35)
Anxiety	8	8 (17.39)	0	0 (0.00)
Delirium	6	6 (13.04)	2	2 (4.35)
Confusional state	4	4 (8.70)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Agitation	3	3 (6.52)	0	0 (0.00)
Insomnia	3	3 (6.52)	0	0 (0.00)
Sleep disorder	3	2 (4.35)	0	0 (0.00)
Hallucination	1	1 (2.17)	0	0 (0.00)
Irritability	1	1 (2.17)	0	0 (0.00)
Mental status changes	1	1 (2.17)	0	0 (0.00)
Mood altered	1	1 (2.17)	0	0 (0.00)
Nightmare	1	1 (2.17)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.17)	0	0 (0.00)
Restlessness	1	1 (2.17)	0	0 (0.00)
Tearfulness	1	1 (2.17)	0	0 (0.00)
Renal and urinary disorders				
- Total	23	14 (30.43)	7	5 (10.87)
Acute kidney injury	5	5 (10.87)	2	2 (4.35)
Renal failure	4	2 (4.35)	3	1 (2.17)
Dysuria	3	3 (6.52)	0	0 (0.00)
Haematuria	3	3 (6.52)	1	1 (2.17)
Cystitis haemorrhagic	1	1 (2.17)	0	0 (0.00)
Incontinence	1	1 (2.17)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Kidney enlargement	1	1 (2.17)	0	0 (0.00)
Proteinuria	1	1 (2.17)	0	0 (0.00)
Renal mass	1	1 (2.17)	0	0 (0.00)
Renal tubular disorder	1	1 (2.17)	1	1 (2.17)
Renal tubular dysfunction	1	1 (2.17)	0	0 (0.00)
Urinary tract disorder	1	1 (2.17)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	87	28 (60.87)	31	13 (28.26)
Cough	15	13 (28.26)	0	0 (0.00)
Hypoxia	13	11 (23.91)	10	8 (17.39)
Pleural effusion	9	8 (17.39)	3	3 (6.52)
Oropharyngeal pain	6	5 (10.87)	0	0 (0.00)
Pulmonary oedema	6	6 (13.04)	3	3 (6.52)
Nasal congestion	5	5 (10.87)	0	0 (0.00)
Tachypnoea	5	4 (8.70)	3	2 (4.35)
Respiratory distress	4	3 (6.52)	3	2 (4.35)
Dyspnoea	3	3 (6.52)	2	2 (4.35)
Respiratory failure	3	3 (6.52)	3	3 (6.52)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Epistaxis	2	2 (4.35)	0	0 (0.00)
Lung infiltration	2	1 (2.17)	1	1 (2.17)
Rhinorrhoea	2	2 (4.35)	0	0 (0.00)
Atelectasis	1	1 (2.17)	1	1 (2.17)
Bradypnoea	1	1 (2.17)	1	1 (2.17)
Bronchospasm	1	1 (2.17)	0	0 (0.00)
Laryngeal oedema	1	1 (2.17)	1	1 (2.17)
Lung disorder	1	1 (2.17)	0	0 (0.00)
Painful respiration	1	1 (2.17)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.17)	0	0 (0.00)
Productive cough	1	1 (2.17)	0	0 (0.00)
Respiratory disorder	1	1 (2.17)	0	0 (0.00)
Rhinitis allergic	1	1 (2.17)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (2.17)	0	0 (0.00)
Wheezing	1	1 (2.17)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	39	20 (43.48)	3	3 (6.52)
Rash	8	4 (8.70)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Pruritus	5	4 (8.70)	0	0 (0.00)
Erythema	3	3 (6.52)	0	0 (0.00)
Blister	2	2 (4.35)	0	0 (0.00)
Dermatitis atopic	2	2 (4.35)	1	1 (2.17)
Dry skin	2	2 (4.35)	0	0 (0.00)
Skin discolouration	2	2 (4.35)	0	0 (0.00)
Dermatitis	1	1 (2.17)	0	0 (0.00)
Dermatitis allergic	1	1 (2.17)	0	0 (0.00)
Eczema	1	1 (2.17)	1	1 (2.17)
Erythema nodosum	1	1 (2.17)	0	0 (0.00)
Ingrowing nail	1	1 (2.17)	0	0 (0.00)
Miliaria	1	1 (2.17)	0	0 (0.00)
Night sweats	1	1 (2.17)	0	0 (0.00)
Papule	1	1 (2.17)	0	0 (0.00)
Photosensitivity reaction	1	1 (2.17)	0	0 (0.00)
Pruritus allergic	1	1 (2.17)	0	0 (0.00)
Scab	1	1 (2.17)	0	0 (0.00)
Skin swelling	1	1 (2.17)	0	0 (0.00)
Skin ulcer	1	1 (2.17)	0	0 (0.00)

Timing: At anytime, Gender: Male

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Urticaria	1	1 (2.17)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.17)	1	1 (2.17)
Vascular disorders				
- Total	25	20 (43.48)	12	11 (23.91)
Hypotension	12	12 (26.09)	6	6 (13.04)
Hypertension	9	9 (19.57)	3	3 (6.52)
Capillary leak syndrome	2	2 (4.35)	1	1 (2.17)
Venoocclusive disease	2	2 (4.35)	2	2 (4.35)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250b
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Gender
Safety Set

Timing: At anytime, Gender: Female				
Primary system organ class Preferred term	**All grades Total events**	**All patients N=34 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=34 n (%)[2]**
Total number of AE per patient	1299	34 (100.00)	440	32 (94.12)
Blood and lymphatic system disorders				
- Total	89	28 (82.35)	53	25 (73.53)
Anaemia	43	16 (47.06)	16	6 (17.65)
Febrile neutropenia	18	15 (44.12)	18	15 (44.12)
Neutropenia	11	7 (20.59)	10	6 (17.65)
B-cell aplasia	3	1 (2.94)	0	0 (0.00)
Coagulopathy	3	3 (8.82)	2	2 (5.88)
Thrombocytopenia	3	3 (8.82)	3	3 (8.82)
Disseminated intravascular coagulation	2	2 (5.88)	2	2 (5.88)
Splenomegaly	2	2 (5.88)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Leukopenia	1	1 (2.94)	1	1 (2.94)
Lymphadenopathy	1	1 (2.94)	0	0 (0.00)
Pancytopenia	1	1 (2.94)	1	1 (2.94)
Cardiac disorders				
- Total	26	15 (44.12)	8	6 (17.65)
Tachycardia	11	8 (23.53)	1	1 (2.94)
Cardiac failure	5	2 (5.88)	3	2 (5.88)
Sinus tachycardia	4	3 (8.82)	0	0 (0.00)
Cardiac arrest	2	2 (5.88)	2	2 (5.88)
Bradycardia	1	1 (2.94)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.94)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.94)	1	1 (2.94)
Sinus bradycardia	1	1 (2.94)	1	1 (2.94)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Ear pruritus	1	1 (2.94)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (11.76)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Adrenal insufficiency	3	3 (8.82)	0	0 (0.00)
Hypothyroidism	1	1 (2.94)	0	0 (0.00)
Eye disorders				
- Total	8	5 (14.71)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.94)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (2.94)	0	0 (0.00)
Eyelid oedema	1	1 (2.94)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.94)	0	0 (0.00)
Periorbital oedema	1	1 (2.94)	0	0 (0.00)
Periorbital swelling	1	1 (2.94)	0	0 (0.00)
Visual field defect	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	84	25 (73.53)	7	6 (17.65)
Vomiting	18	11 (32.35)	1	1 (2.94)
Diarrhoea	15	12 (35.29)	0	0 (0.00)
Nausea	10	8 (23.53)	1	1 (2.94)
Constipation	8	7 (20.59)	0	0 (0.00)
Abdominal pain	7	5 (14.71)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Mouth haemorrhage	3	3 (8.82)	1	1 (2.94)
Stomatitis	3	3 (8.82)	1	1 (2.94)
Abdominal distension	2	2 (5.88)	0	0 (0.00)
Abdominal pain upper	2	2 (5.88)	0	0 (0.00)
Ascites	2	2 (5.88)	0	0 (0.00)
Pancreatitis	2	2 (5.88)	0	0 (0.00)
Abdominal rigidity	1	1 (2.94)	0	0 (0.00)
Anal haemorrhage	1	1 (2.94)	0	0 (0.00)
Dyspepsia	1	1 (2.94)	0	0 (0.00)
Dysphagia	1	1 (2.94)	1	1 (2.94)
Gingival bleeding	1	1 (2.94)	0	0 (0.00)
Gingival erythema	1	1 (2.94)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.94)	1	1 (2.94)
Ileus	1	1 (2.94)	0	0 (0.00)
Lip dry	1	1 (2.94)	0	0 (0.00)
Lip oedema	1	1 (2.94)	0	0 (0.00)
Melaena	1	1 (2.94)	1	1 (2.94)
Proctalgia	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
General disorders and administration site conditions				
- Total	89	25 (73.53)	12	7 (20.59)
Pyrexia	40	16 (47.06)	6	5 (14.71)
Fatigue	8	6 (17.65)	0	0 (0.00)
Chills	6	4 (11.76)	0	0 (0.00)
Oedema peripheral	5	4 (11.76)	0	0 (0.00)
Face oedema	4	4 (11.76)	0	0 (0.00)
Generalised oedema	4	4 (11.76)	0	0 (0.00)
Catheter site pain	3	1 (2.94)	2	1 (2.94)
Pain	3	3 (8.82)	1	1 (2.94)
Drug withdrawal syndrome	2	2 (5.88)	0	0 (0.00)
Influenza like illness	2	2 (5.88)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (5.88)	2	2 (5.88)
Asthenia	1	1 (2.94)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.94)	0	0 (0.00)
Crying	1	1 (2.94)	0	0 (0.00)
Facial pain	1	1 (2.94)	0	0 (0.00)
Localised oedema	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Malaise	1	1 (2.94)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.94)	0	0 (0.00)
Sluggishness	1	1 (2.94)	0	0 (0.00)
Swelling face	1	1 (2.94)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (2.94)	1	1 (2.94)
Hepatobiliary disorders				
- Total	16	9 (26.47)	4	4 (11.76)
Hepatic function abnormal	5	3 (8.82)	1	1 (2.94)
Hyperbilirubinaemia	4	3 (8.82)	1	1 (2.94)
Cholelithiasis	2	2 (5.88)	0	0 (0.00)
Hypertransaminasaemia	2	1 (2.94)	0	0 (0.00)
Cholestasis	1	1 (2.94)	1	1 (2.94)
Gallbladder enlargement	1	1 (2.94)	0	0 (0.00)
Hepatomegaly	1	1 (2.94)	1	1 (2.94)
Immune system disorders				
- Total	93	32 (94.12)	36	21 (61.76)
Cytokine release syndrome	65	30 (88.24)	28	19 (55.88)
Hypogammaglobulinaemia	21	16 (47.06)	4	4 (11.76)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Haemophagocytic lymphohistiocytosis	2	2 (5.88)	1	1 (2.94)
Seasonal allergy	2	2 (5.88)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (2.94)	1	1 (2.94)
Drug hypersensitivity	1	1 (2.94)	1	1 (2.94)
Immunodeficiency	1	1 (2.94)	1	1 (2.94)
Infections and infestations				
- Total	116	24 (70.59)	53	18 (52.94)
Sinusitis	8	5 (14.71)	2	2 (5.88)
Rhinovirus infection	7	5 (14.71)	1	1 (2.94)
Upper respiratory tract infection	7	5 (14.71)	1	1 (2.94)
Bronchopulmonary aspergillosis	6	2 (5.88)	4	2 (5.88)
Gastroenteritis	4	4 (11.76)	2	2 (5.88)
Oral candidiasis	4	3 (8.82)	0	0 (0.00)
Urinary tract infection	4	3 (8.82)	2	1 (2.94)
Bacteraemia	3	2 (5.88)	3	2 (5.88)
Fungal infection	3	2 (5.88)	0	0 (0.00)
Klebsiella infection	3	1 (2.94)	3	1 (2.94)
Staphylococcal bacteraemia	3	2 (5.88)	3	2 (5.88)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Bronchitis	2	2 (5.88)	0	0 (0.00)
Candida infection	2	1 (2.94)	2	1 (2.94)
Conjunctivitis	2	2 (5.88)	0	0 (0.00)
Device related sepsis	2	1 (2.94)	2	1 (2.94)
Encephalitis viral	2	2 (5.88)	2	2 (5.88)
Gastroenteritis viral	2	1 (2.94)	0	0 (0.00)
Nail infection	2	2 (5.88)	0	0 (0.00)
Nasopharyngitis	2	2 (5.88)	0	0 (0.00)
Otitis media	2	2 (5.88)	1	1 (2.94)
Parainfluenzae virus infection	2	2 (5.88)	1	1 (2.94)
Septic shock	2	2 (5.88)	2	2 (5.88)
Staphylococcal infection	2	2 (5.88)	1	1 (2.94)
Acute sinusitis	1	1 (2.94)	0	0 (0.00)
Adenovirus infection	1	1 (2.94)	1	1 (2.94)
Bronchiolitis	1	1 (2.94)	1	1 (2.94)
Clostridium difficile infection	1	1 (2.94)	1	1 (2.94)
Cystitis	1	1 (2.94)	0	0 (0.00)
Ear infection	1	1 (2.94)	0	0 (0.00)
Ear, nose and throat infection	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Encephalitis	1	1 (2.94)	1	1 (2.94)
Enterobacter infection	1	1 (2.94)	1	1 (2.94)
Folliculitis	1	1 (2.94)	0	0 (0.00)
Fungal skin infection	1	1 (2.94)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.94)	0	0 (0.00)
Granulicatella infection	1	1 (2.94)	1	1 (2.94)
Herpes simplex	1	1 (2.94)	1	1 (2.94)
Herpes zoster	1	1 (2.94)	1	1 (2.94)
Human herpesvirus 6 infection	1	1 (2.94)	1	1 (2.94)
Localised infection	1	1 (2.94)	0	0 (0.00)
Mastoiditis	1	1 (2.94)	1	1 (2.94)
Meningitis bacterial	1	1 (2.94)	1	1 (2.94)
Meningitis pneumococcal	1	1 (2.94)	1	1 (2.94)
Myringitis	1	1 (2.94)	0	0 (0.00)
Neutropenic infection	1	1 (2.94)	1	1 (2.94)
Oral herpes	1	1 (2.94)	0	0 (0.00)
Otitis externa	1	1 (2.94)	1	1 (2.94)
Pharyngitis streptococcal	1	1 (2.94)	1	1 (2.94)
Pneumonia respiratory syncytial viral	1	1 (2.94)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pneumonia viral	1	1 (2.94)	1	1 (2.94)
Respiratory syncytial virus infection	1	1 (2.94)	1	1 (2.94)
Respiratory tract infection	1	1 (2.94)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.94)	0	0 (0.00)
Rhinitis	1	1 (2.94)	0	0 (0.00)
Sepsis	1	1 (2.94)	1	1 (2.94)
Skin infection	1	1 (2.94)	0	0 (0.00)
Staphylococcal skin infection	1	1 (2.94)	0	0 (0.00)
Stomatococcal infection	1	1 (2.94)	0	0 (0.00)
Systemic candida	1	1 (2.94)	1	1 (2.94)
Urinary tract infection pseudomonal	1	1 (2.94)	0	0 (0.00)
Urinary tract infection viral	1	1 (2.94)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.94)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.94)	1	1 (2.94)
Injury, poisoning and procedural complications				
- Total	23	12 (35.29)	3	2 (5.88)
Infusion related reaction	6	3 (8.82)	0	0 (0.00)
Wound	3	2 (5.88)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Contusion	2	1 (2.94)	0	0 (0.00)
Procedural pain	2	2 (5.88)	0	0 (0.00)
Abdominal injury	1	1 (2.94)	0	0 (0.00)
Fall	1	1 (2.94)	0	0 (0.00)
Ligament sprain	1	1 (2.94)	0	0 (0.00)
Limb injury	1	1 (2.94)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.94)	0	0 (0.00)
Skin abrasion	1	1 (2.94)	0	0 (0.00)
Skin injury	1	1 (2.94)	0	0 (0.00)
Skin wound	1	1 (2.94)	0	0 (0.00)
Transplant failure	1	1 (2.94)	1	1 (2.94)
Vasoplegia syndrome	1	1 (2.94)	1	1 (2.94)
Investigations				
- Total	250	28 (82.35)	126	24 (70.59)
Neutrophil count decreased	50	12 (35.29)	32	10 (29.41)
Platelet count decreased	39	12 (35.29)	23	7 (20.59)
White blood cell count decreased	36	13 (38.24)	22	9 (26.47)
Lymphocyte count decreased	23	10 (29.41)	17	8 (23.53)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Aspartate aminotransferase increased	19	7 (20.59)	7	5 (14.71)
Alanine aminotransferase increased	10	5 (14.71)	3	3 (8.82)
Blood bilirubin increased	9	4 (11.76)	2	2 (5.88)
International normalised ratio increased	9	6 (17.65)	0	0 (0.00)
Weight increased	5	2 (5.88)	1	1 (2.94)
Blood creatinine increased	4	2 (5.88)	3	1 (2.94)
Blood immunoglobulin M decreased	4	4 (11.76)	0	0 (0.00)
Electrocardiogram QT prolonged	4	3 (8.82)	1	1 (2.94)
Activated partial thromboplastin time prolonged	3	2 (5.88)	0	0 (0.00)
Blood fibrinogen decreased	3	3 (8.82)	1	1 (2.94)
Blood immunoglobulin A decreased	3	3 (8.82)	0	0 (0.00)
Lipase increased	3	1 (2.94)	2	1 (2.94)
Blood glucose increased	2	1 (2.94)	2	1 (2.94)
Blood immunoglobulin G decreased	2	2 (5.88)	0	0 (0.00)
Blood uric acid increased	2	2 (5.88)	1	1 (2.94)
C-reactive protein increased	2	2 (5.88)	2	2 (5.88)
Serum ferritin increased	2	2 (5.88)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Urine output decreased	2	1 (2.94)	2	1 (2.94)
Blood alkaline phosphatase increased	1	1 (2.94)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.94)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.94)	1	1 (2.94)
Blood lactate dehydrogenase increased	1	1 (2.94)	1	1 (2.94)
Blood phosphorus increased	1	1 (2.94)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (2.94)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.94)	0	0 (0.00)
Cardiac murmur	1	1 (2.94)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.94)	0	0 (0.00)
Enterovirus test positive	1	1 (2.94)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.94)	1	1 (2.94)
Haptoglobin decreased	1	1 (2.94)	0	0 (0.00)
Troponin increased	1	1 (2.94)	1	1 (2.94)
Weight decreased	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
- Total	143	24 (70.59)	52	18 (52.94)
Hypokalaemia	28	11 (32.35)	14	6 (17.65)
Hypophosphataemia	19	10 (29.41)	8	6 (17.65)
Decreased appetite	15	15 (44.12)	7	7 (20.59)
Hypocalcaemia	12	7 (20.59)	3	2 (5.88)
Hypoalbuminaemia	11	7 (20.59)	1	1 (2.94)
Hyperglycaemia	8	5 (14.71)	1	1 (2.94)
Hyperuricaemia	6	4 (11.76)	1	1 (2.94)
Hypervolaemia	4	4 (11.76)	3	3 (8.82)
Hypomagnesaemia	4	3 (8.82)	0	0 (0.00)
Acidosis	3	2 (5.88)	2	2 (5.88)
Hypercalcaemia	3	2 (5.88)	1	1 (2.94)
Hyperphosphataemia	3	3 (8.82)	1	1 (2.94)
Hyponatraemia	3	3 (8.82)	0	0 (0.00)
Hyperchloraemia	2	2 (5.88)	0	0 (0.00)
Hypernatraemia	2	2 (5.88)	2	2 (5.88)
Iron overload	2	1 (2.94)	0	0 (0.00)
Metabolic acidosis	2	2 (5.88)	2	2 (5.88)
Tumour lysis syndrome	2	2 (5.88)	2	2 (5.88)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Calcium deficiency	1	1 (2.94)	0	0 (0.00)
Haemosiderosis	1	1 (2.94)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.94)	0	0 (0.00)
Hyperkalaemia	1	1 (2.94)	1	1 (2.94)
Hyperlactacidaemia	1	1 (2.94)	0	0 (0.00)
Hyperlipidaemia	1	1 (2.94)	0	0 (0.00)
Hypermagnesaemia	1	1 (2.94)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (2.94)	0	0 (0.00)
Hypoglycaemia	1	1 (2.94)	0	0 (0.00)
Hypophagia	1	1 (2.94)	0	0 (0.00)
Malnutrition	1	1 (2.94)	1	1 (2.94)
Metabolic syndrome	1	1 (2.94)	0	0 (0.00)
Obesity	1	1 (2.94)	1	1 (2.94)
Polydipsia	1	1 (2.94)	1	1 (2.94)
Musculoskeletal and connective tissue disorders				
- Total	41	21 (61.76)	7	6 (17.65)
Back pain	8	5 (14.71)	1	1 (2.94)
Myalgia	7	7 (20.59)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pain in extremity	7	7 (20.59)	1	1 (2.94)
Bone pain	4	2 (5.88)	0	0 (0.00)
Arthralgia	3	3 (8.82)	1	1 (2.94)
Growth retardation	1	1 (2.94)	0	0 (0.00)
Haemarthrosis	1	1 (2.94)	1	1 (2.94)
Joint effusion	1	1 (2.94)	0	0 (0.00)
Muscle rigidity	1	1 (2.94)	0	0 (0.00)
Muscular weakness	1	1 (2.94)	1	1 (2.94)
Musculoskeletal chest pain	1	1 (2.94)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.94)	0	0 (0.00)
Myositis	1	1 (2.94)	0	0 (0.00)
Neck pain	1	1 (2.94)	0	0 (0.00)
Pain in jaw	1	1 (2.94)	1	1 (2.94)
Rhabdomyolysis	1	1 (2.94)	1	1 (2.94)
Synovitis	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	2 (5.88)	2	2 (5.88)
Bone giant cell tumour benign	2	1 (2.94)	1	1 (2.94)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Myelodysplastic syndrome	1	1 (2.94)	1	1 (2.94)
Nervous system disorders				
- Total	65	23 (67.65)	8	6 (17.65)
Headache	24	15 (44.12)	0	0 (0.00)
Tremor	7	6 (17.65)	0	0 (0.00)
Seizure	6	3 (8.82)	2	2 (5.88)
Cognitive disorder	4	2 (5.88)	1	1 (2.94)
Encephalopathy	4	4 (11.76)	3	3 (8.82)
Somnolence	3	3 (8.82)	1	1 (2.94)
Hyperaesthesia	2	1 (2.94)	0	0 (0.00)
Lethargy	2	2 (5.88)	0	0 (0.00)
Migraine	2	1 (2.94)	0	0 (0.00)
Nervous system disorder	2	1 (2.94)	1	1 (2.94)
Amnesia	1	1 (2.94)	0	0 (0.00)
Aphasia	1	1 (2.94)	0	0 (0.00)
Disturbance in attention	1	1 (2.94)	0	0 (0.00)
Dizziness	1	1 (2.94)	0	0 (0.00)
Dysgeusia	1	1 (2.94)	0	0 (0.00)
Extrapyramidal disorder	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Generalised tonic-clonic seizure	1	1 (2.94)	0	0 (0.00)
Monoparesis	1	1 (2.94)	0	0 (0.00)
Paraesthesia	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	30	18 (52.94)	5	5 (14.71)
Anxiety	6	6 (17.65)	2	2 (5.88)
Agitation	4	3 (8.82)	0	0 (0.00)
Mental status changes	4	4 (11.76)	2	2 (5.88)
Confusional state	3	3 (8.82)	0	0 (0.00)
Delirium	2	2 (5.88)	1	1 (2.94)
Hallucination	2	2 (5.88)	0	0 (0.00)
Irritability	2	2 (5.88)	0	0 (0.00)
Affect lability	1	1 (2.94)	0	0 (0.00)
Automatism	1	1 (2.94)	0	0 (0.00)
Hallucination, visual	1	1 (2.94)	0	0 (0.00)
Insomnia	1	1 (2.94)	0	0 (0.00)
Sleep disorder	1	1 (2.94)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.94)	0	0 (0.00)
Tic	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Renal and urinary disorders				
- Total	25	11 (32.35)	9	7 (20.59)
Acute kidney injury	12	7 (20.59)	7	6 (17.65)
Anuria	2	2 (5.88)	1	1 (2.94)
Pollakiuria	2	2 (5.88)	0	0 (0.00)
Urinary incontinence	2	1 (2.94)	0	0 (0.00)
Urinary retention	2	2 (5.88)	0	0 (0.00)
Azotaemia	1	1 (2.94)	0	0 (0.00)
Bladder dilatation	1	1 (2.94)	0	0 (0.00)
Dysuria	1	1 (2.94)	0	0 (0.00)
Micturition urgency	1	1 (2.94)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.94)	1	1 (2.94)
Reproductive system and breast disorders				
- Total	10	6 (17.65)	2	2 (5.88)
Dysmenorrhoea	2	1 (2.94)	0	0 (0.00)
Endometriosis	2	1 (2.94)	1	1 (2.94)
Vaginal haemorrhage	2	1 (2.94)	0	0 (0.00)
Female genital tract fistula	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Heavy menstrual bleeding	1	1 (2.94)	0	0 (0.00)
Perineal rash	1	1 (2.94)	0	0 (0.00)
Vaginal ulceration	1	1 (2.94)	1	1 (2.94)
Respiratory, thoracic and mediastinal disorders				
- Total	96	27 (79.41)	31	16 (47.06)
Cough	14	10 (29.41)	0	0 (0.00)
Hypoxia	14	9 (26.47)	12	8 (23.53)
Epistaxis	6	5 (14.71)	1	1 (2.94)
Pulmonary oedema	6	6 (17.65)	4	4 (11.76)
Rhinorrhoea	6	4 (11.76)	0	0 (0.00)
Tachypnoea	6	5 (14.71)	3	3 (8.82)
Dyspnoea	5	4 (11.76)	2	2 (5.88)
Nasal congestion	5	4 (11.76)	0	0 (0.00)
Atelectasis	4	2 (5.88)	1	1 (2.94)
Acute respiratory distress syndrome	3	3 (8.82)	3	3 (8.82)
Oropharyngeal pain	3	3 (8.82)	0	0 (0.00)
Respiratory failure	3	3 (8.82)	3	3 (8.82)
Pharyngeal erythema	2	2 (5.88)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Acute respiratory failure	1	1 (2.94)	1	1 (2.94)
Bronchial oedema	1	1 (2.94)	0	0 (0.00)
Dyspnoea exertional	1	1 (2.94)	0	0 (0.00)
Haemoptysis	1	1 (2.94)	0	0 (0.00)
Nasal discomfort	1	1 (2.94)	0	0 (0.00)
Nasal dryness	1	1 (2.94)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.94)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.94)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.94)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.94)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.94)	0	0 (0.00)
Pleural effusion	1	1 (2.94)	0	0 (0.00)
Pulmonary mass	1	1 (2.94)	0	0 (0.00)
Respiratory acidosis	1	1 (2.94)	1	1 (2.94)
Respiratory distress	1	1 (2.94)	0	0 (0.00)
Rhinitis allergic	1	1 (2.94)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (2.94)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (2.94)	0	0 (0.00)
Wheezing	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	56	20 (58.82)	6	4 (11.76)
Dry skin	7	6 (17.65)	0	0 (0.00)
Rash	5	4 (11.76)	0	0 (0.00)
Blister	4	1 (2.94)	0	0 (0.00)
Pruritus	4	3 (8.82)	0	0 (0.00)
Rash maculo-papular	4	3 (8.82)	1	1 (2.94)
Rash papular	4	3 (8.82)	0	0 (0.00)
Hyperhidrosis	3	3 (8.82)	0	0 (0.00)
Decubitus ulcer	2	2 (5.88)	1	1 (2.94)
Dermatitis atopic	2	1 (2.94)	0	0 (0.00)
Eczema	2	2 (5.88)	0	0 (0.00)
Erythema	2	2 (5.88)	0	0 (0.00)
Petechiae	2	2 (5.88)	1	1 (2.94)
Rash macular	2	1 (2.94)	2	1 (2.94)
Rash vesicular	2	1 (2.94)	0	0 (0.00)
Dermatitis diaper	1	1 (2.94)	0	0 (0.00)
Hangnail	1	1 (2.94)	0	0 (0.00)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Ingrowing nail	1	1 (2.94)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.94)	0	0 (0.00)
Purpura	1	1 (2.94)	0	0 (0.00)
Rash erythematous	1	1 (2.94)	0	0 (0.00)
Rash pruritic	1	1 (2.94)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.94)	0	0 (0.00)
Skin lesion	1	1 (2.94)	0	0 (0.00)
Skin necrosis	1	1 (2.94)	1	1 (2.94)
Skin ulcer	1	1 (2.94)	0	0 (0.00)
Social circumstances				
- Total	1	1 (2.94)	0	0 (0.00)
Patient uncooperative	1	1 (2.94)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (2.94)	1	1 (2.94)
Thrombolysis	1	1 (2.94)	1	1 (2.94)
Vascular disorders				
- Total	29	14 (41.18)	15	10 (29.41)

Timing: At anytime, Gender: Female

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Hypotension	17	12 (35.29)	13	10 (29.41)
Hypertension	8	7 (20.59)	2	2 (5.88)
Flushing	1	1 (2.94)	0	0 (0.00)
Hot flush	1	1 (2.94)	0	0 (0.00)
Peripheral ischaemia	1	1 (2.94)	0	0 (0.00)
Thrombosis	1	1 (2.94)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Total number of AE per patient	1295	59 (100.00)	404	48 (81.36)
Blood and lymphatic system disorders				
- Total	76	34 (57.63)	43	25 (42.37)
Anaemia	26	16 (27.12)	8	5 (8.47)
Febrile neutropenia	19	18 (30.51)	19	18 (30.51)
Neutropenia	6	6 (10.17)	4	4 (6.78)
Coagulopathy	5	5 (8.47)	2	2 (3.39)
Thrombocytopenia	5	5 (8.47)	5	5 (8.47)
Disseminated intravascular coagulation	4	4 (6.78)	1	1 (1.69)
Splenomegaly	3	3 (5.08)	0	0 (0.00)
Eosinophilia	2	1 (1.69)	0	0 (0.00)
Leukopenia	2	2 (3.39)	1	1 (1.69)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Pancytopenia	2	2 (3.39)	2	2 (3.39)
B-cell aplasia	1	1 (1.69)	0	0 (0.00)
Lymphopenia	1	1 (1.69)	1	1 (1.69)
Cardiac disorders				
- Total	38	19 (32.20)	7	6 (10.17)
Tachycardia	20	15 (25.42)	3	3 (5.08)
Cardiac failure	4	1 (1.69)	2	1 (1.69)
Sinus tachycardia	4	3 (5.08)	0	0 (0.00)
Bradycardia	3	3 (5.08)	0	0 (0.00)
Left ventricular dysfunction	2	2 (3.39)	2	2 (3.39)
Atrioventricular block first degree	1	1 (1.69)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.69)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.69)	0	0 (0.00)
Pericardial effusion	1	1 (1.69)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.69)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (3.39)	0	0 (0.00)
Ear pain	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Ear pruritus	1	1 (1.69)	0	0 (0.00)
Endocrine disorders				
- Total	3	3 (5.08)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.39)	0	0 (0.00)
Hypothyroidism	1	1 (1.69)	0	0 (0.00)
Eye disorders				
- Total	15	9 (15.25)	0	0 (0.00)
Eyelid oedema	3	2 (3.39)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.39)	0	0 (0.00)
Ocular hyperaemia	2	2 (3.39)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.69)	0	0 (0.00)
Eye oedema	1	1 (1.69)	0	0 (0.00)
Eye pain	1	1 (1.69)	0	0 (0.00)
Periorbital oedema	1	1 (1.69)	0	0 (0.00)
Periorbital swelling	1	1 (1.69)	0	0 (0.00)
Visual field defect	1	1 (1.69)	0	0 (0.00)
Visual impairment	1	1 (1.69)	0	0 (0.00)
Gastrointestinal disorders				

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
- Total	109	38 (64.41)	13	12 (20.34)
Vomiting	24	18 (30.51)	0	0 (0.00)
Nausea	17	14 (23.73)	1	1 (1.69)
Diarrhoea	15	12 (20.34)	1	1 (1.69)
Abdominal pain	12	10 (16.95)	2	2 (3.39)
Constipation	6	6 (10.17)	0	0 (0.00)
Abdominal pain upper	3	3 (5.08)	0	0 (0.00)
Ascites	3	3 (5.08)	0	0 (0.00)
Mouth haemorrhage	3	3 (5.08)	1	1 (1.69)
Abdominal distension	2	2 (3.39)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (3.39)	0	0 (0.00)
Stomatitis	2	2 (3.39)	1	1 (1.69)
Abdominal compartment syndrome	1	1 (1.69)	1	1 (1.69)
Anal fissure	1	1 (1.69)	0	0 (0.00)
Anal haemorrhage	1	1 (1.69)	0	0 (0.00)
Dry mouth	1	1 (1.69)	0	0 (0.00)
Dysphagia	1	1 (1.69)	1	1 (1.69)
Gastrooesophageal reflux disease	1	1 (1.69)	0	0 (0.00)
Gingival bleeding	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Gingival erythema	1	1 (1.69)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.69)	1	1 (1.69)
Haematemesis	1	1 (1.69)	0	0 (0.00)
Ileus	1	1 (1.69)	0	0 (0.00)
Lip dry	1	1 (1.69)	0	0 (0.00)
Melaena	1	1 (1.69)	1	1 (1.69)
Mouth swelling	1	1 (1.69)	0	0 (0.00)
Neutropenic colitis	1	1 (1.69)	1	1 (1.69)
Odynophagia	1	1 (1.69)	0	0 (0.00)
Pancreatitis	1	1 (1.69)	1	1 (1.69)
Proctalgia	1	1 (1.69)	1	1 (1.69)
Trichoglossia	1	1 (1.69)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	91	32 (54.24)	14	7 (11.86)
Pyrexia	30	20 (33.90)	5	5 (8.47)
Face oedema	9	8 (13.56)	1	1 (1.69)
Fatigue	9	9 (15.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Chills	8	5 (8.47)	0	0 (0.00)
Oedema peripheral	6	5 (8.47)	2	1 (1.69)
Catheter site pain	4	2 (3.39)	2	1 (1.69)
Generalised oedema	4	4 (6.78)	0	0 (0.00)
Asthenia	2	2 (3.39)	0	0 (0.00)
Catheter site erythema	2	1 (1.69)	0	0 (0.00)
Influenza like illness	2	2 (3.39)	0	0 (0.00)
Localised oedema	2	2 (3.39)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.69)	0	0 (0.00)
Chest discomfort	1	1 (1.69)	1	1 (1.69)
Crying	1	1 (1.69)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.69)	0	0 (0.00)
Facial pain	1	1 (1.69)	0	0 (0.00)
Malaise	1	1 (1.69)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.69)	1	1 (1.69)
Oedema due to hepatic disease	1	1 (1.69)	0	0 (0.00)
Pain	1	1 (1.69)	1	1 (1.69)
Sluggishness	1	1 (1.69)	0	0 (0.00)
Swelling face	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Systemic inflammatory response syndrome	1	1 (1.69)	1	1 (1.69)
Vascular device occlusion	1	1 (1.69)	0	0 (0.00)
Hepatobiliary disorders				
- Total	16	10 (16.95)	1	1 (1.69)
Hyperbilirubinaemia	4	3 (5.08)	0	0 (0.00)
Cholelithiasis	2	2 (3.39)	0	0 (0.00)
Gallbladder enlargement	2	2 (3.39)	0	0 (0.00)
Hepatomegaly	2	2 (3.39)	0	0 (0.00)
Hypertransaminasaemia	2	2 (3.39)	0	0 (0.00)
Biliary tract disorder	1	1 (1.69)	0	0 (0.00)
Cholestasis	1	1 (1.69)	1	1 (1.69)
Hepatic function abnormal	1	1 (1.69)	0	0 (0.00)
Ocular icterus	1	1 (1.69)	0	0 (0.00)
Immune system disorders				
- Total	118	48 (81.36)	49	31 (52.54)
Cytokine release syndrome	87	43 (72.88)	36	26 (44.07)
Hypogammaglobulinaemia	20	18 (30.51)	7	7 (11.86)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Haemophagocytic lymphohistiocytosis	5	5 (8.47)	3	3 (5.08)
Immunodeficiency	3	3 (5.08)	3	3 (5.08)
Hypersensitivity	1	1 (1.69)	0	0 (0.00)
Seasonal allergy	1	1 (1.69)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.69)	0	0 (0.00)
Infections and infestations				
- Total	47	24 (40.68)	20	12 (20.34)
Staphylococcal infection	5	5 (8.47)	2	2 (3.39)
Candida infection	4	3 (5.08)	2	1 (1.69)
Clostridium difficile infection	4	4 (6.78)	3	3 (5.08)
Conjunctivitis	4	4 (6.78)	0	0 (0.00)
Nail infection	2	2 (3.39)	0	0 (0.00)
Oral candidiasis	2	1 (1.69)	0	0 (0.00)
Oral infection	2	2 (3.39)	0	0 (0.00)
Anal abscess	1	1 (1.69)	1	1 (1.69)
Atypical pneumonia	1	1 (1.69)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (1.69)	1	1 (1.69)
Cholecystitis infective	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Encephalitis	1	1 (1.69)	1	1 (1.69)
Gastroenteritis norovirus	1	1 (1.69)	0	0 (0.00)
Gingivitis	1	1 (1.69)	0	0 (0.00)
Granulicatella infection	1	1 (1.69)	1	1 (1.69)
Herpes simplex	1	1 (1.69)	1	1 (1.69)
Human herpesvirus 6 infection	1	1 (1.69)	1	1 (1.69)
Klebsiella bacteraemia	1	1 (1.69)	0	0 (0.00)
Localised infection	1	1 (1.69)	0	0 (0.00)
Myringitis	1	1 (1.69)	0	0 (0.00)
Oral herpes	1	1 (1.69)	0	0 (0.00)
Paronychia	1	1 (1.69)	0	0 (0.00)
Pneumonia fungal	1	1 (1.69)	1	1 (1.69)
Pneumonia viral	1	1 (1.69)	1	1 (1.69)
Rhinovirus infection	1	1 (1.69)	0	0 (0.00)
Sinusitis	1	1 (1.69)	1	1 (1.69)
Soft tissue infection	1	1 (1.69)	1	1 (1.69)
Staphylococcal bacteraemia	1	1 (1.69)	1	1 (1.69)
Stomatococcal infection	1	1 (1.69)	0	0 (0.00)
Systemic candida	1	1 (1.69)	1	1 (1.69)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Varicella zoster virus infection	1	1 (1.69)	1	1 (1.69)
Injury, poisoning and procedural complications				
- Total	20	11 (18.64)	3	2 (3.39)
Infusion related reaction	3	2 (3.39)	0	0 (0.00)
Wound	3	2 (3.39)	1	1 (1.69)
Contusion	2	1 (1.69)	0	0 (0.00)
Fall	2	2 (3.39)	0	0 (0.00)
Procedural pain	2	2 (3.39)	0	0 (0.00)
Transfusion reaction	2	2 (3.39)	0	0 (0.00)
Scratch	1	1 (1.69)	0	0 (0.00)
Skin abrasion	1	1 (1.69)	0	0 (0.00)
Skin injury	1	1 (1.69)	0	0 (0.00)
Skin wound	1	1 (1.69)	0	0 (0.00)
Transplant failure	1	1 (1.69)	1	1 (1.69)
Vasoplegia syndrome	1	1 (1.69)	1	1 (1.69)
Investigations				
- Total	266	41 (69.49)	122	30 (50.85)
Neutrophil count decreased	39	13 (22.03)	29	10 (16.95)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Platelet count decreased	37	15 (25.42)	18	9 (15.25)
White blood cell count decreased	28	15 (25.42)	17	9 (15.25)
Lymphocyte count decreased	27	12 (20.34)	21	10 (16.95)
Aspartate aminotransferase increased	20	13 (22.03)	7	7 (11.86)
Alanine aminotransferase increased	16	13 (22.03)	3	3 (5.08)
Blood bilirubin increased	14	8 (13.56)	6	6 (10.17)
International normalised ratio increased	9	7 (11.86)	0	0 (0.00)
Activated partial thromboplastin time prolonged	6	4 (6.78)	0	0 (0.00)
Blood creatinine increased	5	3 (5.08)	4	2 (3.39)
Blood immunoglobulin M decreased	5	5 (8.47)	1	1 (1.69)
Immunoglobulins decreased	5	2 (3.39)	0	0 (0.00)
Blood immunoglobulin A decreased	4	4 (6.78)	0	0 (0.00)
Electrocardiogram QT prolonged	4	4 (6.78)	1	1 (1.69)
Lipase increased	4	2 (3.39)	2	1 (1.69)
Weight increased	4	4 (6.78)	1	1 (1.69)
Blood fibrinogen decreased	3	3 (5.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Blood lactate dehydrogenase increased	3	3 (5.08)	0	0 (0.00)
C-reactive protein increased	3	3 (5.08)	2	2 (3.39)
Serum ferritin increased	3	3 (5.08)	1	1 (1.69)
Urine output decreased	3	2 (3.39)	3	2 (3.39)
Blood glucose increased	2	1 (1.69)	2	1 (1.69)
Blood immunoglobulin G decreased	2	2 (3.39)	0	0 (0.00)
Blood uric acid increased	2	2 (3.39)	0	0 (0.00)
Haemoglobin decreased	2	1 (1.69)	1	1 (1.69)
Amylase increased	1	1 (1.69)	0	0 (0.00)
Bacterial test positive	1	1 (1.69)	1	1 (1.69)
Blood alkaline phosphatase increased	1	1 (1.69)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.69)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.69)	1	1 (1.69)
Blood testosterone decreased	1	1 (1.69)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.69)	0	0 (0.00)
Cardiac murmur	1	1 (1.69)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Enterovirus test positive	1	1 (1.69)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.69)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.69)	1	1 (1.69)
Oxygen saturation decreased	1	1 (1.69)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.69)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.69)	0	0 (0.00)
Weight decreased	1	1 (1.69)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	143	32 (54.24)	48	19 (32.20)
Hypokalaemia	29	14 (23.73)	16	8 (13.56)
Hypophosphataemia	20	12 (20.34)	6	6 (10.17)
Decreased appetite	18	18 (30.51)	6	6 (10.17)
Hypocalcaemia	18	11 (18.64)	4	3 (5.08)
Hypoalbuminaemia	11	6 (10.17)	0	0 (0.00)
Hyperglycaemia	7	5 (8.47)	3	3 (5.08)
Hyperuricaemia	6	4 (6.78)	1	1 (1.69)
Hyperphosphataemia	4	4 (6.78)	0	0 (0.00)
Hypervolaemia	4	4 (6.78)	2	2 (3.39)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypomagnesaemia	4	3 (5.08)	0	0 (0.00)
Hypermagnesaemia	3	2 (3.39)	0	0 (0.00)
Acidosis	2	1 (1.69)	1	1 (1.69)
Hypernatraemia	2	2 (3.39)	1	1 (1.69)
Hypertriglyceridaemia	2	2 (3.39)	2	2 (3.39)
Hyponatraemia	2	2 (3.39)	0	0 (0.00)
Metabolic acidosis	2	2 (3.39)	1	1 (1.69)
Dehydration	1	1 (1.69)	0	0 (0.00)
Haemosiderosis	1	1 (1.69)	0	0 (0.00)
Hypercalcaemia	1	1 (1.69)	1	1 (1.69)
Hyperchloraemia	1	1 (1.69)	0	0 (0.00)
Hyperkalaemia	1	1 (1.69)	1	1 (1.69)
Hyperlactacidaemia	1	1 (1.69)	0	0 (0.00)
Malnutrition	1	1 (1.69)	1	1 (1.69)
Polydipsia	1	1 (1.69)	1	1 (1.69)
Tumour lysis syndrome	1	1 (1.69)	1	1 (1.69)
Musculoskeletal and connective tissue disorders				
- Total	40	26 (44.07)	3	3 (5.08)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Pain in extremity	10	10 (16.95)	0	0 (0.00)
Arthralgia	8	8 (13.56)	0	0 (0.00)
Myalgia	8	7 (11.86)	0	0 (0.00)
Back pain	4	4 (6.78)	1	1 (1.69)
Pain in jaw	2	2 (3.39)	1	1 (1.69)
Bone pain	1	1 (1.69)	0	0 (0.00)
Muscle rigidity	1	1 (1.69)	0	0 (0.00)
Muscle spasms	1	1 (1.69)	0	0 (0.00)
Muscular weakness	1	1 (1.69)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.69)	0	0 (0.00)
Myositis	1	1 (1.69)	0	0 (0.00)
Neck pain	1	1 (1.69)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.69)	1	1 (1.69)
Nervous system disorders				
- Total	57	31 (52.54)	13	9 (15.25)
Headache	22	20 (33.90)	2	2 (3.39)
Encephalopathy	8	8 (13.56)	4	4 (6.78)
Somnolence	5	5 (8.47)	2	2 (3.39)
Tremor	5	5 (8.47)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Dizziness	3	3 (5.08)	0	0 (0.00)
Dysgeusia	2	2 (3.39)	0	0 (0.00)
Lethargy	2	2 (3.39)	0	0 (0.00)
Aphasia	1	1 (1.69)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.69)	1	1 (1.69)
Depressed level of consciousness	1	1 (1.69)	1	1 (1.69)
Disturbance in attention	1	1 (1.69)	0	0 (0.00)
Dysarthria	1	1 (1.69)	1	1 (1.69)
Generalised tonic-clonic seizure	1	1 (1.69)	0	0 (0.00)
Hypoaesthesia	1	1 (1.69)	0	0 (0.00)
Monoparesis	1	1 (1.69)	0	0 (0.00)
Neurological decompensation	1	1 (1.69)	1	1 (1.69)
Seizure	1	1 (1.69)	1	1 (1.69)
Psychiatric disorders				
- Total	41	23 (38.98)	5	5 (8.47)
Delirium	7	7 (11.86)	3	3 (5.08)
Agitation	5	4 (6.78)	0	0 (0.00)
Confusional state	5	5 (8.47)	0	0 (0.00)
Anxiety	4	4 (6.78)	1	1 (1.69)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Insomnia	4	4 (6.78)	0	0 (0.00)
Hallucination	3	3 (5.08)	0	0 (0.00)
Irritability	3	3 (5.08)	0	0 (0.00)
Mental status changes	3	3 (5.08)	1	1 (1.69)
Sleep disorder	3	2 (3.39)	0	0 (0.00)
Affect lability	1	1 (1.69)	0	0 (0.00)
Automatism	1	1 (1.69)	0	0 (0.00)
Restlessness	1	1 (1.69)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.69)	0	0 (0.00)
Renal and urinary disorders				
- Total	33	16 (27.12)	10	7 (11.86)
Acute kidney injury	11	7 (11.86)	5	5 (8.47)
Renal failure	4	2 (3.39)	3	1 (1.69)
Dysuria	3	3 (5.08)	0	0 (0.00)
Anuria	2	2 (3.39)	1	1 (1.69)
Pollakiuria	2	2 (3.39)	0	0 (0.00)
Urinary incontinence	2	1 (1.69)	0	0 (0.00)
Azotaemia	1	1 (1.69)	0	0 (0.00)
Bladder dilatation	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Haematuria	1	1 (1.69)	0	0 (0.00)
Incontinence	1	1 (1.69)	0	0 (0.00)
Micturition urgency	1	1 (1.69)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.69)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.69)	1	1 (1.69)
Urinary retention	1	1 (1.69)	0	0 (0.00)
Urinary tract disorder	1	1 (1.69)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (6.78)	1	1 (1.69)
Vaginal haemorrhage	2	1 (1.69)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.69)	0	0 (0.00)
Perineal rash	1	1 (1.69)	0	0 (0.00)
Vaginal ulceration	1	1 (1.69)	1	1 (1.69)
Respiratory, thoracic and mediastinal disorders				
- Total	88	28 (47.46)	34	14 (23.73)
Hypoxia	13	12 (20.34)	8	7 (11.86)
Pulmonary oedema	10	10 (16.95)	5	5 (8.47)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Cough	8	8 (13.56)	0	0 (0.00)
Tachypnoea	8	7 (11.86)	4	4 (6.78)
Atelectasis	5	3 (5.08)	2	2 (3.39)
Oropharyngeal pain	5	4 (6.78)	0	0 (0.00)
Pleural effusion	5	5 (8.47)	2	2 (3.39)
Respiratory distress	4	3 (5.08)	2	1 (1.69)
Dyspnoea	3	3 (5.08)	3	3 (5.08)
Epistaxis	3	3 (5.08)	0	0 (0.00)
Respiratory failure	3	3 (5.08)	3	3 (5.08)
Lung infiltration	2	1 (1.69)	1	1 (1.69)
Nasal congestion	2	2 (3.39)	0	0 (0.00)
Rhinorrhoea	2	2 (3.39)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.69)	1	1 (1.69)
Acute respiratory failure	1	1 (1.69)	1	1 (1.69)
Bradypnoea	1	1 (1.69)	1	1 (1.69)
Nasal discomfort	1	1 (1.69)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.69)	0	0 (0.00)
Painful respiration	1	1 (1.69)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Pharyngeal erythema	1	1 (1.69)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.69)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.69)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.69)	0	0 (0.00)
Productive cough	1	1 (1.69)	0	0 (0.00)
Pulmonary mass	1	1 (1.69)	0	0 (0.00)
Respiratory acidosis	1	1 (1.69)	1	1 (1.69)
Respiratory disorder	1	1 (1.69)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	50	23 (38.98)	3	2 (3.39)
Blister	6	3 (5.08)	0	0 (0.00)
Pruritus	6	5 (8.47)	0	0 (0.00)
Rash	5	5 (8.47)	0	0 (0.00)
Erythema	4	4 (6.78)	0	0 (0.00)
Rash papular	4	3 (5.08)	0	0 (0.00)
Hyperhidrosis	3	3 (5.08)	0	0 (0.00)
Dermatitis atopic	2	2 (3.39)	0	0 (0.00)
Petechiae	2	2 (3.39)	1	1 (1.69)

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Rash vesicular	2	1 (1.69)	0	0 (0.00)
Decubitus ulcer	1	1 (1.69)	0	0 (0.00)
Dermatitis	1	1 (1.69)	0	0 (0.00)
Dermatitis diaper	1	1 (1.69)	0	0 (0.00)
Dry skin	1	1 (1.69)	0	0 (0.00)
Eczema	1	1 (1.69)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.69)	0	0 (0.00)
Pruritus allergic	1	1 (1.69)	0	0 (0.00)
Rash maculo-papular	1	1 (1.69)	0	0 (0.00)
Rash pruritic	1	1 (1.69)	0	0 (0.00)
Scab	1	1 (1.69)	0	0 (0.00)
Skin discolouration	1	1 (1.69)	0	0 (0.00)
Skin lesion	1	1 (1.69)	0	0 (0.00)
Skin necrosis	1	1 (1.69)	1	1 (1.69)
Skin ulcer	1	1 (1.69)	0	0 (0.00)
Urticaria	1	1 (1.69)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.69)	1	1 (1.69)

Social circumstances

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
- Total	1	1 (1.69)	0	0 (0.00)
Patient uncooperative	1	1 (1.69)	0	0 (0.00)
Vascular disorders				
- Total	36	21 (35.59)	15	12 (20.34)
Hypotension	22	19 (32.20)	14	12 (20.34)
Hypertension	9	8 (13.56)	1	1 (1.69)
Capillary leak syndrome	1	1 (1.69)	0	0 (0.00)
Flushing	1	1 (1.69)	0	0 (0.00)
Hot flush	1	1 (1.69)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.69)	0	0 (0.00)
Thrombosis	1	1 (1.69)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Total number of AE per patient	139	10 (100.00)	69	9 (90.00)
Blood and lymphatic system disorders				
- Total	16	8 (80.00)	12	7 (70.00)
Neutropenia	5	3 (30.00)	5	3 (30.00)
Disseminated intravascular coagulation	3	3 (30.00)	1	1 (10.00)
Febrile neutropenia	2	2 (20.00)	2	2 (20.00)
Leukopenia	2	1 (10.00)	2	1 (10.00)
Thrombocytopenia	2	2 (20.00)	2	2 (20.00)
Hypofibrinogenaemia	1	1 (10.00)	0	0 (0.00)
Splenomegaly	1	1 (10.00)	0	0 (0.00)
Cardiac disorders				
- Total	4	3 (30.00)	1	1 (10.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Cardiac dysfunction	2	2 (20.00)	0	0 (0.00)
Cardiac arrest	1	1 (10.00)	1	1 (10.00)
Tachycardia	1	1 (10.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	6 (60.00)	0	0 (0.00)
Constipation	2	2 (20.00)	0	0 (0.00)
Nausea	2	2 (20.00)	0	0 (0.00)
Pancreatitis	2	2 (20.00)	0	0 (0.00)
Diarrhoea	1	1 (10.00)	0	0 (0.00)
Enterocolitis	1	1 (10.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	3 (30.00)	1	1 (10.00)
Pyrexia	2	2 (20.00)	1	1 (10.00)
Fatigue	1	1 (10.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	11	5 (50.00)	5	4 (40.00)
Hepatic function abnormal	10	4 (40.00)	4	3 (30.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Hepatomegaly	1	1 (10.00)	1	1 (10.00)
Immune system disorders				
- Total	18	9 (90.00)	6	5 (50.00)
Cytokine release syndrome	15	8 (80.00)	6	5 (50.00)
Hypogammaglobulinaemia	3	3 (30.00)	0	0 (0.00)
Infections and infestations				
- Total	9	7 (70.00)	6	4 (40.00)
BK virus infection	1	1 (10.00)	0	0 (0.00)
Bacteraemia	1	1 (10.00)	1	1 (10.00)
Encephalitis viral	1	1 (10.00)	1	1 (10.00)
Meningitis bacterial	1	1 (10.00)	1	1 (10.00)
Oral herpes	1	1 (10.00)	1	1 (10.00)
Otitis externa	1	1 (10.00)	0	0 (0.00)
Pneumonia	1	1 (10.00)	1	1 (10.00)
Staphylococcal bacteraemia	1	1 (10.00)	1	1 (10.00)
Urinary tract infection viral	1	1 (10.00)	0	0 (0.00)
Investigations				
- Total	30	7 (70.00)	18	6 (60.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class **Preferred term**	**All grades Total events**	**All patients N=10 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=10 n (%)[2]**
White blood cell count decreased	9	4 (40.00)	9	4 (40.00)
Neutrophil count decreased	4	2 (20.00)	4	2 (20.00)
Blood creatine phosphokinase increased	3	1 (10.00)	1	1 (10.00)
Blood fibrinogen decreased	3	3 (30.00)	1	1 (10.00)
Serum ferritin increased	3	3 (30.00)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (20.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (10.00)	0	0 (0.00)
Blood bilirubin increased	1	1 (10.00)	1	1 (10.00)
Fibrin D dimer increased	1	1 (10.00)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (10.00)	1	1 (10.00)
Haptoglobin decreased	1	1 (10.00)	0	0 (0.00)
Platelet count decreased	1	1 (10.00)	1	1 (10.00)
Metabolism and nutrition disorders				
- Total	9	4 (40.00)	6	3 (30.00)
Hypercalcaemia	2	1 (10.00)	1	1 (10.00)
Tumour lysis syndrome	2	2 (20.00)	2	2 (20.00)
Hyperkalaemia	1	1 (10.00)	1	1 (10.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Hyperphosphataemia	1	1 (10.00)	1	1 (10.00)
Hyperuricaemia	1	1 (10.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (10.00)	0	0 (0.00)
Metabolic acidosis	1	1 (10.00)	1	1 (10.00)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (30.00)	1	1 (10.00)
Arthralgia	1	1 (10.00)	0	0 (0.00)
Muscular weakness	1	1 (10.00)	1	1 (10.00)
Pain in extremity	1	1 (10.00)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (20.00)	0	0 (0.00)
Seizure	2	1 (10.00)	0	0 (0.00)
Headache	1	1 (10.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (30.00)	3	2 (20.00)
Acute kidney injury	3	2 (20.00)	3	2 (20.00)
Haematuria	1	1 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Proteinuria	1	1 (10.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	16	7 (70.00)	10	4 (40.00)
Hypoxia	9	4 (40.00)	9	4 (40.00)
Cough	1	1 (10.00)	0	0 (0.00)
Haemoptysis	1	1 (10.00)	0	0 (0.00)
Nasal congestion	1	1 (10.00)	0	0 (0.00)
Nasal dryness	1	1 (10.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (10.00)	0	0 (0.00)
Pleural effusion	1	1 (10.00)	0	0 (0.00)
Respiratory failure	1	1 (10.00)	1	1 (10.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (30.00)	0	0 (0.00)
Erythema nodosum	1	1 (10.00)	0	0 (0.00)
Pruritus	1	1 (10.00)	0	0 (0.00)
Skin ulcer	1	1 (10.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Vascular disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Hypertension	1	1 (10.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	317	10 (90.91)	146	10 (90.91)
Blood and lymphatic system disorders				
- Total	33	8 (72.73)	21	7 (63.64)
Anaemia	24	5 (45.45)	12	3 (27.27)
Febrile neutropenia	8	6 (54.55)	8	6 (54.55)
Thrombocytopenia	1	1 (9.09)	1	1 (9.09)
Cardiac disorders				
- Total	3	2 (18.18)	2	1 (9.09)
Left ventricular dysfunction	1	1 (9.09)	1	1 (9.09)
Sinus bradycardia	1	1 (9.09)	1	1 (9.09)
Tachycardia	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Endocrine disorders				
- Total	2	2 (18.18)	0	0 (0.00)
Adrenal insufficiency	2	2 (18.18)	0	0 (0.00)
Gastrointestinal disorders				
- Total	18	7 (63.64)	3	2 (18.18)
Vomiting	6	3 (27.27)	1	1 (9.09)
Constipation	3	3 (27.27)	0	0 (0.00)
Diarrhoea	2	2 (18.18)	0	0 (0.00)
Nausea	2	2 (18.18)	1	1 (9.09)
Abdominal distension	1	1 (9.09)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Lip oedema	1	1 (9.09)	0	0 (0.00)
Mouth haemorrhage	1	1 (9.09)	1	1 (9.09)
Pancreatitis	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	18	5 (45.45)	4	3 (27.27)
Pyrexia	12	2 (18.18)	3	2 (18.18)
Chills	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Drug withdrawal syndrome	1	1 (9.09)	0	0 (0.00)
Fatigue	1	1 (9.09)	0	0 (0.00)
Generalised oedema	1	1 (9.09)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (9.09)	1	1 (9.09)
Oedema peripheral	1	1 (9.09)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (18.18)	1	1 (9.09)
Hyperbilirubinaemia	2	2 (18.18)	1	1 (9.09)
Immune system disorders				
- Total	28	10 (90.91)	13	7 (63.64)
Cytokine release syndrome	26	10 (90.91)	13	7 (63.64)
Hypogammaglobulinaemia	2	2 (18.18)	0	0 (0.00)
Infections and infestations				
- Total	8	4 (36.36)	5	3 (27.27)
Conjunctivitis	2	1 (9.09)	0	0 (0.00)
Staphylococcal bacteraemia	2	1 (9.09)	2	1 (9.09)
Adenovirus infection	1	1 (9.09)	1	1 (9.09)
Encephalitis viral	1	1 (9.09)	1	1 (9.09)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Klebsiella infection	1	1 (9.09)	1	1 (9.09)
Rhinovirus infection	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	90	9 (81.82)	57	9 (81.82)
Platelet count decreased	27	5 (45.45)	19	4 (36.36)
White blood cell count decreased	13	5 (45.45)	10	5 (45.45)
Aspartate aminotransferase increased	11	4 (36.36)	6	4 (36.36)
Alanine aminotransferase increased	9	4 (36.36)	3	3 (27.27)
Neutrophil count decreased	5	5 (45.45)	5	5 (45.45)
Blood bilirubin increased	3	3 (27.27)	2	2 (18.18)
International normalised ratio increased	3	2 (18.18)	0	0 (0.00)
Lymphocyte count decreased	3	3 (27.27)	3	3 (27.27)
Activated partial thromboplastin time prolonged	2	2 (18.18)	1	1 (9.09)
Electrocardiogram QT prolonged	2	1 (9.09)	1	1 (9.09)
Serum ferritin increased	2	2 (18.18)	1	1 (9.09)
Blood creatinine increased	1	1 (9.09)	1	1 (9.09)
Blood fibrinogen decreased	1	1 (9.09)	1	1 (9.09)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Blood immunoglobulin A decreased	1	1 (9.09)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (9.09)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (9.09)	1	1 (9.09)
Blood phosphorus increased	1	1 (9.09)	0	0 (0.00)
C-reactive protein increased	1	1 (9.09)	1	1 (9.09)
Electrocardiogram T wave abnormal	1	1 (9.09)	0	0 (0.00)
Fibrin D dimer increased	1	1 (9.09)	1	1 (9.09)
Troponin increased	1	1 (9.09)	1	1 (9.09)
Metabolism and nutrition disorders				
- Total	58	10 (90.91)	22	7 (63.64)
Hypokalaemia	11	5 (45.45)	4	3 (27.27)
Hypophosphataemia	11	5 (45.45)	5	3 (27.27)
Hypoalbuminaemia	7	4 (36.36)	1	1 (9.09)
Decreased appetite	6	6 (54.55)	5	5 (45.45)
Hypocalcaemia	6	5 (45.45)	2	2 (18.18)
Hyperglycaemia	4	3 (27.27)	1	1 (9.09)
Hypomagnesaemia	3	3 (27.27)	0	0 (0.00)
Hyperuricaemia	2	2 (18.18)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Hypervolaemia	2	2 (18.18)	2	2 (18.18)
Acidosis	1	1 (9.09)	1	1 (9.09)
Calcium deficiency	1	1 (9.09)	0	0 (0.00)
Hypercalcaemia	1	1 (9.09)	0	0 (0.00)
Hypoglycaemia	1	1 (9.09)	0	0 (0.00)
Hyponatraemia	1	1 (9.09)	0	0 (0.00)
Tumour lysis syndrome	1	1 (9.09)	1	1 (9.09)
Musculoskeletal and connective tissue disorders				
- Total	10	4 (36.36)	2	1 (9.09)
Back pain	3	2 (18.18)	0	0 (0.00)
Bone pain	3	1 (9.09)	0	0 (0.00)
Myalgia	2	2 (18.18)	0	0 (0.00)
Arthralgia	1	1 (9.09)	1	1 (9.09)
Haemarthrosis	1	1 (9.09)	1	1 (9.09)
Nervous system disorders				
- Total	17	7 (63.64)	1	1 (9.09)
Cognitive disorder	5	3 (27.27)	1	1 (9.09)
Headache	3	2 (18.18)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Hyperaesthesia	2	1 (9.09)	0	0 (0.00)
Tremor	2	1 (9.09)	0	0 (0.00)
Amnesia	1	1 (9.09)	0	0 (0.00)
Dysgeusia	1	1 (9.09)	0	0 (0.00)
Lethargy	1	1 (9.09)	0	0 (0.00)
Neuralgia	1	1 (9.09)	0	0 (0.00)
Paraesthesia	1	1 (9.09)	0	0 (0.00)
Psychiatric disorders				
- Total	6	5 (45.45)	1	1 (9.09)
Anxiety	2	2 (18.18)	1	1 (9.09)
Confusional state	2	2 (18.18)	0	0 (0.00)
Agitation	1	1 (9.09)	0	0 (0.00)
Hallucination, visual	1	1 (9.09)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Urinary retention	1	1 (9.09)	0	0 (0.00)
Reproductive system and breast disorders				

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	1	1 (9.09)	0	0 (0.00)
Female genital tract fistula	1	1 (9.09)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	6 (54.55)	6	5 (45.45)
Cough	2	1 (9.09)	0	0 (0.00)
Pulmonary oedema	2	2 (18.18)	2	2 (18.18)
Acute respiratory distress syndrome	1	1 (9.09)	1	1 (9.09)
Epistaxis	1	1 (9.09)	1	1 (9.09)
Hypoxia	1	1 (9.09)	1	1 (9.09)
Pleural effusion	1	1 (9.09)	1	1 (9.09)
Tachypnoea	1	1 (9.09)	0	0 (0.00)
Wheezing	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	1 (9.09)	1	1 (9.09)
Rash maculo-papular	2	1 (9.09)	1	1 (9.09)
Purpura	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (9.09)	1	1 (9.09)
Thrombolysis	1	1 (9.09)	1	1 (9.09)
Vascular disorders				
- Total	8	6 (54.55)	6	5 (45.45)
Hypertension	4	4 (36.36)	3	3 (27.27)
Hypotension	3	2 (18.18)	2	2 (18.18)
Capillary leak syndrome	1	1 (9.09)	1	1 (9.09)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Total number of AE per patient	413	52 (94.55)	98	24 (43.64)
Blood and lymphatic system disorders				
- Total	23	11 (20.00)	9	5 (9.09)
Anaemia	11	5 (9.09)	3	1 (1.82)
B-cell aplasia	2	1 (1.82)	0	0 (0.00)
Febrile neutropenia	2	2 (3.64)	2	2 (3.64)
Neutropenia	2	2 (3.64)	2	2 (3.64)
Disseminated intravascular coagulation	1	1 (1.82)	1	1 (1.82)
Eosinophilia	1	1 (1.82)	0	0 (0.00)
Leukocytosis	1	1 (1.82)	0	0 (0.00)
Leukopenia	1	1 (1.82)	0	0 (0.00)
Lymphocytosis	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Thrombocytopenia	1	1 (1.82)	1	1 (1.82)
Cardiac disorders				
- Total	6	5 (9.09)	2	1 (1.82)
Tachycardia	2	2 (3.64)	0	0 (0.00)
Cardiac arrest	1	1 (1.82)	1	1 (1.82)
Cardiac failure	1	1 (1.82)	1	1 (1.82)
Left ventricular dysfunction	1	1 (1.82)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.82)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.82)	0	0 (0.00)
Hypothyroidism	1	1 (1.82)	0	0 (0.00)
Eye disorders				
- Total	5	4 (7.27)	0	0 (0.00)
Cataract	2	2 (3.64)	0	0 (0.00)
Hypermetropia	1	1 (1.82)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.82)	0	0 (0.00)
Visual impairment	1	1 (1.82)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
- Total	22	12 (21.82)	0	0 (0.00)
Diarrhoea	4	4 (7.27)	0	0 (0.00)
Vomiting	4	3 (5.45)	0	0 (0.00)
Nausea	3	3 (5.45)	0	0 (0.00)
Abdominal pain	1	1 (1.82)	0	0 (0.00)
Abdominal pain upper	1	1 (1.82)	0	0 (0.00)
Abdominal rigidity	1	1 (1.82)	0	0 (0.00)
Constipation	1	1 (1.82)	0	0 (0.00)
Dyspepsia	1	1 (1.82)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.82)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.82)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.82)	0	0 (0.00)
Pancreatitis	1	1 (1.82)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.82)	0	0 (0.00)
Proctalgia	1	1 (1.82)	0	0 (0.00)
General disorders and administration site conditions				
- Total	24	18 (32.73)	1	1 (1.82)
Pyrexia	11	10 (18.18)	1	1 (1.82)
Fatigue	7	6 (10.91)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Oedema peripheral	2	1 (1.82)	0	0 (0.00)
Asthenia	1	1 (1.82)	0	0 (0.00)
Chills	1	1 (1.82)	0	0 (0.00)
Malaise	1	1 (1.82)	0	0 (0.00)
Pain	1	1 (1.82)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (5.45)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.82)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.82)	0	0 (0.00)
Liver disorder	1	1 (1.82)	0	0 (0.00)
Immune system disorders				
- Total	13	10 (18.18)	3	2 (3.64)
Hypogammaglobulinaemia	8	6 (10.91)	0	0 (0.00)
Graft versus host disease	2	2 (3.64)	2	2 (3.64)
Allergy to immunoglobulin therapy	1	1 (1.82)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.82)	0	0 (0.00)
Engraftment syndrome	1	1 (1.82)	1	1 (1.82)
Infections and infestations				

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
- Total	79	31 (56.36)	26	14 (25.45)
Upper respiratory tract infection	8	6 (10.91)	1	1 (1.82)
Bronchopulmonary aspergillosis	5	1 (1.82)	3	1 (1.82)
Gastroenteritis	5	5 (9.09)	2	2 (3.64)
Nasopharyngitis	4	4 (7.27)	0	0 (0.00)
Parainfluenzae virus infection	4	3 (5.45)	2	2 (3.64)
Rhinovirus infection	4	4 (7.27)	1	1 (1.82)
Sinusitis	4	3 (5.45)	1	1 (1.82)
Metapneumovirus infection	3	3 (5.45)	3	3 (5.45)
Pneumonia	3	3 (5.45)	1	1 (1.82)
Pneumocystis jirovecii pneumonia	2	2 (3.64)	2	2 (3.64)
Respiratory syncytial virus infection	2	2 (3.64)	1	1 (1.82)
Respiratory tract infection	2	2 (3.64)	0	0 (0.00)
Rhinitis	2	2 (3.64)	0	0 (0.00)
Acute sinusitis	1	1 (1.82)	0	0 (0.00)
Adenovirus infection	1	1 (1.82)	1	1 (1.82)
BK virus infection	1	1 (1.82)	1	1 (1.82)
Bacteraemia	1	1 (1.82)	0	0 (0.00)
Cellulitis	1	1 (1.82)	0	0 (0.00)
Coronavirus infection	1	1 (1.82)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Cystitis	1	1 (1.82)	0	0 (0.00)
Device related infection	1	1 (1.82)	1	1 (1.82)
Ear infection	1	1 (1.82)	0	0 (0.00)
Ear, nose and throat infection	1	1 (1.82)	0	0 (0.00)
Encephalitis	1	1 (1.82)	1	1 (1.82)
Gastroenteritis clostridial	1	1 (1.82)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.82)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.82)	0	0 (0.00)
Gingivitis	1	1 (1.82)	0	0 (0.00)
Herpes simplex	1	1 (1.82)	0	0 (0.00)
Influenza	1	1 (1.82)	0	0 (0.00)
Molluscum contagiosum	1	1 (1.82)	0	0 (0.00)
Oral candidiasis	1	1 (1.82)	0	0 (0.00)
Otitis externa	1	1 (1.82)	0	0 (0.00)
Otitis media	1	1 (1.82)	0	0 (0.00)
Paronychia	1	1 (1.82)	0	0 (0.00)
Respiratory tract infection viral	1	1 (1.82)	0	0 (0.00)
Salmonellosis	1	1 (1.82)	0	0 (0.00)
Septic shock	1	1 (1.82)	1	1 (1.82)
Sinusitis fungal	1	1 (1.82)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Staphylococcal sepsis	1	1 (1.82)	1	1 (1.82)
Staphylococcal skin infection	1	1 (1.82)	0	0 (0.00)
Tinea pedis	1	1 (1.82)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.82)	1	1 (1.82)
Viral infection	1	1 (1.82)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	9	8 (14.55)	0	0 (0.00)
Infusion related reaction	3	2 (3.64)	0	0 (0.00)
Contusion	1	1 (1.82)	0	0 (0.00)
Fibula fracture	1	1 (1.82)	0	0 (0.00)
Ligament sprain	1	1 (1.82)	0	0 (0.00)
Limb injury	1	1 (1.82)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.82)	0	0 (0.00)
Skin abrasion	1	1 (1.82)	0	0 (0.00)
Investigations				
- Total	82	24 (43.64)	31	13 (23.64)
Neutrophil count decreased	16	8 (14.55)	9	6 (10.91)
White blood cell count decreased	16	8 (14.55)	3	3 (5.45)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Platelet count decreased	14	4 (7.27)	9	2 (3.64)
Lymphocyte count decreased	6	4 (7.27)	2	2 (3.64)
Immunoglobulins decreased	5	1 (1.82)	0	0 (0.00)
Blood bilirubin increased	4	2 (3.64)	1	1 (1.82)
Alanine aminotransferase increased	3	2 (3.64)	1	1 (1.82)
Weight increased	3	1 (1.82)	1	1 (1.82)
Blood immunoglobulin A decreased	2	2 (3.64)	1	1 (1.82)
Blood creatinine increased	1	1 (1.82)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.82)	1	1 (1.82)
Blood lactate dehydrogenase increased	1	1 (1.82)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.82)	0	0 (0.00)
Blood urea increased	1	1 (1.82)	1	1 (1.82)
Blood uric acid increased	1	1 (1.82)	1	1 (1.82)
Bone density decreased	1	1 (1.82)	0	0 (0.00)
C-reactive protein increased	1	1 (1.82)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.82)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.82)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Oxygen saturation decreased	1	1 (1.82)	0	0 (0.00)
Weight decreased	1	1 (1.82)	1	1 (1.82)
Metabolism and nutrition disorders				
- Total	21	11 (20.00)	7	4 (7.27)
Decreased appetite	5	5 (9.09)	1	1 (1.82)
Hypokalaemia	5	2 (3.64)	3	1 (1.82)
Hyperuricaemia	3	3 (5.45)	0	0 (0.00)
Haemochromatosis	1	1 (1.82)	1	1 (1.82)
Hyperchloraemia	1	1 (1.82)	0	0 (0.00)
Hyperkalaemia	1	1 (1.82)	0	0 (0.00)
Hypervolaemia	1	1 (1.82)	1	1 (1.82)
Hypophosphataemia	1	1 (1.82)	0	0 (0.00)
Iron overload	1	1 (1.82)	0	0 (0.00)
Metabolic syndrome	1	1 (1.82)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.82)	1	1 (1.82)
Musculoskeletal and connective tissue disorders				
- Total	15	11 (20.00)	1	1 (1.82)
Back pain	4	4 (7.27)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Pain in extremity	4	4 (7.27)	0	0 (0.00)
Arthralgia	2	2 (3.64)	0	0 (0.00)
Bone pain	2	2 (3.64)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.82)	0	0 (0.00)
Myalgia	1	1 (1.82)	0	0 (0.00)
Neck pain	1	1 (1.82)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (7.27)	1	1 (1.82)
Skin papilloma	2	2 (3.64)	0	0 (0.00)
Cancer pain	1	1 (1.82)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.82)	1	1 (1.82)
Nervous system disorders				
- Total	21	13 (23.64)	6	2 (3.64)
Headache	10	9 (16.36)	0	0 (0.00)
Hydrocephalus	3	1 (1.82)	3	1 (1.82)
Dizziness	2	1 (1.82)	0	0 (0.00)
Migraine	2	1 (1.82)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.82)	1	1 (1.82)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Cerebral haemorrhage	1	1 (1.82)	1	1 (1.82)
Memory impairment	1	1 (1.82)	0	0 (0.00)
Seizure	1	1 (1.82)	1	1 (1.82)
Psychiatric disorders				
- Total	9	5 (9.09)	0	0 (0.00)
Anxiety	2	2 (3.64)	0	0 (0.00)
Agitation	1	1 (1.82)	0	0 (0.00)
Mental status changes	1	1 (1.82)	0	0 (0.00)
Mood altered	1	1 (1.82)	0	0 (0.00)
Nightmare	1	1 (1.82)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.82)	0	0 (0.00)
Sleep disorder	1	1 (1.82)	0	0 (0.00)
Tearfulness	1	1 (1.82)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (7.27)	3	3 (5.45)
Acute kidney injury	3	3 (5.45)	1	1 (1.82)
Dysuria	1	1 (1.82)	0	0 (0.00)
Haematuria	1	1 (1.82)	1	1 (1.82)
Kidney enlargement	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Renal mass	1	1 (1.82)	0	0 (0.00)
Renal tubular disorder	1	1 (1.82)	1	1 (1.82)
Reproductive system and breast disorders				
- Total	2	1 (1.82)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.82)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	38	17 (30.91)	5	5 (9.09)
Cough	14	11 (20.00)	0	0 (0.00)
Nasal congestion	7	6 (10.91)	0	0 (0.00)
Dyspnoea	2	1 (1.82)	0	0 (0.00)
Epistaxis	2	2 (3.64)	0	0 (0.00)
Hypoxia	2	2 (3.64)	2	2 (3.64)
Oropharyngeal pain	2	2 (3.64)	0	0 (0.00)
Rhinorrhoea	2	2 (3.64)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.82)	1	1 (1.82)
Lung disorder	1	1 (1.82)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.82)	0	0 (0.00)
Pleural effusion	1	1 (1.82)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
Respiratory distress	1	1 (1.82)	1	1 (1.82)
Respiratory failure	1	1 (1.82)	1	1 (1.82)
Rhinitis allergic	1	1 (1.82)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	23	15 (27.27)	0	0 (0.00)
Dry skin	6	5 (9.09)	0	0 (0.00)
Rash	6	4 (7.27)	0	0 (0.00)
Ingrowing nail	2	2 (3.64)	0	0 (0.00)
Dermatitis allergic	1	1 (1.82)	0	0 (0.00)
Dermatitis atopic	1	1 (1.82)	0	0 (0.00)
Eczema	1	1 (1.82)	0	0 (0.00)
Hangnail	1	1 (1.82)	0	0 (0.00)
Miliaria	1	1 (1.82)	0	0 (0.00)
Night sweats	1	1 (1.82)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.82)	0	0 (0.00)
Skin discolouration	1	1 (1.82)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.82)	0	0 (0.00)
Vascular disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=55 n (%)[1]	Grade >= 3 Total events	All patients N=55 n (%)[2]
- Total	5	4 (7.27)	3	3 (5.45)
Hypotension	3	3 (5.45)	2	2 (3.64)
Hypertension	1	1 (1.82)	0	0 (0.00)
Venoocclusive disease	1	1 (1.82)	1	1 (1.82)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Total number of AE per patient	40	7 (77.78)	17	5 (55.56)
Blood and lymphatic system disorders				
- Total	7	4 (44.44)	7	4 (44.44)
Neutropenia	3	3 (33.33)	3	3 (33.33)
Febrile neutropenia	2	1 (11.11)	2	1 (11.11)
Lymphopenia	1	1 (11.11)	1	1 (11.11)
Thrombocytopenia	1	1 (11.11)	1	1 (11.11)
Cardiac disorders				
- Total	1	1 (11.11)	1	1 (11.11)
Cardiac failure	1	1 (11.11)	1	1 (11.11)
Gastrointestinal disorders				
- Total	7	4 (44.44)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Constipation	1	1 (11.11)	0	0 (0.00)
Diarrhoea	1	1 (11.11)	0	0 (0.00)
Enteritis	1	1 (11.11)	0	0 (0.00)
Nausea	1	1 (11.11)	0	0 (0.00)
Stomatitis	1	1 (11.11)	0	0 (0.00)
Trichoglossia	1	1 (11.11)	0	0 (0.00)
Vomiting	1	1 (11.11)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (11.11)	0	0 (0.00)
Pyrexia	1	1 (11.11)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (22.22)	0	0 (0.00)
Hypogammaglobulinaemia	2	2 (22.22)	0	0 (0.00)
Infections and infestations				
- Total	6	2 (22.22)	3	1 (11.11)
Nasopharyngitis	2	1 (11.11)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (11.11)	1	1 (11.11)
Human herpesvirus 6 infection	1	1 (11.11)	1	1 (11.11)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Oral herpes	1	1 (11.11)	0	0 (0.00)
Viral infection	1	1 (11.11)	1	1 (11.11)
Investigations				
- Total	3	2 (22.22)	3	2 (22.22)
Neutrophil count decreased	2	1 (11.11)	2	1 (11.11)
White blood cell count decreased	1	1 (11.11)	1	1 (11.11)
Metabolism and nutrition disorders				
- Total	2	2 (22.22)	1	1 (11.11)
Decreased appetite	1	1 (11.11)	0	0 (0.00)
Metabolic acidosis	1	1 (11.11)	1	1 (11.11)
Musculoskeletal and connective tissue disorders				
- Total	3	1 (11.11)	1	1 (11.11)
Arthralgia	1	1 (11.11)	0	0 (0.00)
Back pain	1	1 (11.11)	1	1 (11.11)
Musculoskeletal chest pain	1	1 (11.11)	0	0 (0.00)
Psychiatric disorders				
- Total	2	1 (11.11)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Anxiety	1	1 (11.11)	0	0 (0.00)
Delirium	1	1 (11.11)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (11.11)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	2 (22.22)	0	0 (0.00)
Pleural effusion	1	1 (11.11)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (11.11)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (22.22)	0	0 (0.00)
Dry skin	1	1 (11.11)	0	0 (0.00)
Skin swelling	1	1 (11.11)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (11.11)	1	1 (11.11)
Hypotension	1	1 (11.11)	1	1 (11.11)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	81	10 (90.91)	31	7 (63.64)
Blood and lymphatic system disorders				
- Total	2	2 (18.18)	1	1 (9.09)
Anaemia	1	1 (9.09)	1	1 (9.09)
Lymphadenopathy	1	1 (9.09)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Cardiac arrest	1	1 (9.09)	1	1 (9.09)
Gastrointestinal disorders				
- Total	9	4 (36.36)	1	1 (9.09)
Constipation	2	1 (9.09)	0	0 (0.00)
Diarrhoea	2	2 (18.18)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Vomiting	2	2 (18.18)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Nausea	1	1 (9.09)	0	0 (0.00)
Pancreatitis	1	1 (9.09)	1	1 (9.09)
General disorders and administration site conditions				
- Total	6	5 (45.45)	2	2 (18.18)
Pyrexia	4	4 (36.36)	1	1 (9.09)
Non-cardiac chest pain	1	1 (9.09)	0	0 (0.00)
Pain	1	1 (9.09)	1	1 (9.09)
Immune system disorders				
- Total	4	4 (36.36)	2	2 (18.18)
Hypogammaglobulinaemia	2	2 (18.18)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (9.09)	1	1 (9.09)
Immunodeficiency	1	1 (9.09)	1	1 (9.09)
Infections and infestations				
- Total	28	6 (54.55)	16	5 (45.45)
Nasopharyngitis	3	2 (18.18)	0	0 (0.00)
Bacteraemia	2	1 (9.09)	2	1 (9.09)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Ear infection	2	1 (9.09)	0	0 (0.00)
Klebsiella infection	2	1 (9.09)	2	1 (9.09)
Otitis media	2	2 (18.18)	1	1 (9.09)
Upper respiratory tract infection	2	2 (18.18)	1	1 (9.09)
Urinary tract infection	2	1 (9.09)	2	1 (9.09)
Conjunctivitis	1	1 (9.09)	0	0 (0.00)
Enterobacter infection	1	1 (9.09)	1	1 (9.09)
Herpes zoster	1	1 (9.09)	1	1 (9.09)
Mastoiditis	1	1 (9.09)	1	1 (9.09)
Nail infection	1	1 (9.09)	0	0 (0.00)
Otitis externa	1	1 (9.09)	1	1 (9.09)
Parainfluenzae virus infection	1	1 (9.09)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (9.09)	1	1 (9.09)
Respiratory syncytial virus infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection	1	1 (9.09)	0	0 (0.00)
Rhinovirus infection	1	1 (9.09)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (9.09)	1	1 (9.09)
Viral upper respiratory tract infection	1	1 (9.09)	1	1 (9.09)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	1	1 (9.09)	0	0 (0.00)
Infusion related reaction	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	6	4 (36.36)	1	1 (9.09)
Platelet count decreased	2	1 (9.09)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (9.09)	0	0 (0.00)
Blood uric acid increased	1	1 (9.09)	1	1 (9.09)
Neutrophil count decreased	1	1 (9.09)	0	0 (0.00)
White blood cell count decreased	1	1 (9.09)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (18.18)	2	2 (18.18)
Hypokalaemia	1	1 (9.09)	1	1 (9.09)
Hypophagia	1	1 (9.09)	0	0 (0.00)
Malnutrition	1	1 (9.09)	1	1 (9.09)
Musculoskeletal and connective tissue disorders				
- Total	4	3 (27.27)	1	1 (9.09)
Back pain	2	1 (9.09)	0	0 (0.00)
Growth retardation	1	1 (9.09)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Pain in extremity	1	1 (9.09)	1	1 (9.09)
Nervous system disorders				
- Total	2	1 (9.09)	0	0 (0.00)
Extrapyramidal disorder	1	1 (9.09)	0	0 (0.00)
Headache	1	1 (9.09)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (36.36)	1	1 (9.09)
Anxiety	3	3 (27.27)	0	0 (0.00)
Mental status changes	1	1 (9.09)	1	1 (9.09)
Respiratory, thoracic and mediastinal disorders				
- Total	6	5 (45.45)	1	1 (9.09)
Bronchial oedema	1	1 (9.09)	0	0 (0.00)
Bronchospasm	1	1 (9.09)	0	0 (0.00)
Epistaxis	1	1 (9.09)	0	0 (0.00)
Hypoxia	1	1 (9.09)	1	1 (9.09)
Rhinitis allergic	1	1 (9.09)	0	0 (0.00)
Rhinorrhoea	1	1 (9.09)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	4	3 (27.27)	1	1 (9.09)
Pruritus	2	1 (9.09)	0	0 (0.00)
Decubitus ulcer	1	1 (9.09)	1	1 (9.09)
Erythema	1	1 (9.09)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Venoocclusive disease	1	1 (9.09)	1	1 (9.09)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Total number of AE per patient	155	24 (61.54)	45	15 (38.46)
Blood and lymphatic system disorders				
- Total	5	3 (7.69)	2	2 (5.13)
Agranulocytosis	1	1 (2.56)	1	1 (2.56)
Anaemia	1	1 (2.56)	0	0 (0.00)
Lymphadenopathy	1	1 (2.56)	0	0 (0.00)
Neutropenia	1	1 (2.56)	1	1 (2.56)
Thrombocytopenia	1	1 (2.56)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.56)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.56)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.56)	0	0 (0.00)
Deafness unilateral	1	1 (2.56)	0	0 (0.00)
Eye disorders				
- Total	2	1 (2.56)	1	1 (2.56)
Eye pain	1	1 (2.56)	1	1 (2.56)
Eyelid oedema	1	1 (2.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	3 (7.69)	1	1 (2.56)
Diarrhoea	2	2 (5.13)	1	1 (2.56)
Irritable bowel syndrome	1	1 (2.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	10	7 (17.95)	1	1 (2.56)
Pyrexia	6	4 (10.26)	1	1 (2.56)
Pain	2	2 (5.13)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.56)	0	0 (0.00)
Xerosis	1	1 (2.56)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Immune system disorders				
- Total	6	6 (15.38)	1	1 (2.56)
Hypogammaglobulinaemia	3	3 (7.69)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.56)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.56)	1	1 (2.56)
Seasonal allergy	1	1 (2.56)	0	0 (0.00)
Infections and infestations				
- Total	67	18 (46.15)	19	12 (30.77)
Sinusitis	8	5 (12.82)	0	0 (0.00)
Conjunctivitis	4	3 (7.69)	0	0 (0.00)
Fungal infection	3	2 (5.13)	0	0 (0.00)
Rhinovirus infection	3	3 (7.69)	0	0 (0.00)
Sepsis	3	3 (7.69)	3	3 (7.69)
Upper respiratory tract infection	3	3 (7.69)	0	0 (0.00)
Bronchitis	2	2 (5.13)	0	0 (0.00)
COVID-19	2	1 (2.56)	1	1 (2.56)
Device related sepsis	2	1 (2.56)	2	1 (2.56)
Gastroenteritis viral	2	1 (2.56)	0	0 (0.00)
Herpes zoster	2	2 (5.13)	1	1 (2.56)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Oral herpes	2	2 (5.13)	0	0 (0.00)
Skin infection	2	2 (5.13)	0	0 (0.00)
Urinary tract infection	2	2 (5.13)	0	0 (0.00)
Acute sinusitis	1	1 (2.56)	0	0 (0.00)
Bronchiolitis	1	1 (2.56)	1	1 (2.56)
Candida infection	1	1 (2.56)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.56)	1	1 (2.56)
Ear infection	1	1 (2.56)	1	1 (2.56)
Folliculitis	1	1 (2.56)	0	0 (0.00)
Gastroenteritis	1	1 (2.56)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.56)	1	1 (2.56)
Gastroenteritis salmonella	1	1 (2.56)	1	1 (2.56)
Herpes virus infection	1	1 (2.56)	0	0 (0.00)
Influenza	1	1 (2.56)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.56)	1	1 (2.56)
Nail infection	1	1 (2.56)	0	0 (0.00)
Neutropenic infection	1	1 (2.56)	1	1 (2.56)
Ophthalmic herpes zoster	1	1 (2.56)	0	0 (0.00)
Oral candidiasis	1	1 (2.56)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Otitis media	1	1 (2.56)	0	0 (0.00)
Otitis media acute	1	1 (2.56)	0	0 (0.00)
Pneumonia	1	1 (2.56)	1	1 (2.56)
Pneumonia respiratory syncytial viral	1	1 (2.56)	1	1 (2.56)
Rhinitis	1	1 (2.56)	0	0 (0.00)
Septic shock	1	1 (2.56)	1	1 (2.56)
Staphylococcal abscess	1	1 (2.56)	1	1 (2.56)
Staphylococcal bacteraemia	1	1 (2.56)	1	1 (2.56)
Streptococcal sepsis	1	1 (2.56)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.56)	0	0 (0.00)
Viral skin infection	1	1 (2.56)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (5.13)	1	1 (2.56)
Infusion related reaction	1	1 (2.56)	1	1 (2.56)
Ligament sprain	1	1 (2.56)	0	0 (0.00)
Investigations				
- Total	13	4 (10.26)	5	1 (2.56)
Neutrophil count decreased	7	2 (5.13)	5	1 (2.56)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Blood bilirubin increased	3	1 (2.56)	0	0 (0.00)
Platelet count decreased	2	2 (5.13)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	3 (7.69)	3	2 (5.13)
Decreased appetite	2	1 (2.56)	2	1 (2.56)
Hyperlipidaemia	1	1 (2.56)	0	0 (0.00)
Hypernatraemia	1	1 (2.56)	1	1 (2.56)
Musculoskeletal and connective tissue disorders				
- Total	4	4 (10.26)	0	0 (0.00)
Pain in extremity	2	2 (5.13)	0	0 (0.00)
Growth retardation	1	1 (2.56)	0	0 (0.00)
Osteonecrosis	1	1 (2.56)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.56)	1	1 (2.56)
Bone giant cell tumour benign	2	1 (2.56)	1	1 (2.56)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Nervous system disorders				
- Total	9	4 (10.26)	3	2 (5.13)
Headache	3	2 (5.13)	1	1 (2.56)
Seizure	3	1 (2.56)	1	1 (2.56)
Nervous system disorder	2	1 (2.56)	1	1 (2.56)
Dysarthria	1	1 (2.56)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (7.69)	0	0 (0.00)
Anxiety	2	2 (5.13)	0	0 (0.00)
Tic	1	1 (2.56)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	7 (17.95)	3	3 (7.69)
Cough	2	2 (5.13)	0	0 (0.00)
Dyspnoea	2	2 (5.13)	0	0 (0.00)
Rhinorrhoea	2	2 (5.13)	0	0 (0.00)
Dyspnoea exertional	1	1 (2.56)	0	0 (0.00)
Epistaxis	1	1 (2.56)	0	0 (0.00)
Hypoxia	1	1 (2.56)	1	1 (2.56)

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=39 n (%)[1]	Grade >= 3 Total events	All patients N=39 n (%)[2]
Laryngeal oedema	1	1 (2.56)	1	1 (2.56)
Oropharyngeal pain	1	1 (2.56)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.56)	0	0 (0.00)
Respiratory failure	1	1 (2.56)	1	1 (2.56)
Sleep apnoea syndrome	1	1 (2.56)	0	0 (0.00)
Wheezing	1	1 (2.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	8	6 (15.38)	4	3 (7.69)
Rash macular	2	1 (2.56)	2	1 (2.56)
Dermatitis atopic	1	1 (2.56)	1	1 (2.56)
Dry skin	1	1 (2.56)	0	0 (0.00)
Eczema	1	1 (2.56)	1	1 (2.56)
Papule	1	1 (2.56)	0	0 (0.00)
Rash	1	1 (2.56)	0	0 (0.00)
Rash erythematous	1	1 (2.56)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	19	3 (50.00)	2	2 (33.33)
Eye disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Mydriasis	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Diarrhoea	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	8	2 (33.33)	1	1 (16.67)
Upper respiratory tract infection	3	1 (16.67)	1	1 (16.67)
Otitis media	2	1 (16.67)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Fungal skin infection	1	1 (16.67)	0	0 (0.00)
Sinusitis	1	1 (16.67)	0	0 (0.00)
Varicella zoster virus infection	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	4	1 (16.67)	0	0 (0.00)
Iron overload	2	1 (16.67)	0	0 (0.00)
Hypercholesterolaemia	1	1 (16.67)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (16.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	1 (16.67)	0	0 (0.00)
Joint effusion	1	1 (16.67)	0	0 (0.00)
Synovitis	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (16.67)	1	1 (16.67)
Endometriosis	2	1 (16.67)	1	1 (16.67)
Vascular disorders				

Timing: >1 year post-CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
- Total	1	1 (16.67)	0	0 (0.00)
Hypertension	1	1 (16.67)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	46	5 (100.00)	16	2 (40.00)
Blood and lymphatic system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hypercoagulation	1	1 (20.00)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Delayed puberty	1	1 (20.00)	0	0 (0.00)
Hypothyroidism	1	1 (20.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Dry eye	1	1 (20.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Gastrointestinal disorders				
- Total	5	3 (60.00)	0	0 (0.00)
Diarrhoea	2	2 (40.00)	0	0 (0.00)
Constipation	1	1 (20.00)	0	0 (0.00)
Nausea	1	1 (20.00)	0	0 (0.00)
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	2 (40.00)	1	1 (20.00)
Fatigue	1	1 (20.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (20.00)	1	1 (20.00)
Pyrexia	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	4	3 (60.00)	2	1 (20.00)
Seasonal allergy	2	2 (40.00)	0	0 (0.00)
Chronic graft versus host disease	1	1 (20.00)	1	1 (20.00)
Haemophagocytic lymphohistiocytosis	1	1 (20.00)	1	1 (20.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Infections and infestations				
- Total	11	3 (60.00)	6	1 (20.00)
COVID-19	1	1 (20.00)	0	0 (0.00)
COVID-19 pneumonia	1	1 (20.00)	1	1 (20.00)
Conjunctivitis	1	1 (20.00)	0	0 (0.00)
Enterovirus infection	1	1 (20.00)	1	1 (20.00)
Influenza	1	1 (20.00)	1	1 (20.00)
Parainfluenzae virus infection	1	1 (20.00)	1	1 (20.00)
Pneumonia	1	1 (20.00)	1	1 (20.00)
Rhinovirus infection	1	1 (20.00)	1	1 (20.00)
Skin infection	1	1 (20.00)	0	0 (0.00)
Syphilis	1	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (20.00)	0	0 (0.00)
Abdominal injury	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	3	2 (40.00)	1	1 (20.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Neutrophil count decreased	1	1 (20.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (20.00)	1	1 (20.00)
SARS-CoV-2 test positive	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (40.00)	2	2 (40.00)
Hyperglycaemia	1	1 (20.00)	1	1 (20.00)
Obesity	1	1 (20.00)	1	1 (20.00)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Arthralgia	1	1 (20.00)	0	0 (0.00)
Osteopenia	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	8	3 (60.00)	3	1 (20.00)
Cough	2	2 (40.00)	0	0 (0.00)
Tachypnoea	2	1 (20.00)	2	1 (20.00)
Dyspnoea	1	1 (20.00)	1	1 (20.00)

Timing: >1 year post-CTL019 infusion, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Pleural effusion	1	1 (20.00)	0	0 (0.00)
Rhinorrhoea	1	1 (20.00)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (20.00)	0	0 (0.00)
Rash	1	1 (20.00)	0	0 (0.00)
Rash maculo-papular	1	1 (20.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (20.00)	1	1 (20.00)
Hypertension	1	1 (20.00)	1	1 (20.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Total number of AE per patient	1863	59 (100.00)	547	53 (89.83)
Blood and lymphatic system disorders				
- Total	104	38 (64.41)	54	28 (47.46)
Anaemia	38	19 (32.20)	11	5 (8.47)
Febrile neutropenia	21	19 (32.20)	21	19 (32.20)
Neutropenia	9	8 (13.56)	7	6 (10.17)
Thrombocytopenia	7	6 (10.17)	6	6 (10.17)
Coagulopathy	5	5 (8.47)	2	2 (3.39)
Disseminated intravascular coagulation	5	5 (8.47)	2	2 (3.39)
B-cell aplasia	3	1 (1.69)	0	0 (0.00)
Eosinophilia	3	1 (1.69)	0	0 (0.00)
Leukopenia	3	2 (3.39)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Splenomegaly	3	3 (5.08)	0	0 (0.00)
Pancytopenia	2	2 (3.39)	2	2 (3.39)
Agranulocytosis	1	1 (1.69)	1	1 (1.69)
Leukocytosis	1	1 (1.69)	0	0 (0.00)
Lymphadenopathy	1	1 (1.69)	0	0 (0.00)
Lymphocytosis	1	1 (1.69)	0	0 (0.00)
Lymphopenia	1	1 (1.69)	1	1 (1.69)
Cardiac disorders				
- Total	44	21 (35.59)	9	7 (11.86)
Tachycardia	22	15 (25.42)	3	3 (5.08)
Cardiac failure	5	2 (3.39)	3	2 (3.39)
Sinus tachycardia	4	3 (5.08)	0	0 (0.00)
Bradycardia	3	3 (5.08)	0	0 (0.00)
Left ventricular dysfunction	3	3 (5.08)	2	2 (3.39)
Atrioventricular block first degree	1	1 (1.69)	0	0 (0.00)
Cardiac arrest	1	1 (1.69)	1	1 (1.69)
Cardiac failure congestive	1	1 (1.69)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.69)	0	0 (0.00)
Pericardial effusion	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Right ventricular dysfunction	1	1 (1.69)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.69)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.69)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.69)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.08)	0	0 (0.00)
Deafness unilateral	1	1 (1.69)	0	0 (0.00)
Ear pain	1	1 (1.69)	0	0 (0.00)
Ear pruritus	1	1 (1.69)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (6.78)	0	0 (0.00)
Adrenal insufficiency	2	2 (3.39)	0	0 (0.00)
Hypothyroidism	2	2 (3.39)	0	0 (0.00)
Eye disorders				
- Total	22	13 (22.03)	1	1 (1.69)
Eyelid oedema	4	3 (5.08)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Ocular hyperaemia	3	3 (5.08)	0	0 (0.00)
Cataract	2	2 (3.39)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.39)	0	0 (0.00)
Eye pain	2	2 (3.39)	1	1 (1.69)
Retinal haemorrhage	2	1 (1.69)	0	0 (0.00)
Visual impairment	2	2 (3.39)	0	0 (0.00)
Eye oedema	1	1 (1.69)	0	0 (0.00)
Hypermetropia	1	1 (1.69)	0	0 (0.00)
Periorbital oedema	1	1 (1.69)	0	0 (0.00)
Periorbital swelling	1	1 (1.69)	0	0 (0.00)
Visual field defect	1	1 (1.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	134	43 (72.88)	14	13 (22.03)
Vomiting	28	19 (32.20)	0	0 (0.00)
Diarrhoea	21	18 (30.51)	2	2 (3.39)
Nausea	20	15 (25.42)	1	1 (1.69)
Abdominal pain	13	10 (16.95)	2	2 (3.39)
Constipation	7	7 (11.86)	0	0 (0.00)
Abdominal pain upper	4	4 (6.78)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Mouth haemorrhage	4	4 (6.78)	1	1 (1.69)
Ascites	3	3 (5.08)	0	0 (0.00)
Abdominal distension	2	2 (3.39)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (3.39)	0	0 (0.00)
Pancreatitis	2	2 (3.39)	1	1 (1.69)
Proctalgia	2	2 (3.39)	1	1 (1.69)
Stomatitis	2	2 (3.39)	1	1 (1.69)
Abdominal compartment syndrome	1	1 (1.69)	1	1 (1.69)
Abdominal rigidity	1	1 (1.69)	0	0 (0.00)
Anal fissure	1	1 (1.69)	0	0 (0.00)
Anal haemorrhage	1	1 (1.69)	0	0 (0.00)
Dry mouth	1	1 (1.69)	0	0 (0.00)
Dyspepsia	1	1 (1.69)	0	0 (0.00)
Dysphagia	1	1 (1.69)	1	1 (1.69)
Gastrointestinal haemorrhage	1	1 (1.69)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.69)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.69)	0	0 (0.00)
Gingival bleeding	1	1 (1.69)	0	0 (0.00)
Gingival erythema	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Gingivitis ulcerative	1	1 (1.69)	1	1 (1.69)
Haematemesis	1	1 (1.69)	0	0 (0.00)
Ileus	1	1 (1.69)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.69)	0	0 (0.00)
Lip dry	1	1 (1.69)	0	0 (0.00)
Melaena	1	1 (1.69)	1	1 (1.69)
Mouth swelling	1	1 (1.69)	0	0 (0.00)
Neutropenic colitis	1	1 (1.69)	1	1 (1.69)
Odynophagia	1	1 (1.69)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.69)	0	0 (0.00)
Trichoglossia	1	1 (1.69)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	125	40 (67.80)	16	9 (15.25)
Pyrexia	47	26 (44.07)	7	7 (11.86)
Fatigue	16	14 (23.73)	0	0 (0.00)
Chills	9	6 (10.17)	0	0 (0.00)
Face oedema	9	8 (13.56)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Oedema peripheral	8	6 (10.17)	2	1 (1.69)
Catheter site pain	4	2 (3.39)	2	1 (1.69)
Generalised oedema	4	4 (6.78)	0	0 (0.00)
Pain	4	4 (6.78)	1	1 (1.69)
Asthenia	3	3 (5.08)	0	0 (0.00)
Catheter site erythema	2	1 (1.69)	0	0 (0.00)
Influenza like illness	2	2 (3.39)	0	0 (0.00)
Localised oedema	2	2 (3.39)	0	0 (0.00)
Malaise	2	2 (3.39)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.69)	0	0 (0.00)
Chest discomfort	1	1 (1.69)	1	1 (1.69)
Crying	1	1 (1.69)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.69)	0	0 (0.00)
Facial pain	1	1 (1.69)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.69)	1	1 (1.69)
Non-cardiac chest pain	1	1 (1.69)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.69)	0	0 (0.00)
Sluggishness	1	1 (1.69)	0	0 (0.00)
Swelling face	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Systemic inflammatory response syndrome	1	1 (1.69)	1	1 (1.69)
Vascular device occlusion	1	1 (1.69)	0	0 (0.00)
Xerosis	1	1 (1.69)	0	0 (0.00)
Hepatobiliary disorders				
- Total	19	12 (20.34)	1	1 (1.69)
Hyperbilirubinaemia	4	3 (5.08)	0	0 (0.00)
Hypertransaminasaemia	3	2 (3.39)	0	0 (0.00)
Cholelithiasis	2	2 (3.39)	0	0 (0.00)
Gallbladder enlargement	2	2 (3.39)	0	0 (0.00)
Hepatomegaly	2	2 (3.39)	0	0 (0.00)
Biliary tract disorder	1	1 (1.69)	0	0 (0.00)
Cholestasis	1	1 (1.69)	1	1 (1.69)
Hepatic cytolysis	1	1 (1.69)	0	0 (0.00)
Hepatic function abnormal	1	1 (1.69)	0	0 (0.00)
Liver disorder	1	1 (1.69)	0	0 (0.00)
Ocular icterus	1	1 (1.69)	0	0 (0.00)
Immune system disorders				
- Total	137	51 (86.44)	53	32 (54.24)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Cytokine release syndrome	87	43 (72.88)	36	26 (44.07)
Hypogammaglobulinaemia	31	24 (40.68)	7	7 (11.86)
Haemophagocytic lymphohistiocytosis	5	5 (8.47)	3	3 (5.08)
Immunodeficiency	3	3 (5.08)	3	3 (5.08)
Drug hypersensitivity	2	2 (3.39)	1	1 (1.69)
Graft versus host disease	2	2 (3.39)	2	2 (3.39)
Seasonal allergy	2	2 (3.39)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (1.69)	0	0 (0.00)
Chronic graft versus host disease	1	1 (1.69)	0	0 (0.00)
Engraftment syndrome	1	1 (1.69)	1	1 (1.69)
Hypersensitivity	1	1 (1.69)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.69)	0	0 (0.00)
Infections and infestations				
- Total	193	44 (74.58)	65	29 (49.15)
Sinusitis	13	6 (10.17)	2	2 (3.39)
Upper respiratory tract infection	11	9 (15.25)	1	1 (1.69)
Conjunctivitis	8	7 (11.86)	0	0 (0.00)
Rhinovirus infection	8	7 (11.86)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Bronchopulmonary aspergillosis	6	2 (3.39)	4	2 (3.39)
Gastroenteritis	6	6 (10.17)	2	2 (3.39)
Candida infection	5	4 (6.78)	2	1 (1.69)
Staphylococcal infection	5	5 (8.47)	2	2 (3.39)
Clostridium difficile infection	4	4 (6.78)	3	3 (5.08)
Nasopharyngitis	4	4 (6.78)	0	0 (0.00)
Oral candidiasis	4	3 (5.08)	0	0 (0.00)
Parainfluenzae virus infection	4	3 (5.08)	2	2 (3.39)
Pneumonia	4	4 (6.78)	2	2 (3.39)
Fungal infection	3	2 (3.39)	0	0 (0.00)
Gastroenteritis viral	3	2 (3.39)	0	0 (0.00)
Metapneumovirus infection	3	3 (5.08)	3	3 (5.08)
Nail infection	3	3 (5.08)	0	0 (0.00)
Oral herpes	3	3 (5.08)	0	0 (0.00)
Rhinitis	3	3 (5.08)	0	0 (0.00)
Sepsis	3	3 (5.08)	3	3 (5.08)
Acute sinusitis	2	2 (3.39)	0	0 (0.00)
Bronchitis	2	2 (3.39)	0	0 (0.00)
COVID-19	2	1 (1.69)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Device related sepsis	2	1 (1.69)	2	1 (1.69)
Ear infection	2	2 (3.39)	1	1 (1.69)
Encephalitis	2	2 (3.39)	2	2 (3.39)
Gingivitis	2	2 (3.39)	0	0 (0.00)
Herpes simplex	2	2 (3.39)	1	1 (1.69)
Herpes zoster	2	2 (3.39)	1	1 (1.69)
Influenza	2	2 (3.39)	0	0 (0.00)
Oral infection	2	2 (3.39)	0	0 (0.00)
Otitis media	2	2 (3.39)	0	0 (0.00)
Paronychia	2	2 (3.39)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (3.39)	2	2 (3.39)
Respiratory syncytial virus infection	2	2 (3.39)	1	1 (1.69)
Respiratory tract infection	2	2 (3.39)	0	0 (0.00)
Septic shock	2	2 (3.39)	2	2 (3.39)
Skin infection	2	2 (3.39)	0	0 (0.00)
Staphylococcal bacteraemia	2	2 (3.39)	2	2 (3.39)
Urinary tract infection	2	2 (3.39)	0	0 (0.00)
Adenovirus infection	1	1 (1.69)	1	1 (1.69)
Anal abscess	1	1 (1.69)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Atypical pneumonia	1	1 (1.69)	0	0 (0.00)
BK virus infection	1	1 (1.69)	1	1 (1.69)
Bacteraemia	1	1 (1.69)	0	0 (0.00)
Bronchiolitis	1	1 (1.69)	1	1 (1.69)
Cellulitis	1	1 (1.69)	0	0 (0.00)
Cholecystitis infective	1	1 (1.69)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.69)	1	1 (1.69)
Coronavirus infection	1	1 (1.69)	1	1 (1.69)
Cystitis	1	1 (1.69)	0	0 (0.00)
Device related infection	1	1 (1.69)	1	1 (1.69)
Ear, nose and throat infection	1	1 (1.69)	0	0 (0.00)
Folliculitis	1	1 (1.69)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.69)	1	1 (1.69)
Gastroenteritis clostridial	1	1 (1.69)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.69)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.69)	1	1 (1.69)
Gastrointestinal infection	1	1 (1.69)	0	0 (0.00)
Granulicatella infection	1	1 (1.69)	1	1 (1.69)
Herpes virus infection	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Human herpesvirus 6 infection	1	1 (1.69)	1	1 (1.69)
Klebsiella bacteraemia	1	1 (1.69)	0	0 (0.00)
Localised infection	1	1 (1.69)	0	0 (0.00)
Meningitis pneumococcal	1	1 (1.69)	1	1 (1.69)
Molluscum contagiosum	1	1 (1.69)	0	0 (0.00)
Myringitis	1	1 (1.69)	0	0 (0.00)
Neutropenic infection	1	1 (1.69)	1	1 (1.69)
Ophthalmic herpes zoster	1	1 (1.69)	0	0 (0.00)
Otitis externa	1	1 (1.69)	0	0 (0.00)
Otitis media acute	1	1 (1.69)	0	0 (0.00)
Pneumonia fungal	1	1 (1.69)	1	1 (1.69)
Pneumonia respiratory syncytial viral	1	1 (1.69)	1	1 (1.69)
Pneumonia viral	1	1 (1.69)	1	1 (1.69)
Respiratory tract infection viral	1	1 (1.69)	0	0 (0.00)
Salmonellosis	1	1 (1.69)	0	0 (0.00)
Sinusitis fungal	1	1 (1.69)	1	1 (1.69)
Soft tissue infection	1	1 (1.69)	1	1 (1.69)
Staphylococcal abscess	1	1 (1.69)	1	1 (1.69)
Staphylococcal sepsis	1	1 (1.69)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Staphylococcal skin infection	1	1 (1.69)	0	0 (0.00)
Stomatococcal infection	1	1 (1.69)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.69)	0	0 (0.00)
Systemic candida	1	1 (1.69)	1	1 (1.69)
Tinea pedis	1	1 (1.69)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.69)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.69)	1	1 (1.69)
Viral haemorrhagic cystitis	1	1 (1.69)	1	1 (1.69)
Viral infection	1	1 (1.69)	0	0 (0.00)
Viral skin infection	1	1 (1.69)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	31	19 (32.20)	4	3 (5.08)
Infusion related reaction	7	4 (6.78)	1	1 (1.69)
Contusion	3	2 (3.39)	0	0 (0.00)
Wound	3	2 (3.39)	1	1 (1.69)
Fall	2	2 (3.39)	0	0 (0.00)
Ligament sprain	2	2 (3.39)	0	0 (0.00)
Procedural pain	2	2 (3.39)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Skin abrasion	2	2 (3.39)	0	0 (0.00)
Transfusion reaction	2	2 (3.39)	0	0 (0.00)
Fibula fracture	1	1 (1.69)	0	0 (0.00)
Limb injury	1	1 (1.69)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.69)	0	0 (0.00)
Scratch	1	1 (1.69)	0	0 (0.00)
Skin injury	1	1 (1.69)	0	0 (0.00)
Skin wound	1	1 (1.69)	0	0 (0.00)
Transplant failure	1	1 (1.69)	1	1 (1.69)
Vasoplegia syndrome	1	1 (1.69)	1	1 (1.69)
Investigations				
- Total	361	44 (74.58)	158	33 (55.93)
Neutrophil count decreased	62	17 (28.81)	43	14 (23.73)
Platelet count decreased	53	18 (30.51)	27	10 (16.95)
White blood cell count decreased	44	16 (27.12)	20	9 (15.25)
Lymphocyte count decreased	33	14 (23.73)	23	12 (20.34)
Blood bilirubin increased	21	9 (15.25)	7	6 (10.17)
Aspartate aminotransferase increased	20	13 (22.03)	7	7 (11.86)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Alanine aminotransferase increased	19	13 (22.03)	4	4 (6.78)
Immunoglobulins decreased	10	2 (3.39)	0	0 (0.00)
International normalised ratio increased	9	7 (11.86)	0	0 (0.00)
Weight increased	7	4 (6.78)	2	2 (3.39)
Activated partial thromboplastin time prolonged	6	4 (6.78)	0	0 (0.00)
Blood creatinine increased	6	4 (6.78)	4	2 (3.39)
Blood immunoglobulin A decreased	6	6 (10.17)	1	1 (1.69)
Blood immunoglobulin M decreased	6	6 (10.17)	2	2 (3.39)
Blood lactate dehydrogenase increased	4	4 (6.78)	0	0 (0.00)
C-reactive protein increased	4	4 (6.78)	2	2 (3.39)
Electrocardiogram QT prolonged	4	4 (6.78)	1	1 (1.69)
Lipase increased	4	2 (3.39)	2	1 (1.69)
Blood fibrinogen decreased	3	3 (5.08)	0	0 (0.00)
Blood immunoglobulin G decreased	3	3 (5.08)	0	0 (0.00)
Blood uric acid increased	3	3 (5.08)	1	1 (1.69)
Serum ferritin increased	3	3 (5.08)	1	1 (1.69)
Urine output decreased	3	2 (3.39)	3	2 (3.39)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Blood glucose increased	2	1 (1.69)	2	1 (1.69)
Haemoglobin decreased	2	1 (1.69)	1	1 (1.69)
Oxygen saturation decreased	2	2 (3.39)	0	0 (0.00)
Weight decreased	2	2 (3.39)	1	1 (1.69)
Amylase increased	1	1 (1.69)	0	0 (0.00)
Bacterial test positive	1	1 (1.69)	1	1 (1.69)
Blood alkaline phosphatase increased	1	1 (1.69)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.69)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.69)	1	1 (1.69)
Blood testosterone decreased	1	1 (1.69)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.69)	0	0 (0.00)
Blood urea increased	1	1 (1.69)	1	1 (1.69)
Bone density decreased	1	1 (1.69)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.69)	0	0 (0.00)
Cardiac murmur	1	1 (1.69)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.69)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Enterovirus test positive	1	1 (1.69)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.69)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.69)	1	1 (1.69)
Heart sounds abnormal	1	1 (1.69)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.69)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.69)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.69)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	168	36 (61.02)	58	21 (35.59)
Hypokalaemia	34	15 (25.42)	19	8 (13.56)
Decreased appetite	25	23 (38.98)	9	7 (11.86)
Hypophosphataemia	21	13 (22.03)	6	6 (10.17)
Hypocalcaemia	18	11 (18.64)	4	3 (5.08)
Hypoalbuminaemia	11	6 (10.17)	0	0 (0.00)
Hyperuricaemia	9	6 (10.17)	1	1 (1.69)
Hyperglycaemia	7	5 (8.47)	3	3 (5.08)
Hypervolaemia	5	5 (8.47)	3	3 (5.08)
Hyperphosphataemia	4	4 (6.78)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Hypomagnesaemia	4	3 (5.08)	0	0 (0.00)
Hypermagnesaemia	3	2 (3.39)	0	0 (0.00)
Hypernatraemia	3	3 (5.08)	2	2 (3.39)
Acidosis	2	1 (1.69)	1	1 (1.69)
Hyperchloraemia	2	2 (3.39)	0	0 (0.00)
Hyperkalaemia	2	2 (3.39)	1	1 (1.69)
Hypertriglyceridaemia	2	2 (3.39)	2	2 (3.39)
Hyponatraemia	2	2 (3.39)	0	0 (0.00)
Metabolic acidosis	2	2 (3.39)	1	1 (1.69)
Tumour lysis syndrome	2	2 (3.39)	2	2 (3.39)
Dehydration	1	1 (1.69)	0	0 (0.00)
Haemochromatosis	1	1 (1.69)	1	1 (1.69)
Haemosiderosis	1	1 (1.69)	0	0 (0.00)
Hypercalcaemia	1	1 (1.69)	1	1 (1.69)
Hyperlactacidaemia	1	1 (1.69)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.69)	0	0 (0.00)
Iron overload	1	1 (1.69)	0	0 (0.00)
Malnutrition	1	1 (1.69)	1	1 (1.69)
Metabolic syndrome	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Polydipsia	1	1 (1.69)	1	1 (1.69)
Musculoskeletal and connective tissue disorders				
- Total	59	34 (57.63)	4	4 (6.78)
Pain in extremity	16	15 (25.42)	0	0 (0.00)
Arthralgia	10	8 (13.56)	0	0 (0.00)
Myalgia	9	8 (13.56)	0	0 (0.00)
Back pain	8	7 (11.86)	2	2 (3.39)
Bone pain	3	3 (5.08)	0	0 (0.00)
Neck pain	2	2 (3.39)	0	0 (0.00)
Pain in jaw	2	2 (3.39)	1	1 (1.69)
Growth retardation	1	1 (1.69)	0	0 (0.00)
Muscle rigidity	1	1 (1.69)	0	0 (0.00)
Muscle spasms	1	1 (1.69)	0	0 (0.00)
Muscular weakness	1	1 (1.69)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.69)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.69)	0	0 (0.00)
Myositis	1	1 (1.69)	0	0 (0.00)
Osteonecrosis	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Rhabdomyolysis	1	1 (1.69)	1	1 (1.69)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (8.47)	2	2 (3.39)
Bone giant cell tumour benign	2	1 (1.69)	1	1 (1.69)
Skin papilloma	2	2 (3.39)	0	0 (0.00)
Cancer pain	1	1 (1.69)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.69)	1	1 (1.69)
Nervous system disorders				
- Total	87	38 (64.41)	22	13 (22.03)
Headache	35	24 (40.68)	3	3 (5.08)
Encephalopathy	8	8 (13.56)	4	4 (6.78)
Dizziness	5	4 (6.78)	0	0 (0.00)
Seizure	5	3 (5.08)	3	3 (5.08)
Somnolence	5	5 (8.47)	2	2 (3.39)
Tremor	5	5 (8.47)	0	0 (0.00)
Hydrocephalus	3	1 (1.69)	3	1 (1.69)
Cerebral haemorrhage	2	2 (3.39)	2	2 (3.39)
Dysarthria	2	2 (3.39)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Dysgeusia	2	2 (3.39)	0	0 (0.00)
Lethargy	2	2 (3.39)	0	0 (0.00)
Migraine	2	1 (1.69)	0	0 (0.00)
Nervous system disorder	2	1 (1.69)	1	1 (1.69)
Aphasia	1	1 (1.69)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.69)	1	1 (1.69)
Depressed level of consciousness	1	1 (1.69)	1	1 (1.69)
Disturbance in attention	1	1 (1.69)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.69)	0	0 (0.00)
Hypoaesthesia	1	1 (1.69)	0	0 (0.00)
Memory impairment	1	1 (1.69)	0	0 (0.00)
Monoparesis	1	1 (1.69)	0	0 (0.00)
Neurological decompensation	1	1 (1.69)	1	1 (1.69)
Psychiatric disorders				
- Total	53	30 (50.85)	5	5 (8.47)
Anxiety	8	8 (13.56)	1	1 (1.69)
Delirium	7	7 (11.86)	3	3 (5.08)
Agitation	6	5 (8.47)	0	0 (0.00)
Confusional state	5	5 (8.47)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Insomnia	4	4 (6.78)	0	0 (0.00)
Mental status changes	4	4 (6.78)	1	1 (1.69)
Sleep disorder	4	3 (5.08)	0	0 (0.00)
Hallucination	3	3 (5.08)	0	0 (0.00)
Irritability	3	3 (5.08)	0	0 (0.00)
Affect lability	1	1 (1.69)	0	0 (0.00)
Automatism	1	1 (1.69)	0	0 (0.00)
Mood altered	1	1 (1.69)	0	0 (0.00)
Nightmare	1	1 (1.69)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.69)	0	0 (0.00)
Restlessness	1	1 (1.69)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.69)	0	0 (0.00)
Tearfulness	1	1 (1.69)	0	0 (0.00)
Tic	1	1 (1.69)	0	0 (0.00)
Renal and urinary disorders				
- Total	41	20 (33.90)	13	10 (16.95)
Acute kidney injury	14	10 (16.95)	6	6 (10.17)
Dysuria	4	4 (6.78)	0	0 (0.00)
Renal failure	4	2 (3.39)	3	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Anuria	2	2 (3.39)	1	1 (1.69)
Haematuria	2	2 (3.39)	1	1 (1.69)
Pollakiuria	2	2 (3.39)	0	0 (0.00)
Urinary incontinence	2	1 (1.69)	0	0 (0.00)
Azotaemia	1	1 (1.69)	0	0 (0.00)
Bladder dilatation	1	1 (1.69)	0	0 (0.00)
Incontinence	1	1 (1.69)	0	0 (0.00)
Kidney enlargement	1	1 (1.69)	0	0 (0.00)
Micturition urgency	1	1 (1.69)	0	0 (0.00)
Renal mass	1	1 (1.69)	0	0 (0.00)
Renal tubular disorder	1	1 (1.69)	1	1 (1.69)
Renal tubular dysfunction	1	1 (1.69)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.69)	1	1 (1.69)
Urinary retention	1	1 (1.69)	0	0 (0.00)
Urinary tract disorder	1	1 (1.69)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	4 (6.78)	1	1 (1.69)
Dysmenorrhoea	2	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Vaginal haemorrhage	2	1 (1.69)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.69)	0	0 (0.00)
Perineal rash	1	1 (1.69)	0	0 (0.00)
Vaginal ulceration	1	1 (1.69)	1	1 (1.69)
Respiratory, thoracic and mediastinal disorders				
- Total	141	39 (66.10)	42	19 (32.20)
Cough	24	19 (32.20)	0	0 (0.00)
Hypoxia	16	14 (23.73)	11	10 (16.95)
Pulmonary oedema	10	10 (16.95)	5	5 (8.47)
Nasal congestion	9	8 (13.56)	0	0 (0.00)
Oropharyngeal pain	8	7 (11.86)	0	0 (0.00)
Tachypnoea	8	7 (11.86)	4	4 (6.78)
Dyspnoea	7	6 (10.17)	3	3 (5.08)
Epistaxis	6	6 (10.17)	0	0 (0.00)
Pleural effusion	6	5 (8.47)	2	2 (3.39)
Rhinorrhoea	6	4 (6.78)	0	0 (0.00)
Atelectasis	5	3 (5.08)	2	2 (3.39)
Respiratory distress	5	4 (6.78)	3	2 (3.39)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Respiratory failure	5	5 (8.47)	5	5 (8.47)
Acute respiratory distress syndrome	2	2 (3.39)	2	2 (3.39)
Lung infiltration	2	1 (1.69)	1	1 (1.69)
Pharyngeal erythema	2	2 (3.39)	0	0 (0.00)
Acute respiratory failure	1	1 (1.69)	1	1 (1.69)
Bradypnoea	1	1 (1.69)	1	1 (1.69)
Dyspnoea exertional	1	1 (1.69)	0	0 (0.00)
Laryngeal oedema	1	1 (1.69)	1	1 (1.69)
Lung disorder	1	1 (1.69)	0	0 (0.00)
Nasal discomfort	1	1 (1.69)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.69)	0	0 (0.00)
Painful respiration	1	1 (1.69)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.69)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.69)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.69)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.69)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.69)	0	0 (0.00)
Productive cough	1	1 (1.69)	0	0 (0.00)
Pulmonary mass	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Respiratory acidosis	1	1 (1.69)	1	1 (1.69)
Respiratory disorder	1	1 (1.69)	0	0 (0.00)
Rhinitis allergic	1	1 (1.69)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.69)	0	0 (0.00)
Wheezing	1	1 (1.69)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	81	32 (54.24)	7	5 (8.47)
Rash	12	7 (11.86)	0	0 (0.00)
Dry skin	8	7 (11.86)	0	0 (0.00)
Blister	6	3 (5.08)	0	0 (0.00)
Pruritus	6	5 (8.47)	0	0 (0.00)
Dermatitis atopic	4	3 (5.08)	1	1 (1.69)
Erythema	4	4 (6.78)	0	0 (0.00)
Rash papular	4	3 (5.08)	0	0 (0.00)
Eczema	3	3 (5.08)	1	1 (1.69)
Hyperhidrosis	3	3 (5.08)	0	0 (0.00)
Ingrowing nail	2	2 (3.39)	0	0 (0.00)
Petechiae	2	2 (3.39)	1	1 (1.69)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Rash macular	2	1 (1.69)	2	1 (1.69)
Rash vesicular	2	1 (1.69)	0	0 (0.00)
Skin discolouration	2	2 (3.39)	0	0 (0.00)
Decubitus ulcer	1	1 (1.69)	0	0 (0.00)
Dermatitis	1	1 (1.69)	0	0 (0.00)
Dermatitis allergic	1	1 (1.69)	0	0 (0.00)
Dermatitis diaper	1	1 (1.69)	0	0 (0.00)
Hangnail	1	1 (1.69)	0	0 (0.00)
Miliaria	1	1 (1.69)	0	0 (0.00)
Night sweats	1	1 (1.69)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.69)	0	0 (0.00)
Papule	1	1 (1.69)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.69)	0	0 (0.00)
Pruritus allergic	1	1 (1.69)	0	0 (0.00)
Rash erythematous	1	1 (1.69)	0	0 (0.00)
Rash maculo-papular	1	1 (1.69)	0	0 (0.00)
Rash pruritic	1	1 (1.69)	0	0 (0.00)
Scab	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Skin hypopigmentation	1	1 (1.69)	0	0 (0.00)
Skin lesion	1	1 (1.69)	0	0 (0.00)
Skin necrosis	1	1 (1.69)	1	1 (1.69)
Skin ulcer	1	1 (1.69)	0	0 (0.00)
Urticaria	1	1 (1.69)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.69)	1	1 (1.69)
Social circumstances				
- Total	1	1 (1.69)	0	0 (0.00)
Patient uncooperative	1	1 (1.69)	0	0 (0.00)
Vascular disorders				
- Total	41	23 (38.98)	18	13 (22.03)
Hypotension	25	21 (35.59)	16	13 (22.03)
Hypertension	10	9 (15.25)	1	1 (1.69)
Capillary leak syndrome	1	1 (1.69)	0	0 (0.00)
Flushing	1	1 (1.69)	0	0 (0.00)
Hot flush	1	1 (1.69)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.69)	0	0 (0.00)
Thrombosis	1	1 (1.69)	0	0 (0.00)

Timing: At anytime, Race: White

Primary system organ class Preferred term	All grades Total events	All patients N=59 n (%)[1]	Grade >= 3 Total events	All patients N=59 n (%)[2]
Venoocclusive disease	1	1 (1.69)	1	1 (1.69)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Total number of AE per patient	198	10 (100.00)	88	9 (90.00)
Blood and lymphatic system disorders				
- Total	23	8 (80.00)	19	7 (70.00)
Neutropenia	8	3 (30.00)	8	3 (30.00)
Febrile neutropenia	4	2 (20.00)	4	2 (20.00)
Disseminated intravascular coagulation	3	3 (30.00)	1	1 (10.00)
Thrombocytopenia	3	2 (20.00)	3	2 (20.00)
Leukopenia	2	1 (10.00)	2	1 (10.00)
Hypofibrinogenaemia	1	1 (10.00)	0	0 (0.00)
Lymphopenia	1	1 (10.00)	1	1 (10.00)
Splenomegaly	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Cardiac disorders				
- Total	5	4 (40.00)	2	2 (20.00)
Cardiac dysfunction	2	2 (20.00)	0	0 (0.00)
Cardiac arrest	1	1 (10.00)	1	1 (10.00)
Cardiac failure	1	1 (10.00)	1	1 (10.00)
Tachycardia	1	1 (10.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (10.00)	0	0 (0.00)
Mydriasis	1	1 (10.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	16	7 (70.00)	0	0 (0.00)
Constipation	3	3 (30.00)	0	0 (0.00)
Diarrhoea	3	3 (30.00)	0	0 (0.00)
Nausea	3	3 (30.00)	0	0 (0.00)
Pancreatitis	2	2 (20.00)	0	0 (0.00)
Enteritis	1	1 (10.00)	0	0 (0.00)
Enterocolitis	1	1 (10.00)	0	0 (0.00)
Stomatitis	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Trichoglossia	1	1 (10.00)	0	0 (0.00)
Vomiting	1	1 (10.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	3 (30.00)	1	1 (10.00)
Pyrexia	3	3 (30.00)	1	1 (10.00)
Fatigue	1	1 (10.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	11	5 (50.00)	5	4 (40.00)
Hepatic function abnormal	10	4 (40.00)	4	3 (30.00)
Hepatomegaly	1	1 (10.00)	1	1 (10.00)
Immune system disorders				
- Total	20	9 (90.00)	6	5 (50.00)
Cytokine release syndrome	15	8 (80.00)	6	5 (50.00)
Hypogammaglobulinaemia	5	5 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	23	8 (80.00)	10	5 (50.00)
Upper respiratory tract infection	3	1 (10.00)	1	1 (10.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Nasopharyngitis	2	1 (10.00)	0	0 (0.00)
Oral herpes	2	1 (10.00)	1	1 (10.00)
Otitis media	2	1 (10.00)	0	0 (0.00)
BK virus infection	1	1 (10.00)	0	0 (0.00)
Bacteraemia	1	1 (10.00)	1	1 (10.00)
Cytomegalovirus infection reactivation	1	1 (10.00)	1	1 (10.00)
Encephalitis viral	1	1 (10.00)	1	1 (10.00)
Fungal skin infection	1	1 (10.00)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (10.00)	1	1 (10.00)
Meningitis bacterial	1	1 (10.00)	1	1 (10.00)
Otitis externa	1	1 (10.00)	0	0 (0.00)
Pneumonia	1	1 (10.00)	1	1 (10.00)
Sinusitis	1	1 (10.00)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (10.00)	1	1 (10.00)
Urinary tract infection viral	1	1 (10.00)	0	0 (0.00)
Varicella zoster virus infection	1	1 (10.00)	0	0 (0.00)
Viral infection	1	1 (10.00)	1	1 (10.00)
Investigations				
- Total	33	7 (70.00)	21	6 (60.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
White blood cell count decreased	10	4 (40.00)	10	4 (40.00)
Neutrophil count decreased	6	2 (20.00)	6	2 (20.00)
Blood creatine phosphokinase increased	3	1 (10.00)	1	1 (10.00)
Blood fibrinogen decreased	3	3 (30.00)	1	1 (10.00)
Serum ferritin increased	3	3 (30.00)	0	0 (0.00)
Aspartate aminotransferase increased	2	2 (20.00)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (10.00)	0	0 (0.00)
Blood bilirubin increased	1	1 (10.00)	1	1 (10.00)
Fibrin D dimer increased	1	1 (10.00)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (10.00)	1	1 (10.00)
Haptoglobin decreased	1	1 (10.00)	0	0 (0.00)
Platelet count decreased	1	1 (10.00)	1	1 (10.00)
Metabolism and nutrition disorders				
- Total	15	6 (60.00)	7	3 (30.00)
Hypercalcaemia	2	1 (10.00)	1	1 (10.00)
Iron overload	2	1 (10.00)	0	0 (0.00)
Metabolic acidosis	2	2 (20.00)	2	2 (20.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Tumour lysis syndrome	2	2 (20.00)	2	2 (20.00)
Decreased appetite	1	1 (10.00)	0	0 (0.00)
Hypercholesterolaemia	1	1 (10.00)	0	0 (0.00)
Hyperkalaemia	1	1 (10.00)	1	1 (10.00)
Hyperphosphataemia	1	1 (10.00)	1	1 (10.00)
Hypertriglyceridaemia	1	1 (10.00)	0	0 (0.00)
Hyperuricaemia	1	1 (10.00)	0	0 (0.00)
Hypoalbuminaemia	1	1 (10.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	8	4 (40.00)	2	2 (20.00)
Arthralgia	2	2 (20.00)	0	0 (0.00)
Back pain	1	1 (10.00)	1	1 (10.00)
Joint effusion	1	1 (10.00)	0	0 (0.00)
Muscular weakness	1	1 (10.00)	1	1 (10.00)
Musculoskeletal chest pain	1	1 (10.00)	0	0 (0.00)
Pain in extremity	1	1 (10.00)	0	0 (0.00)
Synovitis	1	1 (10.00)	0	0 (0.00)
Nervous system disorders				

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
- Total	3	2 (20.00)	0	0 (0.00)
Seizure	2	1 (10.00)	0	0 (0.00)
Headache	1	1 (10.00)	0	0 (0.00)
Psychiatric disorders				
- Total	2	1 (10.00)	0	0 (0.00)
Anxiety	1	1 (10.00)	0	0 (0.00)
Delirium	1	1 (10.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	4 (40.00)	3	2 (20.00)
Acute kidney injury	3	2 (20.00)	3	2 (20.00)
Cystitis haemorrhagic	1	1 (10.00)	0	0 (0.00)
Haematuria	1	1 (10.00)	0	0 (0.00)
Proteinuria	1	1 (10.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (10.00)	1	1 (10.00)
Endometriosis	2	1 (10.00)	1	1 (10.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	18	8 (80.00)	10	4 (40.00)
Hypoxia	9	4 (40.00)	9	4 (40.00)
Pleural effusion	2	2 (20.00)	0	0 (0.00)
Cough	1	1 (10.00)	0	0 (0.00)
Haemoptysis	1	1 (10.00)	0	0 (0.00)
Nasal congestion	1	1 (10.00)	0	0 (0.00)
Nasal dryness	1	1 (10.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (10.00)	0	0 (0.00)
Respiratory failure	1	1 (10.00)	1	1 (10.00)
Upper respiratory tract inflammation	1	1 (10.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	3 (30.00)	0	0 (0.00)
Dry skin	1	1 (10.00)	0	0 (0.00)
Erythema nodosum	1	1 (10.00)	0	0 (0.00)
Pruritus	1	1 (10.00)	0	0 (0.00)
Skin swelling	1	1 (10.00)	0	0 (0.00)

Timing: At anytime, Race: Asian

Primary system organ class Preferred term	All grades Total events	All patients N=10 n (%)[1]	Grade >= 3 Total events	All patients N=10 n (%)[2]
Skin ulcer	1	1 (10.00)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (30.00)	1	1 (10.00)
Hypertension	2	2 (20.00)	0	0 (0.00)
Hypotension	1	1 (10.00)	1	1 (10.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250c
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Race
Safety Set

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	444	11 (100.00)	193	11 (100.00)
Blood and lymphatic system disorders				
- Total	36	9 (81.82)	22	8 (72.73)
Anaemia	25	6 (54.55)	13	4 (36.36)
Febrile neutropenia	8	6 (54.55)	8	6 (54.55)
Hypercoagulation	1	1 (9.09)	0	0 (0.00)
Lymphadenopathy	1	1 (9.09)	0	0 (0.00)
Thrombocytopenia	1	1 (9.09)	1	1 (9.09)
Cardiac disorders				
- Total	4	3 (27.27)	3	2 (18.18)
Cardiac arrest	1	1 (9.09)	1	1 (9.09)
Left ventricular dysfunction	1	1 (9.09)	1	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Sinus bradycardia	1	1 (9.09)	1	1 (9.09)
Tachycardia	1	1 (9.09)	0	0 (0.00)
Endocrine disorders				
- Total	4	3 (27.27)	0	0 (0.00)
Adrenal insufficiency	2	2 (18.18)	0	0 (0.00)
Delayed puberty	1	1 (9.09)	0	0 (0.00)
Hypothyroidism	1	1 (9.09)	0	0 (0.00)
Eye disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Dry eye	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				
- Total	32	10 (90.91)	4	3 (27.27)
Vomiting	9	6 (54.55)	1	1 (9.09)
Constipation	6	4 (36.36)	0	0 (0.00)
Diarrhoea	6	5 (45.45)	0	0 (0.00)
Nausea	4	4 (36.36)	1	1 (9.09)
Abdominal pain	2	1 (9.09)	0	0 (0.00)
Pancreatitis	2	2 (18.18)	1	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Abdominal distension	1	1 (9.09)	0	0 (0.00)
Lip oedema	1	1 (9.09)	0	0 (0.00)
Mouth haemorrhage	1	1 (9.09)	1	1 (9.09)
General disorders and administration site conditions				
- Total	27	10 (90.91)	7	5 (45.45)
Pyrexia	17	6 (54.55)	4	3 (27.27)
Fatigue	2	2 (18.18)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (18.18)	2	2 (18.18)
Chills	1	1 (9.09)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (9.09)	0	0 (0.00)
Generalised oedema	1	1 (9.09)	0	0 (0.00)
Non-cardiac chest pain	1	1 (9.09)	0	0 (0.00)
Oedema peripheral	1	1 (9.09)	0	0 (0.00)
Pain	1	1 (9.09)	1	1 (9.09)
Hepatobiliary disorders				
- Total	2	2 (18.18)	1	1 (9.09)
Hyperbilirubinaemia	2	2 (18.18)	1	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Immune system disorders				
- Total	36	11 (100.00)	17	9 (81.82)
Cytokine release syndrome	26	10 (90.91)	13	7 (63.64)
Hypogammaglobulinaemia	4	4 (36.36)	0	0 (0.00)
Seasonal allergy	2	2 (18.18)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (9.09)	1	1 (9.09)
Chronic graft versus host disease	1	1 (9.09)	1	1 (9.09)
Haemophagocytic lymphohistiocytosis	1	1 (9.09)	1	1 (9.09)
Immunodeficiency	1	1 (9.09)	1	1 (9.09)
Infections and infestations				
- Total	47	8 (72.73)	27	5 (45.45)
Conjunctivitis	4	1 (9.09)	0	0 (0.00)
Klebsiella infection	3	1 (9.09)	3	1 (9.09)
Nasopharyngitis	3	2 (18.18)	0	0 (0.00)
Rhinovirus infection	3	2 (18.18)	1	1 (9.09)
Staphylococcal bacteraemia	3	2 (18.18)	3	2 (18.18)
Upper respiratory tract infection	3	3 (27.27)	1	1 (9.09)
Bacteraemia	2	1 (9.09)	2	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Ear infection	2	1 (9.09)	0	0 (0.00)
Otitis media	2	2 (18.18)	1	1 (9.09)
Parainfluenzae virus infection	2	2 (18.18)	1	1 (9.09)
Urinary tract infection	2	1 (9.09)	2	1 (9.09)
Adenovirus infection	1	1 (9.09)	1	1 (9.09)
COVID-19	1	1 (9.09)	0	0 (0.00)
COVID-19 pneumonia	1	1 (9.09)	1	1 (9.09)
Encephalitis viral	1	1 (9.09)	1	1 (9.09)
Enterobacter infection	1	1 (9.09)	1	1 (9.09)
Enterovirus infection	1	1 (9.09)	1	1 (9.09)
Herpes zoster	1	1 (9.09)	1	1 (9.09)
Influenza	1	1 (9.09)	1	1 (9.09)
Mastoiditis	1	1 (9.09)	1	1 (9.09)
Nail infection	1	1 (9.09)	0	0 (0.00)
Otitis externa	1	1 (9.09)	1	1 (9.09)
Pharyngitis streptococcal	1	1 (9.09)	1	1 (9.09)
Pneumonia	1	1 (9.09)	1	1 (9.09)
Respiratory syncytial virus infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Skin infection	1	1 (9.09)	0	0 (0.00)
Syphilis	1	1 (9.09)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (9.09)	1	1 (9.09)
Injury, poisoning and procedural complications				
- Total	2	2 (18.18)	0	0 (0.00)
Abdominal injury	1	1 (9.09)	0	0 (0.00)
Infusion related reaction	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	99	9 (81.82)	59	9 (81.82)
Platelet count decreased	29	5 (45.45)	19	4 (36.36)
White blood cell count decreased	14	5 (45.45)	10	5 (45.45)
Aspartate aminotransferase increased	11	4 (36.36)	6	4 (36.36)
Alanine aminotransferase increased	9	4 (36.36)	3	3 (27.27)
Neutrophil count decreased	7	5 (45.45)	5	5 (45.45)
Blood bilirubin increased	3	3 (27.27)	2	2 (18.18)
International normalised ratio increased	3	2 (18.18)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Lymphocyte count decreased	3	3 (27.27)	3	3 (27.27)
Activated partial thromboplastin time prolonged	2	2 (18.18)	1	1 (9.09)
Electrocardiogram QT prolonged	2	1 (9.09)	1	1 (9.09)
Serum ferritin increased	2	2 (18.18)	1	1 (9.09)
Blood creatinine increased	1	1 (9.09)	1	1 (9.09)
Blood fibrinogen decreased	1	1 (9.09)	1	1 (9.09)
Blood immunoglobulin A decreased	1	1 (9.09)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (9.09)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (9.09)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (9.09)	1	1 (9.09)
Blood phosphorus increased	1	1 (9.09)	0	0 (0.00)
Blood uric acid increased	1	1 (9.09)	1	1 (9.09)
C-reactive protein increased	1	1 (9.09)	1	1 (9.09)
Electrocardiogram T wave abnormal	1	1 (9.09)	0	0 (0.00)
Fibrin D dimer increased	1	1 (9.09)	1	1 (9.09)
Oxygen saturation decreased	1	1 (9.09)	1	1 (9.09)
SARS-CoV-2 test positive	1	1 (9.09)	0	0 (0.00)
Troponin increased	1	1 (9.09)	1	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Metabolism and nutrition disorders				
- Total	63	10 (90.91)	26	9 (81.82)
Hypokalaemia	12	5 (45.45)	5	3 (27.27)
Hypophosphataemia	11	5 (45.45)	5	3 (27.27)
Hypoalbuminaemia	7	4 (36.36)	1	1 (9.09)
Decreased appetite	6	6 (54.55)	5	5 (45.45)
Hypocalcaemia	6	5 (45.45)	2	2 (18.18)
Hyperglycaemia	5	4 (36.36)	2	2 (18.18)
Hypomagnesaemia	3	3 (27.27)	0	0 (0.00)
Hyperuricaemia	2	2 (18.18)	0	0 (0.00)
Hypervolaemia	2	2 (18.18)	2	2 (18.18)
Acidosis	1	1 (9.09)	1	1 (9.09)
Calcium deficiency	1	1 (9.09)	0	0 (0.00)
Hypercalcaemia	1	1 (9.09)	0	0 (0.00)
Hypoglycaemia	1	1 (9.09)	0	0 (0.00)
Hyponatraemia	1	1 (9.09)	0	0 (0.00)
Hypophagia	1	1 (9.09)	0	0 (0.00)
Malnutrition	1	1 (9.09)	1	1 (9.09)
Obesity	1	1 (9.09)	1	1 (9.09)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Tumour lysis syndrome	1	1 (9.09)	1	1 (9.09)
Musculoskeletal and connective tissue disorders				
- Total	16	6 (54.55)	3	2 (18.18)
Back pain	5	2 (18.18)	0	0 (0.00)
Bone pain	3	1 (9.09)	0	0 (0.00)
Arthralgia	2	2 (18.18)	1	1 (9.09)
Myalgia	2	2 (18.18)	0	0 (0.00)
Growth retardation	1	1 (9.09)	0	0 (0.00)
Haemarthrosis	1	1 (9.09)	1	1 (9.09)
Osteopenia	1	1 (9.09)	0	0 (0.00)
Pain in extremity	1	1 (9.09)	1	1 (9.09)
Nervous system disorders				
- Total	19	7 (63.64)	1	1 (9.09)
Cognitive disorder	5	3 (27.27)	1	1 (9.09)
Headache	4	2 (18.18)	0	0 (0.00)
Hyperaesthesia	2	1 (9.09)	0	0 (0.00)
Tremor	2	1 (9.09)	0	0 (0.00)
Amnesia	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Dysgeusia	1	1 (9.09)	0	0 (0.00)
Extrapyramidal disorder	1	1 (9.09)	0	0 (0.00)
Lethargy	1	1 (9.09)	0	0 (0.00)
Neuralgia	1	1 (9.09)	0	0 (0.00)
Paraesthesia	1	1 (9.09)	0	0 (0.00)
Psychiatric disorders				
- Total	10	8 (72.73)	2	2 (18.18)
Anxiety	5	5 (45.45)	1	1 (9.09)
Confusional state	2	2 (18.18)	0	0 (0.00)
Agitation	1	1 (9.09)	0	0 (0.00)
Hallucination, visual	1	1 (9.09)	0	0 (0.00)
Mental status changes	1	1 (9.09)	1	1 (9.09)
Renal and urinary disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Urinary retention	1	1 (9.09)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Female genital tract fistula	1	1 (9.09)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	24	8 (72.73)	10	6 (54.55)
Cough	4	3 (27.27)	0	0 (0.00)
Tachypnoea	3	2 (18.18)	2	1 (9.09)
Epistaxis	2	1 (9.09)	1	1 (9.09)
Hypoxia	2	2 (18.18)	2	2 (18.18)
Pleural effusion	2	2 (18.18)	1	1 (9.09)
Pulmonary oedema	2	2 (18.18)	2	2 (18.18)
Rhinorrhoea	2	2 (18.18)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (9.09)	1	1 (9.09)
Bronchial oedema	1	1 (9.09)	0	0 (0.00)
Bronchospasm	1	1 (9.09)	0	0 (0.00)
Dyspnoea	1	1 (9.09)	1	1 (9.09)
Rhinitis allergic	1	1 (9.09)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (9.09)	0	0 (0.00)
Wheezing	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Race: Other

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	9	5 (45.45)	2	2 (18.18)
Rash maculo-papular	3	2 (18.18)	1	1 (9.09)
Pruritus	2	1 (9.09)	0	0 (0.00)
Decubitus ulcer	1	1 (9.09)	1	1 (9.09)
Erythema	1	1 (9.09)	0	0 (0.00)
Purpura	1	1 (9.09)	0	0 (0.00)
Rash	1	1 (9.09)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (9.09)	1	1 (9.09)
Thrombolysis	1	1 (9.09)	1	1 (9.09)
Vascular disorders				
- Total	10	8 (72.73)	8	7 (63.64)
Hypertension	5	5 (45.45)	4	4 (36.36)
Hypotension	3	2 (18.18)	2	2 (18.18)
Capillary leak syndrome	1	1 (9.09)	1	1 (9.09)
Venoocclusive disease	1	1 (9.09)	1	1 (9.09)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Total number of AE per patient	383	15 (100.00)	173	12 (80.00)
Blood and lymphatic system disorders				
- Total	32	10 (66.67)	21	9 (60.00)
Anaemia	18	4 (26.67)	9	3 (20.00)
Febrile neutropenia	10	8 (53.33)	10	8 (53.33)
Coagulopathy	2	2 (13.33)	1	1 (6.67)
Disseminated intravascular coagulation	1	1 (6.67)	0	0 (0.00)
Thrombocytopenia	1	1 (6.67)	1	1 (6.67)
Cardiac disorders				
- Total	9	5 (33.33)	2	1 (6.67)
Tachycardia	5	3 (20.00)	0	0 (0.00)
Sinus tachycardia	2	2 (13.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Left ventricular dysfunction	1	1 (6.67)	1	1 (6.67)
Sinus bradycardia	1	1 (6.67)	1	1 (6.67)
Endocrine disorders				
- Total	3	3 (20.00)	0	0 (0.00)
Adrenal insufficiency	3	3 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	14	9 (60.00)	3	3 (20.00)
Constipation	4	4 (26.67)	0	0 (0.00)
Diarrhoea	2	2 (13.33)	0	0 (0.00)
Vomiting	2	2 (13.33)	1	1 (6.67)
Abdominal compartment syndrome	1	1 (6.67)	1	1 (6.67)
Abdominal pain	1	1 (6.67)	0	0 (0.00)
Dry mouth	1	1 (6.67)	0	0 (0.00)
Mouth haemorrhage	1	1 (6.67)	1	1 (6.67)
Nausea	1	1 (6.67)	0	0 (0.00)
Pancreatitis	1	1 (6.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	18	6 (40.00)	3	3 (20.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Pyrexia	7	3 (20.00)	2	2 (13.33)
Oedema peripheral	3	3 (20.00)	0	0 (0.00)
Chills	2	2 (13.33)	0	0 (0.00)
Generalised oedema	2	2 (13.33)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (6.67)	0	0 (0.00)
Face oedema	1	1 (6.67)	0	0 (0.00)
Fatigue	1	1 (6.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (6.67)	1	1 (6.67)
Hepatobiliary disorders				
- Total	4	2 (13.33)	1	1 (6.67)
Biliary tract disorder	1	1 (6.67)	0	0 (0.00)
Gallbladder enlargement	1	1 (6.67)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (6.67)	1	1 (6.67)
Hypertransaminasaemia	1	1 (6.67)	0	0 (0.00)
Immune system disorders				
- Total	42	15 (100.00)	19	9 (60.00)
Cytokine release syndrome	35	13 (86.67)	17	9 (60.00)
Hypogammaglobulinaemia	4	4 (26.67)	1	1 (6.67)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (6.67)	1	1 (6.67)
Seasonal allergy	1	1 (6.67)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (6.67)	0	0 (0.00)
Infections and infestations				
- Total	12	5 (33.33)	5	3 (20.00)
Staphylococcal bacteraemia	3	2 (13.33)	3	2 (13.33)
Adenovirus infection	1	1 (6.67)	1	1 (6.67)
Atypical pneumonia	1	1 (6.67)	0	0 (0.00)
Candida infection	1	1 (6.67)	0	0 (0.00)
Conjunctivitis	1	1 (6.67)	0	0 (0.00)
Encephalitis viral	1	1 (6.67)	1	1 (6.67)
Gastroenteritis norovirus	1	1 (6.67)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (6.67)	0	0 (0.00)
Rhinovirus infection	1	1 (6.67)	0	0 (0.00)
Staphylococcal infection	1	1 (6.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (13.33)	0	0 (0.00)
Infusion related reaction	1	1 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Transfusion reaction	1	1 (6.67)	0	0 (0.00)
Investigations				
- Total	89	10 (66.67)	49	9 (60.00)
Platelet count decreased	19	3 (20.00)	13	3 (20.00)
Aspartate aminotransferase increased	12	7 (46.67)	6	6 (40.00)
White blood cell count decreased	11	3 (20.00)	8	3 (20.00)
Alanine aminotransferase increased	9	5 (33.33)	3	3 (20.00)
Blood bilirubin increased	8	4 (26.67)	4	4 (26.67)
Neutrophil count decreased	8	2 (13.33)	5	2 (13.33)
Blood creatinine increased	3	3 (20.00)	2	2 (13.33)
Activated partial thromboplastin time prolonged	2	2 (13.33)	1	1 (6.67)
Electrocardiogram QT prolonged	2	1 (6.67)	1	1 (6.67)
International normalised ratio increased	2	2 (13.33)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (6.67)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (6.67)	1	1 (6.67)
Blood phosphorus increased	1	1 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Blood uric acid increased	1	1 (6.67)	0	0 (0.00)
C-reactive protein increased	1	1 (6.67)	1	1 (6.67)
Electrocardiogram T wave abnormal	1	1 (6.67)	0	0 (0.00)
Fibrin D dimer increased	1	1 (6.67)	1	1 (6.67)
Serum ferritin increased	1	1 (6.67)	1	1 (6.67)
Staphylococcus test positive	1	1 (6.67)	0	0 (0.00)
Troponin increased	1	1 (6.67)	1	1 (6.67)
Urine output decreased	1	1 (6.67)	1	1 (6.67)
Weight decreased	1	1 (6.67)	0	0 (0.00)
Weight increased	1	1 (6.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	79	12 (80.00)	33	9 (60.00)
Hypokalaemia	11	6 (40.00)	5	3 (20.00)
Hypophosphataemia	11	4 (26.67)	5	3 (20.00)
Hypocalcaemia	10	8 (53.33)	3	3 (20.00)
Hyperglycaemia	8	5 (33.33)	2	2 (13.33)
Decreased appetite	7	7 (46.67)	5	5 (33.33)
Hypoalbuminaemia	7	5 (33.33)	1	1 (6.67)
Hyperuricaemia	4	3 (20.00)	1	1 (6.67)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Acidosis	3	2 (13.33)	2	2 (13.33)
Hypervolaemia	3	3 (20.00)	3	3 (20.00)
Hypomagnesaemia	3	3 (20.00)	0	0 (0.00)
Hypercalcaemia	2	2 (13.33)	1	1 (6.67)
Tumour lysis syndrome	2	2 (13.33)	2	2 (13.33)
Calcium deficiency	1	1 (6.67)	0	0 (0.00)
Hyperkalaemia	1	1 (6.67)	1	1 (6.67)
Hypermagnesaemia	1	1 (6.67)	0	0 (0.00)
Hyperphosphataemia	1	1 (6.67)	0	0 (0.00)
Hypoglycaemia	1	1 (6.67)	0	0 (0.00)
Hyponatraemia	1	1 (6.67)	0	0 (0.00)
Malnutrition	1	1 (6.67)	1	1 (6.67)
Metabolic acidosis	1	1 (6.67)	1	1 (6.67)
Musculoskeletal and connective tissue disorders				
- Total	8	5 (33.33)	2	1 (6.67)
Arthralgia	2	2 (13.33)	1	1 (6.67)
Back pain	2	1 (6.67)	0	0 (0.00)
Myalgia	2	2 (13.33)	0	0 (0.00)
Haemarthrosis	1	1 (6.67)	1	1 (6.67)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Muscle spasms	1	1 (6.67)	0	0 (0.00)
Nervous system disorders				
- Total	21	8 (53.33)	5	3 (20.00)
Cognitive disorder	5	3 (20.00)	1	1 (6.67)
Headache	5	4 (26.67)	0	0 (0.00)
Hyperaesthesia	2	1 (6.67)	0	0 (0.00)
Somnolence	2	2 (13.33)	1	1 (6.67)
Tremor	2	1 (6.67)	0	0 (0.00)
Amnesia	1	1 (6.67)	0	0 (0.00)
Cerebral haemorrhage	1	1 (6.67)	1	1 (6.67)
Encephalopathy	1	1 (6.67)	1	1 (6.67)
Neurological decompensation	1	1 (6.67)	1	1 (6.67)
Paraesthesia	1	1 (6.67)	0	0 (0.00)
Psychiatric disorders				
- Total	7	5 (33.33)	2	2 (13.33)
Anxiety	2	2 (13.33)	1	1 (6.67)
Agitation	1	1 (6.67)	0	0 (0.00)
Delirium	1	1 (6.67)	1	1 (6.67)
Hallucination, visual	1	1 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Insomnia	1	1 (6.67)	0	0 (0.00)
Mental status changes	1	1 (6.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (26.67)	5	3 (20.00)
Acute kidney injury	4	2 (13.33)	2	2 (13.33)
Renal failure	3	1 (6.67)	3	1 (6.67)
Urinary retention	1	1 (6.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Female genital tract fistula	1	1 (6.67)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	17	8 (53.33)	14	7 (46.67)
Pulmonary oedema	4	4 (26.67)	3	3 (20.00)
Hypoxia	3	3 (20.00)	3	3 (20.00)
Pleural effusion	2	2 (13.33)	2	2 (13.33)
Respiratory distress	2	1 (6.67)	2	1 (6.67)
Acute respiratory distress syndrome	1	1 (6.67)	1	1 (6.67)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Acute respiratory failure	1	1 (6.67)	1	1 (6.67)
Nasal congestion	1	1 (6.67)	0	0 (0.00)
Respiratory failure	1	1 (6.67)	1	1 (6.67)
Tachypnoea	1	1 (6.67)	1	1 (6.67)
Wheezing	1	1 (6.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	3 (20.00)	0	0 (0.00)
Blister	1	1 (6.67)	0	0 (0.00)
Hyperhidrosis	1	1 (6.67)	0	0 (0.00)
Pruritus	1	1 (6.67)	0	0 (0.00)
Scab	1	1 (6.67)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (6.67)	1	1 (6.67)
Thrombolysis	1	1 (6.67)	1	1 (6.67)
Vascular disorders				
- Total	12	9 (60.00)	8	7 (46.67)
Hypotension	7	6 (40.00)	5	5 (33.33)
Hypertension	4	4 (26.67)	2	2 (13.33)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Capillary leak syndrome	1	1 (6.67)	1	1 (6.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Total number of AE per patient	1368	64 (98.46)	446	55 (84.62)
Blood and lymphatic system disorders				
- Total	93	40 (61.54)	55	30 (46.15)
Anaemia	32	17 (26.15)	11	5 (7.69)
Febrile neutropenia	19	18 (27.69)	19	18 (27.69)
Neutropenia	11	9 (13.85)	9	7 (10.77)
Thrombocytopenia	7	7 (10.77)	7	7 (10.77)
Disseminated intravascular coagulation	6	6 (9.23)	2	2 (3.08)
Leukopenia	4	3 (4.62)	3	2 (3.08)
Splenomegaly	4	4 (6.15)	0	0 (0.00)
Coagulopathy	3	3 (4.62)	1	1 (1.54)
Eosinophilia	2	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pancytopenia	2	2 (3.08)	2	2 (3.08)
B-cell aplasia	1	1 (1.54)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.54)	0	0 (0.00)
Lymphopenia	1	1 (1.54)	1	1 (1.54)
Cardiac disorders				
- Total	36	19 (29.23)	8	7 (10.77)
Tachycardia	17	14 (21.54)	3	3 (4.62)
Cardiac failure	4	1 (1.54)	2	1 (1.54)
Bradycardia	3	3 (4.62)	0	0 (0.00)
Cardiac dysfunction	2	2 (3.08)	0	0 (0.00)
Left ventricular dysfunction	2	2 (3.08)	2	2 (3.08)
Sinus tachycardia	2	1 (1.54)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.54)	0	0 (0.00)
Cardiac arrest	1	1 (1.54)	1	1 (1.54)
Cardiac failure congestive	1	1 (1.54)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.54)	0	0 (0.00)
Pericardial effusion	1	1 (1.54)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Ear and labyrinth disorders				
- Total	2	2 (3.08)	0	0 (0.00)
Ear pain	1	1 (1.54)	0	0 (0.00)
Ear pruritus	1	1 (1.54)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (3.08)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.54)	0	0 (0.00)
Hypothyroidism	1	1 (1.54)	0	0 (0.00)
Eye disorders				
- Total	15	9 (13.85)	0	0 (0.00)
Eyelid oedema	3	2 (3.08)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.08)	0	0 (0.00)
Ocular hyperaemia	2	2 (3.08)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.54)	0	0 (0.00)
Eye oedema	1	1 (1.54)	0	0 (0.00)
Eye pain	1	1 (1.54)	0	0 (0.00)
Periorbital oedema	1	1 (1.54)	0	0 (0.00)
Periorbital swelling	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Visual field defect	1	1 (1.54)	0	0 (0.00)
Visual impairment	1	1 (1.54)	0	0 (0.00)
Gastrointestinal disorders				
- Total	121	42 (64.62)	13	11 (16.92)
Vomiting	28	19 (29.23)	0	0 (0.00)
Nausea	20	17 (26.15)	2	2 (3.08)
Diarrhoea	16	13 (20.00)	1	1 (1.54)
Abdominal pain	12	10 (15.38)	2	2 (3.08)
Constipation	7	7 (10.77)	0	0 (0.00)
Abdominal distension	3	3 (4.62)	0	0 (0.00)
Abdominal pain upper	3	3 (4.62)	0	0 (0.00)
Ascites	3	3 (4.62)	0	0 (0.00)
Mouth haemorrhage	3	3 (4.62)	1	1 (1.54)
Pancreatitis	3	3 (4.62)	1	1 (1.54)
Gastrointestinal sounds abnormal	2	2 (3.08)	0	0 (0.00)
Stomatitis	2	2 (3.08)	1	1 (1.54)
Anal fissure	1	1 (1.54)	0	0 (0.00)
Anal haemorrhage	1	1 (1.54)	0	0 (0.00)
Dysphagia	1	1 (1.54)	1	1 (1.54)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Enterocolitis	1	1 (1.54)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.54)	0	0 (0.00)
Gingival bleeding	1	1 (1.54)	0	0 (0.00)
Gingival erythema	1	1 (1.54)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.54)	1	1 (1.54)
Haematemesis	1	1 (1.54)	0	0 (0.00)
Ileus	1	1 (1.54)	0	0 (0.00)
Lip dry	1	1 (1.54)	0	0 (0.00)
Lip oedema	1	1 (1.54)	0	0 (0.00)
Melaena	1	1 (1.54)	1	1 (1.54)
Mouth swelling	1	1 (1.54)	0	0 (0.00)
Neutropenic colitis	1	1 (1.54)	1	1 (1.54)
Odynophagia	1	1 (1.54)	0	0 (0.00)
Proctalgia	1	1 (1.54)	1	1 (1.54)
Trichoglossia	1	1 (1.54)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.54)	0	0 (0.00)
General disorders and administration site conditions				
- Total	94	34 (52.31)	16	8 (12.31)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pyrexia	37	21 (32.31)	7	6 (9.23)
Fatigue	10	10 (15.38)	0	0 (0.00)
Face oedema	8	7 (10.77)	1	1 (1.54)
Chills	7	4 (6.15)	0	0 (0.00)
Catheter site pain	4	2 (3.08)	2	1 (1.54)
Oedema peripheral	4	3 (4.62)	2	1 (1.54)
Generalised oedema	3	3 (4.62)	0	0 (0.00)
Asthenia	2	2 (3.08)	0	0 (0.00)
Catheter site erythema	2	1 (1.54)	0	0 (0.00)
Influenza like illness	2	2 (3.08)	0	0 (0.00)
Localised oedema	2	2 (3.08)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.54)	0	0 (0.00)
Chest discomfort	1	1 (1.54)	1	1 (1.54)
Crying	1	1 (1.54)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.54)	0	0 (0.00)
Facial pain	1	1 (1.54)	0	0 (0.00)
Malaise	1	1 (1.54)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.54)	1	1 (1.54)
Oedema due to hepatic disease	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pain	1	1 (1.54)	1	1 (1.54)
Sluggishness	1	1 (1.54)	0	0 (0.00)
Swelling face	1	1 (1.54)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.54)	1	1 (1.54)
Vascular device occlusion	1	1 (1.54)	0	0 (0.00)
Hepatobiliary disorders				
- Total	25	15 (23.08)	6	5 (7.69)
Hepatic function abnormal	11	5 (7.69)	4	3 (4.62)
Hyperbilirubinaemia	5	4 (6.15)	0	0 (0.00)
Hepatomegaly	3	3 (4.62)	1	1 (1.54)
Cholelithiasis	2	2 (3.08)	0	0 (0.00)
Cholestasis	1	1 (1.54)	1	1 (1.54)
Gallbladder enlargement	1	1 (1.54)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.54)	0	0 (0.00)
Ocular icterus	1	1 (1.54)	0	0 (0.00)
Immune system disorders				
- Total	122	52 (80.00)	49	34 (52.31)
Cytokine release syndrome	93	48 (73.85)	38	29 (44.62)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Hypogammaglobulinaemia	21	19 (29.23)	6	6 (9.23)
Haemophagocytic lymphohistiocytosis	4	4 (6.15)	2	2 (3.08)
Immunodeficiency	3	3 (4.62)	3	3 (4.62)
Hypersensitivity	1	1 (1.54)	0	0 (0.00)
Infections and infestations				
- Total	52	30 (46.15)	26	16 (24.62)
Conjunctivitis	5	4 (6.15)	0	0 (0.00)
Clostridium difficile infection	4	4 (6.15)	3	3 (4.62)
Staphylococcal infection	4	4 (6.15)	2	2 (3.08)
Candida infection	3	2 (3.08)	2	1 (1.54)
Nail infection	2	2 (3.08)	0	0 (0.00)
Oral candidiasis	2	1 (1.54)	0	0 (0.00)
Oral herpes	2	2 (3.08)	1	1 (1.54)
Oral infection	2	2 (3.08)	0	0 (0.00)
Anal abscess	1	1 (1.54)	1	1 (1.54)
BK virus infection	1	1 (1.54)	0	0 (0.00)
Bacteraemia	1	1 (1.54)	1	1 (1.54)
Bronchopulmonary aspergillosis	1	1 (1.54)	1	1 (1.54)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Cholecystitis infective	1	1 (1.54)	0	0 (0.00)
Encephalitis	1	1 (1.54)	1	1 (1.54)
Encephalitis viral	1	1 (1.54)	1	1 (1.54)
Gingivitis	1	1 (1.54)	0	0 (0.00)
Granulicatella infection	1	1 (1.54)	1	1 (1.54)
Herpes simplex	1	1 (1.54)	1	1 (1.54)
Human herpesvirus 6 infection	1	1 (1.54)	1	1 (1.54)
Klebsiella infection	1	1 (1.54)	1	1 (1.54)
Localised infection	1	1 (1.54)	0	0 (0.00)
Meningitis bacterial	1	1 (1.54)	1	1 (1.54)
Myringitis	1	1 (1.54)	0	0 (0.00)
Otitis externa	1	1 (1.54)	0	0 (0.00)
Paronychia	1	1 (1.54)	0	0 (0.00)
Pneumonia	1	1 (1.54)	1	1 (1.54)
Pneumonia fungal	1	1 (1.54)	1	1 (1.54)
Pneumonia viral	1	1 (1.54)	1	1 (1.54)
Rhinovirus infection	1	1 (1.54)	0	0 (0.00)
Sinusitis	1	1 (1.54)	1	1 (1.54)
Soft tissue infection	1	1 (1.54)	1	1 (1.54)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Staphylococcal bacteraemia	1	1 (1.54)	1	1 (1.54)
Stomatococcal infection	1	1 (1.54)	0	0 (0.00)
Systemic candida	1	1 (1.54)	1	1 (1.54)
Urinary tract infection viral	1	1 (1.54)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.54)	1	1 (1.54)
Injury, poisoning and procedural complications				
- Total	18	9 (13.85)	3	2 (3.08)
Wound	3	2 (3.08)	1	1 (1.54)
Contusion	2	1 (1.54)	0	0 (0.00)
Fall	2	2 (3.08)	0	0 (0.00)
Infusion related reaction	2	1 (1.54)	0	0 (0.00)
Procedural pain	2	2 (3.08)	0	0 (0.00)
Scratch	1	1 (1.54)	0	0 (0.00)
Skin abrasion	1	1 (1.54)	0	0 (0.00)
Skin injury	1	1 (1.54)	0	0 (0.00)
Skin wound	1	1 (1.54)	0	0 (0.00)
Transfusion reaction	1	1 (1.54)	0	0 (0.00)
Transplant failure	1	1 (1.54)	1	1 (1.54)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Vasoplegia syndrome	1	1 (1.54)	1	1 (1.54)
Investigations				
- Total	297	47 (72.31)	148	36 (55.38)
Platelet count decreased	46	18 (27.69)	25	11 (16.92)
Neutrophil count decreased	40	18 (27.69)	33	15 (23.08)
White blood cell count decreased	39	21 (32.31)	28	15 (23.08)
Lymphocyte count decreased	30	15 (23.08)	24	13 (20.00)
Aspartate aminotransferase increased	21	12 (18.46)	7	5 (7.69)
Alanine aminotransferase increased	17	13 (20.00)	3	3 (4.62)
Blood bilirubin increased	10	8 (12.31)	5	5 (7.69)
International normalised ratio increased	10	7 (10.77)	0	0 (0.00)
Blood fibrinogen decreased	7	7 (10.77)	2	2 (3.08)
Serum ferritin increased	7	7 (10.77)	1	1 (1.54)
Activated partial thromboplastin time prolonged	6	4 (6.15)	0	0 (0.00)
Blood immunoglobulin M decreased	6	6 (9.23)	1	1 (1.54)
Blood immunoglobulin A decreased	5	5 (7.69)	0	0 (0.00)
Immunoglobulins decreased	5	2 (3.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Blood creatine phosphokinase increased	4	2 (3.08)	2	2 (3.08)
Electrocardiogram QT prolonged	4	4 (6.15)	1	1 (1.54)
Lipase increased	4	2 (3.08)	2	1 (1.54)
Blood creatinine increased	3	1 (1.54)	3	1 (1.54)
Blood lactate dehydrogenase increased	3	3 (4.62)	0	0 (0.00)
C-reactive protein increased	3	3 (4.62)	2	2 (3.08)
Weight increased	3	3 (4.62)	1	1 (1.54)
Blood glucose increased	2	1 (1.54)	2	1 (1.54)
Blood immunoglobulin G decreased	2	2 (3.08)	0	0 (0.00)
Fibrin D dimer increased	2	2 (3.08)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (3.08)	2	2 (3.08)
Haemoglobin decreased	2	1 (1.54)	1	1 (1.54)
Urine output decreased	2	1 (1.54)	2	1 (1.54)
Amylase increased	1	1 (1.54)	0	0 (0.00)
Bacterial test positive	1	1 (1.54)	1	1 (1.54)
Blood bicarbonate decreased	1	1 (1.54)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Blood uric acid increased	1	1 (1.54)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.54)	0	0 (0.00)
Cardiac murmur	1	1 (1.54)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.54)	0	0 (0.00)
Enterovirus test positive	1	1 (1.54)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.54)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.54)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.54)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	131	34 (52.31)	43	20 (30.77)
Hypokalaemia	29	13 (20.00)	15	8 (12.31)
Hypophosphataemia	20	13 (20.00)	6	6 (9.23)
Decreased appetite	17	17 (26.15)	6	6 (9.23)
Hypocalcaemia	14	8 (12.31)	3	2 (3.08)
Hypoalbuminaemia	12	6 (9.23)	0	0 (0.00)
Hyperuricaemia	5	4 (6.15)	0	0 (0.00)
Hyperphosphataemia	4	4 (6.15)	1	1 (1.54)
Hypomagnesaemia	4	3 (4.62)	0	0 (0.00)
Hyperglycaemia	3	3 (4.62)	2	2 (3.08)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Hypervolaemia	3	3 (4.62)	1	1 (1.54)
Hypercalcaemia	2	1 (1.54)	1	1 (1.54)
Hypermagnesaemia	2	1 (1.54)	0	0 (0.00)
Hypernatraemia	2	2 (3.08)	1	1 (1.54)
Hypertriglyceridaemia	2	2 (3.08)	2	2 (3.08)
Hyponatraemia	2	2 (3.08)	0	0 (0.00)
Metabolic acidosis	2	2 (3.08)	1	1 (1.54)
Tumour lysis syndrome	2	2 (3.08)	2	2 (3.08)
Dehydration	1	1 (1.54)	0	0 (0.00)
Haemosiderosis	1	1 (1.54)	0	0 (0.00)
Hyperchloraemia	1	1 (1.54)	0	0 (0.00)
Hyperkalaemia	1	1 (1.54)	1	1 (1.54)
Hyperlactacidaemia	1	1 (1.54)	0	0 (0.00)
Polydipsia	1	1 (1.54)	1	1 (1.54)
Musculoskeletal and connective tissue disorders				
- Total	45	28 (43.08)	4	4 (6.15)
Pain in extremity	11	11 (16.92)	0	0 (0.00)
Arthralgia	8	8 (12.31)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Myalgia	8	7 (10.77)	0	0 (0.00)
Back pain	5	5 (7.69)	1	1 (1.54)
Bone pain	4	2 (3.08)	0	0 (0.00)
Muscular weakness	2	2 (3.08)	1	1 (1.54)
Pain in jaw	2	2 (3.08)	1	1 (1.54)
Muscle rigidity	1	1 (1.54)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.54)	0	0 (0.00)
Myositis	1	1 (1.54)	0	0 (0.00)
Neck pain	1	1 (1.54)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.54)	1	1 (1.54)
Nervous system disorders				
- Total	56	32 (49.23)	9	7 (10.77)
Headache	21	19 (29.23)	2	2 (3.08)
Encephalopathy	7	7 (10.77)	3	3 (4.62)
Tremor	5	5 (7.69)	0	0 (0.00)
Dizziness	3	3 (4.62)	0	0 (0.00)
Dysgeusia	3	3 (4.62)	0	0 (0.00)
Lethargy	3	3 (4.62)	0	0 (0.00)
Seizure	3	2 (3.08)	1	1 (1.54)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Somnolence	3	3 (4.62)	1	1 (1.54)
Aphasia	1	1 (1.54)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.54)	1	1 (1.54)
Disturbance in attention	1	1 (1.54)	0	0 (0.00)
Dysarthria	1	1 (1.54)	1	1 (1.54)
Generalised tonic-clonic seizure	1	1 (1.54)	0	0 (0.00)
Hypoaesthesia	1	1 (1.54)	0	0 (0.00)
Monoparesis	1	1 (1.54)	0	0 (0.00)
Neuralgia	1	1 (1.54)	0	0 (0.00)
Psychiatric disorders				
- Total	40	23 (35.38)	4	4 (6.15)
Confusional state	7	7 (10.77)	0	0 (0.00)
Delirium	6	6 (9.23)	2	2 (3.08)
Agitation	5	4 (6.15)	0	0 (0.00)
Anxiety	4	4 (6.15)	1	1 (1.54)
Hallucination	3	3 (4.62)	0	0 (0.00)
Insomnia	3	3 (4.62)	0	0 (0.00)
Irritability	3	3 (4.62)	0	0 (0.00)
Sleep disorder	3	2 (3.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Mental status changes	2	2 (3.08)	1	1 (1.54)
Affect lability	1	1 (1.54)	0	0 (0.00)
Automatism	1	1 (1.54)	0	0 (0.00)
Restlessness	1	1 (1.54)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.54)	0	0 (0.00)
Renal and urinary disorders				
- Total	31	16 (24.62)	8	6 (9.23)
Acute kidney injury	10	7 (10.77)	6	5 (7.69)
Dysuria	3	3 (4.62)	0	0 (0.00)
Anuria	2	2 (3.08)	1	1 (1.54)
Haematuria	2	2 (3.08)	0	0 (0.00)
Pollakiuria	2	2 (3.08)	0	0 (0.00)
Urinary incontinence	2	1 (1.54)	0	0 (0.00)
Azotaemia	1	1 (1.54)	0	0 (0.00)
Bladder dilatation	1	1 (1.54)	0	0 (0.00)
Incontinence	1	1 (1.54)	0	0 (0.00)
Micturition urgency	1	1 (1.54)	0	0 (0.00)
Proteinuria	1	1 (1.54)	0	0 (0.00)
Renal failure	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Renal tubular dysfunction	1	1 (1.54)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.54)	1	1 (1.54)
Urinary retention	1	1 (1.54)	0	0 (0.00)
Urinary tract disorder	1	1 (1.54)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (6.15)	1	1 (1.54)
Vaginal haemorrhage	2	1 (1.54)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.54)	0	0 (0.00)
Perineal rash	1	1 (1.54)	0	0 (0.00)
Vaginal ulceration	1	1 (1.54)	1	1 (1.54)
Respiratory, thoracic and mediastinal disorders				
- Total	97	33 (50.77)	36	16 (24.62)
Hypoxia	20	14 (21.54)	15	9 (13.85)
Cough	11	10 (15.38)	0	0 (0.00)
Pulmonary oedema	8	8 (12.31)	4	4 (6.15)
Tachypnoea	8	7 (10.77)	3	3 (4.62)
Oropharyngeal pain	6	5 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Atelectasis	5	3 (4.62)	2	2 (3.08)
Pleural effusion	5	5 (7.69)	1	1 (1.54)
Epistaxis	4	4 (6.15)	1	1 (1.54)
Dyspnoea	3	3 (4.62)	3	3 (4.62)
Respiratory failure	3	3 (4.62)	3	3 (4.62)
Lung infiltration	2	1 (1.54)	1	1 (1.54)
Nasal congestion	2	2 (3.08)	0	0 (0.00)
Respiratory distress	2	2 (3.08)	0	0 (0.00)
Rhinorrhoea	2	2 (3.08)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.54)	1	1 (1.54)
Bradypnoea	1	1 (1.54)	1	1 (1.54)
Haemoptysis	1	1 (1.54)	0	0 (0.00)
Nasal discomfort	1	1 (1.54)	0	0 (0.00)
Nasal dryness	1	1 (1.54)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.54)	0	0 (0.00)
Painful respiration	1	1 (1.54)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.54)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.54)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pharyngeal haemorrhage	1	1 (1.54)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.54)	0	0 (0.00)
Productive cough	1	1 (1.54)	0	0 (0.00)
Pulmonary mass	1	1 (1.54)	0	0 (0.00)
Respiratory acidosis	1	1 (1.54)	1	1 (1.54)
Respiratory disorder	1	1 (1.54)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	52	24 (36.92)	4	3 (4.62)
Pruritus	6	5 (7.69)	0	0 (0.00)
Blister	5	2 (3.08)	0	0 (0.00)
Rash	5	5 (7.69)	0	0 (0.00)
Erythema	4	4 (6.15)	0	0 (0.00)
Rash papular	4	3 (4.62)	0	0 (0.00)
Rash maculo-papular	3	2 (3.08)	1	1 (1.54)
Dermatitis atopic	2	2 (3.08)	0	0 (0.00)
Hyperhidrosis	2	2 (3.08)	0	0 (0.00)
Petechiae	2	2 (3.08)	1	1 (1.54)
Rash vesicular	2	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Skin ulcer	2	2 (3.08)	0	0 (0.00)
Decubitus ulcer	1	1 (1.54)	0	0 (0.00)
Dermatitis	1	1 (1.54)	0	0 (0.00)
Dermatitis diaper	1	1 (1.54)	0	0 (0.00)
Dry skin	1	1 (1.54)	0	0 (0.00)
Eczema	1	1 (1.54)	0	0 (0.00)
Erythema nodosum	1	1 (1.54)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.54)	0	0 (0.00)
Pruritus allergic	1	1 (1.54)	0	0 (0.00)
Purpura	1	1 (1.54)	0	0 (0.00)
Rash pruritic	1	1 (1.54)	0	0 (0.00)
Skin discolouration	1	1 (1.54)	0	0 (0.00)
Skin lesion	1	1 (1.54)	0	0 (0.00)
Skin necrosis	1	1 (1.54)	1	1 (1.54)
Urticaria	1	1 (1.54)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.54)	1	1 (1.54)
Social circumstances				
- Total	1	1 (1.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Patient uncooperative	1	1 (1.54)	0	0 (0.00)
Vascular disorders				
- Total	33	19 (29.23)	13	10 (15.38)
Hypotension	18	15 (23.08)	11	9 (13.85)
Hypertension	10	9 (13.85)	2	2 (3.08)
Capillary leak syndrome	1	1 (1.54)	0	0 (0.00)
Flushing	1	1 (1.54)	0	0 (0.00)
Hot flush	1	1 (1.54)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.54)	0	0 (0.00)
Thrombosis	1	1 (1.54)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Total number of AE per patient	140	12 (85.71)	50	7 (50.00)
Blood and lymphatic system disorders				
- Total	9	2 (14.29)	5	2 (14.29)
Anaemia	7	2 (14.29)	4	2 (14.29)
Febrile neutropenia	1	1 (7.14)	1	1 (7.14)
Leukocytosis	1	1 (7.14)	0	0 (0.00)
Cardiac disorders				
- Total	3	2 (14.29)	2	1 (7.14)
Cardiac arrest	1	1 (7.14)	1	1 (7.14)
Cardiac failure	1	1 (7.14)	1	1 (7.14)
Tachycardia	1	1 (7.14)	0	0 (0.00)
Eye disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
- Total	1	1 (7.14)	0	0 (0.00)
Visual impairment	1	1 (7.14)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	5 (35.71)	0	0 (0.00)
Diarrhoea	3	3 (21.43)	0	0 (0.00)
Abdominal pain	1	1 (7.14)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (7.14)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (7.14)	0	0 (0.00)
Nausea	1	1 (7.14)	0	0 (0.00)
Vomiting	1	1 (7.14)	0	0 (0.00)
General disorders and administration site conditions				
- Total	9	7 (50.00)	1	1 (7.14)
Pyrexia	4	4 (28.57)	1	1 (7.14)
Fatigue	3	2 (14.29)	0	0 (0.00)
Malaise	1	1 (7.14)	0	0 (0.00)
Non-cardiac chest pain	1	1 (7.14)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (21.43)	1	1 (7.14)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Hypogammaglobulinaemia	2	2 (14.29)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (7.14)	1	1 (7.14)
Infections and infestations				
- Total	25	7 (50.00)	14	6 (42.86)
Upper respiratory tract infection	4	3 (21.43)	1	1 (7.14)
Bacteraemia	3	2 (14.29)	2	1 (7.14)
Respiratory syncytial virus infection	2	2 (14.29)	1	1 (7.14)
Urinary tract infection	2	1 (7.14)	2	1 (7.14)
Adenovirus infection	1	1 (7.14)	1	1 (7.14)
BK virus infection	1	1 (7.14)	1	1 (7.14)
Gastroenteritis	1	1 (7.14)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (7.14)	0	0 (0.00)
Herpes simplex	1	1 (7.14)	0	0 (0.00)
Metapneumovirus infection	1	1 (7.14)	1	1 (7.14)
Otitis media	1	1 (7.14)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (7.14)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (7.14)	1	1 (7.14)
Pneumocystis jirovecii pneumonia	1	1 (7.14)	1	1 (7.14)
Rhinovirus infection	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Septic shock	1	1 (7.14)	1	1 (7.14)
Sinusitis fungal	1	1 (7.14)	1	1 (7.14)
Viral upper respiratory tract infection	1	1 (7.14)	1	1 (7.14)
Injury, poisoning and procedural complications				
- Total	1	1 (7.14)	0	0 (0.00)
Skin abrasion	1	1 (7.14)	0	0 (0.00)
Investigations				
- Total	28	6 (42.86)	15	3 (21.43)
Platelet count decreased	10	1 (7.14)	8	1 (7.14)
Neutrophil count decreased	7	2 (14.29)	4	2 (14.29)
White blood cell count decreased	7	2 (14.29)	2	2 (14.29)
Blood immunoglobulin G decreased	1	1 (7.14)	0	0 (0.00)
Blood uric acid increased	1	1 (7.14)	1	1 (7.14)
Ejection fraction decreased	1	1 (7.14)	0	0 (0.00)
Heart sounds abnormal	1	1 (7.14)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	13	5 (35.71)	5	3 (21.43)
Hypokalaemia	5	2 (14.29)	3	1 (7.14)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Decreased appetite	2	2 (14.29)	0	0 (0.00)
Hyperuricaemia	2	2 (14.29)	0	0 (0.00)
Hyperchloraemia	1	1 (7.14)	0	0 (0.00)
Hyperkalaemia	1	1 (7.14)	0	0 (0.00)
Malnutrition	1	1 (7.14)	1	1 (7.14)
Tumour lysis syndrome	1	1 (7.14)	1	1 (7.14)
Musculoskeletal and connective tissue disorders				
- Total	9	5 (35.71)	1	1 (7.14)
Back pain	3	2 (14.29)	1	1 (7.14)
Pain in extremity	2	2 (14.29)	0	0 (0.00)
Arthralgia	1	1 (7.14)	0	0 (0.00)
Growth retardation	1	1 (7.14)	0	0 (0.00)
Myalgia	1	1 (7.14)	0	0 (0.00)
Neck pain	1	1 (7.14)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (7.14)	0	0 (0.00)
Cancer pain	1	1 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Nervous system disorders				
- Total	3	2 (14.29)	0	0 (0.00)
Headache	2	2 (14.29)	0	0 (0.00)
Extrapyramidal disorder	1	1 (7.14)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (28.57)	0	0 (0.00)
Anxiety	3	3 (21.43)	0	0 (0.00)
Mental status changes	1	1 (7.14)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	2 (14.29)	2	2 (14.29)
Acute kidney injury	2	2 (14.29)	1	1 (7.14)
Dysuria	1	1 (7.14)	0	0 (0.00)
Haematuria	1	1 (7.14)	1	1 (7.14)
Kidney enlargement	1	1 (7.14)	0	0 (0.00)
Renal mass	1	1 (7.14)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	9	5 (35.71)	1	1 (7.14)
Nasal congestion	3	2 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=14 n (%)[1]	Grade >= 3 Total events	All patients N=14 n (%)[2]
Rhinitis allergic	2	2 (14.29)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (7.14)	1	1 (7.14)
Bronchial oedema	1	1 (7.14)	0	0 (0.00)
Cough	1	1 (7.14)	0	0 (0.00)
Oropharyngeal pain	1	1 (7.14)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	4 (28.57)	1	1 (7.14)
Dry skin	2	2 (14.29)	0	0 (0.00)
Pruritus	2	1 (7.14)	0	0 (0.00)
Decubitus ulcer	1	1 (7.14)	1	1 (7.14)
Skin hypopigmentation	1	1 (7.14)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (14.29)	2	2 (14.29)
Hypotension	2	2 (14.29)	2	2 (14.29)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Total number of AE per patient	394	57 (93.44)	96	29 (47.54)
Blood and lymphatic system disorders				
- Total	23	15 (24.59)	12	8 (13.11)
Anaemia	5	4 (6.56)	0	0 (0.00)
Neutropenia	5	5 (8.20)	5	5 (8.20)
Febrile neutropenia	3	2 (3.28)	3	2 (3.28)
B-cell aplasia	2	1 (1.64)	0	0 (0.00)
Thrombocytopenia	2	2 (3.28)	2	2 (3.28)
Disseminated intravascular coagulation	1	1 (1.64)	1	1 (1.64)
Eosinophilia	1	1 (1.64)	0	0 (0.00)
Leukopenia	1	1 (1.64)	0	0 (0.00)
Lymphadenopathy	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Lymphocytosis	1	1 (1.64)	0	0 (0.00)
Lymphopenia	1	1 (1.64)	1	1 (1.64)
Cardiac disorders				
- Total	5	5 (8.20)	2	2 (3.28)
Cardiac arrest	1	1 (1.64)	1	1 (1.64)
Cardiac failure	1	1 (1.64)	1	1 (1.64)
Left ventricular dysfunction	1	1 (1.64)	0	0 (0.00)
Tachycardia	1	1 (1.64)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.64)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.64)	0	0 (0.00)
Hypothyroidism	1	1 (1.64)	0	0 (0.00)
Eye disorders				
- Total	4	3 (4.92)	0	0 (0.00)
Cataract	2	2 (3.28)	0	0 (0.00)
Hypermetropia	1	1 (1.64)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.64)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	30	15 (24.59)	1	1 (1.64)
Vomiting	6	5 (8.20)	0	0 (0.00)
Constipation	4	3 (4.92)	0	0 (0.00)
Diarrhoea	4	4 (6.56)	0	0 (0.00)
Nausea	4	4 (6.56)	0	0 (0.00)
Pancreatitis	2	2 (3.28)	1	1 (1.64)
Abdominal pain	1	1 (1.64)	0	0 (0.00)
Abdominal pain upper	1	1 (1.64)	0	0 (0.00)
Abdominal rigidity	1	1 (1.64)	0	0 (0.00)
Dyspepsia	1	1 (1.64)	0	0 (0.00)
Enteritis	1	1 (1.64)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.64)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.64)	0	0 (0.00)
Proctalgia	1	1 (1.64)	0	0 (0.00)
Stomatitis	1	1 (1.64)	0	0 (0.00)
Trichoglossia	1	1 (1.64)	0	0 (0.00)
General disorders and administration site conditions				
- Total	22	17 (27.87)	2	2 (3.28)
Pyrexia	12	11 (18.03)	1	1 (1.64)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Fatigue	4	4 (6.56)	0	0 (0.00)
Oedema peripheral	2	1 (1.64)	0	0 (0.00)
Pain	2	2 (3.28)	1	1 (1.64)
Asthenia	1	1 (1.64)	0	0 (0.00)
Chills	1	1 (1.64)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.92)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.64)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.64)	0	0 (0.00)
Liver disorder	1	1 (1.64)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (21.31)	4	3 (4.92)
Hypogammaglobulinaemia	10	8 (13.11)	0	0 (0.00)
Graft versus host disease	2	2 (3.28)	2	2 (3.28)
Allergy to immunoglobulin therapy	1	1 (1.64)	0	0 (0.00)
Drug hypersensitivity	1	1 (1.64)	0	0 (0.00)
Engraftment syndrome	1	1 (1.64)	1	1 (1.64)
Immunodeficiency	1	1 (1.64)	1	1 (1.64)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Infections and infestations				
- Total	88	32 (52.46)	31	14 (22.95)
Nasopharyngitis	9	7 (11.48)	0	0 (0.00)
Upper respiratory tract infection	6	5 (8.20)	1	1 (1.64)
Bronchopulmonary aspergillosis	5	1 (1.64)	3	1 (1.64)
Gastroenteritis	4	4 (6.56)	2	2 (3.28)
Parainfluenzae virus infection	4	3 (4.92)	2	2 (3.28)
Rhinovirus infection	4	4 (6.56)	1	1 (1.64)
Sinusitis	4	3 (4.92)	1	1 (1.64)
Ear infection	3	2 (3.28)	0	0 (0.00)
Pneumonia	3	3 (4.92)	1	1 (1.64)
Respiratory tract infection	3	3 (4.92)	0	0 (0.00)
Klebsiella infection	2	1 (1.64)	2	1 (1.64)
Metapneumovirus infection	2	2 (3.28)	2	2 (3.28)
Otitis externa	2	2 (3.28)	1	1 (1.64)
Otitis media	2	2 (3.28)	1	1 (1.64)
Rhinitis	2	2 (3.28)	0	0 (0.00)
Viral infection	2	2 (3.28)	1	1 (1.64)
Acute sinusitis	1	1 (1.64)	0	0 (0.00)
Cellulitis	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Conjunctivitis	1	1 (1.64)	0	0 (0.00)
Coronavirus infection	1	1 (1.64)	1	1 (1.64)
Cystitis	1	1 (1.64)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.64)	1	1 (1.64)
Device related infection	1	1 (1.64)	1	1 (1.64)
Ear, nose and throat infection	1	1 (1.64)	0	0 (0.00)
Encephalitis	1	1 (1.64)	1	1 (1.64)
Enterobacter infection	1	1 (1.64)	1	1 (1.64)
Gastroenteritis viral	1	1 (1.64)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.64)	0	0 (0.00)
Gingivitis	1	1 (1.64)	0	0 (0.00)
Herpes zoster	1	1 (1.64)	1	1 (1.64)
Human herpesvirus 6 infection	1	1 (1.64)	1	1 (1.64)
Influenza	1	1 (1.64)	0	0 (0.00)
Mastoiditis	1	1 (1.64)	1	1 (1.64)
Molluscum contagiosum	1	1 (1.64)	0	0 (0.00)
Nail infection	1	1 (1.64)	0	0 (0.00)
Oral candidiasis	1	1 (1.64)	0	0 (0.00)
Oral herpes	1	1 (1.64)	0	0 (0.00)
Paronychia	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Pneumocystis jirovecii pneumonia	1	1 (1.64)	1	1 (1.64)
Respiratory syncytial virus infection	1	1 (1.64)	1	1 (1.64)
Respiratory tract infection viral	1	1 (1.64)	0	0 (0.00)
Salmonellosis	1	1 (1.64)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (1.64)	1	1 (1.64)
Staphylococcal sepsis	1	1 (1.64)	1	1 (1.64)
Staphylococcal skin infection	1	1 (1.64)	0	0 (0.00)
Tinea pedis	1	1 (1.64)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.64)	1	1 (1.64)
Injury, poisoning and procedural complications				
- Total	9	8 (13.11)	0	0 (0.00)
Infusion related reaction	4	3 (4.92)	0	0 (0.00)
Contusion	1	1 (1.64)	0	0 (0.00)
Fibula fracture	1	1 (1.64)	0	0 (0.00)
Ligament sprain	1	1 (1.64)	0	0 (0.00)
Limb injury	1	1 (1.64)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.64)	0	0 (0.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	63	24 (39.34)	20	13 (21.31)
Neutrophil count decreased	12	8 (13.11)	7	5 (8.20)
White blood cell count decreased	11	8 (13.11)	2	2 (3.28)
Lymphocyte count decreased	6	4 (6.56)	2	2 (3.28)
Platelet count decreased	6	4 (6.56)	1	1 (1.64)
Immunoglobulins decreased	5	1 (1.64)	0	0 (0.00)
Blood bilirubin increased	4	2 (3.28)	1	1 (1.64)
Alanine aminotransferase increased	3	2 (3.28)	1	1 (1.64)
Weight increased	3	1 (1.64)	1	1 (1.64)
Blood immunoglobulin A decreased	2	2 (3.28)	1	1 (1.64)
Blood creatinine increased	1	1 (1.64)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.64)	1	1 (1.64)
Blood lactate dehydrogenase increased	1	1 (1.64)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.64)	0	0 (0.00)
Blood urea increased	1	1 (1.64)	1	1 (1.64)
Blood uric acid increased	1	1 (1.64)	1	1 (1.64)
Bone density decreased	1	1 (1.64)	0	0 (0.00)
C-reactive protein increased	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hepatitis B virus test positive	1	1 (1.64)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.64)	0	0 (0.00)
Weight decreased	1	1 (1.64)	1	1 (1.64)
Metabolism and nutrition disorders				
- Total	13	10 (16.39)	5	4 (6.56)
Decreased appetite	4	4 (6.56)	1	1 (1.64)
Haemochromatosis	1	1 (1.64)	1	1 (1.64)
Hyperuricaemia	1	1 (1.64)	0	0 (0.00)
Hypervolaemia	1	1 (1.64)	1	1 (1.64)
Hypokalaemia	1	1 (1.64)	1	1 (1.64)
Hypophagia	1	1 (1.64)	0	0 (0.00)
Hypophosphataemia	1	1 (1.64)	0	0 (0.00)
Iron overload	1	1 (1.64)	0	0 (0.00)
Metabolic acidosis	1	1 (1.64)	1	1 (1.64)
Metabolic syndrome	1	1 (1.64)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	13	10 (16.39)	2	2 (3.28)
Back pain	4	4 (6.56)	1	1 (1.64)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Pain in extremity	3	3 (4.92)	1	1 (1.64)
Arthralgia	2	2 (3.28)	0	0 (0.00)
Bone pain	2	2 (3.28)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.64)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.64)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (4.92)	1	1 (1.64)
Skin papilloma	2	2 (3.28)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.64)	1	1 (1.64)
Nervous system disorders				
- Total	20	12 (19.67)	6	2 (3.28)
Headache	9	8 (13.11)	0	0 (0.00)
Hydrocephalus	3	1 (1.64)	3	1 (1.64)
Dizziness	2	1 (1.64)	0	0 (0.00)
Migraine	2	1 (1.64)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.64)	1	1 (1.64)
Cerebral haemorrhage	1	1 (1.64)	1	1 (1.64)
Memory impairment	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Seizure	1	1 (1.64)	1	1 (1.64)
Psychiatric disorders				
- Total	11	6 (9.84)	1	1 (1.64)
Anxiety	3	3 (4.92)	0	0 (0.00)
Agitation	1	1 (1.64)	0	0 (0.00)
Delirium	1	1 (1.64)	0	0 (0.00)
Mental status changes	1	1 (1.64)	1	1 (1.64)
Mood altered	1	1 (1.64)	0	0 (0.00)
Nightmare	1	1 (1.64)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.64)	0	0 (0.00)
Sleep disorder	1	1 (1.64)	0	0 (0.00)
Tearfulness	1	1 (1.64)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	3 (4.92)	1	1 (1.64)
Acute kidney injury	1	1 (1.64)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.64)	0	0 (0.00)
Renal tubular disorder	1	1 (1.64)	1	1 (1.64)
Reproductive system and breast disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
- Total	2	1 (1.64)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.64)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	37	19 (31.15)	5	5 (8.20)
Cough	13	10 (16.39)	0	0 (0.00)
Nasal congestion	4	4 (6.56)	0	0 (0.00)
Epistaxis	3	3 (4.92)	0	0 (0.00)
Hypoxia	3	3 (4.92)	3	3 (4.92)
Rhinorrhoea	3	3 (4.92)	0	0 (0.00)
Dyspnoea	2	1 (1.64)	0	0 (0.00)
Pleural effusion	2	2 (3.28)	0	0 (0.00)
Bronchospasm	1	1 (1.64)	0	0 (0.00)
Lung disorder	1	1 (1.64)	0	0 (0.00)
Oropharyngeal pain	1	1 (1.64)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.64)	0	0 (0.00)
Respiratory distress	1	1 (1.64)	1	1 (1.64)
Respiratory failure	1	1 (1.64)	1	1 (1.64)
Upper respiratory tract inflammation	1	1 (1.64)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	23	16 (26.23)	0	0 (0.00)
Rash	6	4 (6.56)	0	0 (0.00)
Dry skin	5	4 (6.56)	0	0 (0.00)
Ingrowing nail	2	2 (3.28)	0	0 (0.00)
Dermatitis allergic	1	1 (1.64)	0	0 (0.00)
Dermatitis atopic	1	1 (1.64)	0	0 (0.00)
Eczema	1	1 (1.64)	0	0 (0.00)
Erythema	1	1 (1.64)	0	0 (0.00)
Hangnail	1	1 (1.64)	0	0 (0.00)
Miliaria	1	1 (1.64)	0	0 (0.00)
Night sweats	1	1 (1.64)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.64)	0	0 (0.00)
Skin discolouration	1	1 (1.64)	0	0 (0.00)
Skin swelling	1	1 (1.64)	0	0 (0.00)
Vascular disorders				
- Total	5	4 (6.56)	3	3 (4.92)
Hypotension	2	2 (3.28)	1	1 (1.64)
Venoocclusive disease	2	2 (3.28)	2	2 (3.28)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=61 n (%)[1]	Grade >= 3 Total events	All patients N=61 n (%)[2]
Hypertension	1	1 (1.64)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	24	4 (57.14)	1	1 (14.29)
Endocrine disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Delayed puberty	1	1 (14.29)	0	0 (0.00)
Hypothyroidism	1	1 (14.29)	0	0 (0.00)
Eye disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Dry eye	1	1 (14.29)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	2 (28.57)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
Diarrhoea	1	1 (14.29)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Nausea	1	1 (14.29)	0	0 (0.00)
Vomiting	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (14.29)	0	0 (0.00)
Fatigue	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Seasonal allergy	2	2 (28.57)	0	0 (0.00)
Infections and infestations				
- Total	5	3 (42.86)	0	0 (0.00)
COVID-19	1	1 (14.29)	0	0 (0.00)
Otitis media acute	1	1 (14.29)	0	0 (0.00)
Skin infection	1	1 (14.29)	0	0 (0.00)
Syphilis	1	1 (14.29)	0	0 (0.00)
Upper respiratory tract infection	1	1 (14.29)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (14.29)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Abdominal injury	1	1 (14.29)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Obesity	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Arthralgia	1	1 (14.29)	0	0 (0.00)
Osteopenia	1	1 (14.29)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	3	2 (28.57)	0	0 (0.00)
Cough	1	1 (14.29)	0	0 (0.00)
Rhinorrhoea	1	1 (14.29)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (14.29)	0	0 (0.00)
Rash	1	1 (14.29)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Rash maculo-papular	1	1 (14.29)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Total number of AE per patient	196	28 (65.12)	62	18 (41.86)
Blood and lymphatic system disorders				
- Total	6	4 (9.30)	2	2 (4.65)
Agranulocytosis	1	1 (2.33)	1	1 (2.33)
Anaemia	1	1 (2.33)	0	0 (0.00)
Hypercoagulation	1	1 (2.33)	0	0 (0.00)
Lymphadenopathy	1	1 (2.33)	0	0 (0.00)
Neutropenia	1	1 (2.33)	1	1 (2.33)
Thrombocytopenia	1	1 (2.33)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Cerebral cavernous malformation	1	1 (2.33)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.33)	0	0 (0.00)
Deafness unilateral	1	1 (2.33)	0	0 (0.00)
Eye disorders				
- Total	3	2 (4.65)	1	1 (2.33)
Eye pain	1	1 (2.33)	1	1 (2.33)
Eyelid oedema	1	1 (2.33)	0	0 (0.00)
Mydriasis	1	1 (2.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	5	5 (11.63)	1	1 (2.33)
Diarrhoea	4	4 (9.30)	1	1 (2.33)
Irritable bowel syndrome	1	1 (2.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	12	8 (18.60)	2	2 (4.65)
Pyrexia	7	5 (11.63)	1	1 (2.33)
Pain	2	2 (4.65)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (2.33)	1	1 (2.33)
Non-cardiac chest pain	1	1 (2.33)	0	0 (0.00)
Xerosis	1	1 (2.33)	0	0 (0.00)
Immune system disorders				
- Total	8	7 (16.28)	3	2 (4.65)
Hypogammaglobulinaemia	3	3 (6.98)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.65)	1	1 (2.33)
Drug hypersensitivity	1	1 (2.33)	1	1 (2.33)
Haemophagocytic lymphohistiocytosis	1	1 (2.33)	1	1 (2.33)
Seasonal allergy	1	1 (2.33)	0	0 (0.00)
Infections and infestations				
- Total	81	20 (46.51)	26	14 (32.56)
Sinusitis	9	6 (13.95)	0	0 (0.00)
Upper respiratory tract infection	6	4 (9.30)	1	1 (2.33)
Conjunctivitis	5	4 (9.30)	0	0 (0.00)
Rhinovirus infection	4	4 (9.30)	1	1 (2.33)
Fungal infection	3	2 (4.65)	0	0 (0.00)
Otitis media	3	2 (4.65)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Sepsis	3	3 (6.98)	3	3 (6.98)
Bronchitis	2	2 (4.65)	0	0 (0.00)
COVID-19	2	1 (2.33)	1	1 (2.33)
Device related sepsis	2	1 (2.33)	2	1 (2.33)
Gastroenteritis viral	2	1 (2.33)	0	0 (0.00)
Herpes zoster	2	2 (4.65)	1	1 (2.33)
Influenza	2	2 (4.65)	1	1 (2.33)
Oral herpes	2	2 (4.65)	0	0 (0.00)
Pneumonia	2	2 (4.65)	2	2 (4.65)
Skin infection	2	2 (4.65)	0	0 (0.00)
Urinary tract infection	2	2 (4.65)	0	0 (0.00)
Acute sinusitis	1	1 (2.33)	0	0 (0.00)
Bronchiolitis	1	1 (2.33)	1	1 (2.33)
COVID-19 pneumonia	1	1 (2.33)	1	1 (2.33)
Candida infection	1	1 (2.33)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.33)	1	1 (2.33)
Ear infection	1	1 (2.33)	1	1 (2.33)
Enterovirus infection	1	1 (2.33)	1	1 (2.33)
Folliculitis	1	1 (2.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Fungal skin infection	1	1 (2.33)	0	0 (0.00)
Gastroenteritis	1	1 (2.33)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.33)	1	1 (2.33)
Gastroenteritis salmonella	1	1 (2.33)	1	1 (2.33)
Herpes virus infection	1	1 (2.33)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.33)	1	1 (2.33)
Nail infection	1	1 (2.33)	0	0 (0.00)
Neutropenic infection	1	1 (2.33)	1	1 (2.33)
Ophthalmic herpes zoster	1	1 (2.33)	0	0 (0.00)
Oral candidiasis	1	1 (2.33)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.33)	1	1 (2.33)
Pneumonia respiratory syncytial viral	1	1 (2.33)	1	1 (2.33)
Rhinitis	1	1 (2.33)	0	0 (0.00)
Septic shock	1	1 (2.33)	1	1 (2.33)
Staphylococcal abscess	1	1 (2.33)	1	1 (2.33)
Staphylococcal bacteraemia	1	1 (2.33)	1	1 (2.33)
Streptococcal sepsis	1	1 (2.33)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.33)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Viral skin infection	1	1 (2.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (4.65)	1	1 (2.33)
Infusion related reaction	1	1 (2.33)	1	1 (2.33)
Ligament sprain	1	1 (2.33)	0	0 (0.00)
Investigations				
- Total	16	6 (13.95)	6	2 (4.65)
Neutrophil count decreased	8	3 (6.98)	5	1 (2.33)
Blood bilirubin increased	3	1 (2.33)	0	0 (0.00)
Platelet count decreased	2	2 (4.65)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.33)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.33)	1	1 (2.33)
SARS-CoV-2 test positive	1	1 (2.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	5 (11.63)	4	3 (6.98)
Decreased appetite	2	1 (2.33)	2	1 (2.33)
Iron overload	2	1 (2.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Hypercholesterolaemia	1	1 (2.33)	0	0 (0.00)
Hyperglycaemia	1	1 (2.33)	1	1 (2.33)
Hyperlipidaemia	1	1 (2.33)	0	0 (0.00)
Hypernatraemia	1	1 (2.33)	1	1 (2.33)
Hypertriglyceridaemia	1	1 (2.33)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	6	5 (11.63)	0	0 (0.00)
Pain in extremity	2	2 (4.65)	0	0 (0.00)
Growth retardation	1	1 (2.33)	0	0 (0.00)
Joint effusion	1	1 (2.33)	0	0 (0.00)
Osteonecrosis	1	1 (2.33)	0	0 (0.00)
Synovitis	1	1 (2.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.33)	1	1 (2.33)
Bone giant cell tumour benign	2	1 (2.33)	1	1 (2.33)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
- Total	9	4 (9.30)	3	2 (4.65)
Headache	3	2 (4.65)	1	1 (2.33)
Seizure	3	1 (2.33)	1	1 (2.33)
Nervous system disorder	2	1 (2.33)	1	1 (2.33)
Dysarthria	1	1 (2.33)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.98)	0	0 (0.00)
Anxiety	2	2 (4.65)	0	0 (0.00)
Tic	1	1 (2.33)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.33)	1	1 (2.33)
Endometriosis	2	1 (2.33)	1	1 (2.33)
Respiratory, thoracic and mediastinal disorders				
- Total	20	8 (18.60)	6	4 (9.30)
Cough	3	3 (6.98)	0	0 (0.00)
Dyspnoea	3	3 (6.98)	1	1 (2.33)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Rhinorrhoea	2	2 (4.65)	0	0 (0.00)
Tachypnoea	2	1 (2.33)	2	1 (2.33)
Dyspnoea exertional	1	1 (2.33)	0	0 (0.00)
Epistaxis	1	1 (2.33)	0	0 (0.00)
Hypoxia	1	1 (2.33)	1	1 (2.33)
Laryngeal oedema	1	1 (2.33)	1	1 (2.33)
Oropharyngeal pain	1	1 (2.33)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.33)	0	0 (0.00)
Pleural effusion	1	1 (2.33)	0	0 (0.00)
Respiratory failure	1	1 (2.33)	1	1 (2.33)
Sleep apnoea syndrome	1	1 (2.33)	0	0 (0.00)
Wheezing	1	1 (2.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	8	6 (13.95)	4	3 (6.98)
Rash macular	2	1 (2.33)	2	1 (2.33)
Dermatitis atopic	1	1 (2.33)	1	1 (2.33)
Dry skin	1	1 (2.33)	0	0 (0.00)
Eczema	1	1 (2.33)	1	1 (2.33)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=43 n (%)[1]	Grade >= 3 Total events	All patients N=43 n (%)[2]
Papule	1	1 (2.33)	0	0 (0.00)
Rash	1	1 (2.33)	0	0 (0.00)
Rash erythematous	1	1 (2.33)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.65)	1	1 (2.33)
Hypertension	2	2 (4.65)	1	1 (2.33)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Total number of AE per patient	547	15 (100.00)	224	13 (86.67)
Blood and lymphatic system disorders				
- Total	41	11 (73.33)	26	10 (66.67)
Anaemia	25	5 (33.33)	13	4 (26.67)
Febrile neutropenia	11	8 (53.33)	11	8 (53.33)
Coagulopathy	2	2 (13.33)	1	1 (6.67)
Disseminated intravascular coagulation	1	1 (6.67)	0	0 (0.00)
Leukocytosis	1	1 (6.67)	0	0 (0.00)
Thrombocytopenia	1	1 (6.67)	1	1 (6.67)
Cardiac disorders				
- Total	12	6 (40.00)	4	2 (13.33)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Tachycardia	6	3 (20.00)	0	0 (0.00)
Sinus tachycardia	2	2 (13.33)	0	0 (0.00)
Cardiac arrest	1	1 (6.67)	1	1 (6.67)
Cardiac failure	1	1 (6.67)	1	1 (6.67)
Left ventricular dysfunction	1	1 (6.67)	1	1 (6.67)
Sinus bradycardia	1	1 (6.67)	1	1 (6.67)
Endocrine disorders				
- Total	5	4 (26.67)	0	0 (0.00)
Adrenal insufficiency	3	3 (20.00)	0	0 (0.00)
Delayed puberty	1	1 (6.67)	0	0 (0.00)
Hypothyroidism	1	1 (6.67)	0	0 (0.00)
Eye disorders				
- Total	2	2 (13.33)	0	0 (0.00)
Dry eye	1	1 (6.67)	0	0 (0.00)
Visual impairment	1	1 (6.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	26	12 (80.00)	3	3 (20.00)
Diarrhoea	6	6 (40.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Constipation	5	4 (26.67)	0	0 (0.00)
Vomiting	4	4 (26.67)	1	1 (6.67)
Nausea	3	3 (20.00)	0	0 (0.00)
Abdominal pain	2	1 (6.67)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (6.67)	1	1 (6.67)
Dry mouth	1	1 (6.67)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (6.67)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (6.67)	0	0 (0.00)
Mouth haemorrhage	1	1 (6.67)	1	1 (6.67)
Pancreatitis	1	1 (6.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	28	11 (73.33)	4	4 (26.67)
Pyrexia	11	6 (40.00)	3	3 (20.00)
Fatigue	5	4 (26.67)	0	0 (0.00)
Oedema peripheral	3	3 (20.00)	0	0 (0.00)
Chills	2	2 (13.33)	0	0 (0.00)
Generalised oedema	2	2 (13.33)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Face oedema	1	1 (6.67)	0	0 (0.00)
Malaise	1	1 (6.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (6.67)	1	1 (6.67)
Non-cardiac chest pain	1	1 (6.67)	0	0 (0.00)
Hepatobiliary disorders				
- Total	4	2 (13.33)	1	1 (6.67)
Biliary tract disorder	1	1 (6.67)	0	0 (0.00)
Gallbladder enlargement	1	1 (6.67)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (6.67)	1	1 (6.67)
Hypertransaminasaemia	1	1 (6.67)	0	0 (0.00)
Immune system disorders				
- Total	47	15 (100.00)	20	9 (60.00)
Cytokine release syndrome	35	13 (86.67)	17	9 (60.00)
Hypogammaglobulinaemia	6	6 (40.00)	1	1 (6.67)
Seasonal allergy	3	3 (20.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (6.67)	1	1 (6.67)
Haemophagocytic lymphohistiocytosis	1	1 (6.67)	1	1 (6.67)
Selective IgG subclass deficiency	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Infections and infestations				
- Total	42	11 (73.33)	19	6 (40.00)
Upper respiratory tract infection	5	4 (26.67)	1	1 (6.67)
Bacteraemia	3	2 (13.33)	2	1 (6.67)
Staphylococcal bacteraemia	3	2 (13.33)	3	2 (13.33)
Adenovirus infection	2	2 (13.33)	2	2 (13.33)
Respiratory syncytial virus infection	2	2 (13.33)	1	1 (6.67)
Rhinovirus infection	2	1 (6.67)	0	0 (0.00)
Urinary tract infection	2	1 (6.67)	2	1 (6.67)
Atypical pneumonia	1	1 (6.67)	0	0 (0.00)
BK virus infection	1	1 (6.67)	1	1 (6.67)
COVID-19	1	1 (6.67)	0	0 (0.00)
Candida infection	1	1 (6.67)	0	0 (0.00)
Conjunctivitis	1	1 (6.67)	0	0 (0.00)
Encephalitis viral	1	1 (6.67)	1	1 (6.67)
Gastroenteritis	1	1 (6.67)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (6.67)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (6.67)	0	0 (0.00)
Herpes simplex	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Klebsiella bacteraemia	1	1 (6.67)	0	0 (0.00)
Metapneumovirus infection	1	1 (6.67)	1	1 (6.67)
Otitis media	1	1 (6.67)	0	0 (0.00)
Otitis media acute	1	1 (6.67)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (6.67)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (6.67)	1	1 (6.67)
Pneumocystis jirovecii pneumonia	1	1 (6.67)	1	1 (6.67)
Septic shock	1	1 (6.67)	1	1 (6.67)
Sinusitis fungal	1	1 (6.67)	1	1 (6.67)
Skin infection	1	1 (6.67)	0	0 (0.00)
Staphylococcal infection	1	1 (6.67)	0	0 (0.00)
Syphilis	1	1 (6.67)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (6.67)	1	1 (6.67)
Injury, poisoning and procedural complications				
- Total	4	4 (26.67)	0	0 (0.00)
Abdominal injury	1	1 (6.67)	0	0 (0.00)
Infusion related reaction	1	1 (6.67)	0	0 (0.00)
Skin abrasion	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Transfusion reaction	1	1 (6.67)	0	0 (0.00)
Investigations				
- Total	117	11 (73.33)	64	10 (66.67)
Platelet count decreased	29	3 (20.00)	21	3 (20.00)
White blood cell count decreased	18	3 (20.00)	10	3 (20.00)
Neutrophil count decreased	15	3 (20.00)	9	3 (20.00)
Aspartate aminotransferase increased	12	7 (46.67)	6	6 (40.00)
Alanine aminotransferase increased	9	5 (33.33)	3	3 (20.00)
Blood bilirubin increased	8	4 (26.67)	4	4 (26.67)
Blood creatinine increased	3	3 (20.00)	2	2 (13.33)
Activated partial thromboplastin time prolonged	2	2 (13.33)	1	1 (6.67)
Blood uric acid increased	2	2 (13.33)	1	1 (6.67)
Electrocardiogram QT prolonged	2	1 (6.67)	1	1 (6.67)
International normalised ratio increased	2	2 (13.33)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (6.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (6.67)	1	1 (6.67)
Blood phosphorus increased	1	1 (6.67)	0	0 (0.00)
C-reactive protein increased	1	1 (6.67)	1	1 (6.67)
Ejection fraction decreased	1	1 (6.67)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (6.67)	0	0 (0.00)
Fibrin D dimer increased	1	1 (6.67)	1	1 (6.67)
Heart sounds abnormal	1	1 (6.67)	0	0 (0.00)
Serum ferritin increased	1	1 (6.67)	1	1 (6.67)
Staphylococcus test positive	1	1 (6.67)	0	0 (0.00)
Troponin increased	1	1 (6.67)	1	1 (6.67)
Urine output decreased	1	1 (6.67)	1	1 (6.67)
Weight decreased	1	1 (6.67)	0	0 (0.00)
Weight increased	1	1 (6.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	93	13 (86.67)	39	10 (66.67)
Hypokalaemia	16	7 (46.67)	8	3 (20.00)
Hypophosphataemia	11	4 (26.67)	5	3 (20.00)
Hypocalcaemia	10	8 (53.33)	3	3 (20.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Decreased appetite	9	9 (60.00)	5	5 (33.33)
Hyperglycaemia	8	5 (33.33)	2	2 (13.33)
Hypoalbuminaemia	7	5 (33.33)	1	1 (6.67)
Hyperuricaemia	6	4 (26.67)	1	1 (6.67)
Acidosis	3	2 (13.33)	2	2 (13.33)
Hypervolaemia	3	3 (20.00)	3	3 (20.00)
Hypomagnesaemia	3	3 (20.00)	0	0 (0.00)
Tumour lysis syndrome	3	3 (20.00)	3	3 (20.00)
Hypercalcaemia	2	2 (13.33)	1	1 (6.67)
Hyperkalaemia	2	2 (13.33)	1	1 (6.67)
Malnutrition	2	2 (13.33)	2	2 (13.33)
Calcium deficiency	1	1 (6.67)	0	0 (0.00)
Hyperchloraemia	1	1 (6.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (6.67)	0	0 (0.00)
Hyperphosphataemia	1	1 (6.67)	0	0 (0.00)
Hypoglycaemia	1	1 (6.67)	0	0 (0.00)
Hyponatraemia	1	1 (6.67)	0	0 (0.00)
Metabolic acidosis	1	1 (6.67)	1	1 (6.67)
Obesity	1	1 (6.67)	1	1 (6.67)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	19	9 (60.00)	3	2 (13.33)
Back pain	5	2 (13.33)	1	1 (6.67)
Arthralgia	4	3 (20.00)	1	1 (6.67)
Myalgia	3	3 (20.00)	0	0 (0.00)
Pain in extremity	2	2 (13.33)	0	0 (0.00)
Growth retardation	1	1 (6.67)	0	0 (0.00)
Haemarthrosis	1	1 (6.67)	1	1 (6.67)
Muscle spasms	1	1 (6.67)	0	0 (0.00)
Neck pain	1	1 (6.67)	0	0 (0.00)
Osteopenia	1	1 (6.67)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (6.67)	0	0 (0.00)
Cancer pain	1	1 (6.67)	0	0 (0.00)
Nervous system disorders				
- Total	24	8 (53.33)	5	3 (20.00)
Headache	7	4 (26.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Cognitive disorder	5	3 (20.00)	1	1 (6.67)
Hyperaesthesia	2	1 (6.67)	0	0 (0.00)
Somnolence	2	2 (13.33)	1	1 (6.67)
Tremor	2	1 (6.67)	0	0 (0.00)
Amnesia	1	1 (6.67)	0	0 (0.00)
Cerebral haemorrhage	1	1 (6.67)	1	1 (6.67)
Encephalopathy	1	1 (6.67)	1	1 (6.67)
Extrapyramidal disorder	1	1 (6.67)	0	0 (0.00)
Neurological decompensation	1	1 (6.67)	1	1 (6.67)
Paraesthesia	1	1 (6.67)	0	0 (0.00)
Psychiatric disorders				
- Total	11	8 (53.33)	2	2 (13.33)
Anxiety	5	5 (33.33)	1	1 (6.67)
Mental status changes	2	2 (13.33)	0	0 (0.00)
Agitation	1	1 (6.67)	0	0 (0.00)
Delirium	1	1 (6.67)	1	1 (6.67)
Hallucination, visual	1	1 (6.67)	0	0 (0.00)
Insomnia	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Renal and urinary disorders				
- Total	14	6 (40.00)	7	5 (33.33)
Acute kidney injury	6	4 (26.67)	3	3 (20.00)
Renal failure	3	1 (6.67)	3	1 (6.67)
Dysuria	1	1 (6.67)	0	0 (0.00)
Haematuria	1	1 (6.67)	1	1 (6.67)
Kidney enlargement	1	1 (6.67)	0	0 (0.00)
Renal mass	1	1 (6.67)	0	0 (0.00)
Urinary retention	1	1 (6.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Female genital tract fistula	1	1 (6.67)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	29	11 (73.33)	15	8 (53.33)
Nasal congestion	4	3 (20.00)	0	0 (0.00)
Pulmonary oedema	4	4 (26.67)	3	3 (20.00)
Hypoxia	3	3 (20.00)	3	3 (20.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Acute respiratory distress syndrome	2	2 (13.33)	2	2 (13.33)
Cough	2	2 (13.33)	0	0 (0.00)
Pleural effusion	2	2 (13.33)	2	2 (13.33)
Respiratory distress	2	1 (6.67)	2	1 (6.67)
Rhinitis allergic	2	2 (13.33)	0	0 (0.00)
Acute respiratory failure	1	1 (6.67)	1	1 (6.67)
Bronchial oedema	1	1 (6.67)	0	0 (0.00)
Oropharyngeal pain	1	1 (6.67)	0	0 (0.00)
Respiratory failure	1	1 (6.67)	1	1 (6.67)
Rhinorrhoea	1	1 (6.67)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (6.67)	0	0 (0.00)
Tachypnoea	1	1 (6.67)	1	1 (6.67)
Wheezing	1	1 (6.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	12	7 (46.67)	1	1 (6.67)
Pruritus	3	2 (13.33)	0	0 (0.00)
Dry skin	2	2 (13.33)	0	0 (0.00)
Blister	1	1 (6.67)	0	0 (0.00)

Timing: At anytime, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Decubitus ulcer	1	1 (6.67)	1	1 (6.67)
Hyperhidrosis	1	1 (6.67)	0	0 (0.00)
Rash	1	1 (6.67)	0	0 (0.00)
Rash maculo-papular	1	1 (6.67)	0	0 (0.00)
Scab	1	1 (6.67)	0	0 (0.00)
Skin hypopigmentation	1	1 (6.67)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (6.67)	1	1 (6.67)
Thrombolysis	1	1 (6.67)	1	1 (6.67)
Vascular disorders				
- Total	14	10 (66.67)	10	8 (53.33)
Hypotension	9	7 (46.67)	7	6 (40.00)
Hypertension	4	4 (26.67)	2	2 (13.33)
Capillary leak syndrome	1	1 (6.67)	1	1 (6.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250d
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Ethnicity
Safety Set

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Total number of AE per patient	1958	65 (100.00)	604	60 (92.31)
Blood and lymphatic system disorders				
- Total	122	44 (67.69)	69	33 (50.77)
Anaemia	38	20 (30.77)	11	5 (7.69)
Febrile neutropenia	22	19 (29.23)	22	19 (29.23)
Neutropenia	17	11 (16.92)	15	9 (13.85)
Thrombocytopenia	10	8 (12.31)	9	8 (12.31)
Disseminated intravascular coagulation	7	7 (10.77)	3	3 (4.62)
Leukopenia	5	3 (4.62)	3	2 (3.08)
Splenomegaly	4	4 (6.15)	0	0 (0.00)
B-cell aplasia	3	1 (1.54)	0	0 (0.00)
Coagulopathy	3	3 (4.62)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Eosinophilia	3	1 (1.54)	0	0 (0.00)
Lymphadenopathy	2	2 (3.08)	0	0 (0.00)
Lymphopenia	2	2 (3.08)	2	2 (3.08)
Pancytopenia	2	2 (3.08)	2	2 (3.08)
Agranulocytosis	1	1 (1.54)	1	1 (1.54)
Hypercoagulation	1	1 (1.54)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.54)	0	0 (0.00)
Lymphocytosis	1	1 (1.54)	0	0 (0.00)
Cardiac disorders				
- Total	41	22 (33.85)	10	9 (13.85)
Tachycardia	18	14 (21.54)	3	3 (4.62)
Cardiac failure	5	2 (3.08)	3	2 (3.08)
Bradycardia	3	3 (4.62)	0	0 (0.00)
Left ventricular dysfunction	3	3 (4.62)	2	2 (3.08)
Cardiac arrest	2	2 (3.08)	2	2 (3.08)
Cardiac dysfunction	2	2 (3.08)	0	0 (0.00)
Sinus tachycardia	2	1 (1.54)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.54)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Mitral valve incompetence	1	1 (1.54)	0	0 (0.00)
Pericardial effusion	1	1 (1.54)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.54)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.54)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.54)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.54)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.62)	0	0 (0.00)
Deafness unilateral	1	1 (1.54)	0	0 (0.00)
Ear pain	1	1 (1.54)	0	0 (0.00)
Ear pruritus	1	1 (1.54)	0	0 (0.00)
Endocrine disorders				
- Total	3	3 (4.62)	0	0 (0.00)
Hypothyroidism	2	2 (3.08)	0	0 (0.00)
Adrenal insufficiency	1	1 (1.54)	0	0 (0.00)
Eye disorders				

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
- Total	22	13 (20.00)	1	1 (1.54)
Eyelid oedema	4	3 (4.62)	0	0 (0.00)
Ocular hyperaemia	3	3 (4.62)	0	0 (0.00)
Cataract	2	2 (3.08)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (3.08)	0	0 (0.00)
Eye pain	2	2 (3.08)	1	1 (1.54)
Retinal haemorrhage	2	1 (1.54)	0	0 (0.00)
Eye oedema	1	1 (1.54)	0	0 (0.00)
Hypermetropia	1	1 (1.54)	0	0 (0.00)
Mydriasis	1	1 (1.54)	0	0 (0.00)
Periorbital oedema	1	1 (1.54)	0	0 (0.00)
Periorbital swelling	1	1 (1.54)	0	0 (0.00)
Visual field defect	1	1 (1.54)	0	0 (0.00)
Visual impairment	1	1 (1.54)	0	0 (0.00)
Gastrointestinal disorders				
- Total	156	48 (73.85)	15	13 (20.00)
Vomiting	34	22 (33.85)	0	0 (0.00)
Diarrhoea	24	20 (30.77)	2	2 (3.08)
Nausea	24	19 (29.23)	2	2 (3.08)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Abdominal pain	13	10 (15.38)	2	2 (3.08)
Constipation	11	10 (15.38)	0	0 (0.00)
Pancreatitis	5	5 (7.69)	2	2 (3.08)
Abdominal pain upper	4	4 (6.15)	0	0 (0.00)
Mouth haemorrhage	4	4 (6.15)	1	1 (1.54)
Abdominal distension	3	3 (4.62)	0	0 (0.00)
Ascites	3	3 (4.62)	0	0 (0.00)
Stomatitis	3	3 (4.62)	1	1 (1.54)
Gastrointestinal sounds abnormal	2	2 (3.08)	0	0 (0.00)
Proctalgia	2	2 (3.08)	1	1 (1.54)
Trichoglossia	2	2 (3.08)	0	0 (0.00)
Abdominal rigidity	1	1 (1.54)	0	0 (0.00)
Anal fissure	1	1 (1.54)	0	0 (0.00)
Anal haemorrhage	1	1 (1.54)	0	0 (0.00)
Dyspepsia	1	1 (1.54)	0	0 (0.00)
Dysphagia	1	1 (1.54)	1	1 (1.54)
Enteritis	1	1 (1.54)	0	0 (0.00)
Enterocolitis	1	1 (1.54)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Gingival bleeding	1	1 (1.54)	0	0 (0.00)
Gingival erythema	1	1 (1.54)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.54)	1	1 (1.54)
Haematemesis	1	1 (1.54)	0	0 (0.00)
Ileus	1	1 (1.54)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.54)	0	0 (0.00)
Lip dry	1	1 (1.54)	0	0 (0.00)
Lip oedema	1	1 (1.54)	0	0 (0.00)
Melaena	1	1 (1.54)	1	1 (1.54)
Mouth swelling	1	1 (1.54)	0	0 (0.00)
Neutropenic colitis	1	1 (1.54)	1	1 (1.54)
Odynophagia	1	1 (1.54)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.54)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.54)	0	0 (0.00)
General disorders and administration site conditions				
- Total	128	42 (64.62)	20	11 (16.92)
Pyrexia	56	29 (44.62)	9	8 (12.31)
Fatigue	14	13 (20.00)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Chills	8	5 (7.69)	0	0 (0.00)
Face oedema	8	7 (10.77)	1	1 (1.54)
Oedema peripheral	6	4 (6.15)	2	1 (1.54)
Pain	5	5 (7.69)	2	2 (3.08)
Catheter site pain	4	2 (3.08)	2	1 (1.54)
Asthenia	3	3 (4.62)	0	0 (0.00)
Generalised oedema	3	3 (4.62)	0	0 (0.00)
Catheter site erythema	2	1 (1.54)	0	0 (0.00)
Influenza like illness	2	2 (3.08)	0	0 (0.00)
Localised oedema	2	2 (3.08)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (3.08)	2	2 (3.08)
Catheter site haemorrhage	1	1 (1.54)	0	0 (0.00)
Chest discomfort	1	1 (1.54)	1	1 (1.54)
Crying	1	1 (1.54)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.54)	0	0 (0.00)
Facial pain	1	1 (1.54)	0	0 (0.00)
Malaise	1	1 (1.54)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.54)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Sluggishness	1	1 (1.54)	0	0 (0.00)
Swelling face	1	1 (1.54)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.54)	1	1 (1.54)
Vascular device occlusion	1	1 (1.54)	0	0 (0.00)
Xerosis	1	1 (1.54)	0	0 (0.00)
Hepatobiliary disorders				
- Total	28	17 (26.15)	6	5 (7.69)
Hepatic function abnormal	11	5 (7.69)	4	3 (4.62)
Hyperbilirubinaemia	5	4 (6.15)	0	0 (0.00)
Hepatomegaly	3	3 (4.62)	1	1 (1.54)
Cholelithiasis	2	2 (3.08)	0	0 (0.00)
Hypertransaminasaemia	2	1 (1.54)	0	0 (0.00)
Cholestasis	1	1 (1.54)	1	1 (1.54)
Gallbladder enlargement	1	1 (1.54)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.54)	0	0 (0.00)
Liver disorder	1	1 (1.54)	0	0 (0.00)
Ocular icterus	1	1 (1.54)	0	0 (0.00)
Immune system disorders				

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
- Total	146	56 (86.15)	56	37 (56.92)
Cytokine release syndrome	93	48 (73.85)	38	29 (44.62)
Hypogammaglobulinaemia	34	27 (41.54)	6	6 (9.23)
Haemophagocytic lymphohistiocytosis	5	5 (7.69)	3	3 (4.62)
Immunodeficiency	4	4 (6.15)	4	4 (6.15)
Chronic graft versus host disease	2	2 (3.08)	1	1 (1.54)
Drug hypersensitivity	2	2 (3.08)	1	1 (1.54)
Graft versus host disease	2	2 (3.08)	2	2 (3.08)
Allergy to immunoglobulin therapy	1	1 (1.54)	0	0 (0.00)
Engraftment syndrome	1	1 (1.54)	1	1 (1.54)
Hypersensitivity	1	1 (1.54)	0	0 (0.00)
Seasonal allergy	1	1 (1.54)	0	0 (0.00)
Infections and infestations				
- Total	221	49 (75.38)	83	33 (50.77)
Sinusitis	14	7 (10.77)	2	2 (3.08)
Upper respiratory tract infection	12	9 (13.85)	2	2 (3.08)
Conjunctivitis	11	7 (10.77)	0	0 (0.00)
Nasopharyngitis	9	7 (10.77)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Rhinovirus infection	9	8 (12.31)	2	2 (3.08)
Bronchopulmonary aspergillosis	6	2 (3.08)	4	2 (3.08)
Pneumonia	6	6 (9.23)	4	4 (6.15)
Gastroenteritis	5	5 (7.69)	2	2 (3.08)
Oral herpes	5	4 (6.15)	1	1 (1.54)
Otitis media	5	4 (6.15)	1	1 (1.54)
Parainfluenzae virus infection	5	4 (6.15)	3	3 (4.62)
Candida infection	4	3 (4.62)	2	1 (1.54)
Clostridium difficile infection	4	4 (6.15)	3	3 (4.62)
Ear infection	4	3 (4.62)	1	1 (1.54)
Nail infection	4	4 (6.15)	0	0 (0.00)
Oral candidiasis	4	3 (4.62)	0	0 (0.00)
Staphylococcal infection	4	4 (6.15)	2	2 (3.08)
Fungal infection	3	2 (3.08)	0	0 (0.00)
Gastroenteritis viral	3	2 (3.08)	0	0 (0.00)
Herpes zoster	3	3 (4.62)	2	2 (3.08)
Influenza	3	3 (4.62)	1	1 (1.54)
Klebsiella infection	3	1 (1.54)	3	1 (1.54)
Otitis externa	3	3 (4.62)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Respiratory tract infection	3	3 (4.62)	0	0 (0.00)
Rhinitis	3	3 (4.62)	0	0 (0.00)
Sepsis	3	3 (4.62)	3	3 (4.62)
Staphylococcal bacteraemia	3	3 (4.62)	3	3 (4.62)
Acute sinusitis	2	2 (3.08)	0	0 (0.00)
Bronchitis	2	2 (3.08)	0	0 (0.00)
COVID-19	2	1 (1.54)	1	1 (1.54)
Device related sepsis	2	1 (1.54)	2	1 (1.54)
Encephalitis	2	2 (3.08)	2	2 (3.08)
Gingivitis	2	2 (3.08)	0	0 (0.00)
Human herpesvirus 6 infection	2	2 (3.08)	2	2 (3.08)
Metapneumovirus infection	2	2 (3.08)	2	2 (3.08)
Oral infection	2	2 (3.08)	0	0 (0.00)
Paronychia	2	2 (3.08)	0	0 (0.00)
Skin infection	2	2 (3.08)	0	0 (0.00)
Urinary tract infection	2	2 (3.08)	0	0 (0.00)
Varicella zoster virus infection	2	2 (3.08)	1	1 (1.54)
Viral infection	2	2 (3.08)	1	1 (1.54)
Anal abscess	1	1 (1.54)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
BK virus infection	1	1 (1.54)	0	0 (0.00)
Bacteraemia	1	1 (1.54)	1	1 (1.54)
Bronchiolitis	1	1 (1.54)	1	1 (1.54)
COVID-19 pneumonia	1	1 (1.54)	1	1 (1.54)
Cellulitis	1	1 (1.54)	0	0 (0.00)
Cholecystitis infective	1	1 (1.54)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.54)	1	1 (1.54)
Coronavirus infection	1	1 (1.54)	1	1 (1.54)
Cystitis	1	1 (1.54)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.54)	1	1 (1.54)
Device related infection	1	1 (1.54)	1	1 (1.54)
Ear, nose and throat infection	1	1 (1.54)	0	0 (0.00)
Encephalitis viral	1	1 (1.54)	1	1 (1.54)
Enterobacter infection	1	1 (1.54)	1	1 (1.54)
Enterovirus infection	1	1 (1.54)	1	1 (1.54)
Folliculitis	1	1 (1.54)	0	0 (0.00)
Fungal skin infection	1	1 (1.54)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.54)	1	1 (1.54)
Gastroenteritis salmonella	1	1 (1.54)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Gastrointestinal infection	1	1 (1.54)	0	0 (0.00)
Granulicatella infection	1	1 (1.54)	1	1 (1.54)
Herpes simplex	1	1 (1.54)	1	1 (1.54)
Herpes virus infection	1	1 (1.54)	0	0 (0.00)
Localised infection	1	1 (1.54)	0	0 (0.00)
Mastoiditis	1	1 (1.54)	1	1 (1.54)
Meningitis bacterial	1	1 (1.54)	1	1 (1.54)
Meningitis pneumococcal	1	1 (1.54)	1	1 (1.54)
Molluscum contagiosum	1	1 (1.54)	0	0 (0.00)
Myringitis	1	1 (1.54)	0	0 (0.00)
Neutropenic infection	1	1 (1.54)	1	1 (1.54)
Ophthalmic herpes zoster	1	1 (1.54)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (1.54)	1	1 (1.54)
Pneumonia fungal	1	1 (1.54)	1	1 (1.54)
Pneumonia respiratory syncytial viral	1	1 (1.54)	1	1 (1.54)
Pneumonia viral	1	1 (1.54)	1	1 (1.54)
Respiratory syncytial virus infection	1	1 (1.54)	1	1 (1.54)
Respiratory tract infection viral	1	1 (1.54)	0	0 (0.00)
Salmonellosis	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Septic shock	1	1 (1.54)	1	1 (1.54)
Soft tissue infection	1	1 (1.54)	1	1 (1.54)
Staphylococcal abscess	1	1 (1.54)	1	1 (1.54)
Staphylococcal sepsis	1	1 (1.54)	1	1 (1.54)
Staphylococcal skin infection	1	1 (1.54)	0	0 (0.00)
Stomatococcal infection	1	1 (1.54)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.54)	0	0 (0.00)
Systemic candida	1	1 (1.54)	1	1 (1.54)
Tinea pedis	1	1 (1.54)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.54)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.54)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.54)	1	1 (1.54)
Viral skin infection	1	1 (1.54)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	29	17 (26.15)	4	3 (4.62)
Infusion related reaction	7	4 (6.15)	1	1 (1.54)
Contusion	3	2 (3.08)	0	0 (0.00)
Wound	3	2 (3.08)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Fall	2	2 (3.08)	0	0 (0.00)
Ligament sprain	2	2 (3.08)	0	0 (0.00)
Procedural pain	2	2 (3.08)	0	0 (0.00)
Fibula fracture	1	1 (1.54)	0	0 (0.00)
Limb injury	1	1 (1.54)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.54)	0	0 (0.00)
Scratch	1	1 (1.54)	0	0 (0.00)
Skin abrasion	1	1 (1.54)	0	0 (0.00)
Skin injury	1	1 (1.54)	0	0 (0.00)
Skin wound	1	1 (1.54)	0	0 (0.00)
Transfusion reaction	1	1 (1.54)	0	0 (0.00)
Transplant failure	1	1 (1.54)	1	1 (1.54)
Vasoplegia syndrome	1	1 (1.54)	1	1 (1.54)
Investigations				
- Total	376	49 (75.38)	174	38 (58.46)
Neutrophil count decreased	60	21 (32.31)	45	18 (27.69)
Platelet count decreased	54	21 (32.31)	26	12 (18.46)
White blood cell count decreased	50	22 (33.85)	30	15 (23.08)
Lymphocyte count decreased	36	17 (26.15)	26	15 (23.08)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Aspartate aminotransferase increased	21	12 (18.46)	7	5 (7.69)
Alanine aminotransferase increased	20	13 (20.00)	4	4 (6.15)
Blood bilirubin increased	17	9 (13.85)	6	5 (7.69)
Immunoglobulins decreased	10	2 (3.08)	0	0 (0.00)
International normalised ratio increased	10	7 (10.77)	0	0 (0.00)
Blood fibrinogen decreased	7	7 (10.77)	2	2 (3.08)
Blood immunoglobulin A decreased	7	7 (10.77)	1	1 (1.54)
Blood immunoglobulin M decreased	7	7 (10.77)	2	2 (3.08)
Serum ferritin increased	7	7 (10.77)	1	1 (1.54)
Activated partial thromboplastin time prolonged	6	4 (6.15)	0	0 (0.00)
Weight increased	6	3 (4.62)	2	2 (3.08)
Blood creatine phosphokinase increased	4	2 (3.08)	2	2 (3.08)
Blood creatinine increased	4	2 (3.08)	3	1 (1.54)
Blood lactate dehydrogenase increased	4	4 (6.15)	0	0 (0.00)
C-reactive protein increased	4	4 (6.15)	2	2 (3.08)
Electrocardiogram QT prolonged	4	4 (6.15)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Lipase increased	4	2 (3.08)	2	1 (1.54)
Blood immunoglobulin G decreased	3	3 (4.62)	0	0 (0.00)
Oxygen saturation decreased	3	3 (4.62)	1	1 (1.54)
Blood glucose increased	2	1 (1.54)	2	1 (1.54)
Blood uric acid increased	2	2 (3.08)	1	1 (1.54)
Fibrin D dimer increased	2	2 (3.08)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (3.08)	2	2 (3.08)
Haemoglobin decreased	2	1 (1.54)	1	1 (1.54)
Urine output decreased	2	1 (1.54)	2	1 (1.54)
Amylase increased	1	1 (1.54)	0	0 (0.00)
Bacterial test positive	1	1 (1.54)	1	1 (1.54)
Blood bicarbonate decreased	1	1 (1.54)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.54)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.54)	0	0 (0.00)
Blood urea increased	1	1 (1.54)	1	1 (1.54)
Bone density decreased	1	1 (1.54)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.54)	0	0 (0.00)
Cardiac murmur	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Coagulation test abnormal	1	1 (1.54)	0	0 (0.00)
Enterovirus test positive	1	1 (1.54)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.54)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.54)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.54)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.54)	0	0 (0.00)
Weight decreased	1	1 (1.54)	1	1 (1.54)
Metabolism and nutrition disorders				
- Total	153	39 (60.00)	52	23 (35.38)
Hypokalaemia	30	13 (20.00)	16	8 (12.31)
Decreased appetite	23	21 (32.31)	9	7 (10.77)
Hypophosphataemia	21	14 (21.54)	6	6 (9.23)
Hypocalcaemia	14	8 (12.31)	3	2 (3.08)
Hypoalbuminaemia	12	6 (9.23)	0	0 (0.00)
Hyperuricaemia	6	5 (7.69)	0	0 (0.00)
Hyperglycaemia	4	4 (6.15)	3	3 (4.62)
Hyperphosphataemia	4	4 (6.15)	1	1 (1.54)
Hypervolaemia	4	4 (6.15)	2	2 (3.08)
Hypomagnesaemia	4	3 (4.62)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Hypernatraemia	3	3 (4.62)	2	2 (3.08)
Hypertriglyceridaemia	3	3 (4.62)	2	2 (3.08)
Iron overload	3	2 (3.08)	0	0 (0.00)
Metabolic acidosis	3	3 (4.62)	2	2 (3.08)
Hypercalcaemia	2	1 (1.54)	1	1 (1.54)
Hypermagnesaemia	2	1 (1.54)	0	0 (0.00)
Hyponatraemia	2	2 (3.08)	0	0 (0.00)
Tumour lysis syndrome	2	2 (3.08)	2	2 (3.08)
Dehydration	1	1 (1.54)	0	0 (0.00)
Haemochromatosis	1	1 (1.54)	1	1 (1.54)
Haemosiderosis	1	1 (1.54)	0	0 (0.00)
Hyperchloraemia	1	1 (1.54)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.54)	0	0 (0.00)
Hyperkalaemia	1	1 (1.54)	1	1 (1.54)
Hyperlactacidaemia	1	1 (1.54)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.54)	0	0 (0.00)
Hypophagia	1	1 (1.54)	0	0 (0.00)
Metabolic syndrome	1	1 (1.54)	0	0 (0.00)
Polydipsia	1	1 (1.54)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	64	35 (53.85)	6	6 (9.23)
Pain in extremity	16	15 (23.08)	1	1 (1.54)
Arthralgia	10	9 (13.85)	0	0 (0.00)
Back pain	9	8 (12.31)	2	2 (3.08)
Myalgia	8	7 (10.77)	0	0 (0.00)
Bone pain	6	4 (6.15)	0	0 (0.00)
Muscular weakness	2	2 (3.08)	1	1 (1.54)
Musculoskeletal chest pain	2	2 (3.08)	0	0 (0.00)
Pain in jaw	2	2 (3.08)	1	1 (1.54)
Growth retardation	1	1 (1.54)	0	0 (0.00)
Joint effusion	1	1 (1.54)	0	0 (0.00)
Muscle rigidity	1	1 (1.54)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.54)	0	0 (0.00)
Myositis	1	1 (1.54)	0	0 (0.00)
Neck pain	1	1 (1.54)	0	0 (0.00)
Osteonecrosis	1	1 (1.54)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.54)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Synovitis	1	1 (1.54)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	5	4 (6.15)	2	2 (3.08)
Bone giant cell tumour benign	2	1 (1.54)	1	1 (1.54)
Skin papilloma	2	2 (3.08)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.54)	1	1 (1.54)
Nervous system disorders				
- Total	85	39 (60.00)	18	11 (16.92)
Headache	33	23 (35.38)	3	3 (4.62)
Encephalopathy	7	7 (10.77)	3	3 (4.62)
Seizure	7	4 (6.15)	3	3 (4.62)
Dizziness	5	4 (6.15)	0	0 (0.00)
Tremor	5	5 (7.69)	0	0 (0.00)
Dysgeusia	3	3 (4.62)	0	0 (0.00)
Hydrocephalus	3	1 (1.54)	3	1 (1.54)
Lethargy	3	3 (4.62)	0	0 (0.00)
Somnolence	3	3 (4.62)	1	1 (1.54)
Dysarthria	2	2 (3.08)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Migraine	2	1 (1.54)	0	0 (0.00)
Nervous system disorder	2	1 (1.54)	1	1 (1.54)
Aphasia	1	1 (1.54)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.54)	1	1 (1.54)
Cerebral haemorrhage	1	1 (1.54)	1	1 (1.54)
Depressed level of consciousness	1	1 (1.54)	1	1 (1.54)
Disturbance in attention	1	1 (1.54)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.54)	0	0 (0.00)
Hypoaesthesia	1	1 (1.54)	0	0 (0.00)
Memory impairment	1	1 (1.54)	0	0 (0.00)
Monoparesis	1	1 (1.54)	0	0 (0.00)
Neuralgia	1	1 (1.54)	0	0 (0.00)
Psychiatric disorders				
- Total	54	31 (47.69)	5	5 (7.69)
Anxiety	9	9 (13.85)	1	1 (1.54)
Confusional state	7	7 (10.77)	0	0 (0.00)
Delirium	7	7 (10.77)	2	2 (3.08)
Agitation	6	5 (7.69)	0	0 (0.00)
Sleep disorder	4	3 (4.62)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Hallucination	3	3 (4.62)	0	0 (0.00)
Insomnia	3	3 (4.62)	0	0 (0.00)
Irritability	3	3 (4.62)	0	0 (0.00)
Mental status changes	3	3 (4.62)	2	2 (3.08)
Affect lability	1	1 (1.54)	0	0 (0.00)
Automatism	1	1 (1.54)	0	0 (0.00)
Mood altered	1	1 (1.54)	0	0 (0.00)
Nightmare	1	1 (1.54)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.54)	0	0 (0.00)
Restlessness	1	1 (1.54)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.54)	0	0 (0.00)
Tearfulness	1	1 (1.54)	0	0 (0.00)
Tic	1	1 (1.54)	0	0 (0.00)
Renal and urinary disorders				
- Total	34	19 (29.23)	9	7 (10.77)
Acute kidney injury	11	8 (12.31)	6	5 (7.69)
Dysuria	3	3 (4.62)	0	0 (0.00)
Anuria	2	2 (3.08)	1	1 (1.54)
Haematuria	2	2 (3.08)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pollakiuria	2	2 (3.08)	0	0 (0.00)
Urinary incontinence	2	1 (1.54)	0	0 (0.00)
Azotaemia	1	1 (1.54)	0	0 (0.00)
Bladder dilatation	1	1 (1.54)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.54)	0	0 (0.00)
Incontinence	1	1 (1.54)	0	0 (0.00)
Micturition urgency	1	1 (1.54)	0	0 (0.00)
Proteinuria	1	1 (1.54)	0	0 (0.00)
Renal failure	1	1 (1.54)	0	0 (0.00)
Renal tubular disorder	1	1 (1.54)	1	1 (1.54)
Renal tubular dysfunction	1	1 (1.54)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.54)	1	1 (1.54)
Urinary retention	1	1 (1.54)	0	0 (0.00)
Urinary tract disorder	1	1 (1.54)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	9	5 (7.69)	2	2 (3.08)
Dysmenorrhoea	2	1 (1.54)	0	0 (0.00)
Endometriosis	2	1 (1.54)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Vaginal haemorrhage	2	1 (1.54)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.54)	0	0 (0.00)
Perineal rash	1	1 (1.54)	0	0 (0.00)
Vaginal ulceration	1	1 (1.54)	1	1 (1.54)
Respiratory, thoracic and mediastinal disorders				
- Total	154	44 (67.69)	47	21 (32.31)
Cough	27	21 (32.31)	0	0 (0.00)
Hypoxia	24	17 (26.15)	19	13 (20.00)
Tachypnoea	10	8 (12.31)	5	4 (6.15)
Dyspnoea	8	7 (10.77)	4	4 (6.15)
Epistaxis	8	7 (10.77)	1	1 (1.54)
Oropharyngeal pain	8	7 (10.77)	0	0 (0.00)
Pleural effusion	8	7 (10.77)	1	1 (1.54)
Pulmonary oedema	8	8 (12.31)	4	4 (6.15)
Rhinorrhoea	7	5 (7.69)	0	0 (0.00)
Nasal congestion	6	6 (9.23)	0	0 (0.00)
Atelectasis	5	3 (4.62)	2	2 (3.08)
Respiratory failure	5	5 (7.69)	5	5 (7.69)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Respiratory distress	3	3 (4.62)	1	1 (1.54)
Lung infiltration	2	1 (1.54)	1	1 (1.54)
Pharyngeal erythema	2	2 (3.08)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.54)	1	1 (1.54)
Bradypnoea	1	1 (1.54)	1	1 (1.54)
Bronchospasm	1	1 (1.54)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.54)	0	0 (0.00)
Haemoptysis	1	1 (1.54)	0	0 (0.00)
Laryngeal oedema	1	1 (1.54)	1	1 (1.54)
Lung disorder	1	1 (1.54)	0	0 (0.00)
Nasal discomfort	1	1 (1.54)	0	0 (0.00)
Nasal dryness	1	1 (1.54)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.54)	0	0 (0.00)
Painful respiration	1	1 (1.54)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.54)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.54)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.54)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.54)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Productive cough	1	1 (1.54)	0	0 (0.00)
Pulmonary mass	1	1 (1.54)	0	0 (0.00)
Respiratory acidosis	1	1 (1.54)	1	1 (1.54)
Respiratory disorder	1	1 (1.54)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.54)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.54)	0	0 (0.00)
Wheezing	1	1 (1.54)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	83	33 (50.77)	8	6 (9.23)
Rash	12	7 (10.77)	0	0 (0.00)
Dry skin	7	6 (9.23)	0	0 (0.00)
Pruritus	6	5 (7.69)	0	0 (0.00)
Blister	5	2 (3.08)	0	0 (0.00)
Erythema	5	5 (7.69)	0	0 (0.00)
Dermatitis atopic	4	3 (4.62)	1	1 (1.54)
Rash papular	4	3 (4.62)	0	0 (0.00)
Eczema	3	3 (4.62)	1	1 (1.54)
Rash maculo-papular	3	2 (3.08)	1	1 (1.54)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Hyperhidrosis	2	2 (3.08)	0	0 (0.00)
Ingrowing nail	2	2 (3.08)	0	0 (0.00)
Petechiae	2	2 (3.08)	1	1 (1.54)
Rash macular	2	1 (1.54)	2	1 (1.54)
Rash vesicular	2	1 (1.54)	0	0 (0.00)
Skin discolouration	2	2 (3.08)	0	0 (0.00)
Skin ulcer	2	2 (3.08)	0	0 (0.00)
Decubitus ulcer	1	1 (1.54)	0	0 (0.00)
Dermatitis	1	1 (1.54)	0	0 (0.00)
Dermatitis allergic	1	1 (1.54)	0	0 (0.00)
Dermatitis diaper	1	1 (1.54)	0	0 (0.00)
Erythema nodosum	1	1 (1.54)	0	0 (0.00)
Hangnail	1	1 (1.54)	0	0 (0.00)
Miliaria	1	1 (1.54)	0	0 (0.00)
Night sweats	1	1 (1.54)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.54)	0	0 (0.00)
Papule	1	1 (1.54)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Pruritus allergic	1	1 (1.54)	0	0 (0.00)
Purpura	1	1 (1.54)	0	0 (0.00)
Rash erythematous	1	1 (1.54)	0	0 (0.00)
Rash pruritic	1	1 (1.54)	0	0 (0.00)
Skin lesion	1	1 (1.54)	0	0 (0.00)
Skin necrosis	1	1 (1.54)	1	1 (1.54)
Skin swelling	1	1 (1.54)	0	0 (0.00)
Urticaria	1	1 (1.54)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.54)	1	1 (1.54)
Social circumstances				
- Total	1	1 (1.54)	0	0 (0.00)
Patient uncooperative	1	1 (1.54)	0	0 (0.00)
Vascular disorders				
- Total	40	24 (36.92)	17	13 (20.00)
Hypotension	20	17 (26.15)	12	10 (15.38)
Hypertension	13	12 (18.46)	3	3 (4.62)
Venoocclusive disease	2	2 (3.08)	2	2 (3.08)
Capillary leak syndrome	1	1 (1.54)	0	0 (0.00)

Timing: At anytime, Ethnicity: Other

Primary system organ class Preferred term	All grades Total events	All patients N=65 n (%)[1]	Grade >= 3 Total events	All patients N=65 n (%)[2]
Flushing	1	1 (1.54)	0	0 (0.00)
Hot flush	1	1 (1.54)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.54)	0	0 (0.00)
Thrombosis	1	1 (1.54)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	211	6 (100.00)	82	4 (66.67)
Blood and lymphatic system disorders				
- Total	13	4 (66.67)	6	4 (66.67)
Anaemia	7	2 (33.33)	0	0 (0.00)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Coagulopathy	1	1 (16.67)	1	1 (16.67)
Disseminated intravascular coagulation	1	1 (16.67)	1	1 (16.67)
Thrombocytopenia	1	1 (16.67)	1	1 (16.67)
Cardiac disorders				
- Total	7	3 (50.00)	1	1 (16.67)
Tachycardia	6	3 (50.00)	1	1 (16.67)
Sinus tachycardia	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Eye disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Eyelid oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	2 (33.33)	1	1 (16.67)
Abdominal distension	1	1 (16.67)	0	0 (0.00)
Ascites	1	1 (16.67)	0	0 (0.00)
Constipation	1	1 (16.67)	0	0 (0.00)
Melaena	1	1 (16.67)	1	1 (16.67)
Mouth haemorrhage	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	16	4 (66.67)	3	2 (33.33)
Pyrexia	8	3 (50.00)	1	1 (16.67)
Catheter site pain	1	1 (16.67)	0	0 (0.00)
Chills	1	1 (16.67)	0	0 (0.00)
Face oedema	1	1 (16.67)	0	0 (0.00)
Fatigue	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Generalised oedema	1	1 (16.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (16.67)	1	1 (16.67)
Oedema peripheral	1	1 (16.67)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (16.67)	1	1 (16.67)
Hepatobiliary disorders				
- Total	3	1 (16.67)	1	1 (16.67)
Cholelithiasis	1	1 (16.67)	0	0 (0.00)
Cholestasis	1	1 (16.67)	1	1 (16.67)
Gallbladder enlargement	1	1 (16.67)	0	0 (0.00)
Immune system disorders				
- Total	14	5 (83.33)	7	2 (33.33)
Cytokine release syndrome	10	5 (83.33)	5	2 (33.33)
Hypogammaglobulinaemia	2	2 (33.33)	1	1 (16.67)
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	1	1 (16.67)
Seasonal allergy	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	3	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Conjunctivitis	1	1 (16.67)	0	0 (0.00)
Encephalitis	1	1 (16.67)	1	1 (16.67)
Localised infection	1	1 (16.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	2 (33.33)	2	1 (16.67)
Wound	2	1 (16.67)	1	1 (16.67)
Infusion related reaction	1	1 (16.67)	0	0 (0.00)
Skin injury	1	1 (16.67)	0	0 (0.00)
Skin wound	1	1 (16.67)	0	0 (0.00)
Vasoplegia syndrome	1	1 (16.67)	1	1 (16.67)
Investigations				
- Total	56	3 (50.00)	26	3 (50.00)
Neutrophil count decreased	21	3 (50.00)	15	3 (50.00)
White blood cell count decreased	6	2 (33.33)	2	1 (16.67)
Aspartate aminotransferase increased	5	1 (16.67)	1	1 (16.67)
Blood bilirubin increased	5	1 (16.67)	1	1 (16.67)
Platelet count decreased	4	1 (16.67)	2	1 (16.67)
Alanine aminotransferase increased	3	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Lipase increased	3	1 (16.67)	2	1 (16.67)
Blood alkaline phosphatase increased	1	1 (16.67)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (16.67)	1	1 (16.67)
Blood creatinine increased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (16.67)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (16.67)	0	0 (0.00)
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Lymphocyte count decreased	1	1 (16.67)	1	1 (16.67)
Weight increased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	40	5 (83.33)	14	3 (50.00)
Hypokalaemia	10	1 (16.67)	7	1 (16.67)
Hypocalcaemia	6	2 (33.33)	2	1 (16.67)
Hypophosphataemia	6	3 (50.00)	2	2 (33.33)
Hyperglycaemia	3	1 (16.67)	0	0 (0.00)
Hyperuricaemia	3	2 (33.33)	1	1 (16.67)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Acidosis	2	1 (16.67)	1	1 (16.67)
Decreased appetite	2	2 (33.33)	0	0 (0.00)
Hypoalbuminaemia	2	1 (16.67)	0	0 (0.00)
Haemosiderosis	1	1 (16.67)	0	0 (0.00)
Hyperlactacidaemia	1	1 (16.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (16.67)	0	0 (0.00)
Hypernatraemia	1	1 (16.67)	1	1 (16.67)
Hypomagnesaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (33.33)	1	1 (16.67)
Myalgia	1	1 (16.67)	0	0 (0.00)
Myositis	1	1 (16.67)	0	0 (0.00)
Rhabdomyolysis	1	1 (16.67)	1	1 (16.67)
Nervous system disorders				
- Total	7	4 (66.67)	1	1 (16.67)
Headache	3	3 (50.00)	0	0 (0.00)
Encephalopathy	1	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Monoparesis	1	1 (16.67)	0	0 (0.00)
Somnolence	1	1 (16.67)	0	0 (0.00)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (33.33)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Sleep disorder	1	1 (16.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	2 (33.33)	3	2 (33.33)
Acute kidney injury	4	2 (33.33)	2	2 (33.33)
Bladder dilatation	1	1 (16.67)	0	0 (0.00)
Renal tubular necrosis	1	1 (16.67)	1	1 (16.67)
Urinary retention	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (16.67)	1	1 (16.67)
Vaginal ulceration	1	1 (16.67)	1	1 (16.67)
Respiratory, thoracic and mediastinal disorders				

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
- Total	11	3 (50.00)	8	2 (33.33)
Atelectasis	3	1 (16.67)	1	1 (16.67)
Tachypnoea	2	2 (33.33)	2	2 (33.33)
Acute respiratory distress syndrome	1	1 (16.67)	1	1 (16.67)
Acute respiratory failure	1	1 (16.67)	1	1 (16.67)
Dyspnoea	1	1 (16.67)	1	1 (16.67)
Hypoxia	1	1 (16.67)	1	1 (16.67)
Nasal congestion	1	1 (16.67)	0	0 (0.00)
Respiratory acidosis	1	1 (16.67)	1	1 (16.67)
Skin and subcutaneous tissue disorders				
- Total	9	3 (50.00)	2	1 (16.67)
Rash	2	2 (33.33)	0	0 (0.00)
Decubitus ulcer	1	1 (16.67)	0	0 (0.00)
Erythema	1	1 (16.67)	0	0 (0.00)
Hyperhidrosis	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	1	1 (16.67)
Pruritus	1	1 (16.67)	0	0 (0.00)
Skin necrosis	1	1 (16.67)	1	1 (16.67)
Skin ulcer	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Vascular disorders				
- Total	6	2 (33.33)	4	2 (33.33)
Hypotension	4	2 (33.33)	3	2 (33.33)
Hypertension	2	1 (16.67)	1	1 (16.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	1540	73 (98.65)	537	63 (85.14)
Blood and lymphatic system disorders				
- Total	112	46 (62.16)	70	35 (47.30)
Anaemia	43	19 (25.68)	20	8 (10.81)
Febrile neutropenia	26	23 (31.08)	26	23 (31.08)
Neutropenia	11	9 (12.16)	9	7 (9.46)
Thrombocytopenia	7	7 (9.46)	7	7 (9.46)
Disseminated intravascular coagulation	6	6 (8.11)	1	1 (1.35)
Coagulopathy	4	4 (5.41)	1	1 (1.35)
Leukopenia	4	3 (4.05)	3	2 (2.70)
Splenomegaly	4	4 (5.41)	0	0 (0.00)
Eosinophilia	2	1 (1.35)	0	0 (0.00)
Pancytopenia	2	2 (2.70)	2	2 (2.70)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
B-cell aplasia	1	1 (1.35)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.35)	0	0 (0.00)
Lymphopenia	1	1 (1.35)	1	1 (1.35)
Cardiac disorders				
- Total	38	21 (28.38)	9	7 (9.46)
Tachycardia	16	14 (18.92)	2	2 (2.70)
Cardiac failure	4	1 (1.35)	2	1 (1.35)
Bradycardia	3	3 (4.05)	0	0 (0.00)
Left ventricular dysfunction	3	3 (4.05)	3	3 (4.05)
Sinus tachycardia	3	2 (2.70)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.70)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.35)	0	0 (0.00)
Cardiac arrest	1	1 (1.35)	1	1 (1.35)
Cardiac failure congestive	1	1 (1.35)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.35)	0	0 (0.00)
Pericardial effusion	1	1 (1.35)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Sinus bradycardia	1	1 (1.35)	1	1 (1.35)
Ear and labyrinth disorders				

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
- Total	2	2 (2.70)	0	0 (0.00)
Ear pain	1	1 (1.35)	0	0 (0.00)
Ear pruritus	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.76)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.41)	0	0 (0.00)
Hypothyroidism	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	14	8 (10.81)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.70)	0	0 (0.00)
Eyelid oedema	2	1 (1.35)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.70)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.35)	0	0 (0.00)
Eye oedema	1	1 (1.35)	0	0 (0.00)
Eye pain	1	1 (1.35)	0	0 (0.00)
Periorbital oedema	1	1 (1.35)	0	0 (0.00)
Periorbital swelling	1	1 (1.35)	0	0 (0.00)
Visual field defect	1	1 (1.35)	0	0 (0.00)
Visual impairment	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastrointestinal disorders				
- Total	129	49 (66.22)	15	13 (17.57)
Vomiting	30	21 (28.38)	1	1 (1.35)
Nausea	20	17 (22.97)	2	2 (2.70)
Diarrhoea	18	15 (20.27)	1	1 (1.35)
Abdominal pain	13	11 (14.86)	2	2 (2.70)
Constipation	10	10 (13.51)	0	0 (0.00)
Pancreatitis	4	4 (5.41)	1	1 (1.35)
Abdominal pain upper	3	3 (4.05)	0	0 (0.00)
Mouth haemorrhage	3	3 (4.05)	2	2 (2.70)
Abdominal distension	2	2 (2.70)	0	0 (0.00)
Ascites	2	2 (2.70)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.70)	0	0 (0.00)
Stomatitis	2	2 (2.70)	1	1 (1.35)
Abdominal compartment syndrome	1	1 (1.35)	1	1 (1.35)
Anal fissure	1	1 (1.35)	0	0 (0.00)
Anal haemorrhage	1	1 (1.35)	0	0 (0.00)
Dry mouth	1	1 (1.35)	0	0 (0.00)
Dysphagia	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Enterocolitis	1	1 (1.35)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.35)	0	0 (0.00)
Gingival bleeding	1	1 (1.35)	0	0 (0.00)
Gingival erythema	1	1 (1.35)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.35)	1	1 (1.35)
Haematemesis	1	1 (1.35)	0	0 (0.00)
Ileus	1	1 (1.35)	0	0 (0.00)
Lip dry	1	1 (1.35)	0	0 (0.00)
Lip oedema	1	1 (1.35)	0	0 (0.00)
Mouth swelling	1	1 (1.35)	0	0 (0.00)
Neutropenic colitis	1	1 (1.35)	1	1 (1.35)
Odynophagia	1	1 (1.35)	0	0 (0.00)
Proctalgia	1	1 (1.35)	1	1 (1.35)
Trichoglossia	1	1 (1.35)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	96	36 (48.65)	16	9 (12.16)
Pyrexia	36	21 (28.38)	8	7 (9.46)
Fatigue	10	10 (13.51)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Chills	8	5 (6.76)	0	0 (0.00)
Face oedema	8	7 (9.46)	1	1 (1.35)
Oedema peripheral	6	5 (6.76)	2	1 (1.35)
Generalised oedema	4	4 (5.41)	0	0 (0.00)
Catheter site pain	3	1 (1.35)	2	1 (1.35)
Asthenia	2	2 (2.70)	0	0 (0.00)
Catheter site erythema	2	1 (1.35)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.70)	0	0 (0.00)
Influenza like illness	2	2 (2.70)	0	0 (0.00)
Localised oedema	2	2 (2.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.35)	0	0 (0.00)
Chest discomfort	1	1 (1.35)	1	1 (1.35)
Crying	1	1 (1.35)	0	0 (0.00)
Facial pain	1	1 (1.35)	0	0 (0.00)
Malaise	1	1 (1.35)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.35)	1	1 (1.35)
Oedema due to hepatic disease	1	1 (1.35)	0	0 (0.00)
Pain	1	1 (1.35)	1	1 (1.35)
Sluggishness	1	1 (1.35)	0	0 (0.00)
Swelling face	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Vascular device occlusion	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	26	16 (21.62)	6	5 (6.76)
Hepatic function abnormal	11	5 (6.76)	4	3 (4.05)
Hyperbilirubinaemia	6	5 (6.76)	1	1 (1.35)
Hepatomegaly	3	3 (4.05)	1	1 (1.35)
Hypertransaminasaemia	2	2 (2.70)	0	0 (0.00)
Biliary tract disorder	1	1 (1.35)	0	0 (0.00)
Cholelithiasis	1	1 (1.35)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.35)	0	0 (0.00)
Ocular icterus	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	150	62 (83.78)	61	41 (55.41)
Cytokine release syndrome	118	56 (75.68)	50	36 (48.65)
Hypogammaglobulinaemia	23	21 (28.38)	6	6 (8.11)
Haemophagocytic lymphohistiocytosis	4	4 (5.41)	2	2 (2.70)
Immunodeficiency	3	3 (4.05)	3	3 (4.05)
Hypersensitivity	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Selective IgG subclass deficiency	1	1 (1.35)	0	0 (0.00)
Infections and infestations				
- Total	61	34 (45.95)	30	18 (24.32)
Conjunctivitis	5	4 (5.41)	0	0 (0.00)
Staphylococcal infection	5	5 (6.76)	2	2 (2.70)
Candida infection	4	3 (4.05)	2	1 (1.35)
Clostridium difficile infection	4	4 (5.41)	3	3 (4.05)
Staphylococcal bacteraemia	4	3 (4.05)	4	3 (4.05)
Encephalitis viral	2	2 (2.70)	2	2 (2.70)
Nail infection	2	2 (2.70)	0	0 (0.00)
Oral candidiasis	2	1 (1.35)	0	0 (0.00)
Oral herpes	2	2 (2.70)	1	1 (1.35)
Oral infection	2	2 (2.70)	0	0 (0.00)
Rhinovirus infection	2	2 (2.70)	0	0 (0.00)
Adenovirus infection	1	1 (1.35)	1	1 (1.35)
Anal abscess	1	1 (1.35)	1	1 (1.35)
Atypical pneumonia	1	1 (1.35)	0	0 (0.00)
BK virus infection	1	1 (1.35)	0	0 (0.00)
Bacteraemia	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Bronchopulmonary aspergillosis	1	1 (1.35)	1	1 (1.35)
Cholecystitis infective	1	1 (1.35)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.35)	0	0 (0.00)
Gingivitis	1	1 (1.35)	0	0 (0.00)
Granulicatella infection	1	1 (1.35)	1	1 (1.35)
Herpes simplex	1	1 (1.35)	1	1 (1.35)
Human herpesvirus 6 infection	1	1 (1.35)	1	1 (1.35)
Klebsiella bacteraemia	1	1 (1.35)	0	0 (0.00)
Klebsiella infection	1	1 (1.35)	1	1 (1.35)
Meningitis bacterial	1	1 (1.35)	1	1 (1.35)
Myringitis	1	1 (1.35)	0	0 (0.00)
Otitis externa	1	1 (1.35)	0	0 (0.00)
Paronychia	1	1 (1.35)	0	0 (0.00)
Pneumonia	1	1 (1.35)	1	1 (1.35)
Pneumonia fungal	1	1 (1.35)	1	1 (1.35)
Pneumonia viral	1	1 (1.35)	1	1 (1.35)
Sinusitis	1	1 (1.35)	1	1 (1.35)
Soft tissue infection	1	1 (1.35)	1	1 (1.35)
Stomatococcal infection	1	1 (1.35)	0	0 (0.00)
Systemic candida	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Urinary tract infection viral	1	1 (1.35)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	14	9 (12.16)	1	1 (1.35)
Contusion	2	1 (1.35)	0	0 (0.00)
Fall	2	2 (2.70)	0	0 (0.00)
Infusion related reaction	2	1 (1.35)	0	0 (0.00)
Procedural pain	2	2 (2.70)	0	0 (0.00)
Transfusion reaction	2	2 (2.70)	0	0 (0.00)
Scratch	1	1 (1.35)	0	0 (0.00)
Skin abrasion	1	1 (1.35)	0	0 (0.00)
Transplant failure	1	1 (1.35)	1	1 (1.35)
Wound	1	1 (1.35)	0	0 (0.00)
Investigations				
- Total	330	54 (72.97)	171	42 (56.76)
Platelet count decreased	61	20 (27.03)	36	13 (17.57)
White blood cell count decreased	44	22 (29.73)	34	17 (22.97)
Lymphocyte count decreased	29	14 (18.92)	23	12 (16.22)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Aspartate aminotransferase increased	28	18 (24.32)	12	10 (13.51)
Neutrophil count decreased	27	17 (22.97)	23	14 (18.92)
Alanine aminotransferase increased	23	17 (22.97)	5	5 (6.76)
Blood bilirubin increased	13	11 (14.86)	8	8 (10.81)
International normalised ratio increased	11	8 (10.81)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (8.11)	1	1 (1.35)
Serum ferritin increased	8	8 (10.81)	2	2 (2.70)
Blood fibrinogen decreased	7	7 (9.46)	2	2 (2.70)
Blood creatinine increased	5	3 (4.05)	5	3 (4.05)
Blood immunoglobulin A decreased	5	5 (6.76)	0	0 (0.00)
Blood immunoglobulin M decreased	5	5 (6.76)	1	1 (1.35)
Electrocardiogram QT prolonged	5	4 (5.41)	2	2 (2.70)
Immunoglobulins decreased	5	2 (2.70)	0	0 (0.00)
Blood lactate dehydrogenase increased	4	4 (5.41)	1	1 (1.35)
C-reactive protein increased	4	4 (5.41)	3	3 (4.05)
Blood creatine phosphokinase increased	3	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Fibrin D dimer increased	3	3 (4.05)	1	1 (1.35)
Urine output decreased	3	2 (2.70)	3	2 (2.70)
Weight increased	3	3 (4.05)	1	1 (1.35)
Blood glucose increased	2	1 (1.35)	2	1 (1.35)
Blood uric acid increased	2	2 (2.70)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (2.70)	2	2 (2.70)
Haemoglobin decreased	2	1 (1.35)	1	1 (1.35)
Amylase increased	1	1 (1.35)	0	0 (0.00)
Bacterial test positive	1	1 (1.35)	1	1 (1.35)
Blood bicarbonate decreased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.35)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.35)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.35)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.35)	0	0 (0.00)
Cardiac murmur	1	1 (1.35)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.35)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.35)	0	0 (0.00)
Enterovirus test positive	1	1 (1.35)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Lipase increased	1	1 (1.35)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.35)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.35)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.35)	0	0 (0.00)
Troponin increased	1	1 (1.35)	1	1 (1.35)
Weight decreased	1	1 (1.35)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	170	41 (55.41)	62	26 (35.14)
Hypokalaemia	30	18 (24.32)	13	10 (13.51)
Hypophosphataemia	25	14 (18.92)	9	7 (9.46)
Decreased appetite	22	22 (29.73)	11	11 (14.86)
Hypocalcaemia	18	14 (18.92)	4	4 (5.41)
Hypoalbuminaemia	17	10 (13.51)	1	1 (1.35)
Hyperglycaemia	8	7 (9.46)	4	4 (5.41)
Hyperuricaemia	6	5 (6.76)	0	0 (0.00)
Hypervolaemia	6	6 (8.11)	4	4 (5.41)
Hypomagnesaemia	6	5 (6.76)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.76)	1	1 (1.35)
Hypercalcaemia	4	3 (4.05)	2	2 (2.70)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Tumour lysis syndrome	4	4 (5.41)	4	4 (5.41)
Metabolic acidosis	3	3 (4.05)	2	2 (2.70)
Hyperkalaemia	2	2 (2.70)	2	2 (2.70)
Hypermagnesaemia	2	1 (1.35)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (2.70)	2	2 (2.70)
Hyponatraemia	2	2 (2.70)	0	0 (0.00)
Acidosis	1	1 (1.35)	1	1 (1.35)
Calcium deficiency	1	1 (1.35)	0	0 (0.00)
Dehydration	1	1 (1.35)	0	0 (0.00)
Hyperchloraemia	1	1 (1.35)	0	0 (0.00)
Hypernatraemia	1	1 (1.35)	0	0 (0.00)
Hypoglycaemia	1	1 (1.35)	0	0 (0.00)
Malnutrition	1	1 (1.35)	1	1 (1.35)
Polydipsia	1	1 (1.35)	1	1 (1.35)
Musculoskeletal and connective tissue disorders				
- Total	50	31 (41.89)	5	4 (5.41)
Pain in extremity	11	11 (14.86)	0	0 (0.00)
Arthralgia	10	10 (13.51)	1	1 (1.35)
Myalgia	9	8 (10.81)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Back pain	7	6 (8.11)	1	1 (1.35)
Bone pain	4	2 (2.70)	0	0 (0.00)
Muscular weakness	2	2 (2.70)	1	1 (1.35)
Pain in jaw	2	2 (2.70)	1	1 (1.35)
Haemarthrosis	1	1 (1.35)	1	1 (1.35)
Muscle rigidity	1	1 (1.35)	0	0 (0.00)
Muscle spasms	1	1 (1.35)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.35)	0	0 (0.00)
Neck pain	1	1 (1.35)	0	0 (0.00)
Nervous system disorders				
- Total	70	36 (48.65)	13	9 (12.16)
Headache	23	20 (27.03)	2	2 (2.70)
Encephalopathy	7	7 (9.46)	3	3 (4.05)
Tremor	6	5 (6.76)	0	0 (0.00)
Cognitive disorder	5	3 (4.05)	1	1 (1.35)
Somnolence	4	4 (5.41)	2	2 (2.70)
Dizziness	3	3 (4.05)	0	0 (0.00)
Dysgeusia	3	3 (4.05)	0	0 (0.00)
Lethargy	3	3 (4.05)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Seizure	3	2 (2.70)	1	1 (1.35)
Hyperaesthesia	2	1 (1.35)	0	0 (0.00)
Amnesia	1	1 (1.35)	0	0 (0.00)
Aphasia	1	1 (1.35)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.35)	1	1 (1.35)
Depressed level of consciousness	1	1 (1.35)	1	1 (1.35)
Disturbance in attention	1	1 (1.35)	0	0 (0.00)
Dysarthria	1	1 (1.35)	1	1 (1.35)
Generalised tonic-clonic seizure	1	1 (1.35)	0	0 (0.00)
Hypoaesthesia	1	1 (1.35)	0	0 (0.00)
Neuralgia	1	1 (1.35)	0	0 (0.00)
Neurological decompensation	1	1 (1.35)	1	1 (1.35)
Paraesthesia	1	1 (1.35)	0	0 (0.00)
Psychiatric disorders				
- Total	45	26 (35.14)	6	6 (8.11)
Delirium	7	7 (9.46)	3	3 (4.05)
Agitation	6	5 (6.76)	0	0 (0.00)
Anxiety	6	6 (8.11)	2	2 (2.70)
Confusional state	6	6 (8.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Insomnia	4	4 (5.41)	0	0 (0.00)
Hallucination	3	3 (4.05)	0	0 (0.00)
Irritability	3	3 (4.05)	0	0 (0.00)
Mental status changes	3	3 (4.05)	1	1 (1.35)
Sleep disorder	2	1 (1.35)	0	0 (0.00)
Affect lability	1	1 (1.35)	0	0 (0.00)
Automatism	1	1 (1.35)	0	0 (0.00)
Hallucination, visual	1	1 (1.35)	0	0 (0.00)
Restlessness	1	1 (1.35)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	32	18 (24.32)	10	7 (9.46)
Acute kidney injury	10	7 (9.46)	6	5 (6.76)
Renal failure	4	2 (2.70)	3	1 (1.35)
Dysuria	3	3 (4.05)	0	0 (0.00)
Anuria	2	2 (2.70)	1	1 (1.35)
Haematuria	2	2 (2.70)	0	0 (0.00)
Pollakiuria	2	2 (2.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Azotaemia	1	1 (1.35)	0	0 (0.00)
Incontinence	1	1 (1.35)	0	0 (0.00)
Micturition urgency	1	1 (1.35)	0	0 (0.00)
Proteinuria	1	1 (1.35)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.35)	0	0 (0.00)
Urinary retention	1	1 (1.35)	0	0 (0.00)
Urinary tract disorder	1	1 (1.35)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (5.41)	0	0 (0.00)
Vaginal haemorrhage	2	1 (1.35)	0	0 (0.00)
Female genital tract fistula	1	1 (1.35)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.35)	0	0 (0.00)
Perineal rash	1	1 (1.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	103	38 (51.35)	42	21 (28.38)
Hypoxia	22	16 (21.62)	17	11 (14.86)
Pulmonary oedema	12	12 (16.22)	7	7 (9.46)
Cough	11	10 (13.51)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pleural effusion	7	7 (9.46)	3	3 (4.05)
Tachypnoea	7	6 (8.11)	2	2 (2.70)
Oropharyngeal pain	6	5 (6.76)	0	0 (0.00)
Epistaxis	4	4 (5.41)	1	1 (1.35)
Respiratory distress	4	3 (4.05)	2	1 (1.35)
Respiratory failure	4	4 (5.41)	4	4 (5.41)
Atelectasis	2	2 (2.70)	1	1 (1.35)
Dyspnoea	2	2 (2.70)	2	2 (2.70)
Lung infiltration	2	1 (1.35)	1	1 (1.35)
Nasal congestion	2	2 (2.70)	0	0 (0.00)
Rhinorrhoea	2	2 (2.70)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.35)	1	1 (1.35)
Bradypnoea	1	1 (1.35)	1	1 (1.35)
Haemoptysis	1	1 (1.35)	0	0 (0.00)
Nasal discomfort	1	1 (1.35)	0	0 (0.00)
Nasal dryness	1	1 (1.35)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.35)	0	0 (0.00)
Painful respiration	1	1 (1.35)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.35)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pharyngeal exudate	1	1 (1.35)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.35)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.35)	0	0 (0.00)
Productive cough	1	1 (1.35)	0	0 (0.00)
Pulmonary mass	1	1 (1.35)	0	0 (0.00)
Respiratory disorder	1	1 (1.35)	0	0 (0.00)
Wheezing	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	47	24 (32.43)	2	2 (2.70)
Blister	6	3 (4.05)	0	0 (0.00)
Pruritus	6	5 (6.76)	0	0 (0.00)
Rash papular	4	3 (4.05)	0	0 (0.00)
Erythema	3	3 (4.05)	0	0 (0.00)
Rash	3	3 (4.05)	0	0 (0.00)
Rash maculo-papular	3	2 (2.70)	1	1 (1.35)
Dermatitis atopic	2	2 (2.70)	0	0 (0.00)
Hyperhidrosis	2	2 (2.70)	0	0 (0.00)
Rash vesicular	2	1 (1.35)	0	0 (0.00)
Dermatitis	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dermatitis diaper	1	1 (1.35)	0	0 (0.00)
Dry skin	1	1 (1.35)	0	0 (0.00)
Eczema	1	1 (1.35)	0	0 (0.00)
Erythema nodosum	1	1 (1.35)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.35)	0	0 (0.00)
Petechiae	1	1 (1.35)	0	0 (0.00)
Pruritus allergic	1	1 (1.35)	0	0 (0.00)
Purpura	1	1 (1.35)	0	0 (0.00)
Rash pruritic	1	1 (1.35)	0	0 (0.00)
Scab	1	1 (1.35)	0	0 (0.00)
Skin discolouration	1	1 (1.35)	0	0 (0.00)
Skin lesion	1	1 (1.35)	0	0 (0.00)
Skin ulcer	1	1 (1.35)	0	0 (0.00)
Urticaria	1	1 (1.35)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.35)	1	1 (1.35)
Social circumstances				
- Total	1	1 (1.35)	0	0 (0.00)
Patient uncooperative	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (1.35)	1	1 (1.35)
Thrombolysis	1	1 (1.35)	1	1 (1.35)
Vascular disorders				
- Total	39	26 (35.14)	17	15 (20.27)
Hypotension	21	19 (25.68)	13	12 (16.22)
Hypertension	12	12 (16.22)	3	3 (4.05)
Capillary leak syndrome	2	2 (2.70)	1	1 (1.35)
Flushing	1	1 (1.35)	0	0 (0.00)
Hot flush	1	1 (1.35)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.35)	0	0 (0.00)
Thrombosis	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	30	4 (80.00)	3	1 (20.00)
Blood and lymphatic system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Lymphocytosis	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	1 (20.00)	0	0 (0.00)
Fatigue	2	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	5	2 (40.00)	0	0 (0.00)
Upper respiratory tract infection	2	1 (20.00)	0	0 (0.00)
Gastroenteritis	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Gastrointestinal infection	1	1 (20.00)	0	0 (0.00)
Otitis externa	1	1 (20.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (20.00)	0	0 (0.00)
Fibula fracture	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	11	2 (40.00)	3	1 (20.00)
Neutrophil count decreased	6	2 (40.00)	2	1 (20.00)
White blood cell count decreased	5	1 (20.00)	1	1 (20.00)
Metabolism and nutrition disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hyperuricaemia	1	1 (20.00)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Persistent depressive disorder	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	1 (20.00)	0	0 (0.00)
Nasal congestion	2	1 (20.00)	0	0 (0.00)
Cough	1	1 (20.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Dry skin	2	2 (40.00)	0	0 (0.00)
Skin hypopigmentation	1	1 (20.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Total number of AE per patient	504	65 (92.86)	143	35 (50.00)
Blood and lymphatic system disorders				
- Total	31	16 (22.86)	17	10 (14.29)
Anaemia	12	6 (8.57)	4	2 (2.86)
Neutropenia	5	5 (7.14)	5	5 (7.14)
Febrile neutropenia	4	3 (4.29)	4	3 (4.29)
B-cell aplasia	2	1 (1.43)	0	0 (0.00)
Thrombocytopenia	2	2 (2.86)	2	2 (2.86)
Disseminated intravascular coagulation	1	1 (1.43)	1	1 (1.43)
Eosinophilia	1	1 (1.43)	0	0 (0.00)
Leukocytosis	1	1 (1.43)	0	0 (0.00)
Leukopenia	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Lymphadenopathy	1	1 (1.43)	0	0 (0.00)
Lymphopenia	1	1 (1.43)	1	1 (1.43)
Cardiac disorders				
- Total	8	7 (10.00)	4	3 (4.29)
Cardiac arrest	2	2 (2.86)	2	2 (2.86)
Cardiac failure	2	2 (2.86)	2	2 (2.86)
Tachycardia	2	2 (2.86)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.43)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.43)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.43)	0	0 (0.00)
Hypothyroidism	1	1 (1.43)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.71)	0	0 (0.00)
Cataract	2	2 (2.86)	0	0 (0.00)
Hypermetropia	1	1 (1.43)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.43)	0	0 (0.00)
Visual impairment	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Gastrointestinal disorders				
- Total	38	20 (28.57)	1	1 (1.43)
Diarrhoea	7	7 (10.00)	0	0 (0.00)
Vomiting	7	6 (8.57)	0	0 (0.00)
Nausea	5	5 (7.14)	0	0 (0.00)
Constipation	4	3 (4.29)	0	0 (0.00)
Abdominal pain	2	2 (2.86)	0	0 (0.00)
Pancreatitis	2	2 (2.86)	1	1 (1.43)
Abdominal pain upper	1	1 (1.43)	0	0 (0.00)
Abdominal rigidity	1	1 (1.43)	0	0 (0.00)
Dyspepsia	1	1 (1.43)	0	0 (0.00)
Enteritis	1	1 (1.43)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.43)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.43)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.43)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.43)	0	0 (0.00)
Proctalgia	1	1 (1.43)	0	0 (0.00)
Stomatitis	1	1 (1.43)	0	0 (0.00)
Trichoglossia	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
General disorders and administration site conditions				
- Total	29	23 (32.86)	3	3 (4.29)
Pyrexia	16	15 (21.43)	2	2 (2.86)
Fatigue	5	5 (7.14)	0	0 (0.00)
Oedema peripheral	2	1 (1.43)	0	0 (0.00)
Pain	2	2 (2.86)	1	1 (1.43)
Asthenia	1	1 (1.43)	0	0 (0.00)
Chills	1	1 (1.43)	0	0 (0.00)
Malaise	1	1 (1.43)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.43)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.29)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.43)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.43)	0	0 (0.00)
Liver disorder	1	1 (1.43)	0	0 (0.00)
Immune system disorders				
- Total	19	16 (22.86)	5	4 (5.71)
Hypogammaglobulinaemia	12	10 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Allergy to immunoglobulin therapy	2	2 (2.86)	1	1 (1.43)
Graft versus host disease	2	2 (2.86)	2	2 (2.86)
Drug hypersensitivity	1	1 (1.43)	0	0 (0.00)
Engraftment syndrome	1	1 (1.43)	1	1 (1.43)
Immunodeficiency	1	1 (1.43)	1	1 (1.43)
Infections and infestations				
- Total	108	37 (52.86)	45	20 (28.57)
Nasopharyngitis	9	7 (10.00)	0	0 (0.00)
Upper respiratory tract infection	8	7 (10.00)	2	2 (2.86)
Bronchopulmonary aspergillosis	5	1 (1.43)	3	1 (1.43)
Parainfluenzae virus infection	5	4 (5.71)	2	2 (2.86)
Rhinovirus infection	5	5 (7.14)	1	1 (1.43)
Gastroenteritis	4	4 (5.71)	2	2 (2.86)
Sinusitis	4	3 (4.29)	1	1 (1.43)
Bacteraemia	3	2 (2.86)	2	1 (1.43)
Ear infection	3	2 (2.86)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.29)	3	3 (4.29)
Otitis media	3	3 (4.29)	1	1 (1.43)
Pneumonia	3	3 (4.29)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Respiratory syncytial virus infection	3	3 (4.29)	2	2 (2.86)
Respiratory tract infection	3	3 (4.29)	0	0 (0.00)
Klebsiella infection	2	1 (1.43)	2	1 (1.43)
Pneumocystis jirovecii pneumonia	2	2 (2.86)	2	2 (2.86)
Rhinitis	2	2 (2.86)	0	0 (0.00)
Urinary tract infection	2	1 (1.43)	2	1 (1.43)
Viral infection	2	2 (2.86)	1	1 (1.43)
Acute sinusitis	1	1 (1.43)	0	0 (0.00)
Adenovirus infection	1	1 (1.43)	1	1 (1.43)
BK virus infection	1	1 (1.43)	1	1 (1.43)
Cellulitis	1	1 (1.43)	0	0 (0.00)
Conjunctivitis	1	1 (1.43)	0	0 (0.00)
Coronavirus infection	1	1 (1.43)	1	1 (1.43)
Cystitis	1	1 (1.43)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.43)	1	1 (1.43)
Device related infection	1	1 (1.43)	1	1 (1.43)
Ear, nose and throat infection	1	1 (1.43)	0	0 (0.00)
Encephalitis	1	1 (1.43)	1	1 (1.43)
Enterobacter infection	1	1 (1.43)	1	1 (1.43)
Gastroenteritis clostridial	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Gastroenteritis viral	1	1 (1.43)	0	0 (0.00)
Gingivitis	1	1 (1.43)	0	0 (0.00)
Herpes simplex	1	1 (1.43)	0	0 (0.00)
Herpes zoster	1	1 (1.43)	1	1 (1.43)
Human herpesvirus 6 infection	1	1 (1.43)	1	1 (1.43)
Influenza	1	1 (1.43)	0	0 (0.00)
Mastoiditis	1	1 (1.43)	1	1 (1.43)
Molluscum contagiosum	1	1 (1.43)	0	0 (0.00)
Nail infection	1	1 (1.43)	0	0 (0.00)
Oral candidiasis	1	1 (1.43)	0	0 (0.00)
Oral herpes	1	1 (1.43)	0	0 (0.00)
Otitis externa	1	1 (1.43)	1	1 (1.43)
Paronychia	1	1 (1.43)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.43)	1	1 (1.43)
Respiratory tract infection viral	1	1 (1.43)	0	0 (0.00)
Salmonellosis	1	1 (1.43)	0	0 (0.00)
Septic shock	1	1 (1.43)	1	1 (1.43)
Sinusitis fungal	1	1 (1.43)	1	1 (1.43)
Staphylococcal bacteraemia	1	1 (1.43)	1	1 (1.43)
Staphylococcal sepsis	1	1 (1.43)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Staphylococcal skin infection	1	1 (1.43)	0	0 (0.00)
Tinea pedis	1	1 (1.43)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.43)	1	1 (1.43)
Viral upper respiratory tract infection	1	1 (1.43)	1	1 (1.43)
Injury, poisoning and procedural complications				
- Total	9	8 (11.43)	0	0 (0.00)
Infusion related reaction	4	3 (4.29)	0	0 (0.00)
Contusion	1	1 (1.43)	0	0 (0.00)
Ligament sprain	1	1 (1.43)	0	0 (0.00)
Limb injury	1	1 (1.43)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.43)	0	0 (0.00)
Skin abrasion	1	1 (1.43)	0	0 (0.00)
Investigations				
- Total	80	28 (40.00)	32	15 (21.43)
Platelet count decreased	16	5 (7.14)	9	2 (2.86)
Neutrophil count decreased	13	8 (11.43)	9	6 (8.57)
White blood cell count decreased	13	9 (12.86)	3	3 (4.29)
Lymphocyte count decreased	6	4 (5.71)	2	2 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Immunoglobulins decreased	5	1 (1.43)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.86)	1	1 (1.43)
Alanine aminotransferase increased	3	2 (2.86)	1	1 (1.43)
Weight increased	3	1 (1.43)	1	1 (1.43)
Blood immunoglobulin A decreased	2	2 (2.86)	1	1 (1.43)
Blood uric acid increased	2	2 (2.86)	2	2 (2.86)
Blood creatinine increased	1	1 (1.43)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.43)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.43)	1	1 (1.43)
Blood lactate dehydrogenase increased	1	1 (1.43)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.43)	0	0 (0.00)
Blood urea increased	1	1 (1.43)	1	1 (1.43)
Bone density decreased	1	1 (1.43)	0	0 (0.00)
C-reactive protein increased	1	1 (1.43)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.43)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.43)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.43)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Weight decreased	1	1 (1.43)	1	1 (1.43)
Metabolism and nutrition disorders				
- Total	25	14 (20.00)	10	7 (10.00)
Decreased appetite	6	6 (8.57)	1	1 (1.43)
Hypokalaemia	6	3 (4.29)	4	2 (2.86)
Hyperuricaemia	2	2 (2.86)	0	0 (0.00)
Haemochromatosis	1	1 (1.43)	1	1 (1.43)
Hyperchloraemia	1	1 (1.43)	0	0 (0.00)
Hyperkalaemia	1	1 (1.43)	0	0 (0.00)
Hypervolaemia	1	1 (1.43)	1	1 (1.43)
Hypophagia	1	1 (1.43)	0	0 (0.00)
Hypophosphataemia	1	1 (1.43)	0	0 (0.00)
Iron overload	1	1 (1.43)	0	0 (0.00)
Malnutrition	1	1 (1.43)	1	1 (1.43)
Metabolic acidosis	1	1 (1.43)	1	1 (1.43)
Metabolic syndrome	1	1 (1.43)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.43)	1	1 (1.43)
Musculoskeletal and connective tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
- Total	22	15 (21.43)	3	3 (4.29)
Back pain	7	6 (8.57)	2	2 (2.86)
Pain in extremity	5	5 (7.14)	1	1 (1.43)
Arthralgia	3	3 (4.29)	0	0 (0.00)
Bone pain	2	2 (2.86)	0	0 (0.00)
Growth retardation	1	1 (1.43)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.43)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.43)	0	0 (0.00)
Myalgia	1	1 (1.43)	0	0 (0.00)
Neck pain	1	1 (1.43)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.71)	1	1 (1.43)
Skin papilloma	2	2 (2.86)	0	0 (0.00)
Cancer pain	1	1 (1.43)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.43)	1	1 (1.43)
Nervous system disorders				
- Total	22	13 (18.57)	6	2 (2.86)
Headache	10	9 (12.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Hydrocephalus	3	1 (1.43)	3	1 (1.43)
Dizziness	2	1 (1.43)	0	0 (0.00)
Migraine	2	1 (1.43)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.43)	1	1 (1.43)
Cerebral haemorrhage	1	1 (1.43)	1	1 (1.43)
Extrapyramidal disorder	1	1 (1.43)	0	0 (0.00)
Memory impairment	1	1 (1.43)	0	0 (0.00)
Seizure	1	1 (1.43)	1	1 (1.43)
Psychiatric disorders				
- Total	14	9 (12.86)	1	1 (1.43)
Anxiety	6	6 (8.57)	0	0 (0.00)
Mental status changes	2	2 (2.86)	1	1 (1.43)
Agitation	1	1 (1.43)	0	0 (0.00)
Delirium	1	1 (1.43)	0	0 (0.00)
Mood altered	1	1 (1.43)	0	0 (0.00)
Nightmare	1	1 (1.43)	0	0 (0.00)
Sleep disorder	1	1 (1.43)	0	0 (0.00)
Tearfulness	1	1 (1.43)	0	0 (0.00)
Renal and urinary disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
- Total	9	5 (7.14)	3	3 (4.29)
Acute kidney injury	3	3 (4.29)	1	1 (1.43)
Cystitis haemorrhagic	1	1 (1.43)	0	0 (0.00)
Dysuria	1	1 (1.43)	0	0 (0.00)
Haematuria	1	1 (1.43)	1	1 (1.43)
Kidney enlargement	1	1 (1.43)	0	0 (0.00)
Renal mass	1	1 (1.43)	0	0 (0.00)
Renal tubular disorder	1	1 (1.43)	1	1 (1.43)
Reproductive system and breast disorders				
- Total	2	1 (1.43)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.43)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	42	23 (32.86)	6	6 (8.57)
Cough	13	10 (14.29)	0	0 (0.00)
Nasal congestion	5	5 (7.14)	0	0 (0.00)
Epistaxis	3	3 (4.29)	0	0 (0.00)
Hypoxia	3	3 (4.29)	3	3 (4.29)
Rhinorrhoea	3	3 (4.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Dyspnoea	2	1 (1.43)	0	0 (0.00)
Pleural effusion	2	2 (2.86)	0	0 (0.00)
Rhinitis allergic	2	2 (2.86)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.43)	1	1 (1.43)
Bronchial oedema	1	1 (1.43)	0	0 (0.00)
Bronchospasm	1	1 (1.43)	0	0 (0.00)
Lung disorder	1	1 (1.43)	0	0 (0.00)
Oropharyngeal pain	1	1 (1.43)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.43)	0	0 (0.00)
Respiratory distress	1	1 (1.43)	1	1 (1.43)
Respiratory failure	1	1 (1.43)	1	1 (1.43)
Upper respiratory tract inflammation	1	1 (1.43)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	26	18 (25.71)	1	1 (1.43)
Rash	6	4 (5.71)	0	0 (0.00)
Dry skin	5	4 (5.71)	0	0 (0.00)
Ingrowing nail	2	2 (2.86)	0	0 (0.00)
Pruritus	2	1 (1.43)	0	0 (0.00)
Decubitus ulcer	1	1 (1.43)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Dermatitis allergic	1	1 (1.43)	0	0 (0.00)
Dermatitis atopic	1	1 (1.43)	0	0 (0.00)
Eczema	1	1 (1.43)	0	0 (0.00)
Erythema	1	1 (1.43)	0	0 (0.00)
Hangnail	1	1 (1.43)	0	0 (0.00)
Miliaria	1	1 (1.43)	0	0 (0.00)
Night sweats	1	1 (1.43)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.43)	0	0 (0.00)
Skin discolouration	1	1 (1.43)	0	0 (0.00)
Skin swelling	1	1 (1.43)	0	0 (0.00)
Vascular disorders				
- Total	7	6 (8.57)	5	5 (7.14)
Hypotension	4	4 (5.71)	3	3 (4.29)
Venoocclusive disease	2	2 (2.86)	2	2 (2.86)
Hypertension	1	1 (1.43)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	8	1 (33.33)	4	1 (33.33)
Gastrointestinal disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Irritable bowel syndrome	1	1 (33.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (33.33)	0	0 (0.00)
Pyrexia	1	1 (33.33)	0	0 (0.00)
Infections and infestations				
- Total	6	1 (33.33)	4	1 (33.33)
Clostridium difficile colitis	1	1 (33.33)	1	1 (33.33)
Gastroenteritis Escherichia coli	1	1 (33.33)	1	1 (33.33)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Gastroenteritis salmonella	1	1 (33.33)	1	1 (33.33)
Pneumonia	1	1 (33.33)	1	1 (33.33)
Rhinovirus infection	1	1 (33.33)	0	0 (0.00)
Sinusitis	1	1 (33.33)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Total number of AE per patient	212	31 (65.96)	59	18 (38.30)
Blood and lymphatic system disorders				
- Total	6	4 (8.51)	2	2 (4.26)
Agranulocytosis	1	1 (2.13)	1	1 (2.13)
Anaemia	1	1 (2.13)	0	0 (0.00)
Hypercoagulation	1	1 (2.13)	0	0 (0.00)
Lymphadenopathy	1	1 (2.13)	0	0 (0.00)
Neutropenia	1	1 (2.13)	1	1 (2.13)
Thrombocytopenia	1	1 (2.13)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.13)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.13)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.13)	0	0 (0.00)
Deafness unilateral	1	1 (2.13)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.13)	0	0 (0.00)
Delayed puberty	1	1 (2.13)	0	0 (0.00)
Hypothyroidism	1	1 (2.13)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.38)	1	1 (2.13)
Dry eye	1	1 (2.13)	0	0 (0.00)
Eye pain	1	1 (2.13)	1	1 (2.13)
Eyelid oedema	1	1 (2.13)	0	0 (0.00)
Mydriasis	1	1 (2.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	6 (12.77)	1	1 (2.13)
Diarrhoea	5	5 (10.64)	1	1 (2.13)
Constipation	1	1 (2.13)	0	0 (0.00)
Nausea	1	1 (2.13)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Vomiting	1	1 (2.13)	0	0 (0.00)
General disorders and administration site conditions				
- Total	12	8 (17.02)	2	2 (4.26)
Pyrexia	6	4 (8.51)	1	1 (2.13)
Pain	2	2 (4.26)	0	0 (0.00)
Fatigue	1	1 (2.13)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.13)	1	1 (2.13)
Non-cardiac chest pain	1	1 (2.13)	0	0 (0.00)
Xerosis	1	1 (2.13)	0	0 (0.00)
Immune system disorders				
- Total	10	9 (19.15)	3	2 (4.26)
Hypogammaglobulinaemia	3	3 (6.38)	0	0 (0.00)
Seasonal allergy	3	3 (6.38)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.26)	1	1 (2.13)
Drug hypersensitivity	1	1 (2.13)	1	1 (2.13)
Haemophagocytic lymphohistiocytosis	1	1 (2.13)	1	1 (2.13)
Infections and infestations				

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
- Total	80	22 (46.81)	22	13 (27.66)
Sinusitis	8	5 (10.64)	0	0 (0.00)
Upper respiratory tract infection	7	5 (10.64)	1	1 (2.13)
Conjunctivitis	5	4 (8.51)	0	0 (0.00)
COVID-19	3	2 (4.26)	1	1 (2.13)
Fungal infection	3	2 (4.26)	0	0 (0.00)
Otitis media	3	2 (4.26)	0	0 (0.00)
Rhinovirus infection	3	3 (6.38)	1	1 (2.13)
Sepsis	3	3 (6.38)	3	3 (6.38)
Skin infection	3	3 (6.38)	0	0 (0.00)
Bronchitis	2	2 (4.26)	0	0 (0.00)
Device related sepsis	2	1 (2.13)	2	1 (2.13)
Gastroenteritis viral	2	1 (2.13)	0	0 (0.00)
Herpes zoster	2	2 (4.26)	1	1 (2.13)
Influenza	2	2 (4.26)	1	1 (2.13)
Oral herpes	2	2 (4.26)	0	0 (0.00)
Urinary tract infection	2	2 (4.26)	0	0 (0.00)
Acute sinusitis	1	1 (2.13)	0	0 (0.00)
Bronchiolitis	1	1 (2.13)	1	1 (2.13)
COVID-19 pneumonia	1	1 (2.13)	1	1 (2.13)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Candida infection	1	1 (2.13)	0	0 (0.00)
Ear infection	1	1 (2.13)	1	1 (2.13)
Enterovirus infection	1	1 (2.13)	1	1 (2.13)
Folliculitis	1	1 (2.13)	0	0 (0.00)
Fungal skin infection	1	1 (2.13)	0	0 (0.00)
Gastroenteritis	1	1 (2.13)	0	0 (0.00)
Herpes virus infection	1	1 (2.13)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.13)	1	1 (2.13)
Nail infection	1	1 (2.13)	0	0 (0.00)
Neutropenic infection	1	1 (2.13)	1	1 (2.13)
Ophthalmic herpes zoster	1	1 (2.13)	0	0 (0.00)
Oral candidiasis	1	1 (2.13)	0	0 (0.00)
Otitis media acute	1	1 (2.13)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.13)	1	1 (2.13)
Pneumonia	1	1 (2.13)	1	1 (2.13)
Pneumonia respiratory syncytial viral	1	1 (2.13)	1	1 (2.13)
Rhinitis	1	1 (2.13)	0	0 (0.00)
Septic shock	1	1 (2.13)	1	1 (2.13)
Staphylococcal abscess	1	1 (2.13)	1	1 (2.13)
Staphylococcal bacteraemia	1	1 (2.13)	1	1 (2.13)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Streptococcal sepsis	1	1 (2.13)	0	0 (0.00)
Syphilis	1	1 (2.13)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.13)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.13)	0	0 (0.00)
Viral skin infection	1	1 (2.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (6.38)	1	1 (2.13)
Abdominal injury	1	1 (2.13)	0	0 (0.00)
Infusion related reaction	1	1 (2.13)	1	1 (2.13)
Ligament sprain	1	1 (2.13)	0	0 (0.00)
Investigations				
- Total	16	6 (12.77)	6	2 (4.26)
Neutrophil count decreased	8	3 (6.38)	5	1 (2.13)
Blood bilirubin increased	3	1 (2.13)	0	0 (0.00)
Platelet count decreased	2	2 (4.26)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.13)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.13)	1	1 (2.13)
SARS-CoV-2 test positive	1	1 (2.13)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Metabolism and nutrition disorders				
- Total	10	6 (12.77)	5	4 (8.51)
Decreased appetite	2	1 (2.13)	2	1 (2.13)
Iron overload	2	1 (2.13)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.13)	0	0 (0.00)
Hyperglycaemia	1	1 (2.13)	1	1 (2.13)
Hyperlipidaemia	1	1 (2.13)	0	0 (0.00)
Hypernatraemia	1	1 (2.13)	1	1 (2.13)
Hypertriglyceridaemia	1	1 (2.13)	0	0 (0.00)
Obesity	1	1 (2.13)	1	1 (2.13)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (14.89)	0	0 (0.00)
Pain in extremity	2	2 (4.26)	0	0 (0.00)
Arthralgia	1	1 (2.13)	0	0 (0.00)
Growth retardation	1	1 (2.13)	0	0 (0.00)
Joint effusion	1	1 (2.13)	0	0 (0.00)
Osteonecrosis	1	1 (2.13)	0	0 (0.00)
Osteopenia	1	1 (2.13)	0	0 (0.00)
Synovitis	1	1 (2.13)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.13)	1	1 (2.13)
Bone giant cell tumour benign	2	1 (2.13)	1	1 (2.13)
Nervous system disorders				
- Total	9	4 (8.51)	3	2 (4.26)
Headache	3	2 (4.26)	1	1 (2.13)
Seizure	3	1 (2.13)	1	1 (2.13)
Nervous system disorder	2	1 (2.13)	1	1 (2.13)
Dysarthria	1	1 (2.13)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.38)	0	0 (0.00)
Anxiety	2	2 (4.26)	0	0 (0.00)
Tic	1	1 (2.13)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.13)	1	1 (2.13)
Endometriosis	2	1 (2.13)	1	1 (2.13)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	23	10 (21.28)	6	4 (8.51)
Cough	4	4 (8.51)	0	0 (0.00)
Dyspnoea	3	3 (6.38)	1	1 (2.13)
Rhinorrhoea	3	3 (6.38)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.26)	0	0 (0.00)
Tachypnoea	2	1 (2.13)	2	1 (2.13)
Dyspnoea exertional	1	1 (2.13)	0	0 (0.00)
Epistaxis	1	1 (2.13)	0	0 (0.00)
Hypoxia	1	1 (2.13)	1	1 (2.13)
Laryngeal oedema	1	1 (2.13)	1	1 (2.13)
Oropharyngeal pain	1	1 (2.13)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.13)	0	0 (0.00)
Pleural effusion	1	1 (2.13)	0	0 (0.00)
Respiratory failure	1	1 (2.13)	1	1 (2.13)
Wheezing	1	1 (2.13)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (14.89)	4	3 (6.38)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=47 n (%)[1]	Grade >= 3 Total events	All patients N=47 n (%)[2]
Rash	2	2 (4.26)	0	0 (0.00)
Rash macular	2	1 (2.13)	2	1 (2.13)
Dermatitis atopic	1	1 (2.13)	1	1 (2.13)
Dry skin	1	1 (2.13)	0	0 (0.00)
Eczema	1	1 (2.13)	1	1 (2.13)
Papule	1	1 (2.13)	0	0 (0.00)
Rash erythematous	1	1 (2.13)	0	0 (0.00)
Rash maculo-papular	1	1 (2.13)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.26)	1	1 (2.13)
Hypertension	2	2 (4.26)	1	1 (2.13)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	249	6 (100.00)	89	5 (83.33)
Blood and lymphatic system disorders				
- Total	14	5 (83.33)	6	4 (66.67)
Anaemia	7	2 (33.33)	0	0 (0.00)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Coagulopathy	1	1 (16.67)	1	1 (16.67)
Disseminated intravascular coagulation	1	1 (16.67)	1	1 (16.67)
Lymphocytosis	1	1 (16.67)	0	0 (0.00)
Thrombocytopenia	1	1 (16.67)	1	1 (16.67)
Cardiac disorders				
- Total	7	3 (50.00)	1	1 (16.67)
Tachycardia	6	3 (50.00)	1	1 (16.67)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Sinus tachycardia	1	1 (16.67)	0	0 (0.00)
Eye disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Eyelid oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	7	2 (33.33)	1	1 (16.67)
Abdominal distension	1	1 (16.67)	0	0 (0.00)
Ascites	1	1 (16.67)	0	0 (0.00)
Constipation	1	1 (16.67)	0	0 (0.00)
Irritable bowel syndrome	1	1 (16.67)	0	0 (0.00)
Melaena	1	1 (16.67)	1	1 (16.67)
Mouth haemorrhage	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	19	4 (66.67)	3	2 (33.33)
Pyrexia	9	3 (50.00)	1	1 (16.67)
Fatigue	3	2 (33.33)	0	0 (0.00)
Catheter site pain	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Chills	1	1 (16.67)	0	0 (0.00)
Face oedema	1	1 (16.67)	0	0 (0.00)
Generalised oedema	1	1 (16.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (16.67)	1	1 (16.67)
Oedema peripheral	1	1 (16.67)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (16.67)	1	1 (16.67)
Hepatobiliary disorders				
- Total	3	1 (16.67)	1	1 (16.67)
Cholelithiasis	1	1 (16.67)	0	0 (0.00)
Cholestasis	1	1 (16.67)	1	1 (16.67)
Gallbladder enlargement	1	1 (16.67)	0	0 (0.00)
Immune system disorders				
- Total	14	5 (83.33)	7	2 (33.33)
Cytokine release syndrome	10	5 (83.33)	5	2 (33.33)
Hypogammaglobulinaemia	2	2 (33.33)	1	1 (16.67)
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	1	1 (16.67)
Seasonal allergy	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Infections and infestations				
- Total	14	3 (50.00)	5	2 (33.33)
Upper respiratory tract infection	2	1 (16.67)	0	0 (0.00)
Clostridium difficile colitis	1	1 (16.67)	1	1 (16.67)
Conjunctivitis	1	1 (16.67)	0	0 (0.00)
Encephalitis	1	1 (16.67)	1	1 (16.67)
Gastroenteritis	1	1 (16.67)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (16.67)	1	1 (16.67)
Gastroenteritis salmonella	1	1 (16.67)	1	1 (16.67)
Gastrointestinal infection	1	1 (16.67)	0	0 (0.00)
Localised infection	1	1 (16.67)	0	0 (0.00)
Otitis externa	1	1 (16.67)	0	0 (0.00)
Pneumonia	1	1 (16.67)	1	1 (16.67)
Rhinovirus infection	1	1 (16.67)	0	0 (0.00)
Sinusitis	1	1 (16.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	3 (50.00)	2	1 (16.67)
Wound	2	1 (16.67)	1	1 (16.67)
Fibula fracture	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Infusion related reaction	1	1 (16.67)	0	0 (0.00)
Skin injury	1	1 (16.67)	0	0 (0.00)
Skin wound	1	1 (16.67)	0	0 (0.00)
Vasoplegia syndrome	1	1 (16.67)	1	1 (16.67)
Investigations				
- Total	67	3 (50.00)	29	3 (50.00)
Neutrophil count decreased	27	3 (50.00)	17	3 (50.00)
White blood cell count decreased	11	2 (33.33)	3	1 (16.67)
Aspartate aminotransferase increased	5	1 (16.67)	1	1 (16.67)
Blood bilirubin increased	5	1 (16.67)	1	1 (16.67)
Platelet count decreased	4	1 (16.67)	2	1 (16.67)
Alanine aminotransferase increased	3	1 (16.67)	1	1 (16.67)
Lipase increased	3	1 (16.67)	2	1 (16.67)
Blood alkaline phosphatase increased	1	1 (16.67)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (16.67)	1	1 (16.67)
Blood creatinine increased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Blood immunoglobulin M decreased	1	1 (16.67)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (16.67)	0	0 (0.00)
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Lymphocyte count decreased	1	1 (16.67)	1	1 (16.67)
Weight increased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	41	5 (83.33)	14	3 (50.00)
Hypokalaemia	10	1 (16.67)	7	1 (16.67)
Hypocalcaemia	6	2 (33.33)	2	1 (16.67)
Hypophosphataemia	6	3 (50.00)	2	2 (33.33)
Hyperuricaemia	4	2 (33.33)	1	1 (16.67)
Hyperglycaemia	3	1 (16.67)	0	0 (0.00)
Acidosis	2	1 (16.67)	1	1 (16.67)
Decreased appetite	2	2 (33.33)	0	0 (0.00)
Hypoalbuminaemia	2	1 (16.67)	0	0 (0.00)
Haemosiderosis	1	1 (16.67)	0	0 (0.00)
Hyperlactacidaemia	1	1 (16.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (16.67)	0	0 (0.00)
Hypernatraemia	1	1 (16.67)	1	1 (16.67)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Hypomagnesaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (33.33)	1	1 (16.67)
Myalgia	1	1 (16.67)	0	0 (0.00)
Myositis	1	1 (16.67)	0	0 (0.00)
Rhabdomyolysis	1	1 (16.67)	1	1 (16.67)
Nervous system disorders				
- Total	8	4 (66.67)	1	1 (16.67)
Headache	4	3 (50.00)	0	0 (0.00)
Encephalopathy	1	1 (16.67)	1	1 (16.67)
Monoparesis	1	1 (16.67)	0	0 (0.00)
Somnolence	1	1 (16.67)	0	0 (0.00)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (50.00)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Persistent depressive disorder	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Sleep disorder	1	1 (16.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	2 (33.33)	3	2 (33.33)
Acute kidney injury	4	2 (33.33)	2	2 (33.33)
Bladder dilatation	1	1 (16.67)	0	0 (0.00)
Renal tubular necrosis	1	1 (16.67)	1	1 (16.67)
Urinary retention	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (16.67)	1	1 (16.67)
Vaginal ulceration	1	1 (16.67)	1	1 (16.67)
Respiratory, thoracic and mediastinal disorders				
- Total	15	3 (50.00)	8	2 (33.33)
Atelectasis	3	1 (16.67)	1	1 (16.67)
Nasal congestion	3	2 (33.33)	0	0 (0.00)
Tachypnoea	2	2 (33.33)	2	2 (33.33)
Acute respiratory distress syndrome	1	1 (16.67)	1	1 (16.67)
Acute respiratory failure	1	1 (16.67)	1	1 (16.67)

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Cough	1	1 (16.67)	0	0 (0.00)
Dyspnoea	1	1 (16.67)	1	1 (16.67)
Hypoxia	1	1 (16.67)	1	1 (16.67)
Oropharyngeal pain	1	1 (16.67)	0	0 (0.00)
Respiratory acidosis	1	1 (16.67)	1	1 (16.67)
Skin and subcutaneous tissue disorders				
- Total	12	4 (66.67)	2	1 (16.67)
Dry skin	2	2 (33.33)	0	0 (0.00)
Rash	2	2 (33.33)	0	0 (0.00)
Decubitus ulcer	1	1 (16.67)	0	0 (0.00)
Erythema	1	1 (16.67)	0	0 (0.00)
Hyperhidrosis	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	1	1 (16.67)
Pruritus	1	1 (16.67)	0	0 (0.00)
Skin hypopigmentation	1	1 (16.67)	0	0 (0.00)
Skin necrosis	1	1 (16.67)	1	1 (16.67)
Skin ulcer	1	1 (16.67)	0	0 (0.00)
Vascular disorders				

Timing: At anytime, Response status at study entry: Primary refractory

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
- Total	6	2 (33.33)	4	2 (33.33)
Hypotension	4	2 (33.33)	3	2 (33.33)
Hypertension	2	1 (16.67)	1	1 (16.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250e
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Response status at study entry
Safety Set

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	2256	74 (100.00)	739	68 (91.89)
Blood and lymphatic system disorders				
- Total	149	50 (67.57)	89	39 (52.70)
Anaemia	56	23 (31.08)	24	9 (12.16)
Febrile neutropenia	30	24 (32.43)	30	24 (32.43)
Neutropenia	17	11 (14.86)	15	9 (12.16)
Thrombocytopenia	10	8 (10.81)	9	8 (10.81)
Disseminated intravascular coagulation	7	7 (9.46)	2	2 (2.70)
Leukopenia	5	3 (4.05)	3	2 (2.70)
Coagulopathy	4	4 (5.41)	1	1 (1.35)
Splenomegaly	4	4 (5.41)	0	0 (0.00)
B-cell aplasia	3	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Eosinophilia	3	1 (1.35)	0	0 (0.00)
Lymphadenopathy	2	2 (2.70)	0	0 (0.00)
Lymphopenia	2	2 (2.70)	2	2 (2.70)
Pancytopenia	2	2 (2.70)	2	2 (2.70)
Agranulocytosis	1	1 (1.35)	1	1 (1.35)
Hypercoagulation	1	1 (1.35)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.35)	0	0 (0.00)
Leukocytosis	1	1 (1.35)	0	0 (0.00)
Cardiac disorders				
- Total	46	25 (33.78)	13	10 (13.51)
Tachycardia	18	14 (18.92)	2	2 (2.70)
Cardiac failure	6	3 (4.05)	4	3 (4.05)
Left ventricular dysfunction	4	4 (5.41)	3	3 (4.05)
Bradycardia	3	3 (4.05)	0	0 (0.00)
Cardiac arrest	3	3 (4.05)	3	3 (4.05)
Sinus tachycardia	3	2 (2.70)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.70)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.35)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Mitral valve incompetence	1	1 (1.35)	0	0 (0.00)
Pericardial effusion	1	1 (1.35)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Sinus bradycardia	1	1 (1.35)	1	1 (1.35)
Tricuspid valve incompetence	1	1 (1.35)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.35)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.05)	0	0 (0.00)
Deafness unilateral	1	1 (1.35)	0	0 (0.00)
Ear pain	1	1 (1.35)	0	0 (0.00)
Ear pruritus	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	8	7 (9.46)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.41)	0	0 (0.00)
Hypothyroidism	3	3 (4.05)	0	0 (0.00)
Delayed puberty	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Eye disorders				
- Total	23	14 (18.92)	1	1 (1.35)
Eyelid oedema	3	2 (2.70)	0	0 (0.00)
Ocular hyperaemia	3	3 (4.05)	0	0 (0.00)
Cataract	2	2 (2.70)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.70)	0	0 (0.00)
Eye pain	2	2 (2.70)	1	1 (1.35)
Retinal haemorrhage	2	1 (1.35)	0	0 (0.00)
Visual impairment	2	2 (2.70)	0	0 (0.00)
Dry eye	1	1 (1.35)	0	0 (0.00)
Eye oedema	1	1 (1.35)	0	0 (0.00)
Hypermetropia	1	1 (1.35)	0	0 (0.00)
Mydriasis	1	1 (1.35)	0	0 (0.00)
Periorbital oedema	1	1 (1.35)	0	0 (0.00)
Periorbital swelling	1	1 (1.35)	0	0 (0.00)
Visual field defect	1	1 (1.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	175	58 (78.38)	17	15 (20.27)
Vomiting	38	26 (35.14)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Diarrhoea	30	26 (35.14)	2	2 (2.70)
Nausea	26	21 (28.38)	2	2 (2.70)
Abdominal pain	15	11 (14.86)	2	2 (2.70)
Constipation	15	13 (17.57)	0	0 (0.00)
Pancreatitis	6	6 (8.11)	2	2 (2.70)
Abdominal pain upper	4	4 (5.41)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.41)	2	2 (2.70)
Stomatitis	3	3 (4.05)	1	1 (1.35)
Abdominal distension	2	2 (2.70)	0	0 (0.00)
Ascites	2	2 (2.70)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.70)	0	0 (0.00)
Proctalgia	2	2 (2.70)	1	1 (1.35)
Trichoglossia	2	2 (2.70)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.35)	1	1 (1.35)
Abdominal rigidity	1	1 (1.35)	0	0 (0.00)
Anal fissure	1	1 (1.35)	0	0 (0.00)
Anal haemorrhage	1	1 (1.35)	0	0 (0.00)
Dry mouth	1	1 (1.35)	0	0 (0.00)
Dyspepsia	1	1 (1.35)	0	0 (0.00)
Dysphagia	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Enteritis	1	1 (1.35)	0	0 (0.00)
Enterocolitis	1	1 (1.35)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.35)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.35)	0	0 (0.00)
Gingival bleeding	1	1 (1.35)	0	0 (0.00)
Gingival erythema	1	1 (1.35)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.35)	1	1 (1.35)
Haematemesis	1	1 (1.35)	0	0 (0.00)
Ileus	1	1 (1.35)	0	0 (0.00)
Lip dry	1	1 (1.35)	0	0 (0.00)
Lip oedema	1	1 (1.35)	0	0 (0.00)
Mouth swelling	1	1 (1.35)	0	0 (0.00)
Neutropenic colitis	1	1 (1.35)	1	1 (1.35)
Odynophagia	1	1 (1.35)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.35)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	137	49 (66.22)	21	13 (17.57)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pyrexia	58	32 (43.24)	11	10 (13.51)
Fatigue	16	15 (20.27)	0	0 (0.00)
Chills	9	6 (8.11)	0	0 (0.00)
Face oedema	8	7 (9.46)	1	1 (1.35)
Oedema peripheral	8	6 (8.11)	2	1 (1.35)
Pain	5	5 (6.76)	2	2 (2.70)
Generalised oedema	4	4 (5.41)	0	0 (0.00)
Asthenia	3	3 (4.05)	0	0 (0.00)
Catheter site pain	3	1 (1.35)	2	1 (1.35)
Catheter site erythema	2	1 (1.35)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.70)	0	0 (0.00)
Influenza like illness	2	2 (2.70)	0	0 (0.00)
Localised oedema	2	2 (2.70)	0	0 (0.00)
Malaise	2	2 (2.70)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.70)	2	2 (2.70)
Non-cardiac chest pain	2	2 (2.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.35)	0	0 (0.00)
Chest discomfort	1	1 (1.35)	1	1 (1.35)
Crying	1	1 (1.35)	0	0 (0.00)
Facial pain	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Oedema due to hepatic disease	1	1 (1.35)	0	0 (0.00)
Sluggishness	1	1 (1.35)	0	0 (0.00)
Swelling face	1	1 (1.35)	0	0 (0.00)
Vascular device occlusion	1	1 (1.35)	0	0 (0.00)
Xerosis	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	29	18 (24.32)	6	5 (6.76)
Hepatic function abnormal	11	5 (6.76)	4	3 (4.05)
Hyperbilirubinaemia	6	5 (6.76)	1	1 (1.35)
Hepatomegaly	3	3 (4.05)	1	1 (1.35)
Hypertransaminasaemia	3	2 (2.70)	0	0 (0.00)
Biliary tract disorder	1	1 (1.35)	0	0 (0.00)
Cholelithiasis	1	1 (1.35)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.35)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.35)	0	0 (0.00)
Liver disorder	1	1 (1.35)	0	0 (0.00)
Ocular icterus	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	179	66 (89.19)	69	44 (59.46)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Cytokine release syndrome	118	56 (75.68)	50	36 (48.65)
Hypogammaglobulinaemia	38	31 (41.89)	6	6 (8.11)
Haemophagocytic lymphohistiocytosis	5	5 (6.76)	3	3 (4.05)
Immunodeficiency	4	4 (5.41)	4	4 (5.41)
Seasonal allergy	3	3 (4.05)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.70)	1	1 (1.35)
Chronic graft versus host disease	2	2 (2.70)	1	1 (1.35)
Drug hypersensitivity	2	2 (2.70)	1	1 (1.35)
Graft versus host disease	2	2 (2.70)	2	2 (2.70)
Engraftment syndrome	1	1 (1.35)	1	1 (1.35)
Hypersensitivity	1	1 (1.35)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.35)	0	0 (0.00)
Infections and infestations				
- Total	249	57 (77.03)	97	37 (50.00)
Upper respiratory tract infection	15	12 (16.22)	3	3 (4.05)
Sinusitis	13	6 (8.11)	2	2 (2.70)
Conjunctivitis	11	7 (9.46)	0	0 (0.00)
Rhinovirus infection	10	8 (10.81)	2	2 (2.70)
Nasopharyngitis	9	7 (9.46)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Bronchopulmonary aspergillosis	6	2 (2.70)	4	2 (2.70)
Otitis media	6	5 (6.76)	1	1 (1.35)
Parainfluenzae virus infection	6	5 (6.76)	3	3 (4.05)
Staphylococcal bacteraemia	6	5 (6.76)	6	5 (6.76)
Candida infection	5	4 (5.41)	2	1 (1.35)
Gastroenteritis	5	5 (6.76)	2	2 (2.70)
Oral herpes	5	4 (5.41)	1	1 (1.35)
Pneumonia	5	5 (6.76)	3	3 (4.05)
Staphylococcal infection	5	5 (6.76)	2	2 (2.70)
Bacteraemia	4	3 (4.05)	3	2 (2.70)
Clostridium difficile infection	4	4 (5.41)	3	3 (4.05)
Ear infection	4	3 (4.05)	1	1 (1.35)
Nail infection	4	4 (5.41)	0	0 (0.00)
Oral candidiasis	4	3 (4.05)	0	0 (0.00)
Urinary tract infection	4	3 (4.05)	2	1 (1.35)
COVID-19	3	2 (2.70)	1	1 (1.35)
Fungal infection	3	2 (2.70)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.70)	0	0 (0.00)
Herpes zoster	3	3 (4.05)	2	2 (2.70)
Influenza	3	3 (4.05)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Klebsiella infection	3	1 (1.35)	3	1 (1.35)
Metapneumovirus infection	3	3 (4.05)	3	3 (4.05)
Respiratory syncytial virus infection	3	3 (4.05)	2	2 (2.70)
Respiratory tract infection	3	3 (4.05)	0	0 (0.00)
Rhinitis	3	3 (4.05)	0	0 (0.00)
Sepsis	3	3 (4.05)	3	3 (4.05)
Skin infection	3	3 (4.05)	0	0 (0.00)
Acute sinusitis	2	2 (2.70)	0	0 (0.00)
Adenovirus infection	2	2 (2.70)	2	2 (2.70)
BK virus infection	2	2 (2.70)	1	1 (1.35)
Bronchitis	2	2 (2.70)	0	0 (0.00)
Device related sepsis	2	1 (1.35)	2	1 (1.35)
Encephalitis viral	2	2 (2.70)	2	2 (2.70)
Gingivitis	2	2 (2.70)	0	0 (0.00)
Herpes simplex	2	2 (2.70)	1	1 (1.35)
Human herpesvirus 6 infection	2	2 (2.70)	2	2 (2.70)
Oral infection	2	2 (2.70)	0	0 (0.00)
Otitis externa	2	2 (2.70)	1	1 (1.35)
Paronychia	2	2 (2.70)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.70)	2	2 (2.70)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Septic shock	2	2 (2.70)	2	2 (2.70)
Varicella zoster virus infection	2	2 (2.70)	1	1 (1.35)
Viral infection	2	2 (2.70)	1	1 (1.35)
Anal abscess	1	1 (1.35)	1	1 (1.35)
Atypical pneumonia	1	1 (1.35)	0	0 (0.00)
Bronchiolitis	1	1 (1.35)	1	1 (1.35)
COVID-19 pneumonia	1	1 (1.35)	1	1 (1.35)
Cellulitis	1	1 (1.35)	0	0 (0.00)
Cholecystitis infective	1	1 (1.35)	0	0 (0.00)
Coronavirus infection	1	1 (1.35)	1	1 (1.35)
Cystitis	1	1 (1.35)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.35)	1	1 (1.35)
Device related infection	1	1 (1.35)	1	1 (1.35)
Ear, nose and throat infection	1	1 (1.35)	0	0 (0.00)
Encephalitis	1	1 (1.35)	1	1 (1.35)
Enterobacter infection	1	1 (1.35)	1	1 (1.35)
Enterovirus infection	1	1 (1.35)	1	1 (1.35)
Folliculitis	1	1 (1.35)	0	0 (0.00)
Fungal skin infection	1	1 (1.35)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastroenteritis norovirus	1	1 (1.35)	0	0 (0.00)
Granulicatella infection	1	1 (1.35)	1	1 (1.35)
Herpes virus infection	1	1 (1.35)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.35)	0	0 (0.00)
Mastoiditis	1	1 (1.35)	1	1 (1.35)
Meningitis bacterial	1	1 (1.35)	1	1 (1.35)
Meningitis pneumococcal	1	1 (1.35)	1	1 (1.35)
Molluscum contagiosum	1	1 (1.35)	0	0 (0.00)
Myringitis	1	1 (1.35)	0	0 (0.00)
Neutropenic infection	1	1 (1.35)	1	1 (1.35)
Ophthalmic herpes zoster	1	1 (1.35)	0	0 (0.00)
Otitis media acute	1	1 (1.35)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.35)	1	1 (1.35)
Pneumonia fungal	1	1 (1.35)	1	1 (1.35)
Pneumonia respiratory syncytial viral	1	1 (1.35)	1	1 (1.35)
Pneumonia viral	1	1 (1.35)	1	1 (1.35)
Respiratory tract infection viral	1	1 (1.35)	0	0 (0.00)
Salmonellosis	1	1 (1.35)	0	0 (0.00)
Sinusitis fungal	1	1 (1.35)	1	1 (1.35)
Soft tissue infection	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Staphylococcal abscess	1	1 (1.35)	1	1 (1.35)
Staphylococcal sepsis	1	1 (1.35)	1	1 (1.35)
Staphylococcal skin infection	1	1 (1.35)	0	0 (0.00)
Stomatococcal infection	1	1 (1.35)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.35)	0	0 (0.00)
Syphilis	1	1 (1.35)	0	0 (0.00)
Systemic candida	1	1 (1.35)	1	1 (1.35)
Tinea pedis	1	1 (1.35)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.35)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.35)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.35)	1	1 (1.35)
Viral skin infection	1	1 (1.35)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	26	18 (24.32)	2	2 (2.70)
Infusion related reaction	7	4 (5.41)	1	1 (1.35)
Contusion	3	2 (2.70)	0	0 (0.00)
Fall	2	2 (2.70)	0	0 (0.00)
Ligament sprain	2	2 (2.70)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Procedural pain	2	2 (2.70)	0	0 (0.00)
Skin abrasion	2	2 (2.70)	0	0 (0.00)
Transfusion reaction	2	2 (2.70)	0	0 (0.00)
Abdominal injury	1	1 (1.35)	0	0 (0.00)
Limb injury	1	1 (1.35)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.35)	0	0 (0.00)
Scratch	1	1 (1.35)	0	0 (0.00)
Transplant failure	1	1 (1.35)	1	1 (1.35)
Wound	1	1 (1.35)	0	0 (0.00)
Investigations				
- Total	426	57 (77.03)	209	45 (60.81)
Platelet count decreased	79	23 (31.08)	45	14 (18.92)
White blood cell count decreased	57	23 (31.08)	37	17 (22.97)
Neutrophil count decreased	48	21 (28.38)	37	18 (24.32)
Lymphocyte count decreased	35	16 (21.62)	25	14 (18.92)
Aspartate aminotransferase increased	28	18 (24.32)	12	10 (13.51)
Alanine aminotransferase increased	26	17 (22.97)	6	6 (8.11)
Blood bilirubin increased	20	12 (16.22)	9	8 (10.81)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
International normalised ratio increased	11	8 (10.81)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.70)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (8.11)	1	1 (1.35)
Serum ferritin increased	8	8 (10.81)	2	2 (2.70)
Blood fibrinogen decreased	7	7 (9.46)	2	2 (2.70)
Blood immunoglobulin A decreased	7	7 (9.46)	1	1 (1.35)
Blood creatinine increased	6	4 (5.41)	5	3 (4.05)
Blood immunoglobulin M decreased	6	6 (8.11)	2	2 (2.70)
Weight increased	6	3 (4.05)	2	2 (2.70)
Blood lactate dehydrogenase increased	5	5 (6.76)	1	1 (1.35)
C-reactive protein increased	5	5 (6.76)	3	3 (4.05)
Electrocardiogram QT prolonged	5	4 (5.41)	2	2 (2.70)
Blood uric acid increased	4	4 (5.41)	2	2 (2.70)
Blood creatine phosphokinase increased	3	1 (1.35)	1	1 (1.35)
Blood immunoglobulin G decreased	3	3 (4.05)	0	0 (0.00)
Fibrin D dimer increased	3	3 (4.05)	1	1 (1.35)
Oxygen saturation decreased	3	3 (4.05)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Urine output decreased	3	2 (2.70)	3	2 (2.70)
Blood glucose increased	2	1 (1.35)	2	1 (1.35)
Gamma-glutamyltransferase increased	2	2 (2.70)	2	2 (2.70)
Haemoglobin decreased	2	1 (1.35)	1	1 (1.35)
Weight decreased	2	2 (2.70)	1	1 (1.35)
Amylase increased	1	1 (1.35)	0	0 (0.00)
Bacterial test positive	1	1 (1.35)	1	1 (1.35)
Blood bicarbonate decreased	1	1 (1.35)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.35)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.35)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.35)	0	0 (0.00)
Blood urea increased	1	1 (1.35)	1	1 (1.35)
Bone density decreased	1	1 (1.35)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.35)	0	0 (0.00)
Cardiac murmur	1	1 (1.35)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.35)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.35)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Enterovirus test positive	1	1 (1.35)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.35)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.35)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.35)	0	0 (0.00)
Lipase increased	1	1 (1.35)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.35)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.35)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.35)	0	0 (0.00)
Troponin increased	1	1 (1.35)	1	1 (1.35)
Metabolism and nutrition disorders				
- Total	205	47 (63.51)	77	30 (40.54)
Hypokalaemia	36	19 (25.68)	17	10 (13.51)
Decreased appetite	30	28 (37.84)	14	12 (16.22)
Hypophosphataemia	26	15 (20.27)	9	7 (9.46)
Hypocalcaemia	18	14 (18.92)	4	4 (5.41)
Hypoalbuminaemia	17	10 (13.51)	1	1 (1.35)
Hyperglycaemia	9	8 (10.81)	5	5 (6.76)
Hyperuricaemia	8	7 (9.46)	0	0 (0.00)
Hypervolaemia	7	7 (9.46)	5	5 (6.76)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypomagnesaemia	6	5 (6.76)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.76)	1	1 (1.35)
Tumour lysis syndrome	5	5 (6.76)	5	5 (6.76)
Hypercalcaemia	4	3 (4.05)	2	2 (2.70)
Metabolic acidosis	4	4 (5.41)	3	3 (4.05)
Hyperkalaemia	3	3 (4.05)	2	2 (2.70)
Hypertriglyceridaemia	3	3 (4.05)	2	2 (2.70)
Iron overload	3	2 (2.70)	0	0 (0.00)
Hyperchloraemia	2	2 (2.70)	0	0 (0.00)
Hypermagnesaemia	2	1 (1.35)	0	0 (0.00)
Hypernatraemia	2	2 (2.70)	1	1 (1.35)
Hyponatraemia	2	2 (2.70)	0	0 (0.00)
Malnutrition	2	2 (2.70)	2	2 (2.70)
Acidosis	1	1 (1.35)	1	1 (1.35)
Calcium deficiency	1	1 (1.35)	0	0 (0.00)
Dehydration	1	1 (1.35)	0	0 (0.00)
Haemochromatosis	1	1 (1.35)	1	1 (1.35)
Hypercholesterolaemia	1	1 (1.35)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.35)	0	0 (0.00)
Hypoglycaemia	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypophagia	1	1 (1.35)	0	0 (0.00)
Metabolic syndrome	1	1 (1.35)	0	0 (0.00)
Obesity	1	1 (1.35)	1	1 (1.35)
Polydipsia	1	1 (1.35)	1	1 (1.35)
Musculoskeletal and connective tissue disorders				
- Total	80	42 (56.76)	8	7 (9.46)
Pain in extremity	18	17 (22.97)	1	1 (1.35)
Arthralgia	14	12 (16.22)	1	1 (1.35)
Back pain	14	10 (13.51)	3	3 (4.05)
Myalgia	10	9 (12.16)	0	0 (0.00)
Bone pain	6	4 (5.41)	0	0 (0.00)
Growth retardation	2	2 (2.70)	0	0 (0.00)
Muscular weakness	2	2 (2.70)	1	1 (1.35)
Musculoskeletal chest pain	2	2 (2.70)	0	0 (0.00)
Neck pain	2	2 (2.70)	0	0 (0.00)
Pain in jaw	2	2 (2.70)	1	1 (1.35)
Haemarthrosis	1	1 (1.35)	1	1 (1.35)
Joint effusion	1	1 (1.35)	0	0 (0.00)
Muscle rigidity	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Muscle spasms	1	1 (1.35)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.35)	0	0 (0.00)
Osteonecrosis	1	1 (1.35)	0	0 (0.00)
Osteopenia	1	1 (1.35)	0	0 (0.00)
Synovitis	1	1 (1.35)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (6.76)	2	2 (2.70)
Bone giant cell tumour benign	2	1 (1.35)	1	1 (1.35)
Skin papilloma	2	2 (2.70)	0	0 (0.00)
Cancer pain	1	1 (1.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.35)	1	1 (1.35)
Nervous system disorders				
- Total	101	43 (58.11)	22	13 (17.57)
Headache	36	24 (32.43)	3	3 (4.05)
Encephalopathy	7	7 (9.46)	3	3 (4.05)
Seizure	7	4 (5.41)	3	3 (4.05)
Tremor	6	5 (6.76)	0	0 (0.00)
Cognitive disorder	5	3 (4.05)	1	1 (1.35)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dizziness	5	4 (5.41)	0	0 (0.00)
Somnolence	4	4 (5.41)	2	2 (2.70)
Dysgeusia	3	3 (4.05)	0	0 (0.00)
Hydrocephalus	3	1 (1.35)	3	1 (1.35)
Lethargy	3	3 (4.05)	0	0 (0.00)
Cerebral haemorrhage	2	2 (2.70)	2	2 (2.70)
Dysarthria	2	2 (2.70)	1	1 (1.35)
Hyperaesthesia	2	1 (1.35)	0	0 (0.00)
Migraine	2	1 (1.35)	0	0 (0.00)
Nervous system disorder	2	1 (1.35)	1	1 (1.35)
Amnesia	1	1 (1.35)	0	0 (0.00)
Aphasia	1	1 (1.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.35)	1	1 (1.35)
Depressed level of consciousness	1	1 (1.35)	1	1 (1.35)
Disturbance in attention	1	1 (1.35)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.35)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.35)	0	0 (0.00)
Hypoaesthesia	1	1 (1.35)	0	0 (0.00)
Memory impairment	1	1 (1.35)	0	0 (0.00)
Neuralgia	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Neurological decompensation	1	1 (1.35)	1	1 (1.35)
Paraesthesia	1	1 (1.35)	0	0 (0.00)
Psychiatric disorders				
- Total	62	36 (48.65)	7	7 (9.46)
Anxiety	14	14 (18.92)	2	2 (2.70)
Delirium	8	8 (10.81)	3	3 (4.05)
Agitation	7	6 (8.11)	0	0 (0.00)
Confusional state	6	6 (8.11)	0	0 (0.00)
Mental status changes	5	5 (6.76)	2	2 (2.70)
Insomnia	4	4 (5.41)	0	0 (0.00)
Hallucination	3	3 (4.05)	0	0 (0.00)
Irritability	3	3 (4.05)	0	0 (0.00)
Sleep disorder	3	2 (2.70)	0	0 (0.00)
Affect lability	1	1 (1.35)	0	0 (0.00)
Automatism	1	1 (1.35)	0	0 (0.00)
Hallucination, visual	1	1 (1.35)	0	0 (0.00)
Mood altered	1	1 (1.35)	0	0 (0.00)
Nightmare	1	1 (1.35)	0	0 (0.00)
Restlessness	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Social avoidant behaviour	1	1 (1.35)	0	0 (0.00)
Tearfulness	1	1 (1.35)	0	0 (0.00)
Tic	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	41	23 (31.08)	13	10 (13.51)
Acute kidney injury	13	10 (13.51)	7	6 (8.11)
Dysuria	4	4 (5.41)	0	0 (0.00)
Renal failure	4	2 (2.70)	3	1 (1.35)
Haematuria	3	3 (4.05)	1	1 (1.35)
Anuria	2	2 (2.70)	1	1 (1.35)
Pollakiuria	2	2 (2.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.35)	0	0 (0.00)
Azotaemia	1	1 (1.35)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.35)	0	0 (0.00)
Incontinence	1	1 (1.35)	0	0 (0.00)
Kidney enlargement	1	1 (1.35)	0	0 (0.00)
Micturition urgency	1	1 (1.35)	0	0 (0.00)
Proteinuria	1	1 (1.35)	0	0 (0.00)
Renal mass	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Renal tubular disorder	1	1 (1.35)	1	1 (1.35)
Renal tubular dysfunction	1	1 (1.35)	0	0 (0.00)
Urinary retention	1	1 (1.35)	0	0 (0.00)
Urinary tract disorder	1	1 (1.35)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	9	5 (6.76)	1	1 (1.35)
Dysmenorrhoea	2	1 (1.35)	0	0 (0.00)
Endometriosis	2	1 (1.35)	1	1 (1.35)
Vaginal haemorrhage	2	1 (1.35)	0	0 (0.00)
Female genital tract fistula	1	1 (1.35)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.35)	0	0 (0.00)
Perineal rash	1	1 (1.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	168	52 (70.27)	54	27 (36.49)
Cough	28	22 (29.73)	0	0 (0.00)
Hypoxia	26	19 (25.68)	21	15 (20.27)
Pulmonary oedema	12	12 (16.22)	7	7 (9.46)
Pleural effusion	10	9 (12.16)	3	3 (4.05)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Tachypnoea	9	7 (9.46)	4	3 (4.05)
Epistaxis	8	7 (9.46)	1	1 (1.35)
Oropharyngeal pain	8	7 (9.46)	0	0 (0.00)
Rhinorrhoea	8	6 (8.11)	0	0 (0.00)
Dyspnoea	7	6 (8.11)	3	3 (4.05)
Nasal congestion	7	7 (9.46)	0	0 (0.00)
Respiratory failure	6	6 (8.11)	6	6 (8.11)
Respiratory distress	5	4 (5.41)	3	2 (2.70)
Acute respiratory distress syndrome	2	2 (2.70)	2	2 (2.70)
Atelectasis	2	2 (2.70)	1	1 (1.35)
Lung infiltration	2	1 (1.35)	1	1 (1.35)
Pharyngeal erythema	2	2 (2.70)	0	0 (0.00)
Rhinitis allergic	2	2 (2.70)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.70)	0	0 (0.00)
Wheezing	2	2 (2.70)	0	0 (0.00)
Bradypnoea	1	1 (1.35)	1	1 (1.35)
Bronchial oedema	1	1 (1.35)	0	0 (0.00)
Bronchospasm	1	1 (1.35)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.35)	0	0 (0.00)
Haemoptysis	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Laryngeal oedema	1	1 (1.35)	1	1 (1.35)
Lung disorder	1	1 (1.35)	0	0 (0.00)
Nasal discomfort	1	1 (1.35)	0	0 (0.00)
Nasal dryness	1	1 (1.35)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.35)	0	0 (0.00)
Painful respiration	1	1 (1.35)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.35)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.35)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.35)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.35)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.35)	0	0 (0.00)
Productive cough	1	1 (1.35)	0	0 (0.00)
Pulmonary mass	1	1 (1.35)	0	0 (0.00)
Respiratory disorder	1	1 (1.35)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	83	36 (48.65)	7	6 (8.11)
Rash	11	6 (8.11)	0	0 (0.00)
Pruritus	8	6 (8.11)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dry skin	7	6 (8.11)	0	0 (0.00)
Blister	6	3 (4.05)	0	0 (0.00)
Dermatitis atopic	4	3 (4.05)	1	1 (1.35)
Erythema	4	4 (5.41)	0	0 (0.00)
Rash maculo-papular	4	3 (4.05)	1	1 (1.35)
Rash papular	4	3 (4.05)	0	0 (0.00)
Eczema	3	3 (4.05)	1	1 (1.35)
Hyperhidrosis	2	2 (2.70)	0	0 (0.00)
Ingrowing nail	2	2 (2.70)	0	0 (0.00)
Rash macular	2	1 (1.35)	2	1 (1.35)
Rash vesicular	2	1 (1.35)	0	0 (0.00)
Skin discolouration	2	2 (2.70)	0	0 (0.00)
Decubitus ulcer	1	1 (1.35)	1	1 (1.35)
Dermatitis	1	1 (1.35)	0	0 (0.00)
Dermatitis allergic	1	1 (1.35)	0	0 (0.00)
Dermatitis diaper	1	1 (1.35)	0	0 (0.00)
Erythema nodosum	1	1 (1.35)	0	0 (0.00)
Hangnail	1	1 (1.35)	0	0 (0.00)
Miliaria	1	1 (1.35)	0	0 (0.00)
Night sweats	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.35)	0	0 (0.00)
Papule	1	1 (1.35)	0	0 (0.00)
Petechiae	1	1 (1.35)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.35)	0	0 (0.00)
Pruritus allergic	1	1 (1.35)	0	0 (0.00)
Purpura	1	1 (1.35)	0	0 (0.00)
Rash erythematous	1	1 (1.35)	0	0 (0.00)
Rash pruritic	1	1 (1.35)	0	0 (0.00)
Scab	1	1 (1.35)	0	0 (0.00)
Skin lesion	1	1 (1.35)	0	0 (0.00)
Skin swelling	1	1 (1.35)	0	0 (0.00)
Skin ulcer	1	1 (1.35)	0	0 (0.00)
Urticaria	1	1 (1.35)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.35)	1	1 (1.35)
Social circumstances				
- Total	1	1 (1.35)	0	0 (0.00)
Patient uncooperative	1	1 (1.35)	0	0 (0.00)
Surgical and medical procedures				

Timing: At anytime, Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
- Total	1	1 (1.35)	1	1 (1.35)
Thrombolysis	1	1 (1.35)	1	1 (1.35)
Vascular disorders				
- Total	48	32 (43.24)	23	19 (25.68)
Hypotension	25	22 (29.73)	16	14 (18.92)
Hypertension	15	15 (20.27)	4	4 (5.41)
Capillary leak syndrome	2	2 (2.70)	1	1 (1.35)
Venoocclusive disease	2	2 (2.70)	2	2 (2.70)
Flushing	1	1 (1.35)	0	0 (0.00)
Hot flush	1	1 (1.35)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.35)	0	0 (0.00)
Thrombosis	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	22	2 (100.00)	16	2 (100.00)
Blood and lymphatic system disorders				
- Total	2	2 (100.00)	2	2 (100.00)
Febrile neutropenia	1	1 (50.00)	1	1 (50.00)
Pancytopenia	1	1 (50.00)	1	1 (50.00)
Immune system disorders				
- Total	7	2 (100.00)	4	2 (100.00)
Cytokine release syndrome	7	2 (100.00)	4	2 (100.00)
Investigations				
- Total	5	1 (50.00)	5	1 (50.00)
Activated partial thromboplastin time prolonged	1	1 (50.00)	1	1 (50.00)
Alanine aminotransferase increased	1	1 (50.00)	1	1 (50.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Aspartate aminotransferase increased	1	1 (50.00)	1	1 (50.00)
Blood bilirubin increased	1	1 (50.00)	1	1 (50.00)
Blood creatinine increased	1	1 (50.00)	1	1 (50.00)
Metabolism and nutrition disorders				
- Total	3	1 (50.00)	3	1 (50.00)
Hypocalcaemia	1	1 (50.00)	1	1 (50.00)
Hypokalaemia	1	1 (50.00)	1	1 (50.00)
Tumour lysis syndrome	1	1 (50.00)	1	1 (50.00)
Nervous system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Cognitive disorder	1	1 (50.00)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Anxiety	1	1 (50.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (50.00)	1	1 (50.00)
Pleural effusion	1	1 (50.00)	1	1 (50.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Wheezing	1	1 (50.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Capillary leak syndrome	1	1 (50.00)	1	1 (50.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Total number of AE per patient	1729	77 (98.72)	603	65 (83.33)
Blood and lymphatic system disorders				
- Total	123	48 (61.54)	74	37 (47.44)
Anaemia	50	21 (26.92)	20	8 (10.26)
Febrile neutropenia	28	25 (32.05)	28	25 (32.05)
Neutropenia	11	9 (11.54)	9	7 (8.97)
Thrombocytopenia	8	8 (10.26)	8	8 (10.26)
Disseminated intravascular coagulation	7	7 (8.97)	2	2 (2.56)
Coagulopathy	5	5 (6.41)	2	2 (2.56)
Leukopenia	4	3 (3.85)	3	2 (2.56)
Splenomegaly	4	4 (5.13)	0	0 (0.00)
Eosinophilia	2	1 (1.28)	0	0 (0.00)
B-cell aplasia	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Hypofibrinogenaemia	1	1 (1.28)	0	0 (0.00)
Lymphopenia	1	1 (1.28)	1	1 (1.28)
Pancytopenia	1	1 (1.28)	1	1 (1.28)
Cardiac disorders				
- Total	45	24 (30.77)	10	8 (10.26)
Tachycardia	22	17 (21.79)	3	3 (3.85)
Cardiac failure	4	1 (1.28)	2	1 (1.28)
Sinus tachycardia	4	3 (3.85)	0	0 (0.00)
Bradycardia	3	3 (3.85)	0	0 (0.00)
Left ventricular dysfunction	3	3 (3.85)	3	3 (3.85)
Cardiac dysfunction	2	2 (2.56)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.28)	0	0 (0.00)
Cardiac arrest	1	1 (1.28)	1	1 (1.28)
Cardiac failure congestive	1	1 (1.28)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.28)	0	0 (0.00)
Pericardial effusion	1	1 (1.28)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.28)	0	0 (0.00)
Sinus bradycardia	1	1 (1.28)	1	1 (1.28)
Ear and labyrinth disorders				

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
- Total	2	2 (2.56)	0	0 (0.00)
Ear pain	1	1 (1.28)	0	0 (0.00)
Ear pruritus	1	1 (1.28)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.41)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.13)	0	0 (0.00)
Hypothyroidism	1	1 (1.28)	0	0 (0.00)
Eye disorders				
- Total	15	9 (11.54)	0	0 (0.00)
Eyelid oedema	3	2 (2.56)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.56)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.56)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.28)	0	0 (0.00)
Eye oedema	1	1 (1.28)	0	0 (0.00)
Eye pain	1	1 (1.28)	0	0 (0.00)
Periorbital oedema	1	1 (1.28)	0	0 (0.00)
Periorbital swelling	1	1 (1.28)	0	0 (0.00)
Visual field defect	1	1 (1.28)	0	0 (0.00)
Visual impairment	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Gastrointestinal disorders				
- Total	135	51 (65.38)	16	14 (17.95)
Vomiting	30	21 (26.92)	1	1 (1.28)
Nausea	21	18 (23.08)	2	2 (2.56)
Diarrhoea	18	15 (19.23)	1	1 (1.28)
Abdominal pain	13	11 (14.10)	2	2 (2.56)
Constipation	11	11 (14.10)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.13)	2	2 (2.56)
Pancreatitis	4	4 (5.13)	1	1 (1.28)
Abdominal distension	3	3 (3.85)	0	0 (0.00)
Abdominal pain upper	3	3 (3.85)	0	0 (0.00)
Ascites	3	3 (3.85)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.56)	0	0 (0.00)
Stomatitis	2	2 (2.56)	1	1 (1.28)
Abdominal compartment syndrome	1	1 (1.28)	1	1 (1.28)
Anal fissure	1	1 (1.28)	0	0 (0.00)
Anal haemorrhage	1	1 (1.28)	0	0 (0.00)
Dry mouth	1	1 (1.28)	0	0 (0.00)
Dysphagia	1	1 (1.28)	1	1 (1.28)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Enterocolitis	1	1 (1.28)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.28)	0	0 (0.00)
Gingival bleeding	1	1 (1.28)	0	0 (0.00)
Gingival erythema	1	1 (1.28)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.28)	1	1 (1.28)
Haematemesis	1	1 (1.28)	0	0 (0.00)
Ileus	1	1 (1.28)	0	0 (0.00)
Lip dry	1	1 (1.28)	0	0 (0.00)
Lip oedema	1	1 (1.28)	0	0 (0.00)
Melaena	1	1 (1.28)	1	1 (1.28)
Mouth swelling	1	1 (1.28)	0	0 (0.00)
Neutropenic colitis	1	1 (1.28)	1	1 (1.28)
Odynophagia	1	1 (1.28)	0	0 (0.00)
Proctalgia	1	1 (1.28)	1	1 (1.28)
Trichoglossia	1	1 (1.28)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.28)	0	0 (0.00)
General disorders and administration site conditions				
- Total	112	40 (51.28)	19	11 (14.10)
Pyrexia	44	24 (30.77)	9	8 (10.26)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Fatigue	11	11 (14.10)	0	0 (0.00)
Chills	9	6 (7.69)	0	0 (0.00)
Face oedema	9	8 (10.26)	1	1 (1.28)
Oedema peripheral	7	6 (7.69)	2	1 (1.28)
Generalised oedema	5	5 (6.41)	0	0 (0.00)
Catheter site pain	4	2 (2.56)	2	1 (1.28)
Asthenia	2	2 (2.56)	0	0 (0.00)
Catheter site erythema	2	1 (1.28)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.56)	0	0 (0.00)
Influenza like illness	2	2 (2.56)	0	0 (0.00)
Localised oedema	2	2 (2.56)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.56)	2	2 (2.56)
Catheter site haemorrhage	1	1 (1.28)	0	0 (0.00)
Chest discomfort	1	1 (1.28)	1	1 (1.28)
Crying	1	1 (1.28)	0	0 (0.00)
Facial pain	1	1 (1.28)	0	0 (0.00)
Malaise	1	1 (1.28)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.28)	0	0 (0.00)
Pain	1	1 (1.28)	1	1 (1.28)
Sluggishness	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Swelling face	1	1 (1.28)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.28)	1	1 (1.28)
Vascular device occlusion	1	1 (1.28)	0	0 (0.00)
Hepatobiliary disorders				
- Total	29	17 (21.79)	7	6 (7.69)
Hepatic function abnormal	11	5 (6.41)	4	3 (3.85)
Hyperbilirubinaemia	6	5 (6.41)	1	1 (1.28)
Hepatomegaly	3	3 (3.85)	1	1 (1.28)
Cholelithiasis	2	2 (2.56)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.56)	0	0 (0.00)
Hypertransaminasaemia	2	2 (2.56)	0	0 (0.00)
Biliary tract disorder	1	1 (1.28)	0	0 (0.00)
Cholestasis	1	1 (1.28)	1	1 (1.28)
Ocular icterus	1	1 (1.28)	0	0 (0.00)
Immune system disorders				
- Total	157	65 (83.33)	64	41 (52.56)
Cytokine release syndrome	121	59 (75.64)	51	36 (46.15)
Hypogammaglobulinaemia	25	23 (29.49)	7	7 (8.97)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Haemophagocytic lymphohistiocytosis	5	5 (6.41)	3	3 (3.85)
Immunodeficiency	3	3 (3.85)	3	3 (3.85)
Hypersensitivity	1	1 (1.28)	0	0 (0.00)
Seasonal allergy	1	1 (1.28)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.28)	0	0 (0.00)
Infections and infestations				
- Total	64	35 (44.87)	31	19 (24.36)
Conjunctivitis	6	5 (6.41)	0	0 (0.00)
Staphylococcal infection	5	5 (6.41)	2	2 (2.56)
Candida infection	4	3 (3.85)	2	1 (1.28)
Clostridium difficile infection	4	4 (5.13)	3	3 (3.85)
Staphylococcal bacteraemia	4	3 (3.85)	4	3 (3.85)
Encephalitis viral	2	2 (2.56)	2	2 (2.56)
Nail infection	2	2 (2.56)	0	0 (0.00)
Oral candidiasis	2	1 (1.28)	0	0 (0.00)
Oral herpes	2	2 (2.56)	1	1 (1.28)
Oral infection	2	2 (2.56)	0	0 (0.00)
Rhinovirus infection	2	2 (2.56)	0	0 (0.00)
Adenovirus infection	1	1 (1.28)	1	1 (1.28)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Anal abscess	1	1 (1.28)	1	1 (1.28)
Atypical pneumonia	1	1 (1.28)	0	0 (0.00)
BK virus infection	1	1 (1.28)	0	0 (0.00)
Bacteraemia	1	1 (1.28)	1	1 (1.28)
Bronchopulmonary aspergillosis	1	1 (1.28)	1	1 (1.28)
Cholecystitis infective	1	1 (1.28)	0	0 (0.00)
Encephalitis	1	1 (1.28)	1	1 (1.28)
Gastroenteritis norovirus	1	1 (1.28)	0	0 (0.00)
Gingivitis	1	1 (1.28)	0	0 (0.00)
Granulicatella infection	1	1 (1.28)	1	1 (1.28)
Herpes simplex	1	1 (1.28)	1	1 (1.28)
Human herpesvirus 6 infection	1	1 (1.28)	1	1 (1.28)
Klebsiella bacteraemia	1	1 (1.28)	0	0 (0.00)
Klebsiella infection	1	1 (1.28)	1	1 (1.28)
Localised infection	1	1 (1.28)	0	0 (0.00)
Meningitis bacterial	1	1 (1.28)	1	1 (1.28)
Myringitis	1	1 (1.28)	0	0 (0.00)
Otitis externa	1	1 (1.28)	0	0 (0.00)
Paronychia	1	1 (1.28)	0	0 (0.00)
Pneumonia	1	1 (1.28)	1	1 (1.28)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Pneumonia fungal	1	1 (1.28)	1	1 (1.28)
Pneumonia viral	1	1 (1.28)	1	1 (1.28)
Sinusitis	1	1 (1.28)	1	1 (1.28)
Soft tissue infection	1	1 (1.28)	1	1 (1.28)
Stomatococcal infection	1	1 (1.28)	0	0 (0.00)
Systemic candida	1	1 (1.28)	1	1 (1.28)
Urinary tract infection viral	1	1 (1.28)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.28)	1	1 (1.28)
Injury, poisoning and procedural complications				
- Total	20	11 (14.10)	3	2 (2.56)
Infusion related reaction	3	2 (2.56)	0	0 (0.00)
Wound	3	2 (2.56)	1	1 (1.28)
Contusion	2	1 (1.28)	0	0 (0.00)
Fall	2	2 (2.56)	0	0 (0.00)
Procedural pain	2	2 (2.56)	0	0 (0.00)
Transfusion reaction	2	2 (2.56)	0	0 (0.00)
Scratch	1	1 (1.28)	0	0 (0.00)
Skin abrasion	1	1 (1.28)	0	0 (0.00)
Skin injury	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Skin wound	1	1 (1.28)	0	0 (0.00)
Transplant failure	1	1 (1.28)	1	1 (1.28)
Vasoplegia syndrome	1	1 (1.28)	1	1 (1.28)
Investigations				
- Total	381	56 (71.79)	192	44 (56.41)
Platelet count decreased	65	21 (26.92)	38	14 (17.95)
White blood cell count decreased	50	24 (30.77)	36	18 (23.08)
Neutrophil count decreased	48	20 (25.64)	38	17 (21.79)
Aspartate aminotransferase increased	32	18 (23.08)	12	10 (12.82)
Lymphocyte count decreased	30	15 (19.23)	24	13 (16.67)
Alanine aminotransferase increased	25	17 (21.79)	5	5 (6.41)
Blood bilirubin increased	17	11 (14.10)	8	8 (10.26)
International normalised ratio increased	12	9 (11.54)	0	0 (0.00)
Serum ferritin increased	8	8 (10.26)	2	2 (2.56)
Activated partial thromboplastin time prolonged	7	5 (6.41)	0	0 (0.00)
Blood fibrinogen decreased	7	7 (8.97)	2	2 (2.56)
Blood immunoglobulin M decreased	6	6 (7.69)	1	1 (1.28)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Electrocardiogram QT prolonged	6	5 (6.41)	2	2 (2.56)
Blood creatinine increased	5	3 (3.85)	4	2 (2.56)
Blood immunoglobulin A decreased	5	5 (6.41)	0	0 (0.00)
Immunoglobulins decreased	5	2 (2.56)	0	0 (0.00)
Blood creatine phosphokinase increased	4	2 (2.56)	2	2 (2.56)
Blood lactate dehydrogenase increased	4	4 (5.13)	1	1 (1.28)
C-reactive protein increased	4	4 (5.13)	3	3 (3.85)
Lipase increased	4	2 (2.56)	2	1 (1.28)
Weight increased	4	4 (5.13)	1	1 (1.28)
Fibrin D dimer increased	3	3 (3.85)	1	1 (1.28)
Urine output decreased	3	2 (2.56)	3	2 (2.56)
Blood glucose increased	2	1 (1.28)	2	1 (1.28)
Blood immunoglobulin G decreased	2	2 (2.56)	0	0 (0.00)
Blood uric acid increased	2	2 (2.56)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (2.56)	2	2 (2.56)
Haemoglobin decreased	2	1 (1.28)	1	1 (1.28)
Amylase increased	1	1 (1.28)	0	0 (0.00)
Bacterial test positive	1	1 (1.28)	1	1 (1.28)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Blood alkaline phosphatase increased	1	1 (1.28)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.28)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.28)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.28)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.28)	0	0 (0.00)
Cardiac murmur	1	1 (1.28)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.28)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.28)	0	0 (0.00)
Enterovirus test positive	1	1 (1.28)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.28)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.28)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.28)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.28)	0	0 (0.00)
Troponin increased	1	1 (1.28)	1	1 (1.28)
Weight decreased	1	1 (1.28)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	207	45 (57.69)	73	28 (35.90)
Hypokalaemia	39	18 (23.08)	19	10 (12.82)
Hypophosphataemia	31	17 (21.79)	11	9 (11.54)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Decreased appetite	24	24 (30.77)	11	11 (14.10)
Hypocalcaemia	23	15 (19.23)	5	4 (5.13)
Hypoalbuminaemia	19	11 (14.10)	1	1 (1.28)
Hyperglycaemia	11	8 (10.26)	4	4 (5.13)
Hyperuricaemia	9	7 (8.97)	1	1 (1.28)
Hypomagnesaemia	7	6 (7.69)	0	0 (0.00)
Hypervolaemia	6	6 (7.69)	4	4 (5.13)
Hyperphosphataemia	5	5 (6.41)	1	1 (1.28)
Hypercalcaemia	4	3 (3.85)	2	2 (2.56)
Acidosis	3	2 (2.56)	2	2 (2.56)
Hypermagnesaemia	3	2 (2.56)	0	0 (0.00)
Hyponatraemia	3	3 (3.85)	0	0 (0.00)
Metabolic acidosis	3	3 (3.85)	2	2 (2.56)
Tumour lysis syndrome	3	3 (3.85)	3	3 (3.85)
Hyperkalaemia	2	2 (2.56)	2	2 (2.56)
Hypernatraemia	2	2 (2.56)	1	1 (1.28)
Hypertriglyceridaemia	2	2 (2.56)	2	2 (2.56)
Calcium deficiency	1	1 (1.28)	0	0 (0.00)
Dehydration	1	1 (1.28)	0	0 (0.00)
Haemosiderosis	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Hyperchloraemia	1	1 (1.28)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.28)	0	0 (0.00)
Hypoglycaemia	1	1 (1.28)	0	0 (0.00)
Malnutrition	1	1 (1.28)	1	1 (1.28)
Polydipsia	1	1 (1.28)	1	1 (1.28)
Musculoskeletal and connective tissue disorders				
- Total	53	33 (42.31)	6	5 (6.41)
Pain in extremity	11	11 (14.10)	0	0 (0.00)
Arthralgia	10	10 (12.82)	1	1 (1.28)
Myalgia	10	9 (11.54)	0	0 (0.00)
Back pain	7	6 (7.69)	1	1 (1.28)
Bone pain	4	2 (2.56)	0	0 (0.00)
Muscular weakness	2	2 (2.56)	1	1 (1.28)
Pain in jaw	2	2 (2.56)	1	1 (1.28)
Haemarthrosis	1	1 (1.28)	1	1 (1.28)
Muscle rigidity	1	1 (1.28)	0	0 (0.00)
Muscle spasms	1	1 (1.28)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.28)	0	0 (0.00)
Myositis	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Neck pain	1	1 (1.28)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.28)	1	1 (1.28)
Nervous system disorders				
- Total	76	39 (50.00)	14	10 (12.82)
Headache	26	23 (29.49)	2	2 (2.56)
Encephalopathy	8	8 (10.26)	4	4 (5.13)
Tremor	7	6 (7.69)	0	0 (0.00)
Somnolence	5	5 (6.41)	2	2 (2.56)
Cognitive disorder	4	2 (2.56)	1	1 (1.28)
Dizziness	3	3 (3.85)	0	0 (0.00)
Dysgeusia	3	3 (3.85)	0	0 (0.00)
Lethargy	3	3 (3.85)	0	0 (0.00)
Seizure	3	2 (2.56)	1	1 (1.28)
Hyperaesthesia	2	1 (1.28)	0	0 (0.00)
Amnesia	1	1 (1.28)	0	0 (0.00)
Aphasia	1	1 (1.28)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.28)	1	1 (1.28)
Depressed level of consciousness	1	1 (1.28)	1	1 (1.28)
Disturbance in attention	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Dysarthria	1	1 (1.28)	1	1 (1.28)
Generalised tonic-clonic seizure	1	1 (1.28)	0	0 (0.00)
Hypoaesthesia	1	1 (1.28)	0	0 (0.00)
Monoparesis	1	1 (1.28)	0	0 (0.00)
Neuralgia	1	1 (1.28)	0	0 (0.00)
Neurological decompensation	1	1 (1.28)	1	1 (1.28)
Paraesthesia	1	1 (1.28)	0	0 (0.00)
Psychiatric disorders				
- Total	46	27 (34.62)	6	6 (7.69)
Confusional state	7	7 (8.97)	0	0 (0.00)
Delirium	7	7 (8.97)	3	3 (3.85)
Agitation	6	5 (6.41)	0	0 (0.00)
Anxiety	5	5 (6.41)	2	2 (2.56)
Insomnia	4	4 (5.13)	0	0 (0.00)
Hallucination	3	3 (3.85)	0	0 (0.00)
Irritability	3	3 (3.85)	0	0 (0.00)
Mental status changes	3	3 (3.85)	1	1 (1.28)
Sleep disorder	3	2 (2.56)	0	0 (0.00)
Affect lability	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Automatism	1	1 (1.28)	0	0 (0.00)
Hallucination, visual	1	1 (1.28)	0	0 (0.00)
Restlessness	1	1 (1.28)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.28)	0	0 (0.00)
Renal and urinary disorders				
- Total	39	20 (25.64)	13	9 (11.54)
Acute kidney injury	14	9 (11.54)	8	7 (8.97)
Renal failure	4	2 (2.56)	3	1 (1.28)
Dysuria	3	3 (3.85)	0	0 (0.00)
Anuria	2	2 (2.56)	1	1 (1.28)
Haematuria	2	2 (2.56)	0	0 (0.00)
Pollakiuria	2	2 (2.56)	0	0 (0.00)
Urinary incontinence	2	1 (1.28)	0	0 (0.00)
Urinary retention	2	2 (2.56)	0	0 (0.00)
Azotaemia	1	1 (1.28)	0	0 (0.00)
Bladder dilatation	1	1 (1.28)	0	0 (0.00)
Incontinence	1	1 (1.28)	0	0 (0.00)
Micturition urgency	1	1 (1.28)	0	0 (0.00)
Proteinuria	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Renal tubular dysfunction	1	1 (1.28)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.28)	1	1 (1.28)
Urinary tract disorder	1	1 (1.28)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (6.41)	1	1 (1.28)
Vaginal haemorrhage	2	1 (1.28)	0	0 (0.00)
Female genital tract fistula	1	1 (1.28)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.28)	0	0 (0.00)
Perineal rash	1	1 (1.28)	0	0 (0.00)
Vaginal ulceration	1	1 (1.28)	1	1 (1.28)
Respiratory, thoracic and mediastinal disorders				
- Total	112	40 (51.28)	49	22 (28.21)
Hypoxia	23	17 (21.79)	18	12 (15.38)
Pulmonary oedema	12	12 (15.38)	7	7 (8.97)
Cough	11	10 (12.82)	0	0 (0.00)
Tachypnoea	9	8 (10.26)	4	4 (5.13)
Oropharyngeal pain	6	5 (6.41)	0	0 (0.00)
Pleural effusion	6	6 (7.69)	2	2 (2.56)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Atelectasis	5	3 (3.85)	2	2 (2.56)
Epistaxis	4	4 (5.13)	1	1 (1.28)
Respiratory distress	4	3 (3.85)	2	1 (1.28)
Respiratory failure	4	4 (5.13)	4	4 (5.13)
Dyspnoea	3	3 (3.85)	3	3 (3.85)
Nasal congestion	3	3 (3.85)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (2.56)	2	2 (2.56)
Lung infiltration	2	1 (1.28)	1	1 (1.28)
Rhinorrhoea	2	2 (2.56)	0	0 (0.00)
Acute respiratory failure	1	1 (1.28)	1	1 (1.28)
Bradypnoea	1	1 (1.28)	1	1 (1.28)
Haemoptysis	1	1 (1.28)	0	0 (0.00)
Nasal discomfort	1	1 (1.28)	0	0 (0.00)
Nasal dryness	1	1 (1.28)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.28)	0	0 (0.00)
Painful respiration	1	1 (1.28)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.28)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.28)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.28)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Pharyngeal oedema	1	1 (1.28)	0	0 (0.00)
Productive cough	1	1 (1.28)	0	0 (0.00)
Pulmonary mass	1	1 (1.28)	0	0 (0.00)
Respiratory acidosis	1	1 (1.28)	1	1 (1.28)
Respiratory disorder	1	1 (1.28)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	56	27 (34.62)	4	3 (3.85)
Pruritus	7	6 (7.69)	0	0 (0.00)
Blister	6	3 (3.85)	0	0 (0.00)
Rash	5	5 (6.41)	0	0 (0.00)
Erythema	4	4 (5.13)	0	0 (0.00)
Rash papular	4	3 (3.85)	0	0 (0.00)
Hyperhidrosis	3	3 (3.85)	0	0 (0.00)
Rash maculo-papular	3	2 (2.56)	1	1 (1.28)
Dermatitis atopic	2	2 (2.56)	0	0 (0.00)
Petechiae	2	2 (2.56)	1	1 (1.28)
Rash vesicular	2	1 (1.28)	0	0 (0.00)
Skin ulcer	2	2 (2.56)	0	0 (0.00)
Decubitus ulcer	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Dermatitis	1	1 (1.28)	0	0 (0.00)
Dermatitis diaper	1	1 (1.28)	0	0 (0.00)
Dry skin	1	1 (1.28)	0	0 (0.00)
Eczema	1	1 (1.28)	0	0 (0.00)
Erythema nodosum	1	1 (1.28)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.28)	0	0 (0.00)
Pruritus allergic	1	1 (1.28)	0	0 (0.00)
Purpura	1	1 (1.28)	0	0 (0.00)
Rash pruritic	1	1 (1.28)	0	0 (0.00)
Scab	1	1 (1.28)	0	0 (0.00)
Skin discolouration	1	1 (1.28)	0	0 (0.00)
Skin lesion	1	1 (1.28)	0	0 (0.00)
Skin necrosis	1	1 (1.28)	1	1 (1.28)
Urticaria	1	1 (1.28)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.28)	1	1 (1.28)
Social circumstances				
- Total	1	1 (1.28)	0	0 (0.00)
Patient uncooperative	1	1 (1.28)	0	0 (0.00)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (1.28)	1	1 (1.28)
Thrombolysis	1	1 (1.28)	1	1 (1.28)
Vascular disorders				
- Total	44	27 (34.62)	20	16 (20.51)
Hypotension	25	21 (26.92)	16	14 (17.95)
Hypertension	14	13 (16.67)	4	4 (5.13)
Capillary leak syndrome	1	1 (1.28)	0	0 (0.00)
Flushing	1	1 (1.28)	0	0 (0.00)
Hot flush	1	1 (1.28)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.28)	0	0 (0.00)
Thrombosis	1	1 (1.28)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	24	2 (100.00)	13	2 (100.00)
Blood and lymphatic system disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Disseminated intravascular coagulation	1	1 (50.00)	1	1 (50.00)
Cardiac disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Left ventricular dysfunction	1	1 (50.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Peritoneal haematoma	1	1 (50.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
General disorders and administration site conditions				
- Total	1	1 (50.00)	1	1 (50.00)
Pyrexia	1	1 (50.00)	1	1 (50.00)
Hepatobiliary disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Hepatic cytolysis	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	5	2 (100.00)	4	2 (100.00)
Encephalitis	1	1 (50.00)	1	1 (50.00)
Paronychia	1	1 (50.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (50.00)	1	1 (50.00)
Upper respiratory tract infection	1	1 (50.00)	1	1 (50.00)
Viral haemorrhagic cystitis	1	1 (50.00)	1	1 (50.00)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
- Total	1	1 (50.00)	1	1 (50.00)
Weight decreased	1	1 (50.00)	1	1 (50.00)
Metabolism and nutrition disorders				
- Total	3	1 (50.00)	2	1 (50.00)
Decreased appetite	1	1 (50.00)	1	1 (50.00)
Haemochromatosis	1	1 (50.00)	1	1 (50.00)
Hypophosphataemia	1	1 (50.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Growth retardation	1	1 (50.00)	0	0 (0.00)
Nervous system disorders				
- Total	4	1 (50.00)	3	1 (50.00)
Autonomic neuropathy	1	1 (50.00)	1	1 (50.00)
Cerebral haemorrhage	1	1 (50.00)	1	1 (50.00)
Memory impairment	1	1 (50.00)	0	0 (0.00)
Seizure	1	1 (50.00)	1	1 (50.00)
Psychiatric disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
- Total	1	1 (50.00)	0	0 (0.00)
Sleep disorder	1	1 (50.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Renal tubular disorder	1	1 (50.00)	1	1 (50.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Lung disorder	1	1 (50.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Hypotension	1	1 (50.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Total number of AE per patient	510	67 (91.78)	133	34 (46.58)
Blood and lymphatic system disorders				
- Total	31	16 (21.92)	16	9 (12.33)
Anaemia	12	6 (8.22)	4	2 (2.74)
Neutropenia	5	5 (6.85)	5	5 (6.85)
Febrile neutropenia	4	3 (4.11)	4	3 (4.11)
B-cell aplasia	2	1 (1.37)	0	0 (0.00)
Thrombocytopenia	2	2 (2.74)	2	2 (2.74)
Eosinophilia	1	1 (1.37)	0	0 (0.00)
Leukocytosis	1	1 (1.37)	0	0 (0.00)
Leukopenia	1	1 (1.37)	0	0 (0.00)
Lymphadenopathy	1	1 (1.37)	0	0 (0.00)
Lymphocytosis	1	1 (1.37)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Lymphopenia	1	1 (1.37)	1	1 (1.37)
Cardiac disorders				
- Total	7	6 (8.22)	4	3 (4.11)
Cardiac arrest	2	2 (2.74)	2	2 (2.74)
Cardiac failure	2	2 (2.74)	2	2 (2.74)
Tachycardia	2	2 (2.74)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.37)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.37)	0	0 (0.00)
Hypothyroidism	1	1 (1.37)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.48)	0	0 (0.00)
Cataract	2	2 (2.74)	0	0 (0.00)
Hypermetropia	1	1 (1.37)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.37)	0	0 (0.00)
Visual impairment	1	1 (1.37)	0	0 (0.00)
Gastrointestinal disorders				
- Total	37	19 (26.03)	1	1 (1.37)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Diarrhoea	7	7 (9.59)	0	0 (0.00)
Vomiting	7	6 (8.22)	0	0 (0.00)
Nausea	5	5 (6.85)	0	0 (0.00)
Constipation	4	3 (4.11)	0	0 (0.00)
Abdominal pain	2	2 (2.74)	0	0 (0.00)
Pancreatitis	2	2 (2.74)	1	1 (1.37)
Abdominal pain upper	1	1 (1.37)	0	0 (0.00)
Abdominal rigidity	1	1 (1.37)	0	0 (0.00)
Dyspepsia	1	1 (1.37)	0	0 (0.00)
Enteritis	1	1 (1.37)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.37)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.37)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.37)	0	0 (0.00)
Proctalgia	1	1 (1.37)	0	0 (0.00)
Stomatitis	1	1 (1.37)	0	0 (0.00)
Trichoglossia	1	1 (1.37)	0	0 (0.00)
General disorders and administration site conditions				
- Total	30	23 (31.51)	2	2 (2.74)
Pyrexia	15	14 (19.18)	1	1 (1.37)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Fatigue	7	6 (8.22)	0	0 (0.00)
Oedema peripheral	2	1 (1.37)	0	0 (0.00)
Pain	2	2 (2.74)	1	1 (1.37)
Asthenia	1	1 (1.37)	0	0 (0.00)
Chills	1	1 (1.37)	0	0 (0.00)
Malaise	1	1 (1.37)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.37)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (2.74)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.37)	0	0 (0.00)
Liver disorder	1	1 (1.37)	0	0 (0.00)
Immune system disorders				
- Total	18	15 (20.55)	5	4 (5.48)
Hypogammaglobulinaemia	11	9 (12.33)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.74)	1	1 (1.37)
Graft versus host disease	2	2 (2.74)	2	2 (2.74)
Drug hypersensitivity	1	1 (1.37)	0	0 (0.00)
Engraftment syndrome	1	1 (1.37)	1	1 (1.37)
Immunodeficiency	1	1 (1.37)	1	1 (1.37)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Infections and infestations				
- Total	108	37 (50.68)	41	18 (24.66)
Nasopharyngitis	9	7 (9.59)	0	0 (0.00)
Upper respiratory tract infection	9	7 (9.59)	1	1 (1.37)
Bronchopulmonary aspergillosis	5	1 (1.37)	3	1 (1.37)
Gastroenteritis	5	5 (6.85)	2	2 (2.74)
Parainfluenzae virus infection	5	4 (5.48)	2	2 (2.74)
Rhinovirus infection	5	5 (6.85)	1	1 (1.37)
Sinusitis	4	3 (4.11)	1	1 (1.37)
Bacteraemia	3	2 (2.74)	2	1 (1.37)
Ear infection	3	2 (2.74)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.11)	3	3 (4.11)
Otitis media	3	3 (4.11)	1	1 (1.37)
Pneumonia	3	3 (4.11)	1	1 (1.37)
Respiratory tract infection	3	3 (4.11)	0	0 (0.00)
Klebsiella infection	2	1 (1.37)	2	1 (1.37)
Otitis externa	2	2 (2.74)	1	1 (1.37)
Pneumocystis jirovecii pneumonia	2	2 (2.74)	2	2 (2.74)
Respiratory syncytial virus infection	2	2 (2.74)	1	1 (1.37)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Rhinitis	2	2 (2.74)	0	0 (0.00)
Urinary tract infection	2	1 (1.37)	2	1 (1.37)
Viral infection	2	2 (2.74)	1	1 (1.37)
Acute sinusitis	1	1 (1.37)	0	0 (0.00)
Adenovirus infection	1	1 (1.37)	1	1 (1.37)
BK virus infection	1	1 (1.37)	1	1 (1.37)
Cellulitis	1	1 (1.37)	0	0 (0.00)
Conjunctivitis	1	1 (1.37)	0	0 (0.00)
Coronavirus infection	1	1 (1.37)	1	1 (1.37)
Cystitis	1	1 (1.37)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.37)	1	1 (1.37)
Device related infection	1	1 (1.37)	1	1 (1.37)
Ear, nose and throat infection	1	1 (1.37)	0	0 (0.00)
Enterobacter infection	1	1 (1.37)	1	1 (1.37)
Gastroenteritis clostridial	1	1 (1.37)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.37)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.37)	0	0 (0.00)
Gingivitis	1	1 (1.37)	0	0 (0.00)
Herpes simplex	1	1 (1.37)	0	0 (0.00)
Herpes zoster	1	1 (1.37)	1	1 (1.37)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Human herpesvirus 6 infection	1	1 (1.37)	1	1 (1.37)
Influenza	1	1 (1.37)	0	0 (0.00)
Mastoiditis	1	1 (1.37)	1	1 (1.37)
Molluscum contagiosum	1	1 (1.37)	0	0 (0.00)
Nail infection	1	1 (1.37)	0	0 (0.00)
Oral candidiasis	1	1 (1.37)	0	0 (0.00)
Oral herpes	1	1 (1.37)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.37)	1	1 (1.37)
Respiratory tract infection viral	1	1 (1.37)	0	0 (0.00)
Salmonellosis	1	1 (1.37)	0	0 (0.00)
Septic shock	1	1 (1.37)	1	1 (1.37)
Sinusitis fungal	1	1 (1.37)	1	1 (1.37)
Staphylococcal bacteraemia	1	1 (1.37)	1	1 (1.37)
Staphylococcal sepsis	1	1 (1.37)	1	1 (1.37)
Staphylococcal skin infection	1	1 (1.37)	0	0 (0.00)
Tinea pedis	1	1 (1.37)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.37)	1	1 (1.37)
Injury, poisoning and procedural complications				
- Total	10	9 (12.33)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Infusion related reaction	4	3 (4.11)	0	0 (0.00)
Contusion	1	1 (1.37)	0	0 (0.00)
Fibula fracture	1	1 (1.37)	0	0 (0.00)
Ligament sprain	1	1 (1.37)	0	0 (0.00)
Limb injury	1	1 (1.37)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.37)	0	0 (0.00)
Skin abrasion	1	1 (1.37)	0	0 (0.00)
Investigations				
- Total	90	29 (39.73)	34	15 (20.55)
Neutrophil count decreased	19	10 (13.70)	11	7 (9.59)
White blood cell count decreased	18	10 (13.70)	4	4 (5.48)
Platelet count decreased	16	5 (6.85)	9	2 (2.74)
Lymphocyte count decreased	6	4 (5.48)	2	2 (2.74)
Immunoglobulins decreased	5	1 (1.37)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.74)	1	1 (1.37)
Alanine aminotransferase increased	3	2 (2.74)	1	1 (1.37)
Weight increased	3	1 (1.37)	1	1 (1.37)
Blood immunoglobulin A decreased	2	2 (2.74)	1	1 (1.37)
Blood uric acid increased	2	2 (2.74)	2	2 (2.74)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Blood creatinine increased	1	1 (1.37)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.37)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.37)	1	1 (1.37)
Blood lactate dehydrogenase increased	1	1 (1.37)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.37)	0	0 (0.00)
Blood urea increased	1	1 (1.37)	1	1 (1.37)
Bone density decreased	1	1 (1.37)	0	0 (0.00)
C-reactive protein increased	1	1 (1.37)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.37)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.37)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.37)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.37)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	23	14 (19.18)	8	6 (8.22)
Hypokalaemia	6	3 (4.11)	4	2 (2.74)
Decreased appetite	5	5 (6.85)	0	0 (0.00)
Hyperuricaemia	3	3 (4.11)	0	0 (0.00)
Hyperchloraemia	1	1 (1.37)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Hyperkalaemia	1	1 (1.37)	0	0 (0.00)
Hypervolaemia	1	1 (1.37)	1	1 (1.37)
Hypophagia	1	1 (1.37)	0	0 (0.00)
Iron overload	1	1 (1.37)	0	0 (0.00)
Malnutrition	1	1 (1.37)	1	1 (1.37)
Metabolic acidosis	1	1 (1.37)	1	1 (1.37)
Metabolic syndrome	1	1 (1.37)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.37)	1	1 (1.37)
Musculoskeletal and connective tissue disorders				
- Total	21	14 (19.18)	3	3 (4.11)
Back pain	7	6 (8.22)	2	2 (2.74)
Pain in extremity	5	5 (6.85)	1	1 (1.37)
Arthralgia	3	3 (4.11)	0	0 (0.00)
Bone pain	2	2 (2.74)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.37)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.37)	0	0 (0.00)
Myalgia	1	1 (1.37)	0	0 (0.00)
Neck pain	1	1 (1.37)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.48)	1	1 (1.37)
Skin papilloma	2	2 (2.74)	0	0 (0.00)
Cancer pain	1	1 (1.37)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.37)	1	1 (1.37)
Nervous system disorders				
- Total	19	13 (17.81)	3	1 (1.37)
Headache	11	10 (13.70)	0	0 (0.00)
Hydrocephalus	3	1 (1.37)	3	1 (1.37)
Dizziness	2	1 (1.37)	0	0 (0.00)
Migraine	2	1 (1.37)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.37)	0	0 (0.00)
Psychiatric disorders				
- Total	14	9 (12.33)	1	1 (1.37)
Anxiety	6	6 (8.22)	0	0 (0.00)
Mental status changes	2	2 (2.74)	1	1 (1.37)
Agitation	1	1 (1.37)	0	0 (0.00)
Delirium	1	1 (1.37)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Mood altered	1	1 (1.37)	0	0 (0.00)
Nightmare	1	1 (1.37)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.37)	0	0 (0.00)
Tearfulness	1	1 (1.37)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (5.48)	2	2 (2.74)
Acute kidney injury	3	3 (4.11)	1	1 (1.37)
Cystitis haemorrhagic	1	1 (1.37)	0	0 (0.00)
Dysuria	1	1 (1.37)	0	0 (0.00)
Haematuria	1	1 (1.37)	1	1 (1.37)
Kidney enlargement	1	1 (1.37)	0	0 (0.00)
Renal mass	1	1 (1.37)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (1.37)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.37)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	45	23 (31.51)	6	6 (8.22)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Cough	14	11 (15.07)	0	0 (0.00)
Nasal congestion	7	6 (8.22)	0	0 (0.00)
Epistaxis	3	3 (4.11)	0	0 (0.00)
Hypoxia	3	3 (4.11)	3	3 (4.11)
Rhinorrhoea	3	3 (4.11)	0	0 (0.00)
Dyspnoea	2	1 (1.37)	0	0 (0.00)
Oropharyngeal pain	2	2 (2.74)	0	0 (0.00)
Pleural effusion	2	2 (2.74)	0	0 (0.00)
Rhinitis allergic	2	2 (2.74)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.37)	1	1 (1.37)
Bronchial oedema	1	1 (1.37)	0	0 (0.00)
Bronchospasm	1	1 (1.37)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.37)	0	0 (0.00)
Respiratory distress	1	1 (1.37)	1	1 (1.37)
Respiratory failure	1	1 (1.37)	1	1 (1.37)
Upper respiratory tract inflammation	1	1 (1.37)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	29	20 (27.40)	1	1 (1.37)
Dry skin	7	6 (8.22)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Rash	6	4 (5.48)	0	0 (0.00)
Ingrowing nail	2	2 (2.74)	0	0 (0.00)
Pruritus	2	1 (1.37)	0	0 (0.00)
Decubitus ulcer	1	1 (1.37)	1	1 (1.37)
Dermatitis allergic	1	1 (1.37)	0	0 (0.00)
Dermatitis atopic	1	1 (1.37)	0	0 (0.00)
Eczema	1	1 (1.37)	0	0 (0.00)
Erythema	1	1 (1.37)	0	0 (0.00)
Hangnail	1	1 (1.37)	0	0 (0.00)
Miliaria	1	1 (1.37)	0	0 (0.00)
Night sweats	1	1 (1.37)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.37)	0	0 (0.00)
Skin discolouration	1	1 (1.37)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.37)	0	0 (0.00)
Skin swelling	1	1 (1.37)	0	0 (0.00)
Vascular disorders				
- Total	6	5 (6.85)	5	5 (6.85)
Hypotension	3	3 (4.11)	3	3 (4.11)
Venoocclusive disease	2	2 (2.74)	2	2 (2.74)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=73 n (%)[1]	Grade >= 3 Total events	All patients N=73 n (%)[2]
Hypertension	1	1 (1.37)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	15	2 (100.00)	3	1 (50.00)
Endocrine disorders				
- Total	2	1 (50.00)	0	0 (0.00)
Delayed puberty	1	1 (50.00)	0	0 (0.00)
Hypothyroidism	1	1 (50.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Dry eye	1	1 (50.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	1 (50.00)	0	0 (0.00)
Diarrhoea	1	1 (50.00)	0	0 (0.00)
Nausea	1	1 (50.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Vomiting	1	1 (50.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (50.00)	0	0 (0.00)
Fatigue	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Seasonal allergy	1	1 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	1	1 (50.00)	1	1 (50.00)
Sepsis	1	1 (50.00)	1	1 (50.00)
Metabolism and nutrition disorders				
- Total	2	1 (50.00)	2	1 (50.00)
Decreased appetite	2	1 (50.00)	2	1 (50.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Osteopenia	1	1 (50.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Nervous system disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Dysarthria	1	1 (50.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (50.00)	0	0 (0.00)
Cough	1	1 (50.00)	0	0 (0.00)
Rhinorrhoea	1	1 (50.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Total number of AE per patient	205	30 (62.50)	60	18 (37.50)
Blood and lymphatic system disorders				
- Total	6	4 (8.33)	2	2 (4.17)
Agranulocytosis	1	1 (2.08)	1	1 (2.08)
Anaemia	1	1 (2.08)	0	0 (0.00)
Hypercoagulation	1	1 (2.08)	0	0 (0.00)
Lymphadenopathy	1	1 (2.08)	0	0 (0.00)
Neutropenia	1	1 (2.08)	1	1 (2.08)
Thrombocytopenia	1	1 (2.08)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.08)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.08)	0	0 (0.00)
Deafness unilateral	1	1 (2.08)	0	0 (0.00)
Eye disorders				
- Total	3	2 (4.17)	1	1 (2.08)
Eye pain	1	1 (2.08)	1	1 (2.08)
Eyelid oedema	1	1 (2.08)	0	0 (0.00)
Mydriasis	1	1 (2.08)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	6 (12.50)	1	1 (2.08)
Diarrhoea	4	4 (8.33)	1	1 (2.08)
Constipation	1	1 (2.08)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.08)	0	0 (0.00)
General disorders and administration site conditions				
- Total	12	8 (16.67)	2	2 (4.17)
Pyrexia	7	5 (10.42)	1	1 (2.08)
Pain	2	2 (4.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (2.08)	1	1 (2.08)
Non-cardiac chest pain	1	1 (2.08)	0	0 (0.00)
Xerosis	1	1 (2.08)	0	0 (0.00)
Immune system disorders				
- Total	9	8 (16.67)	3	2 (4.17)
Hypogammaglobulinaemia	3	3 (6.25)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.17)	1	1 (2.08)
Seasonal allergy	2	2 (4.17)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.08)	1	1 (2.08)
Haemophagocytic lymphohistiocytosis	1	1 (2.08)	1	1 (2.08)
Infections and infestations				
- Total	85	22 (45.83)	25	13 (27.08)
Sinusitis	9	6 (12.50)	0	0 (0.00)
Upper respiratory tract infection	7	5 (10.42)	1	1 (2.08)
Conjunctivitis	5	4 (8.33)	0	0 (0.00)
Rhinovirus infection	4	4 (8.33)	1	1 (2.08)
COVID-19	3	2 (4.17)	1	1 (2.08)
Fungal infection	3	2 (4.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Otitis media	3	2 (4.17)	0	0 (0.00)
Skin infection	3	3 (6.25)	0	0 (0.00)
Bronchitis	2	2 (4.17)	0	0 (0.00)
Device related sepsis	2	1 (2.08)	2	1 (2.08)
Gastroenteritis viral	2	1 (2.08)	0	0 (0.00)
Herpes zoster	2	2 (4.17)	1	1 (2.08)
Influenza	2	2 (4.17)	1	1 (2.08)
Oral herpes	2	2 (4.17)	0	0 (0.00)
Pneumonia	2	2 (4.17)	2	2 (4.17)
Sepsis	2	2 (4.17)	2	2 (4.17)
Urinary tract infection	2	2 (4.17)	0	0 (0.00)
Acute sinusitis	1	1 (2.08)	0	0 (0.00)
Bronchiolitis	1	1 (2.08)	1	1 (2.08)
COVID-19 pneumonia	1	1 (2.08)	1	1 (2.08)
Candida infection	1	1 (2.08)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.08)	1	1 (2.08)
Ear infection	1	1 (2.08)	1	1 (2.08)
Enterovirus infection	1	1 (2.08)	1	1 (2.08)
Folliculitis	1	1 (2.08)	0	0 (0.00)
Fungal skin infection	1	1 (2.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Gastroenteritis	1	1 (2.08)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.08)	1	1 (2.08)
Gastroenteritis salmonella	1	1 (2.08)	1	1 (2.08)
Herpes virus infection	1	1 (2.08)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.08)	1	1 (2.08)
Nail infection	1	1 (2.08)	0	0 (0.00)
Neutropenic infection	1	1 (2.08)	1	1 (2.08)
Ophthalmic herpes zoster	1	1 (2.08)	0	0 (0.00)
Oral candidiasis	1	1 (2.08)	0	0 (0.00)
Otitis media acute	1	1 (2.08)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.08)	1	1 (2.08)
Pneumonia respiratory syncytial viral	1	1 (2.08)	1	1 (2.08)
Rhinitis	1	1 (2.08)	0	0 (0.00)
Septic shock	1	1 (2.08)	1	1 (2.08)
Staphylococcal abscess	1	1 (2.08)	1	1 (2.08)
Staphylococcal bacteraemia	1	1 (2.08)	1	1 (2.08)
Streptococcal sepsis	1	1 (2.08)	0	0 (0.00)
Syphilis	1	1 (2.08)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.08)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Viral skin infection	1	1 (2.08)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (6.25)	1	1 (2.08)
Abdominal injury	1	1 (2.08)	0	0 (0.00)
Infusion related reaction	1	1 (2.08)	1	1 (2.08)
Ligament sprain	1	1 (2.08)	0	0 (0.00)
Investigations				
- Total	16	6 (12.50)	6	2 (4.17)
Neutrophil count decreased	8	3 (6.25)	5	1 (2.08)
Blood bilirubin increased	3	1 (2.08)	0	0 (0.00)
Platelet count decreased	2	2 (4.17)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.08)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.08)	1	1 (2.08)
SARS-CoV-2 test positive	1	1 (2.08)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	5 (10.42)	3	3 (6.25)
Iron overload	2	1 (2.08)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hyperglycaemia	1	1 (2.08)	1	1 (2.08)
Hyperlipidaemia	1	1 (2.08)	0	0 (0.00)
Hypernatraemia	1	1 (2.08)	1	1 (2.08)
Hypertriglyceridaemia	1	1 (2.08)	0	0 (0.00)
Obesity	1	1 (2.08)	1	1 (2.08)
Musculoskeletal and connective tissue disorders				
- Total	7	6 (12.50)	0	0 (0.00)
Pain in extremity	2	2 (4.17)	0	0 (0.00)
Arthralgia	1	1 (2.08)	0	0 (0.00)
Growth retardation	1	1 (2.08)	0	0 (0.00)
Joint effusion	1	1 (2.08)	0	0 (0.00)
Osteonecrosis	1	1 (2.08)	0	0 (0.00)
Synovitis	1	1 (2.08)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.08)	1	1 (2.08)
Bone giant cell tumour benign	2	1 (2.08)	1	1 (2.08)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
- Total	8	3 (6.25)	3	2 (4.17)
Headache	3	2 (4.17)	1	1 (2.08)
Seizure	3	1 (2.08)	1	1 (2.08)
Nervous system disorder	2	1 (2.08)	1	1 (2.08)
Psychiatric disorders				
- Total	3	3 (6.25)	0	0 (0.00)
Anxiety	2	2 (4.17)	0	0 (0.00)
Tic	1	1 (2.08)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.08)	1	1 (2.08)
Endometriosis	2	1 (2.08)	1	1 (2.08)
Respiratory, thoracic and mediastinal disorders				
- Total	21	9 (18.75)	6	4 (8.33)
Cough	3	3 (6.25)	0	0 (0.00)
Dyspnoea	3	3 (6.25)	1	1 (2.08)
Rhinorrhoea	2	2 (4.17)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Tachypnoea	2	1 (2.08)	2	1 (2.08)
Dyspnoea exertional	1	1 (2.08)	0	0 (0.00)
Epistaxis	1	1 (2.08)	0	0 (0.00)
Hypoxia	1	1 (2.08)	1	1 (2.08)
Laryngeal oedema	1	1 (2.08)	1	1 (2.08)
Oropharyngeal pain	1	1 (2.08)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.08)	0	0 (0.00)
Pleural effusion	1	1 (2.08)	0	0 (0.00)
Respiratory failure	1	1 (2.08)	1	1 (2.08)
Wheezing	1	1 (2.08)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (14.58)	4	3 (6.25)
Rash	2	2 (4.17)	0	0 (0.00)
Rash macular	2	1 (2.08)	2	1 (2.08)
Dermatitis atopic	1	1 (2.08)	1	1 (2.08)
Dry skin	1	1 (2.08)	0	0 (0.00)
Eczema	1	1 (2.08)	1	1 (2.08)
Papule	1	1 (2.08)	0	0 (0.00)
Rash erythematous	1	1 (2.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Rash maculo-papular	1	1 (2.08)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.17)	1	1 (2.08)
Hypertension	2	2 (4.17)	1	1 (2.08)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Total number of AE per patient	61	2 (100.00)	32	2 (100.00)
Blood and lymphatic system disorders				
- Total	3	2 (100.00)	3	2 (100.00)
Disseminated intravascular coagulation	1	1 (50.00)	1	1 (50.00)
Febrile neutropenia	1	1 (50.00)	1	1 (50.00)
Pancytopenia	1	1 (50.00)	1	1 (50.00)
Cardiac disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Left ventricular dysfunction	1	1 (50.00)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Delayed puberty	1	1 (50.00)	0	0 (0.00)
Hypothyroidism	1	1 (50.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (50.00)	0	0 (0.00)
Dry eye	1	1 (50.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	2 (100.00)	0	0 (0.00)
Diarrhoea	1	1 (50.00)	0	0 (0.00)
Nausea	1	1 (50.00)	0	0 (0.00)
Peritoneal haematoma	1	1 (50.00)	0	0 (0.00)
Vomiting	1	1 (50.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	1 (50.00)	1	1 (50.00)
Fatigue	1	1 (50.00)	0	0 (0.00)
Pyrexia	1	1 (50.00)	1	1 (50.00)
Hepatobiliary disorders				
- Total	1	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Hepatic cytolysis	1	1 (50.00)	0	0 (0.00)
Immune system disorders				
- Total	9	2 (100.00)	4	2 (100.00)
Cytokine release syndrome	7	2 (100.00)	4	2 (100.00)
Hypogammaglobulinaemia	1	1 (50.00)	0	0 (0.00)
Seasonal allergy	1	1 (50.00)	0	0 (0.00)
Infections and infestations				
- Total	6	2 (100.00)	5	2 (100.00)
Encephalitis	1	1 (50.00)	1	1 (50.00)
Paronychia	1	1 (50.00)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (50.00)	1	1 (50.00)
Sepsis	1	1 (50.00)	1	1 (50.00)
Upper respiratory tract infection	1	1 (50.00)	1	1 (50.00)
Viral haemorrhagic cystitis	1	1 (50.00)	1	1 (50.00)
Investigations				
- Total	6	2 (100.00)	6	2 (100.00)
Activated partial thromboplastin time prolonged	1	1 (50.00)	1	1 (50.00)
Alanine aminotransferase increased	1	1 (50.00)	1	1 (50.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Aspartate aminotransferase increased	1	1 (50.00)	1	1 (50.00)
Blood bilirubin increased	1	1 (50.00)	1	1 (50.00)
Blood creatinine increased	1	1 (50.00)	1	1 (50.00)
Weight decreased	1	1 (50.00)	1	1 (50.00)
Metabolism and nutrition disorders				
- Total	8	2 (100.00)	7	2 (100.00)
Decreased appetite	3	1 (50.00)	3	1 (50.00)
Haemochromatosis	1	1 (50.00)	1	1 (50.00)
Hypocalcaemia	1	1 (50.00)	1	1 (50.00)
Hypokalaemia	1	1 (50.00)	1	1 (50.00)
Hypophosphataemia	1	1 (50.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (50.00)	1	1 (50.00)
Musculoskeletal and connective tissue disorders				
- Total	2	1 (50.00)	0	0 (0.00)
Growth retardation	1	1 (50.00)	0	0 (0.00)
Osteopenia	1	1 (50.00)	0	0 (0.00)
Nervous system disorders				

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
- Total	6	2 (100.00)	3	1 (50.00)
Autonomic neuropathy	1	1 (50.00)	1	1 (50.00)
Cerebral haemorrhage	1	1 (50.00)	1	1 (50.00)
Cognitive disorder	1	1 (50.00)	0	0 (0.00)
Dysarthria	1	1 (50.00)	0	0 (0.00)
Memory impairment	1	1 (50.00)	0	0 (0.00)
Seizure	1	1 (50.00)	1	1 (50.00)
Psychiatric disorders				
- Total	2	2 (100.00)	0	0 (0.00)
Anxiety	1	1 (50.00)	0	0 (0.00)
Sleep disorder	1	1 (50.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (50.00)	1	1 (50.00)
Renal tubular disorder	1	1 (50.00)	1	1 (50.00)
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (100.00)	1	1 (50.00)
Cough	1	1 (50.00)	0	0 (0.00)
Lung disorder	1	1 (50.00)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All grades Total events	All patients N=2 n (%)[1]	Grade >= 3 Total events	All patients N=2 n (%)[2]
Pleural effusion	1	1 (50.00)	1	1 (50.00)
Rhinorrhoea	1	1 (50.00)	0	0 (0.00)
Wheezing	1	1 (50.00)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (100.00)	1	1 (50.00)
Capillary leak syndrome	1	1 (50.00)	1	1 (50.00)
Hypotension	1	1 (50.00)	0	0 (0.00)

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Table 250f
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Total number of AE per patient	2444	78 (100.00)	796	71 (91.03)
Blood and lymphatic system disorders				
- Total	160	53 (67.95)	92	41 (52.56)
Anaemia	63	25 (32.05)	24	9 (11.54)
Febrile neutropenia	32	26 (33.33)	32	26 (33.33)
Neutropenia	17	11 (14.10)	15	9 (11.54)
Thrombocytopenia	11	9 (11.54)	10	9 (11.54)
Disseminated intravascular coagulation	7	7 (8.97)	2	2 (2.56)
Coagulopathy	5	5 (6.41)	2	2 (2.56)
Leukopenia	5	3 (3.85)	3	2 (2.56)
Splenomegaly	4	4 (5.13)	0	0 (0.00)
B-cell aplasia	3	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Eosinophilia	3	1 (1.28)	0	0 (0.00)
Lymphadenopathy	2	2 (2.56)	0	0 (0.00)
Lymphopenia	2	2 (2.56)	2	2 (2.56)
Agranulocytosis	1	1 (1.28)	1	1 (1.28)
Hypercoagulation	1	1 (1.28)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.28)	0	0 (0.00)
Leukocytosis	1	1 (1.28)	0	0 (0.00)
Lymphocytosis	1	1 (1.28)	0	0 (0.00)
Pancytopenia	1	1 (1.28)	1	1 (1.28)
Cardiac disorders				
- Total	52	27 (34.62)	14	11 (14.10)
Tachycardia	24	17 (21.79)	3	3 (3.85)
Cardiac failure	6	3 (3.85)	4	3 (3.85)
Sinus tachycardia	4	3 (3.85)	0	0 (0.00)
Bradycardia	3	3 (3.85)	0	0 (0.00)
Cardiac arrest	3	3 (3.85)	3	3 (3.85)
Left ventricular dysfunction	3	3 (3.85)	3	3 (3.85)
Cardiac dysfunction	2	2 (2.56)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Cardiac failure congestive	1	1 (1.28)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.28)	0	0 (0.00)
Pericardial effusion	1	1 (1.28)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.28)	0	0 (0.00)
Sinus bradycardia	1	1 (1.28)	1	1 (1.28)
Tricuspid valve incompetence	1	1 (1.28)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.28)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.28)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (3.85)	0	0 (0.00)
Deafness unilateral	1	1 (1.28)	0	0 (0.00)
Ear pain	1	1 (1.28)	0	0 (0.00)
Ear pruritus	1	1 (1.28)	0	0 (0.00)
Endocrine disorders				
- Total	6	6 (7.69)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.13)	0	0 (0.00)
Hypothyroidism	2	2 (2.56)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Eye disorders				
- Total	23	14 (17.95)	1	1 (1.28)
Eyelid oedema	4	3 (3.85)	0	0 (0.00)
Ocular hyperaemia	3	3 (3.85)	0	0 (0.00)
Cataract	2	2 (2.56)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.56)	0	0 (0.00)
Eye pain	2	2 (2.56)	1	1 (1.28)
Retinal haemorrhage	2	1 (1.28)	0	0 (0.00)
Visual impairment	2	2 (2.56)	0	0 (0.00)
Eye oedema	1	1 (1.28)	0	0 (0.00)
Hypermetropia	1	1 (1.28)	0	0 (0.00)
Mydriasis	1	1 (1.28)	0	0 (0.00)
Periorbital oedema	1	1 (1.28)	0	0 (0.00)
Periorbital swelling	1	1 (1.28)	0	0 (0.00)
Visual field defect	1	1 (1.28)	0	0 (0.00)
Gastrointestinal disorders				
- Total	178	58 (74.36)	18	16 (20.51)
Vomiting	37	25 (32.05)	1	1 (1.28)
Diarrhoea	29	25 (32.05)	2	2 (2.56)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Nausea	26	21 (26.92)	2	2 (2.56)
Constipation	16	14 (17.95)	0	0 (0.00)
Abdominal pain	15	11 (14.10)	2	2 (2.56)
Pancreatitis	6	6 (7.69)	2	2 (2.56)
Mouth haemorrhage	5	5 (6.41)	2	2 (2.56)
Abdominal pain upper	4	4 (5.13)	0	0 (0.00)
Abdominal distension	3	3 (3.85)	0	0 (0.00)
Ascites	3	3 (3.85)	0	0 (0.00)
Stomatitis	3	3 (3.85)	1	1 (1.28)
Gastrointestinal sounds abnormal	2	2 (2.56)	0	0 (0.00)
Proctalgia	2	2 (2.56)	1	1 (1.28)
Trichoglossia	2	2 (2.56)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.28)	1	1 (1.28)
Abdominal rigidity	1	1 (1.28)	0	0 (0.00)
Anal fissure	1	1 (1.28)	0	0 (0.00)
Anal haemorrhage	1	1 (1.28)	0	0 (0.00)
Dry mouth	1	1 (1.28)	0	0 (0.00)
Dyspepsia	1	1 (1.28)	0	0 (0.00)
Dysphagia	1	1 (1.28)	1	1 (1.28)
Enteritis	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Enterocolitis	1	1 (1.28)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.28)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.28)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.28)	0	0 (0.00)
Gingival bleeding	1	1 (1.28)	0	0 (0.00)
Gingival erythema	1	1 (1.28)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.28)	1	1 (1.28)
Haematemesis	1	1 (1.28)	0	0 (0.00)
Ileus	1	1 (1.28)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.28)	0	0 (0.00)
Lip dry	1	1 (1.28)	0	0 (0.00)
Lip oedema	1	1 (1.28)	0	0 (0.00)
Melaena	1	1 (1.28)	1	1 (1.28)
Mouth swelling	1	1 (1.28)	0	0 (0.00)
Neutropenic colitis	1	1 (1.28)	1	1 (1.28)
Odynophagia	1	1 (1.28)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.28)	0	0 (0.00)
General disorders and administration site conditions				
- Total	154	52 (66.67)	23	14 (17.95)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Pyrexia	66	34 (43.59)	11	10 (12.82)
Fatigue	18	16 (20.51)	0	0 (0.00)
Chills	10	7 (8.97)	0	0 (0.00)
Face oedema	9	8 (10.26)	1	1 (1.28)
Oedema peripheral	9	7 (8.97)	2	1 (1.28)
Generalised oedema	5	5 (6.41)	0	0 (0.00)
Pain	5	5 (6.41)	2	2 (2.56)
Catheter site pain	4	2 (2.56)	2	1 (1.28)
Asthenia	3	3 (3.85)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (3.85)	3	3 (3.85)
Catheter site erythema	2	1 (1.28)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.56)	0	0 (0.00)
Influenza like illness	2	2 (2.56)	0	0 (0.00)
Localised oedema	2	2 (2.56)	0	0 (0.00)
Malaise	2	2 (2.56)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.56)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.28)	0	0 (0.00)
Chest discomfort	1	1 (1.28)	1	1 (1.28)
Crying	1	1 (1.28)	0	0 (0.00)
Facial pain	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Oedema due to hepatic disease	1	1 (1.28)	0	0 (0.00)
Sluggishness	1	1 (1.28)	0	0 (0.00)
Swelling face	1	1 (1.28)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.28)	1	1 (1.28)
Vascular device occlusion	1	1 (1.28)	0	0 (0.00)
Xerosis	1	1 (1.28)	0	0 (0.00)
Hepatobiliary disorders				
- Total	31	18 (23.08)	7	6 (7.69)
Hepatic function abnormal	11	5 (6.41)	4	3 (3.85)
Hyperbilirubinaemia	6	5 (6.41)	1	1 (1.28)
Hepatomegaly	3	3 (3.85)	1	1 (1.28)
Hypertransaminasaemia	3	2 (2.56)	0	0 (0.00)
Cholelithiasis	2	2 (2.56)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.56)	0	0 (0.00)
Biliary tract disorder	1	1 (1.28)	0	0 (0.00)
Cholestasis	1	1 (1.28)	1	1 (1.28)
Liver disorder	1	1 (1.28)	0	0 (0.00)
Ocular icterus	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Immune system disorders				
- Total	184	69 (88.46)	72	44 (56.41)
Cytokine release syndrome	121	59 (75.64)	51	36 (46.15)
Hypogammaglobulinaemia	39	32 (41.03)	7	7 (8.97)
Haemophagocytic lymphohistiocytosis	6	6 (7.69)	4	4 (5.13)
Immunodeficiency	4	4 (5.13)	4	4 (5.13)
Seasonal allergy	3	3 (3.85)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.56)	1	1 (1.28)
Chronic graft versus host disease	2	2 (2.56)	1	1 (1.28)
Drug hypersensitivity	2	2 (2.56)	1	1 (1.28)
Graft versus host disease	2	2 (2.56)	2	2 (2.56)
Engraftment syndrome	1	1 (1.28)	1	1 (1.28)
Hypersensitivity	1	1 (1.28)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.28)	0	0 (0.00)
Infections and infestations				
- Total	257	58 (74.36)	97	37 (47.44)
Upper respiratory tract infection	16	12 (15.38)	2	2 (2.56)
Sinusitis	14	7 (8.97)	2	2 (2.56)
Conjunctivitis	12	8 (10.26)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Rhinovirus infection	11	9 (11.54)	2	2 (2.56)
Nasopharyngitis	9	7 (8.97)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.56)	4	2 (2.56)
Gastroenteritis	6	6 (7.69)	2	2 (2.56)
Otitis media	6	5 (6.41)	1	1 (1.28)
Parainfluenzae virus infection	6	5 (6.41)	3	3 (3.85)
Pneumonia	6	6 (7.69)	4	4 (5.13)
Staphylococcal bacteraemia	6	5 (6.41)	6	5 (6.41)
Candida infection	5	4 (5.13)	2	1 (1.28)
Oral herpes	5	4 (5.13)	1	1 (1.28)
Staphylococcal infection	5	5 (6.41)	2	2 (2.56)
Bacteraemia	4	3 (3.85)	3	2 (2.56)
Clostridium difficile infection	4	4 (5.13)	3	3 (3.85)
Ear infection	4	3 (3.85)	1	1 (1.28)
Nail infection	4	4 (5.13)	0	0 (0.00)
Oral candidiasis	4	3 (3.85)	0	0 (0.00)
Urinary tract infection	4	3 (3.85)	2	1 (1.28)
COVID-19	3	2 (2.56)	1	1 (1.28)
Fungal infection	3	2 (2.56)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.56)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Herpes zoster	3	3 (3.85)	2	2 (2.56)
Influenza	3	3 (3.85)	1	1 (1.28)
Klebsiella infection	3	1 (1.28)	3	1 (1.28)
Metapneumovirus infection	3	3 (3.85)	3	3 (3.85)
Otitis externa	3	3 (3.85)	1	1 (1.28)
Respiratory tract infection	3	3 (3.85)	0	0 (0.00)
Rhinitis	3	3 (3.85)	0	0 (0.00)
Skin infection	3	3 (3.85)	0	0 (0.00)
Acute sinusitis	2	2 (2.56)	0	0 (0.00)
Adenovirus infection	2	2 (2.56)	2	2 (2.56)
BK virus infection	2	2 (2.56)	1	1 (1.28)
Bronchitis	2	2 (2.56)	0	0 (0.00)
Device related sepsis	2	1 (1.28)	2	1 (1.28)
Encephalitis viral	2	2 (2.56)	2	2 (2.56)
Gingivitis	2	2 (2.56)	0	0 (0.00)
Herpes simplex	2	2 (2.56)	1	1 (1.28)
Human herpesvirus 6 infection	2	2 (2.56)	2	2 (2.56)
Oral infection	2	2 (2.56)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.56)	2	2 (2.56)
Respiratory syncytial virus infection	2	2 (2.56)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Sepsis	2	2 (2.56)	2	2 (2.56)
Septic shock	2	2 (2.56)	2	2 (2.56)
Varicella zoster virus infection	2	2 (2.56)	1	1 (1.28)
Viral infection	2	2 (2.56)	1	1 (1.28)
Anal abscess	1	1 (1.28)	1	1 (1.28)
Atypical pneumonia	1	1 (1.28)	0	0 (0.00)
Bronchiolitis	1	1 (1.28)	1	1 (1.28)
COVID-19 pneumonia	1	1 (1.28)	1	1 (1.28)
Cellulitis	1	1 (1.28)	0	0 (0.00)
Cholecystitis infective	1	1 (1.28)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.28)	1	1 (1.28)
Coronavirus infection	1	1 (1.28)	1	1 (1.28)
Cystitis	1	1 (1.28)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.28)	1	1 (1.28)
Device related infection	1	1 (1.28)	1	1 (1.28)
Ear, nose and throat infection	1	1 (1.28)	0	0 (0.00)
Encephalitis	1	1 (1.28)	1	1 (1.28)
Enterobacter infection	1	1 (1.28)	1	1 (1.28)
Enterovirus infection	1	1 (1.28)	1	1 (1.28)
Folliculitis	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Fungal skin infection	1	1 (1.28)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.28)	1	1 (1.28)
Gastroenteritis clostridial	1	1 (1.28)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.28)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.28)	1	1 (1.28)
Gastrointestinal infection	1	1 (1.28)	0	0 (0.00)
Granulicatella infection	1	1 (1.28)	1	1 (1.28)
Herpes virus infection	1	1 (1.28)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.28)	0	0 (0.00)
Localised infection	1	1 (1.28)	0	0 (0.00)
Mastoiditis	1	1 (1.28)	1	1 (1.28)
Meningitis bacterial	1	1 (1.28)	1	1 (1.28)
Meningitis pneumococcal	1	1 (1.28)	1	1 (1.28)
Molluscum contagiosum	1	1 (1.28)	0	0 (0.00)
Myringitis	1	1 (1.28)	0	0 (0.00)
Neutropenic infection	1	1 (1.28)	1	1 (1.28)
Ophthalmic herpes zoster	1	1 (1.28)	0	0 (0.00)
Otitis media acute	1	1 (1.28)	0	0 (0.00)
Paronychia	1	1 (1.28)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.28)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Pneumonia fungal	1	1 (1.28)	1	1 (1.28)
Pneumonia respiratory syncytial viral	1	1 (1.28)	1	1 (1.28)
Pneumonia viral	1	1 (1.28)	1	1 (1.28)
Respiratory tract infection viral	1	1 (1.28)	0	0 (0.00)
Salmonellosis	1	1 (1.28)	0	0 (0.00)
Sinusitis fungal	1	1 (1.28)	1	1 (1.28)
Soft tissue infection	1	1 (1.28)	1	1 (1.28)
Staphylococcal abscess	1	1 (1.28)	1	1 (1.28)
Staphylococcal sepsis	1	1 (1.28)	1	1 (1.28)
Staphylococcal skin infection	1	1 (1.28)	0	0 (0.00)
Stomatococcal infection	1	1 (1.28)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.28)	0	0 (0.00)
Syphilis	1	1 (1.28)	0	0 (0.00)
Systemic candida	1	1 (1.28)	1	1 (1.28)
Tinea pedis	1	1 (1.28)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.28)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.28)	0	0 (0.00)
Viral skin infection	1	1 (1.28)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.28)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Injury, poisoning and procedural complications				
- Total	33	21 (26.92)	4	3 (3.85)
Infusion related reaction	8	5 (6.41)	1	1 (1.28)
Contusion	3	2 (2.56)	0	0 (0.00)
Wound	3	2 (2.56)	1	1 (1.28)
Fall	2	2 (2.56)	0	0 (0.00)
Ligament sprain	2	2 (2.56)	0	0 (0.00)
Procedural pain	2	2 (2.56)	0	0 (0.00)
Skin abrasion	2	2 (2.56)	0	0 (0.00)
Transfusion reaction	2	2 (2.56)	0	0 (0.00)
Abdominal injury	1	1 (1.28)	0	0 (0.00)
Fibula fracture	1	1 (1.28)	0	0 (0.00)
Limb injury	1	1 (1.28)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.28)	0	0 (0.00)
Scratch	1	1 (1.28)	0	0 (0.00)
Skin injury	1	1 (1.28)	0	0 (0.00)
Skin wound	1	1 (1.28)	0	0 (0.00)
Transplant failure	1	1 (1.28)	1	1 (1.28)
Vasoplegia syndrome	1	1 (1.28)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Investigations				
- Total	487	58 (74.36)	232	46 (58.97)
Platelet count decreased	83	24 (30.77)	47	15 (19.23)
Neutrophil count decreased	75	24 (30.77)	54	21 (26.92)
White blood cell count decreased	68	25 (32.05)	40	18 (23.08)
Lymphocyte count decreased	36	17 (21.79)	26	15 (19.23)
Aspartate aminotransferase increased	32	18 (23.08)	12	10 (12.82)
Alanine aminotransferase increased	28	17 (21.79)	6	6 (7.69)
Blood bilirubin increased	24	12 (15.38)	9	8 (10.26)
International normalised ratio increased	12	9 (11.54)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.56)	0	0 (0.00)
Serum ferritin increased	8	8 (10.26)	2	2 (2.56)
Activated partial thromboplastin time prolonged	7	5 (6.41)	0	0 (0.00)
Blood fibrinogen decreased	7	7 (8.97)	2	2 (2.56)
Blood immunoglobulin A decreased	7	7 (8.97)	1	1 (1.28)
Blood immunoglobulin M decreased	7	7 (8.97)	2	2 (2.56)
Weight increased	7	4 (5.13)	2	2 (2.56)
Blood creatinine increased	6	4 (5.13)	4	2 (2.56)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Electrocardiogram QT prolonged	6	5 (6.41)	2	2 (2.56)
Blood lactate dehydrogenase increased	5	5 (6.41)	1	1 (1.28)
C-reactive protein increased	5	5 (6.41)	3	3 (3.85)
Blood creatine phosphokinase increased	4	2 (2.56)	2	2 (2.56)
Blood immunoglobulin G decreased	4	4 (5.13)	0	0 (0.00)
Blood uric acid increased	4	4 (5.13)	2	2 (2.56)
Lipase increased	4	2 (2.56)	2	1 (1.28)
Fibrin D dimer increased	3	3 (3.85)	1	1 (1.28)
Oxygen saturation decreased	3	3 (3.85)	1	1 (1.28)
Urine output decreased	3	2 (2.56)	3	2 (2.56)
Blood glucose increased	2	1 (1.28)	2	1 (1.28)
Gamma-glutamyltransferase increased	2	2 (2.56)	2	2 (2.56)
Haemoglobin decreased	2	1 (1.28)	1	1 (1.28)
Amylase increased	1	1 (1.28)	0	0 (0.00)
Bacterial test positive	1	1 (1.28)	1	1 (1.28)
Blood alkaline phosphatase increased	1	1 (1.28)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Blood phosphorus increased	1	1 (1.28)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.28)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.28)	0	0 (0.00)
Blood urea increased	1	1 (1.28)	1	1 (1.28)
Bone density decreased	1	1 (1.28)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.28)	0	0 (0.00)
Cardiac murmur	1	1 (1.28)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.28)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.28)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.28)	0	0 (0.00)
Enterovirus test positive	1	1 (1.28)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.28)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.28)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.28)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.28)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.28)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.28)	0	0 (0.00)
Troponin increased	1	1 (1.28)	1	1 (1.28)
Weight decreased	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Metabolism and nutrition disorders				
- Total	238	50 (64.10)	84	31 (39.74)
Hypokalaemia	45	19 (24.36)	23	10 (12.82)
Hypophosphataemia	31	17 (21.79)	11	9 (11.54)
Decreased appetite	29	29 (37.18)	11	11 (14.10)
Hypocalcaemia	23	15 (19.23)	5	4 (5.13)
Hypoalbuminaemia	19	11 (14.10)	1	1 (1.28)
Hyperglycaemia	12	9 (11.54)	5	5 (6.41)
Hyperuricaemia	12	9 (11.54)	1	1 (1.28)
Hypervolaemia	7	7 (8.97)	5	5 (6.41)
Hypomagnesaemia	7	6 (7.69)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.41)	1	1 (1.28)
Hypercalcaemia	4	3 (3.85)	2	2 (2.56)
Metabolic acidosis	4	4 (5.13)	3	3 (3.85)
Tumour lysis syndrome	4	4 (5.13)	4	4 (5.13)
Acidosis	3	2 (2.56)	2	2 (2.56)
Hyperkalaemia	3	3 (3.85)	2	2 (2.56)
Hypermagnesaemia	3	2 (2.56)	0	0 (0.00)
Hypernatraemia	3	3 (3.85)	2	2 (2.56)
Hypertriglyceridaemia	3	3 (3.85)	2	2 (2.56)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Hyponatraemia	3	3 (3.85)	0	0 (0.00)
Iron overload	3	2 (2.56)	0	0 (0.00)
Hyperchloraemia	2	2 (2.56)	0	0 (0.00)
Malnutrition	2	2 (2.56)	2	2 (2.56)
Calcium deficiency	1	1 (1.28)	0	0 (0.00)
Dehydration	1	1 (1.28)	0	0 (0.00)
Haemosiderosis	1	1 (1.28)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.28)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.28)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.28)	0	0 (0.00)
Hypoglycaemia	1	1 (1.28)	0	0 (0.00)
Hypophagia	1	1 (1.28)	0	0 (0.00)
Metabolic syndrome	1	1 (1.28)	0	0 (0.00)
Obesity	1	1 (1.28)	1	1 (1.28)
Polydipsia	1	1 (1.28)	1	1 (1.28)
Musculoskeletal and connective tissue disorders				
- Total	81	43 (55.13)	9	8 (10.26)
Pain in extremity	18	17 (21.79)	1	1 (1.28)
Arthralgia	14	12 (15.38)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Back pain	14	10 (12.82)	3	3 (3.85)
Myalgia	11	10 (12.82)	0	0 (0.00)
Bone pain	6	4 (5.13)	0	0 (0.00)
Muscular weakness	2	2 (2.56)	1	1 (1.28)
Musculoskeletal chest pain	2	2 (2.56)	0	0 (0.00)
Neck pain	2	2 (2.56)	0	0 (0.00)
Pain in jaw	2	2 (2.56)	1	1 (1.28)
Growth retardation	1	1 (1.28)	0	0 (0.00)
Haemarthrosis	1	1 (1.28)	1	1 (1.28)
Joint effusion	1	1 (1.28)	0	0 (0.00)
Muscle rigidity	1	1 (1.28)	0	0 (0.00)
Muscle spasms	1	1 (1.28)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.28)	0	0 (0.00)
Myositis	1	1 (1.28)	0	0 (0.00)
Osteonecrosis	1	1 (1.28)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.28)	1	1 (1.28)
Synovitis	1	1 (1.28)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (6.41)	2	2 (2.56)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Bone giant cell tumour benign	2	1 (1.28)	1	1 (1.28)
Skin papilloma	2	2 (2.56)	0	0 (0.00)
Cancer pain	1	1 (1.28)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.28)	1	1 (1.28)
Nervous system disorders				
- Total	103	45 (57.69)	20	13 (16.67)
Headache	40	27 (34.62)	3	3 (3.85)
Encephalopathy	8	8 (10.26)	4	4 (5.13)
Tremor	7	6 (7.69)	0	0 (0.00)
Seizure	6	3 (3.85)	2	2 (2.56)
Dizziness	5	4 (5.13)	0	0 (0.00)
Somnolence	5	5 (6.41)	2	2 (2.56)
Cognitive disorder	4	2 (2.56)	1	1 (1.28)
Dysgeusia	3	3 (3.85)	0	0 (0.00)
Hydrocephalus	3	1 (1.28)	3	1 (1.28)
Lethargy	3	3 (3.85)	0	0 (0.00)
Hyperaesthesia	2	1 (1.28)	0	0 (0.00)
Migraine	2	1 (1.28)	0	0 (0.00)
Nervous system disorder	2	1 (1.28)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Amnesia	1	1 (1.28)	0	0 (0.00)
Aphasia	1	1 (1.28)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.28)	1	1 (1.28)
Depressed level of consciousness	1	1 (1.28)	1	1 (1.28)
Disturbance in attention	1	1 (1.28)	0	0 (0.00)
Dysarthria	1	1 (1.28)	1	1 (1.28)
Extrapyramidal disorder	1	1 (1.28)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.28)	0	0 (0.00)
Hypoaesthesia	1	1 (1.28)	0	0 (0.00)
Monoparesis	1	1 (1.28)	0	0 (0.00)
Neuralgia	1	1 (1.28)	0	0 (0.00)
Neurological decompensation	1	1 (1.28)	1	1 (1.28)
Paraesthesia	1	1 (1.28)	0	0 (0.00)
Psychiatric disorders				
- Total	63	37 (47.44)	7	7 (8.97)
Anxiety	13	13 (16.67)	2	2 (2.56)
Delirium	8	8 (10.26)	3	3 (3.85)
Agitation	7	6 (7.69)	0	0 (0.00)
Confusional state	7	7 (8.97)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Mental status changes	5	5 (6.41)	2	2 (2.56)
Insomnia	4	4 (5.13)	0	0 (0.00)
Hallucination	3	3 (3.85)	0	0 (0.00)
Irritability	3	3 (3.85)	0	0 (0.00)
Sleep disorder	3	2 (2.56)	0	0 (0.00)
Affect lability	1	1 (1.28)	0	0 (0.00)
Automatism	1	1 (1.28)	0	0 (0.00)
Hallucination, visual	1	1 (1.28)	0	0 (0.00)
Mood altered	1	1 (1.28)	0	0 (0.00)
Nightmare	1	1 (1.28)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.28)	0	0 (0.00)
Restlessness	1	1 (1.28)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.28)	0	0 (0.00)
Tearfulness	1	1 (1.28)	0	0 (0.00)
Tic	1	1 (1.28)	0	0 (0.00)
Renal and urinary disorders				
- Total	47	24 (30.77)	15	11 (14.10)
Acute kidney injury	17	12 (15.38)	9	8 (10.26)
Dysuria	4	4 (5.13)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Renal failure	4	2 (2.56)	3	1 (1.28)
Haematuria	3	3 (3.85)	1	1 (1.28)
Anuria	2	2 (2.56)	1	1 (1.28)
Pollakiuria	2	2 (2.56)	0	0 (0.00)
Urinary incontinence	2	1 (1.28)	0	0 (0.00)
Urinary retention	2	2 (2.56)	0	0 (0.00)
Azotaemia	1	1 (1.28)	0	0 (0.00)
Bladder dilatation	1	1 (1.28)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.28)	0	0 (0.00)
Incontinence	1	1 (1.28)	0	0 (0.00)
Kidney enlargement	1	1 (1.28)	0	0 (0.00)
Micturition urgency	1	1 (1.28)	0	0 (0.00)
Proteinuria	1	1 (1.28)	0	0 (0.00)
Renal mass	1	1 (1.28)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.28)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.28)	1	1 (1.28)
Urinary tract disorder	1	1 (1.28)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	10	6 (7.69)	2	2 (2.56)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Dysmenorrhoea	2	1 (1.28)	0	0 (0.00)
Endometriosis	2	1 (1.28)	1	1 (1.28)
Vaginal haemorrhage	2	1 (1.28)	0	0 (0.00)
Female genital tract fistula	1	1 (1.28)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.28)	0	0 (0.00)
Perineal rash	1	1 (1.28)	0	0 (0.00)
Vaginal ulceration	1	1 (1.28)	1	1 (1.28)
Respiratory, thoracic and mediastinal disorders				
- Total	178	53 (67.95)	61	28 (35.90)
Cough	28	22 (28.21)	0	0 (0.00)
Hypoxia	27	20 (25.64)	22	16 (20.51)
Pulmonary oedema	12	12 (15.38)	7	7 (8.97)
Tachypnoea	11	9 (11.54)	6	5 (6.41)
Nasal congestion	10	9 (11.54)	0	0 (0.00)
Oropharyngeal pain	9	8 (10.26)	0	0 (0.00)
Pleural effusion	9	8 (10.26)	2	2 (2.56)
Dyspnoea	8	7 (8.97)	4	4 (5.13)
Epistaxis	8	7 (8.97)	1	1 (1.28)
Rhinorrhoea	7	5 (6.41)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Respiratory failure	6	6 (7.69)	6	6 (7.69)
Atelectasis	5	3 (3.85)	2	2 (2.56)
Respiratory distress	5	4 (5.13)	3	2 (2.56)
Acute respiratory distress syndrome	3	3 (3.85)	3	3 (3.85)
Lung infiltration	2	1 (1.28)	1	1 (1.28)
Pharyngeal erythema	2	2 (2.56)	0	0 (0.00)
Rhinitis allergic	2	2 (2.56)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.56)	0	0 (0.00)
Acute respiratory failure	1	1 (1.28)	1	1 (1.28)
Bradypnoea	1	1 (1.28)	1	1 (1.28)
Bronchial oedema	1	1 (1.28)	0	0 (0.00)
Bronchospasm	1	1 (1.28)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.28)	0	0 (0.00)
Haemoptysis	1	1 (1.28)	0	0 (0.00)
Laryngeal oedema	1	1 (1.28)	1	1 (1.28)
Nasal discomfort	1	1 (1.28)	0	0 (0.00)
Nasal dryness	1	1 (1.28)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.28)	0	0 (0.00)
Painful respiration	1	1 (1.28)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Paranasal sinus inflammation	1	1 (1.28)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.28)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.28)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.28)	0	0 (0.00)
Productive cough	1	1 (1.28)	0	0 (0.00)
Pulmonary mass	1	1 (1.28)	0	0 (0.00)
Respiratory acidosis	1	1 (1.28)	1	1 (1.28)
Respiratory disorder	1	1 (1.28)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.28)	0	0 (0.00)
Wheezing	1	1 (1.28)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	95	40 (51.28)	9	7 (8.97)
Rash	13	8 (10.26)	0	0 (0.00)
Dry skin	9	8 (10.26)	0	0 (0.00)
Pruritus	9	7 (8.97)	0	0 (0.00)
Blister	6	3 (3.85)	0	0 (0.00)
Erythema	5	5 (6.41)	0	0 (0.00)
Dermatitis atopic	4	3 (3.85)	1	1 (1.28)
Rash maculo-papular	4	3 (3.85)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Rash papular	4	3 (3.85)	0	0 (0.00)
Eczema	3	3 (3.85)	1	1 (1.28)
Hyperhidrosis	3	3 (3.85)	0	0 (0.00)
Decubitus ulcer	2	2 (2.56)	1	1 (1.28)
Ingrowing nail	2	2 (2.56)	0	0 (0.00)
Petechiae	2	2 (2.56)	1	1 (1.28)
Rash macular	2	1 (1.28)	2	1 (1.28)
Rash vesicular	2	1 (1.28)	0	0 (0.00)
Skin discolouration	2	2 (2.56)	0	0 (0.00)
Skin ulcer	2	2 (2.56)	0	0 (0.00)
Dermatitis	1	1 (1.28)	0	0 (0.00)
Dermatitis allergic	1	1 (1.28)	0	0 (0.00)
Dermatitis diaper	1	1 (1.28)	0	0 (0.00)
Erythema nodosum	1	1 (1.28)	0	0 (0.00)
Hangnail	1	1 (1.28)	0	0 (0.00)
Miliaria	1	1 (1.28)	0	0 (0.00)
Night sweats	1	1 (1.28)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.28)	0	0 (0.00)
Papule	1	1 (1.28)	0	0 (0.00)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Photosensitivity reaction	1	1 (1.28)	0	0 (0.00)
Pruritus allergic	1	1 (1.28)	0	0 (0.00)
Purpura	1	1 (1.28)	0	0 (0.00)
Rash erythematous	1	1 (1.28)	0	0 (0.00)
Rash pruritic	1	1 (1.28)	0	0 (0.00)
Scab	1	1 (1.28)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.28)	0	0 (0.00)
Skin lesion	1	1 (1.28)	0	0 (0.00)
Skin necrosis	1	1 (1.28)	1	1 (1.28)
Skin swelling	1	1 (1.28)	0	0 (0.00)
Urticaria	1	1 (1.28)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.28)	1	1 (1.28)
Social circumstances				
- Total	1	1 (1.28)	0	0 (0.00)
Patient uncooperative	1	1 (1.28)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.28)	1	1 (1.28)
Thrombolysis	1	1 (1.28)	1	1 (1.28)

Timing: At anytime, Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All grades Total events	All patients N=78 n (%)[1]	Grade >= 3 Total events	All patients N=78 n (%)[2]
Vascular disorders				
- Total	52	32 (41.03)	26	20 (25.64)
Hypotension	28	23 (29.49)	19	16 (20.51)
Hypertension	17	16 (20.51)	5	5 (6.41)
Venoocclusive disease	2	2 (2.56)	2	2 (2.56)
Capillary leak syndrome	1	1 (1.28)	0	0 (0.00)
Flushing	1	1 (1.28)	0	0 (0.00)
Hot flush	1	1 (1.28)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.28)	0	0 (0.00)
Thrombosis	1	1 (1.28)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	15	1 (100.00)	0	0 (0.00)
Blood and lymphatic system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Anaemia	1	1 (100.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	1 (100.00)	0	0 (0.00)
Abdominal pain	1	1 (100.00)	0	0 (0.00)
Anal haemorrhage	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	4	1 (100.00)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (100.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (100.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (100.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Blood uric acid increased	1	1 (100.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Decreased appetite	1	1 (100.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Pain in extremity	1	1 (100.00)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Irritability	1	1 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (100.00)	0	0 (0.00)
Cough	1	1 (100.00)	0	0 (0.00)
Rhinorrhoea	1	1 (100.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	1 (100.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Dry skin	1	1 (100.00)	0	0 (0.00)
Rash papular	1	1 (100.00)	0	0 (0.00)
Rash pruritic	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	1736	78 (98.73)	619	67 (84.81)
Blood and lymphatic system disorders				
- Total	124	49 (62.03)	76	39 (49.37)
Anaemia	49	20 (25.32)	20	8 (10.13)
Febrile neutropenia	29	26 (32.91)	29	26 (32.91)
Neutropenia	11	9 (11.39)	9	7 (8.86)
Thrombocytopenia	8	8 (10.13)	8	8 (10.13)
Disseminated intravascular coagulation	7	7 (8.86)	2	2 (2.53)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	4	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
Eosinophilia	2	1 (1.27)	0	0 (0.00)
Pancytopenia	2	2 (2.53)	2	2 (2.53)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
B-cell aplasia	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Lymphopenia	1	1 (1.27)	1	1 (1.27)
Cardiac disorders				
- Total	45	24 (30.38)	10	8 (10.13)
Tachycardia	22	17 (21.52)	3	3 (3.80)
Cardiac failure	4	1 (1.27)	2	1 (1.27)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Left ventricular dysfunction	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)
Cardiac arrest	1	1 (1.27)	1	1 (1.27)
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)
Ear and labyrinth disorders				

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	2	2 (2.53)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.33)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)
Hypothyroidism	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	15	9 (11.39)	0	0 (0.00)
Eyelid oedema	3	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.53)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Eye pain	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)
Visual field defect	1	1 (1.27)	0	0 (0.00)
Visual impairment	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Gastrointestinal disorders				
- Total	133	50 (63.29)	16	14 (17.72)
Vomiting	30	21 (26.58)	1	1 (1.27)
Nausea	21	18 (22.78)	2	2 (2.53)
Diarrhoea	18	15 (18.99)	1	1 (1.27)
Abdominal pain	12	10 (12.66)	2	2 (2.53)
Constipation	11	11 (13.92)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.06)	2	2 (2.53)
Pancreatitis	4	4 (5.06)	1	1 (1.27)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Abdominal pain upper	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Stomatitis	2	2 (2.53)	1	1 (1.27)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Anal fissure	1	1 (1.27)	0	0 (0.00)
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enterocolitis	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Proctalgia	1	1 (1.27)	1	1 (1.27)
Trichoglossia	1	1 (1.27)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
General disorders and administration site conditions				
- Total	112	40 (50.63)	19	11 (13.92)
Pyrexia	44	24 (30.38)	9	8 (10.13)
Fatigue	11	11 (13.92)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Chills	9	6 (7.59)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	7	6 (7.59)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	2	2 (2.53)	0	0 (0.00)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.53)	2	2 (2.53)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)
Facial pain	1	1 (1.27)	0	0 (0.00)
Malaise	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Pain	1	1 (1.27)	1	1 (1.27)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	29	17 (21.52)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Hypertransaminasaemia	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	164	67 (84.81)	68	43 (54.43)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	25	23 (29.11)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	5	5 (6.33)	3	3 (3.80)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Immunodeficiency	3	3 (3.80)	3	3 (3.80)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Seasonal allergy	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				
- Total	64	35 (44.30)	31	19 (24.05)
Conjunctivitis	6	5 (6.33)	0	0 (0.00)
Staphylococcal infection	5	5 (6.33)	2	2 (2.53)
Candida infection	4	3 (3.80)	2	1 (1.27)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Staphylococcal bacteraemia	4	3 (3.80)	4	3 (3.80)
Encephalitis viral	2	2 (2.53)	2	2 (2.53)
Nail infection	2	2 (2.53)	0	0 (0.00)
Oral candidiasis	2	1 (1.27)	0	0 (0.00)
Oral herpes	2	2 (2.53)	1	1 (1.27)
Oral infection	2	2 (2.53)	0	0 (0.00)
Rhinovirus infection	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	1	1 (1.27)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)
BK virus infection	1	1 (1.27)	0	0 (0.00)
Bacteraemia	1	1 (1.27)	1	1 (1.27)
Bronchopulmonary aspergillosis	1	1 (1.27)	1	1 (1.27)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Encephalitis	1	1 (1.27)	1	1 (1.27)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gingivitis	1	1 (1.27)	0	0 (0.00)
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes simplex	1	1 (1.27)	1	1 (1.27)
Human herpesvirus 6 infection	1	1 (1.27)	1	1 (1.27)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)
Klebsiella infection	1	1 (1.27)	1	1 (1.27)
Localised infection	1	1 (1.27)	0	0 (0.00)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Myringitis	1	1 (1.27)	0	0 (0.00)
Otitis externa	1	1 (1.27)	0	0 (0.00)
Paronychia	1	1 (1.27)	0	0 (0.00)
Pneumonia	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Sinusitis	1	1 (1.27)	1	1 (1.27)
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	20	11 (13.92)	3	2 (2.53)
Infusion related reaction	3	2 (2.53)	0	0 (0.00)
Wound	3	2 (2.53)	1	1 (1.27)
Contusion	2	1 (1.27)	0	0 (0.00)
Fall	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)
Skin abrasion	1	1 (1.27)	0	0 (0.00)
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	382	56 (70.89)	197	45 (56.96)
Platelet count decreased	65	21 (26.58)	38	14 (17.72)
White blood cell count decreased	50	24 (30.38)	36	18 (22.78)
Neutrophil count decreased	48	20 (25.32)	38	17 (21.52)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Lymphocyte count decreased	30	15 (18.99)	24	13 (16.46)
Alanine aminotransferase increased	26	18 (22.78)	6	6 (7.59)
Blood bilirubin increased	18	12 (15.19)	9	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)
Blood creatinine increased	6	4 (5.06)	5	3 (3.80)
Blood fibrinogen decreased	6	6 (7.59)	2	2 (2.53)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood immunoglobulin M decreased	5	5 (6.33)	1	1 (1.27)
Immunoglobulins decreased	5	2 (2.53)	0	0 (0.00)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood immunoglobulin A decreased	4	4 (5.06)	0	0 (0.00)
Blood lactate dehydrogenase increased	4	4 (5.06)	1	1 (1.27)
C-reactive protein increased	4	4 (5.06)	3	3 (3.80)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Weight increased	4	4 (5.06)	1	1 (1.27)
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Blood immunoglobulin G decreased	2	2 (2.53)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (2.53)	2	2 (2.53)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Blood uric acid increased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)
Weight decreased	1	1 (1.27)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	209	45 (56.96)	76	29 (36.71)
Hypokalaemia	40	19 (24.05)	20	11 (13.92)
Hypophosphataemia	31	17 (21.52)	11	9 (11.39)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Decreased appetite	23	23 (29.11)	11	11 (13.92)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	11	8 (10.13)	4	4 (5.06)
Hyperuricaemia	9	7 (8.86)	1	1 (1.27)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hypervolaemia	6	6 (7.59)	4	4 (5.06)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)
Tumour lysis syndrome	4	4 (5.06)	4	4 (5.06)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Metabolic acidosis	3	3 (3.80)	2	2 (2.53)
Hyperkalaemia	2	2 (2.53)	2	2 (2.53)
Hypernatraemia	2	2 (2.53)	1	1 (1.27)
Hypertriglyceridaemia	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hyperchloraemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Malnutrition	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				
- Total	52	32 (40.51)	6	5 (6.33)
Arthralgia	10	10 (12.66)	1	1 (1.27)
Myalgia	10	9 (11.39)	0	0 (0.00)
Pain in extremity	10	10 (12.66)	0	0 (0.00)
Back pain	7	6 (7.59)	1	1 (1.27)
Bone pain	4	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.27)	0	0 (0.00)
Myositis	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neck pain	1	1 (1.27)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	77	40 (50.63)	14	10 (12.66)
Headache	26	23 (29.11)	2	2 (2.53)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Tremor	7	6 (7.59)	0	0 (0.00)
Cognitive disorder	5	3 (3.80)	1	1 (1.27)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dizziness	3	3 (3.80)	0	0 (0.00)
Dysgeusia	3	3 (3.80)	0	0 (0.00)
Lethargy	3	3 (3.80)	0	0 (0.00)
Seizure	3	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Dysarthria	1	1 (1.27)	1	1 (1.27)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)
Paraesthesia	1	1 (1.27)	0	0 (0.00)
Psychiatric disorders				
- Total	46	27 (34.18)	6	6 (7.59)
Confusional state	7	7 (8.86)	0	0 (0.00)
Delirium	7	7 (8.86)	3	3 (3.80)
Agitation	6	5 (6.33)	0	0 (0.00)
Anxiety	6	6 (7.59)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Mental status changes	3	3 (3.80)	1	1 (1.27)
Sleep disorder	3	2 (2.53)	0	0 (0.00)
Irritability	2	2 (2.53)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	39	20 (25.32)	13	9 (11.39)
Acute kidney injury	14	9 (11.39)	8	7 (8.86)
Renal failure	4	2 (2.53)	3	1 (1.27)
Dysuria	3	3 (3.80)	0	0 (0.00)
Anuria	2	2 (2.53)	1	1 (1.27)
Haematuria	2	2 (2.53)	0	0 (0.00)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)
Proteinuria	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (6.33)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				
- Total	112	40 (50.63)	50	23 (29.11)
Hypoxia	23	17 (21.52)	18	12 (15.19)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Cough	10	9 (11.39)	0	0 (0.00)
Tachypnoea	9	8 (10.13)	4	4 (5.06)
Pleural effusion	7	7 (8.86)	3	3 (3.80)
Oropharyngeal pain	6	5 (6.33)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Atelectasis	5	3 (3.80)	2	2 (2.53)
Epistaxis	4	4 (5.06)	1	1 (1.27)
Respiratory distress	4	3 (3.80)	2	1 (1.27)
Respiratory failure	4	4 (5.06)	4	4 (5.06)
Dyspnoea	3	3 (3.80)	3	3 (3.80)
Nasal congestion	3	3 (3.80)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (2.53)	2	2 (2.53)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)
Respiratory disorder	1	1 (1.27)	0	0 (0.00)
Rhinorrhoea	1	1 (1.27)	0	0 (0.00)
Wheezing	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	53	26 (32.91)	4	3 (3.80)
Pruritus	7	6 (7.59)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Rash	5	5 (6.33)	0	0 (0.00)
Erythema	4	4 (5.06)	0	0 (0.00)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Rash maculo-papular	3	2 (2.53)	1	1 (1.27)
Rash papular	3	2 (2.53)	0	0 (0.00)
Dermatitis atopic	2	2 (2.53)	0	0 (0.00)
Petechiae	2	2 (2.53)	1	1 (1.27)
Rash vesicular	2	1 (1.27)	0	0 (0.00)
Skin ulcer	2	2 (2.53)	0	0 (0.00)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Decubitus ulcer	1	1 (1.27)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Eczema	1	1 (1.27)	0	0 (0.00)
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)
Skin discolouration	1	1 (1.27)	0	0 (0.00)
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)
Vascular disorders				
- Total	45	28 (35.44)	21	17 (21.52)
Hypotension	25	21 (26.58)	16	14 (17.72)
Hypertension	14	13 (16.46)	4	4 (5.06)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Flushing	1	1 (1.27)	0	0 (0.00)
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	10	1 (100.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	1 (100.00)	0	0 (0.00)
Diarrhoea	1	1 (100.00)	0	0 (0.00)
Nausea	1	1 (100.00)	0	0 (0.00)
Proctalgia	1	1 (100.00)	0	0 (0.00)
Vomiting	1	1 (100.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	3	1 (100.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Platelet count decreased	2	1 (100.00)	0	0 (0.00)
White blood cell count decreased	1	1 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	1 (100.00)	0	0 (0.00)
Cough	1	1 (100.00)	0	0 (0.00)
Rhinorrhoea	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	524	68 (91.89)	146	36 (48.65)
Blood and lymphatic system disorders				
- Total	32	17 (22.97)	17	10 (13.51)
Anaemia	12	6 (8.11)	4	2 (2.70)
Neutropenia	5	5 (6.76)	5	5 (6.76)
Febrile neutropenia	4	3 (4.05)	4	3 (4.05)
B-cell aplasia	2	1 (1.35)	0	0 (0.00)
Thrombocytopenia	2	2 (2.70)	2	2 (2.70)
Disseminated intravascular coagulation	1	1 (1.35)	1	1 (1.35)
Eosinophilia	1	1 (1.35)	0	0 (0.00)
Leukocytosis	1	1 (1.35)	0	0 (0.00)
Leukopenia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Lymphadenopathy	1	1 (1.35)	0	0 (0.00)
Lymphocytosis	1	1 (1.35)	0	0 (0.00)
Lymphopenia	1	1 (1.35)	1	1 (1.35)
Cardiac disorders				
- Total	8	7 (9.46)	4	3 (4.05)
Cardiac arrest	2	2 (2.70)	2	2 (2.70)
Cardiac failure	2	2 (2.70)	2	2 (2.70)
Tachycardia	2	2 (2.70)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Hypothyroidism	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.41)	0	0 (0.00)
Cataract	2	2 (2.70)	0	0 (0.00)
Hypermetropia	1	1 (1.35)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Visual impairment	1	1 (1.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	34	19 (25.68)	1	1 (1.35)
Diarrhoea	6	6 (8.11)	0	0 (0.00)
Vomiting	6	5 (6.76)	0	0 (0.00)
Constipation	4	3 (4.05)	0	0 (0.00)
Nausea	4	4 (5.41)	0	0 (0.00)
Abdominal pain	2	2 (2.70)	0	0 (0.00)
Pancreatitis	2	2 (2.70)	1	1 (1.35)
Abdominal pain upper	1	1 (1.35)	0	0 (0.00)
Abdominal rigidity	1	1 (1.35)	0	0 (0.00)
Dyspepsia	1	1 (1.35)	0	0 (0.00)
Enteritis	1	1 (1.35)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.35)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.35)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.35)	0	0 (0.00)
Stomatitis	1	1 (1.35)	0	0 (0.00)
Trichoglossia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
General disorders and administration site conditions				
- Total	31	24 (32.43)	3	3 (4.05)
Pyrexia	16	15 (20.27)	2	2 (2.70)
Fatigue	7	6 (8.11)	0	0 (0.00)
Oedema peripheral	2	1 (1.35)	0	0 (0.00)
Pain	2	2 (2.70)	1	1 (1.35)
Asthenia	1	1 (1.35)	0	0 (0.00)
Chills	1	1 (1.35)	0	0 (0.00)
Malaise	1	1 (1.35)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.05)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.35)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.35)	0	0 (0.00)
Liver disorder	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	18	15 (20.27)	5	4 (5.41)
Hypogammaglobulinaemia	11	9 (12.16)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Allergy to immunoglobulin therapy	2	2 (2.70)	1	1 (1.35)
Graft versus host disease	2	2 (2.70)	2	2 (2.70)
Drug hypersensitivity	1	1 (1.35)	0	0 (0.00)
Engraftment syndrome	1	1 (1.35)	1	1 (1.35)
Immunodeficiency	1	1 (1.35)	1	1 (1.35)
Infections and infestations				
- Total	113	39 (52.70)	45	20 (27.03)
Upper respiratory tract infection	10	8 (10.81)	2	2 (2.70)
Nasopharyngitis	9	7 (9.46)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (1.35)	3	1 (1.35)
Gastroenteritis	5	5 (6.76)	2	2 (2.70)
Parainfluenzae virus infection	5	4 (5.41)	2	2 (2.70)
Rhinovirus infection	5	5 (6.76)	1	1 (1.35)
Sinusitis	4	3 (4.05)	1	1 (1.35)
Bacteraemia	3	2 (2.70)	2	1 (1.35)
Ear infection	3	2 (2.70)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.05)	3	3 (4.05)
Otitis media	3	3 (4.05)	1	1 (1.35)
Pneumonia	3	3 (4.05)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Respiratory syncytial virus infection	3	3 (4.05)	2	2 (2.70)
Respiratory tract infection	3	3 (4.05)	0	0 (0.00)
Klebsiella infection	2	1 (1.35)	2	1 (1.35)
Otitis externa	2	2 (2.70)	1	1 (1.35)
Pneumocystis jirovecii pneumonia	2	2 (2.70)	2	2 (2.70)
Rhinitis	2	2 (2.70)	0	0 (0.00)
Urinary tract infection	2	1 (1.35)	2	1 (1.35)
Viral infection	2	2 (2.70)	1	1 (1.35)
Acute sinusitis	1	1 (1.35)	0	0 (0.00)
Adenovirus infection	1	1 (1.35)	1	1 (1.35)
BK virus infection	1	1 (1.35)	1	1 (1.35)
Cellulitis	1	1 (1.35)	0	0 (0.00)
Conjunctivitis	1	1 (1.35)	0	0 (0.00)
Coronavirus infection	1	1 (1.35)	1	1 (1.35)
Cystitis	1	1 (1.35)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.35)	1	1 (1.35)
Device related infection	1	1 (1.35)	1	1 (1.35)
Ear, nose and throat infection	1	1 (1.35)	0	0 (0.00)
Encephalitis	1	1 (1.35)	1	1 (1.35)
Enterobacter infection	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastroenteritis clostridial	1	1 (1.35)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.35)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.35)	0	0 (0.00)
Gingivitis	1	1 (1.35)	0	0 (0.00)
Herpes simplex	1	1 (1.35)	0	0 (0.00)
Herpes zoster	1	1 (1.35)	1	1 (1.35)
Human herpesvirus 6 infection	1	1 (1.35)	1	1 (1.35)
Influenza	1	1 (1.35)	0	0 (0.00)
Mastoiditis	1	1 (1.35)	1	1 (1.35)
Molluscum contagiosum	1	1 (1.35)	0	0 (0.00)
Nail infection	1	1 (1.35)	0	0 (0.00)
Oral candidiasis	1	1 (1.35)	0	0 (0.00)
Oral herpes	1	1 (1.35)	0	0 (0.00)
Paronychia	1	1 (1.35)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.35)	1	1 (1.35)
Respiratory tract infection viral	1	1 (1.35)	0	0 (0.00)
Salmonellosis	1	1 (1.35)	0	0 (0.00)
Septic shock	1	1 (1.35)	1	1 (1.35)
Sinusitis fungal	1	1 (1.35)	1	1 (1.35)
Staphylococcal bacteraemia	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Staphylococcal sepsis	1	1 (1.35)	1	1 (1.35)
Staphylococcal skin infection	1	1 (1.35)	0	0 (0.00)
Tinea pedis	1	1 (1.35)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.35)	1	1 (1.35)
Viral upper respiratory tract infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	10	9 (12.16)	0	0 (0.00)
Infusion related reaction	4	3 (4.05)	0	0 (0.00)
Contusion	1	1 (1.35)	0	0 (0.00)
Fibula fracture	1	1 (1.35)	0	0 (0.00)
Ligament sprain	1	1 (1.35)	0	0 (0.00)
Limb injury	1	1 (1.35)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.35)	0	0 (0.00)
Skin abrasion	1	1 (1.35)	0	0 (0.00)
Investigations				
- Total	88	29 (39.19)	35	16 (21.62)
Neutrophil count decreased	19	10 (13.51)	11	7 (9.46)
White blood cell count decreased	17	9 (12.16)	4	4 (5.41)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Platelet count decreased	14	4 (5.41)	9	2 (2.70)
Lymphocyte count decreased	6	4 (5.41)	2	2 (2.70)
Immunoglobulins decreased	5	1 (1.35)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.70)	1	1 (1.35)
Alanine aminotransferase increased	3	2 (2.70)	1	1 (1.35)
Weight increased	3	1 (1.35)	1	1 (1.35)
Blood immunoglobulin A decreased	2	2 (2.70)	1	1 (1.35)
Blood uric acid increased	2	2 (2.70)	2	2 (2.70)
Blood creatinine increased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.35)	1	1 (1.35)
Blood lactate dehydrogenase increased	1	1 (1.35)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.35)	0	0 (0.00)
Blood urea increased	1	1 (1.35)	1	1 (1.35)
Bone density decreased	1	1 (1.35)	0	0 (0.00)
C-reactive protein increased	1	1 (1.35)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.35)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hepatitis B virus test positive	1	1 (1.35)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.35)	0	0 (0.00)
Weight decreased	1	1 (1.35)	1	1 (1.35)
Metabolism and nutrition disorders				
- Total	26	15 (20.27)	10	7 (9.46)
Decreased appetite	6	6 (8.11)	1	1 (1.35)
Hypokalaemia	6	3 (4.05)	4	2 (2.70)
Hyperuricaemia	3	3 (4.05)	0	0 (0.00)
Haemochromatosis	1	1 (1.35)	1	1 (1.35)
Hyperchloraemia	1	1 (1.35)	0	0 (0.00)
Hyperkalaemia	1	1 (1.35)	0	0 (0.00)
Hypervolaemia	1	1 (1.35)	1	1 (1.35)
Hypophagia	1	1 (1.35)	0	0 (0.00)
Hypophosphataemia	1	1 (1.35)	0	0 (0.00)
Iron overload	1	1 (1.35)	0	0 (0.00)
Malnutrition	1	1 (1.35)	1	1 (1.35)
Metabolic acidosis	1	1 (1.35)	1	1 (1.35)
Metabolic syndrome	1	1 (1.35)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	22	15 (20.27)	3	3 (4.05)
Back pain	7	6 (8.11)	2	2 (2.70)
Pain in extremity	5	5 (6.76)	1	1 (1.35)
Arthralgia	3	3 (4.05)	0	0 (0.00)
Bone pain	2	2 (2.70)	0	0 (0.00)
Growth retardation	1	1 (1.35)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.35)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.35)	0	0 (0.00)
Myalgia	1	1 (1.35)	0	0 (0.00)
Neck pain	1	1 (1.35)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.41)	1	1 (1.35)
Skin papilloma	2	2 (2.70)	0	0 (0.00)
Cancer pain	1	1 (1.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.35)	1	1 (1.35)
Nervous system disorders				
- Total	23	14 (18.92)	6	2 (2.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Headache	11	10 (13.51)	0	0 (0.00)
Hydrocephalus	3	1 (1.35)	3	1 (1.35)
Dizziness	2	1 (1.35)	0	0 (0.00)
Migraine	2	1 (1.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.35)	1	1 (1.35)
Cerebral haemorrhage	1	1 (1.35)	1	1 (1.35)
Extrapyramidal disorder	1	1 (1.35)	0	0 (0.00)
Memory impairment	1	1 (1.35)	0	0 (0.00)
Seizure	1	1 (1.35)	1	1 (1.35)
Psychiatric disorders				
- Total	15	10 (13.51)	1	1 (1.35)
Anxiety	6	6 (8.11)	0	0 (0.00)
Mental status changes	2	2 (2.70)	1	1 (1.35)
Agitation	1	1 (1.35)	0	0 (0.00)
Delirium	1	1 (1.35)	0	0 (0.00)
Mood altered	1	1 (1.35)	0	0 (0.00)
Nightmare	1	1 (1.35)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.35)	0	0 (0.00)
Sleep disorder	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Tearfulness	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	5 (6.76)	3	3 (4.05)
Acute kidney injury	3	3 (4.05)	1	1 (1.35)
Cystitis haemorrhagic	1	1 (1.35)	0	0 (0.00)
Dysuria	1	1 (1.35)	0	0 (0.00)
Haematuria	1	1 (1.35)	1	1 (1.35)
Kidney enlargement	1	1 (1.35)	0	0 (0.00)
Renal mass	1	1 (1.35)	0	0 (0.00)
Renal tubular disorder	1	1 (1.35)	1	1 (1.35)
Reproductive system and breast disorders				
- Total	2	1 (1.35)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	44	23 (31.08)	6	6 (8.11)
Cough	13	10 (13.51)	0	0 (0.00)
Nasal congestion	7	6 (8.11)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Epistaxis	3	3 (4.05)	0	0 (0.00)
Hypoxia	3	3 (4.05)	3	3 (4.05)
Dyspnoea	2	1 (1.35)	0	0 (0.00)
Oropharyngeal pain	2	2 (2.70)	0	0 (0.00)
Pleural effusion	2	2 (2.70)	0	0 (0.00)
Rhinitis allergic	2	2 (2.70)	0	0 (0.00)
Rhinorrhoea	2	2 (2.70)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.35)	1	1 (1.35)
Bronchial oedema	1	1 (1.35)	0	0 (0.00)
Bronchospasm	1	1 (1.35)	0	0 (0.00)
Lung disorder	1	1 (1.35)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.35)	0	0 (0.00)
Respiratory distress	1	1 (1.35)	1	1 (1.35)
Respiratory failure	1	1 (1.35)	1	1 (1.35)
Upper respiratory tract inflammation	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	29	20 (27.03)	1	1 (1.35)
Dry skin	7	6 (8.11)	0	0 (0.00)
Rash	6	4 (5.41)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Ingrowing nail	2	2 (2.70)	0	0 (0.00)
Pruritus	2	1 (1.35)	0	0 (0.00)
Decubitus ulcer	1	1 (1.35)	1	1 (1.35)
Dermatitis allergic	1	1 (1.35)	0	0 (0.00)
Dermatitis atopic	1	1 (1.35)	0	0 (0.00)
Eczema	1	1 (1.35)	0	0 (0.00)
Erythema	1	1 (1.35)	0	0 (0.00)
Hangnail	1	1 (1.35)	0	0 (0.00)
Miliaria	1	1 (1.35)	0	0 (0.00)
Night sweats	1	1 (1.35)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.35)	0	0 (0.00)
Skin discolouration	1	1 (1.35)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.35)	0	0 (0.00)
Skin swelling	1	1 (1.35)	0	0 (0.00)
Vascular disorders				
- Total	7	6 (8.11)	5	5 (6.76)
Hypotension	4	4 (5.41)	3	3 (4.05)
Venoocclusive disease	2	2 (2.70)	2	2 (2.70)
Hypertension	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=0 n (%)[1]	Grade >= 3 Total events	All patients N=0 n (%)[2]
Total number of AE per patient				

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Total number of AE per patient	220	32 (64.00)	63	19 (38.00)
Blood and lymphatic system disorders				
- Total	6	4 (8.00)	2	2 (4.00)
Agranulocytosis	1	1 (2.00)	1	1 (2.00)
Anaemia	1	1 (2.00)	0	0 (0.00)
Hypercoagulation	1	1 (2.00)	0	0 (0.00)
Lymphadenopathy	1	1 (2.00)	0	0 (0.00)
Neutropenia	1	1 (2.00)	1	1 (2.00)
Thrombocytopenia	1	1 (2.00)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.00)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.00)	0	0 (0.00)
Deafness unilateral	1	1 (2.00)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.00)	0	0 (0.00)
Delayed puberty	1	1 (2.00)	0	0 (0.00)
Hypothyroidism	1	1 (2.00)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.00)	1	1 (2.00)
Dry eye	1	1 (2.00)	0	0 (0.00)
Eye pain	1	1 (2.00)	1	1 (2.00)
Eyelid oedema	1	1 (2.00)	0	0 (0.00)
Mydriasis	1	1 (2.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	7 (14.00)	1	1 (2.00)
Diarrhoea	5	5 (10.00)	1	1 (2.00)
Constipation	1	1 (2.00)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Nausea	1	1 (2.00)	0	0 (0.00)
Vomiting	1	1 (2.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	13	9 (18.00)	2	2 (4.00)
Pyrexia	7	5 (10.00)	1	1 (2.00)
Pain	2	2 (4.00)	0	0 (0.00)
Fatigue	1	1 (2.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.00)	1	1 (2.00)
Non-cardiac chest pain	1	1 (2.00)	0	0 (0.00)
Xerosis	1	1 (2.00)	0	0 (0.00)
Immune system disorders				
- Total	10	9 (18.00)	3	2 (4.00)
Hypogammaglobulinaemia	3	3 (6.00)	0	0 (0.00)
Seasonal allergy	3	3 (6.00)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.00)	1	1 (2.00)
Drug hypersensitivity	1	1 (2.00)	1	1 (2.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.00)	1	1 (2.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Infections and infestations				
- Total	86	23 (46.00)	26	14 (28.00)
Sinusitis	9	6 (12.00)	0	0 (0.00)
Upper respiratory tract infection	7	5 (10.00)	1	1 (2.00)
Conjunctivitis	5	4 (8.00)	0	0 (0.00)
Rhinovirus infection	4	4 (8.00)	1	1 (2.00)
COVID-19	3	2 (4.00)	1	1 (2.00)
Fungal infection	3	2 (4.00)	0	0 (0.00)
Otitis media	3	2 (4.00)	0	0 (0.00)
Sepsis	3	3 (6.00)	3	3 (6.00)
Skin infection	3	3 (6.00)	0	0 (0.00)
Bronchitis	2	2 (4.00)	0	0 (0.00)
Device related sepsis	2	1 (2.00)	2	1 (2.00)
Gastroenteritis viral	2	1 (2.00)	0	0 (0.00)
Herpes zoster	2	2 (4.00)	1	1 (2.00)
Influenza	2	2 (4.00)	1	1 (2.00)
Oral herpes	2	2 (4.00)	0	0 (0.00)
Pneumonia	2	2 (4.00)	2	2 (4.00)
Urinary tract infection	2	2 (4.00)	0	0 (0.00)
Acute sinusitis	1	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Bronchiolitis	1	1 (2.00)	1	1 (2.00)
COVID-19 pneumonia	1	1 (2.00)	1	1 (2.00)
Candida infection	1	1 (2.00)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.00)	1	1 (2.00)
Ear infection	1	1 (2.00)	1	1 (2.00)
Enterovirus infection	1	1 (2.00)	1	1 (2.00)
Folliculitis	1	1 (2.00)	0	0 (0.00)
Fungal skin infection	1	1 (2.00)	0	0 (0.00)
Gastroenteritis	1	1 (2.00)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.00)	1	1 (2.00)
Gastroenteritis salmonella	1	1 (2.00)	1	1 (2.00)
Herpes virus infection	1	1 (2.00)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.00)	1	1 (2.00)
Nail infection	1	1 (2.00)	0	0 (0.00)
Neutropenic infection	1	1 (2.00)	1	1 (2.00)
Ophthalmic herpes zoster	1	1 (2.00)	0	0 (0.00)
Oral candidiasis	1	1 (2.00)	0	0 (0.00)
Otitis media acute	1	1 (2.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.00)	1	1 (2.00)
Pneumonia respiratory syncytial viral	1	1 (2.00)	1	1 (2.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Rhinitis	1	1 (2.00)	0	0 (0.00)
Septic shock	1	1 (2.00)	1	1 (2.00)
Staphylococcal abscess	1	1 (2.00)	1	1 (2.00)
Staphylococcal bacteraemia	1	1 (2.00)	1	1 (2.00)
Streptococcal sepsis	1	1 (2.00)	0	0 (0.00)
Syphilis	1	1 (2.00)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.00)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.00)	0	0 (0.00)
Viral skin infection	1	1 (2.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (6.00)	1	1 (2.00)
Abdominal injury	1	1 (2.00)	0	0 (0.00)
Infusion related reaction	1	1 (2.00)	1	1 (2.00)
Ligament sprain	1	1 (2.00)	0	0 (0.00)
Investigations				
- Total	16	6 (12.00)	6	2 (4.00)
Neutrophil count decreased	8	3 (6.00)	5	1 (2.00)
Blood bilirubin increased	3	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Platelet count decreased	2	2 (4.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.00)	1	1 (2.00)
SARS-CoV-2 test positive	1	1 (2.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	6 (12.00)	5	4 (8.00)
Decreased appetite	2	1 (2.00)	2	1 (2.00)
Iron overload	2	1 (2.00)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.00)	0	0 (0.00)
Hyperglycaemia	1	1 (2.00)	1	1 (2.00)
Hyperlipidaemia	1	1 (2.00)	0	0 (0.00)
Hypernatraemia	1	1 (2.00)	1	1 (2.00)
Hypertriglyceridaemia	1	1 (2.00)	0	0 (0.00)
Obesity	1	1 (2.00)	1	1 (2.00)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (14.00)	0	0 (0.00)
Pain in extremity	2	2 (4.00)	0	0 (0.00)
Arthralgia	1	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Growth retardation	1	1 (2.00)	0	0 (0.00)
Joint effusion	1	1 (2.00)	0	0 (0.00)
Osteonecrosis	1	1 (2.00)	0	0 (0.00)
Osteopenia	1	1 (2.00)	0	0 (0.00)
Synovitis	1	1 (2.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.00)	1	1 (2.00)
Bone giant cell tumour benign	2	1 (2.00)	1	1 (2.00)
Nervous system disorders				
- Total	9	4 (8.00)	3	2 (4.00)
Headache	3	2 (4.00)	1	1 (2.00)
Seizure	3	1 (2.00)	1	1 (2.00)
Nervous system disorder	2	1 (2.00)	1	1 (2.00)
Dysarthria	1	1 (2.00)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.00)	0	0 (0.00)
Anxiety	2	2 (4.00)	0	0 (0.00)
Tic	1	1 (2.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (2.00)	1	1 (2.00)
Endometriosis	2	1 (2.00)	1	1 (2.00)
Respiratory, thoracic and mediastinal disorders				
- Total	23	10 (20.00)	6	4 (8.00)
Cough	4	4 (8.00)	0	0 (0.00)
Dyspnoea	3	3 (6.00)	1	1 (2.00)
Rhinorrhoea	3	3 (6.00)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.00)	0	0 (0.00)
Tachypnoea	2	1 (2.00)	2	1 (2.00)
Dyspnoea exertional	1	1 (2.00)	0	0 (0.00)
Epistaxis	1	1 (2.00)	0	0 (0.00)
Hypoxia	1	1 (2.00)	1	1 (2.00)
Laryngeal oedema	1	1 (2.00)	1	1 (2.00)
Oropharyngeal pain	1	1 (2.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.00)	0	0 (0.00)
Pleural effusion	1	1 (2.00)	0	0 (0.00)
Respiratory failure	1	1 (2.00)	1	1 (2.00)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Wheezing	1	1 (2.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (14.00)	4	3 (6.00)
Rash	2	2 (4.00)	0	0 (0.00)
Rash macular	2	1 (2.00)	2	1 (2.00)
Dermatitis atopic	1	1 (2.00)	1	1 (2.00)
Dry skin	1	1 (2.00)	0	0 (0.00)
Eczema	1	1 (2.00)	1	1 (2.00)
Papule	1	1 (2.00)	0	0 (0.00)
Rash erythematous	1	1 (2.00)	0	0 (0.00)
Rash maculo-papular	1	1 (2.00)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.00)	1	1 (2.00)
Hypertension	2	2 (4.00)	1	1 (2.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	25	1 (100.00)	0	0 (0.00)
Blood and lymphatic system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Anaemia	1	1 (100.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	1 (100.00)	0	0 (0.00)
Abdominal pain	1	1 (100.00)	0	0 (0.00)
Anal haemorrhage	1	1 (100.00)	0	0 (0.00)
Diarrhoea	1	1 (100.00)	0	0 (0.00)
Nausea	1	1 (100.00)	0	0 (0.00)
Proctalgia	1	1 (100.00)	0	0 (0.00)
Vomiting	1	1 (100.00)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Immune system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	7	1 (100.00)	0	0 (0.00)
Platelet count decreased	2	1 (100.00)	0	0 (0.00)
Blood fibrinogen decreased	1	1 (100.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (100.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (100.00)	0	0 (0.00)
Blood uric acid increased	1	1 (100.00)	0	0 (0.00)
White blood cell count decreased	1	1 (100.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Decreased appetite	1	1 (100.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Pain in extremity	1	1 (100.00)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Psychiatric disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Irritability	1	1 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	1 (100.00)	0	0 (0.00)
Cough	2	1 (100.00)	0	0 (0.00)
Rhinorrhoea	2	1 (100.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	1 (100.00)	0	0 (0.00)
Dry skin	1	1 (100.00)	0	0 (0.00)
Rash papular	1	1 (100.00)	0	0 (0.00)
Rash pruritic	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250g
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and MLL rearrangement
Safety Set

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	2480	79 (100.00)	828	73 (92.41)
Blood and lymphatic system disorders				
- Total	162	54 (68.35)	95	43 (54.43)
Anaemia	62	24 (30.38)	24	9 (11.39)
Febrile neutropenia	33	27 (34.18)	33	27 (34.18)
Neutropenia	17	11 (13.92)	15	9 (11.39)
Thrombocytopenia	11	9 (11.39)	10	9 (11.39)
Disseminated intravascular coagulation	8	8 (10.13)	3	3 (3.80)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	5	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
B-cell aplasia	3	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Eosinophilia	3	1 (1.27)	0	0 (0.00)
Lymphadenopathy	2	2 (2.53)	0	0 (0.00)
Lymphopenia	2	2 (2.53)	2	2 (2.53)
Pancytopenia	2	2 (2.53)	2	2 (2.53)
Agranulocytosis	1	1 (1.27)	1	1 (1.27)
Hypercoagulation	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Leukocytosis	1	1 (1.27)	0	0 (0.00)
Lymphocytosis	1	1 (1.27)	0	0 (0.00)
Cardiac disorders				
- Total	53	28 (35.44)	14	11 (13.92)
Tachycardia	24	17 (21.52)	3	3 (3.80)
Cardiac failure	6	3 (3.80)	4	3 (3.80)
Left ventricular dysfunction	4	4 (5.06)	3	3 (3.80)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Cardiac arrest	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)
Tricuspid valve incompetence	1	1 (1.27)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.27)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.27)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (3.80)	0	0 (0.00)
Deafness unilateral	1	1 (1.27)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	8	7 (8.86)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)
Hypothyroidism	3	3 (3.80)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Delayed puberty	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	24	15 (18.99)	1	1 (1.27)
Eyelid oedema	4	3 (3.80)	0	0 (0.00)
Ocular hyperaemia	3	3 (3.80)	0	0 (0.00)
Cataract	2	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Eye pain	2	2 (2.53)	1	1 (1.27)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Visual impairment	2	2 (2.53)	0	0 (0.00)
Dry eye	1	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Hypermetropia	1	1 (1.27)	0	0 (0.00)
Mydriasis	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)
Visual field defect	1	1 (1.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	176	59 (74.68)	18	16 (20.25)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Vomiting	37	25 (31.65)	1	1 (1.27)
Diarrhoea	29	25 (31.65)	2	2 (2.53)
Nausea	26	21 (26.58)	2	2 (2.53)
Constipation	16	14 (17.72)	0	0 (0.00)
Abdominal pain	14	10 (12.66)	2	2 (2.53)
Pancreatitis	6	6 (7.59)	2	2 (2.53)
Mouth haemorrhage	5	5 (6.33)	2	2 (2.53)
Abdominal pain upper	4	4 (5.06)	0	0 (0.00)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Stomatitis	3	3 (3.80)	1	1 (1.27)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Trichoglossia	2	2 (2.53)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Abdominal rigidity	1	1 (1.27)	0	0 (0.00)
Anal fissure	1	1 (1.27)	0	0 (0.00)
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dyspepsia	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enteritis	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Enterocolitis	1	1 (1.27)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.27)	0	0 (0.00)
Proctalgia	1	1 (1.27)	1	1 (1.27)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
General disorders and administration site conditions				
- Total	156	53 (67.09)	24	15 (18.99)
Pyrexia	67	35 (44.30)	12	11 (13.92)
Fatigue	19	17 (21.52)	0	0 (0.00)
Chills	10	7 (8.86)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	9	7 (8.86)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Pain	5	5 (6.33)	2	2 (2.53)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	3	3 (3.80)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (3.80)	3	3 (3.80)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Malaise	2	2 (2.53)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.53)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)
Facial pain	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Xerosis	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	32	19 (24.05)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Hypertransaminasaemia	3	2 (2.53)	0	0 (0.00)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hepatic cytolysis	1	1 (1.27)	0	0 (0.00)
Liver disorder	1	1 (1.27)	0	0 (0.00)
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	192	70 (88.61)	76	46 (58.23)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	39	32 (40.51)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	6	6 (7.59)	4	4 (5.06)
Immunodeficiency	4	4 (5.06)	4	4 (5.06)
Seasonal allergy	4	4 (5.06)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.53)	1	1 (1.27)
Chronic graft versus host disease	2	2 (2.53)	1	1 (1.27)
Drug hypersensitivity	2	2 (2.53)	1	1 (1.27)
Graft versus host disease	2	2 (2.53)	2	2 (2.53)
Engraftment syndrome	1	1 (1.27)	1	1 (1.27)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	263	60 (75.95)	102	39 (49.37)
Upper respiratory tract infection	17	13 (16.46)	3	3 (3.80)
Sinusitis	14	7 (8.86)	2	2 (2.53)
Conjunctivitis	12	8 (10.13)	0	0 (0.00)
Rhinovirus infection	11	9 (11.39)	2	2 (2.53)
Nasopharyngitis	9	7 (8.86)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.53)	4	2 (2.53)
Gastroenteritis	6	6 (7.59)	2	2 (2.53)
Otitis media	6	5 (6.33)	1	1 (1.27)
Parainfluenzae virus infection	6	5 (6.33)	3	3 (3.80)
Pneumonia	6	6 (7.59)	4	4 (5.06)
Staphylococcal bacteraemia	6	5 (6.33)	6	5 (6.33)
Candida infection	5	4 (5.06)	2	1 (1.27)
Oral herpes	5	4 (5.06)	1	1 (1.27)
Staphylococcal infection	5	5 (6.33)	2	2 (2.53)
Bacteraemia	4	3 (3.80)	3	2 (2.53)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Ear infection	4	3 (3.80)	1	1 (1.27)
Nail infection	4	4 (5.06)	0	0 (0.00)
Oral candidiasis	4	3 (3.80)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Urinary tract infection	4	3 (3.80)	2	1 (1.27)
COVID-19	3	2 (2.53)	1	1 (1.27)
Fungal infection	3	2 (2.53)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.53)	0	0 (0.00)
Herpes zoster	3	3 (3.80)	2	2 (2.53)
Influenza	3	3 (3.80)	1	1 (1.27)
Klebsiella infection	3	1 (1.27)	3	1 (1.27)
Metapneumovirus infection	3	3 (3.80)	3	3 (3.80)
Otitis externa	3	3 (3.80)	1	1 (1.27)
Respiratory syncytial virus infection	3	3 (3.80)	2	2 (2.53)
Respiratory tract infection	3	3 (3.80)	0	0 (0.00)
Rhinitis	3	3 (3.80)	0	0 (0.00)
Sepsis	3	3 (3.80)	3	3 (3.80)
Skin infection	3	3 (3.80)	0	0 (0.00)
Acute sinusitis	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	2	2 (2.53)	2	2 (2.53)
BK virus infection	2	2 (2.53)	1	1 (1.27)
Bronchitis	2	2 (2.53)	0	0 (0.00)
Device related sepsis	2	1 (1.27)	2	1 (1.27)
Encephalitis	2	2 (2.53)	2	2 (2.53)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Encephalitis viral	2	2 (2.53)	2	2 (2.53)
Gingivitis	2	2 (2.53)	0	0 (0.00)
Herpes simplex	2	2 (2.53)	1	1 (1.27)
Human herpesvirus 6 infection	2	2 (2.53)	2	2 (2.53)
Oral infection	2	2 (2.53)	0	0 (0.00)
Paronychia	2	2 (2.53)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.53)	2	2 (2.53)
Septic shock	2	2 (2.53)	2	2 (2.53)
Varicella zoster virus infection	2	2 (2.53)	1	1 (1.27)
Viral infection	2	2 (2.53)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)
Bronchiolitis	1	1 (1.27)	1	1 (1.27)
COVID-19 pneumonia	1	1 (1.27)	1	1 (1.27)
Cellulitis	1	1 (1.27)	0	0 (0.00)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.27)	1	1 (1.27)
Coronavirus infection	1	1 (1.27)	1	1 (1.27)
Cystitis	1	1 (1.27)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Device related infection	1	1 (1.27)	1	1 (1.27)
Ear, nose and throat infection	1	1 (1.27)	0	0 (0.00)
Enterobacter infection	1	1 (1.27)	1	1 (1.27)
Enterovirus infection	1	1 (1.27)	1	1 (1.27)
Folliculitis	1	1 (1.27)	0	0 (0.00)
Fungal skin infection	1	1 (1.27)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.27)	1	1 (1.27)
Gastroenteritis clostridial	1	1 (1.27)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.27)	1	1 (1.27)
Gastrointestinal infection	1	1 (1.27)	0	0 (0.00)
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes virus infection	1	1 (1.27)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)
Localised infection	1	1 (1.27)	0	0 (0.00)
Mastoiditis	1	1 (1.27)	1	1 (1.27)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Meningitis pneumococcal	1	1 (1.27)	1	1 (1.27)
Molluscum contagiosum	1	1 (1.27)	0	0 (0.00)
Myringitis	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neutropenic infection	1	1 (1.27)	1	1 (1.27)
Ophthalmic herpes zoster	1	1 (1.27)	0	0 (0.00)
Otitis media acute	1	1 (1.27)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)
Pneumonia respiratory syncytial viral	1	1 (1.27)	1	1 (1.27)
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Respiratory tract infection viral	1	1 (1.27)	0	0 (0.00)
Salmonellosis	1	1 (1.27)	0	0 (0.00)
Sinusitis fungal	1	1 (1.27)	1	1 (1.27)
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Staphylococcal abscess	1	1 (1.27)	1	1 (1.27)
Staphylococcal sepsis	1	1 (1.27)	1	1 (1.27)
Staphylococcal skin infection	1	1 (1.27)	0	0 (0.00)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.27)	0	0 (0.00)
Syphilis	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Tinea pedis	1	1 (1.27)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.27)	1	1 (1.27)
Viral skin infection	1	1 (1.27)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	33	21 (26.58)	4	3 (3.80)
Infusion related reaction	8	5 (6.33)	1	1 (1.27)
Contusion	3	2 (2.53)	0	0 (0.00)
Wound	3	2 (2.53)	1	1 (1.27)
Fall	2	2 (2.53)	0	0 (0.00)
Ligament sprain	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Skin abrasion	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Abdominal injury	1	1 (1.27)	0	0 (0.00)
Fibula fracture	1	1 (1.27)	0	0 (0.00)
Limb injury	1	1 (1.27)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.27)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	486	59 (74.68)	238	48 (60.76)
Platelet count decreased	81	23 (29.11)	47	15 (18.99)
Neutrophil count decreased	75	24 (30.38)	54	21 (26.58)
White blood cell count decreased	67	24 (30.38)	40	18 (22.78)
Lymphocyte count decreased	36	17 (21.52)	26	15 (18.99)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Alanine aminotransferase increased	29	18 (22.78)	7	7 (8.86)
Blood bilirubin increased	25	13 (16.46)	10	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.53)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood creatinine increased	7	5 (6.33)	5	3 (3.80)
Weight increased	7	4 (5.06)	2	2 (2.53)
Blood fibrinogen decreased	6	6 (7.59)	2	2 (2.53)
Blood immunoglobulin A decreased	6	6 (7.59)	1	1 (1.27)
Blood immunoglobulin M decreased	6	6 (7.59)	2	2 (2.53)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)
Blood lactate dehydrogenase increased	5	5 (6.33)	1	1 (1.27)
C-reactive protein increased	5	5 (6.33)	3	3 (3.80)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood immunoglobulin G decreased	4	4 (5.06)	0	0 (0.00)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Blood uric acid increased	3	3 (3.80)	2	2 (2.53)
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Oxygen saturation decreased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Gamma-glutamyltransferase increased	2	2 (2.53)	2	2 (2.53)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Weight decreased	2	2 (2.53)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.27)	0	0 (0.00)
Blood urea increased	1	1 (1.27)	1	1 (1.27)
Bone density decreased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hepatitis B virus test positive	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)
Metabolism and nutrition disorders				
- Total	245	51 (64.56)	91	33 (41.77)
Hypokalaemia	46	20 (25.32)	24	11 (13.92)
Hypophosphataemia	32	18 (22.78)	11	9 (11.39)
Decreased appetite	31	29 (36.71)	14	12 (15.19)
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	12	9 (11.39)	5	5 (6.33)
Hyperuricaemia	12	9 (11.39)	1	1 (1.27)
Hypervolaemia	7	7 (8.86)	5	5 (6.33)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Tumour lysis syndrome	5	5 (6.33)	5	5 (6.33)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Metabolic acidosis	4	4 (5.06)	3	3 (3.80)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hyperkalaemia	3	3 (3.80)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hypernatraemia	3	3 (3.80)	2	2 (2.53)
Hypertriglyceridaemia	3	3 (3.80)	2	2 (2.53)
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Iron overload	3	2 (2.53)	0	0 (0.00)
Hyperchloraemia	2	2 (2.53)	0	0 (0.00)
Malnutrition	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemochromatosis	1	1 (1.27)	1	1 (1.27)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Hypophagia	1	1 (1.27)	0	0 (0.00)
Metabolic syndrome	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Obesity	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				
- Total	82	43 (54.43)	9	8 (10.13)
Pain in extremity	17	16 (20.25)	1	1 (1.27)
Arthralgia	14	12 (15.19)	1	1 (1.27)
Back pain	14	10 (12.66)	3	3 (3.80)
Myalgia	11	10 (12.66)	0	0 (0.00)
Bone pain	6	4 (5.06)	0	0 (0.00)
Growth retardation	2	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Musculoskeletal chest pain	2	2 (2.53)	0	0 (0.00)
Neck pain	2	2 (2.53)	0	0 (0.00)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Joint effusion	1	1 (1.27)	0	0 (0.00)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Myositis	1	1 (1.27)	0	0 (0.00)
Osteonecrosis	1	1 (1.27)	0	0 (0.00)
Osteopenia	1	1 (1.27)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)
Synovitis	1	1 (1.27)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (6.33)	2	2 (2.53)
Bone giant cell tumour benign	2	1 (1.27)	1	1 (1.27)
Skin papilloma	2	2 (2.53)	0	0 (0.00)
Cancer pain	1	1 (1.27)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	109	47 (59.49)	23	14 (17.72)
Headache	40	27 (34.18)	3	3 (3.80)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Seizure	7	4 (5.06)	3	3 (3.80)
Tremor	7	6 (7.59)	0	0 (0.00)
Cognitive disorder	5	3 (3.80)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Dizziness	5	4 (5.06)	0	0 (0.00)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dysgeusia	3	3 (3.80)	0	0 (0.00)
Hydrocephalus	3	1 (1.27)	3	1 (1.27)
Lethargy	3	3 (3.80)	0	0 (0.00)
Cerebral haemorrhage	2	2 (2.53)	2	2 (2.53)
Dysarthria	2	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Migraine	2	1 (1.27)	0	0 (0.00)
Nervous system disorder	2	1 (1.27)	1	1 (1.27)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.27)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Memory impairment	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)
Paraesthesia	1	1 (1.27)	0	0 (0.00)
Psychiatric disorders				
- Total	64	38 (48.10)	7	7 (8.86)
Anxiety	14	14 (17.72)	2	2 (2.53)
Delirium	8	8 (10.13)	3	3 (3.80)
Agitation	7	6 (7.59)	0	0 (0.00)
Confusional state	7	7 (8.86)	0	0 (0.00)
Mental status changes	5	5 (6.33)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Sleep disorder	4	3 (3.80)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Irritability	2	2 (2.53)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Mood altered	1	1 (1.27)	0	0 (0.00)
Nightmare	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Persistent depressive disorder	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)
Tearfulness	1	1 (1.27)	0	0 (0.00)
Tic	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	48	25 (31.65)	16	12 (15.19)
Acute kidney injury	17	12 (15.19)	9	8 (10.13)
Dysuria	4	4 (5.06)	0	0 (0.00)
Renal failure	4	2 (2.53)	3	1 (1.27)
Haematuria	3	3 (3.80)	1	1 (1.27)
Anuria	2	2 (2.53)	1	1 (1.27)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Kidney enlargement	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)
Proteinuria	1	1 (1.27)	0	0 (0.00)
Renal mass	1	1 (1.27)	0	0 (0.00)
Renal tubular disorder	1	1 (1.27)	1	1 (1.27)
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	10	6 (7.59)	2	2 (2.53)
Dysmenorrhoea	2	1 (1.27)	0	0 (0.00)
Endometriosis	2	1 (1.27)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	179	54 (68.35)	62	29 (36.71)
Cough	27	22 (27.85)	0	0 (0.00)
Hypoxia	27	20 (25.32)	22	16 (20.25)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Tachypnoea	11	9 (11.39)	6	5 (6.33)
Nasal congestion	10	9 (11.39)	0	0 (0.00)
Pleural effusion	10	9 (11.39)	3	3 (3.80)
Oropharyngeal pain	9	8 (10.13)	0	0 (0.00)
Dyspnoea	8	7 (8.86)	4	4 (5.06)
Epistaxis	8	7 (8.86)	1	1 (1.27)
Respiratory failure	6	6 (7.59)	6	6 (7.59)
Rhinorrhoea	6	5 (6.33)	0	0 (0.00)
Atelectasis	5	3 (3.80)	2	2 (2.53)
Respiratory distress	5	4 (5.06)	3	2 (2.53)
Acute respiratory distress syndrome	3	3 (3.80)	3	3 (3.80)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Pharyngeal erythema	2	2 (2.53)	0	0 (0.00)
Rhinitis allergic	2	2 (2.53)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.53)	0	0 (0.00)
Wheezing	2	2 (2.53)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Bronchial oedema	1	1 (1.27)	0	0 (0.00)
Bronchospasm	1	1 (1.27)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.27)	0	0 (0.00)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Laryngeal oedema	1	1 (1.27)	1	1 (1.27)
Lung disorder	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Respiratory disorder	1	1 (1.27)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	92	39 (49.37)	9	7 (8.86)
Rash	13	8 (10.13)	0	0 (0.00)
Pruritus	9	7 (8.86)	0	0 (0.00)
Dry skin	8	7 (8.86)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Erythema	5	5 (6.33)	0	0 (0.00)
Dermatitis atopic	4	3 (3.80)	1	1 (1.27)
Rash maculo-papular	4	3 (3.80)	1	1 (1.27)
Eczema	3	3 (3.80)	1	1 (1.27)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Rash papular	3	2 (2.53)	0	0 (0.00)
Decubitus ulcer	2	2 (2.53)	1	1 (1.27)
Ingrowing nail	2	2 (2.53)	0	0 (0.00)
Petechiae	2	2 (2.53)	1	1 (1.27)
Rash macular	2	1 (1.27)	2	1 (1.27)
Rash vesicular	2	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin discolouration	2	2 (2.53)	0	0 (0.00)
Skin ulcer	2	2 (2.53)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis allergic	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Hangnail	1	1 (1.27)	0	0 (0.00)
Miliaria	1	1 (1.27)	0	0 (0.00)
Night sweats	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Papule	1	1 (1.27)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Rash erythematous	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.27)	0	0 (0.00)
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin swelling	1	1 (1.27)	0	0 (0.00)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)
Vascular disorders				
- Total	54	34 (43.04)	27	21 (26.58)
Hypotension	29	24 (30.38)	19	16 (20.25)
Hypertension	17	16 (20.25)	5	5 (6.33)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Venoocclusive disease	2	2 (2.53)	2	2 (2.53)
Flushing	1	1 (1.27)	0	0 (0.00)
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	12	1 (100.00)	5	1 (100.00)
Gastrointestinal disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Constipation	1	1 (100.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	7	1 (100.00)	5	1 (100.00)
Lymphocyte count decreased	3	1 (100.00)	1	1 (100.00)
Neutrophil count decreased	2	1 (100.00)	2	1 (100.00)
White blood cell count decreased	2	1 (100.00)	2	1 (100.00)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	3	1 (100.00)	0	0 (0.00)
Rash vesicular	2	1 (100.00)	0	0 (0.00)
Dermatitis atopic	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	1739	78 (98.73)	614	66 (83.54)
Blood and lymphatic system disorders				
- Total	125	50 (63.29)	76	39 (49.37)
Anaemia	50	21 (26.58)	20	8 (10.13)
Febrile neutropenia	29	26 (32.91)	29	26 (32.91)
Neutropenia	11	9 (11.39)	9	7 (8.86)
Thrombocytopenia	8	8 (10.13)	8	8 (10.13)
Disseminated intravascular coagulation	7	7 (8.86)	2	2 (2.53)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	4	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
Eosinophilia	2	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pancytopenia	2	2 (2.53)	2	2 (2.53)
B-cell aplasia	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Lymphopenia	1	1 (1.27)	1	1 (1.27)
Cardiac disorders				
- Total	45	24 (30.38)	10	8 (10.13)
Tachycardia	22	17 (21.52)	3	3 (3.80)
Cardiac failure	4	1 (1.27)	2	1 (1.27)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Left ventricular dysfunction	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)
Cardiac arrest	1	1 (1.27)	1	1 (1.27)
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Ear and labyrinth disorders				
- Total	2	2 (2.53)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.33)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)
Hypothyroidism	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	15	9 (11.39)	0	0 (0.00)
Eyelid oedema	3	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.53)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Eye pain	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Visual field defect	1	1 (1.27)	0	0 (0.00)
Visual impairment	1	1 (1.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	134	50 (63.29)	16	14 (17.72)
Vomiting	30	21 (26.58)	1	1 (1.27)
Nausea	21	18 (22.78)	2	2 (2.53)
Diarrhoea	18	15 (18.99)	1	1 (1.27)
Abdominal pain	13	11 (13.92)	2	2 (2.53)
Constipation	10	10 (12.66)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.06)	2	2 (2.53)
Pancreatitis	4	4 (5.06)	1	1 (1.27)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Abdominal pain upper	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Stomatitis	2	2 (2.53)	1	1 (1.27)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Anal fissure	1	1 (1.27)	0	0 (0.00)
Anal haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enterocolitis	1	1 (1.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Proctalgia	1	1 (1.27)	1	1 (1.27)
Trichoglossia	1	1 (1.27)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
General disorders and administration site conditions				
- Total	112	40 (50.63)	19	11 (13.92)
Pyrexia	44	24 (30.38)	9	8 (10.13)
Fatigue	11	11 (13.92)	0	0 (0.00)
Chills	9	6 (7.59)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	7	6 (7.59)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	2	2 (2.53)	0	0 (0.00)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.53)	2	2 (2.53)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Facial pain	1	1 (1.27)	0	0 (0.00)
Malaise	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Pain	1	1 (1.27)	1	1 (1.27)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	29	17 (21.52)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Hypertransaminasaemia	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	163	66 (83.54)	68	43 (54.43)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	24	22 (27.85)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	5	5 (6.33)	3	3 (3.80)
Immunodeficiency	3	3 (3.80)	3	3 (3.80)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Seasonal allergy	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				
- Total	64	35 (44.30)	31	19 (24.05)
Conjunctivitis	6	5 (6.33)	0	0 (0.00)
Staphylococcal infection	5	5 (6.33)	2	2 (2.53)
Candida infection	4	3 (3.80)	2	1 (1.27)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Staphylococcal bacteraemia	4	3 (3.80)	4	3 (3.80)
Encephalitis viral	2	2 (2.53)	2	2 (2.53)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Nail infection	2	2 (2.53)	0	0 (0.00)
Oral candidiasis	2	1 (1.27)	0	0 (0.00)
Oral herpes	2	2 (2.53)	1	1 (1.27)
Oral infection	2	2 (2.53)	0	0 (0.00)
Rhinovirus infection	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	1	1 (1.27)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)
BK virus infection	1	1 (1.27)	0	0 (0.00)
Bacteraemia	1	1 (1.27)	1	1 (1.27)
Bronchopulmonary aspergillosis	1	1 (1.27)	1	1 (1.27)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Encephalitis	1	1 (1.27)	1	1 (1.27)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gingivitis	1	1 (1.27)	0	0 (0.00)
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes simplex	1	1 (1.27)	1	1 (1.27)
Human herpesvirus 6 infection	1	1 (1.27)	1	1 (1.27)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Klebsiella infection	1	1 (1.27)	1	1 (1.27)
Localised infection	1	1 (1.27)	0	0 (0.00)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Myringitis	1	1 (1.27)	0	0 (0.00)
Otitis externa	1	1 (1.27)	0	0 (0.00)
Paronychia	1	1 (1.27)	0	0 (0.00)
Pneumonia	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Sinusitis	1	1 (1.27)	1	1 (1.27)
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	20	11 (13.92)	3	2 (2.53)
Infusion related reaction	3	2 (2.53)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Wound	3	2 (2.53)	1	1 (1.27)
Contusion	2	1 (1.27)	0	0 (0.00)
Fall	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)
Skin abrasion	1	1 (1.27)	0	0 (0.00)
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	379	56 (70.89)	192	44 (55.70)
Platelet count decreased	65	21 (26.58)	38	14 (17.72)
White blood cell count decreased	48	23 (29.11)	34	17 (21.52)
Neutrophil count decreased	46	19 (24.05)	36	16 (20.25)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Lymphocyte count decreased	27	14 (17.72)	23	12 (15.19)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Alanine aminotransferase increased	26	18 (22.78)	6	6 (7.59)
Blood bilirubin increased	18	12 (15.19)	9	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)
Blood fibrinogen decreased	7	7 (8.86)	2	2 (2.53)
Blood creatinine increased	6	4 (5.06)	5	3 (3.80)
Blood immunoglobulin M decreased	6	6 (7.59)	1	1 (1.27)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)
Blood immunoglobulin A decreased	5	5 (6.33)	0	0 (0.00)
Immunoglobulins decreased	5	2 (2.53)	0	0 (0.00)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood lactate dehydrogenase increased	4	4 (5.06)	1	1 (1.27)
C-reactive protein increased	4	4 (5.06)	3	3 (3.80)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Weight increased	4	4 (5.06)	1	1 (1.27)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Blood immunoglobulin G decreased	2	2 (2.53)	0	0 (0.00)
Blood uric acid increased	2	2 (2.53)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (2.53)	2	2 (2.53)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)
Weight decreased	1	1 (1.27)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	210	46 (58.23)	76	29 (36.71)
Hypokalaemia	40	19 (24.05)	20	11 (13.92)
Hypophosphataemia	31	17 (21.52)	11	9 (11.39)
Decreased appetite	24	24 (30.38)	11	11 (13.92)
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	11	8 (10.13)	4	4 (5.06)
Hyperuricaemia	9	7 (8.86)	1	1 (1.27)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hypervolaemia	6	6 (7.59)	4	4 (5.06)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Tumour lysis syndrome	4	4 (5.06)	4	4 (5.06)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Metabolic acidosis	3	3 (3.80)	2	2 (2.53)
Hyperkalaemia	2	2 (2.53)	2	2 (2.53)
Hypernatraemia	2	2 (2.53)	1	1 (1.27)
Hypertriglyceridaemia	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)
Hyperchloraemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Malnutrition	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				
- Total	53	33 (41.77)	6	5 (6.33)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pain in extremity	11	11 (13.92)	0	0 (0.00)
Arthralgia	10	10 (12.66)	1	1 (1.27)
Myalgia	10	9 (11.39)	0	0 (0.00)
Back pain	7	6 (7.59)	1	1 (1.27)
Bone pain	4	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.27)	0	0 (0.00)
Myositis	1	1 (1.27)	0	0 (0.00)
Neck pain	1	1 (1.27)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	77	40 (50.63)	14	10 (12.66)
Headache	26	23 (29.11)	2	2 (2.53)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Tremor	7	6 (7.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cognitive disorder	5	3 (3.80)	1	1 (1.27)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dizziness	3	3 (3.80)	0	0 (0.00)
Dysgeusia	3	3 (3.80)	0	0 (0.00)
Lethargy	3	3 (3.80)	0	0 (0.00)
Seizure	3	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)
Dysarthria	1	1 (1.27)	1	1 (1.27)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)
Paraesthesia	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Psychiatric disorders				
- Total	47	28 (35.44)	6	6 (7.59)
Confusional state	7	7 (8.86)	0	0 (0.00)
Delirium	7	7 (8.86)	3	3 (3.80)
Agitation	6	5 (6.33)	0	0 (0.00)
Anxiety	6	6 (7.59)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Irritability	3	3 (3.80)	0	0 (0.00)
Mental status changes	3	3 (3.80)	1	1 (1.27)
Sleep disorder	3	2 (2.53)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	39	20 (25.32)	13	9 (11.39)
Acute kidney injury	14	9 (11.39)	8	7 (8.86)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Renal failure	4	2 (2.53)	3	1 (1.27)
Dysuria	3	3 (3.80)	0	0 (0.00)
Anuria	2	2 (2.53)	1	1 (1.27)
Haematuria	2	2 (2.53)	0	0 (0.00)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)
Proteinuria	1	1 (1.27)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (6.33)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				
- Total	114	41 (51.90)	50	23 (29.11)
Hypoxia	23	17 (21.52)	18	12 (15.19)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Cough	11	10 (12.66)	0	0 (0.00)
Tachypnoea	9	8 (10.13)	4	4 (5.06)
Pleural effusion	7	7 (8.86)	3	3 (3.80)
Oropharyngeal pain	6	5 (6.33)	0	0 (0.00)
Atelectasis	5	3 (3.80)	2	2 (2.53)
Epistaxis	4	4 (5.06)	1	1 (1.27)
Respiratory distress	4	3 (3.80)	2	1 (1.27)
Respiratory failure	4	4 (5.06)	4	4 (5.06)
Dyspnoea	3	3 (3.80)	3	3 (3.80)
Nasal congestion	3	3 (3.80)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Acute respiratory distress syndrome	2	2 (2.53)	2	2 (2.53)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Rhinorrhoea	2	2 (2.53)	0	0 (0.00)
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)
Respiratory disorder	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Wheezing	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	53	26 (32.91)	4	3 (3.80)
Pruritus	7	6 (7.59)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Rash	5	5 (6.33)	0	0 (0.00)
Erythema	4	4 (5.06)	0	0 (0.00)
Rash papular	4	3 (3.80)	0	0 (0.00)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Rash maculo-papular	3	2 (2.53)	1	1 (1.27)
Petechiae	2	2 (2.53)	1	1 (1.27)
Skin ulcer	2	2 (2.53)	0	0 (0.00)
Decubitus ulcer	1	1 (1.27)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis atopic	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Dry skin	1	1 (1.27)	0	0 (0.00)
Eczema	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Rash pruritic	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)
Skin discolouration	1	1 (1.27)	0	0 (0.00)
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Vascular disorders				
- Total	45	28 (35.44)	21	17 (21.52)
Hypotension	25	21 (26.58)	16	14 (17.72)
Hypertension	14	13 (16.46)	4	4 (5.06)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Flushing	1	1 (1.27)	0	0 (0.00)
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	10	1 (100.00)	3	1 (100.00)
Infections and infestations				
- Total	2	1 (100.00)	0	0 (0.00)
Cystitis	1	1 (100.00)	0	0 (0.00)
Nasopharyngitis	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	6	1 (100.00)	3	1 (100.00)
White blood cell count decreased	3	1 (100.00)	1	1 (100.00)
Neutrophil count decreased	2	1 (100.00)	2	1 (100.00)
Platelet count decreased	1	1 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
- Total	1	1 (100.00)	0	0 (0.00)
Cough	1	1 (100.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Dermatitis atopic	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	524	68 (91.89)	143	35 (47.30)
Blood and lymphatic system disorders				
- Total	32	17 (22.97)	17	10 (13.51)
Anaemia	12	6 (8.11)	4	2 (2.70)
Neutropenia	5	5 (6.76)	5	5 (6.76)
Febrile neutropenia	4	3 (4.05)	4	3 (4.05)
B-cell aplasia	2	1 (1.35)	0	0 (0.00)
Thrombocytopenia	2	2 (2.70)	2	2 (2.70)
Disseminated intravascular coagulation	1	1 (1.35)	1	1 (1.35)
Eosinophilia	1	1 (1.35)	0	0 (0.00)
Leukocytosis	1	1 (1.35)	0	0 (0.00)
Leukopenia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Lymphadenopathy	1	1 (1.35)	0	0 (0.00)
Lymphocytosis	1	1 (1.35)	0	0 (0.00)
Lymphopenia	1	1 (1.35)	1	1 (1.35)
Cardiac disorders				
- Total	8	7 (9.46)	4	3 (4.05)
Cardiac arrest	2	2 (2.70)	2	2 (2.70)
Cardiac failure	2	2 (2.70)	2	2 (2.70)
Tachycardia	2	2 (2.70)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Hypothyroidism	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.41)	0	0 (0.00)
Cataract	2	2 (2.70)	0	0 (0.00)
Hypermetropia	1	1 (1.35)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Visual impairment	1	1 (1.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	20 (27.03)	1	1 (1.35)
Diarrhoea	7	7 (9.46)	0	0 (0.00)
Vomiting	7	6 (8.11)	0	0 (0.00)
Nausea	5	5 (6.76)	0	0 (0.00)
Constipation	4	3 (4.05)	0	0 (0.00)
Abdominal pain	2	2 (2.70)	0	0 (0.00)
Pancreatitis	2	2 (2.70)	1	1 (1.35)
Abdominal pain upper	1	1 (1.35)	0	0 (0.00)
Abdominal rigidity	1	1 (1.35)	0	0 (0.00)
Dyspepsia	1	1 (1.35)	0	0 (0.00)
Enteritis	1	1 (1.35)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.35)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.35)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.35)	0	0 (0.00)
Proctalgia	1	1 (1.35)	0	0 (0.00)
Stomatitis	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Trichoglossia	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	31	24 (32.43)	3	3 (4.05)
Pyrexia	16	15 (20.27)	2	2 (2.70)
Fatigue	7	6 (8.11)	0	0 (0.00)
Oedema peripheral	2	1 (1.35)	0	0 (0.00)
Pain	2	2 (2.70)	1	1 (1.35)
Asthenia	1	1 (1.35)	0	0 (0.00)
Chills	1	1 (1.35)	0	0 (0.00)
Malaise	1	1 (1.35)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.05)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.35)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.35)	0	0 (0.00)
Liver disorder	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	19	16 (21.62)	5	4 (5.41)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypogammaglobulinaemia	12	10 (13.51)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.70)	1	1 (1.35)
Graft versus host disease	2	2 (2.70)	2	2 (2.70)
Drug hypersensitivity	1	1 (1.35)	0	0 (0.00)
Engraftment syndrome	1	1 (1.35)	1	1 (1.35)
Immunodeficiency	1	1 (1.35)	1	1 (1.35)
Infections and infestations				
- Total	111	38 (51.35)	45	20 (27.03)
Upper respiratory tract infection	10	8 (10.81)	2	2 (2.70)
Nasopharyngitis	8	6 (8.11)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (1.35)	3	1 (1.35)
Gastroenteritis	5	5 (6.76)	2	2 (2.70)
Parainfluenzae virus infection	5	4 (5.41)	2	2 (2.70)
Rhinovirus infection	5	5 (6.76)	1	1 (1.35)
Sinusitis	4	3 (4.05)	1	1 (1.35)
Bacteraemia	3	2 (2.70)	2	1 (1.35)
Ear infection	3	2 (2.70)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.05)	3	3 (4.05)
Otitis media	3	3 (4.05)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pneumonia	3	3 (4.05)	1	1 (1.35)
Respiratory syncytial virus infection	3	3 (4.05)	2	2 (2.70)
Respiratory tract infection	3	3 (4.05)	0	0 (0.00)
Klebsiella infection	2	1 (1.35)	2	1 (1.35)
Otitis externa	2	2 (2.70)	1	1 (1.35)
Pneumocystis jirovecii pneumonia	2	2 (2.70)	2	2 (2.70)
Rhinitis	2	2 (2.70)	0	0 (0.00)
Urinary tract infection	2	1 (1.35)	2	1 (1.35)
Viral infection	2	2 (2.70)	1	1 (1.35)
Acute sinusitis	1	1 (1.35)	0	0 (0.00)
Adenovirus infection	1	1 (1.35)	1	1 (1.35)
BK virus infection	1	1 (1.35)	1	1 (1.35)
Cellulitis	1	1 (1.35)	0	0 (0.00)
Conjunctivitis	1	1 (1.35)	0	0 (0.00)
Coronavirus infection	1	1 (1.35)	1	1 (1.35)
Cytomegalovirus infection reactivation	1	1 (1.35)	1	1 (1.35)
Device related infection	1	1 (1.35)	1	1 (1.35)
Ear, nose and throat infection	1	1 (1.35)	0	0 (0.00)
Encephalitis	1	1 (1.35)	1	1 (1.35)
Enterobacter infection	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastroenteritis clostridial	1	1 (1.35)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.35)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.35)	0	0 (0.00)
Gingivitis	1	1 (1.35)	0	0 (0.00)
Herpes simplex	1	1 (1.35)	0	0 (0.00)
Herpes zoster	1	1 (1.35)	1	1 (1.35)
Human herpesvirus 6 infection	1	1 (1.35)	1	1 (1.35)
Influenza	1	1 (1.35)	0	0 (0.00)
Mastoiditis	1	1 (1.35)	1	1 (1.35)
Molluscum contagiosum	1	1 (1.35)	0	0 (0.00)
Nail infection	1	1 (1.35)	0	0 (0.00)
Oral candidiasis	1	1 (1.35)	0	0 (0.00)
Oral herpes	1	1 (1.35)	0	0 (0.00)
Paronychia	1	1 (1.35)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.35)	1	1 (1.35)
Respiratory tract infection viral	1	1 (1.35)	0	0 (0.00)
Salmonellosis	1	1 (1.35)	0	0 (0.00)
Septic shock	1	1 (1.35)	1	1 (1.35)
Sinusitis fungal	1	1 (1.35)	1	1 (1.35)
Staphylococcal bacteraemia	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Staphylococcal sepsis	1	1 (1.35)	1	1 (1.35)
Staphylococcal skin infection	1	1 (1.35)	0	0 (0.00)
Tinea pedis	1	1 (1.35)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.35)	1	1 (1.35)
Viral upper respiratory tract infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	10	9 (12.16)	0	0 (0.00)
Infusion related reaction	4	3 (4.05)	0	0 (0.00)
Contusion	1	1 (1.35)	0	0 (0.00)
Fibula fracture	1	1 (1.35)	0	0 (0.00)
Ligament sprain	1	1 (1.35)	0	0 (0.00)
Limb injury	1	1 (1.35)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.35)	0	0 (0.00)
Skin abrasion	1	1 (1.35)	0	0 (0.00)
Investigations				
- Total	85	29 (39.19)	32	15 (20.27)
Neutrophil count decreased	17	9 (12.16)	9	6 (8.11)
Platelet count decreased	15	4 (5.41)	9	2 (2.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
White blood cell count decreased	15	9 (12.16)	3	3 (4.05)
Lymphocyte count decreased	6	4 (5.41)	2	2 (2.70)
Immunoglobulins decreased	5	1 (1.35)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.70)	1	1 (1.35)
Alanine aminotransferase increased	3	2 (2.70)	1	1 (1.35)
Weight increased	3	1 (1.35)	1	1 (1.35)
Blood immunoglobulin A decreased	2	2 (2.70)	1	1 (1.35)
Blood uric acid increased	2	2 (2.70)	2	2 (2.70)
Blood creatinine increased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.35)	1	1 (1.35)
Blood lactate dehydrogenase increased	1	1 (1.35)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.35)	0	0 (0.00)
Blood urea increased	1	1 (1.35)	1	1 (1.35)
Bone density decreased	1	1 (1.35)	0	0 (0.00)
C-reactive protein increased	1	1 (1.35)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.35)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hepatitis B virus test positive	1	1 (1.35)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.35)	0	0 (0.00)
Weight decreased	1	1 (1.35)	1	1 (1.35)
Metabolism and nutrition disorders				
- Total	26	15 (20.27)	10	7 (9.46)
Decreased appetite	6	6 (8.11)	1	1 (1.35)
Hypokalaemia	6	3 (4.05)	4	2 (2.70)
Hyperuricaemia	3	3 (4.05)	0	0 (0.00)
Haemochromatosis	1	1 (1.35)	1	1 (1.35)
Hyperchloraemia	1	1 (1.35)	0	0 (0.00)
Hyperkalaemia	1	1 (1.35)	0	0 (0.00)
Hypervolaemia	1	1 (1.35)	1	1 (1.35)
Hypophagia	1	1 (1.35)	0	0 (0.00)
Hypophosphataemia	1	1 (1.35)	0	0 (0.00)
Iron overload	1	1 (1.35)	0	0 (0.00)
Malnutrition	1	1 (1.35)	1	1 (1.35)
Metabolic acidosis	1	1 (1.35)	1	1 (1.35)
Metabolic syndrome	1	1 (1.35)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	22	15 (20.27)	3	3 (4.05)
Back pain	7	6 (8.11)	2	2 (2.70)
Pain in extremity	5	5 (6.76)	1	1 (1.35)
Arthralgia	3	3 (4.05)	0	0 (0.00)
Bone pain	2	2 (2.70)	0	0 (0.00)
Growth retardation	1	1 (1.35)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.35)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.35)	0	0 (0.00)
Myalgia	1	1 (1.35)	0	0 (0.00)
Neck pain	1	1 (1.35)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.41)	1	1 (1.35)
Skin papilloma	2	2 (2.70)	0	0 (0.00)
Cancer pain	1	1 (1.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.35)	1	1 (1.35)
Nervous system disorders				
- Total	23	14 (18.92)	6	2 (2.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Headache	11	10 (13.51)	0	0 (0.00)
Hydrocephalus	3	1 (1.35)	3	1 (1.35)
Dizziness	2	1 (1.35)	0	0 (0.00)
Migraine	2	1 (1.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.35)	1	1 (1.35)
Cerebral haemorrhage	1	1 (1.35)	1	1 (1.35)
Extrapyramidal disorder	1	1 (1.35)	0	0 (0.00)
Memory impairment	1	1 (1.35)	0	0 (0.00)
Seizure	1	1 (1.35)	1	1 (1.35)
Psychiatric disorders				
- Total	15	10 (13.51)	1	1 (1.35)
Anxiety	6	6 (8.11)	0	0 (0.00)
Mental status changes	2	2 (2.70)	1	1 (1.35)
Agitation	1	1 (1.35)	0	0 (0.00)
Delirium	1	1 (1.35)	0	0 (0.00)
Mood altered	1	1 (1.35)	0	0 (0.00)
Nightmare	1	1 (1.35)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.35)	0	0 (0.00)
Sleep disorder	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Tearfulness	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	5 (6.76)	3	3 (4.05)
Acute kidney injury	3	3 (4.05)	1	1 (1.35)
Cystitis haemorrhagic	1	1 (1.35)	0	0 (0.00)
Dysuria	1	1 (1.35)	0	0 (0.00)
Haematuria	1	1 (1.35)	1	1 (1.35)
Kidney enlargement	1	1 (1.35)	0	0 (0.00)
Renal mass	1	1 (1.35)	0	0 (0.00)
Renal tubular disorder	1	1 (1.35)	1	1 (1.35)
Reproductive system and breast disorders				
- Total	2	1 (1.35)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	45	23 (31.08)	6	6 (8.11)
Cough	13	10 (13.51)	0	0 (0.00)
Nasal congestion	7	6 (8.11)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Epistaxis	3	3 (4.05)	0	0 (0.00)
Hypoxia	3	3 (4.05)	3	3 (4.05)
Rhinorrhoea	3	3 (4.05)	0	0 (0.00)
Dyspnoea	2	1 (1.35)	0	0 (0.00)
Oropharyngeal pain	2	2 (2.70)	0	0 (0.00)
Pleural effusion	2	2 (2.70)	0	0 (0.00)
Rhinitis allergic	2	2 (2.70)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.35)	1	1 (1.35)
Bronchial oedema	1	1 (1.35)	0	0 (0.00)
Bronchospasm	1	1 (1.35)	0	0 (0.00)
Lung disorder	1	1 (1.35)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.35)	0	0 (0.00)
Respiratory distress	1	1 (1.35)	1	1 (1.35)
Respiratory failure	1	1 (1.35)	1	1 (1.35)
Upper respiratory tract inflammation	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	28	19 (25.68)	1	1 (1.35)
Dry skin	7	6 (8.11)	0	0 (0.00)
Rash	6	4 (5.41)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Ingrowing nail	2	2 (2.70)	0	0 (0.00)
Pruritus	2	1 (1.35)	0	0 (0.00)
Decubitus ulcer	1	1 (1.35)	1	1 (1.35)
Dermatitis allergic	1	1 (1.35)	0	0 (0.00)
Eczema	1	1 (1.35)	0	0 (0.00)
Erythema	1	1 (1.35)	0	0 (0.00)
Hangnail	1	1 (1.35)	0	0 (0.00)
Miliaria	1	1 (1.35)	0	0 (0.00)
Night sweats	1	1 (1.35)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.35)	0	0 (0.00)
Skin discolouration	1	1 (1.35)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.35)	0	0 (0.00)
Skin swelling	1	1 (1.35)	0	0 (0.00)
Vascular disorders				
- Total	7	6 (8.11)	5	5 (6.76)
Hypotension	4	4 (5.41)	3	3 (4.05)
Venoocclusive disease	2	2 (2.70)	2	2 (2.70)
Hypertension	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

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Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	4	1 (100.00)	0	0 (0.00)
Blood and lymphatic system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Lymphadenopathy	1	1 (100.00)	0	0 (0.00)
Infections and infestations				
- Total	2	1 (100.00)	0	0 (0.00)
Bronchitis	1	1 (100.00)	0	0 (0.00)
Gastroenteritis	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	1	1 (100.00)	0	0 (0.00)
Platelet count decreased	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Total number of AE per patient	216	31 (63.27)	63	19 (38.78)
Blood and lymphatic system disorders				
- Total	5	3 (6.12)	2	2 (4.08)
Agranulocytosis	1	1 (2.04)	1	1 (2.04)
Anaemia	1	1 (2.04)	0	0 (0.00)
Hypercoagulation	1	1 (2.04)	0	0 (0.00)
Neutropenia	1	1 (2.04)	1	1 (2.04)
Thrombocytopenia	1	1 (2.04)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.04)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.04)	0	0 (0.00)
Deafness unilateral	1	1 (2.04)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.04)	0	0 (0.00)
Delayed puberty	1	1 (2.04)	0	0 (0.00)
Hypothyroidism	1	1 (2.04)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.12)	1	1 (2.04)
Dry eye	1	1 (2.04)	0	0 (0.00)
Eye pain	1	1 (2.04)	1	1 (2.04)
Eyelid oedema	1	1 (2.04)	0	0 (0.00)
Mydriasis	1	1 (2.04)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	7 (14.29)	1	1 (2.04)
Diarrhoea	5	5 (10.20)	1	1 (2.04)
Constipation	1	1 (2.04)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Nausea	1	1 (2.04)	0	0 (0.00)
Vomiting	1	1 (2.04)	0	0 (0.00)
General disorders and administration site conditions				
- Total	13	9 (18.37)	2	2 (4.08)
Pyrexia	7	5 (10.20)	1	1 (2.04)
Pain	2	2 (4.08)	0	0 (0.00)
Fatigue	1	1 (2.04)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.04)	1	1 (2.04)
Non-cardiac chest pain	1	1 (2.04)	0	0 (0.00)
Xerosis	1	1 (2.04)	0	0 (0.00)
Immune system disorders				
- Total	10	9 (18.37)	3	2 (4.08)
Hypogammaglobulinaemia	3	3 (6.12)	0	0 (0.00)
Seasonal allergy	3	3 (6.12)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.08)	1	1 (2.04)
Drug hypersensitivity	1	1 (2.04)	1	1 (2.04)
Haemophagocytic lymphohistiocytosis	1	1 (2.04)	1	1 (2.04)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Infections and infestations				
- Total	84	22 (44.90)	26	14 (28.57)
Sinusitis	9	6 (12.24)	0	0 (0.00)
Upper respiratory tract infection	7	5 (10.20)	1	1 (2.04)
Conjunctivitis	5	4 (8.16)	0	0 (0.00)
Rhinovirus infection	4	4 (8.16)	1	1 (2.04)
COVID-19	3	2 (4.08)	1	1 (2.04)
Fungal infection	3	2 (4.08)	0	0 (0.00)
Otitis media	3	2 (4.08)	0	0 (0.00)
Sepsis	3	3 (6.12)	3	3 (6.12)
Skin infection	3	3 (6.12)	0	0 (0.00)
Device related sepsis	2	1 (2.04)	2	1 (2.04)
Gastroenteritis viral	2	1 (2.04)	0	0 (0.00)
Herpes zoster	2	2 (4.08)	1	1 (2.04)
Influenza	2	2 (4.08)	1	1 (2.04)
Oral herpes	2	2 (4.08)	0	0 (0.00)
Pneumonia	2	2 (4.08)	2	2 (4.08)
Urinary tract infection	2	2 (4.08)	0	0 (0.00)
Acute sinusitis	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Bronchiolitis	1	1 (2.04)	1	1 (2.04)
Bronchitis	1	1 (2.04)	0	0 (0.00)
COVID-19 pneumonia	1	1 (2.04)	1	1 (2.04)
Candida infection	1	1 (2.04)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.04)	1	1 (2.04)
Ear infection	1	1 (2.04)	1	1 (2.04)
Enterovirus infection	1	1 (2.04)	1	1 (2.04)
Folliculitis	1	1 (2.04)	0	0 (0.00)
Fungal skin infection	1	1 (2.04)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.04)	1	1 (2.04)
Gastroenteritis salmonella	1	1 (2.04)	1	1 (2.04)
Herpes virus infection	1	1 (2.04)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.04)	1	1 (2.04)
Nail infection	1	1 (2.04)	0	0 (0.00)
Neutropenic infection	1	1 (2.04)	1	1 (2.04)
Ophthalmic herpes zoster	1	1 (2.04)	0	0 (0.00)
Oral candidiasis	1	1 (2.04)	0	0 (0.00)
Otitis media acute	1	1 (2.04)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.04)	1	1 (2.04)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Pneumonia respiratory syncytial viral	1	1 (2.04)	1	1 (2.04)
Rhinitis	1	1 (2.04)	0	0 (0.00)
Septic shock	1	1 (2.04)	1	1 (2.04)
Staphylococcal abscess	1	1 (2.04)	1	1 (2.04)
Staphylococcal bacteraemia	1	1 (2.04)	1	1 (2.04)
Streptococcal sepsis	1	1 (2.04)	0	0 (0.00)
Syphilis	1	1 (2.04)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.04)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.04)	0	0 (0.00)
Viral skin infection	1	1 (2.04)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (6.12)	1	1 (2.04)
Abdominal injury	1	1 (2.04)	0	0 (0.00)
Infusion related reaction	1	1 (2.04)	1	1 (2.04)
Ligament sprain	1	1 (2.04)	0	0 (0.00)
Investigations				
- Total	15	5 (10.20)	6	2 (4.08)
Neutrophil count decreased	8	3 (6.12)	5	1 (2.04)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Blood bilirubin increased	3	1 (2.04)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.04)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.04)	1	1 (2.04)
Platelet count decreased	1	1 (2.04)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (2.04)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	6 (12.24)	5	4 (8.16)
Decreased appetite	2	1 (2.04)	2	1 (2.04)
Iron overload	2	1 (2.04)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.04)	0	0 (0.00)
Hyperglycaemia	1	1 (2.04)	1	1 (2.04)
Hyperlipidaemia	1	1 (2.04)	0	0 (0.00)
Hypernatraemia	1	1 (2.04)	1	1 (2.04)
Hypertriglyceridaemia	1	1 (2.04)	0	0 (0.00)
Obesity	1	1 (2.04)	1	1 (2.04)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (14.29)	0	0 (0.00)
Pain in extremity	2	2 (4.08)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Arthralgia	1	1 (2.04)	0	0 (0.00)
Growth retardation	1	1 (2.04)	0	0 (0.00)
Joint effusion	1	1 (2.04)	0	0 (0.00)
Osteonecrosis	1	1 (2.04)	0	0 (0.00)
Osteopenia	1	1 (2.04)	0	0 (0.00)
Synovitis	1	1 (2.04)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.04)	1	1 (2.04)
Bone giant cell tumour benign	2	1 (2.04)	1	1 (2.04)
Nervous system disorders				
- Total	9	4 (8.16)	3	2 (4.08)
Headache	3	2 (4.08)	1	1 (2.04)
Seizure	3	1 (2.04)	1	1 (2.04)
Nervous system disorder	2	1 (2.04)	1	1 (2.04)
Dysarthria	1	1 (2.04)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.12)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Anxiety	2	2 (4.08)	0	0 (0.00)
Tic	1	1 (2.04)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.04)	1	1 (2.04)
Endometriosis	2	1 (2.04)	1	1 (2.04)
Respiratory, thoracic and mediastinal disorders				
- Total	23	10 (20.41)	6	4 (8.16)
Cough	4	4 (8.16)	0	0 (0.00)
Dyspnoea	3	3 (6.12)	1	1 (2.04)
Rhinorrhoea	3	3 (6.12)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.08)	0	0 (0.00)
Tachypnoea	2	1 (2.04)	2	1 (2.04)
Dyspnoea exertional	1	1 (2.04)	0	0 (0.00)
Epistaxis	1	1 (2.04)	0	0 (0.00)
Hypoxia	1	1 (2.04)	1	1 (2.04)
Laryngeal oedema	1	1 (2.04)	1	1 (2.04)
Oropharyngeal pain	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Pharyngeal erythema	1	1 (2.04)	0	0 (0.00)
Pleural effusion	1	1 (2.04)	0	0 (0.00)
Respiratory failure	1	1 (2.04)	1	1 (2.04)
Wheezing	1	1 (2.04)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (14.29)	4	3 (6.12)
Rash	2	2 (4.08)	0	0 (0.00)
Rash macular	2	1 (2.04)	2	1 (2.04)
Dermatitis atopic	1	1 (2.04)	1	1 (2.04)
Dry skin	1	1 (2.04)	0	0 (0.00)
Eczema	1	1 (2.04)	1	1 (2.04)
Papule	1	1 (2.04)	0	0 (0.00)
Rash erythematous	1	1 (2.04)	0	0 (0.00)
Rash maculo-papular	1	1 (2.04)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.08)	1	1 (2.04)
Hypertension	2	2 (4.08)	1	1 (2.04)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: At anytime, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	26	1 (100.00)	8	1 (100.00)
Blood and lymphatic system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Lymphadenopathy	1	1 (100.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Constipation	1	1 (100.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (100.00)	0	0 (0.00)
Infections and infestations				

Timing: At anytime, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
- Total	4	1 (100.00)	0	0 (0.00)
Bronchitis	1	1 (100.00)	0	0 (0.00)
Cystitis	1	1 (100.00)	0	0 (0.00)
Gastroenteritis	1	1 (100.00)	0	0 (0.00)
Nasopharyngitis	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	14	1 (100.00)	8	1 (100.00)
White blood cell count decreased	5	1 (100.00)	3	1 (100.00)
Neutrophil count decreased	4	1 (100.00)	4	1 (100.00)
Lymphocyte count decreased	3	1 (100.00)	1	1 (100.00)
Platelet count decreased	2	1 (100.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Cough	1	1 (100.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	1 (100.00)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Dermatitis atopic	2	1 (100.00)	0	0 (0.00)
Rash vesicular	2	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250h
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Hypodiploidy
Safety Set

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	2479	79 (100.00)	820	72 (91.14)
Blood and lymphatic system disorders				
- Total	162	54 (68.35)	95	43 (54.43)
Anaemia	63	25 (31.65)	24	9 (11.39)
Febrile neutropenia	33	27 (34.18)	33	27 (34.18)
Neutropenia	17	11 (13.92)	15	9 (11.39)
Thrombocytopenia	11	9 (11.39)	10	9 (11.39)
Disseminated intravascular coagulation	8	8 (10.13)	3	3 (3.80)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	5	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
B-cell aplasia	3	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Eosinophilia	3	1 (1.27)	0	0 (0.00)
Lymphopenia	2	2 (2.53)	2	2 (2.53)
Pancytopenia	2	2 (2.53)	2	2 (2.53)
Agranulocytosis	1	1 (1.27)	1	1 (1.27)
Hypercoagulation	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Leukocytosis	1	1 (1.27)	0	0 (0.00)
Lymphadenopathy	1	1 (1.27)	0	0 (0.00)
Lymphocytosis	1	1 (1.27)	0	0 (0.00)
Cardiac disorders				
- Total	53	28 (35.44)	14	11 (13.92)
Tachycardia	24	17 (21.52)	3	3 (3.80)
Cardiac failure	6	3 (3.80)	4	3 (3.80)
Left ventricular dysfunction	4	4 (5.06)	3	3 (3.80)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Cardiac arrest	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)
Tricuspid valve incompetence	1	1 (1.27)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.27)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.27)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (3.80)	0	0 (0.00)
Deafness unilateral	1	1 (1.27)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	8	7 (8.86)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hypothyroidism	3	3 (3.80)	0	0 (0.00)
Delayed puberty	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	24	15 (18.99)	1	1 (1.27)
Eyelid oedema	4	3 (3.80)	0	0 (0.00)
Ocular hyperaemia	3	3 (3.80)	0	0 (0.00)
Cataract	2	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Eye pain	2	2 (2.53)	1	1 (1.27)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Visual impairment	2	2 (2.53)	0	0 (0.00)
Dry eye	1	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Hypermetropia	1	1 (1.27)	0	0 (0.00)
Mydriasis	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)
Visual field defect	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Gastrointestinal disorders				
- Total	181	59 (74.68)	18	16 (20.25)
Vomiting	38	26 (32.91)	1	1 (1.27)
Diarrhoea	30	26 (32.91)	2	2 (2.53)
Nausea	27	22 (27.85)	2	2 (2.53)
Abdominal pain	15	11 (13.92)	2	2 (2.53)
Constipation	15	13 (16.46)	0	0 (0.00)
Pancreatitis	6	6 (7.59)	2	2 (2.53)
Mouth haemorrhage	5	5 (6.33)	2	2 (2.53)
Abdominal pain upper	4	4 (5.06)	0	0 (0.00)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Stomatitis	3	3 (3.80)	1	1 (1.27)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Proctalgia	2	2 (2.53)	1	1 (1.27)
Trichoglossia	2	2 (2.53)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Abdominal rigidity	1	1 (1.27)	0	0 (0.00)
Anal fissure	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Anal haemorrhage	1	1 (1.27)	0	0 (0.00)
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dyspepsia	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enteritis	1	1 (1.27)	0	0 (0.00)
Enterocolitis	1	1 (1.27)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.27)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
General disorders and administration site conditions				
- Total	156	53 (67.09)	24	15 (18.99)
Pyrexia	67	35 (44.30)	12	11 (13.92)
Fatigue	19	17 (21.52)	0	0 (0.00)
Chills	10	7 (8.86)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	9	7 (8.86)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Pain	5	5 (6.33)	2	2 (2.53)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	3	3 (3.80)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (3.80)	3	3 (3.80)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Malaise	2	2 (2.53)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.53)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)
Facial pain	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Xerosis	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	32	19 (24.05)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Hypertransaminasaemia	3	2 (2.53)	0	0 (0.00)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)
Hepatic cytolysis	1	1 (1.27)	0	0 (0.00)
Liver disorder	1	1 (1.27)	0	0 (0.00)
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	192	70 (88.61)	76	46 (58.23)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	39	32 (40.51)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	6	6 (7.59)	4	4 (5.06)
Immunodeficiency	4	4 (5.06)	4	4 (5.06)
Seasonal allergy	4	4 (5.06)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.53)	1	1 (1.27)
Chronic graft versus host disease	2	2 (2.53)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Drug hypersensitivity	2	2 (2.53)	1	1 (1.27)
Graft versus host disease	2	2 (2.53)	2	2 (2.53)
Engraftment syndrome	1	1 (1.27)	1	1 (1.27)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				
- Total	259	59 (74.68)	102	39 (49.37)
Upper respiratory tract infection	17	13 (16.46)	3	3 (3.80)
Sinusitis	14	7 (8.86)	2	2 (2.53)
Conjunctivitis	12	8 (10.13)	0	0 (0.00)
Rhinovirus infection	11	9 (11.39)	2	2 (2.53)
Nasopharyngitis	8	6 (7.59)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.53)	4	2 (2.53)
Otitis media	6	5 (6.33)	1	1 (1.27)
Parainfluenzae virus infection	6	5 (6.33)	3	3 (3.80)
Pneumonia	6	6 (7.59)	4	4 (5.06)
Staphylococcal bacteraemia	6	5 (6.33)	6	5 (6.33)
Candida infection	5	4 (5.06)	2	1 (1.27)
Gastroenteritis	5	5 (6.33)	2	2 (2.53)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Oral herpes	5	4 (5.06)	1	1 (1.27)
Staphylococcal infection	5	5 (6.33)	2	2 (2.53)
Bacteraemia	4	3 (3.80)	3	2 (2.53)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Ear infection	4	3 (3.80)	1	1 (1.27)
Nail infection	4	4 (5.06)	0	0 (0.00)
Oral candidiasis	4	3 (3.80)	0	0 (0.00)
Urinary tract infection	4	3 (3.80)	2	1 (1.27)
COVID-19	3	2 (2.53)	1	1 (1.27)
Fungal infection	3	2 (2.53)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.53)	0	0 (0.00)
Herpes zoster	3	3 (3.80)	2	2 (2.53)
Influenza	3	3 (3.80)	1	1 (1.27)
Klebsiella infection	3	1 (1.27)	3	1 (1.27)
Metapneumovirus infection	3	3 (3.80)	3	3 (3.80)
Otitis externa	3	3 (3.80)	1	1 (1.27)
Respiratory syncytial virus infection	3	3 (3.80)	2	2 (2.53)
Respiratory tract infection	3	3 (3.80)	0	0 (0.00)
Rhinitis	3	3 (3.80)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Sepsis	3	3 (3.80)	3	3 (3.80)
Skin infection	3	3 (3.80)	0	0 (0.00)
Acute sinusitis	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	2	2 (2.53)	2	2 (2.53)
BK virus infection	2	2 (2.53)	1	1 (1.27)
Device related sepsis	2	1 (1.27)	2	1 (1.27)
Encephalitis	2	2 (2.53)	2	2 (2.53)
Encephalitis viral	2	2 (2.53)	2	2 (2.53)
Gingivitis	2	2 (2.53)	0	0 (0.00)
Herpes simplex	2	2 (2.53)	1	1 (1.27)
Human herpesvirus 6 infection	2	2 (2.53)	2	2 (2.53)
Oral infection	2	2 (2.53)	0	0 (0.00)
Paronychia	2	2 (2.53)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.53)	2	2 (2.53)
Septic shock	2	2 (2.53)	2	2 (2.53)
Varicella zoster virus infection	2	2 (2.53)	1	1 (1.27)
Viral infection	2	2 (2.53)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Bronchiolitis	1	1 (1.27)	1	1 (1.27)
Bronchitis	1	1 (1.27)	0	0 (0.00)
COVID-19 pneumonia	1	1 (1.27)	1	1 (1.27)
Cellulitis	1	1 (1.27)	0	0 (0.00)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.27)	1	1 (1.27)
Coronavirus infection	1	1 (1.27)	1	1 (1.27)
Cytomegalovirus infection reactivation	1	1 (1.27)	1	1 (1.27)
Device related infection	1	1 (1.27)	1	1 (1.27)
Ear, nose and throat infection	1	1 (1.27)	0	0 (0.00)
Enterobacter infection	1	1 (1.27)	1	1 (1.27)
Enterovirus infection	1	1 (1.27)	1	1 (1.27)
Folliculitis	1	1 (1.27)	0	0 (0.00)
Fungal skin infection	1	1 (1.27)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.27)	1	1 (1.27)
Gastroenteritis clostridial	1	1 (1.27)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.27)	1	1 (1.27)
Gastrointestinal infection	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes virus infection	1	1 (1.27)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)
Localised infection	1	1 (1.27)	0	0 (0.00)
Mastoiditis	1	1 (1.27)	1	1 (1.27)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Meningitis pneumococcal	1	1 (1.27)	1	1 (1.27)
Molluscum contagiosum	1	1 (1.27)	0	0 (0.00)
Myringitis	1	1 (1.27)	0	0 (0.00)
Neutropenic infection	1	1 (1.27)	1	1 (1.27)
Ophthalmic herpes zoster	1	1 (1.27)	0	0 (0.00)
Otitis media acute	1	1 (1.27)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)
Pneumonia respiratory syncytial viral	1	1 (1.27)	1	1 (1.27)
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Respiratory tract infection viral	1	1 (1.27)	0	0 (0.00)
Salmonellosis	1	1 (1.27)	0	0 (0.00)
Sinusitis fungal	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Staphylococcal abscess	1	1 (1.27)	1	1 (1.27)
Staphylococcal sepsis	1	1 (1.27)	1	1 (1.27)
Staphylococcal skin infection	1	1 (1.27)	0	0 (0.00)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.27)	0	0 (0.00)
Syphilis	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Tinea pedis	1	1 (1.27)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.27)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.27)	1	1 (1.27)
Viral skin infection	1	1 (1.27)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	33	21 (26.58)	4	3 (3.80)
Infusion related reaction	8	5 (6.33)	1	1 (1.27)
Contusion	3	2 (2.53)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Wound	3	2 (2.53)	1	1 (1.27)
Fall	2	2 (2.53)	0	0 (0.00)
Ligament sprain	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Skin abrasion	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Abdominal injury	1	1 (1.27)	0	0 (0.00)
Fibula fracture	1	1 (1.27)	0	0 (0.00)
Limb injury	1	1 (1.27)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.27)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	479	59 (74.68)	230	47 (59.49)
Platelet count decreased	81	23 (29.11)	47	15 (18.99)
Neutrophil count decreased	71	23 (29.11)	50	20 (25.32)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
White blood cell count decreased	63	24 (30.38)	37	17 (21.52)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Lymphocyte count decreased	33	16 (20.25)	25	14 (17.72)
Alanine aminotransferase increased	29	18 (22.78)	7	7 (8.86)
Blood bilirubin increased	25	13 (16.46)	10	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.53)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)
Blood creatinine increased	7	5 (6.33)	5	3 (3.80)
Blood fibrinogen decreased	7	7 (8.86)	2	2 (2.53)
Blood immunoglobulin A decreased	7	7 (8.86)	1	1 (1.27)
Blood immunoglobulin M decreased	7	7 (8.86)	2	2 (2.53)
Weight increased	7	4 (5.06)	2	2 (2.53)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)
Blood lactate dehydrogenase increased	5	5 (6.33)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
C-reactive protein increased	5	5 (6.33)	3	3 (3.80)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood immunoglobulin G decreased	4	4 (5.06)	0	0 (0.00)
Blood uric acid increased	4	4 (5.06)	2	2 (2.53)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Oxygen saturation decreased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Gamma-glutamyltransferase increased	2	2 (2.53)	2	2 (2.53)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)
Weight decreased	2	2 (2.53)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.27)	0	0 (0.00)
Blood urea increased	1	1 (1.27)	1	1 (1.27)
Bone density decreased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.27)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)
Metabolism and nutrition disorders				

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	246	52 (65.82)	91	33 (41.77)
Hypokalaemia	46	20 (25.32)	24	11 (13.92)
Decreased appetite	32	30 (37.97)	14	12 (15.19)
Hypophosphataemia	32	18 (22.78)	11	9 (11.39)
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	12	9 (11.39)	5	5 (6.33)
Hyperuricaemia	12	9 (11.39)	1	1 (1.27)
Hypervolaemia	7	7 (8.86)	5	5 (6.33)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Tumour lysis syndrome	5	5 (6.33)	5	5 (6.33)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)
Metabolic acidosis	4	4 (5.06)	3	3 (3.80)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hyperkalaemia	3	3 (3.80)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hypernatraemia	3	3 (3.80)	2	2 (2.53)
Hypertriglyceridaemia	3	3 (3.80)	2	2 (2.53)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Iron overload	3	2 (2.53)	0	0 (0.00)
Hyperchloraemia	2	2 (2.53)	0	0 (0.00)
Malnutrition	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemochromatosis	1	1 (1.27)	1	1 (1.27)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Hypophagia	1	1 (1.27)	0	0 (0.00)
Metabolic syndrome	1	1 (1.27)	0	0 (0.00)
Obesity	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				
- Total	83	44 (55.70)	9	8 (10.13)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pain in extremity	18	17 (21.52)	1	1 (1.27)
Arthralgia	14	12 (15.19)	1	1 (1.27)
Back pain	14	10 (12.66)	3	3 (3.80)
Myalgia	11	10 (12.66)	0	0 (0.00)
Bone pain	6	4 (5.06)	0	0 (0.00)
Growth retardation	2	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Musculoskeletal chest pain	2	2 (2.53)	0	0 (0.00)
Neck pain	2	2 (2.53)	0	0 (0.00)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Joint effusion	1	1 (1.27)	0	0 (0.00)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.27)	0	0 (0.00)
Myositis	1	1 (1.27)	0	0 (0.00)
Osteonecrosis	1	1 (1.27)	0	0 (0.00)
Osteopenia	1	1 (1.27)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Synovitis	1	1 (1.27)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (6.33)	2	2 (2.53)
Bone giant cell tumour benign	2	1 (1.27)	1	1 (1.27)
Skin papilloma	2	2 (2.53)	0	0 (0.00)
Cancer pain	1	1 (1.27)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	109	47 (59.49)	23	14 (17.72)
Headache	40	27 (34.18)	3	3 (3.80)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Seizure	7	4 (5.06)	3	3 (3.80)
Tremor	7	6 (7.59)	0	0 (0.00)
Cognitive disorder	5	3 (3.80)	1	1 (1.27)
Dizziness	5	4 (5.06)	0	0 (0.00)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dysgeusia	3	3 (3.80)	0	0 (0.00)
Hydrocephalus	3	1 (1.27)	3	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Lethargy	3	3 (3.80)	0	0 (0.00)
Cerebral haemorrhage	2	2 (2.53)	2	2 (2.53)
Dysarthria	2	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Migraine	2	1 (1.27)	0	0 (0.00)
Nervous system disorder	2	1 (1.27)	1	1 (1.27)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.27)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Memory impairment	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)
Paraesthesia	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Psychiatric disorders				
- Total	65	39 (49.37)	7	7 (8.86)
Anxiety	14	14 (17.72)	2	2 (2.53)
Delirium	8	8 (10.13)	3	3 (3.80)
Agitation	7	6 (7.59)	0	0 (0.00)
Confusional state	7	7 (8.86)	0	0 (0.00)
Mental status changes	5	5 (6.33)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Sleep disorder	4	3 (3.80)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Irritability	3	3 (3.80)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Mood altered	1	1 (1.27)	0	0 (0.00)
Nightmare	1	1 (1.27)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Tearfulness	1	1 (1.27)	0	0 (0.00)
Tic	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	48	25 (31.65)	16	12 (15.19)
Acute kidney injury	17	12 (15.19)	9	8 (10.13)
Dysuria	4	4 (5.06)	0	0 (0.00)
Renal failure	4	2 (2.53)	3	1 (1.27)
Haematuria	3	3 (3.80)	1	1 (1.27)
Anuria	2	2 (2.53)	1	1 (1.27)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)
Kidney enlargement	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)
Proteinuria	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Renal mass	1	1 (1.27)	0	0 (0.00)
Renal tubular disorder	1	1 (1.27)	1	1 (1.27)
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	10	6 (7.59)	2	2 (2.53)
Dysmenorrhoea	2	1 (1.27)	0	0 (0.00)
Endometriosis	2	1 (1.27)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				
- Total	182	54 (68.35)	62	29 (36.71)
Cough	28	22 (27.85)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hypoxia	27	20 (25.32)	22	16 (20.25)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Tachypnoea	11	9 (11.39)	6	5 (6.33)
Nasal congestion	10	9 (11.39)	0	0 (0.00)
Pleural effusion	10	9 (11.39)	3	3 (3.80)
Oropharyngeal pain	9	8 (10.13)	0	0 (0.00)
Dyspnoea	8	7 (8.86)	4	4 (5.06)
Epistaxis	8	7 (8.86)	1	1 (1.27)
Rhinorrhoea	8	6 (7.59)	0	0 (0.00)
Respiratory failure	6	6 (7.59)	6	6 (7.59)
Atelectasis	5	3 (3.80)	2	2 (2.53)
Respiratory distress	5	4 (5.06)	3	2 (2.53)
Acute respiratory distress syndrome	3	3 (3.80)	3	3 (3.80)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Pharyngeal erythema	2	2 (2.53)	0	0 (0.00)
Rhinitis allergic	2	2 (2.53)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.53)	0	0 (0.00)
Wheezing	2	2 (2.53)	0	0 (0.00)
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Bronchial oedema	1	1 (1.27)	0	0 (0.00)
Bronchospasm	1	1 (1.27)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.27)	0	0 (0.00)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Laryngeal oedema	1	1 (1.27)	1	1 (1.27)
Lung disorder	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Respiratory disorder	1	1 (1.27)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	91	39 (49.37)	9	7 (8.86)
Rash	13	8 (10.13)	0	0 (0.00)
Dry skin	9	8 (10.13)	0	0 (0.00)
Pruritus	9	7 (8.86)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Erythema	5	5 (6.33)	0	0 (0.00)
Rash maculo-papular	4	3 (3.80)	1	1 (1.27)
Rash papular	4	3 (3.80)	0	0 (0.00)
Eczema	3	3 (3.80)	1	1 (1.27)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Decubitus ulcer	2	2 (2.53)	1	1 (1.27)
Dermatitis atopic	2	2 (2.53)	1	1 (1.27)
Ingrowing nail	2	2 (2.53)	0	0 (0.00)
Petechiae	2	2 (2.53)	1	1 (1.27)
Rash macular	2	1 (1.27)	2	1 (1.27)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin discolouration	2	2 (2.53)	0	0 (0.00)
Skin ulcer	2	2 (2.53)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis allergic	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Hangnail	1	1 (1.27)	0	0 (0.00)
Miliaria	1	1 (1.27)	0	0 (0.00)
Night sweats	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Papule	1	1 (1.27)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Rash erythematous	1	1 (1.27)	0	0 (0.00)
Rash pruritic	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)
Skin swelling	1	1 (1.27)	0	0 (0.00)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)
Vascular disorders				
- Total	54	34 (43.04)	27	21 (26.58)
Hypotension	29	24 (30.38)	19	16 (20.25)
Hypertension	17	16 (20.25)	5	5 (6.33)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Venoocclusive disease	2	2 (2.53)	2	2 (2.53)
Flushing	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, Hypodiploidy: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	3	1 (100.00)	1	1 (100.00)
General disorders and administration site conditions				
- Total	1	1 (100.00)	0	0 (0.00)
Pyrexia	1	1 (100.00)	0	0 (0.00)
Infections and infestations				
- Total	1	1 (100.00)	0	0 (0.00)
Staphylococcal infection	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	1	1 (100.00)	1	1 (100.00)
Gamma-glutamyltransferase increased	1	1 (100.00)	1	1 (100.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

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Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	1748	78 (98.73)	618	66 (83.54)
Blood and lymphatic system disorders				
- Total	125	50 (63.29)	76	39 (49.37)
Anaemia	50	21 (26.58)	20	8 (10.13)
Febrile neutropenia	29	26 (32.91)	29	26 (32.91)
Neutropenia	11	9 (11.39)	9	7 (8.86)
Thrombocytopenia	8	8 (10.13)	8	8 (10.13)
Disseminated intravascular coagulation	7	7 (8.86)	2	2 (2.53)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	4	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
Eosinophilia	2	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pancytopenia	2	2 (2.53)	2	2 (2.53)
B-cell aplasia	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Lymphopenia	1	1 (1.27)	1	1 (1.27)
Cardiac disorders				
- Total	45	24 (30.38)	10	8 (10.13)
Tachycardia	22	17 (21.52)	3	3 (3.80)
Cardiac failure	4	1 (1.27)	2	1 (1.27)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Left ventricular dysfunction	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)
Cardiac arrest	1	1 (1.27)	1	1 (1.27)
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Ear and labyrinth disorders				
- Total	2	2 (2.53)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.33)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)
Hypothyroidism	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	15	9 (11.39)	0	0 (0.00)
Eyelid oedema	3	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.53)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Eye pain	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Visual field defect	1	1 (1.27)	0	0 (0.00)
Visual impairment	1	1 (1.27)	0	0 (0.00)
Gastrointestinal disorders				
- Total	135	51 (64.56)	16	14 (17.72)
Vomiting	30	21 (26.58)	1	1 (1.27)
Nausea	21	18 (22.78)	2	2 (2.53)
Diarrhoea	18	15 (18.99)	1	1 (1.27)
Abdominal pain	13	11 (13.92)	2	2 (2.53)
Constipation	11	11 (13.92)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.06)	2	2 (2.53)
Pancreatitis	4	4 (5.06)	1	1 (1.27)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Abdominal pain upper	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Stomatitis	2	2 (2.53)	1	1 (1.27)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Anal fissure	1	1 (1.27)	0	0 (0.00)
Anal haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enterocolitis	1	1 (1.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Proctalgia	1	1 (1.27)	1	1 (1.27)
Trichoglossia	1	1 (1.27)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
General disorders and administration site conditions				
- Total	111	39 (49.37)	19	11 (13.92)
Pyrexia	43	23 (29.11)	9	8 (10.13)
Fatigue	11	11 (13.92)	0	0 (0.00)
Chills	9	6 (7.59)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	7	6 (7.59)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	2	2 (2.53)	0	0 (0.00)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.53)	2	2 (2.53)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Facial pain	1	1 (1.27)	0	0 (0.00)
Malaise	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Pain	1	1 (1.27)	1	1 (1.27)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	29	17 (21.52)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Hypertransaminasaemia	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	164	67 (84.81)	68	43 (54.43)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	25	23 (29.11)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	5	5 (6.33)	3	3 (3.80)
Immunodeficiency	3	3 (3.80)	3	3 (3.80)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Seasonal allergy	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				
- Total	63	34 (43.04)	31	19 (24.05)
Conjunctivitis	6	5 (6.33)	0	0 (0.00)
Candida infection	4	3 (3.80)	2	1 (1.27)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Staphylococcal bacteraemia	4	3 (3.80)	4	3 (3.80)
Staphylococcal infection	4	4 (5.06)	2	2 (2.53)
Encephalitis viral	2	2 (2.53)	2	2 (2.53)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Nail infection	2	2 (2.53)	0	0 (0.00)
Oral candidiasis	2	1 (1.27)	0	0 (0.00)
Oral herpes	2	2 (2.53)	1	1 (1.27)
Oral infection	2	2 (2.53)	0	0 (0.00)
Rhinovirus infection	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	1	1 (1.27)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)
BK virus infection	1	1 (1.27)	0	0 (0.00)
Bacteraemia	1	1 (1.27)	1	1 (1.27)
Bronchopulmonary aspergillosis	1	1 (1.27)	1	1 (1.27)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Encephalitis	1	1 (1.27)	1	1 (1.27)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gingivitis	1	1 (1.27)	0	0 (0.00)
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes simplex	1	1 (1.27)	1	1 (1.27)
Human herpesvirus 6 infection	1	1 (1.27)	1	1 (1.27)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Klebsiella infection	1	1 (1.27)	1	1 (1.27)
Localised infection	1	1 (1.27)	0	0 (0.00)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Myringitis	1	1 (1.27)	0	0 (0.00)
Otitis externa	1	1 (1.27)	0	0 (0.00)
Paronychia	1	1 (1.27)	0	0 (0.00)
Pneumonia	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Sinusitis	1	1 (1.27)	1	1 (1.27)
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	20	11 (13.92)	3	2 (2.53)
Infusion related reaction	3	2 (2.53)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Wound	3	2 (2.53)	1	1 (1.27)
Contusion	2	1 (1.27)	0	0 (0.00)
Fall	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)
Skin abrasion	1	1 (1.27)	0	0 (0.00)
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	385	56 (70.89)	196	44 (55.70)
Platelet count decreased	65	21 (26.58)	38	14 (17.72)
White blood cell count decreased	50	24 (30.38)	36	18 (22.78)
Neutrophil count decreased	48	20 (25.32)	38	17 (21.52)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Lymphocyte count decreased	30	15 (18.99)	24	13 (16.46)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Alanine aminotransferase increased	26	18 (22.78)	6	6 (7.59)
Blood bilirubin increased	18	12 (15.19)	9	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)
Blood fibrinogen decreased	7	7 (8.86)	2	2 (2.53)
Blood creatinine increased	6	4 (5.06)	5	3 (3.80)
Blood immunoglobulin M decreased	6	6 (7.59)	1	1 (1.27)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)
Blood immunoglobulin A decreased	5	5 (6.33)	0	0 (0.00)
Immunoglobulins decreased	5	2 (2.53)	0	0 (0.00)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood lactate dehydrogenase increased	4	4 (5.06)	1	1 (1.27)
C-reactive protein increased	4	4 (5.06)	3	3 (3.80)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Weight increased	4	4 (5.06)	1	1 (1.27)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Blood immunoglobulin G decreased	2	2 (2.53)	0	0 (0.00)
Blood uric acid increased	2	2 (2.53)	0	0 (0.00)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)
Weight decreased	1	1 (1.27)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	210	46 (58.23)	76	29 (36.71)
Hypokalaemia	40	19 (24.05)	20	11 (13.92)
Hypophosphataemia	31	17 (21.52)	11	9 (11.39)
Decreased appetite	24	24 (30.38)	11	11 (13.92)
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	11	8 (10.13)	4	4 (5.06)
Hyperuricaemia	9	7 (8.86)	1	1 (1.27)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hypervolaemia	6	6 (7.59)	4	4 (5.06)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Tumour lysis syndrome	4	4 (5.06)	4	4 (5.06)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Metabolic acidosis	3	3 (3.80)	2	2 (2.53)
Hyperkalaemia	2	2 (2.53)	2	2 (2.53)
Hypernatraemia	2	2 (2.53)	1	1 (1.27)
Hypertriglyceridaemia	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)
Hyperchloraemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Malnutrition	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				
- Total	53	33 (41.77)	6	5 (6.33)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Pain in extremity	11	11 (13.92)	0	0 (0.00)
Arthralgia	10	10 (12.66)	1	1 (1.27)
Myalgia	10	9 (11.39)	0	0 (0.00)
Back pain	7	6 (7.59)	1	1 (1.27)
Bone pain	4	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.27)	0	0 (0.00)
Myositis	1	1 (1.27)	0	0 (0.00)
Neck pain	1	1 (1.27)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	77	40 (50.63)	14	10 (12.66)
Headache	26	23 (29.11)	2	2 (2.53)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Tremor	7	6 (7.59)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cognitive disorder	5	3 (3.80)	1	1 (1.27)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dizziness	3	3 (3.80)	0	0 (0.00)
Dysgeusia	3	3 (3.80)	0	0 (0.00)
Lethargy	3	3 (3.80)	0	0 (0.00)
Seizure	3	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)
Dysarthria	1	1 (1.27)	1	1 (1.27)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)
Paraesthesia	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Psychiatric disorders				
- Total	47	28 (35.44)	6	6 (7.59)
Confusional state	7	7 (8.86)	0	0 (0.00)
Delirium	7	7 (8.86)	3	3 (3.80)
Agitation	6	5 (6.33)	0	0 (0.00)
Anxiety	6	6 (7.59)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Irritability	3	3 (3.80)	0	0 (0.00)
Mental status changes	3	3 (3.80)	1	1 (1.27)
Sleep disorder	3	2 (2.53)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	39	20 (25.32)	13	9 (11.39)
Acute kidney injury	14	9 (11.39)	8	7 (8.86)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Renal failure	4	2 (2.53)	3	1 (1.27)
Dysuria	3	3 (3.80)	0	0 (0.00)
Anuria	2	2 (2.53)	1	1 (1.27)
Haematuria	2	2 (2.53)	0	0 (0.00)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)
Proteinuria	1	1 (1.27)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (6.33)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				
- Total	114	41 (51.90)	50	23 (29.11)
Hypoxia	23	17 (21.52)	18	12 (15.19)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Cough	11	10 (12.66)	0	0 (0.00)
Tachypnoea	9	8 (10.13)	4	4 (5.06)
Pleural effusion	7	7 (8.86)	3	3 (3.80)
Oropharyngeal pain	6	5 (6.33)	0	0 (0.00)
Atelectasis	5	3 (3.80)	2	2 (2.53)
Epistaxis	4	4 (5.06)	1	1 (1.27)
Respiratory distress	4	3 (3.80)	2	1 (1.27)
Respiratory failure	4	4 (5.06)	4	4 (5.06)
Dyspnoea	3	3 (3.80)	3	3 (3.80)
Nasal congestion	3	3 (3.80)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Acute respiratory distress syndrome	2	2 (2.53)	2	2 (2.53)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Rhinorrhoea	2	2 (2.53)	0	0 (0.00)
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)
Respiratory disorder	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Wheezing	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	56	27 (34.18)	4	3 (3.80)
Pruritus	7	6 (7.59)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Rash	5	5 (6.33)	0	0 (0.00)
Erythema	4	4 (5.06)	0	0 (0.00)
Rash papular	4	3 (3.80)	0	0 (0.00)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Rash maculo-papular	3	2 (2.53)	1	1 (1.27)
Dermatitis atopic	2	2 (2.53)	0	0 (0.00)
Petechiae	2	2 (2.53)	1	1 (1.27)
Rash vesicular	2	1 (1.27)	0	0 (0.00)
Skin ulcer	2	2 (2.53)	0	0 (0.00)
Decubitus ulcer	1	1 (1.27)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Dry skin	1	1 (1.27)	0	0 (0.00)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Eczema	1	1 (1.27)	0	0 (0.00)
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Rash pruritic	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)
Skin discolouration	1	1 (1.27)	0	0 (0.00)
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Vascular disorders				
- Total	45	28 (35.44)	21	17 (21.52)
Hypotension	25	21 (26.58)	16	14 (17.72)
Hypertension	14	13 (16.46)	4	4 (5.06)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Flushing	1	1 (1.27)	0	0 (0.00)
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	1	1 (100.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Photosensitivity reaction	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	533	68 (91.89)	146	36 (48.65)
Blood and lymphatic system disorders				
- Total	32	17 (22.97)	17	10 (13.51)
Anaemia	12	6 (8.11)	4	2 (2.70)
Neutropenia	5	5 (6.76)	5	5 (6.76)
Febrile neutropenia	4	3 (4.05)	4	3 (4.05)
B-cell aplasia	2	1 (1.35)	0	0 (0.00)
Thrombocytopenia	2	2 (2.70)	2	2 (2.70)
Disseminated intravascular coagulation	1	1 (1.35)	1	1 (1.35)
Eosinophilia	1	1 (1.35)	0	0 (0.00)
Leukocytosis	1	1 (1.35)	0	0 (0.00)
Leukopenia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Lymphadenopathy	1	1 (1.35)	0	0 (0.00)
Lymphocytosis	1	1 (1.35)	0	0 (0.00)
Lymphopenia	1	1 (1.35)	1	1 (1.35)
Cardiac disorders				
- Total	8	7 (9.46)	4	3 (4.05)
Cardiac arrest	2	2 (2.70)	2	2 (2.70)
Cardiac failure	2	2 (2.70)	2	2 (2.70)
Tachycardia	2	2 (2.70)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Hypothyroidism	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.41)	0	0 (0.00)
Cataract	2	2 (2.70)	0	0 (0.00)
Hypermetropia	1	1 (1.35)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Visual impairment	1	1 (1.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	38	20 (27.03)	1	1 (1.35)
Diarrhoea	7	7 (9.46)	0	0 (0.00)
Vomiting	7	6 (8.11)	0	0 (0.00)
Nausea	5	5 (6.76)	0	0 (0.00)
Constipation	4	3 (4.05)	0	0 (0.00)
Abdominal pain	2	2 (2.70)	0	0 (0.00)
Pancreatitis	2	2 (2.70)	1	1 (1.35)
Abdominal pain upper	1	1 (1.35)	0	0 (0.00)
Abdominal rigidity	1	1 (1.35)	0	0 (0.00)
Dyspepsia	1	1 (1.35)	0	0 (0.00)
Enteritis	1	1 (1.35)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.35)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.35)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.35)	0	0 (0.00)
Proctalgia	1	1 (1.35)	0	0 (0.00)
Stomatitis	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Trichoglossia	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	31	24 (32.43)	3	3 (4.05)
Pyrexia	16	15 (20.27)	2	2 (2.70)
Fatigue	7	6 (8.11)	0	0 (0.00)
Oedema peripheral	2	1 (1.35)	0	0 (0.00)
Pain	2	2 (2.70)	1	1 (1.35)
Asthenia	1	1 (1.35)	0	0 (0.00)
Chills	1	1 (1.35)	0	0 (0.00)
Malaise	1	1 (1.35)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.05)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.35)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.35)	0	0 (0.00)
Liver disorder	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	19	16 (21.62)	5	4 (5.41)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypogammaglobulinaemia	12	10 (13.51)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.70)	1	1 (1.35)
Graft versus host disease	2	2 (2.70)	2	2 (2.70)
Drug hypersensitivity	1	1 (1.35)	0	0 (0.00)
Engraftment syndrome	1	1 (1.35)	1	1 (1.35)
Immunodeficiency	1	1 (1.35)	1	1 (1.35)
Infections and infestations				
- Total	113	39 (52.70)	45	20 (27.03)
Upper respiratory tract infection	10	8 (10.81)	2	2 (2.70)
Nasopharyngitis	9	7 (9.46)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (1.35)	3	1 (1.35)
Gastroenteritis	5	5 (6.76)	2	2 (2.70)
Parainfluenzae virus infection	5	4 (5.41)	2	2 (2.70)
Rhinovirus infection	5	5 (6.76)	1	1 (1.35)
Sinusitis	4	3 (4.05)	1	1 (1.35)
Bacteraemia	3	2 (2.70)	2	1 (1.35)
Ear infection	3	2 (2.70)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.05)	3	3 (4.05)
Otitis media	3	3 (4.05)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pneumonia	3	3 (4.05)	1	1 (1.35)
Respiratory syncytial virus infection	3	3 (4.05)	2	2 (2.70)
Respiratory tract infection	3	3 (4.05)	0	0 (0.00)
Klebsiella infection	2	1 (1.35)	2	1 (1.35)
Otitis externa	2	2 (2.70)	1	1 (1.35)
Pneumocystis jirovecii pneumonia	2	2 (2.70)	2	2 (2.70)
Rhinitis	2	2 (2.70)	0	0 (0.00)
Urinary tract infection	2	1 (1.35)	2	1 (1.35)
Viral infection	2	2 (2.70)	1	1 (1.35)
Acute sinusitis	1	1 (1.35)	0	0 (0.00)
Adenovirus infection	1	1 (1.35)	1	1 (1.35)
BK virus infection	1	1 (1.35)	1	1 (1.35)
Cellulitis	1	1 (1.35)	0	0 (0.00)
Conjunctivitis	1	1 (1.35)	0	0 (0.00)
Coronavirus infection	1	1 (1.35)	1	1 (1.35)
Cystitis	1	1 (1.35)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.35)	1	1 (1.35)
Device related infection	1	1 (1.35)	1	1 (1.35)
Ear, nose and throat infection	1	1 (1.35)	0	0 (0.00)
Encephalitis	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Enterobacter infection	1	1 (1.35)	1	1 (1.35)
Gastroenteritis clostridial	1	1 (1.35)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.35)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.35)	0	0 (0.00)
Gingivitis	1	1 (1.35)	0	0 (0.00)
Herpes simplex	1	1 (1.35)	0	0 (0.00)
Herpes zoster	1	1 (1.35)	1	1 (1.35)
Human herpesvirus 6 infection	1	1 (1.35)	1	1 (1.35)
Influenza	1	1 (1.35)	0	0 (0.00)
Mastoiditis	1	1 (1.35)	1	1 (1.35)
Molluscum contagiosum	1	1 (1.35)	0	0 (0.00)
Nail infection	1	1 (1.35)	0	0 (0.00)
Oral candidiasis	1	1 (1.35)	0	0 (0.00)
Oral herpes	1	1 (1.35)	0	0 (0.00)
Paronychia	1	1 (1.35)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.35)	1	1 (1.35)
Respiratory tract infection viral	1	1 (1.35)	0	0 (0.00)
Salmonellosis	1	1 (1.35)	0	0 (0.00)
Septic shock	1	1 (1.35)	1	1 (1.35)
Sinusitis fungal	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Staphylococcal bacteraemia	1	1 (1.35)	1	1 (1.35)
Staphylococcal sepsis	1	1 (1.35)	1	1 (1.35)
Staphylococcal skin infection	1	1 (1.35)	0	0 (0.00)
Tinea pedis	1	1 (1.35)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.35)	1	1 (1.35)
Viral upper respiratory tract infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	10	9 (12.16)	0	0 (0.00)
Infusion related reaction	4	3 (4.05)	0	0 (0.00)
Contusion	1	1 (1.35)	0	0 (0.00)
Fibula fracture	1	1 (1.35)	0	0 (0.00)
Ligament sprain	1	1 (1.35)	0	0 (0.00)
Limb injury	1	1 (1.35)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.35)	0	0 (0.00)
Skin abrasion	1	1 (1.35)	0	0 (0.00)
Investigations				
- Total	91	30 (40.54)	35	16 (21.62)
Neutrophil count decreased	19	10 (13.51)	11	7 (9.46)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
White blood cell count decreased	18	10 (13.51)	4	4 (5.41)
Platelet count decreased	16	5 (6.76)	9	2 (2.70)
Lymphocyte count decreased	6	4 (5.41)	2	2 (2.70)
Immunoglobulins decreased	5	1 (1.35)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.70)	1	1 (1.35)
Alanine aminotransferase increased	3	2 (2.70)	1	1 (1.35)
Weight increased	3	1 (1.35)	1	1 (1.35)
Blood immunoglobulin A decreased	2	2 (2.70)	1	1 (1.35)
Blood uric acid increased	2	2 (2.70)	2	2 (2.70)
Blood creatinine increased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.35)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.35)	1	1 (1.35)
Blood lactate dehydrogenase increased	1	1 (1.35)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.35)	0	0 (0.00)
Blood urea increased	1	1 (1.35)	1	1 (1.35)
Bone density decreased	1	1 (1.35)	0	0 (0.00)
C-reactive protein increased	1	1 (1.35)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Heart sounds abnormal	1	1 (1.35)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.35)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.35)	0	0 (0.00)
Weight decreased	1	1 (1.35)	1	1 (1.35)
Metabolism and nutrition disorders				
- Total	26	15 (20.27)	10	7 (9.46)
Decreased appetite	6	6 (8.11)	1	1 (1.35)
Hypokalaemia	6	3 (4.05)	4	2 (2.70)
Hyperuricaemia	3	3 (4.05)	0	0 (0.00)
Haemochromatosis	1	1 (1.35)	1	1 (1.35)
Hyperchloraemia	1	1 (1.35)	0	0 (0.00)
Hyperkalaemia	1	1 (1.35)	0	0 (0.00)
Hypervolaemia	1	1 (1.35)	1	1 (1.35)
Hypophagia	1	1 (1.35)	0	0 (0.00)
Hypophosphataemia	1	1 (1.35)	0	0 (0.00)
Iron overload	1	1 (1.35)	0	0 (0.00)
Malnutrition	1	1 (1.35)	1	1 (1.35)
Metabolic acidosis	1	1 (1.35)	1	1 (1.35)
Metabolic syndrome	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Tumour lysis syndrome	1	1 (1.35)	1	1 (1.35)
Musculoskeletal and connective tissue disorders				
- Total	22	15 (20.27)	3	3 (4.05)
Back pain	7	6 (8.11)	2	2 (2.70)
Pain in extremity	5	5 (6.76)	1	1 (1.35)
Arthralgia	3	3 (4.05)	0	0 (0.00)
Bone pain	2	2 (2.70)	0	0 (0.00)
Growth retardation	1	1 (1.35)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.35)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.35)	0	0 (0.00)
Myalgia	1	1 (1.35)	0	0 (0.00)
Neck pain	1	1 (1.35)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.41)	1	1 (1.35)
Skin papilloma	2	2 (2.70)	0	0 (0.00)
Cancer pain	1	1 (1.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.35)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Nervous system disorders				
- Total	23	14 (18.92)	6	2 (2.70)
Headache	11	10 (13.51)	0	0 (0.00)
Hydrocephalus	3	1 (1.35)	3	1 (1.35)
Dizziness	2	1 (1.35)	0	0 (0.00)
Migraine	2	1 (1.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.35)	1	1 (1.35)
Cerebral haemorrhage	1	1 (1.35)	1	1 (1.35)
Extrapyramidal disorder	1	1 (1.35)	0	0 (0.00)
Memory impairment	1	1 (1.35)	0	0 (0.00)
Seizure	1	1 (1.35)	1	1 (1.35)
Psychiatric disorders				
- Total	15	10 (13.51)	1	1 (1.35)
Anxiety	6	6 (8.11)	0	0 (0.00)
Mental status changes	2	2 (2.70)	1	1 (1.35)
Agitation	1	1 (1.35)	0	0 (0.00)
Delirium	1	1 (1.35)	0	0 (0.00)
Mood altered	1	1 (1.35)	0	0 (0.00)
Nightmare	1	1 (1.35)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Persistent depressive disorder	1	1 (1.35)	0	0 (0.00)
Sleep disorder	1	1 (1.35)	0	0 (0.00)
Tearfulness	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	5 (6.76)	3	3 (4.05)
Acute kidney injury	3	3 (4.05)	1	1 (1.35)
Cystitis haemorrhagic	1	1 (1.35)	0	0 (0.00)
Dysuria	1	1 (1.35)	0	0 (0.00)
Haematuria	1	1 (1.35)	1	1 (1.35)
Kidney enlargement	1	1 (1.35)	0	0 (0.00)
Renal mass	1	1 (1.35)	0	0 (0.00)
Renal tubular disorder	1	1 (1.35)	1	1 (1.35)
Reproductive system and breast disorders				
- Total	2	1 (1.35)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	46	24 (32.43)	6	6 (8.11)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Cough	14	11 (14.86)	0	0 (0.00)
Nasal congestion	7	6 (8.11)	0	0 (0.00)
Epistaxis	3	3 (4.05)	0	0 (0.00)
Hypoxia	3	3 (4.05)	3	3 (4.05)
Rhinorrhoea	3	3 (4.05)	0	0 (0.00)
Dyspnoea	2	1 (1.35)	0	0 (0.00)
Oropharyngeal pain	2	2 (2.70)	0	0 (0.00)
Pleural effusion	2	2 (2.70)	0	0 (0.00)
Rhinitis allergic	2	2 (2.70)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.35)	1	1 (1.35)
Bronchial oedema	1	1 (1.35)	0	0 (0.00)
Bronchospasm	1	1 (1.35)	0	0 (0.00)
Lung disorder	1	1 (1.35)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.35)	0	0 (0.00)
Respiratory distress	1	1 (1.35)	1	1 (1.35)
Respiratory failure	1	1 (1.35)	1	1 (1.35)
Upper respiratory tract inflammation	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	28	19 (25.68)	1	1 (1.35)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dry skin	7	6 (8.11)	0	0 (0.00)
Rash	6	4 (5.41)	0	0 (0.00)
Ingrowing nail	2	2 (2.70)	0	0 (0.00)
Pruritus	2	1 (1.35)	0	0 (0.00)
Decubitus ulcer	1	1 (1.35)	1	1 (1.35)
Dermatitis allergic	1	1 (1.35)	0	0 (0.00)
Dermatitis atopic	1	1 (1.35)	0	0 (0.00)
Eczema	1	1 (1.35)	0	0 (0.00)
Erythema	1	1 (1.35)	0	0 (0.00)
Hangnail	1	1 (1.35)	0	0 (0.00)
Miliaria	1	1 (1.35)	0	0 (0.00)
Night sweats	1	1 (1.35)	0	0 (0.00)
Skin discolouration	1	1 (1.35)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.35)	0	0 (0.00)
Skin swelling	1	1 (1.35)	0	0 (0.00)
Vascular disorders				
- Total	7	6 (8.11)	5	5 (6.76)
Hypotension	4	4 (5.41)	3	3 (4.05)
Venoocclusive disease	2	2 (2.70)	2	2 (2.70)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypertension	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient				

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Total number of AE per patient	220	32 (65.31)	63	19 (38.78)
Blood and lymphatic system disorders				
- Total	6	4 (8.16)	2	2 (4.08)
Agranulocytosis	1	1 (2.04)	1	1 (2.04)
Anaemia	1	1 (2.04)	0	0 (0.00)
Hypercoagulation	1	1 (2.04)	0	0 (0.00)
Lymphadenopathy	1	1 (2.04)	0	0 (0.00)
Neutropenia	1	1 (2.04)	1	1 (2.04)
Thrombocytopenia	1	1 (2.04)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.04)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.04)	0	0 (0.00)
Deafness unilateral	1	1 (2.04)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.04)	0	0 (0.00)
Delayed puberty	1	1 (2.04)	0	0 (0.00)
Hypothyroidism	1	1 (2.04)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.12)	1	1 (2.04)
Dry eye	1	1 (2.04)	0	0 (0.00)
Eye pain	1	1 (2.04)	1	1 (2.04)
Eyelid oedema	1	1 (2.04)	0	0 (0.00)
Mydriasis	1	1 (2.04)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	7 (14.29)	1	1 (2.04)
Diarrhoea	5	5 (10.20)	1	1 (2.04)
Constipation	1	1 (2.04)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Nausea	1	1 (2.04)	0	0 (0.00)
Vomiting	1	1 (2.04)	0	0 (0.00)
General disorders and administration site conditions				
- Total	13	9 (18.37)	2	2 (4.08)
Pyrexia	7	5 (10.20)	1	1 (2.04)
Pain	2	2 (4.08)	0	0 (0.00)
Fatigue	1	1 (2.04)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.04)	1	1 (2.04)
Non-cardiac chest pain	1	1 (2.04)	0	0 (0.00)
Xerosis	1	1 (2.04)	0	0 (0.00)
Immune system disorders				
- Total	10	9 (18.37)	3	2 (4.08)
Hypogammaglobulinaemia	3	3 (6.12)	0	0 (0.00)
Seasonal allergy	3	3 (6.12)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.08)	1	1 (2.04)
Drug hypersensitivity	1	1 (2.04)	1	1 (2.04)
Haemophagocytic lymphohistiocytosis	1	1 (2.04)	1	1 (2.04)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Infections and infestations				
- Total	86	23 (46.94)	26	14 (28.57)
Sinusitis	9	6 (12.24)	0	0 (0.00)
Upper respiratory tract infection	7	5 (10.20)	1	1 (2.04)
Conjunctivitis	5	4 (8.16)	0	0 (0.00)
Rhinovirus infection	4	4 (8.16)	1	1 (2.04)
COVID-19	3	2 (4.08)	1	1 (2.04)
Fungal infection	3	2 (4.08)	0	0 (0.00)
Otitis media	3	2 (4.08)	0	0 (0.00)
Sepsis	3	3 (6.12)	3	3 (6.12)
Skin infection	3	3 (6.12)	0	0 (0.00)
Bronchitis	2	2 (4.08)	0	0 (0.00)
Device related sepsis	2	1 (2.04)	2	1 (2.04)
Gastroenteritis viral	2	1 (2.04)	0	0 (0.00)
Herpes zoster	2	2 (4.08)	1	1 (2.04)
Influenza	2	2 (4.08)	1	1 (2.04)
Oral herpes	2	2 (4.08)	0	0 (0.00)
Pneumonia	2	2 (4.08)	2	2 (4.08)
Urinary tract infection	2	2 (4.08)	0	0 (0.00)
Acute sinusitis	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Bronchiolitis	1	1 (2.04)	1	1 (2.04)
COVID-19 pneumonia	1	1 (2.04)	1	1 (2.04)
Candida infection	1	1 (2.04)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.04)	1	1 (2.04)
Ear infection	1	1 (2.04)	1	1 (2.04)
Enterovirus infection	1	1 (2.04)	1	1 (2.04)
Folliculitis	1	1 (2.04)	0	0 (0.00)
Fungal skin infection	1	1 (2.04)	0	0 (0.00)
Gastroenteritis	1	1 (2.04)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.04)	1	1 (2.04)
Gastroenteritis salmonella	1	1 (2.04)	1	1 (2.04)
Herpes virus infection	1	1 (2.04)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.04)	1	1 (2.04)
Nail infection	1	1 (2.04)	0	0 (0.00)
Neutropenic infection	1	1 (2.04)	1	1 (2.04)
Ophthalmic herpes zoster	1	1 (2.04)	0	0 (0.00)
Oral candidiasis	1	1 (2.04)	0	0 (0.00)
Otitis media acute	1	1 (2.04)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.04)	1	1 (2.04)
Pneumonia respiratory syncytial viral	1	1 (2.04)	1	1 (2.04)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Rhinitis	1	1 (2.04)	0	0 (0.00)
Septic shock	1	1 (2.04)	1	1 (2.04)
Staphylococcal abscess	1	1 (2.04)	1	1 (2.04)
Staphylococcal bacteraemia	1	1 (2.04)	1	1 (2.04)
Streptococcal sepsis	1	1 (2.04)	0	0 (0.00)
Syphilis	1	1 (2.04)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.04)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.04)	0	0 (0.00)
Viral skin infection	1	1 (2.04)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (6.12)	1	1 (2.04)
Abdominal injury	1	1 (2.04)	0	0 (0.00)
Infusion related reaction	1	1 (2.04)	1	1 (2.04)
Ligament sprain	1	1 (2.04)	0	0 (0.00)
Investigations				
- Total	16	6 (12.24)	6	2 (4.08)
Neutrophil count decreased	8	3 (6.12)	5	1 (2.04)
Blood bilirubin increased	3	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Platelet count decreased	2	2 (4.08)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.04)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.04)	1	1 (2.04)
SARS-CoV-2 test positive	1	1 (2.04)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	6 (12.24)	5	4 (8.16)
Decreased appetite	2	1 (2.04)	2	1 (2.04)
Iron overload	2	1 (2.04)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.04)	0	0 (0.00)
Hyperglycaemia	1	1 (2.04)	1	1 (2.04)
Hyperlipidaemia	1	1 (2.04)	0	0 (0.00)
Hypernatraemia	1	1 (2.04)	1	1 (2.04)
Hypertriglyceridaemia	1	1 (2.04)	0	0 (0.00)
Obesity	1	1 (2.04)	1	1 (2.04)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (14.29)	0	0 (0.00)
Pain in extremity	2	2 (4.08)	0	0 (0.00)
Arthralgia	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Growth retardation	1	1 (2.04)	0	0 (0.00)
Joint effusion	1	1 (2.04)	0	0 (0.00)
Osteonecrosis	1	1 (2.04)	0	0 (0.00)
Osteopenia	1	1 (2.04)	0	0 (0.00)
Synovitis	1	1 (2.04)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.04)	1	1 (2.04)
Bone giant cell tumour benign	2	1 (2.04)	1	1 (2.04)
Nervous system disorders				
- Total	9	4 (8.16)	3	2 (4.08)
Headache	3	2 (4.08)	1	1 (2.04)
Seizure	3	1 (2.04)	1	1 (2.04)
Nervous system disorder	2	1 (2.04)	1	1 (2.04)
Dysarthria	1	1 (2.04)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.12)	0	0 (0.00)
Anxiety	2	2 (4.08)	0	0 (0.00)
Tic	1	1 (2.04)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (2.04)	1	1 (2.04)
Endometriosis	2	1 (2.04)	1	1 (2.04)
Respiratory, thoracic and mediastinal disorders				
- Total	23	10 (20.41)	6	4 (8.16)
Cough	4	4 (8.16)	0	0 (0.00)
Dyspnoea	3	3 (6.12)	1	1 (2.04)
Rhinorrhoea	3	3 (6.12)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.08)	0	0 (0.00)
Tachypnoea	2	1 (2.04)	2	1 (2.04)
Dyspnoea exertional	1	1 (2.04)	0	0 (0.00)
Epistaxis	1	1 (2.04)	0	0 (0.00)
Hypoxia	1	1 (2.04)	1	1 (2.04)
Laryngeal oedema	1	1 (2.04)	1	1 (2.04)
Oropharyngeal pain	1	1 (2.04)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.04)	0	0 (0.00)
Pleural effusion	1	1 (2.04)	0	0 (0.00)
Respiratory failure	1	1 (2.04)	1	1 (2.04)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=49 n (%)[1]	Grade >= 3 Total events	All patients N=49 n (%)[2]
Wheezing	1	1 (2.04)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (14.29)	4	3 (6.12)
Rash	2	2 (4.08)	0	0 (0.00)
Rash macular	2	1 (2.04)	2	1 (2.04)
Dermatitis atopic	1	1 (2.04)	1	1 (2.04)
Dry skin	1	1 (2.04)	0	0 (0.00)
Eczema	1	1 (2.04)	1	1 (2.04)
Papule	1	1 (2.04)	0	0 (0.00)
Rash erythematous	1	1 (2.04)	0	0 (0.00)
Rash maculo-papular	1	1 (2.04)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.08)	1	1 (2.04)
Hypertension	2	2 (4.08)	1	1 (2.04)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Total number of AE per patient	4	1 (100.00)	1	1 (100.00)
General disorders and administration site conditions				
- Total	1	1 (100.00)	0	0 (0.00)
Pyrexia	1	1 (100.00)	0	0 (0.00)
Infections and infestations				
- Total	1	1 (100.00)	0	0 (0.00)
Staphylococcal infection	1	1 (100.00)	0	0 (0.00)
Investigations				
- Total	1	1 (100.00)	1	1 (100.00)
Gamma-glutamyltransferase increased	1	1 (100.00)	1	1 (100.00)

Timing: At anytime, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=1 n (%)[1]	Grade >= 3 Total events	All patients N=1 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	1	1 (100.00)	0	0 (0.00)
Photosensitivity reaction	1	1 (100.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250i
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and BCR-ABL1-like
Safety Set

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Total number of AE per patient	2501	79 (100.00)	827	72 (91.14)
Blood and lymphatic system disorders				
- Total	163	55 (69.62)	95	43 (54.43)
Anaemia	63	25 (31.65)	24	9 (11.39)
Febrile neutropenia	33	27 (34.18)	33	27 (34.18)
Neutropenia	17	11 (13.92)	15	9 (11.39)
Thrombocytopenia	11	9 (11.39)	10	9 (11.39)
Disseminated intravascular coagulation	8	8 (10.13)	3	3 (3.80)
Coagulopathy	5	5 (6.33)	2	2 (2.53)
Leukopenia	5	3 (3.80)	3	2 (2.53)
Splenomegaly	4	4 (5.06)	0	0 (0.00)
B-cell aplasia	3	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Eosinophilia	3	1 (1.27)	0	0 (0.00)
Lymphadenopathy	2	2 (2.53)	0	0 (0.00)
Lymphopenia	2	2 (2.53)	2	2 (2.53)
Pancytopenia	2	2 (2.53)	2	2 (2.53)
Agranulocytosis	1	1 (1.27)	1	1 (1.27)
Hypercoagulation	1	1 (1.27)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.27)	0	0 (0.00)
Leukocytosis	1	1 (1.27)	0	0 (0.00)
Lymphocytosis	1	1 (1.27)	0	0 (0.00)
Cardiac disorders				
- Total	53	28 (35.44)	14	11 (13.92)
Tachycardia	24	17 (21.52)	3	3 (3.80)
Cardiac failure	6	3 (3.80)	4	3 (3.80)
Left ventricular dysfunction	4	4 (5.06)	3	3 (3.80)
Sinus tachycardia	4	3 (3.80)	0	0 (0.00)
Bradycardia	3	3 (3.80)	0	0 (0.00)
Cardiac arrest	3	3 (3.80)	3	3 (3.80)
Cardiac dysfunction	2	2 (2.53)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cardiac failure congestive	1	1 (1.27)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.27)	0	0 (0.00)
Pericardial effusion	1	1 (1.27)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.27)	0	0 (0.00)
Sinus bradycardia	1	1 (1.27)	1	1 (1.27)
Tricuspid valve incompetence	1	1 (1.27)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.27)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.27)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (3.80)	0	0 (0.00)
Deafness unilateral	1	1 (1.27)	0	0 (0.00)
Ear pain	1	1 (1.27)	0	0 (0.00)
Ear pruritus	1	1 (1.27)	0	0 (0.00)
Endocrine disorders				
- Total	8	7 (8.86)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.06)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hypothyroidism	3	3 (3.80)	0	0 (0.00)
Delayed puberty	1	1 (1.27)	0	0 (0.00)
Eye disorders				
- Total	24	15 (18.99)	1	1 (1.27)
Eyelid oedema	4	3 (3.80)	0	0 (0.00)
Ocular hyperaemia	3	3 (3.80)	0	0 (0.00)
Cataract	2	2 (2.53)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.53)	0	0 (0.00)
Eye pain	2	2 (2.53)	1	1 (1.27)
Retinal haemorrhage	2	1 (1.27)	0	0 (0.00)
Visual impairment	2	2 (2.53)	0	0 (0.00)
Dry eye	1	1 (1.27)	0	0 (0.00)
Eye oedema	1	1 (1.27)	0	0 (0.00)
Hypermetropia	1	1 (1.27)	0	0 (0.00)
Mydriasis	1	1 (1.27)	0	0 (0.00)
Periorbital oedema	1	1 (1.27)	0	0 (0.00)
Periorbital swelling	1	1 (1.27)	0	0 (0.00)
Visual field defect	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Gastrointestinal disorders				
- Total	182	60 (75.95)	18	16 (20.25)
Vomiting	38	26 (32.91)	1	1 (1.27)
Diarrhoea	30	26 (32.91)	2	2 (2.53)
Nausea	27	22 (27.85)	2	2 (2.53)
Constipation	16	14 (17.72)	0	0 (0.00)
Abdominal pain	15	11 (13.92)	2	2 (2.53)
Pancreatitis	6	6 (7.59)	2	2 (2.53)
Mouth haemorrhage	5	5 (6.33)	2	2 (2.53)
Abdominal pain upper	4	4 (5.06)	0	0 (0.00)
Abdominal distension	3	3 (3.80)	0	0 (0.00)
Ascites	3	3 (3.80)	0	0 (0.00)
Stomatitis	3	3 (3.80)	1	1 (1.27)
Gastrointestinal sounds abnormal	2	2 (2.53)	0	0 (0.00)
Proctalgia	2	2 (2.53)	1	1 (1.27)
Trichoglossia	2	2 (2.53)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.27)	1	1 (1.27)
Abdominal rigidity	1	1 (1.27)	0	0 (0.00)
Anal fissure	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Anal haemorrhage	1	1 (1.27)	0	0 (0.00)
Dry mouth	1	1 (1.27)	0	0 (0.00)
Dyspepsia	1	1 (1.27)	0	0 (0.00)
Dysphagia	1	1 (1.27)	1	1 (1.27)
Enteritis	1	1 (1.27)	0	0 (0.00)
Enterocolitis	1	1 (1.27)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.27)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.27)	0	0 (0.00)
Gingival bleeding	1	1 (1.27)	0	0 (0.00)
Gingival erythema	1	1 (1.27)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.27)	1	1 (1.27)
Haematemesis	1	1 (1.27)	0	0 (0.00)
Ileus	1	1 (1.27)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.27)	0	0 (0.00)
Lip dry	1	1 (1.27)	0	0 (0.00)
Lip oedema	1	1 (1.27)	0	0 (0.00)
Melaena	1	1 (1.27)	1	1 (1.27)
Mouth swelling	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neutropenic colitis	1	1 (1.27)	1	1 (1.27)
Odynophagia	1	1 (1.27)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.27)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.27)	0	0 (0.00)
General disorders and administration site conditions				
- Total	155	52 (65.82)	24	15 (18.99)
Pyrexia	66	34 (43.04)	12	11 (13.92)
Fatigue	19	17 (21.52)	0	0 (0.00)
Chills	10	7 (8.86)	0	0 (0.00)
Face oedema	9	8 (10.13)	1	1 (1.27)
Oedema peripheral	9	7 (8.86)	2	1 (1.27)
Generalised oedema	5	5 (6.33)	0	0 (0.00)
Pain	5	5 (6.33)	2	2 (2.53)
Catheter site pain	4	2 (2.53)	2	1 (1.27)
Asthenia	3	3 (3.80)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (3.80)	3	3 (3.80)
Catheter site erythema	2	1 (1.27)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.53)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Influenza like illness	2	2 (2.53)	0	0 (0.00)
Localised oedema	2	2 (2.53)	0	0 (0.00)
Malaise	2	2 (2.53)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.53)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.27)	0	0 (0.00)
Chest discomfort	1	1 (1.27)	1	1 (1.27)
Crying	1	1 (1.27)	0	0 (0.00)
Facial pain	1	1 (1.27)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.27)	0	0 (0.00)
Sluggishness	1	1 (1.27)	0	0 (0.00)
Swelling face	1	1 (1.27)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.27)	1	1 (1.27)
Vascular device occlusion	1	1 (1.27)	0	0 (0.00)
Xerosis	1	1 (1.27)	0	0 (0.00)
Hepatobiliary disorders				
- Total	32	19 (24.05)	7	6 (7.59)
Hepatic function abnormal	11	5 (6.33)	4	3 (3.80)
Hyperbilirubinaemia	6	5 (6.33)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hepatomegaly	3	3 (3.80)	1	1 (1.27)
Hypertransaminasaemia	3	2 (2.53)	0	0 (0.00)
Cholelithiasis	2	2 (2.53)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.53)	0	0 (0.00)
Biliary tract disorder	1	1 (1.27)	0	0 (0.00)
Cholestasis	1	1 (1.27)	1	1 (1.27)
Hepatic cytolysis	1	1 (1.27)	0	0 (0.00)
Liver disorder	1	1 (1.27)	0	0 (0.00)
Ocular icterus	1	1 (1.27)	0	0 (0.00)
Immune system disorders				
- Total	193	71 (89.87)	76	46 (58.23)
Cytokine release syndrome	128	61 (77.22)	55	38 (48.10)
Hypogammaglobulinaemia	40	33 (41.77)	7	7 (8.86)
Haemophagocytic lymphohistiocytosis	6	6 (7.59)	4	4 (5.06)
Immunodeficiency	4	4 (5.06)	4	4 (5.06)
Seasonal allergy	4	4 (5.06)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.53)	1	1 (1.27)
Chronic graft versus host disease	2	2 (2.53)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Drug hypersensitivity	2	2 (2.53)	1	1 (1.27)
Graft versus host disease	2	2 (2.53)	2	2 (2.53)
Engraftment syndrome	1	1 (1.27)	1	1 (1.27)
Hypersensitivity	1	1 (1.27)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.27)	0	0 (0.00)
Infections and infestations				
- Total	262	59 (74.68)	102	39 (49.37)
Upper respiratory tract infection	17	13 (16.46)	3	3 (3.80)
Sinusitis	14	7 (8.86)	2	2 (2.53)
Conjunctivitis	12	8 (10.13)	0	0 (0.00)
Rhinovirus infection	11	9 (11.39)	2	2 (2.53)
Nasopharyngitis	9	7 (8.86)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.53)	4	2 (2.53)
Gastroenteritis	6	6 (7.59)	2	2 (2.53)
Otitis media	6	5 (6.33)	1	1 (1.27)
Parainfluenzae virus infection	6	5 (6.33)	3	3 (3.80)
Pneumonia	6	6 (7.59)	4	4 (5.06)
Staphylococcal bacteraemia	6	5 (6.33)	6	5 (6.33)
Candida infection	5	4 (5.06)	2	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Oral herpes	5	4 (5.06)	1	1 (1.27)
Bacteraemia	4	3 (3.80)	3	2 (2.53)
Clostridium difficile infection	4	4 (5.06)	3	3 (3.80)
Ear infection	4	3 (3.80)	1	1 (1.27)
Nail infection	4	4 (5.06)	0	0 (0.00)
Oral candidiasis	4	3 (3.80)	0	0 (0.00)
Staphylococcal infection	4	4 (5.06)	2	2 (2.53)
Urinary tract infection	4	3 (3.80)	2	1 (1.27)
COVID-19	3	2 (2.53)	1	1 (1.27)
Fungal infection	3	2 (2.53)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.53)	0	0 (0.00)
Herpes zoster	3	3 (3.80)	2	2 (2.53)
Influenza	3	3 (3.80)	1	1 (1.27)
Klebsiella infection	3	1 (1.27)	3	1 (1.27)
Metapneumovirus infection	3	3 (3.80)	3	3 (3.80)
Otitis externa	3	3 (3.80)	1	1 (1.27)
Respiratory syncytial virus infection	3	3 (3.80)	2	2 (2.53)
Respiratory tract infection	3	3 (3.80)	0	0 (0.00)
Rhinitis	3	3 (3.80)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Sepsis	3	3 (3.80)	3	3 (3.80)
Skin infection	3	3 (3.80)	0	0 (0.00)
Acute sinusitis	2	2 (2.53)	0	0 (0.00)
Adenovirus infection	2	2 (2.53)	2	2 (2.53)
BK virus infection	2	2 (2.53)	1	1 (1.27)
Bronchitis	2	2 (2.53)	0	0 (0.00)
Device related sepsis	2	1 (1.27)	2	1 (1.27)
Encephalitis	2	2 (2.53)	2	2 (2.53)
Encephalitis viral	2	2 (2.53)	2	2 (2.53)
Gingivitis	2	2 (2.53)	0	0 (0.00)
Herpes simplex	2	2 (2.53)	1	1 (1.27)
Human herpesvirus 6 infection	2	2 (2.53)	2	2 (2.53)
Oral infection	2	2 (2.53)	0	0 (0.00)
Paronychia	2	2 (2.53)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.53)	2	2 (2.53)
Septic shock	2	2 (2.53)	2	2 (2.53)
Varicella zoster virus infection	2	2 (2.53)	1	1 (1.27)
Viral infection	2	2 (2.53)	1	1 (1.27)
Anal abscess	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Atypical pneumonia	1	1 (1.27)	0	0 (0.00)
Bronchiolitis	1	1 (1.27)	1	1 (1.27)
COVID-19 pneumonia	1	1 (1.27)	1	1 (1.27)
Cellulitis	1	1 (1.27)	0	0 (0.00)
Cholecystitis infective	1	1 (1.27)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.27)	1	1 (1.27)
Coronavirus infection	1	1 (1.27)	1	1 (1.27)
Cystitis	1	1 (1.27)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.27)	1	1 (1.27)
Device related infection	1	1 (1.27)	1	1 (1.27)
Ear, nose and throat infection	1	1 (1.27)	0	0 (0.00)
Enterobacter infection	1	1 (1.27)	1	1 (1.27)
Enterovirus infection	1	1 (1.27)	1	1 (1.27)
Folliculitis	1	1 (1.27)	0	0 (0.00)
Fungal skin infection	1	1 (1.27)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.27)	1	1 (1.27)
Gastroenteritis clostridial	1	1 (1.27)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.27)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Gastrointestinal infection	1	1 (1.27)	0	0 (0.00)
Granulicatella infection	1	1 (1.27)	1	1 (1.27)
Herpes virus infection	1	1 (1.27)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.27)	0	0 (0.00)
Localised infection	1	1 (1.27)	0	0 (0.00)
Mastoiditis	1	1 (1.27)	1	1 (1.27)
Meningitis bacterial	1	1 (1.27)	1	1 (1.27)
Meningitis pneumococcal	1	1 (1.27)	1	1 (1.27)
Molluscum contagiosum	1	1 (1.27)	0	0 (0.00)
Myringitis	1	1 (1.27)	0	0 (0.00)
Neutropenic infection	1	1 (1.27)	1	1 (1.27)
Ophthalmic herpes zoster	1	1 (1.27)	0	0 (0.00)
Otitis media acute	1	1 (1.27)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.27)	1	1 (1.27)
Pneumonia fungal	1	1 (1.27)	1	1 (1.27)
Pneumonia respiratory syncytial viral	1	1 (1.27)	1	1 (1.27)
Pneumonia viral	1	1 (1.27)	1	1 (1.27)
Respiratory tract infection viral	1	1 (1.27)	0	0 (0.00)
Salmonellosis	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Sinusitis fungal	1	1 (1.27)	1	1 (1.27)
Soft tissue infection	1	1 (1.27)	1	1 (1.27)
Staphylococcal abscess	1	1 (1.27)	1	1 (1.27)
Staphylococcal sepsis	1	1 (1.27)	1	1 (1.27)
Staphylococcal skin infection	1	1 (1.27)	0	0 (0.00)
Stomatococcal infection	1	1 (1.27)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.27)	0	0 (0.00)
Syphilis	1	1 (1.27)	0	0 (0.00)
Systemic candida	1	1 (1.27)	1	1 (1.27)
Tinea pedis	1	1 (1.27)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.27)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.27)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.27)	1	1 (1.27)
Viral skin infection	1	1 (1.27)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.27)	1	1 (1.27)
Injury, poisoning and procedural complications				
- Total	33	21 (26.58)	4	3 (3.80)
Infusion related reaction	8	5 (6.33)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Contusion	3	2 (2.53)	0	0 (0.00)
Wound	3	2 (2.53)	1	1 (1.27)
Fall	2	2 (2.53)	0	0 (0.00)
Ligament sprain	2	2 (2.53)	0	0 (0.00)
Procedural pain	2	2 (2.53)	0	0 (0.00)
Skin abrasion	2	2 (2.53)	0	0 (0.00)
Transfusion reaction	2	2 (2.53)	0	0 (0.00)
Abdominal injury	1	1 (1.27)	0	0 (0.00)
Fibula fracture	1	1 (1.27)	0	0 (0.00)
Limb injury	1	1 (1.27)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.27)	0	0 (0.00)
Scratch	1	1 (1.27)	0	0 (0.00)
Skin injury	1	1 (1.27)	0	0 (0.00)
Skin wound	1	1 (1.27)	0	0 (0.00)
Transplant failure	1	1 (1.27)	1	1 (1.27)
Vasoplegia syndrome	1	1 (1.27)	1	1 (1.27)
Investigations				
- Total	492	59 (74.68)	237	47 (59.49)
Platelet count decreased	83	24 (30.38)	47	15 (18.99)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Neutrophil count decreased	75	24 (30.38)	54	21 (26.58)
White blood cell count decreased	68	25 (31.65)	40	18 (22.78)
Lymphocyte count decreased	36	17 (21.52)	26	15 (18.99)
Aspartate aminotransferase increased	33	19 (24.05)	13	11 (13.92)
Alanine aminotransferase increased	29	18 (22.78)	7	7 (8.86)
Blood bilirubin increased	25	13 (16.46)	10	9 (11.39)
International normalised ratio increased	12	9 (11.39)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.53)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (7.59)	1	1 (1.27)
Serum ferritin increased	8	8 (10.13)	2	2 (2.53)
Blood creatinine increased	7	5 (6.33)	5	3 (3.80)
Blood fibrinogen decreased	7	7 (8.86)	2	2 (2.53)
Blood immunoglobulin A decreased	7	7 (8.86)	1	1 (1.27)
Blood immunoglobulin M decreased	7	7 (8.86)	2	2 (2.53)
Weight increased	7	4 (5.06)	2	2 (2.53)
Electrocardiogram QT prolonged	6	5 (6.33)	2	2 (2.53)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood lactate dehydrogenase increased	5	5 (6.33)	1	1 (1.27)
C-reactive protein increased	5	5 (6.33)	3	3 (3.80)
Blood creatine phosphokinase increased	4	2 (2.53)	2	2 (2.53)
Blood immunoglobulin G decreased	4	4 (5.06)	0	0 (0.00)
Blood uric acid increased	4	4 (5.06)	2	2 (2.53)
Lipase increased	4	2 (2.53)	2	1 (1.27)
Fibrin D dimer increased	3	3 (3.80)	1	1 (1.27)
Oxygen saturation decreased	3	3 (3.80)	1	1 (1.27)
Urine output decreased	3	2 (2.53)	3	2 (2.53)
Blood glucose increased	2	1 (1.27)	2	1 (1.27)
Haemoglobin decreased	2	1 (1.27)	1	1 (1.27)
Weight decreased	2	2 (2.53)	1	1 (1.27)
Amylase increased	1	1 (1.27)	0	0 (0.00)
Bacterial test positive	1	1 (1.27)	1	1 (1.27)
Blood alkaline phosphatase increased	1	1 (1.27)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.27)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Blood testosterone decreased	1	1 (1.27)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.27)	0	0 (0.00)
Blood urea increased	1	1 (1.27)	1	1 (1.27)
Bone density decreased	1	1 (1.27)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.27)	0	0 (0.00)
Cardiac murmur	1	1 (1.27)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.27)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.27)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.27)	0	0 (0.00)
Enterovirus test positive	1	1 (1.27)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.27)	1	1 (1.27)
Haptoglobin decreased	1	1 (1.27)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.27)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.27)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.27)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.27)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.27)	0	0 (0.00)
Troponin increased	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Metabolism and nutrition disorders				
- Total	246	52 (65.82)	91	33 (41.77)
Hypokalaemia	46	20 (25.32)	24	11 (13.92)
Decreased appetite	32	30 (37.97)	14	12 (15.19)
Hypophosphataemia	32	18 (22.78)	11	9 (11.39)
Hypocalcaemia	24	16 (20.25)	6	5 (6.33)
Hypoalbuminaemia	19	11 (13.92)	1	1 (1.27)
Hyperglycaemia	12	9 (11.39)	5	5 (6.33)
Hyperuricaemia	12	9 (11.39)	1	1 (1.27)
Hypervolaemia	7	7 (8.86)	5	5 (6.33)
Hypomagnesaemia	7	6 (7.59)	0	0 (0.00)
Hyperphosphataemia	5	5 (6.33)	1	1 (1.27)
Tumour lysis syndrome	5	5 (6.33)	5	5 (6.33)
Hypercalcaemia	4	3 (3.80)	2	2 (2.53)
Metabolic acidosis	4	4 (5.06)	3	3 (3.80)
Acidosis	3	2 (2.53)	2	2 (2.53)
Hyperkalaemia	3	3 (3.80)	2	2 (2.53)
Hypermagnesaemia	3	2 (2.53)	0	0 (0.00)
Hypernatraemia	3	3 (3.80)	2	2 (2.53)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hypertriglyceridaemia	3	3 (3.80)	2	2 (2.53)
Hyponatraemia	3	3 (3.80)	0	0 (0.00)
Iron overload	3	2 (2.53)	0	0 (0.00)
Hyperchloraemia	2	2 (2.53)	0	0 (0.00)
Malnutrition	2	2 (2.53)	2	2 (2.53)
Calcium deficiency	1	1 (1.27)	0	0 (0.00)
Dehydration	1	1 (1.27)	0	0 (0.00)
Haemochromatosis	1	1 (1.27)	1	1 (1.27)
Haemosiderosis	1	1 (1.27)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.27)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.27)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.27)	0	0 (0.00)
Hypoglycaemia	1	1 (1.27)	0	0 (0.00)
Hypophagia	1	1 (1.27)	0	0 (0.00)
Metabolic syndrome	1	1 (1.27)	0	0 (0.00)
Obesity	1	1 (1.27)	1	1 (1.27)
Polydipsia	1	1 (1.27)	1	1 (1.27)
Musculoskeletal and connective tissue disorders				

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
- Total	83	44 (55.70)	9	8 (10.13)
Pain in extremity	18	17 (21.52)	1	1 (1.27)
Arthralgia	14	12 (15.19)	1	1 (1.27)
Back pain	14	10 (12.66)	3	3 (3.80)
Myalgia	11	10 (12.66)	0	0 (0.00)
Bone pain	6	4 (5.06)	0	0 (0.00)
Growth retardation	2	2 (2.53)	0	0 (0.00)
Muscular weakness	2	2 (2.53)	1	1 (1.27)
Musculoskeletal chest pain	2	2 (2.53)	0	0 (0.00)
Neck pain	2	2 (2.53)	0	0 (0.00)
Pain in jaw	2	2 (2.53)	1	1 (1.27)
Haemarthrosis	1	1 (1.27)	1	1 (1.27)
Joint effusion	1	1 (1.27)	0	0 (0.00)
Muscle rigidity	1	1 (1.27)	0	0 (0.00)
Muscle spasms	1	1 (1.27)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.27)	0	0 (0.00)
Myositis	1	1 (1.27)	0	0 (0.00)
Osteonecrosis	1	1 (1.27)	0	0 (0.00)
Osteopenia	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Rhabdomyolysis	1	1 (1.27)	1	1 (1.27)
Synovitis	1	1 (1.27)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (6.33)	2	2 (2.53)
Bone giant cell tumour benign	2	1 (1.27)	1	1 (1.27)
Skin papilloma	2	2 (2.53)	0	0 (0.00)
Cancer pain	1	1 (1.27)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.27)	1	1 (1.27)
Nervous system disorders				
- Total	109	47 (59.49)	23	14 (17.72)
Headache	40	27 (34.18)	3	3 (3.80)
Encephalopathy	8	8 (10.13)	4	4 (5.06)
Seizure	7	4 (5.06)	3	3 (3.80)
Tremor	7	6 (7.59)	0	0 (0.00)
Cognitive disorder	5	3 (3.80)	1	1 (1.27)
Dizziness	5	4 (5.06)	0	0 (0.00)
Somnolence	5	5 (6.33)	2	2 (2.53)
Dysgeusia	3	3 (3.80)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Hydrocephalus	3	1 (1.27)	3	1 (1.27)
Lethargy	3	3 (3.80)	0	0 (0.00)
Cerebral haemorrhage	2	2 (2.53)	2	2 (2.53)
Dysarthria	2	2 (2.53)	1	1 (1.27)
Hyperaesthesia	2	1 (1.27)	0	0 (0.00)
Migraine	2	1 (1.27)	0	0 (0.00)
Nervous system disorder	2	1 (1.27)	1	1 (1.27)
Amnesia	1	1 (1.27)	0	0 (0.00)
Aphasia	1	1 (1.27)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.27)	1	1 (1.27)
Depressed level of consciousness	1	1 (1.27)	1	1 (1.27)
Disturbance in attention	1	1 (1.27)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.27)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.27)	0	0 (0.00)
Hypoaesthesia	1	1 (1.27)	0	0 (0.00)
Memory impairment	1	1 (1.27)	0	0 (0.00)
Monoparesis	1	1 (1.27)	0	0 (0.00)
Neuralgia	1	1 (1.27)	0	0 (0.00)
Neurological decompensation	1	1 (1.27)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Paraesthesia	1	1 (1.27)	0	0 (0.00)
Psychiatric disorders				
- Total	65	39 (49.37)	7	7 (8.86)
Anxiety	14	14 (17.72)	2	2 (2.53)
Delirium	8	8 (10.13)	3	3 (3.80)
Agitation	7	6 (7.59)	0	0 (0.00)
Confusional state	7	7 (8.86)	0	0 (0.00)
Mental status changes	5	5 (6.33)	2	2 (2.53)
Insomnia	4	4 (5.06)	0	0 (0.00)
Sleep disorder	4	3 (3.80)	0	0 (0.00)
Hallucination	3	3 (3.80)	0	0 (0.00)
Irritability	3	3 (3.80)	0	0 (0.00)
Affect lability	1	1 (1.27)	0	0 (0.00)
Automatism	1	1 (1.27)	0	0 (0.00)
Hallucination, visual	1	1 (1.27)	0	0 (0.00)
Mood altered	1	1 (1.27)	0	0 (0.00)
Nightmare	1	1 (1.27)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.27)	0	0 (0.00)
Restlessness	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Social avoidant behaviour	1	1 (1.27)	0	0 (0.00)
Tearfulness	1	1 (1.27)	0	0 (0.00)
Tic	1	1 (1.27)	0	0 (0.00)
Renal and urinary disorders				
- Total	48	25 (31.65)	16	12 (15.19)
Acute kidney injury	17	12 (15.19)	9	8 (10.13)
Dysuria	4	4 (5.06)	0	0 (0.00)
Renal failure	4	2 (2.53)	3	1 (1.27)
Haematuria	3	3 (3.80)	1	1 (1.27)
Anuria	2	2 (2.53)	1	1 (1.27)
Pollakiuria	2	2 (2.53)	0	0 (0.00)
Urinary incontinence	2	1 (1.27)	0	0 (0.00)
Urinary retention	2	2 (2.53)	0	0 (0.00)
Azotaemia	1	1 (1.27)	0	0 (0.00)
Bladder dilatation	1	1 (1.27)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.27)	0	0 (0.00)
Incontinence	1	1 (1.27)	0	0 (0.00)
Kidney enlargement	1	1 (1.27)	0	0 (0.00)
Micturition urgency	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Proteinuria	1	1 (1.27)	0	0 (0.00)
Renal mass	1	1 (1.27)	0	0 (0.00)
Renal tubular disorder	1	1 (1.27)	1	1 (1.27)
Renal tubular dysfunction	1	1 (1.27)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.27)	1	1 (1.27)
Urinary tract disorder	1	1 (1.27)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	10	6 (7.59)	2	2 (2.53)
Dysmenorrhoea	2	1 (1.27)	0	0 (0.00)
Endometriosis	2	1 (1.27)	1	1 (1.27)
Vaginal haemorrhage	2	1 (1.27)	0	0 (0.00)
Female genital tract fistula	1	1 (1.27)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.27)	0	0 (0.00)
Perineal rash	1	1 (1.27)	0	0 (0.00)
Vaginal ulceration	1	1 (1.27)	1	1 (1.27)
Respiratory, thoracic and mediastinal disorders				
- Total	183	55 (69.62)	62	29 (36.71)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Cough	29	23 (29.11)	0	0 (0.00)
Hypoxia	27	20 (25.32)	22	16 (20.25)
Pulmonary oedema	12	12 (15.19)	7	7 (8.86)
Tachypnoea	11	9 (11.39)	6	5 (6.33)
Nasal congestion	10	9 (11.39)	0	0 (0.00)
Pleural effusion	10	9 (11.39)	3	3 (3.80)
Oropharyngeal pain	9	8 (10.13)	0	0 (0.00)
Dyspnoea	8	7 (8.86)	4	4 (5.06)
Epistaxis	8	7 (8.86)	1	1 (1.27)
Rhinorrhoea	8	6 (7.59)	0	0 (0.00)
Respiratory failure	6	6 (7.59)	6	6 (7.59)
Atelectasis	5	3 (3.80)	2	2 (2.53)
Respiratory distress	5	4 (5.06)	3	2 (2.53)
Acute respiratory distress syndrome	3	3 (3.80)	3	3 (3.80)
Lung infiltration	2	1 (1.27)	1	1 (1.27)
Pharyngeal erythema	2	2 (2.53)	0	0 (0.00)
Rhinitis allergic	2	2 (2.53)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.53)	0	0 (0.00)
Wheezing	2	2 (2.53)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Acute respiratory failure	1	1 (1.27)	1	1 (1.27)
Bradypnoea	1	1 (1.27)	1	1 (1.27)
Bronchial oedema	1	1 (1.27)	0	0 (0.00)
Bronchospasm	1	1 (1.27)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.27)	0	0 (0.00)
Haemoptysis	1	1 (1.27)	0	0 (0.00)
Laryngeal oedema	1	1 (1.27)	1	1 (1.27)
Lung disorder	1	1 (1.27)	0	0 (0.00)
Nasal discomfort	1	1 (1.27)	0	0 (0.00)
Nasal dryness	1	1 (1.27)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.27)	0	0 (0.00)
Painful respiration	1	1 (1.27)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.27)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.27)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.27)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.27)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.27)	0	0 (0.00)
Productive cough	1	1 (1.27)	0	0 (0.00)
Pulmonary mass	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Respiratory acidosis	1	1 (1.27)	1	1 (1.27)
Respiratory disorder	1	1 (1.27)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.27)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	94	39 (49.37)	9	7 (8.86)
Rash	13	8 (10.13)	0	0 (0.00)
Dry skin	9	8 (10.13)	0	0 (0.00)
Pruritus	9	7 (8.86)	0	0 (0.00)
Blister	6	3 (3.80)	0	0 (0.00)
Erythema	5	5 (6.33)	0	0 (0.00)
Dermatitis atopic	4	3 (3.80)	1	1 (1.27)
Rash maculo-papular	4	3 (3.80)	1	1 (1.27)
Rash papular	4	3 (3.80)	0	0 (0.00)
Eczema	3	3 (3.80)	1	1 (1.27)
Hyperhidrosis	3	3 (3.80)	0	0 (0.00)
Decubitus ulcer	2	2 (2.53)	1	1 (1.27)
Ingrowing nail	2	2 (2.53)	0	0 (0.00)
Petechiae	2	2 (2.53)	1	1 (1.27)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Rash macular	2	1 (1.27)	2	1 (1.27)
Rash vesicular	2	1 (1.27)	0	0 (0.00)
Skin discolouration	2	2 (2.53)	0	0 (0.00)
Skin ulcer	2	2 (2.53)	0	0 (0.00)
Dermatitis	1	1 (1.27)	0	0 (0.00)
Dermatitis allergic	1	1 (1.27)	0	0 (0.00)
Dermatitis diaper	1	1 (1.27)	0	0 (0.00)
Erythema nodosum	1	1 (1.27)	0	0 (0.00)
Hangnail	1	1 (1.27)	0	0 (0.00)
Miliaria	1	1 (1.27)	0	0 (0.00)
Night sweats	1	1 (1.27)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.27)	0	0 (0.00)
Papule	1	1 (1.27)	0	0 (0.00)
Pruritus allergic	1	1 (1.27)	0	0 (0.00)
Purpura	1	1 (1.27)	0	0 (0.00)
Rash erythematous	1	1 (1.27)	0	0 (0.00)
Rash pruritic	1	1 (1.27)	0	0 (0.00)
Scab	1	1 (1.27)	0	0 (0.00)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Skin hypopigmentation	1	1 (1.27)	0	0 (0.00)
Skin lesion	1	1 (1.27)	0	0 (0.00)
Skin necrosis	1	1 (1.27)	1	1 (1.27)
Skin swelling	1	1 (1.27)	0	0 (0.00)
Urticaria	1	1 (1.27)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.27)	1	1 (1.27)
Social circumstances				
- Total	1	1 (1.27)	0	0 (0.00)
Patient uncooperative	1	1 (1.27)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.27)	1	1 (1.27)
Thrombolysis	1	1 (1.27)	1	1 (1.27)
Vascular disorders				
- Total	54	34 (43.04)	27	21 (26.58)
Hypotension	29	24 (30.38)	19	16 (20.25)
Hypertension	17	16 (20.25)	5	5 (6.33)
Capillary leak syndrome	2	2 (2.53)	1	1 (1.27)
Venoocclusive disease	2	2 (2.53)	2	2 (2.53)

Timing: At anytime, BCR-ABL1-like: No

Primary system organ class Preferred term	All grades Total events	All patients N=79 n (%)[1]	Grade >= 3 Total events	All patients N=79 n (%)[2]
Flushing	1	1 (1.27)	0	0 (0.00)
Hot flush	1	1 (1.27)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.27)	0	0 (0.00)
Thrombosis	1	1 (1.27)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Total number of AE per patient	575	26 (96.30)	194	20 (74.07)
Blood and lymphatic system disorders				
- Total	18	12 (44.44)	8	7 (25.93)
Anaemia	4	4 (14.81)	0	0 (0.00)
Disseminated intravascular coagulation	4	4 (14.81)	1	1 (3.70)
Febrile neutropenia	3	3 (11.11)	3	3 (11.11)
Neutropenia	3	3 (11.11)	2	2 (7.41)
Thrombocytopenia	2	2 (7.41)	2	2 (7.41)
Coagulopathy	1	1 (3.70)	0	0 (0.00)
Splenomegaly	1	1 (3.70)	0	0 (0.00)
Cardiac disorders				
- Total	11	7 (25.93)	2	2 (7.41)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Tachycardia	5	3 (11.11)	2	2 (7.41)
Sinus tachycardia	3	2 (7.41)	0	0 (0.00)
Bradycardia	2	2 (7.41)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.70)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Ear pruritus	1	1 (3.70)	0	0 (0.00)
Eye disorders				
- Total	6	3 (11.11)	0	0 (0.00)
Eyelid oedema	3	2 (7.41)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.70)	0	0 (0.00)
Eye pain	1	1 (3.70)	0	0 (0.00)
Periorbital oedema	1	1 (3.70)	0	0 (0.00)
Gastrointestinal disorders				
- Total	45	20 (74.07)	5	5 (18.52)
Vomiting	9	7 (25.93)	0	0 (0.00)
Diarrhoea	8	6 (22.22)	1	1 (3.70)
Abdominal pain	5	5 (18.52)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Nausea	5	4 (14.81)	0	0 (0.00)
Abdominal pain upper	3	3 (11.11)	0	0 (0.00)
Pancreatitis	3	3 (11.11)	1	1 (3.70)
Constipation	2	2 (7.41)	0	0 (0.00)
Abdominal distension	1	1 (3.70)	0	0 (0.00)
Anal haemorrhage	1	1 (3.70)	0	0 (0.00)
Ascites	1	1 (3.70)	0	0 (0.00)
Dysphagia	1	1 (3.70)	1	1 (3.70)
Enterocolitis	1	1 (3.70)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.70)	0	0 (0.00)
Gingival erythema	1	1 (3.70)	0	0 (0.00)
Melaena	1	1 (3.70)	1	1 (3.70)
Mouth haemorrhage	1	1 (3.70)	0	0 (0.00)
Proctalgia	1	1 (3.70)	1	1 (3.70)
General disorders and administration site conditions				
- Total	26	12 (44.44)	3	2 (7.41)
Pyrexia	8	6 (22.22)	1	1 (3.70)
Fatigue	4	4 (14.81)	0	0 (0.00)
Face oedema	3	3 (11.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Catheter site erythema	2	1 (3.70)	0	0 (0.00)
Oedema peripheral	2	2 (7.41)	0	0 (0.00)
Asthenia	1	1 (3.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.70)	0	0 (0.00)
Generalised oedema	1	1 (3.70)	0	0 (0.00)
Localised oedema	1	1 (3.70)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.70)	1	1 (3.70)
Oedema due to hepatic disease	1	1 (3.70)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.70)	1	1 (3.70)
Hepatobiliary disorders				
- Total	16	6 (22.22)	5	4 (14.81)
Hepatic function abnormal	9	3 (11.11)	4	3 (11.11)
Hyperbilirubinaemia	3	2 (7.41)	0	0 (0.00)
Cholelithiasis	1	1 (3.70)	0	0 (0.00)
Cholestasis	1	1 (3.70)	1	1 (3.70)
Gallbladder enlargement	1	1 (3.70)	0	0 (0.00)
Hypertransaminasaemia	1	1 (3.70)	0	0 (0.00)
Immune system disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	59	21 (77.78)	28	18 (66.67)
Cytokine release syndrome	46	20 (74.07)	22	17 (62.96)
Hypogammaglobulinaemia	8	7 (25.93)	3	3 (11.11)
Haemophagocytic lymphohistiocytosis	4	4 (14.81)	2	2 (7.41)
Immunodeficiency	1	1 (3.70)	1	1 (3.70)
Infections and infestations				
- Total	23	16 (59.26)	9	7 (25.93)
Clostridium difficile infection	2	2 (7.41)	1	1 (3.70)
Conjunctivitis	2	2 (7.41)	0	0 (0.00)
Oral infection	2	2 (7.41)	0	0 (0.00)
Staphylococcal infection	2	2 (7.41)	1	1 (3.70)
Anal abscess	1	1 (3.70)	1	1 (3.70)
BK virus infection	1	1 (3.70)	0	0 (0.00)
Bacteraemia	1	1 (3.70)	1	1 (3.70)
Bronchopulmonary aspergillosis	1	1 (3.70)	1	1 (3.70)
Cholecystitis infective	1	1 (3.70)	0	0 (0.00)
Encephalitis	1	1 (3.70)	1	1 (3.70)
Encephalitis viral	1	1 (3.70)	1	1 (3.70)
Gastroenteritis norovirus	1	1 (3.70)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Localised infection	1	1 (3.70)	0	0 (0.00)
Meningitis bacterial	1	1 (3.70)	1	1 (3.70)
Myringitis	1	1 (3.70)	0	0 (0.00)
Nail infection	1	1 (3.70)	0	0 (0.00)
Otitis externa	1	1 (3.70)	0	0 (0.00)
Paronychia	1	1 (3.70)	0	0 (0.00)
Pneumonia	1	1 (3.70)	1	1 (3.70)
Injury, poisoning and procedural complications				
- Total	13	6 (22.22)	2	1 (3.70)
Wound	3	2 (7.41)	1	1 (3.70)
Contusion	2	1 (3.70)	0	0 (0.00)
Procedural pain	2	2 (7.41)	0	0 (0.00)
Fall	1	1 (3.70)	0	0 (0.00)
Scratch	1	1 (3.70)	0	0 (0.00)
Skin abrasion	1	1 (3.70)	0	0 (0.00)
Skin injury	1	1 (3.70)	0	0 (0.00)
Skin wound	1	1 (3.70)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.70)	1	1 (3.70)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Investigations				
- Total	131	19 (70.37)	62	13 (48.15)
Neutrophil count decreased	27	7 (25.93)	22	6 (22.22)
Platelet count decreased	12	5 (18.52)	5	3 (11.11)
White blood cell count decreased	11	7 (25.93)	10	6 (22.22)
Lymphocyte count decreased	10	6 (22.22)	6	4 (14.81)
Alanine aminotransferase increased	9	6 (22.22)	3	3 (11.11)
Aspartate aminotransferase increased	6	5 (18.52)	1	1 (3.70)
Blood bilirubin increased	5	4 (14.81)	2	2 (7.41)
Blood fibrinogen decreased	5	5 (18.52)	1	1 (3.70)
Blood creatine phosphokinase increased	4	2 (7.41)	2	2 (7.41)
International normalised ratio increased	4	2 (7.41)	0	0 (0.00)
Lipase increased	4	2 (7.41)	2	1 (3.70)
Serum ferritin increased	4	4 (14.81)	0	0 (0.00)
Activated partial thromboplastin time prolonged	3	2 (7.41)	0	0 (0.00)
Blood creatinine increased	3	1 (3.70)	3	1 (3.70)
Electrocardiogram QT prolonged	3	3 (11.11)	1	1 (3.70)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Blood immunoglobulin M decreased	2	2 (7.41)	0	0 (0.00)
Blood lactate dehydrogenase increased	2	2 (7.41)	0	0 (0.00)
Haemoglobin decreased	2	1 (3.70)	1	1 (3.70)
Urine output decreased	2	1 (3.70)	2	1 (3.70)
Amylase increased	1	1 (3.70)	0	0 (0.00)
Bacterial test positive	1	1 (3.70)	1	1 (3.70)
Blood bicarbonate decreased	1	1 (3.70)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (3.70)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.70)	0	0 (0.00)
Blood uric acid increased	1	1 (3.70)	0	0 (0.00)
C-reactive protein increased	1	1 (3.70)	0	0 (0.00)
Cardiac murmur	1	1 (3.70)	0	0 (0.00)
Coagulation test abnormal	1	1 (3.70)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.70)	0	0 (0.00)
Immunoglobulins decreased	1	1 (3.70)	0	0 (0.00)
Weight decreased	1	1 (3.70)	0	0 (0.00)
Weight increased	1	1 (3.70)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	64	17 (62.96)	25	11 (40.74)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Hypokalaemia	19	9 (33.33)	12	6 (22.22)
Hypophosphataemia	10	7 (25.93)	3	3 (11.11)
Hypocalcaemia	8	4 (14.81)	3	2 (7.41)
Decreased appetite	7	7 (25.93)	3	3 (11.11)
Hypoalbuminaemia	4	3 (11.11)	0	0 (0.00)
Hypomagnesaemia	3	2 (7.41)	0	0 (0.00)
Hypernatraemia	2	2 (7.41)	1	1 (3.70)
Hyperphosphataemia	2	2 (7.41)	0	0 (0.00)
Tumour lysis syndrome	2	2 (7.41)	2	2 (7.41)
Haemosiderosis	1	1 (3.70)	0	0 (0.00)
Hyperchloraemia	1	1 (3.70)	0	0 (0.00)
Hyperlactacidaemia	1	1 (3.70)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.70)	1	1 (3.70)
Hyperuricaemia	1	1 (3.70)	0	0 (0.00)
Hypervolaemia	1	1 (3.70)	0	0 (0.00)
Hyponatraemia	1	1 (3.70)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	16	12 (44.44)	1	1 (3.70)
Pain in extremity	5	5 (18.52)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Arthralgia	4	4 (14.81)	0	0 (0.00)
Myalgia	2	2 (7.41)	0	0 (0.00)
Back pain	1	1 (3.70)	0	0 (0.00)
Muscle rigidity	1	1 (3.70)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.70)	0	0 (0.00)
Myositis	1	1 (3.70)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.70)	1	1 (3.70)
Nervous system disorders				
- Total	24	12 (44.44)	3	2 (7.41)
Headache	9	7 (25.93)	0	0 (0.00)
Encephalopathy	3	3 (11.11)	2	2 (7.41)
Tremor	3	3 (11.11)	0	0 (0.00)
Dizziness	2	2 (7.41)	0	0 (0.00)
Seizure	2	1 (3.70)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (3.70)	0	0 (0.00)
Hypoaesthesia	1	1 (3.70)	0	0 (0.00)
Monoparesis	1	1 (3.70)	0	0 (0.00)
Neuralgia	1	1 (3.70)	0	0 (0.00)
Somnolence	1	1 (3.70)	1	1 (3.70)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Psychiatric disorders				
- Total	17	10 (37.04)	2	2 (7.41)
Delirium	3	3 (11.11)	0	0 (0.00)
Insomnia	3	3 (11.11)	0	0 (0.00)
Agitation	2	1 (3.70)	0	0 (0.00)
Anxiety	2	2 (7.41)	1	1 (3.70)
Confusional state	2	2 (7.41)	0	0 (0.00)
Mental status changes	2	2 (7.41)	1	1 (3.70)
Automatism	1	1 (3.70)	0	0 (0.00)
Irritability	1	1 (3.70)	0	0 (0.00)
Sleep disorder	1	1 (3.70)	0	0 (0.00)
Renal and urinary disorders				
- Total	18	8 (29.63)	6	4 (14.81)
Acute kidney injury	7	4 (14.81)	5	4 (14.81)
Anuria	1	1 (3.70)	0	0 (0.00)
Azotaemia	1	1 (3.70)	0	0 (0.00)
Bladder dilatation	1	1 (3.70)	0	0 (0.00)
Dysuria	1	1 (3.70)	0	0 (0.00)
Haematuria	1	1 (3.70)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Micturition urgency	1	1 (3.70)	0	0 (0.00)
Pollakiuria	1	1 (3.70)	0	0 (0.00)
Proteinuria	1	1 (3.70)	0	0 (0.00)
Renal failure	1	1 (3.70)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.70)	1	1 (3.70)
Urinary retention	1	1 (3.70)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (7.41)	1	1 (3.70)
Perineal rash	1	1 (3.70)	0	0 (0.00)
Vaginal ulceration	1	1 (3.70)	1	1 (3.70)
Respiratory, thoracic and mediastinal disorders				
- Total	44	13 (48.15)	20	8 (29.63)
Hypoxia	12	8 (29.63)	10	6 (22.22)
Atelectasis	4	2 (7.41)	2	2 (7.41)
Pleural effusion	4	4 (14.81)	1	1 (3.70)
Pulmonary oedema	4	4 (14.81)	1	1 (3.70)
Tachypnoea	4	3 (11.11)	2	2 (7.41)
Cough	3	3 (11.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Oropharyngeal pain	3	2 (7.41)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (3.70)	1	1 (3.70)
Bradypnoea	1	1 (3.70)	1	1 (3.70)
Dyspnoea	1	1 (3.70)	1	1 (3.70)
Epistaxis	1	1 (3.70)	0	0 (0.00)
Nasal discomfort	1	1 (3.70)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (3.70)	0	0 (0.00)
Productive cough	1	1 (3.70)	0	0 (0.00)
Respiratory acidosis	1	1 (3.70)	1	1 (3.70)
Respiratory distress	1	1 (3.70)	0	0 (0.00)
Rhinorrhoea	1	1 (3.70)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	24	8 (29.63)	3	2 (7.41)
Blister	4	1 (3.70)	0	0 (0.00)
Pruritus	3	2 (7.41)	0	0 (0.00)
Petechiae	2	2 (7.41)	1	1 (3.70)
Rash	2	2 (7.41)	0	0 (0.00)
Skin ulcer	2	2 (7.41)	0	0 (0.00)
Decubitus ulcer	1	1 (3.70)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Dermatitis diaper	1	1 (3.70)	0	0 (0.00)
Dry skin	1	1 (3.70)	0	0 (0.00)
Erythema	1	1 (3.70)	0	0 (0.00)
Erythema nodosum	1	1 (3.70)	0	0 (0.00)
Pruritus allergic	1	1 (3.70)	0	0 (0.00)
Rash papular	1	1 (3.70)	0	0 (0.00)
Rash pruritic	1	1 (3.70)	0	0 (0.00)
Skin necrosis	1	1 (3.70)	1	1 (3.70)
Urticaria	1	1 (3.70)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (3.70)	1	1 (3.70)
Vascular disorders				
- Total	17	10 (37.04)	9	6 (22.22)
Hypotension	9	7 (25.93)	7	5 (18.52)
Hypertension	6	5 (18.52)	2	2 (7.41)
Capillary leak syndrome	1	1 (3.70)	0	0 (0.00)
Thrombosis	1	1 (3.70)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Total number of AE per patient	1176	53 (100.00)	425	47 (88.68)
Blood and lymphatic system disorders				
- Total	107	38 (71.70)	68	32 (60.38)
Anaemia	46	17 (32.08)	20	8 (15.09)
Febrile neutropenia	26	23 (43.40)	26	23 (43.40)
Neutropenia	8	6 (11.32)	7	5 (9.43)
Thrombocytopenia	6	6 (11.32)	6	6 (11.32)
Coagulopathy	4	4 (7.55)	2	2 (3.77)
Leukopenia	4	3 (5.66)	3	2 (3.77)
Disseminated intravascular coagulation	3	3 (5.66)	1	1 (1.89)
Splenomegaly	3	3 (5.66)	0	0 (0.00)
Eosinophilia	2	1 (1.89)	0	0 (0.00)
Pancytopenia	2	2 (3.77)	2	2 (3.77)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
B-cell aplasia	1	1 (1.89)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.89)	0	0 (0.00)
Lymphopenia	1	1 (1.89)	1	1 (1.89)
Cardiac disorders				
- Total	34	17 (32.08)	8	6 (11.32)
Tachycardia	17	14 (26.42)	1	1 (1.89)
Cardiac failure	4	1 (1.89)	2	1 (1.89)
Left ventricular dysfunction	3	3 (5.66)	3	3 (5.66)
Atrioventricular block first degree	1	1 (1.89)	0	0 (0.00)
Bradycardia	1	1 (1.89)	0	0 (0.00)
Cardiac arrest	1	1 (1.89)	1	1 (1.89)
Cardiac dysfunction	1	1 (1.89)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.89)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.89)	0	0 (0.00)
Pericardial effusion	1	1 (1.89)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.89)	0	0 (0.00)
Sinus bradycardia	1	1 (1.89)	1	1 (1.89)
Sinus tachycardia	1	1 (1.89)	0	0 (0.00)
Ear and labyrinth disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
- Total	1	1 (1.89)	0	0 (0.00)
Ear pain	1	1 (1.89)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (9.43)	0	0 (0.00)
Adrenal insufficiency	4	4 (7.55)	0	0 (0.00)
Hypothyroidism	1	1 (1.89)	0	0 (0.00)
Eye disorders				
- Total	9	6 (11.32)	0	0 (0.00)
Ocular hyperaemia	2	2 (3.77)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.89)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (1.89)	0	0 (0.00)
Eye oedema	1	1 (1.89)	0	0 (0.00)
Periorbital swelling	1	1 (1.89)	0	0 (0.00)
Visual field defect	1	1 (1.89)	0	0 (0.00)
Visual impairment	1	1 (1.89)	0	0 (0.00)
Gastrointestinal disorders				
- Total	90	31 (58.49)	11	9 (16.98)
Vomiting	21	14 (26.42)	1	1 (1.89)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Nausea	16	14 (26.42)	2	2 (3.77)
Diarrhoea	10	9 (16.98)	0	0 (0.00)
Constipation	9	9 (16.98)	0	0 (0.00)
Abdominal pain	8	6 (11.32)	2	2 (3.77)
Mouth haemorrhage	3	3 (5.66)	2	2 (3.77)
Abdominal distension	2	2 (3.77)	0	0 (0.00)
Ascites	2	2 (3.77)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (3.77)	0	0 (0.00)
Stomatitis	2	2 (3.77)	1	1 (1.89)
Abdominal compartment syndrome	1	1 (1.89)	1	1 (1.89)
Anal fissure	1	1 (1.89)	0	0 (0.00)
Dry mouth	1	1 (1.89)	0	0 (0.00)
Gingival bleeding	1	1 (1.89)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.89)	1	1 (1.89)
Haematemesis	1	1 (1.89)	0	0 (0.00)
Ileus	1	1 (1.89)	0	0 (0.00)
Lip dry	1	1 (1.89)	0	0 (0.00)
Lip oedema	1	1 (1.89)	0	0 (0.00)
Mouth swelling	1	1 (1.89)	0	0 (0.00)
Neutropenic colitis	1	1 (1.89)	1	1 (1.89)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Odynophagia	1	1 (1.89)	0	0 (0.00)
Pancreatitis	1	1 (1.89)	0	0 (0.00)
Trichoglossia	1	1 (1.89)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.89)	0	0 (0.00)
General disorders and administration site conditions				
- Total	86	28 (52.83)	16	9 (16.98)
Pyrexia	36	18 (33.96)	8	7 (13.21)
Chills	9	6 (11.32)	0	0 (0.00)
Fatigue	7	7 (13.21)	0	0 (0.00)
Face oedema	6	5 (9.43)	1	1 (1.89)
Oedema peripheral	5	4 (7.55)	2	1 (1.89)
Catheter site pain	4	2 (3.77)	2	1 (1.89)
Generalised oedema	4	4 (7.55)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (3.77)	0	0 (0.00)
Influenza like illness	2	2 (3.77)	0	0 (0.00)
Asthenia	1	1 (1.89)	0	0 (0.00)
Chest discomfort	1	1 (1.89)	1	1 (1.89)
Crying	1	1 (1.89)	0	0 (0.00)
Facial pain	1	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Localised oedema	1	1 (1.89)	0	0 (0.00)
Malaise	1	1 (1.89)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.89)	1	1 (1.89)
Pain	1	1 (1.89)	1	1 (1.89)
Sluggishness	1	1 (1.89)	0	0 (0.00)
Swelling face	1	1 (1.89)	0	0 (0.00)
Vascular device occlusion	1	1 (1.89)	0	0 (0.00)
Hepatobiliary disorders				
- Total	13	11 (20.75)	2	2 (3.77)
Hepatomegaly	3	3 (5.66)	1	1 (1.89)
Hyperbilirubinaemia	3	3 (5.66)	1	1 (1.89)
Hepatic function abnormal	2	2 (3.77)	0	0 (0.00)
Biliary tract disorder	1	1 (1.89)	0	0 (0.00)
Cholelithiasis	1	1 (1.89)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.89)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.89)	0	0 (0.00)
Ocular icterus	1	1 (1.89)	0	0 (0.00)
Immune system disorders				
- Total	105	46 (86.79)	40	25 (47.17)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Cytokine release syndrome	82	41 (77.36)	33	21 (39.62)
Hypogammaglobulinaemia	17	16 (30.19)	4	4 (7.55)
Immunodeficiency	2	2 (3.77)	2	2 (3.77)
Haemophagocytic lymphohistiocytosis	1	1 (1.89)	1	1 (1.89)
Hypersensitivity	1	1 (1.89)	0	0 (0.00)
Seasonal allergy	1	1 (1.89)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.89)	0	0 (0.00)
Infections and infestations				
- Total	41	19 (35.85)	22	12 (22.64)
Candida infection	4	3 (5.66)	2	1 (1.89)
Conjunctivitis	4	3 (5.66)	0	0 (0.00)
Staphylococcal bacteraemia	4	3 (5.66)	4	3 (5.66)
Staphylococcal infection	3	3 (5.66)	1	1 (1.89)
Clostridium difficile infection	2	2 (3.77)	2	2 (3.77)
Oral candidiasis	2	1 (1.89)	0	0 (0.00)
Oral herpes	2	2 (3.77)	1	1 (1.89)
Rhinovirus infection	2	2 (3.77)	0	0 (0.00)
Adenovirus infection	1	1 (1.89)	1	1 (1.89)
Atypical pneumonia	1	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Encephalitis viral	1	1 (1.89)	1	1 (1.89)
Gingivitis	1	1 (1.89)	0	0 (0.00)
Granulicatella infection	1	1 (1.89)	1	1 (1.89)
Herpes simplex	1	1 (1.89)	1	1 (1.89)
Human herpesvirus 6 infection	1	1 (1.89)	1	1 (1.89)
Klebsiella bacteraemia	1	1 (1.89)	0	0 (0.00)
Klebsiella infection	1	1 (1.89)	1	1 (1.89)
Nail infection	1	1 (1.89)	0	0 (0.00)
Pneumonia fungal	1	1 (1.89)	1	1 (1.89)
Pneumonia viral	1	1 (1.89)	1	1 (1.89)
Sinusitis	1	1 (1.89)	1	1 (1.89)
Soft tissue infection	1	1 (1.89)	1	1 (1.89)
Stomatococcal infection	1	1 (1.89)	0	0 (0.00)
Systemic candida	1	1 (1.89)	1	1 (1.89)
Urinary tract infection viral	1	1 (1.89)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.89)	1	1 (1.89)
Injury, poisoning and procedural complications				
- Total	7	5 (9.43)	1	1 (1.89)
Infusion related reaction	3	2 (3.77)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Transfusion reaction	2	2 (3.77)	0	0 (0.00)
Fall	1	1 (1.89)	0	0 (0.00)
Transplant failure	1	1 (1.89)	1	1 (1.89)
Investigations				
- Total	255	38 (71.70)	135	32 (60.38)
Platelet count decreased	53	16 (30.19)	33	11 (20.75)
White blood cell count decreased	39	17 (32.08)	26	12 (22.64)
Aspartate aminotransferase increased	27	14 (26.42)	12	10 (18.87)
Neutrophil count decreased	21	13 (24.53)	16	11 (20.75)
Lymphocyte count decreased	20	9 (16.98)	18	9 (16.98)
Alanine aminotransferase increased	17	12 (22.64)	3	3 (5.66)
Blood bilirubin increased	13	8 (15.09)	7	7 (13.21)
International normalised ratio increased	8	7 (13.21)	0	0 (0.00)
Activated partial thromboplastin time prolonged	5	4 (7.55)	1	1 (1.89)
Blood immunoglobulin A decreased	4	4 (7.55)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (7.55)	1	1 (1.89)
Immunoglobulins decreased	4	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Serum ferritin increased	4	4 (7.55)	2	2 (3.77)
Blood creatinine increased	3	3 (5.66)	2	2 (3.77)
C-reactive protein increased	3	3 (5.66)	3	3 (5.66)
Electrocardiogram QT prolonged	3	2 (3.77)	1	1 (1.89)
Weight increased	3	3 (5.66)	1	1 (1.89)
Blood fibrinogen decreased	2	2 (3.77)	1	1 (1.89)
Blood glucose increased	2	1 (1.89)	2	1 (1.89)
Blood lactate dehydrogenase increased	2	2 (3.77)	1	1 (1.89)
Fibrin D dimer increased	2	2 (3.77)	1	1 (1.89)
Gamma-glutamyltransferase increased	2	2 (3.77)	2	2 (3.77)
Blood alkaline phosphatase increased	1	1 (1.89)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.89)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.89)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.89)	0	0 (0.00)
Blood uric acid increased	1	1 (1.89)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.89)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.89)	0	0 (0.00)
Enterovirus test positive	1	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Haptoglobin decreased	1	1 (1.89)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.89)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.89)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.89)	0	0 (0.00)
Troponin increased	1	1 (1.89)	1	1 (1.89)
Urine output decreased	1	1 (1.89)	1	1 (1.89)
Metabolism and nutrition disorders				
- Total	146	29 (54.72)	51	18 (33.96)
Hypokalaemia	21	10 (18.87)	8	5 (9.43)
Hypophosphataemia	21	10 (18.87)	8	6 (11.32)
Decreased appetite	17	17 (32.08)	8	8 (15.09)
Hypocalcaemia	16	12 (22.64)	3	3 (5.66)
Hypoalbuminaemia	15	8 (15.09)	1	1 (1.89)
Hyperglycaemia	11	8 (15.09)	4	4 (7.55)
Hyperuricaemia	8	6 (11.32)	1	1 (1.89)
Hypervolaemia	5	5 (9.43)	4	4 (7.55)
Hypercalcaemia	4	3 (5.66)	2	2 (3.77)
Hypomagnesaemia	4	4 (7.55)	0	0 (0.00)
Acidosis	3	2 (3.77)	2	2 (3.77)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Hypermagnesaemia	3	2 (3.77)	0	0 (0.00)
Hyperphosphataemia	3	3 (5.66)	1	1 (1.89)
Metabolic acidosis	3	3 (5.66)	2	2 (3.77)
Hyperkalaemia	2	2 (3.77)	2	2 (3.77)
Hyponatraemia	2	2 (3.77)	0	0 (0.00)
Tumour lysis syndrome	2	2 (3.77)	2	2 (3.77)
Calcium deficiency	1	1 (1.89)	0	0 (0.00)
Dehydration	1	1 (1.89)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (1.89)	1	1 (1.89)
Hypoglycaemia	1	1 (1.89)	0	0 (0.00)
Malnutrition	1	1 (1.89)	1	1 (1.89)
Polydipsia	1	1 (1.89)	1	1 (1.89)
Musculoskeletal and connective tissue disorders				
- Total	37	21 (39.62)	5	4 (7.55)
Myalgia	8	7 (13.21)	0	0 (0.00)
Arthralgia	6	6 (11.32)	1	1 (1.89)
Back pain	6	5 (9.43)	1	1 (1.89)
Pain in extremity	6	6 (11.32)	0	0 (0.00)
Bone pain	4	2 (3.77)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Muscular weakness	2	2 (3.77)	1	1 (1.89)
Pain in jaw	2	2 (3.77)	1	1 (1.89)
Haemarthrosis	1	1 (1.89)	1	1 (1.89)
Muscle spasms	1	1 (1.89)	0	0 (0.00)
Neck pain	1	1 (1.89)	0	0 (0.00)
Nervous system disorders				
- Total	53	28 (52.83)	11	8 (15.09)
Headache	17	16 (30.19)	2	2 (3.77)
Cognitive disorder	5	3 (5.66)	1	1 (1.89)
Encephalopathy	5	5 (9.43)	2	2 (3.77)
Somnolence	4	4 (7.55)	1	1 (1.89)
Tremor	4	3 (5.66)	0	0 (0.00)
Dysgeusia	3	3 (5.66)	0	0 (0.00)
Lethargy	3	3 (5.66)	0	0 (0.00)
Hyperaesthesia	2	1 (1.89)	0	0 (0.00)
Amnesia	1	1 (1.89)	0	0 (0.00)
Aphasia	1	1 (1.89)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.89)	1	1 (1.89)
Depressed level of consciousness	1	1 (1.89)	1	1 (1.89)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Disturbance in attention	1	1 (1.89)	0	0 (0.00)
Dizziness	1	1 (1.89)	0	0 (0.00)
Dysarthria	1	1 (1.89)	1	1 (1.89)
Neurological decompensation	1	1 (1.89)	1	1 (1.89)
Paraesthesia	1	1 (1.89)	0	0 (0.00)
Seizure	1	1 (1.89)	1	1 (1.89)
Psychiatric disorders				
- Total	30	18 (33.96)	4	4 (7.55)
Confusional state	5	5 (9.43)	0	0 (0.00)
Agitation	4	4 (7.55)	0	0 (0.00)
Anxiety	4	4 (7.55)	1	1 (1.89)
Delirium	4	4 (7.55)	3	3 (5.66)
Hallucination	3	3 (5.66)	0	0 (0.00)
Irritability	2	2 (3.77)	0	0 (0.00)
Sleep disorder	2	1 (1.89)	0	0 (0.00)
Affect lability	1	1 (1.89)	0	0 (0.00)
Hallucination, visual	1	1 (1.89)	0	0 (0.00)
Insomnia	1	1 (1.89)	0	0 (0.00)
Mental status changes	1	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Restlessness	1	1 (1.89)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.89)	0	0 (0.00)
Renal and urinary disorders				
- Total	21	12 (22.64)	7	5 (9.43)
Acute kidney injury	7	5 (9.43)	3	3 (5.66)
Renal failure	3	1 (1.89)	3	1 (1.89)
Dysuria	2	2 (3.77)	0	0 (0.00)
Urinary incontinence	2	1 (1.89)	0	0 (0.00)
Anuria	1	1 (1.89)	1	1 (1.89)
Haematuria	1	1 (1.89)	0	0 (0.00)
Incontinence	1	1 (1.89)	0	0 (0.00)
Pollakiuria	1	1 (1.89)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.89)	0	0 (0.00)
Urinary retention	1	1 (1.89)	0	0 (0.00)
Urinary tract disorder	1	1 (1.89)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (5.66)	0	0 (0.00)
Vaginal haemorrhage	2	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Female genital tract fistula	1	1 (1.89)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.89)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	70	28 (52.83)	30	15 (28.30)
Hypoxia	11	9 (16.98)	8	6 (11.32)
Cough	8	7 (13.21)	0	0 (0.00)
Pulmonary oedema	8	8 (15.09)	6	6 (11.32)
Tachypnoea	5	5 (9.43)	2	2 (3.77)
Respiratory failure	4	4 (7.55)	4	4 (7.55)
Epistaxis	3	3 (5.66)	1	1 (1.89)
Nasal congestion	3	3 (5.66)	0	0 (0.00)
Oropharyngeal pain	3	3 (5.66)	0	0 (0.00)
Pleural effusion	3	3 (5.66)	2	2 (3.77)
Respiratory distress	3	2 (3.77)	2	1 (1.89)
Dyspnoea	2	2 (3.77)	2	2 (3.77)
Lung infiltration	2	1 (1.89)	1	1 (1.89)
Acute respiratory distress syndrome	1	1 (1.89)	1	1 (1.89)
Acute respiratory failure	1	1 (1.89)	1	1 (1.89)
Atelectasis	1	1 (1.89)	0	0 (0.00)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Haemoptysis	1	1 (1.89)	0	0 (0.00)
Nasal dryness	1	1 (1.89)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.89)	0	0 (0.00)
Painful respiration	1	1 (1.89)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.89)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.89)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.89)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.89)	0	0 (0.00)
Pulmonary mass	1	1 (1.89)	0	0 (0.00)
Respiratory disorder	1	1 (1.89)	0	0 (0.00)
Rhinorrhoea	1	1 (1.89)	0	0 (0.00)
Wheezing	1	1 (1.89)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	32	19 (35.85)	1	1 (1.89)
Pruritus	4	4 (7.55)	0	0 (0.00)
Erythema	3	3 (5.66)	0	0 (0.00)
Hyperhidrosis	3	3 (5.66)	0	0 (0.00)
Rash	3	3 (5.66)	0	0 (0.00)
Rash maculo-papular	3	2 (3.77)	1	1 (1.89)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Rash papular	3	2 (3.77)	0	0 (0.00)
Blister	2	2 (3.77)	0	0 (0.00)
Dermatitis atopic	2	2 (3.77)	0	0 (0.00)
Rash vesicular	2	1 (1.89)	0	0 (0.00)
Dermatitis	1	1 (1.89)	0	0 (0.00)
Eczema	1	1 (1.89)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.89)	0	0 (0.00)
Purpura	1	1 (1.89)	0	0 (0.00)
Scab	1	1 (1.89)	0	0 (0.00)
Skin discolouration	1	1 (1.89)	0	0 (0.00)
Skin lesion	1	1 (1.89)	0	0 (0.00)
Social circumstances				
- Total	1	1 (1.89)	0	0 (0.00)
Patient uncooperative	1	1 (1.89)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.89)	1	1 (1.89)
Thrombolysis	1	1 (1.89)	1	1 (1.89)
Vascular disorders				

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
- Total	28	18 (33.96)	12	11 (20.75)
Hypotension	16	14 (26.42)	9	9 (16.98)
Hypertension	8	8 (15.09)	2	2 (3.77)
Capillary leak syndrome	1	1 (1.89)	1	1 (1.89)
Flushing	1	1 (1.89)	0	0 (0.00)
Hot flush	1	1 (1.89)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.89)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	143	22 (88.00)	43	14 (56.00)
Blood and lymphatic system disorders				
- Total	7	4 (16.00)	5	4 (16.00)
Neutropenia	3	3 (12.00)	3	3 (12.00)
Anaemia	2	1 (4.00)	0	0 (0.00)
Febrile neutropenia	1	1 (4.00)	1	1 (4.00)
Thrombocytopenia	1	1 (4.00)	1	1 (4.00)
Cardiac disorders				
- Total	2	2 (8.00)	1	1 (4.00)
Cardiac failure	1	1 (4.00)	1	1 (4.00)
Tachycardia	1	1 (4.00)	0	0 (0.00)
Endocrine disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
- Total	1	1 (4.00)	0	0 (0.00)
Hypothyroidism	1	1 (4.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	12	6 (24.00)	1	1 (4.00)
Constipation	3	2 (8.00)	0	0 (0.00)
Diarrhoea	2	2 (8.00)	0	0 (0.00)
Nausea	2	2 (8.00)	0	0 (0.00)
Enteritis	1	1 (4.00)	0	0 (0.00)
Pancreatitis	1	1 (4.00)	1	1 (4.00)
Proctalgia	1	1 (4.00)	0	0 (0.00)
Trichoglossia	1	1 (4.00)	0	0 (0.00)
Vomiting	1	1 (4.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	9	7 (28.00)	1	1 (4.00)
Pyrexia	5	5 (20.00)	1	1 (4.00)
Oedema peripheral	2	1 (4.00)	0	0 (0.00)
Asthenia	1	1 (4.00)	0	0 (0.00)
Fatigue	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Hepatobiliary disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Hypertransaminasaemia	1	1 (4.00)	0	0 (0.00)
Liver disorder	1	1 (4.00)	0	0 (0.00)
Immune system disorders				
- Total	7	6 (24.00)	3	2 (8.00)
Hypogammaglobulinaemia	3	3 (12.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (4.00)	0	0 (0.00)
Engraftment syndrome	1	1 (4.00)	1	1 (4.00)
Graft versus host disease	1	1 (4.00)	1	1 (4.00)
Immunodeficiency	1	1 (4.00)	1	1 (4.00)
Infections and infestations				
- Total	28	12 (48.00)	8	6 (24.00)
Nasopharyngitis	4	3 (12.00)	0	0 (0.00)
Sinusitis	4	3 (12.00)	1	1 (4.00)
Gastroenteritis	2	2 (8.00)	1	1 (4.00)
Respiratory tract infection	2	2 (8.00)	0	0 (0.00)
Rhinovirus infection	2	2 (8.00)	0	0 (0.00)
Coronavirus infection	1	1 (4.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Device related infection	1	1 (4.00)	1	1 (4.00)
Ear infection	1	1 (4.00)	0	0 (0.00)
Gastroenteritis viral	1	1 (4.00)	0	0 (0.00)
Influenza	1	1 (4.00)	0	0 (0.00)
Metapneumovirus infection	1	1 (4.00)	1	1 (4.00)
Nail infection	1	1 (4.00)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (4.00)	1	1 (4.00)
Pneumonia	1	1 (4.00)	0	0 (0.00)
Salmonellosis	1	1 (4.00)	0	0 (0.00)
Septic shock	1	1 (4.00)	1	1 (4.00)
Staphylococcal sepsis	1	1 (4.00)	1	1 (4.00)
Tinea pedis	1	1 (4.00)	0	0 (0.00)
Viral infection	1	1 (4.00)	0	0 (0.00)
Investigations				
- Total	21	9 (36.00)	10	7 (28.00)
Platelet count decreased	3	2 (8.00)	1	1 (4.00)
Weight increased	3	1 (4.00)	1	1 (4.00)
Blood bilirubin increased	2	1 (4.00)	1	1 (4.00)
Blood uric acid increased	2	2 (8.00)	2	2 (8.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Neutrophil count decreased	2	1 (4.00)	2	1 (4.00)
Alanine aminotransferase increased	1	1 (4.00)	0	0 (0.00)
Blood creatinine increased	1	1 (4.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (4.00)	1	1 (4.00)
Blood immunoglobulin M decreased	1	1 (4.00)	1	1 (4.00)
Blood thyroid stimulating hormone increased	1	1 (4.00)	0	0 (0.00)
Blood urea increased	1	1 (4.00)	1	1 (4.00)
Lymphocyte count decreased	1	1 (4.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (4.00)	0	0 (0.00)
White blood cell count decreased	1	1 (4.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	6 (24.00)	3	3 (12.00)
Hyperuricaemia	2	2 (8.00)	0	0 (0.00)
Decreased appetite	1	1 (4.00)	0	0 (0.00)
Hyperchloraemia	1	1 (4.00)	0	0 (0.00)
Hypervolaemia	1	1 (4.00)	1	1 (4.00)
Hypokalaemia	1	1 (4.00)	0	0 (0.00)
Metabolic acidosis	1	1 (4.00)	1	1 (4.00)
Metabolic syndrome	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Tumour lysis syndrome	1	1 (4.00)	1	1 (4.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Pain in extremity	1	1 (4.00)	0	0 (0.00)
Nervous system disorders				
- Total	6	4 (16.00)	3	1 (4.00)
Headache	3	3 (12.00)	0	0 (0.00)
Hydrocephalus	3	1 (4.00)	3	1 (4.00)
Psychiatric disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Anxiety	1	1 (4.00)	0	0 (0.00)
Mental status changes	1	1 (4.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	3 (12.00)	1	1 (4.00)
Acute kidney injury	2	2 (8.00)	1	1 (4.00)
Cystitis haemorrhagic	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (4.00)	0	0 (0.00)
Dysmenorrhoea	2	1 (4.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	8 (32.00)	3	3 (12.00)
Cough	4	4 (16.00)	0	0 (0.00)
Nasal congestion	2	2 (8.00)	0	0 (0.00)
Pleural effusion	2	2 (8.00)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (4.00)	1	1 (4.00)
Epistaxis	1	1 (4.00)	0	0 (0.00)
Hypoxia	1	1 (4.00)	1	1 (4.00)
Oropharyngeal pain	1	1 (4.00)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (4.00)	0	0 (0.00)
Respiratory distress	1	1 (4.00)	1	1 (4.00)
Rhinorrhoea	1	1 (4.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	11	6 (24.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Rash	4	2 (8.00)	0	0 (0.00)
Dry skin	2	2 (8.00)	0	0 (0.00)
Eczema	1	1 (4.00)	0	0 (0.00)
Hangnail	1	1 (4.00)	0	0 (0.00)
Ingrowing nail	1	1 (4.00)	0	0 (0.00)
Skin discolouration	1	1 (4.00)	0	0 (0.00)
Skin swelling	1	1 (4.00)	0	0 (0.00)
Vascular disorders				
- Total	5	4 (16.00)	4	4 (16.00)
Hypotension	2	2 (8.00)	2	2 (8.00)
Venoocclusive disease	2	2 (8.00)	2	2 (8.00)
Hypertension	1	1 (4.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Total number of AE per patient	391	47 (94.00)	103	22 (44.00)
Blood and lymphatic system disorders				
- Total	25	13 (26.00)	12	6 (12.00)
Anaemia	10	5 (10.00)	4	2 (4.00)
Febrile neutropenia	3	2 (4.00)	3	2 (4.00)
B-cell aplasia	2	1 (2.00)	0	0 (0.00)
Neutropenia	2	2 (4.00)	2	2 (4.00)
Disseminated intravascular coagulation	1	1 (2.00)	1	1 (2.00)
Eosinophilia	1	1 (2.00)	0	0 (0.00)
Leukocytosis	1	1 (2.00)	0	0 (0.00)
Leukopenia	1	1 (2.00)	0	0 (0.00)
Lymphadenopathy	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Lymphocytosis	1	1 (2.00)	0	0 (0.00)
Lymphopenia	1	1 (2.00)	1	1 (2.00)
Thrombocytopenia	1	1 (2.00)	1	1 (2.00)
Cardiac disorders				
- Total	6	5 (10.00)	3	2 (4.00)
Cardiac arrest	2	2 (4.00)	2	2 (4.00)
Cardiac failure	1	1 (2.00)	1	1 (2.00)
Left ventricular dysfunction	1	1 (2.00)	0	0 (0.00)
Tachycardia	1	1 (2.00)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.00)	0	0 (0.00)
Eye disorders				
- Total	5	4 (8.00)	0	0 (0.00)
Cataract	2	2 (4.00)	0	0 (0.00)
Hypermetropia	1	1 (2.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.00)	0	0 (0.00)
Visual impairment	1	1 (2.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	26	14 (28.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Vomiting	6	5 (10.00)	0	0 (0.00)
Diarrhoea	5	5 (10.00)	0	0 (0.00)
Nausea	3	3 (6.00)	0	0 (0.00)
Abdominal pain	2	2 (4.00)	0	0 (0.00)
Abdominal pain upper	1	1 (2.00)	0	0 (0.00)
Abdominal rigidity	1	1 (2.00)	0	0 (0.00)
Constipation	1	1 (2.00)	0	0 (0.00)
Dyspepsia	1	1 (2.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.00)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.00)	0	0 (0.00)
Pancreatitis	1	1 (2.00)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.00)	0	0 (0.00)
Stomatitis	1	1 (2.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	22	17 (34.00)	2	2 (4.00)
Pyrexia	11	10 (20.00)	1	1 (2.00)
Fatigue	6	5 (10.00)	0	0 (0.00)
Pain	2	2 (4.00)	1	1 (2.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Chills	1	1 (2.00)	0	0 (0.00)
Malaise	1	1 (2.00)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (2.00)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.00)	0	0 (0.00)
Immune system disorders				
- Total	12	10 (20.00)	2	2 (4.00)
Hypogammaglobulinaemia	9	7 (14.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (2.00)	1	1 (2.00)
Drug hypersensitivity	1	1 (2.00)	0	0 (0.00)
Graft versus host disease	1	1 (2.00)	1	1 (2.00)
Infections and infestations				
- Total	85	27 (54.00)	37	14 (28.00)
Upper respiratory tract infection	10	8 (16.00)	2	2 (4.00)
Bronchopulmonary aspergillosis	5	1 (2.00)	3	1 (2.00)
Nasopharyngitis	5	4 (8.00)	0	0 (0.00)
Parainfluenzae virus infection	5	4 (8.00)	2	2 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Bacteraemia	3	2 (4.00)	2	1 (2.00)
Gastroenteritis	3	3 (6.00)	1	1 (2.00)
Otitis media	3	3 (6.00)	1	1 (2.00)
Respiratory syncytial virus infection	3	3 (6.00)	2	2 (4.00)
Rhinovirus infection	3	3 (6.00)	1	1 (2.00)
Ear infection	2	1 (2.00)	0	0 (0.00)
Klebsiella infection	2	1 (2.00)	2	1 (2.00)
Metapneumovirus infection	2	2 (4.00)	2	2 (4.00)
Otitis externa	2	2 (4.00)	1	1 (2.00)
Pneumonia	2	2 (4.00)	1	1 (2.00)
Rhinitis	2	2 (4.00)	0	0 (0.00)
Urinary tract infection	2	1 (2.00)	2	1 (2.00)
Acute sinusitis	1	1 (2.00)	0	0 (0.00)
Adenovirus infection	1	1 (2.00)	1	1 (2.00)
BK virus infection	1	1 (2.00)	1	1 (2.00)
Cellulitis	1	1 (2.00)	0	0 (0.00)
Conjunctivitis	1	1 (2.00)	0	0 (0.00)
Cystitis	1	1 (2.00)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.00)	1	1 (2.00)
Ear, nose and throat infection	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Encephalitis	1	1 (2.00)	1	1 (2.00)
Enterobacter infection	1	1 (2.00)	1	1 (2.00)
Gastroenteritis clostridial	1	1 (2.00)	0	0 (0.00)
Gastrointestinal infection	1	1 (2.00)	0	0 (0.00)
Gingivitis	1	1 (2.00)	0	0 (0.00)
Herpes simplex	1	1 (2.00)	0	0 (0.00)
Herpes zoster	1	1 (2.00)	1	1 (2.00)
Human herpesvirus 6 infection	1	1 (2.00)	1	1 (2.00)
Mastoiditis	1	1 (2.00)	1	1 (2.00)
Molluscum contagiosum	1	1 (2.00)	0	0 (0.00)
Oral candidiasis	1	1 (2.00)	0	0 (0.00)
Oral herpes	1	1 (2.00)	0	0 (0.00)
Paronychia	1	1 (2.00)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (2.00)	1	1 (2.00)
Pneumocystis jirovecii pneumonia	1	1 (2.00)	1	1 (2.00)
Respiratory tract infection	1	1 (2.00)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.00)	0	0 (0.00)
Sinusitis fungal	1	1 (2.00)	1	1 (2.00)
Staphylococcal bacteraemia	1	1 (2.00)	1	1 (2.00)
Staphylococcal skin infection	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Viral haemorrhagic cystitis	1	1 (2.00)	1	1 (2.00)
Viral infection	1	1 (2.00)	1	1 (2.00)
Viral upper respiratory tract infection	1	1 (2.00)	1	1 (2.00)
Injury, poisoning and procedural complications				
- Total	10	9 (18.00)	0	0 (0.00)
Infusion related reaction	4	3 (6.00)	0	0 (0.00)
Contusion	1	1 (2.00)	0	0 (0.00)
Fibula fracture	1	1 (2.00)	0	0 (0.00)
Ligament sprain	1	1 (2.00)	0	0 (0.00)
Limb injury	1	1 (2.00)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.00)	0	0 (0.00)
Skin abrasion	1	1 (2.00)	0	0 (0.00)
Investigations				
- Total	70	21 (42.00)	25	9 (18.00)
Neutrophil count decreased	17	9 (18.00)	9	6 (12.00)
White blood cell count decreased	17	9 (18.00)	4	4 (8.00)
Platelet count decreased	13	3 (6.00)	8	1 (2.00)
Immunoglobulins decreased	5	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Lymphocyte count decreased	5	3 (6.00)	2	2 (4.00)
Alanine aminotransferase increased	2	1 (2.00)	1	1 (2.00)
Blood bilirubin increased	2	1 (2.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (2.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.00)	0	0 (0.00)
Bone density decreased	1	1 (2.00)	0	0 (0.00)
C-reactive protein increased	1	1 (2.00)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.00)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.00)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.00)	0	0 (0.00)
Weight decreased	1	1 (2.00)	1	1 (2.00)
Metabolism and nutrition disorders				
- Total	17	9 (18.00)	7	4 (8.00)
Decreased appetite	5	5 (10.00)	1	1 (2.00)
Hypokalaemia	5	2 (4.00)	4	2 (4.00)
Haemochromatosis	1	1 (2.00)	1	1 (2.00)
Hyperkalaemia	1	1 (2.00)	0	0 (0.00)
Hyperuricaemia	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hypophagia	1	1 (2.00)	0	0 (0.00)
Hypophosphataemia	1	1 (2.00)	0	0 (0.00)
Iron overload	1	1 (2.00)	0	0 (0.00)
Malnutrition	1	1 (2.00)	1	1 (2.00)
Musculoskeletal and connective tissue disorders				
- Total	21	14 (28.00)	3	3 (6.00)
Back pain	7	6 (12.00)	2	2 (4.00)
Pain in extremity	4	4 (8.00)	1	1 (2.00)
Arthralgia	3	3 (6.00)	0	0 (0.00)
Bone pain	2	2 (4.00)	0	0 (0.00)
Growth retardation	1	1 (2.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.00)	0	0 (0.00)
Myalgia	1	1 (2.00)	0	0 (0.00)
Neck pain	1	1 (2.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (8.00)	1	1 (2.00)
Skin papilloma	2	2 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Cancer pain	1	1 (2.00)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.00)	1	1 (2.00)
Nervous system disorders				
- Total	17	10 (20.00)	3	1 (2.00)
Headache	8	7 (14.00)	0	0 (0.00)
Dizziness	2	1 (2.00)	0	0 (0.00)
Migraine	2	1 (2.00)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.00)	1	1 (2.00)
Cerebral haemorrhage	1	1 (2.00)	1	1 (2.00)
Extrapyramidal disorder	1	1 (2.00)	0	0 (0.00)
Memory impairment	1	1 (2.00)	0	0 (0.00)
Seizure	1	1 (2.00)	1	1 (2.00)
Psychiatric disorders				
- Total	13	8 (16.00)	1	1 (2.00)
Anxiety	5	5 (10.00)	0	0 (0.00)
Agitation	1	1 (2.00)	0	0 (0.00)
Delirium	1	1 (2.00)	0	0 (0.00)
Mental status changes	1	1 (2.00)	1	1 (2.00)
Mood altered	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Nightmare	1	1 (2.00)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.00)	0	0 (0.00)
Sleep disorder	1	1 (2.00)	0	0 (0.00)
Tearfulness	1	1 (2.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	2 (4.00)	2	2 (4.00)
Acute kidney injury	1	1 (2.00)	0	0 (0.00)
Dysuria	1	1 (2.00)	0	0 (0.00)
Haematuria	1	1 (2.00)	1	1 (2.00)
Kidney enlargement	1	1 (2.00)	0	0 (0.00)
Renal mass	1	1 (2.00)	0	0 (0.00)
Renal tubular disorder	1	1 (2.00)	1	1 (2.00)
Respiratory, thoracic and mediastinal disorders				
- Total	31	16 (32.00)	3	3 (6.00)
Cough	10	7 (14.00)	0	0 (0.00)
Nasal congestion	5	4 (8.00)	0	0 (0.00)
Dyspnoea	2	1 (2.00)	0	0 (0.00)
Epistaxis	2	2 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hypoxia	2	2 (4.00)	2	2 (4.00)
Rhinitis allergic	2	2 (4.00)	0	0 (0.00)
Rhinorrhoea	2	2 (4.00)	0	0 (0.00)
Bronchial oedema	1	1 (2.00)	0	0 (0.00)
Bronchospasm	1	1 (2.00)	0	0 (0.00)
Lung disorder	1	1 (2.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.00)	0	0 (0.00)
Respiratory failure	1	1 (2.00)	1	1 (2.00)
Upper respiratory tract inflammation	1	1 (2.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	18	14 (28.00)	1	1 (2.00)
Dry skin	5	4 (8.00)	0	0 (0.00)
Pruritus	2	1 (2.00)	0	0 (0.00)
Rash	2	2 (4.00)	0	0 (0.00)
Decubitus ulcer	1	1 (2.00)	1	1 (2.00)
Dermatitis allergic	1	1 (2.00)	0	0 (0.00)
Dermatitis atopic	1	1 (2.00)	0	0 (0.00)
Erythema	1	1 (2.00)	0	0 (0.00)
Ingrowing nail	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Miliaria	1	1 (2.00)	0	0 (0.00)
Night sweats	1	1 (2.00)	0	0 (0.00)
Photosensitivity reaction	1	1 (2.00)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.00)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.00)	1	1 (2.00)
Hypotension	2	2 (4.00)	1	1 (2.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Total number of AE per patient	80	10 (62.50)	23	8 (50.00)
Blood and lymphatic system disorders				
- Total	4	2 (12.50)	2	2 (12.50)
Agranulocytosis	1	1 (6.25)	1	1 (6.25)
Anaemia	1	1 (6.25)	0	0 (0.00)
Neutropenia	1	1 (6.25)	1	1 (6.25)
Thrombocytopenia	1	1 (6.25)	0	0 (0.00)
Eye disorders				
- Total	2	1 (6.25)	1	1 (6.25)
Eye pain	1	1 (6.25)	1	1 (6.25)
Eyelid oedema	1	1 (6.25)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
- Total	2	2 (12.50)	1	1 (6.25)
Diarrhoea	2	2 (12.50)	1	1 (6.25)
General disorders and administration site conditions				
- Total	3	3 (18.75)	1	1 (6.25)
Pyrexia	2	2 (12.50)	1	1 (6.25)
Xerosis	1	1 (6.25)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (18.75)	1	1 (6.25)
Drug hypersensitivity	1	1 (6.25)	1	1 (6.25)
Hypogammaglobulinaemia	1	1 (6.25)	0	0 (0.00)
Seasonal allergy	1	1 (6.25)	0	0 (0.00)
Infections and infestations				
- Total	44	9 (56.25)	11	8 (50.00)
Sinusitis	6	3 (18.75)	0	0 (0.00)
Conjunctivitis	4	3 (18.75)	0	0 (0.00)
Upper respiratory tract infection	4	2 (12.50)	1	1 (6.25)
Otitis media	3	2 (12.50)	0	0 (0.00)
COVID-19	2	1 (6.25)	1	1 (6.25)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Device related sepsis	2	1 (6.25)	2	1 (6.25)
Gastroenteritis viral	2	1 (6.25)	0	0 (0.00)
Herpes zoster	2	2 (12.50)	1	1 (6.25)
Oral herpes	2	2 (12.50)	0	0 (0.00)
Sepsis	2	2 (12.50)	2	2 (12.50)
Skin infection	2	2 (12.50)	0	0 (0.00)
Bronchiolitis	1	1 (6.25)	1	1 (6.25)
Bronchitis	1	1 (6.25)	0	0 (0.00)
Candida infection	1	1 (6.25)	0	0 (0.00)
Ear infection	1	1 (6.25)	1	1 (6.25)
Folliculitis	1	1 (6.25)	0	0 (0.00)
Herpes virus infection	1	1 (6.25)	0	0 (0.00)
Nail infection	1	1 (6.25)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (6.25)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (6.25)	1	1 (6.25)
Rhinitis	1	1 (6.25)	0	0 (0.00)
Rhinovirus infection	1	1 (6.25)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (6.25)	1	1 (6.25)
Streptococcal sepsis	1	1 (6.25)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Injury, poisoning and procedural complications				
- Total	2	2 (12.50)	1	1 (6.25)
Infusion related reaction	1	1 (6.25)	1	1 (6.25)
Ligament sprain	1	1 (6.25)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (6.25)	0	0 (0.00)
Hyperlipidaemia	1	1 (6.25)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (12.50)	0	0 (0.00)
Osteonecrosis	1	1 (6.25)	0	0 (0.00)
Pain in extremity	1	1 (6.25)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (12.50)	1	1 (6.25)
Headache	3	2 (12.50)	1	1 (6.25)
Respiratory, thoracic and mediastinal disorders				
- Total	8	4 (25.00)	1	1 (6.25)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=16 n (%)[1]	Grade >= 3 Total events	All patients N=16 n (%)[2]
Cough	1	1 (6.25)	0	0 (0.00)
Dyspnoea	1	1 (6.25)	0	0 (0.00)
Epistaxis	1	1 (6.25)	0	0 (0.00)
Hypoxia	1	1 (6.25)	1	1 (6.25)
Oropharyngeal pain	1	1 (6.25)	0	0 (0.00)
Rhinorrhoea	1	1 (6.25)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (6.25)	0	0 (0.00)
Wheezing	1	1 (6.25)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	4 (25.00)	3	2 (12.50)
Rash macular	2	1 (6.25)	2	1 (6.25)
Eczema	1	1 (6.25)	1	1 (6.25)
Papule	1	1 (6.25)	0	0 (0.00)
Rash	1	1 (6.25)	0	0 (0.00)
Rash erythematous	1	1 (6.25)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Total number of AE per patient	140	22 (64.71)	40	11 (32.35)
Blood and lymphatic system disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Hypercoagulation	1	1 (2.94)	0	0 (0.00)
Lymphadenopathy	1	1 (2.94)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.94)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.94)	0	0 (0.00)
Deafness unilateral	1	1 (2.94)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Endocrine disorders				
- Total	2	1 (2.94)	0	0 (0.00)
Delayed puberty	1	1 (2.94)	0	0 (0.00)
Hypothyroidism	1	1 (2.94)	0	0 (0.00)
Eye disorders				
- Total	2	2 (5.88)	0	0 (0.00)
Dry eye	1	1 (2.94)	0	0 (0.00)
Mydriasis	1	1 (2.94)	0	0 (0.00)
Gastrointestinal disorders				
- Total	7	5 (14.71)	0	0 (0.00)
Diarrhoea	3	3 (8.82)	0	0 (0.00)
Constipation	1	1 (2.94)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.94)	0	0 (0.00)
Nausea	1	1 (2.94)	0	0 (0.00)
Vomiting	1	1 (2.94)	0	0 (0.00)
General disorders and administration site conditions				
- Total	10	6 (17.65)	1	1 (2.94)
Pyrexia	5	3 (8.82)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Pain	2	2 (5.88)	0	0 (0.00)
Fatigue	1	1 (2.94)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.94)	1	1 (2.94)
Non-cardiac chest pain	1	1 (2.94)	0	0 (0.00)
Immune system disorders				
- Total	7	6 (17.65)	2	1 (2.94)
Chronic graft versus host disease	2	2 (5.88)	1	1 (2.94)
Hypogammaglobulinaemia	2	2 (5.88)	0	0 (0.00)
Seasonal allergy	2	2 (5.88)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (2.94)	1	1 (2.94)
Infections and infestations				
- Total	42	14 (41.18)	15	6 (17.65)
Fungal infection	3	2 (5.88)	0	0 (0.00)
Rhinovirus infection	3	3 (8.82)	1	1 (2.94)
Sinusitis	3	3 (8.82)	0	0 (0.00)
Upper respiratory tract infection	3	3 (8.82)	0	0 (0.00)
Influenza	2	2 (5.88)	1	1 (2.94)
Pneumonia	2	2 (5.88)	2	2 (5.88)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Urinary tract infection	2	2 (5.88)	0	0 (0.00)
Acute sinusitis	1	1 (2.94)	0	0 (0.00)
Bronchitis	1	1 (2.94)	0	0 (0.00)
COVID-19	1	1 (2.94)	0	0 (0.00)
COVID-19 pneumonia	1	1 (2.94)	1	1 (2.94)
Clostridium difficile colitis	1	1 (2.94)	1	1 (2.94)
Conjunctivitis	1	1 (2.94)	0	0 (0.00)
Enterovirus infection	1	1 (2.94)	1	1 (2.94)
Fungal skin infection	1	1 (2.94)	0	0 (0.00)
Gastroenteritis	1	1 (2.94)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.94)	1	1 (2.94)
Gastroenteritis salmonella	1	1 (2.94)	1	1 (2.94)
Meningitis pneumococcal	1	1 (2.94)	1	1 (2.94)
Neutropenic infection	1	1 (2.94)	1	1 (2.94)
Oral candidiasis	1	1 (2.94)	0	0 (0.00)
Otitis media acute	1	1 (2.94)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.94)	1	1 (2.94)
Sepsis	1	1 (2.94)	1	1 (2.94)
Septic shock	1	1 (2.94)	1	1 (2.94)
Skin infection	1	1 (2.94)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Staphylococcal abscess	1	1 (2.94)	1	1 (2.94)
Syphilis	1	1 (2.94)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.94)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.94)	0	0 (0.00)
Viral skin infection	1	1 (2.94)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (2.94)	0	0 (0.00)
Abdominal injury	1	1 (2.94)	0	0 (0.00)
Investigations				
- Total	16	6 (17.65)	6	2 (5.88)
Neutrophil count decreased	8	3 (8.82)	5	1 (2.94)
Blood bilirubin increased	3	1 (2.94)	0	0 (0.00)
Platelet count decreased	2	2 (5.88)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.94)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.94)	1	1 (2.94)
SARS-CoV-2 test positive	1	1 (2.94)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	5 (14.71)	5	4 (11.76)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Decreased appetite	2	1 (2.94)	2	1 (2.94)
Iron overload	2	1 (2.94)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.94)	0	0 (0.00)
Hyperglycaemia	1	1 (2.94)	1	1 (2.94)
Hypernatraemia	1	1 (2.94)	1	1 (2.94)
Hypertriglyceridaemia	1	1 (2.94)	0	0 (0.00)
Obesity	1	1 (2.94)	1	1 (2.94)
Musculoskeletal and connective tissue disorders				
- Total	6	5 (14.71)	0	0 (0.00)
Arthralgia	1	1 (2.94)	0	0 (0.00)
Growth retardation	1	1 (2.94)	0	0 (0.00)
Joint effusion	1	1 (2.94)	0	0 (0.00)
Osteopenia	1	1 (2.94)	0	0 (0.00)
Pain in extremity	1	1 (2.94)	0	0 (0.00)
Synovitis	1	1 (2.94)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.94)	1	1 (2.94)
Bone giant cell tumour benign	2	1 (2.94)	1	1 (2.94)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Nervous system disorders				
- Total	6	2 (5.88)	2	1 (2.94)
Seizure	3	1 (2.94)	1	1 (2.94)
Nervous system disorder	2	1 (2.94)	1	1 (2.94)
Dysarthria	1	1 (2.94)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (8.82)	0	0 (0.00)
Anxiety	2	2 (5.88)	0	0 (0.00)
Tic	1	1 (2.94)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.94)	1	1 (2.94)
Endometriosis	2	1 (2.94)	1	1 (2.94)
Respiratory, thoracic and mediastinal disorders				
- Total	15	6 (17.65)	5	3 (8.82)
Cough	3	3 (8.82)	0	0 (0.00)
Dyspnoea	2	2 (5.88)	1	1 (2.94)
Rhinorrhoea	2	2 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=34 n (%)[1]	Grade >= 3 Total events	All patients N=34 n (%)[2]
Tachypnoea	2	1 (2.94)	2	1 (2.94)
Dyspnoea exertional	1	1 (2.94)	0	0 (0.00)
Laryngeal oedema	1	1 (2.94)	1	1 (2.94)
Pharyngeal erythema	1	1 (2.94)	0	0 (0.00)
Pleural effusion	1	1 (2.94)	0	0 (0.00)
Respiratory failure	1	1 (2.94)	1	1 (2.94)
Sleep apnoea syndrome	1	1 (2.94)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	3 (8.82)	1	1 (2.94)
Dermatitis atopic	1	1 (2.94)	1	1 (2.94)
Dry skin	1	1 (2.94)	0	0 (0.00)
Rash	1	1 (2.94)	0	0 (0.00)
Rash maculo-papular	1	1 (2.94)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (5.88)	1	1 (2.94)
Hypertension	2	2 (5.88)	1	1 (2.94)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse

events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Total number of AE per patient	798	27 (100.00)	260	23 (85.19)
Blood and lymphatic system disorders				
- Total	29	14 (51.85)	15	10 (37.04)
Anaemia	7	6 (22.22)	0	0 (0.00)
Neutropenia	7	5 (18.52)	6	4 (14.81)
Disseminated intravascular coagulation	4	4 (14.81)	1	1 (3.70)
Febrile neutropenia	4	4 (14.81)	4	4 (14.81)
Thrombocytopenia	4	3 (11.11)	3	3 (11.11)
Agranulocytosis	1	1 (3.70)	1	1 (3.70)
Coagulopathy	1	1 (3.70)	0	0 (0.00)
Splenomegaly	1	1 (3.70)	0	0 (0.00)
Cardiac disorders				

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	13	8 (29.63)	3	3 (11.11)
Tachycardia	6	3 (11.11)	2	2 (7.41)
Sinus tachycardia	3	2 (7.41)	0	0 (0.00)
Bradycardia	2	2 (7.41)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.70)	0	0 (0.00)
Cardiac failure	1	1 (3.70)	1	1 (3.70)
Ear and labyrinth disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Ear pruritus	1	1 (3.70)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Hypothyroidism	1	1 (3.70)	0	0 (0.00)
Eye disorders				
- Total	8	4 (14.81)	1	1 (3.70)
Eyelid oedema	4	3 (11.11)	0	0 (0.00)
Eye pain	2	2 (7.41)	1	1 (3.70)
Conjunctival haemorrhage	1	1 (3.70)	0	0 (0.00)
Periorbital oedema	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Gastrointestinal disorders				
- Total	59	21 (77.78)	7	7 (25.93)
Diarrhoea	12	10 (37.04)	2	2 (7.41)
Vomiting	10	8 (29.63)	0	0 (0.00)
Nausea	7	5 (18.52)	0	0 (0.00)
Abdominal pain	5	5 (18.52)	0	0 (0.00)
Constipation	5	4 (14.81)	0	0 (0.00)
Pancreatitis	4	4 (14.81)	2	2 (7.41)
Abdominal pain upper	3	3 (11.11)	0	0 (0.00)
Proctalgia	2	2 (7.41)	1	1 (3.70)
Abdominal distension	1	1 (3.70)	0	0 (0.00)
Anal haemorrhage	1	1 (3.70)	0	0 (0.00)
Ascites	1	1 (3.70)	0	0 (0.00)
Dysphagia	1	1 (3.70)	1	1 (3.70)
Enteritis	1	1 (3.70)	0	0 (0.00)
Enterocolitis	1	1 (3.70)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (3.70)	0	0 (0.00)
Gingival erythema	1	1 (3.70)	0	0 (0.00)
Melaena	1	1 (3.70)	1	1 (3.70)
Mouth haemorrhage	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Trichoglossia	1	1 (3.70)	0	0 (0.00)
General disorders and administration site conditions				
- Total	38	15 (55.56)	5	4 (14.81)
Pyrexia	15	10 (37.04)	3	3 (11.11)
Fatigue	5	5 (18.52)	0	0 (0.00)
Oedema peripheral	4	3 (11.11)	0	0 (0.00)
Face oedema	3	3 (11.11)	0	0 (0.00)
Asthenia	2	2 (7.41)	0	0 (0.00)
Catheter site erythema	2	1 (3.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.70)	0	0 (0.00)
Generalised oedema	1	1 (3.70)	0	0 (0.00)
Localised oedema	1	1 (3.70)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.70)	1	1 (3.70)
Oedema due to hepatic disease	1	1 (3.70)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.70)	1	1 (3.70)
Xerosis	1	1 (3.70)	0	0 (0.00)
Hepatobiliary disorders				
- Total	18	7 (25.93)	5	4 (14.81)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Hepatic function abnormal	9	3 (11.11)	4	3 (11.11)
Hyperbilirubinaemia	3	2 (7.41)	0	0 (0.00)
Hypertransaminasaemia	2	1 (3.70)	0	0 (0.00)
Cholelithiasis	1	1 (3.70)	0	0 (0.00)
Cholestasis	1	1 (3.70)	1	1 (3.70)
Gallbladder enlargement	1	1 (3.70)	0	0 (0.00)
Liver disorder	1	1 (3.70)	0	0 (0.00)
Immune system disorders				
- Total	69	24 (88.89)	32	19 (70.37)
Cytokine release syndrome	46	20 (74.07)	22	17 (62.96)
Hypogammaglobulinaemia	12	11 (40.74)	3	3 (11.11)
Haemophagocytic lymphohistiocytosis	4	4 (14.81)	2	2 (7.41)
Immunodeficiency	2	2 (7.41)	2	2 (7.41)
Allergy to immunoglobulin therapy	1	1 (3.70)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.70)	1	1 (3.70)
Engraftment syndrome	1	1 (3.70)	1	1 (3.70)
Graft versus host disease	1	1 (3.70)	1	1 (3.70)
Seasonal allergy	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Infections and infestations				
- Total	95	21 (77.78)	28	16 (59.26)
Sinusitis	10	3 (11.11)	1	1 (3.70)
Conjunctivitis	6	5 (18.52)	0	0 (0.00)
Nasopharyngitis	4	3 (11.11)	0	0 (0.00)
Upper respiratory tract infection	4	2 (7.41)	1	1 (3.70)
Gastroenteritis viral	3	2 (7.41)	0	0 (0.00)
Nail infection	3	3 (11.11)	0	0 (0.00)
Otitis media	3	2 (7.41)	0	0 (0.00)
Rhinovirus infection	3	3 (11.11)	0	0 (0.00)
COVID-19	2	1 (3.70)	1	1 (3.70)
Clostridium difficile infection	2	2 (7.41)	1	1 (3.70)
Device related sepsis	2	1 (3.70)	2	1 (3.70)
Ear infection	2	2 (7.41)	1	1 (3.70)
Gastroenteritis	2	2 (7.41)	1	1 (3.70)
Herpes zoster	2	2 (7.41)	1	1 (3.70)
Oral herpes	2	2 (7.41)	0	0 (0.00)
Oral infection	2	2 (7.41)	0	0 (0.00)
Pneumonia	2	2 (7.41)	1	1 (3.70)
Respiratory tract infection	2	2 (7.41)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Sepsis	2	2 (7.41)	2	2 (7.41)
Skin infection	2	2 (7.41)	0	0 (0.00)
Staphylococcal infection	2	2 (7.41)	1	1 (3.70)
Anal abscess	1	1 (3.70)	1	1 (3.70)
BK virus infection	1	1 (3.70)	0	0 (0.00)
Bacteraemia	1	1 (3.70)	1	1 (3.70)
Bronchiolitis	1	1 (3.70)	1	1 (3.70)
Bronchitis	1	1 (3.70)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (3.70)	1	1 (3.70)
Candida infection	1	1 (3.70)	0	0 (0.00)
Cholecystitis infective	1	1 (3.70)	0	0 (0.00)
Coronavirus infection	1	1 (3.70)	1	1 (3.70)
Device related infection	1	1 (3.70)	1	1 (3.70)
Encephalitis	1	1 (3.70)	1	1 (3.70)
Encephalitis viral	1	1 (3.70)	1	1 (3.70)
Folliculitis	1	1 (3.70)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (3.70)	0	0 (0.00)
Herpes virus infection	1	1 (3.70)	0	0 (0.00)
Influenza	1	1 (3.70)	0	0 (0.00)
Localised infection	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Meningitis bacterial	1	1 (3.70)	1	1 (3.70)
Metapneumovirus infection	1	1 (3.70)	1	1 (3.70)
Myringitis	1	1 (3.70)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (3.70)	0	0 (0.00)
Otitis externa	1	1 (3.70)	0	0 (0.00)
Paronychia	1	1 (3.70)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (3.70)	1	1 (3.70)
Pneumonia respiratory syncytial viral	1	1 (3.70)	1	1 (3.70)
Rhinitis	1	1 (3.70)	0	0 (0.00)
Salmonellosis	1	1 (3.70)	0	0 (0.00)
Septic shock	1	1 (3.70)	1	1 (3.70)
Staphylococcal bacteraemia	1	1 (3.70)	1	1 (3.70)
Staphylococcal sepsis	1	1 (3.70)	1	1 (3.70)
Streptococcal sepsis	1	1 (3.70)	0	0 (0.00)
Tinea pedis	1	1 (3.70)	0	0 (0.00)
Viral infection	1	1 (3.70)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	15	8 (29.63)	3	2 (7.41)
Wound	3	2 (7.41)	1	1 (3.70)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Contusion	2	1 (3.70)	0	0 (0.00)
Procedural pain	2	2 (7.41)	0	0 (0.00)
Fall	1	1 (3.70)	0	0 (0.00)
Infusion related reaction	1	1 (3.70)	1	1 (3.70)
Ligament sprain	1	1 (3.70)	0	0 (0.00)
Scratch	1	1 (3.70)	0	0 (0.00)
Skin abrasion	1	1 (3.70)	0	0 (0.00)
Skin injury	1	1 (3.70)	0	0 (0.00)
Skin wound	1	1 (3.70)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.70)	1	1 (3.70)
Investigations				
- Total	152	19 (70.37)	72	15 (55.56)
Neutrophil count decreased	29	7 (25.93)	24	6 (22.22)
Platelet count decreased	15	7 (25.93)	6	4 (14.81)
White blood cell count decreased	12	8 (29.63)	10	6 (22.22)
Lymphocyte count decreased	11	6 (22.22)	6	4 (14.81)
Alanine aminotransferase increased	10	6 (22.22)	3	3 (11.11)
Blood bilirubin increased	7	4 (14.81)	3	2 (7.41)
Aspartate aminotransferase increased	6	5 (18.52)	1	1 (3.70)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Blood fibrinogen decreased	5	5 (18.52)	1	1 (3.70)
Blood creatine phosphokinase increased	4	2 (7.41)	2	2 (7.41)
Blood creatinine increased	4	2 (7.41)	3	1 (3.70)
International normalised ratio increased	4	2 (7.41)	0	0 (0.00)
Lipase increased	4	2 (7.41)	2	1 (3.70)
Serum ferritin increased	4	4 (14.81)	0	0 (0.00)
Weight increased	4	1 (3.70)	1	1 (3.70)
Activated partial thromboplastin time prolonged	3	2 (7.41)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (11.11)	1	1 (3.70)
Blood uric acid increased	3	3 (11.11)	2	2 (7.41)
Electrocardiogram QT prolonged	3	3 (11.11)	1	1 (3.70)
Blood immunoglobulin A decreased	2	2 (7.41)	1	1 (3.70)
Blood lactate dehydrogenase increased	2	2 (7.41)	0	0 (0.00)
Haemoglobin decreased	2	1 (3.70)	1	1 (3.70)
Urine output decreased	2	1 (3.70)	2	1 (3.70)
Amylase increased	1	1 (3.70)	0	0 (0.00)
Bacterial test positive	1	1 (3.70)	1	1 (3.70)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Blood bicarbonate decreased	1	1 (3.70)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.70)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (3.70)	0	0 (0.00)
Blood urea increased	1	1 (3.70)	1	1 (3.70)
C-reactive protein increased	1	1 (3.70)	0	0 (0.00)
Cardiac murmur	1	1 (3.70)	0	0 (0.00)
Coagulation test abnormal	1	1 (3.70)	0	0 (0.00)
Fibrin D dimer increased	1	1 (3.70)	0	0 (0.00)
Immunoglobulins decreased	1	1 (3.70)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.70)	0	0 (0.00)
Weight decreased	1	1 (3.70)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	74	17 (62.96)	28	11 (40.74)
Hypokalaemia	20	10 (37.04)	12	6 (22.22)
Hypophosphataemia	10	7 (25.93)	3	3 (11.11)
Decreased appetite	8	8 (29.63)	3	3 (11.11)
Hypocalcaemia	8	4 (14.81)	3	2 (7.41)
Hypoalbuminaemia	4	3 (11.11)	0	0 (0.00)
Hyperuricaemia	3	3 (11.11)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Hypomagnesaemia	3	2 (7.41)	0	0 (0.00)
Tumour lysis syndrome	3	3 (11.11)	3	3 (11.11)
Hyperchloraemia	2	2 (7.41)	0	0 (0.00)
Hypernatraemia	2	2 (7.41)	1	1 (3.70)
Hyperphosphataemia	2	2 (7.41)	0	0 (0.00)
Hypervolaemia	2	2 (7.41)	1	1 (3.70)
Haemosiderosis	1	1 (3.70)	0	0 (0.00)
Hyperlactacidaemia	1	1 (3.70)	0	0 (0.00)
Hyperlipidaemia	1	1 (3.70)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.70)	1	1 (3.70)
Hyponatraemia	1	1 (3.70)	0	0 (0.00)
Metabolic acidosis	1	1 (3.70)	1	1 (3.70)
Metabolic syndrome	1	1 (3.70)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	19	13 (48.15)	1	1 (3.70)
Pain in extremity	7	7 (25.93)	0	0 (0.00)
Arthralgia	4	4 (14.81)	0	0 (0.00)
Myalgia	2	2 (7.41)	0	0 (0.00)
Back pain	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Muscle rigidity	1	1 (3.70)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.70)	0	0 (0.00)
Myositis	1	1 (3.70)	0	0 (0.00)
Osteonecrosis	1	1 (3.70)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.70)	1	1 (3.70)
Nervous system disorders				
- Total	33	14 (51.85)	7	4 (14.81)
Headache	15	8 (29.63)	1	1 (3.70)
Encephalopathy	3	3 (11.11)	2	2 (7.41)
Hydrocephalus	3	1 (3.70)	3	1 (3.70)
Tremor	3	3 (11.11)	0	0 (0.00)
Dizziness	2	2 (7.41)	0	0 (0.00)
Seizure	2	1 (3.70)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (3.70)	0	0 (0.00)
Hypoaesthesia	1	1 (3.70)	0	0 (0.00)
Monoparesis	1	1 (3.70)	0	0 (0.00)
Neuralgia	1	1 (3.70)	0	0 (0.00)
Somnolence	1	1 (3.70)	1	1 (3.70)
Psychiatric disorders				

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	19	12 (44.44)	2	2 (7.41)
Anxiety	3	3 (11.11)	1	1 (3.70)
Delirium	3	3 (11.11)	0	0 (0.00)
Insomnia	3	3 (11.11)	0	0 (0.00)
Mental status changes	3	3 (11.11)	1	1 (3.70)
Agitation	2	1 (3.70)	0	0 (0.00)
Confusional state	2	2 (7.41)	0	0 (0.00)
Automatism	1	1 (3.70)	0	0 (0.00)
Irritability	1	1 (3.70)	0	0 (0.00)
Sleep disorder	1	1 (3.70)	0	0 (0.00)
Renal and urinary disorders				
- Total	21	11 (40.74)	7	5 (18.52)
Acute kidney injury	9	6 (22.22)	6	5 (18.52)
Anuria	1	1 (3.70)	0	0 (0.00)
Azotaemia	1	1 (3.70)	0	0 (0.00)
Bladder dilatation	1	1 (3.70)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (3.70)	0	0 (0.00)
Dysuria	1	1 (3.70)	0	0 (0.00)
Haematuria	1	1 (3.70)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Micturition urgency	1	1 (3.70)	0	0 (0.00)
Pollakiuria	1	1 (3.70)	0	0 (0.00)
Proteinuria	1	1 (3.70)	0	0 (0.00)
Renal failure	1	1 (3.70)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.70)	1	1 (3.70)
Urinary retention	1	1 (3.70)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	2 (7.41)	1	1 (3.70)
Dysmenorrhoea	2	1 (3.70)	0	0 (0.00)
Perineal rash	1	1 (3.70)	0	0 (0.00)
Vaginal ulceration	1	1 (3.70)	1	1 (3.70)
Respiratory, thoracic and mediastinal disorders				
- Total	67	19 (70.37)	24	9 (33.33)
Hypoxia	14	9 (33.33)	12	8 (29.63)
Cough	8	7 (25.93)	0	0 (0.00)
Pleural effusion	6	5 (18.52)	1	1 (3.70)
Oropharyngeal pain	5	4 (14.81)	0	0 (0.00)
Atelectasis	4	2 (7.41)	2	2 (7.41)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Pulmonary oedema	4	4 (14.81)	1	1 (3.70)
Tachypnoea	4	3 (11.11)	2	2 (7.41)
Epistaxis	3	3 (11.11)	0	0 (0.00)
Rhinorrhoea	3	2 (7.41)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (7.41)	2	2 (7.41)
Dyspnoea	2	2 (7.41)	1	1 (3.70)
Nasal congestion	2	2 (7.41)	0	0 (0.00)
Respiratory distress	2	2 (7.41)	1	1 (3.70)
Bradypnoea	1	1 (3.70)	1	1 (3.70)
Nasal discomfort	1	1 (3.70)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (3.70)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (3.70)	0	0 (0.00)
Productive cough	1	1 (3.70)	0	0 (0.00)
Respiratory acidosis	1	1 (3.70)	1	1 (3.70)
Sleep apnoea syndrome	1	1 (3.70)	0	0 (0.00)
Wheezing	1	1 (3.70)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	41	12 (44.44)	6	4 (14.81)
Rash	7	3 (11.11)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Blister	4	1 (3.70)	0	0 (0.00)
Dry skin	3	3 (11.11)	0	0 (0.00)
Pruritus	3	2 (7.41)	0	0 (0.00)
Eczema	2	2 (7.41)	1	1 (3.70)
Petechiae	2	2 (7.41)	1	1 (3.70)
Rash macular	2	1 (3.70)	2	1 (3.70)
Skin ulcer	2	2 (7.41)	0	0 (0.00)
Decubitus ulcer	1	1 (3.70)	0	0 (0.00)
Dermatitis diaper	1	1 (3.70)	0	0 (0.00)
Erythema	1	1 (3.70)	0	0 (0.00)
Erythema nodosum	1	1 (3.70)	0	0 (0.00)
Hangnail	1	1 (3.70)	0	0 (0.00)
Ingrowing nail	1	1 (3.70)	0	0 (0.00)
Papule	1	1 (3.70)	0	0 (0.00)
Pruritus allergic	1	1 (3.70)	0	0 (0.00)
Rash erythematous	1	1 (3.70)	0	0 (0.00)
Rash papular	1	1 (3.70)	0	0 (0.00)
Rash pruritic	1	1 (3.70)	0	0 (0.00)
Skin discolouration	1	1 (3.70)	0	0 (0.00)
Skin necrosis	1	1 (3.70)	1	1 (3.70)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Skin swelling	1	1 (3.70)	0	0 (0.00)
Urticaria	1	1 (3.70)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (3.70)	1	1 (3.70)
Vascular disorders				
- Total	22	12 (44.44)	13	8 (29.63)
Hypotension	11	8 (29.63)	9	6 (22.22)
Hypertension	7	6 (22.22)	2	2 (7.41)
Venoocclusive disease	2	2 (7.41)	2	2 (7.41)
Capillary leak syndrome	1	1 (3.70)	0	0 (0.00)
Thrombosis	1	1 (3.70)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250j
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Complex Karyotypes
Safety Set

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Total number of AE per patient	1707	53 (100.00)	568	50 (94.34)
Blood and lymphatic system disorders				
- Total	134	41 (77.36)	80	33 (62.26)
Anaemia	56	19 (35.85)	24	9 (16.98)
Febrile neutropenia	29	23 (43.40)	29	23 (43.40)
Neutropenia	10	6 (11.32)	9	5 (9.43)
Thrombocytopenia	7	6 (11.32)	7	6 (11.32)
Leukopenia	5	3 (5.66)	3	2 (3.77)
Coagulopathy	4	4 (7.55)	2	2 (3.77)
Disseminated intravascular coagulation	4	4 (7.55)	2	2 (3.77)
B-cell aplasia	3	1 (1.89)	0	0 (0.00)
Eosinophilia	3	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Splenomegaly	3	3 (5.66)	0	0 (0.00)
Lymphadenopathy	2	2 (3.77)	0	0 (0.00)
Lymphopenia	2	2 (3.77)	2	2 (3.77)
Pancytopenia	2	2 (3.77)	2	2 (3.77)
Hypercoagulation	1	1 (1.89)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.89)	0	0 (0.00)
Leukocytosis	1	1 (1.89)	0	0 (0.00)
Lymphocytosis	1	1 (1.89)	0	0 (0.00)
Cardiac disorders				
- Total	40	20 (37.74)	11	8 (15.09)
Tachycardia	18	14 (26.42)	1	1 (1.89)
Cardiac failure	5	2 (3.77)	3	2 (3.77)
Left ventricular dysfunction	4	4 (7.55)	3	3 (5.66)
Cardiac arrest	3	3 (5.66)	3	3 (5.66)
Atrioventricular block first degree	1	1 (1.89)	0	0 (0.00)
Bradycardia	1	1 (1.89)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.89)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.89)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Pericardial effusion	1	1 (1.89)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.89)	0	0 (0.00)
Sinus bradycardia	1	1 (1.89)	1	1 (1.89)
Sinus tachycardia	1	1 (1.89)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.89)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.89)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.89)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (3.77)	0	0 (0.00)
Deafness unilateral	1	1 (1.89)	0	0 (0.00)
Ear pain	1	1 (1.89)	0	0 (0.00)
Endocrine disorders				
- Total	7	6 (11.32)	0	0 (0.00)
Adrenal insufficiency	4	4 (7.55)	0	0 (0.00)
Hypothyroidism	2	2 (3.77)	0	0 (0.00)
Delayed puberty	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Eye disorders				
- Total	16	11 (20.75)	0	0 (0.00)
Ocular hyperaemia	3	3 (5.66)	0	0 (0.00)
Cataract	2	2 (3.77)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.89)	0	0 (0.00)
Visual impairment	2	2 (3.77)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (1.89)	0	0 (0.00)
Dry eye	1	1 (1.89)	0	0 (0.00)
Eye oedema	1	1 (1.89)	0	0 (0.00)
Hypermetropia	1	1 (1.89)	0	0 (0.00)
Mydriasis	1	1 (1.89)	0	0 (0.00)
Periorbital swelling	1	1 (1.89)	0	0 (0.00)
Visual field defect	1	1 (1.89)	0	0 (0.00)
Gastrointestinal disorders				
- Total	123	39 (73.58)	11	9 (16.98)
Vomiting	28	18 (33.96)	1	1 (1.89)
Nausea	20	17 (32.08)	2	2 (3.77)
Diarrhoea	18	16 (30.19)	0	0 (0.00)
Constipation	11	10 (18.87)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Abdominal pain	10	6 (11.32)	2	2 (3.77)
Mouth haemorrhage	4	4 (7.55)	2	2 (3.77)
Stomatitis	3	3 (5.66)	1	1 (1.89)
Abdominal distension	2	2 (3.77)	0	0 (0.00)
Ascites	2	2 (3.77)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (3.77)	0	0 (0.00)
Pancreatitis	2	2 (3.77)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.89)	1	1 (1.89)
Abdominal pain upper	1	1 (1.89)	0	0 (0.00)
Abdominal rigidity	1	1 (1.89)	0	0 (0.00)
Anal fissure	1	1 (1.89)	0	0 (0.00)
Dry mouth	1	1 (1.89)	0	0 (0.00)
Dyspepsia	1	1 (1.89)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.89)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.89)	0	0 (0.00)
Gingival bleeding	1	1 (1.89)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.89)	1	1 (1.89)
Haematemesis	1	1 (1.89)	0	0 (0.00)
Ileus	1	1 (1.89)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Lip dry	1	1 (1.89)	0	0 (0.00)
Lip oedema	1	1 (1.89)	0	0 (0.00)
Mouth swelling	1	1 (1.89)	0	0 (0.00)
Neutropenic colitis	1	1 (1.89)	1	1 (1.89)
Odynophagia	1	1 (1.89)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.89)	0	0 (0.00)
Trichoglossia	1	1 (1.89)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.89)	0	0 (0.00)
General disorders and administration site conditions				
- Total	118	38 (71.70)	19	11 (20.75)
Pyrexia	52	25 (47.17)	9	8 (15.09)
Fatigue	14	12 (22.64)	0	0 (0.00)
Chills	10	7 (13.21)	0	0 (0.00)
Face oedema	6	5 (9.43)	1	1 (1.89)
Oedema peripheral	5	4 (7.55)	2	1 (1.89)
Pain	5	5 (9.43)	2	2 (3.77)
Catheter site pain	4	2 (3.77)	2	1 (1.89)
Generalised oedema	4	4 (7.55)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (3.77)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Influenza like illness	2	2 (3.77)	0	0 (0.00)
Malaise	2	2 (3.77)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (3.77)	2	2 (3.77)
Non-cardiac chest pain	2	2 (3.77)	0	0 (0.00)
Asthenia	1	1 (1.89)	0	0 (0.00)
Chest discomfort	1	1 (1.89)	1	1 (1.89)
Crying	1	1 (1.89)	0	0 (0.00)
Facial pain	1	1 (1.89)	0	0 (0.00)
Localised oedema	1	1 (1.89)	0	0 (0.00)
Sluggishness	1	1 (1.89)	0	0 (0.00)
Swelling face	1	1 (1.89)	0	0 (0.00)
Vascular device occlusion	1	1 (1.89)	0	0 (0.00)
Hepatobiliary disorders				
- Total	14	12 (22.64)	2	2 (3.77)
Hepatomegaly	3	3 (5.66)	1	1 (1.89)
Hyperbilirubinaemia	3	3 (5.66)	1	1 (1.89)
Hepatic function abnormal	2	2 (3.77)	0	0 (0.00)
Biliary tract disorder	1	1 (1.89)	0	0 (0.00)
Cholelithiasis	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Gallbladder enlargement	1	1 (1.89)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.89)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.89)	0	0 (0.00)
Ocular icterus	1	1 (1.89)	0	0 (0.00)
Immune system disorders				
- Total	124	47 (88.68)	44	27 (50.94)
Cytokine release syndrome	82	41 (77.36)	33	21 (39.62)
Hypogammaglobulinaemia	28	22 (41.51)	4	4 (7.55)
Seasonal allergy	3	3 (5.66)	0	0 (0.00)
Chronic graft versus host disease	2	2 (3.77)	1	1 (1.89)
Haemophagocytic lymphohistiocytosis	2	2 (3.77)	2	2 (3.77)
Immunodeficiency	2	2 (3.77)	2	2 (3.77)
Allergy to immunoglobulin therapy	1	1 (1.89)	1	1 (1.89)
Drug hypersensitivity	1	1 (1.89)	0	0 (0.00)
Graft versus host disease	1	1 (1.89)	1	1 (1.89)
Hypersensitivity	1	1 (1.89)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.89)	0	0 (0.00)
Infections and infestations				

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
- Total	168	39 (73.58)	74	23 (43.40)
Upper respiratory tract infection	13	11 (20.75)	2	2 (3.77)
Rhinovirus infection	8	6 (11.32)	2	2 (3.77)
Conjunctivitis	6	3 (5.66)	0	0 (0.00)
Parainfluenzae virus infection	6	5 (9.43)	3	3 (5.66)
Bronchopulmonary aspergillosis	5	1 (1.89)	3	1 (1.89)
Nasopharyngitis	5	4 (7.55)	0	0 (0.00)
Staphylococcal bacteraemia	5	4 (7.55)	5	4 (7.55)
Candida infection	4	3 (5.66)	2	1 (1.89)
Gastroenteritis	4	4 (7.55)	1	1 (1.89)
Oral candidiasis	4	3 (5.66)	0	0 (0.00)
Pneumonia	4	4 (7.55)	3	3 (5.66)
Sinusitis	4	4 (7.55)	1	1 (1.89)
Urinary tract infection	4	3 (5.66)	2	1 (1.89)
Bacteraemia	3	2 (3.77)	2	1 (1.89)
Fungal infection	3	2 (3.77)	0	0 (0.00)
Klebsiella infection	3	1 (1.89)	3	1 (1.89)
Oral herpes	3	2 (3.77)	1	1 (1.89)
Otitis media	3	3 (5.66)	1	1 (1.89)
Respiratory syncytial virus infection	3	3 (5.66)	2	2 (3.77)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Staphylococcal infection	3	3 (5.66)	1	1 (1.89)
Acute sinusitis	2	2 (3.77)	0	0 (0.00)
Adenovirus infection	2	2 (3.77)	2	2 (3.77)
Clostridium difficile infection	2	2 (3.77)	2	2 (3.77)
Ear infection	2	1 (1.89)	0	0 (0.00)
Gingivitis	2	2 (3.77)	0	0 (0.00)
Herpes simplex	2	2 (3.77)	1	1 (1.89)
Human herpesvirus 6 infection	2	2 (3.77)	2	2 (3.77)
Influenza	2	2 (3.77)	1	1 (1.89)
Metapneumovirus infection	2	2 (3.77)	2	2 (3.77)
Otitis externa	2	2 (3.77)	1	1 (1.89)
Rhinitis	2	2 (3.77)	0	0 (0.00)
Varicella zoster virus infection	2	2 (3.77)	1	1 (1.89)
Atypical pneumonia	1	1 (1.89)	0	0 (0.00)
BK virus infection	1	1 (1.89)	1	1 (1.89)
Bronchitis	1	1 (1.89)	0	0 (0.00)
COVID-19	1	1 (1.89)	0	0 (0.00)
COVID-19 pneumonia	1	1 (1.89)	1	1 (1.89)
Cellulitis	1	1 (1.89)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.89)	1	1 (1.89)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Cystitis	1	1 (1.89)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.89)	1	1 (1.89)
Ear, nose and throat infection	1	1 (1.89)	0	0 (0.00)
Encephalitis	1	1 (1.89)	1	1 (1.89)
Encephalitis viral	1	1 (1.89)	1	1 (1.89)
Enterobacter infection	1	1 (1.89)	1	1 (1.89)
Enterovirus infection	1	1 (1.89)	1	1 (1.89)
Fungal skin infection	1	1 (1.89)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.89)	1	1 (1.89)
Gastroenteritis clostridial	1	1 (1.89)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.89)	1	1 (1.89)
Gastrointestinal infection	1	1 (1.89)	0	0 (0.00)
Granulicatella infection	1	1 (1.89)	1	1 (1.89)
Herpes zoster	1	1 (1.89)	1	1 (1.89)
Klebsiella bacteraemia	1	1 (1.89)	0	0 (0.00)
Mastoiditis	1	1 (1.89)	1	1 (1.89)
Meningitis pneumococcal	1	1 (1.89)	1	1 (1.89)
Molluscum contagiosum	1	1 (1.89)	0	0 (0.00)
Nail infection	1	1 (1.89)	0	0 (0.00)
Neutropenic infection	1	1 (1.89)	1	1 (1.89)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Otitis media acute	1	1 (1.89)	0	0 (0.00)
Paronychia	1	1 (1.89)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.89)	1	1 (1.89)
Pneumocystis jirovecii pneumonia	1	1 (1.89)	1	1 (1.89)
Pneumonia fungal	1	1 (1.89)	1	1 (1.89)
Pneumonia viral	1	1 (1.89)	1	1 (1.89)
Respiratory tract infection	1	1 (1.89)	0	0 (0.00)
Respiratory tract infection viral	1	1 (1.89)	0	0 (0.00)
Sepsis	1	1 (1.89)	1	1 (1.89)
Septic shock	1	1 (1.89)	1	1 (1.89)
Sinusitis fungal	1	1 (1.89)	1	1 (1.89)
Skin infection	1	1 (1.89)	0	0 (0.00)
Soft tissue infection	1	1 (1.89)	1	1 (1.89)
Staphylococcal abscess	1	1 (1.89)	1	1 (1.89)
Staphylococcal skin infection	1	1 (1.89)	0	0 (0.00)
Stomatococcal infection	1	1 (1.89)	0	0 (0.00)
Syphilis	1	1 (1.89)	0	0 (0.00)
Systemic candida	1	1 (1.89)	1	1 (1.89)
Urinary tract infection pseudomonal	1	1 (1.89)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Viral haemorrhagic cystitis	1	1 (1.89)	1	1 (1.89)
Viral infection	1	1 (1.89)	1	1 (1.89)
Viral skin infection	1	1 (1.89)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.89)	1	1 (1.89)
Injury, poisoning and procedural complications				
- Total	18	13 (24.53)	1	1 (1.89)
Infusion related reaction	7	4 (7.55)	0	0 (0.00)
Transfusion reaction	2	2 (3.77)	0	0 (0.00)
Abdominal injury	1	1 (1.89)	0	0 (0.00)
Contusion	1	1 (1.89)	0	0 (0.00)
Fall	1	1 (1.89)	0	0 (0.00)
Fibula fracture	1	1 (1.89)	0	0 (0.00)
Ligament sprain	1	1 (1.89)	0	0 (0.00)
Limb injury	1	1 (1.89)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.89)	0	0 (0.00)
Skin abrasion	1	1 (1.89)	0	0 (0.00)
Transplant failure	1	1 (1.89)	1	1 (1.89)
Investigations				

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
- Total	341	41 (77.36)	166	33 (62.26)
Platelet count decreased	68	17 (32.08)	41	11 (20.75)
White blood cell count decreased	56	17 (32.08)	30	12 (22.64)
Neutrophil count decreased	46	17 (32.08)	30	15 (28.30)
Aspartate aminotransferase increased	27	14 (26.42)	12	10 (18.87)
Lymphocyte count decreased	25	11 (20.75)	20	11 (20.75)
Alanine aminotransferase increased	19	12 (22.64)	4	4 (7.55)
Blood bilirubin increased	18	9 (16.98)	7	7 (13.21)
Immunoglobulins decreased	9	1 (1.89)	0	0 (0.00)
International normalised ratio increased	8	7 (13.21)	0	0 (0.00)
Activated partial thromboplastin time prolonged	5	4 (7.55)	1	1 (1.89)
Blood immunoglobulin A decreased	5	5 (9.43)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (7.55)	1	1 (1.89)
C-reactive protein increased	4	4 (7.55)	3	3 (5.66)
Serum ferritin increased	4	4 (7.55)	2	2 (3.77)
Blood creatinine increased	3	3 (5.66)	2	2 (3.77)
Blood immunoglobulin G decreased	3	3 (5.66)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Blood lactate dehydrogenase increased	3	3 (5.66)	1	1 (1.89)
Electrocardiogram QT prolonged	3	2 (3.77)	1	1 (1.89)
Weight increased	3	3 (5.66)	1	1 (1.89)
Blood fibrinogen decreased	2	2 (3.77)	1	1 (1.89)
Blood glucose increased	2	1 (1.89)	2	1 (1.89)
Fibrin D dimer increased	2	2 (3.77)	1	1 (1.89)
Gamma-glutamyltransferase increased	2	2 (3.77)	2	2 (3.77)
Oxygen saturation decreased	2	2 (3.77)	1	1 (1.89)
Blood alkaline phosphatase increased	1	1 (1.89)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.89)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.89)	0	0 (0.00)
Blood uric acid increased	1	1 (1.89)	0	0 (0.00)
Bone density decreased	1	1 (1.89)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.89)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.89)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.89)	0	0 (0.00)
Enterovirus test positive	1	1 (1.89)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Heart sounds abnormal	1	1 (1.89)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.89)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.89)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.89)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.89)	0	0 (0.00)
Troponin increased	1	1 (1.89)	1	1 (1.89)
Urine output decreased	1	1 (1.89)	1	1 (1.89)
Weight decreased	1	1 (1.89)	1	1 (1.89)
Metabolism and nutrition disorders				
- Total	172	35 (66.04)	63	22 (41.51)
Hypokalaemia	26	10 (18.87)	12	5 (9.43)
Decreased appetite	24	22 (41.51)	11	9 (16.98)
Hypophosphataemia	22	11 (20.75)	8	6 (11.32)
Hypocalcaemia	16	12 (22.64)	3	3 (5.66)
Hypoalbuminaemia	15	8 (15.09)	1	1 (1.89)
Hyperglycaemia	12	9 (16.98)	5	5 (9.43)
Hyperuricaemia	9	6 (11.32)	1	1 (1.89)
Hypervolaemia	5	5 (9.43)	4	4 (7.55)
Hypercalcaemia	4	3 (5.66)	2	2 (3.77)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Hypomagnesaemia	4	4 (7.55)	0	0 (0.00)
Acidosis	3	2 (3.77)	2	2 (3.77)
Hyperkalaemia	3	3 (5.66)	2	2 (3.77)
Hypermagnesaemia	3	2 (3.77)	0	0 (0.00)
Hyperphosphataemia	3	3 (5.66)	1	1 (1.89)
Iron overload	3	2 (3.77)	0	0 (0.00)
Metabolic acidosis	3	3 (5.66)	2	2 (3.77)
Hypertriglyceridaemia	2	2 (3.77)	1	1 (1.89)
Hyponatraemia	2	2 (3.77)	0	0 (0.00)
Malnutrition	2	2 (3.77)	2	2 (3.77)
Tumour lysis syndrome	2	2 (3.77)	2	2 (3.77)
Calcium deficiency	1	1 (1.89)	0	0 (0.00)
Dehydration	1	1 (1.89)	0	0 (0.00)
Haemochromatosis	1	1 (1.89)	1	1 (1.89)
Hypercholesterolaemia	1	1 (1.89)	0	0 (0.00)
Hypernatraemia	1	1 (1.89)	1	1 (1.89)
Hypoglycaemia	1	1 (1.89)	0	0 (0.00)
Hypophagia	1	1 (1.89)	0	0 (0.00)
Obesity	1	1 (1.89)	1	1 (1.89)
Polydipsia	1	1 (1.89)	1	1 (1.89)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	64	31 (58.49)	8	7 (13.21)
Back pain	13	9 (16.98)	3	3 (5.66)
Pain in extremity	11	10 (18.87)	1	1 (1.89)
Arthralgia	10	8 (15.09)	1	1 (1.89)
Myalgia	9	8 (15.09)	0	0 (0.00)
Bone pain	6	4 (7.55)	0	0 (0.00)
Growth retardation	2	2 (3.77)	0	0 (0.00)
Muscular weakness	2	2 (3.77)	1	1 (1.89)
Neck pain	2	2 (3.77)	0	0 (0.00)
Pain in jaw	2	2 (3.77)	1	1 (1.89)
Haemarthrosis	1	1 (1.89)	1	1 (1.89)
Joint effusion	1	1 (1.89)	0	0 (0.00)
Muscle spasms	1	1 (1.89)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.89)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.89)	0	0 (0.00)
Osteopenia	1	1 (1.89)	0	0 (0.00)
Synovitis	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (9.43)	2	2 (3.77)
Bone giant cell tumour benign	2	1 (1.89)	1	1 (1.89)
Skin papilloma	2	2 (3.77)	0	0 (0.00)
Cancer pain	1	1 (1.89)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.89)	1	1 (1.89)
Nervous system disorders				
- Total	76	33 (62.26)	16	10 (18.87)
Headache	25	19 (35.85)	2	2 (3.77)
Cognitive disorder	5	3 (5.66)	1	1 (1.89)
Encephalopathy	5	5 (9.43)	2	2 (3.77)
Seizure	5	3 (5.66)	3	3 (5.66)
Somnolence	4	4 (7.55)	1	1 (1.89)
Tremor	4	3 (5.66)	0	0 (0.00)
Dizziness	3	2 (3.77)	0	0 (0.00)
Dysgeusia	3	3 (5.66)	0	0 (0.00)
Lethargy	3	3 (5.66)	0	0 (0.00)
Cerebral haemorrhage	2	2 (3.77)	2	2 (3.77)
Dysarthria	2	2 (3.77)	1	1 (1.89)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Hyperaesthesia	2	1 (1.89)	0	0 (0.00)
Migraine	2	1 (1.89)	0	0 (0.00)
Nervous system disorder	2	1 (1.89)	1	1 (1.89)
Amnesia	1	1 (1.89)	0	0 (0.00)
Aphasia	1	1 (1.89)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.89)	1	1 (1.89)
Depressed level of consciousness	1	1 (1.89)	1	1 (1.89)
Disturbance in attention	1	1 (1.89)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.89)	0	0 (0.00)
Memory impairment	1	1 (1.89)	0	0 (0.00)
Neurological decompensation	1	1 (1.89)	1	1 (1.89)
Paraesthesia	1	1 (1.89)	0	0 (0.00)
Psychiatric disorders				
- Total	46	27 (50.94)	5	5 (9.43)
Anxiety	11	11 (20.75)	1	1 (1.89)
Agitation	5	5 (9.43)	0	0 (0.00)
Confusional state	5	5 (9.43)	0	0 (0.00)
Delirium	5	5 (9.43)	3	3 (5.66)
Hallucination	3	3 (5.66)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Sleep disorder	3	2 (3.77)	0	0 (0.00)
Irritability	2	2 (3.77)	0	0 (0.00)
Mental status changes	2	2 (3.77)	1	1 (1.89)
Affect lability	1	1 (1.89)	0	0 (0.00)
Hallucination, visual	1	1 (1.89)	0	0 (0.00)
Insomnia	1	1 (1.89)	0	0 (0.00)
Mood altered	1	1 (1.89)	0	0 (0.00)
Nightmare	1	1 (1.89)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.89)	0	0 (0.00)
Restlessness	1	1 (1.89)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.89)	0	0 (0.00)
Tearfulness	1	1 (1.89)	0	0 (0.00)
Tic	1	1 (1.89)	0	0 (0.00)
Renal and urinary disorders				
- Total	27	14 (26.42)	9	7 (13.21)
Acute kidney injury	8	6 (11.32)	3	3 (5.66)
Dysuria	3	3 (5.66)	0	0 (0.00)
Renal failure	3	1 (1.89)	3	1 (1.89)
Haematuria	2	2 (3.77)	1	1 (1.89)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Urinary incontinence	2	1 (1.89)	0	0 (0.00)
Anuria	1	1 (1.89)	1	1 (1.89)
Incontinence	1	1 (1.89)	0	0 (0.00)
Kidney enlargement	1	1 (1.89)	0	0 (0.00)
Pollakiuria	1	1 (1.89)	0	0 (0.00)
Renal mass	1	1 (1.89)	0	0 (0.00)
Renal tubular disorder	1	1 (1.89)	1	1 (1.89)
Renal tubular dysfunction	1	1 (1.89)	0	0 (0.00)
Urinary retention	1	1 (1.89)	0	0 (0.00)
Urinary tract disorder	1	1 (1.89)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	4 (7.55)	1	1 (1.89)
Endometriosis	2	1 (1.89)	1	1 (1.89)
Vaginal haemorrhage	2	1 (1.89)	0	0 (0.00)
Female genital tract fistula	1	1 (1.89)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.89)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	116	36 (67.92)	38	20 (37.74)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Cough	21	16 (30.19)	0	0 (0.00)
Hypoxia	13	11 (20.75)	10	8 (15.09)
Nasal congestion	8	7 (13.21)	0	0 (0.00)
Pulmonary oedema	8	8 (15.09)	6	6 (11.32)
Tachypnoea	7	6 (11.32)	4	3 (5.66)
Dyspnoea	6	5 (9.43)	3	3 (5.66)
Respiratory failure	6	6 (11.32)	6	6 (11.32)
Epistaxis	5	4 (7.55)	1	1 (1.89)
Rhinorrhoea	5	4 (7.55)	0	0 (0.00)
Oropharyngeal pain	4	4 (7.55)	0	0 (0.00)
Pleural effusion	4	4 (7.55)	2	2 (3.77)
Respiratory distress	3	2 (3.77)	2	1 (1.89)
Lung infiltration	2	1 (1.89)	1	1 (1.89)
Pharyngeal erythema	2	2 (3.77)	0	0 (0.00)
Rhinitis allergic	2	2 (3.77)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.89)	1	1 (1.89)
Acute respiratory failure	1	1 (1.89)	1	1 (1.89)
Atelectasis	1	1 (1.89)	0	0 (0.00)
Bronchial oedema	1	1 (1.89)	0	0 (0.00)
Bronchospasm	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Dyspnoea exertional	1	1 (1.89)	0	0 (0.00)
Haemoptysis	1	1 (1.89)	0	0 (0.00)
Laryngeal oedema	1	1 (1.89)	1	1 (1.89)
Lung disorder	1	1 (1.89)	0	0 (0.00)
Nasal dryness	1	1 (1.89)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.89)	0	0 (0.00)
Painful respiration	1	1 (1.89)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.89)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.89)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.89)	0	0 (0.00)
Pulmonary mass	1	1 (1.89)	0	0 (0.00)
Respiratory disorder	1	1 (1.89)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.89)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.89)	0	0 (0.00)
Wheezing	1	1 (1.89)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	54	28 (52.83)	3	3 (5.66)
Dry skin	6	5 (9.43)	0	0 (0.00)
Pruritus	6	5 (9.43)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Rash	6	5 (9.43)	0	0 (0.00)
Dermatitis atopic	4	3 (5.66)	1	1 (1.89)
Erythema	4	4 (7.55)	0	0 (0.00)
Rash maculo-papular	4	3 (5.66)	1	1 (1.89)
Hyperhidrosis	3	3 (5.66)	0	0 (0.00)
Rash papular	3	2 (3.77)	0	0 (0.00)
Blister	2	2 (3.77)	0	0 (0.00)
Rash vesicular	2	1 (1.89)	0	0 (0.00)
Decubitus ulcer	1	1 (1.89)	1	1 (1.89)
Dermatitis	1	1 (1.89)	0	0 (0.00)
Dermatitis allergic	1	1 (1.89)	0	0 (0.00)
Eczema	1	1 (1.89)	0	0 (0.00)
Ingrowing nail	1	1 (1.89)	0	0 (0.00)
Miliaria	1	1 (1.89)	0	0 (0.00)
Night sweats	1	1 (1.89)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.89)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.89)	0	0 (0.00)
Purpura	1	1 (1.89)	0	0 (0.00)
Scab	1	1 (1.89)	0	0 (0.00)

Timing: At anytime, Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All grades Total events	All patients N=53 n (%)[1]	Grade >= 3 Total events	All patients N=53 n (%)[2]
Skin discolouration	1	1 (1.89)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.89)	0	0 (0.00)
Skin lesion	1	1 (1.89)	0	0 (0.00)
Social circumstances				
- Total	1	1 (1.89)	0	0 (0.00)
Patient uncooperative	1	1 (1.89)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.89)	1	1 (1.89)
Thrombolysis	1	1 (1.89)	1	1 (1.89)
Vascular disorders				
- Total	32	22 (41.51)	14	13 (24.53)
Hypotension	18	16 (30.19)	10	10 (18.87)
Hypertension	10	10 (18.87)	3	3 (5.66)
Capillary leak syndrome	1	1 (1.89)	1	1 (1.89)
Flushing	1	1 (1.89)	0	0 (0.00)
Hot flush	1	1 (1.89)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.89)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

/vob/CCTL019/haq/haq_eu_7/pgm/saf/t250_gd_b2202.sas@@/main/1 15AUG23:06:00 **Final**

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	359	27 (96.43)	120	22 (78.57)
Blood and lymphatic system disorders				
- Total	31	15 (53.57)	22	11 (39.29)
Anaemia	10	5 (17.86)	8	4 (14.29)
Febrile neutropenia	6	6 (21.43)	6	6 (21.43)
Neutropenia	3	3 (10.71)	2	2 (7.14)
Coagulopathy	2	2 (7.14)	1	1 (3.57)
Disseminated intravascular coagulation	2	2 (7.14)	0	0 (0.00)
Eosinophilia	2	1 (3.57)	0	0 (0.00)
Pancytopenia	2	2 (7.14)	2	2 (7.14)
Thrombocytopenia	2	2 (7.14)	2	2 (7.14)
Leukopenia	1	1 (3.57)	1	1 (3.57)

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Splenomegaly	1	1 (3.57)	0	0 (0.00)
Cardiac disorders				
- Total	3	2 (7.14)	0	0 (0.00)
Sinus tachycardia	2	1 (3.57)	0	0 (0.00)
Pericardial effusion	1	1 (3.57)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (7.14)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.57)	0	0 (0.00)
Hypothyroidism	1	1 (3.57)	0	0 (0.00)
Eye disorders				
- Total	7	3 (10.71)	0	0 (0.00)
Eyelid oedema	2	1 (3.57)	0	0 (0.00)
Retinal haemorrhage	2	1 (3.57)	0	0 (0.00)
Eye oedema	1	1 (3.57)	0	0 (0.00)
Eye pain	1	1 (3.57)	0	0 (0.00)
Visual field defect	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	38	16 (57.14)	2	2 (7.14)
Vomiting	11	7 (25.00)	0	0 (0.00)
Abdominal pain	6	5 (17.86)	0	0 (0.00)
Diarrhoea	6	5 (17.86)	0	0 (0.00)
Nausea	6	4 (14.29)	1	1 (3.57)
Constipation	3	3 (10.71)	0	0 (0.00)
Abdominal pain upper	2	2 (7.14)	0	0 (0.00)
Ascites	1	1 (3.57)	0	0 (0.00)
Mouth swelling	1	1 (3.57)	0	0 (0.00)
Odynophagia	1	1 (3.57)	0	0 (0.00)
Stomatitis	1	1 (3.57)	1	1 (3.57)
General disorders and administration site conditions				
- Total	21	11 (39.29)	3	1 (3.57)
Pyrexia	6	5 (17.86)	0	0 (0.00)
Face oedema	4	3 (10.71)	1	1 (3.57)
Oedema peripheral	3	2 (7.14)	2	1 (3.57)
Asthenia	2	2 (7.14)	0	0 (0.00)
Catheter site erythema	2	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Fatigue	1	1 (3.57)	0	0 (0.00)
Generalised oedema	1	1 (3.57)	0	0 (0.00)
Influenza like illness	1	1 (3.57)	0	0 (0.00)
Localised oedema	1	1 (3.57)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (10.71)	0	0 (0.00)
Cholelithiasis	1	1 (3.57)	0	0 (0.00)
Hepatomegaly	1	1 (3.57)	0	0 (0.00)
Hyperbilirubinaemia	1	1 (3.57)	0	0 (0.00)
Immune system disorders				
- Total	53	21 (75.00)	24	16 (57.14)
Cytokine release syndrome	38	19 (67.86)	17	13 (46.43)
Hypogammaglobulinaemia	10	10 (35.71)	4	4 (14.29)
Immunodeficiency	3	3 (10.71)	3	3 (10.71)
Haemophagocytic lymphohistiocytosis	1	1 (3.57)	0	0 (0.00)
Hypersensitivity	1	1 (3.57)	0	0 (0.00)
Infections and infestations				

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	17	12 (42.86)	6	5 (17.86)
Conjunctivitis	4	3 (10.71)	0	0 (0.00)
Nail infection	2	2 (7.14)	0	0 (0.00)
Oral infection	2	2 (7.14)	0	0 (0.00)
Staphylococcal infection	2	2 (7.14)	1	1 (3.57)
Adenovirus infection	1	1 (3.57)	1	1 (3.57)
Bronchopulmonary aspergillosis	1	1 (3.57)	1	1 (3.57)
Encephalitis viral	1	1 (3.57)	1	1 (3.57)
Gingivitis	1	1 (3.57)	0	0 (0.00)
Myringitis	1	1 (3.57)	0	0 (0.00)
Pneumonia fungal	1	1 (3.57)	1	1 (3.57)
Pneumonia viral	1	1 (3.57)	1	1 (3.57)
Injury, poisoning and procedural complications				
- Total	4	3 (10.71)	0	0 (0.00)
Infusion related reaction	2	1 (3.57)	0	0 (0.00)
Fall	1	1 (3.57)	0	0 (0.00)
Procedural pain	1	1 (3.57)	0	0 (0.00)
Investigations				

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	67	16 (57.14)	42	11 (39.29)
Lymphocyte count decreased	18	7 (25.00)	15	6 (21.43)
White blood cell count decreased	15	6 (21.43)	10	5 (17.86)
Neutrophil count decreased	8	6 (21.43)	7	5 (17.86)
Alanine aminotransferase increased	6	2 (7.14)	2	2 (7.14)
Platelet count decreased	6	5 (17.86)	3	3 (10.71)
Immunoglobulins decreased	5	2 (7.14)	0	0 (0.00)
Aspartate aminotransferase increased	2	1 (3.57)	1	1 (3.57)
Blood bilirubin increased	1	1 (3.57)	1	1 (3.57)
Blood fibrinogen decreased	1	1 (3.57)	1	1 (3.57)
Blood lactate dehydrogenase increased	1	1 (3.57)	0	0 (0.00)
C-reactive protein increased	1	1 (3.57)	1	1 (3.57)
Gamma-glutamyltransferase increased	1	1 (3.57)	1	1 (3.57)
Prothrombin time prolonged	1	1 (3.57)	0	0 (0.00)
Serum ferritin increased	1	1 (3.57)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	24	10 (35.71)	11	5 (17.86)

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hypokalaemia	5	5 (17.86)	3	3 (10.71)
Hypophosphataemia	5	3 (10.71)	5	3 (10.71)
Decreased appetite	4	4 (14.29)	1	1 (3.57)
Hypomagnesaemia	4	3 (10.71)	0	0 (0.00)
Hyperglycaemia	2	2 (7.14)	1	1 (3.57)
Hypernatraemia	1	1 (3.57)	0	0 (0.00)
Hyperuricaemia	1	1 (3.57)	0	0 (0.00)
Hypoalbuminaemia	1	1 (3.57)	0	0 (0.00)
Hypocalcaemia	1	1 (3.57)	1	1 (3.57)
Musculoskeletal and connective tissue disorders				
- Total	16	11 (39.29)	1	1 (3.57)
Arthralgia	4	4 (14.29)	0	0 (0.00)
Back pain	4	4 (14.29)	1	1 (3.57)
Pain in extremity	4	4 (14.29)	0	0 (0.00)
Muscular weakness	1	1 (3.57)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.57)	0	0 (0.00)
Myalgia	1	1 (3.57)	0	0 (0.00)
Pain in jaw	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Nervous system disorders				
- Total	21	14 (50.00)	2	2 (7.14)
Headache	9	9 (32.14)	0	0 (0.00)
Encephalopathy	3	3 (10.71)	1	1 (3.57)
Tremor	3	2 (7.14)	0	0 (0.00)
Hyperaesthesia	2	1 (3.57)	0	0 (0.00)
Amnesia	1	1 (3.57)	0	0 (0.00)
Dysgeusia	1	1 (3.57)	0	0 (0.00)
Neuralgia	1	1 (3.57)	0	0 (0.00)
Seizure	1	1 (3.57)	1	1 (3.57)
Psychiatric disorders				
- Total	11	9 (32.14)	1	1 (3.57)
Anxiety	2	2 (7.14)	1	1 (3.57)
Confusional state	2	2 (7.14)	0	0 (0.00)
Hallucination	2	2 (7.14)	0	0 (0.00)
Insomnia	2	2 (7.14)	0	0 (0.00)
Sleep disorder	2	1 (3.57)	0	0 (0.00)
Hallucination, visual	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Renal and urinary disorders				
- Total	5	5 (17.86)	1	1 (3.57)
Dysuria	2	2 (7.14)	0	0 (0.00)
Anuria	1	1 (3.57)	1	1 (3.57)
Renal failure	1	1 (3.57)	0	0 (0.00)
Urinary tract disorder	1	1 (3.57)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.57)	0	0 (0.00)
Female genital tract fistula	1	1 (3.57)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	17	9 (32.14)	3	3 (10.71)
Cough	4	4 (14.29)	0	0 (0.00)
Pulmonary oedema	4	4 (14.29)	3	3 (10.71)
Hypoxia	3	3 (10.71)	0	0 (0.00)
Oropharyngeal pain	3	2 (7.14)	0	0 (0.00)
Painful respiration	1	1 (3.57)	0	0 (0.00)
Productive cough	1	1 (3.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Europe				
Primary system organ class Preferred term	**All grades Total events**	**All patients N=28 n (%)[1]**	**Grade >= 3 Total events**	**All patients N=28 n (%)[2]**
Respiratory disorder	1	1 (3.57)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	13	7 (25.00)	0	0 (0.00)
Pruritus	3	2 (7.14)	0	0 (0.00)
Dermatitis atopic	2	2 (7.14)	0	0 (0.00)
Rash	2	2 (7.14)	0	0 (0.00)
Rash vesicular	2	1 (3.57)	0	0 (0.00)
Erythema	1	1 (3.57)	0	0 (0.00)
Pruritus allergic	1	1 (3.57)	0	0 (0.00)
Rash maculo-papular	1	1 (3.57)	0	0 (0.00)
Urticaria	1	1 (3.57)	0	0 (0.00)
Vascular disorders				
- Total	5	5 (17.86)	2	2 (7.14)
Hypotension	3	3 (10.71)	1	1 (3.57)
Hypertension	2	2 (7.14)	1	1 (3.57)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse

events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Total number of AE per patient	1283	45 (100.00)	448	38 (84.44)
Blood and lymphatic system disorders				
- Total	81	29 (64.44)	46	24 (53.33)
Anaemia	39	15 (33.33)	12	4 (8.89)
Febrile neutropenia	23	20 (44.44)	23	20 (44.44)
Thrombocytopenia	5	5 (11.11)	5	5 (11.11)
Coagulopathy	3	3 (6.67)	1	1 (2.22)
Disseminated intravascular coagulation	3	3 (6.67)	2	2 (4.44)
Neutropenia	3	3 (6.67)	2	2 (4.44)
Splenomegaly	3	3 (6.67)	0	0 (0.00)
Leukopenia	1	1 (2.22)	0	0 (0.00)
Lymphopenia	1	1 (2.22)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Cardiac disorders				
- Total	40	20 (44.44)	10	8 (17.78)
Tachycardia	22	17 (37.78)	3	3 (6.67)
Cardiac failure	4	1 (2.22)	2	1 (2.22)
Bradycardia	3	3 (6.67)	0	0 (0.00)
Left ventricular dysfunction	3	3 (6.67)	3	3 (6.67)
Sinus tachycardia	2	2 (4.44)	0	0 (0.00)
Atrioventricular block first degree	1	1 (2.22)	0	0 (0.00)
Cardiac arrest	1	1 (2.22)	1	1 (2.22)
Cardiac failure congestive	1	1 (2.22)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.22)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.22)	0	0 (0.00)
Sinus bradycardia	1	1 (2.22)	1	1 (2.22)
Ear and labyrinth disorders				
- Total	2	2 (4.44)	0	0 (0.00)
Ear pain	1	1 (2.22)	0	0 (0.00)
Ear pruritus	1	1 (2.22)	0	0 (0.00)
Endocrine disorders				

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
- Total	3	3 (6.67)	0	0 (0.00)
Adrenal insufficiency	3	3 (6.67)	0	0 (0.00)
Eye disorders				
- Total	8	6 (13.33)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (4.44)	0	0 (0.00)
Ocular hyperaemia	2	2 (4.44)	0	0 (0.00)
Eyelid oedema	1	1 (2.22)	0	0 (0.00)
Periorbital oedema	1	1 (2.22)	0	0 (0.00)
Periorbital swelling	1	1 (2.22)	0	0 (0.00)
Visual impairment	1	1 (2.22)	0	0 (0.00)
Gastrointestinal disorders				
- Total	89	29 (64.44)	14	12 (26.67)
Vomiting	19	14 (31.11)	1	1 (2.22)
Nausea	13	12 (26.67)	1	1 (2.22)
Diarrhoea	11	9 (20.00)	1	1 (2.22)
Constipation	7	7 (15.56)	0	0 (0.00)
Abdominal pain	6	5 (11.11)	2	2 (4.44)
Mouth haemorrhage	4	4 (8.89)	2	2 (4.44)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Abdominal distension	3	3 (6.67)	0	0 (0.00)
Ascites	2	2 (4.44)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.44)	0	0 (0.00)
Pancreatitis	2	2 (4.44)	1	1 (2.22)
Abdominal compartment syndrome	1	1 (2.22)	1	1 (2.22)
Abdominal pain upper	1	1 (2.22)	0	0 (0.00)
Anal fissure	1	1 (2.22)	0	0 (0.00)
Anal haemorrhage	1	1 (2.22)	0	0 (0.00)
Dry mouth	1	1 (2.22)	0	0 (0.00)
Dysphagia	1	1 (2.22)	1	1 (2.22)
Gastrooesophageal reflux disease	1	1 (2.22)	0	0 (0.00)
Gingival bleeding	1	1 (2.22)	0	0 (0.00)
Gingival erythema	1	1 (2.22)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.22)	1	1 (2.22)
Haematemesis	1	1 (2.22)	0	0 (0.00)
Ileus	1	1 (2.22)	0	0 (0.00)
Lip dry	1	1 (2.22)	0	0 (0.00)
Lip oedema	1	1 (2.22)	0	0 (0.00)
Melaena	1	1 (2.22)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Neutropenic colitis	1	1 (2.22)	1	1 (2.22)
Proctalgia	1	1 (2.22)	1	1 (2.22)
Stomatitis	1	1 (2.22)	0	0 (0.00)
Trichoglossia	1	1 (2.22)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.22)	0	0 (0.00)
General disorders and administration site conditions				
- Total	88	28 (62.22)	16	10 (22.22)
Pyrexia	37	18 (40.00)	9	8 (17.78)
Fatigue	10	10 (22.22)	0	0 (0.00)
Chills	9	6 (13.33)	0	0 (0.00)
Catheter site pain	4	2 (4.44)	2	1 (2.22)
Face oedema	4	4 (8.89)	0	0 (0.00)
Generalised oedema	4	4 (8.89)	0	0 (0.00)
Oedema peripheral	4	4 (8.89)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (4.44)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (4.44)	2	2 (4.44)
Catheter site haemorrhage	1	1 (2.22)	0	0 (0.00)
Chest discomfort	1	1 (2.22)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Crying	1	1 (2.22)	0	0 (0.00)
Facial pain	1	1 (2.22)	0	0 (0.00)
Localised oedema	1	1 (2.22)	0	0 (0.00)
Malaise	1	1 (2.22)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.22)	0	0 (0.00)
Pain	1	1 (2.22)	1	1 (2.22)
Sluggishness	1	1 (2.22)	0	0 (0.00)
Swelling face	1	1 (2.22)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (2.22)	1	1 (2.22)
Vascular device occlusion	1	1 (2.22)	0	0 (0.00)
Hepatobiliary disorders				
- Total	16	10 (22.22)	3	3 (6.67)
Hyperbilirubinaemia	5	4 (8.89)	1	1 (2.22)
Gallbladder enlargement	2	2 (4.44)	0	0 (0.00)
Hepatomegaly	2	2 (4.44)	1	1 (2.22)
Hypertransaminasaemia	2	2 (4.44)	0	0 (0.00)
Biliary tract disorder	1	1 (2.22)	0	0 (0.00)
Cholelithiasis	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Cholestasis	1	1 (2.22)	1	1 (2.22)
Hepatic function abnormal	1	1 (2.22)	0	0 (0.00)
Ocular icterus	1	1 (2.22)	0	0 (0.00)
Immune system disorders				
- Total	97	39 (86.67)	38	22 (48.89)
Cytokine release syndrome	78	36 (80.00)	32	20 (44.44)
Hypogammaglobulinaemia	13	11 (24.44)	3	3 (6.67)
Haemophagocytic lymphohistiocytosis	4	4 (8.89)	3	3 (6.67)
Seasonal allergy	1	1 (2.22)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (2.22)	0	0 (0.00)
Infections and infestations				
- Total	40	18 (40.00)	21	12 (26.67)
Candida infection	4	3 (6.67)	2	1 (2.22)
Clostridium difficile infection	4	4 (8.89)	3	3 (6.67)
Staphylococcal bacteraemia	4	3 (6.67)	4	3 (6.67)
Staphylococcal infection	3	3 (6.67)	1	1 (2.22)
Conjunctivitis	2	2 (4.44)	0	0 (0.00)
Oral candidiasis	2	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Oral herpes	2	2 (4.44)	1	1 (2.22)
Rhinovirus infection	2	2 (4.44)	0	0 (0.00)
Anal abscess	1	1 (2.22)	1	1 (2.22)
Atypical pneumonia	1	1 (2.22)	0	0 (0.00)
Cholecystitis infective	1	1 (2.22)	0	0 (0.00)
Encephalitis	1	1 (2.22)	1	1 (2.22)
Gastroenteritis norovirus	1	1 (2.22)	0	0 (0.00)
Granulicatella infection	1	1 (2.22)	1	1 (2.22)
Herpes simplex	1	1 (2.22)	1	1 (2.22)
Human herpesvirus 6 infection	1	1 (2.22)	1	1 (2.22)
Klebsiella bacteraemia	1	1 (2.22)	0	0 (0.00)
Klebsiella infection	1	1 (2.22)	1	1 (2.22)
Localised infection	1	1 (2.22)	0	0 (0.00)
Paronychia	1	1 (2.22)	0	0 (0.00)
Sinusitis	1	1 (2.22)	1	1 (2.22)
Soft tissue infection	1	1 (2.22)	1	1 (2.22)
Stomatococcal infection	1	1 (2.22)	0	0 (0.00)
Systemic candida	1	1 (2.22)	1	1 (2.22)
Varicella zoster virus infection	1	1 (2.22)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Injury, poisoning and procedural complications				
- Total	16	8 (17.78)	3	2 (4.44)
Wound	3	2 (4.44)	1	1 (2.22)
Contusion	2	1 (2.22)	0	0 (0.00)
Transfusion reaction	2	2 (4.44)	0	0 (0.00)
Fall	1	1 (2.22)	0	0 (0.00)
Infusion related reaction	1	1 (2.22)	0	0 (0.00)
Procedural pain	1	1 (2.22)	0	0 (0.00)
Scratch	1	1 (2.22)	0	0 (0.00)
Skin abrasion	1	1 (2.22)	0	0 (0.00)
Skin injury	1	1 (2.22)	0	0 (0.00)
Skin wound	1	1 (2.22)	0	0 (0.00)
Transplant failure	1	1 (2.22)	1	1 (2.22)
Vasoplegia syndrome	1	1 (2.22)	1	1 (2.22)
Investigations				
- Total	295	36 (80.00)	138	29 (64.44)
Platelet count decreased	57	14 (31.11)	33	9 (20.00)
Neutrophil count decreased	35	11 (24.44)	26	9 (20.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Aspartate aminotransferase increased	31	18 (40.00)	12	10 (22.22)
White blood cell count decreased	26	14 (31.11)	17	9 (20.00)
Alanine aminotransferase increased	20	16 (35.56)	4	4 (8.89)
Blood bilirubin increased	17	11 (24.44)	8	8 (17.78)
International normalised ratio increased	12	9 (20.00)	0	0 (0.00)
Lymphocyte count decreased	12	8 (17.78)	9	7 (15.56)
Activated partial thromboplastin time prolonged	8	6 (13.33)	1	1 (2.22)
Blood creatinine increased	6	4 (8.89)	5	3 (6.67)
Blood immunoglobulin M decreased	6	6 (13.33)	1	1 (2.22)
Electrocardiogram QT prolonged	6	5 (11.11)	2	2 (4.44)
Blood immunoglobulin A decreased	5	5 (11.11)	0	0 (0.00)
Blood fibrinogen decreased	4	4 (8.89)	1	1 (2.22)
Lipase increased	4	2 (4.44)	2	1 (2.22)
Serum ferritin increased	4	4 (8.89)	2	2 (4.44)
Weight increased	4	4 (8.89)	1	1 (2.22)
Blood lactate dehydrogenase increased	3	3 (6.67)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
C-reactive protein increased	3	3 (6.67)	2	2 (4.44)
Fibrin D dimer increased	3	3 (6.67)	1	1 (2.22)
Urine output decreased	3	2 (4.44)	3	2 (4.44)
Blood glucose increased	2	1 (2.22)	2	1 (2.22)
Blood immunoglobulin G decreased	2	2 (4.44)	0	0 (0.00)
Blood uric acid increased	2	2 (4.44)	0	0 (0.00)
Haemoglobin decreased	2	1 (2.22)	1	1 (2.22)
Amylase increased	1	1 (2.22)	0	0 (0.00)
Bacterial test positive	1	1 (2.22)	1	1 (2.22)
Blood alkaline phosphatase increased	1	1 (2.22)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.22)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.22)	1	1 (2.22)
Blood phosphorus increased	1	1 (2.22)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.22)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.22)	0	0 (0.00)
Cardiac murmur	1	1 (2.22)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.22)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Enterovirus test positive	1	1 (2.22)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (2.22)	1	1 (2.22)
Haptoglobin decreased	1	1 (2.22)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.22)	0	0 (0.00)
Staphylococcus test positive	1	1 (2.22)	0	0 (0.00)
Troponin increased	1	1 (2.22)	1	1 (2.22)
Weight decreased	1	1 (2.22)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	183	34 (75.56)	63	22 (48.89)
Hypokalaemia	35	14 (31.11)	17	8 (17.78)
Hypophosphataemia	26	14 (31.11)	6	6 (13.33)
Hypocalcaemia	23	15 (33.33)	5	4 (8.89)
Decreased appetite	20	20 (44.44)	10	10 (22.22)
Hypoalbuminaemia	17	9 (20.00)	1	1 (2.22)
Hyperglycaemia	9	6 (13.33)	3	3 (6.67)
Hyperuricaemia	8	6 (13.33)	1	1 (2.22)
Hypervolaemia	6	6 (13.33)	4	4 (8.89)
Hyperphosphataemia	5	5 (11.11)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hypercalcaemia	4	3 (6.67)	2	2 (4.44)
Acidosis	3	2 (4.44)	2	2 (4.44)
Hypermagnesaemia	3	2 (4.44)	0	0 (0.00)
Hypomagnesaemia	3	3 (6.67)	0	0 (0.00)
Hyponatraemia	3	3 (6.67)	0	0 (0.00)
Metabolic acidosis	3	3 (6.67)	2	2 (4.44)
Hyperkalaemia	2	2 (4.44)	2	2 (4.44)
Hypertriglyceridaemia	2	2 (4.44)	2	2 (4.44)
Tumour lysis syndrome	2	2 (4.44)	2	2 (4.44)
Calcium deficiency	1	1 (2.22)	0	0 (0.00)
Dehydration	1	1 (2.22)	0	0 (0.00)
Haemosiderosis	1	1 (2.22)	0	0 (0.00)
Hyperchloraemia	1	1 (2.22)	0	0 (0.00)
Hyperlactacidaemia	1	1 (2.22)	0	0 (0.00)
Hypernatraemia	1	1 (2.22)	1	1 (2.22)
Hypoglycaemia	1	1 (2.22)	0	0 (0.00)
Malnutrition	1	1 (2.22)	1	1 (2.22)
Polydipsia	1	1 (2.22)	1	1 (2.22)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	36	21 (46.67)	5	4 (8.89)
Myalgia	9	8 (17.78)	0	0 (0.00)
Arthralgia	6	6 (13.33)	1	1 (2.22)
Pain in extremity	6	6 (13.33)	0	0 (0.00)
Bone pain	4	2 (4.44)	0	0 (0.00)
Back pain	3	2 (4.44)	0	0 (0.00)
Haemarthrosis	1	1 (2.22)	1	1 (2.22)
Muscle rigidity	1	1 (2.22)	0	0 (0.00)
Muscle spasms	1	1 (2.22)	0	0 (0.00)
Muscular weakness	1	1 (2.22)	1	1 (2.22)
Myositis	1	1 (2.22)	0	0 (0.00)
Neck pain	1	1 (2.22)	0	0 (0.00)
Pain in jaw	1	1 (2.22)	1	1 (2.22)
Rhabdomyolysis	1	1 (2.22)	1	1 (2.22)
Nervous system disorders				
- Total	53	24 (53.33)	12	8 (17.78)
Headache	16	13 (28.89)	2	2 (4.44)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Cognitive disorder	5	3 (6.67)	1	1 (2.22)
Encephalopathy	5	5 (11.11)	3	3 (6.67)
Somnolence	5	5 (11.11)	2	2 (4.44)
Tremor	4	4 (8.89)	0	0 (0.00)
Dizziness	3	3 (6.67)	0	0 (0.00)
Lethargy	3	3 (6.67)	0	0 (0.00)
Dysgeusia	2	2 (4.44)	0	0 (0.00)
Aphasia	1	1 (2.22)	0	0 (0.00)
Cerebral haemorrhage	1	1 (2.22)	1	1 (2.22)
Depressed level of consciousness	1	1 (2.22)	1	1 (2.22)
Disturbance in attention	1	1 (2.22)	0	0 (0.00)
Dysarthria	1	1 (2.22)	1	1 (2.22)
Generalised tonic-clonic seizure	1	1 (2.22)	0	0 (0.00)
Hypoaesthesia	1	1 (2.22)	0	0 (0.00)
Monoparesis	1	1 (2.22)	0	0 (0.00)
Neurological decompensation	1	1 (2.22)	1	1 (2.22)
Paraesthesia	1	1 (2.22)	0	0 (0.00)
Psychiatric disorders				
- Total	36	19 (42.22)	5	5 (11.11)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Delirium	7	7 (15.56)	3	3 (6.67)
Agitation	6	5 (11.11)	0	0 (0.00)
Confusional state	5	5 (11.11)	0	0 (0.00)
Anxiety	4	4 (8.89)	1	1 (2.22)
Irritability	3	3 (6.67)	0	0 (0.00)
Mental status changes	3	3 (6.67)	1	1 (2.22)
Insomnia	2	2 (4.44)	0	0 (0.00)
Affect lability	1	1 (2.22)	0	0 (0.00)
Automatism	1	1 (2.22)	0	0 (0.00)
Hallucination	1	1 (2.22)	0	0 (0.00)
Restlessness	1	1 (2.22)	0	0 (0.00)
Sleep disorder	1	1 (2.22)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.22)	0	0 (0.00)
Renal and urinary disorders				
- Total	29	12 (26.67)	9	6 (13.33)
Acute kidney injury	11	7 (15.56)	5	5 (11.11)
Renal failure	3	1 (2.22)	3	1 (2.22)
Pollakiuria	2	2 (4.44)	0	0 (0.00)
Urinary incontinence	2	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Urinary retention	2	2 (4.44)	0	0 (0.00)
Anuria	1	1 (2.22)	0	0 (0.00)
Azotaemia	1	1 (2.22)	0	0 (0.00)
Bladder dilatation	1	1 (2.22)	0	0 (0.00)
Dysuria	1	1 (2.22)	0	0 (0.00)
Haematuria	1	1 (2.22)	0	0 (0.00)
Incontinence	1	1 (2.22)	0	0 (0.00)
Micturition urgency	1	1 (2.22)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.22)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.22)	1	1 (2.22)
Reproductive system and breast disorders				
- Total	4	3 (6.67)	1	1 (2.22)
Vaginal haemorrhage	2	1 (2.22)	0	0 (0.00)
Perineal rash	1	1 (2.22)	0	0 (0.00)
Vaginal ulceration	1	1 (2.22)	1	1 (2.22)
Respiratory, thoracic and mediastinal disorders				
- Total	87	27 (60.00)	40	17 (37.78)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hypoxia	13	11 (24.44)	11	9 (20.00)
Tachypnoea	9	8 (17.78)	4	4 (8.89)
Pulmonary oedema	8	8 (17.78)	4	4 (8.89)
Cough	7	6 (13.33)	0	0 (0.00)
Pleural effusion	6	6 (13.33)	3	3 (6.67)
Atelectasis	5	3 (6.67)	2	2 (4.44)
Respiratory distress	4	3 (6.67)	2	1 (2.22)
Respiratory failure	4	4 (8.89)	4	4 (8.89)
Dyspnoea	3	3 (6.67)	3	3 (6.67)
Epistaxis	3	3 (6.67)	1	1 (2.22)
Nasal congestion	3	3 (6.67)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (4.44)	2	2 (4.44)
Lung infiltration	2	1 (2.22)	1	1 (2.22)
Oropharyngeal pain	2	2 (4.44)	0	0 (0.00)
Rhinorrhoea	2	2 (4.44)	0	0 (0.00)
Acute respiratory failure	1	1 (2.22)	1	1 (2.22)
Bradypnoea	1	1 (2.22)	1	1 (2.22)
Haemoptysis	1	1 (2.22)	0	0 (0.00)
Nasal discomfort	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Nasal dryness	1	1 (2.22)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.22)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.22)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.22)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.22)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.22)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.22)	0	0 (0.00)
Pulmonary mass	1	1 (2.22)	0	0 (0.00)
Respiratory acidosis	1	1 (2.22)	1	1 (2.22)
Wheezing	1	1 (2.22)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	39	16 (35.56)	4	3 (6.67)
Blister	6	3 (6.67)	0	0 (0.00)
Rash papular	4	3 (6.67)	0	0 (0.00)
Erythema	3	3 (6.67)	0	0 (0.00)
Hyperhidrosis	3	3 (6.67)	0	0 (0.00)
Pruritus	3	3 (6.67)	0	0 (0.00)
Rash	3	3 (6.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Petechiae	2	2 (4.44)	1	1 (2.22)
Rash maculo-papular	2	1 (2.22)	1	1 (2.22)
Decubitus ulcer	1	1 (2.22)	0	0 (0.00)
Dermatitis	1	1 (2.22)	0	0 (0.00)
Dermatitis diaper	1	1 (2.22)	0	0 (0.00)
Dry skin	1	1 (2.22)	0	0 (0.00)
Eczema	1	1 (2.22)	0	0 (0.00)
Purpura	1	1 (2.22)	0	0 (0.00)
Rash pruritic	1	1 (2.22)	0	0 (0.00)
Scab	1	1 (2.22)	0	0 (0.00)
Skin discolouration	1	1 (2.22)	0	0 (0.00)
Skin lesion	1	1 (2.22)	0	0 (0.00)
Skin necrosis	1	1 (2.22)	1	1 (2.22)
Skin ulcer	1	1 (2.22)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.22)	1	1 (2.22)
Social circumstances				
- Total	1	1 (2.22)	0	0 (0.00)
Patient uncooperative	1	1 (2.22)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (2.22)	1	1 (2.22)
Thrombolysis	1	1 (2.22)	1	1 (2.22)
Vascular disorders				
- Total	39	22 (48.89)	19	15 (33.33)
Hypotension	22	18 (40.00)	15	13 (28.89)
Hypertension	11	10 (22.22)	3	3 (6.67)
Capillary leak syndrome	2	2 (4.44)	1	1 (2.22)
Flushing	1	1 (2.22)	0	0 (0.00)
Hot flush	1	1 (2.22)	0	0 (0.00)
Peripheral ischaemia	1	1 (2.22)	0	0 (0.00)
Thrombosis	1	1 (2.22)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	109	7 (100.00)	51	7 (100.00)
Blood and lymphatic system disorders				
- Total	13	6 (85.71)	8	4 (57.14)
Neutropenia	5	3 (42.86)	5	3 (42.86)
Disseminated intravascular coagulation	2	2 (28.57)	0	0 (0.00)
Leukopenia	2	1 (14.29)	2	1 (14.29)
Anaemia	1	1 (14.29)	0	0 (0.00)
B-cell aplasia	1	1 (14.29)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (14.29)	0	0 (0.00)
Thrombocytopenia	1	1 (14.29)	1	1 (14.29)
Cardiac disorders				
- Total	2	2 (28.57)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Cardiac dysfunction	2	2 (28.57)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	6 (85.71)	0	0 (0.00)
Nausea	2	2 (28.57)	0	0 (0.00)
Pancreatitis	2	2 (28.57)	0	0 (0.00)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)
Diarrhoea	1	1 (14.29)	0	0 (0.00)
Enterocolitis	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	1 (14.29)	0	0 (0.00)
Face oedema	1	1 (14.29)	0	0 (0.00)
Influenza like illness	1	1 (14.29)	0	0 (0.00)
Pyrexia	1	1 (14.29)	0	0 (0.00)
Hepatobiliary disorders				
- Total	10	4 (57.14)	4	3 (42.86)
Hepatic function abnormal	10	4 (57.14)	4	3 (42.86)

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Immune system disorders				
- Total	14	7 (100.00)	6	5 (71.43)
Cytokine release syndrome	12	6 (85.71)	6	5 (71.43)
Hypogammaglobulinaemia	2	2 (28.57)	0	0 (0.00)
Infections and infestations				
- Total	7	5 (71.43)	4	2 (28.57)
BK virus infection	1	1 (14.29)	0	0 (0.00)
Bacteraemia	1	1 (14.29)	1	1 (14.29)
Encephalitis viral	1	1 (14.29)	1	1 (14.29)
Meningitis bacterial	1	1 (14.29)	1	1 (14.29)
Otitis externa	1	1 (14.29)	0	0 (0.00)
Pneumonia	1	1 (14.29)	1	1 (14.29)
Urinary tract infection viral	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	24	5 (71.43)	17	5 (71.43)
White blood cell count decreased	9	4 (57.14)	9	4 (57.14)
Neutrophil count decreased	5	3 (42.86)	5	3 (42.86)
Blood creatine phosphokinase increased	3	1 (14.29)	1	1 (14.29)

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Serum ferritin increased	3	3 (42.86)	0	0 (0.00)
Blood fibrinogen decreased	2	2 (28.57)	0	0 (0.00)
Platelet count decreased	2	2 (28.57)	2	2 (28.57)
Metabolism and nutrition disorders				
- Total	3	2 (28.57)	2	2 (28.57)
Tumour lysis syndrome	2	2 (28.57)	2	2 (28.57)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Pain in extremity	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	3	2 (28.57)	0	0 (0.00)
Seizure	2	1 (14.29)	0	0 (0.00)
Headache	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	3 (42.86)	3	2 (28.57)
Acute kidney injury	3	2 (28.57)	3	2 (28.57)

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Haematuria	1	1 (14.29)	0	0 (0.00)
Proteinuria	1	1 (14.29)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (14.29)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	5 (71.43)	7	3 (42.86)
Hypoxia	7	3 (42.86)	7	3 (42.86)
Epistaxis	1	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	4 (57.14)	0	0 (0.00)
Erythema nodosum	1	1 (14.29)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (14.29)	0	0 (0.00)
Pruritus	1	1 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Skin ulcer	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Hypertension	1	1 (14.29)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	159	28 (100.00)	46	14 (50.00)
Blood and lymphatic system disorders				
- Total	10	7 (25.00)	5	4 (14.29)
Anaemia	3	2 (7.14)	0	0 (0.00)
Neutropenia	2	2 (7.14)	2	2 (7.14)
Disseminated intravascular coagulation	1	1 (3.57)	1	1 (3.57)
Eosinophilia	1	1 (3.57)	0	0 (0.00)
Febrile neutropenia	1	1 (3.57)	1	1 (3.57)
Lymphadenopathy	1	1 (3.57)	0	0 (0.00)
Thrombocytopenia	1	1 (3.57)	1	1 (3.57)
Cardiac disorders				
- Total	1	1 (3.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Left ventricular dysfunction	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				
- Total	15	7 (25.00)	1	1 (3.57)
Constipation	3	2 (7.14)	0	0 (0.00)
Vomiting	3	2 (7.14)	0	0 (0.00)
Pancreatitis	2	2 (7.14)	1	1 (3.57)
Abdominal pain upper	1	1 (3.57)	0	0 (0.00)
Abdominal rigidity	1	1 (3.57)	0	0 (0.00)
Diarrhoea	1	1 (3.57)	0	0 (0.00)
Dyspepsia	1	1 (3.57)	0	0 (0.00)
Mouth haemorrhage	1	1 (3.57)	0	0 (0.00)
Nausea	1	1 (3.57)	0	0 (0.00)
Peritoneal haematoma	1	1 (3.57)	0	0 (0.00)
General disorders and administration site conditions				
- Total	7	5 (17.86)	0	0 (0.00)
Pyrexia	5	4 (14.29)	0	0 (0.00)
Asthenia	1	1 (3.57)	0	0 (0.00)
Non-cardiac chest pain	1	1 (3.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hepatobiliary disorders				
- Total	2	2 (7.14)	0	0 (0.00)
Hepatic cytolysis	1	1 (3.57)	0	0 (0.00)
Liver disorder	1	1 (3.57)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (10.71)	2	2 (7.14)
Allergy to immunoglobulin therapy	1	1 (3.57)	0	0 (0.00)
Graft versus host disease	1	1 (3.57)	1	1 (3.57)
Immunodeficiency	1	1 (3.57)	1	1 (3.57)
Infections and infestations				
- Total	52	20 (71.43)	18	9 (32.14)
Nasopharyngitis	7	6 (21.43)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (3.57)	3	1 (3.57)
Gastroenteritis	3	3 (10.71)	2	2 (7.14)
Respiratory tract infection	3	3 (10.71)	0	0 (0.00)
Bacteraemia	2	1 (3.57)	2	1 (3.57)
Ear infection	2	1 (3.57)	0	0 (0.00)
Pneumonia	2	2 (7.14)	1	1 (3.57)
Rhinitis	2	2 (7.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Sinusitis	2	1 (3.57)	1	1 (3.57)
Upper respiratory tract infection	2	2 (7.14)	0	0 (0.00)
Urinary tract infection	2	1 (3.57)	2	1 (3.57)
Conjunctivitis	1	1 (3.57)	0	0 (0.00)
Cystitis	1	1 (3.57)	0	0 (0.00)
Device related infection	1	1 (3.57)	1	1 (3.57)
Ear, nose and throat infection	1	1 (3.57)	0	0 (0.00)
Encephalitis	1	1 (3.57)	1	1 (3.57)
Herpes zoster	1	1 (3.57)	1	1 (3.57)
Molluscum contagiosum	1	1 (3.57)	0	0 (0.00)
Nail infection	1	1 (3.57)	0	0 (0.00)
Oral candidiasis	1	1 (3.57)	0	0 (0.00)
Otitis media	1	1 (3.57)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.57)	0	0 (0.00)
Paronychia	1	1 (3.57)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (3.57)	1	1 (3.57)
Respiratory tract infection viral	1	1 (3.57)	0	0 (0.00)
Rhinovirus infection	1	1 (3.57)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (3.57)	1	1 (3.57)
Staphylococcal sepsis	1	1 (3.57)	1	1 (3.57)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Staphylococcal skin infection	1	1 (3.57)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (3.57)	1	1 (3.57)
Viral infection	1	1 (3.57)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	1 (3.57)	0	0 (0.00)
Infusion related reaction	2	1 (3.57)	0	0 (0.00)
Investigations				
- Total	21	8 (28.57)	6	4 (14.29)
Immunoglobulins decreased	5	1 (3.57)	0	0 (0.00)
White blood cell count decreased	5	3 (10.71)	1	1 (3.57)
Neutrophil count decreased	4	2 (7.14)	3	2 (7.14)
Platelet count decreased	3	2 (7.14)	0	0 (0.00)
Blood uric acid increased	1	1 (3.57)	1	1 (3.57)
Bone density decreased	1	1 (3.57)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (3.57)	0	0 (0.00)
Weight decreased	1	1 (3.57)	1	1 (3.57)
Metabolism and nutrition disorders				
- Total	4	2 (7.14)	3	2 (7.14)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Decreased appetite	1	1 (3.57)	1	1 (3.57)
Haemochromatosis	1	1 (3.57)	1	1 (3.57)
Hypophosphataemia	1	1 (3.57)	0	0 (0.00)
Malnutrition	1	1 (3.57)	1	1 (3.57)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (7.14)	0	0 (0.00)
Back pain	2	2 (7.14)	0	0 (0.00)
Arthralgia	1	1 (3.57)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (10.71)	1	1 (3.57)
Skin papilloma	2	2 (7.14)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.57)	1	1 (3.57)
Nervous system disorders				
- Total	10	4 (14.29)	6	2 (7.14)
Headache	3	2 (7.14)	0	0 (0.00)
Hydrocephalus	3	1 (3.57)	3	1 (3.57)
Autonomic neuropathy	1	1 (3.57)	1	1 (3.57)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Cerebral haemorrhage	1	1 (3.57)	1	1 (3.57)
Memory impairment	1	1 (3.57)	0	0 (0.00)
Seizure	1	1 (3.57)	1	1 (3.57)
Psychiatric disorders				
- Total	3	3 (10.71)	0	0 (0.00)
Anxiety	2	2 (7.14)	0	0 (0.00)
Sleep disorder	1	1 (3.57)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (3.57)	1	1 (3.57)
Renal tubular disorder	1	1 (3.57)	1	1 (3.57)
Respiratory, thoracic and mediastinal disorders				
- Total	10	8 (28.57)	1	1 (3.57)
Cough	6	4 (14.29)	0	0 (0.00)
Bronchial oedema	1	1 (3.57)	0	0 (0.00)
Bronchospasm	1	1 (3.57)	0	0 (0.00)
Lung disorder	1	1 (3.57)	0	0 (0.00)
Respiratory failure	1	1 (3.57)	1	1 (3.57)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	10	7 (25.00)	1	1 (3.57)
Rash	3	1 (3.57)	0	0 (0.00)
Decubitus ulcer	1	1 (3.57)	1	1 (3.57)
Dermatitis allergic	1	1 (3.57)	0	0 (0.00)
Dermatitis atopic	1	1 (3.57)	0	0 (0.00)
Dry skin	1	1 (3.57)	0	0 (0.00)
Erythema	1	1 (3.57)	0	0 (0.00)
Hangnail	1	1 (3.57)	0	0 (0.00)
Photosensitivity reaction	1	1 (3.57)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (7.14)	1	1 (3.57)
Hypotension	1	1 (3.57)	0	0 (0.00)
Venoocclusive disease	1	1 (3.57)	1	1 (3.57)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	343	35 (87.50)	87	17 (42.50)
Blood and lymphatic system disorders				
- Total	16	6 (15.00)	9	3 (7.50)
Anaemia	8	3 (7.50)	4	2 (5.00)
Febrile neutropenia	3	2 (5.00)	3	2 (5.00)
Leukocytosis	1	1 (2.50)	0	0 (0.00)
Leukopenia	1	1 (2.50)	0	0 (0.00)
Lymphocytosis	1	1 (2.50)	0	0 (0.00)
Lymphopenia	1	1 (2.50)	1	1 (2.50)
Thrombocytopenia	1	1 (2.50)	1	1 (2.50)
Cardiac disorders				
- Total	6	5 (12.50)	3	2 (5.00)
Cardiac arrest	2	2 (5.00)	2	2 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Tachycardia	2	2 (5.00)	0	0 (0.00)
Cardiac failure	1	1 (2.50)	1	1 (2.50)
Tricuspid valve incompetence	1	1 (2.50)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.50)	0	0 (0.00)
Hypothyroidism	1	1 (2.50)	0	0 (0.00)
Eye disorders				
- Total	5	4 (10.00)	0	0 (0.00)
Cataract	2	2 (5.00)	0	0 (0.00)
Hypermetropia	1	1 (2.50)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.50)	0	0 (0.00)
Visual impairment	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	19	10 (25.00)	0	0 (0.00)
Diarrhoea	6	6 (15.00)	0	0 (0.00)
Nausea	4	4 (10.00)	0	0 (0.00)
Vomiting	4	4 (10.00)	0	0 (0.00)
Abdominal pain	2	2 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Gastrointestinal haemorrhage	1	1 (2.50)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.50)	0	0 (0.00)
Proctalgia	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	23	18 (45.00)	3	3 (7.50)
Pyrexia	10	10 (25.00)	2	2 (5.00)
Fatigue	7	6 (15.00)	0	0 (0.00)
Oedema peripheral	2	1 (2.50)	0	0 (0.00)
Pain	2	2 (5.00)	1	1 (2.50)
Chills	1	1 (2.50)	0	0 (0.00)
Malaise	1	1 (2.50)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (2.50)	0	0 (0.00)
Hypertransaminasaemia	1	1 (2.50)	0	0 (0.00)
Immune system disorders				
- Total	14	11 (27.50)	3	2 (5.00)
Hypogammaglobulinaemia	10	8 (20.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (2.50)	1	1 (2.50)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Drug hypersensitivity	1	1 (2.50)	0	0 (0.00)
Engraftment syndrome	1	1 (2.50)	1	1 (2.50)
Graft versus host disease	1	1 (2.50)	1	1 (2.50)
Infections and infestations				
- Total	54	17 (42.50)	23	10 (25.00)
Upper respiratory tract infection	6	5 (12.50)	1	1 (2.50)
Metapneumovirus infection	3	3 (7.50)	3	3 (7.50)
Parainfluenzae virus infection	3	2 (5.00)	1	1 (2.50)
Rhinovirus infection	3	3 (7.50)	0	0 (0.00)
Gastroenteritis	2	2 (5.00)	0	0 (0.00)
Klebsiella infection	2	1 (2.50)	2	1 (2.50)
Otitis externa	2	2 (5.00)	1	1 (2.50)
Otitis media	2	2 (5.00)	1	1 (2.50)
Respiratory syncytial virus infection	2	2 (5.00)	1	1 (2.50)
Sinusitis	2	2 (5.00)	0	0 (0.00)
Acute sinusitis	1	1 (2.50)	0	0 (0.00)
Adenovirus infection	1	1 (2.50)	1	1 (2.50)
BK virus infection	1	1 (2.50)	1	1 (2.50)
Bacteraemia	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Cellulitis	1	1 (2.50)	0	0 (0.00)
Coronavirus infection	1	1 (2.50)	1	1 (2.50)
Cytomegalovirus infection reactivation	1	1 (2.50)	1	1 (2.50)
Ear infection	1	1 (2.50)	0	0 (0.00)
Enterobacter infection	1	1 (2.50)	1	1 (2.50)
Gastroenteritis clostridial	1	1 (2.50)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.50)	0	0 (0.00)
Gastrointestinal infection	1	1 (2.50)	0	0 (0.00)
Gingivitis	1	1 (2.50)	0	0 (0.00)
Herpes simplex	1	1 (2.50)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.50)	1	1 (2.50)
Influenza	1	1 (2.50)	0	0 (0.00)
Mastoiditis	1	1 (2.50)	1	1 (2.50)
Oral herpes	1	1 (2.50)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (2.50)	1	1 (2.50)
Pneumocystis jirovecii pneumonia	1	1 (2.50)	1	1 (2.50)
Pneumonia	1	1 (2.50)	0	0 (0.00)
Salmonellosis	1	1 (2.50)	0	0 (0.00)
Septic shock	1	1 (2.50)	1	1 (2.50)
Sinusitis fungal	1	1 (2.50)	1	1 (2.50)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Tinea pedis	1	1 (2.50)	0	0 (0.00)
Viral infection	1	1 (2.50)	1	1 (2.50)
Viral upper respiratory tract infection	1	1 (2.50)	1	1 (2.50)
Injury, poisoning and procedural complications				
- Total	8	8 (20.00)	0	0 (0.00)
Infusion related reaction	2	2 (5.00)	0	0 (0.00)
Contusion	1	1 (2.50)	0	0 (0.00)
Fibula fracture	1	1 (2.50)	0	0 (0.00)
Ligament sprain	1	1 (2.50)	0	0 (0.00)
Limb injury	1	1 (2.50)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.50)	0	0 (0.00)
Skin abrasion	1	1 (2.50)	0	0 (0.00)
Investigations				
- Total	67	20 (50.00)	26	10 (25.00)
Neutrophil count decreased	13	7 (17.50)	6	4 (10.00)
Platelet count decreased	13	3 (7.50)	9	2 (5.00)
White blood cell count decreased	12	6 (15.00)	2	2 (5.00)
Lymphocyte count decreased	6	4 (10.00)	2	2 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood bilirubin increased	4	2 (5.00)	1	1 (2.50)
Alanine aminotransferase increased	3	2 (5.00)	1	1 (2.50)
Weight increased	3	1 (2.50)	1	1 (2.50)
Blood immunoglobulin A decreased	2	2 (5.00)	1	1 (2.50)
Blood creatinine increased	1	1 (2.50)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.50)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.50)	1	1 (2.50)
Blood lactate dehydrogenase increased	1	1 (2.50)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (2.50)	0	0 (0.00)
Blood urea increased	1	1 (2.50)	1	1 (2.50)
Blood uric acid increased	1	1 (2.50)	1	1 (2.50)
C-reactive protein increased	1	1 (2.50)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.50)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.50)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.50)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	21	12 (30.00)	6	4 (10.00)
Hypokalaemia	6	3 (7.50)	4	2 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Decreased appetite	5	5 (12.50)	0	0 (0.00)
Hyperuricaemia	3	3 (7.50)	0	0 (0.00)
Hyperchloraemia	1	1 (2.50)	0	0 (0.00)
Hyperkalaemia	1	1 (2.50)	0	0 (0.00)
Hypervolaemia	1	1 (2.50)	1	1 (2.50)
Hypophagia	1	1 (2.50)	0	0 (0.00)
Iron overload	1	1 (2.50)	0	0 (0.00)
Metabolic syndrome	1	1 (2.50)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				
- Total	19	13 (32.50)	3	3 (7.50)
Back pain	5	4 (10.00)	2	2 (5.00)
Pain in extremity	5	5 (12.50)	1	1 (2.50)
Arthralgia	2	2 (5.00)	0	0 (0.00)
Bone pain	2	2 (5.00)	0	0 (0.00)
Growth retardation	1	1 (2.50)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.50)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.50)	0	0 (0.00)
Myalgia	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Neck pain	1	1 (2.50)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.50)	0	0 (0.00)
Cancer pain	1	1 (2.50)	0	0 (0.00)
Nervous system disorders				
- Total	12	9 (22.50)	0	0 (0.00)
Headache	7	7 (17.50)	0	0 (0.00)
Dizziness	2	1 (2.50)	0	0 (0.00)
Migraine	2	1 (2.50)	0	0 (0.00)
Extrapyramidal disorder	1	1 (2.50)	0	0 (0.00)
Psychiatric disorders				
- Total	12	7 (17.50)	1	1 (2.50)
Anxiety	4	4 (10.00)	0	0 (0.00)
Mental status changes	2	2 (5.00)	1	1 (2.50)
Agitation	1	1 (2.50)	0	0 (0.00)
Delirium	1	1 (2.50)	0	0 (0.00)
Mood altered	1	1 (2.50)	0	0 (0.00)
Nightmare	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Persistent depressive disorder	1	1 (2.50)	0	0 (0.00)
Tearfulness	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	3 (7.50)	2	2 (5.00)
Acute kidney injury	3	3 (7.50)	1	1 (2.50)
Dysuria	1	1 (2.50)	0	0 (0.00)
Haematuria	1	1 (2.50)	1	1 (2.50)
Kidney enlargement	1	1 (2.50)	0	0 (0.00)
Renal mass	1	1 (2.50)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.50)	0	0 (0.00)
Dysmenorrhoea	2	1 (2.50)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	34	14 (35.00)	5	5 (12.50)
Cough	8	7 (17.50)	0	0 (0.00)
Nasal congestion	7	6 (15.00)	0	0 (0.00)
Epistaxis	3	3 (7.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypoxia	3	3 (7.50)	3	3 (7.50)
Rhinorrhoea	3	3 (7.50)	0	0 (0.00)
Dyspnoea	2	1 (2.50)	0	0 (0.00)
Oropharyngeal pain	2	2 (5.00)	0	0 (0.00)
Rhinitis allergic	2	2 (5.00)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (2.50)	1	1 (2.50)
Paranasal sinus inflammation	1	1 (2.50)	0	0 (0.00)
Pleural effusion	1	1 (2.50)	0	0 (0.00)
Respiratory distress	1	1 (2.50)	1	1 (2.50)
Skin and subcutaneous tissue disorders				
- Total	17	11 (27.50)	0	0 (0.00)
Dry skin	5	4 (10.00)	0	0 (0.00)
Rash	3	3 (7.50)	0	0 (0.00)
Ingrowing nail	2	2 (5.00)	0	0 (0.00)
Pruritus	2	1 (2.50)	0	0 (0.00)
Eczema	1	1 (2.50)	0	0 (0.00)
Miliaria	1	1 (2.50)	0	0 (0.00)
Night sweats	1	1 (2.50)	0	0 (0.00)
Skin discolouration	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Skin hypopigmentation	1	1 (2.50)	0	0 (0.00)
Vascular disorders				
- Total	4	3 (7.50)	3	3 (7.50)
Hypotension	2	2 (5.00)	2	2 (5.00)
Hypertension	1	1 (2.50)	0	0 (0.00)
Venoocclusive disease	1	1 (2.50)	1	1 (2.50)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	32	6 (85.71)	13	5 (71.43)
Blood and lymphatic system disorders				
- Total	6	4 (57.14)	3	3 (42.86)
Neutropenia	3	3 (42.86)	3	3 (42.86)
B-cell aplasia	2	1 (14.29)	0	0 (0.00)
Anaemia	1	1 (14.29)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Cardiac failure	1	1 (14.29)	1	1 (14.29)
Gastrointestinal disorders				
- Total	4	3 (42.86)	0	0 (0.00)
Constipation	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Enteritis	1	1 (14.29)	0	0 (0.00)
Stomatitis	1	1 (14.29)	0	0 (0.00)
Trichoglossia	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (14.29)	0	0 (0.00)
Pyrexia	1	1 (14.29)	0	0 (0.00)
Immune system disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Hypogammaglobulinaemia	2	2 (28.57)	0	0 (0.00)
Infections and infestations				
- Total	7	2 (28.57)	4	1 (14.29)
Nasopharyngitis	2	1 (14.29)	0	0 (0.00)
Upper respiratory tract infection	2	1 (14.29)	1	1 (14.29)
Parainfluenzae virus infection	1	1 (14.29)	1	1 (14.29)
Respiratory syncytial virus infection	1	1 (14.29)	1	1 (14.29)
Rhinovirus infection	1	1 (14.29)	1	1 (14.29)
Investigations				

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
- Total	3	2 (28.57)	3	2 (28.57)
Neutrophil count decreased	2	1 (14.29)	2	1 (14.29)
White blood cell count decreased	1	1 (14.29)	1	1 (14.29)
Metabolism and nutrition disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Metabolic acidosis	1	1 (14.29)	1	1 (14.29)
Nervous system disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Headache	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (14.29)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Pleural effusion	1	1 (14.29)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (14.29)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	2	2 (28.57)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)
Skin swelling	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (14.29)	1	1 (14.29)
Hypotension	1	1 (14.29)	1	1 (14.29)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Total number of AE per patient	84	14 (63.64)	36	9 (40.91)
Blood and lymphatic system disorders				
- Total	6	4 (18.18)	2	2 (9.09)
Agranulocytosis	1	1 (4.55)	1	1 (4.55)
Anaemia	1	1 (4.55)	0	0 (0.00)
Hypercoagulation	1	1 (4.55)	0	0 (0.00)
Lymphadenopathy	1	1 (4.55)	0	0 (0.00)
Neutropenia	1	1 (4.55)	1	1 (4.55)
Thrombocytopenia	1	1 (4.55)	0	0 (0.00)
Eye disorders				
- Total	2	1 (4.55)	1	1 (4.55)
Eye pain	1	1 (4.55)	1	1 (4.55)

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Eyelid oedema	1	1 (4.55)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	3 (13.64)	1	1 (4.55)
Diarrhoea	3	3 (13.64)	1	1 (4.55)
General disorders and administration site conditions				
- Total	4	3 (13.64)	2	2 (9.09)
Pyrexia	3	3 (13.64)	1	1 (4.55)
Multiple organ dysfunction syndrome	1	1 (4.55)	1	1 (4.55)
Immune system disorders				
- Total	4	3 (13.64)	3	2 (9.09)
Chronic graft versus host disease	2	2 (9.09)	1	1 (4.55)
Drug hypersensitivity	1	1 (4.55)	1	1 (4.55)
Haemophagocytic lymphohistiocytosis	1	1 (4.55)	1	1 (4.55)
Infections and infestations				
- Total	32	11 (50.00)	14	7 (31.82)
Conjunctivitis	3	3 (13.64)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Sepsis	3	3 (13.64)	3	3 (13.64)
COVID-19	2	1 (4.55)	1	1 (4.55)
Device related sepsis	2	1 (4.55)	2	1 (4.55)
Fungal infection	2	1 (4.55)	0	0 (0.00)
Bronchitis	1	1 (4.55)	0	0 (0.00)
COVID-19 pneumonia	1	1 (4.55)	1	1 (4.55)
Candida infection	1	1 (4.55)	0	0 (0.00)
Enterovirus infection	1	1 (4.55)	1	1 (4.55)
Gastroenteritis	1	1 (4.55)	0	0 (0.00)
Herpes virus infection	1	1 (4.55)	0	0 (0.00)
Herpes zoster	1	1 (4.55)	1	1 (4.55)
Influenza	1	1 (4.55)	1	1 (4.55)
Neutropenic infection	1	1 (4.55)	1	1 (4.55)
Ophthalmic herpes zoster	1	1 (4.55)	0	0 (0.00)
Oral herpes	1	1 (4.55)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (4.55)	1	1 (4.55)
Pneumonia	1	1 (4.55)	1	1 (4.55)
Rhinitis	1	1 (4.55)	0	0 (0.00)
Rhinovirus infection	1	1 (4.55)	1	1 (4.55)

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Sinusitis	1	1 (4.55)	0	0 (0.00)
Skin infection	1	1 (4.55)	0	0 (0.00)
Streptococcal sepsis	1	1 (4.55)	0	0 (0.00)
Upper respiratory tract infection	1	1 (4.55)	0	0 (0.00)
Viral skin infection	1	1 (4.55)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (4.55)	0	0 (0.00)
Ligament sprain	1	1 (4.55)	0	0 (0.00)
Investigations				
- Total	4	3 (13.64)	1	1 (4.55)
Blood immunoglobulin G decreased	1	1 (4.55)	0	0 (0.00)
Oxygen saturation decreased	1	1 (4.55)	1	1 (4.55)
Platelet count decreased	1	1 (4.55)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (4.55)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (9.09)	3	2 (9.09)
Decreased appetite	2	1 (4.55)	2	1 (4.55)

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Hyperglycaemia	1	1 (4.55)	1	1 (4.55)
Musculoskeletal and connective tissue disorders				
- Total	4	4 (18.18)	0	0 (0.00)
Pain in extremity	2	2 (9.09)	0	0 (0.00)
Growth retardation	1	1 (4.55)	0	0 (0.00)
Osteonecrosis	1	1 (4.55)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (4.55)	1	1 (4.55)
Bone giant cell tumour benign	2	1 (4.55)	1	1 (4.55)
Nervous system disorders				
- Total	3	2 (9.09)	1	1 (4.55)
Headache	2	1 (4.55)	1	1 (4.55)
Dysarthria	1	1 (4.55)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	4 (18.18)	3	1 (4.55)

Timing: >1 year post-CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Cough	2	2 (9.09)	0	0 (0.00)
Tachypnoea	2	1 (4.55)	2	1 (4.55)
Dyspnoea	1	1 (4.55)	1	1 (4.55)
Dyspnoea exertional	1	1 (4.55)	0	0 (0.00)
Epistaxis	1	1 (4.55)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.55)	0	0 (0.00)
Pharyngeal erythema	1	1 (4.55)	0	0 (0.00)
Pleural effusion	1	1 (4.55)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	4 (18.18)	3	2 (9.09)
Rash macular	2	1 (4.55)	2	1 (4.55)
Dermatitis atopic	1	1 (4.55)	1	1 (4.55)
Dry skin	1	1 (4.55)	0	0 (0.00)
Papule	1	1 (4.55)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (4.55)	1	1 (4.55)
Hypertension	1	1 (4.55)	1	1 (4.55)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Total number of AE per patient	117	16 (69.57)	21	8 (34.78)
Congenital, familial and genetic disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (4.35)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Deafness unilateral	1	1 (4.35)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (4.35)	0	0 (0.00)
Delayed puberty	1	1 (4.35)	0	0 (0.00)
Hypothyroidism	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Eye disorders				
- Total	2	2 (8.70)	0	0 (0.00)
Dry eye	1	1 (4.35)	0	0 (0.00)
Mydriasis	1	1 (4.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	4 (17.39)	0	0 (0.00)
Diarrhoea	2	2 (8.70)	0	0 (0.00)
Constipation	1	1 (4.35)	0	0 (0.00)
Irritable bowel syndrome	1	1 (4.35)	0	0 (0.00)
Nausea	1	1 (4.35)	0	0 (0.00)
Vomiting	1	1 (4.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	5 (21.74)	0	0 (0.00)
Fatigue	1	1 (4.35)	0	0 (0.00)
Non-cardiac chest pain	1	1 (4.35)	0	0 (0.00)
Pain	1	1 (4.35)	0	0 (0.00)
Pyrexia	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Xerosis	1	1 (4.35)	0	0 (0.00)
Immune system disorders				
- Total	6	6 (26.09)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (13.04)	0	0 (0.00)
Seasonal allergy	3	3 (13.04)	0	0 (0.00)
Infections and infestations				
- Total	46	10 (43.48)	11	6 (26.09)
Sinusitis	7	4 (17.39)	0	0 (0.00)
Upper respiratory tract infection	3	3 (13.04)	0	0 (0.00)
Conjunctivitis	2	1 (4.35)	0	0 (0.00)
Gastroenteritis viral	2	1 (4.35)	0	0 (0.00)
Rhinovirus infection	2	2 (8.70)	0	0 (0.00)
Skin infection	2	2 (8.70)	0	0 (0.00)
Acute sinusitis	1	1 (4.35)	0	0 (0.00)
Bronchiolitis	1	1 (4.35)	1	1 (4.35)
Bronchitis	1	1 (4.35)	0	0 (0.00)
COVID-19	1	1 (4.35)	0	0 (0.00)
Clostridium difficile colitis	1	1 (4.35)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Ear infection	1	1 (4.35)	1	1 (4.35)
Folliculitis	1	1 (4.35)	0	0 (0.00)
Fungal infection	1	1 (4.35)	0	0 (0.00)
Fungal skin infection	1	1 (4.35)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (4.35)	1	1 (4.35)
Gastroenteritis salmonella	1	1 (4.35)	1	1 (4.35)
Herpes zoster	1	1 (4.35)	0	0 (0.00)
Influenza	1	1 (4.35)	0	0 (0.00)
Meningitis pneumococcal	1	1 (4.35)	1	1 (4.35)
Nail infection	1	1 (4.35)	0	0 (0.00)
Oral candidiasis	1	1 (4.35)	0	0 (0.00)
Oral herpes	1	1 (4.35)	0	0 (0.00)
Otitis media	1	1 (4.35)	0	0 (0.00)
Otitis media acute	1	1 (4.35)	0	0 (0.00)
Pneumonia	1	1 (4.35)	1	1 (4.35)
Pneumonia respiratory syncytial viral	1	1 (4.35)	1	1 (4.35)
Septic shock	1	1 (4.35)	1	1 (4.35)
Staphylococcal abscess	1	1 (4.35)	1	1 (4.35)
Staphylococcal bacteraemia	1	1 (4.35)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Syphilis	1	1 (4.35)	0	0 (0.00)
Urinary tract infection	1	1 (4.35)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (4.35)	0	0 (0.00)
Varicella zoster virus infection	1	1 (4.35)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (8.70)	1	1 (4.35)
Abdominal injury	1	1 (4.35)	0	0 (0.00)
Infusion related reaction	1	1 (4.35)	1	1 (4.35)
Investigations				
- Total	6	2 (8.70)	0	0 (0.00)
Blood bilirubin increased	3	1 (4.35)	0	0 (0.00)
Neutrophil count decreased	2	2 (8.70)	0	0 (0.00)
Platelet count decreased	1	1 (4.35)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	7	4 (17.39)	2	2 (8.70)
Iron overload	2	1 (4.35)	0	0 (0.00)
Hypercholesterolaemia	1	1 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Hyperlipidaemia	1	1 (4.35)	0	0 (0.00)
Hypernatraemia	1	1 (4.35)	1	1 (4.35)
Hypertriglyceridaemia	1	1 (4.35)	0	0 (0.00)
Obesity	1	1 (4.35)	1	1 (4.35)
Musculoskeletal and connective tissue disorders				
- Total	4	3 (13.04)	0	0 (0.00)
Arthralgia	1	1 (4.35)	0	0 (0.00)
Joint effusion	1	1 (4.35)	0	0 (0.00)
Osteopenia	1	1 (4.35)	0	0 (0.00)
Synovitis	1	1 (4.35)	0	0 (0.00)
Nervous system disorders				
- Total	6	2 (8.70)	2	1 (4.35)
Seizure	3	1 (4.35)	1	1 (4.35)
Nervous system disorder	2	1 (4.35)	1	1 (4.35)
Headache	1	1 (4.35)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (8.70)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Anxiety	1	1 (4.35)	0	0 (0.00)
Tic	1	1 (4.35)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (4.35)	1	1 (4.35)
Endometriosis	2	1 (4.35)	1	1 (4.35)
Respiratory, thoracic and mediastinal disorders				
- Total	13	6 (26.09)	3	3 (13.04)
Rhinorrhoea	3	3 (13.04)	0	0 (0.00)
Cough	2	2 (8.70)	0	0 (0.00)
Dyspnoea	2	2 (8.70)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (8.70)	0	0 (0.00)
Hypoxia	1	1 (4.35)	1	1 (4.35)
Laryngeal oedema	1	1 (4.35)	1	1 (4.35)
Respiratory failure	1	1 (4.35)	1	1 (4.35)
Wheezing	1	1 (4.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: >1 year post-CTL019 infusion, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
- Total	5	3 (13.04)	1	1 (4.35)
Rash	2	2 (8.70)	0	0 (0.00)
Eczema	1	1 (4.35)	1	1 (4.35)
Rash erythematous	1	1 (4.35)	0	0 (0.00)
Rash maculo-papular	1	1 (4.35)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Hypertension	1	1 (4.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	19	2 (40.00)	6	2 (40.00)
General disorders and administration site conditions				
- Total	4	1 (20.00)	0	0 (0.00)
Pyrexia	3	1 (20.00)	0	0 (0.00)
Pain	1	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	8	2 (40.00)	1	1 (20.00)
Upper respiratory tract infection	3	1 (20.00)	1	1 (20.00)
Otitis media	2	1 (20.00)	0	0 (0.00)
Rhinovirus infection	1	1 (20.00)	0	0 (0.00)
Sinusitis	1	1 (20.00)	0	0 (0.00)
Urinary tract infection	1	1 (20.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Investigations				
- Total	6	1 (20.00)	5	1 (20.00)
Neutrophil count decreased	6	1 (20.00)	5	1 (20.00)
Psychiatric disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Anxiety	1	1 (20.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Total number of AE per patient	602	28 (100.00)	202	26 (92.86)
Blood and lymphatic system disorders				
- Total	47	18 (64.29)	29	14 (50.00)
Anaemia	14	8 (28.57)	8	4 (14.29)
Febrile neutropenia	7	7 (25.00)	7	7 (25.00)
Neutropenia	6	5 (17.86)	5	4 (14.29)
Thrombocytopenia	4	3 (10.71)	3	3 (10.71)
Disseminated intravascular coagulation	3	3 (10.71)	1	1 (3.57)
Eosinophilia	3	1 (3.57)	0	0 (0.00)
Coagulopathy	2	2 (7.14)	1	1 (3.57)
Lymphadenopathy	2	2 (7.14)	0	0 (0.00)
Pancytopenia	2	2 (7.14)	2	2 (7.14)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Agranulocytosis	1	1 (3.57)	1	1 (3.57)
Hypercoagulation	1	1 (3.57)	0	0 (0.00)
Leukopenia	1	1 (3.57)	1	1 (3.57)
Splenomegaly	1	1 (3.57)	0	0 (0.00)
Cardiac disorders				
- Total	4	3 (10.71)	0	0 (0.00)
Sinus tachycardia	2	1 (3.57)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.57)	0	0 (0.00)
Pericardial effusion	1	1 (3.57)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (7.14)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.57)	0	0 (0.00)
Hypothyroidism	1	1 (3.57)	0	0 (0.00)
Eye disorders				
- Total	9	4 (14.29)	1	1 (3.57)
Eyelid oedema	3	2 (7.14)	0	0 (0.00)
Eye pain	2	2 (7.14)	1	1 (3.57)
Retinal haemorrhage	2	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Eye oedema	1	1 (3.57)	0	0 (0.00)
Visual field defect	1	1 (3.57)	0	0 (0.00)
Gastrointestinal disorders				
- Total	56	21 (75.00)	4	4 (14.29)
Vomiting	14	8 (28.57)	0	0 (0.00)
Diarrhoea	10	8 (28.57)	1	1 (3.57)
Nausea	7	4 (14.29)	1	1 (3.57)
Abdominal pain	6	5 (17.86)	0	0 (0.00)
Constipation	6	5 (17.86)	0	0 (0.00)
Abdominal pain upper	3	3 (10.71)	0	0 (0.00)
Pancreatitis	2	2 (7.14)	1	1 (3.57)
Abdominal rigidity	1	1 (3.57)	0	0 (0.00)
Ascites	1	1 (3.57)	0	0 (0.00)
Dyspepsia	1	1 (3.57)	0	0 (0.00)
Mouth haemorrhage	1	1 (3.57)	0	0 (0.00)
Mouth swelling	1	1 (3.57)	0	0 (0.00)
Odynophagia	1	1 (3.57)	0	0 (0.00)
Peritoneal haematoma	1	1 (3.57)	0	0 (0.00)
Stomatitis	1	1 (3.57)	1	1 (3.57)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
General disorders and administration site conditions				
- Total	32	15 (53.57)	5	3 (10.71)
Pyrexia	14	9 (32.14)	1	1 (3.57)
Face oedema	4	3 (10.71)	1	1 (3.57)
Asthenia	3	3 (10.71)	0	0 (0.00)
Oedema peripheral	3	2 (7.14)	2	1 (3.57)
Catheter site erythema	2	1 (3.57)	0	0 (0.00)
Fatigue	1	1 (3.57)	0	0 (0.00)
Generalised oedema	1	1 (3.57)	0	0 (0.00)
Influenza like illness	1	1 (3.57)	0	0 (0.00)
Localised oedema	1	1 (3.57)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.57)	1	1 (3.57)
Non-cardiac chest pain	1	1 (3.57)	0	0 (0.00)
Hepatobiliary disorders				
- Total	5	5 (17.86)	0	0 (0.00)
Cholelithiasis	1	1 (3.57)	0	0 (0.00)
Hepatic cytolysis	1	1 (3.57)	0	0 (0.00)
Hepatomegaly	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hyperbilirubinaemia	1	1 (3.57)	0	0 (0.00)
Liver disorder	1	1 (3.57)	0	0 (0.00)
Immune system disorders				
- Total	60	22 (78.57)	29	19 (67.86)
Cytokine release syndrome	38	19 (67.86)	17	13 (46.43)
Hypogammaglobulinaemia	10	10 (35.71)	4	4 (14.29)
Immunodeficiency	4	4 (14.29)	4	4 (14.29)
Chronic graft versus host disease	2	2 (7.14)	1	1 (3.57)
Haemophagocytic lymphohistiocytosis	2	2 (7.14)	1	1 (3.57)
Allergy to immunoglobulin therapy	1	1 (3.57)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.57)	1	1 (3.57)
Graft versus host disease	1	1 (3.57)	1	1 (3.57)
Hypersensitivity	1	1 (3.57)	0	0 (0.00)
Infections and infestations				
- Total	101	25 (89.29)	38	15 (53.57)
Conjunctivitis	8	5 (17.86)	0	0 (0.00)
Nasopharyngitis	7	6 (21.43)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (7.14)	4	2 (7.14)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Gastroenteritis	4	4 (14.29)	2	2 (7.14)
Nail infection	3	3 (10.71)	0	0 (0.00)
Pneumonia	3	3 (10.71)	2	2 (7.14)
Respiratory tract infection	3	3 (10.71)	0	0 (0.00)
Rhinitis	3	3 (10.71)	0	0 (0.00)
Sepsis	3	3 (10.71)	3	3 (10.71)
Sinusitis	3	1 (3.57)	1	1 (3.57)
Upper respiratory tract infection	3	3 (10.71)	0	0 (0.00)
Bacteraemia	2	1 (3.57)	2	1 (3.57)
COVID-19	2	1 (3.57)	1	1 (3.57)
Device related sepsis	2	1 (3.57)	2	1 (3.57)
Ear infection	2	1 (3.57)	0	0 (0.00)
Fungal infection	2	1 (3.57)	0	0 (0.00)
Herpes zoster	2	2 (7.14)	2	2 (7.14)
Oral infection	2	2 (7.14)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (7.14)	1	1 (3.57)
Rhinovirus infection	2	2 (7.14)	1	1 (3.57)
Staphylococcal infection	2	2 (7.14)	1	1 (3.57)
Urinary tract infection	2	1 (3.57)	2	1 (3.57)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Adenovirus infection	1	1 (3.57)	1	1 (3.57)
Bronchitis	1	1 (3.57)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.57)	1	1 (3.57)
Candida infection	1	1 (3.57)	0	0 (0.00)
Cystitis	1	1 (3.57)	0	0 (0.00)
Device related infection	1	1 (3.57)	1	1 (3.57)
Ear, nose and throat infection	1	1 (3.57)	0	0 (0.00)
Encephalitis	1	1 (3.57)	1	1 (3.57)
Encephalitis viral	1	1 (3.57)	1	1 (3.57)
Enterovirus infection	1	1 (3.57)	1	1 (3.57)
Gingivitis	1	1 (3.57)	0	0 (0.00)
Herpes virus infection	1	1 (3.57)	0	0 (0.00)
Influenza	1	1 (3.57)	1	1 (3.57)
Molluscum contagiosum	1	1 (3.57)	0	0 (0.00)
Myringitis	1	1 (3.57)	0	0 (0.00)
Neutropenic infection	1	1 (3.57)	1	1 (3.57)
Ophthalmic herpes zoster	1	1 (3.57)	0	0 (0.00)
Oral candidiasis	1	1 (3.57)	0	0 (0.00)
Oral herpes	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Otitis media	1	1 (3.57)	0	0 (0.00)
Paronychia	1	1 (3.57)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (3.57)	1	1 (3.57)
Pneumonia fungal	1	1 (3.57)	1	1 (3.57)
Pneumonia viral	1	1 (3.57)	1	1 (3.57)
Respiratory tract infection viral	1	1 (3.57)	0	0 (0.00)
Skin infection	1	1 (3.57)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (3.57)	1	1 (3.57)
Staphylococcal sepsis	1	1 (3.57)	1	1 (3.57)
Staphylococcal skin infection	1	1 (3.57)	0	0 (0.00)
Streptococcal sepsis	1	1 (3.57)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (3.57)	1	1 (3.57)
Viral infection	1	1 (3.57)	0	0 (0.00)
Viral skin infection	1	1 (3.57)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	7	4 (14.29)	0	0 (0.00)
Infusion related reaction	4	1 (3.57)	0	0 (0.00)
Fall	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Ligament sprain	1	1 (3.57)	0	0 (0.00)
Procedural pain	1	1 (3.57)	0	0 (0.00)
Investigations				
- Total	92	18 (64.29)	49	12 (42.86)
White blood cell count decreased	20	6 (21.43)	11	5 (17.86)
Lymphocyte count decreased	18	7 (25.00)	15	6 (21.43)
Neutrophil count decreased	12	6 (21.43)	10	6 (21.43)
Immunoglobulins decreased	10	2 (7.14)	0	0 (0.00)
Platelet count decreased	10	6 (21.43)	3	3 (10.71)
Alanine aminotransferase increased	6	2 (7.14)	2	2 (7.14)
Aspartate aminotransferase increased	2	1 (3.57)	1	1 (3.57)
Blood bilirubin increased	1	1 (3.57)	1	1 (3.57)
Blood fibrinogen decreased	1	1 (3.57)	1	1 (3.57)
Blood immunoglobulin G decreased	1	1 (3.57)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.57)	0	0 (0.00)
Blood uric acid increased	1	1 (3.57)	1	1 (3.57)
Bone density decreased	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
C-reactive protein increased	1	1 (3.57)	1	1 (3.57)
Gamma-glutamyltransferase increased	1	1 (3.57)	1	1 (3.57)
Hepatitis B virus test positive	1	1 (3.57)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.57)	1	1 (3.57)
Prothrombin time prolonged	1	1 (3.57)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (3.57)	0	0 (0.00)
Serum ferritin increased	1	1 (3.57)	0	0 (0.00)
Weight decreased	1	1 (3.57)	1	1 (3.57)
Metabolism and nutrition disorders				
- Total	31	11 (39.29)	17	7 (25.00)
Decreased appetite	7	5 (17.86)	4	2 (7.14)
Hypophosphataemia	6	4 (14.29)	5	3 (10.71)
Hypokalaemia	5	5 (17.86)	3	3 (10.71)
Hypomagnesaemia	4	3 (10.71)	0	0 (0.00)
Hyperglycaemia	3	3 (10.71)	2	2 (7.14)
Haemochromatosis	1	1 (3.57)	1	1 (3.57)
Hypernatraemia	1	1 (3.57)	0	0 (0.00)
Hyperuricaemia	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Hypoalbuminaemia	1	1 (3.57)	0	0 (0.00)
Hypocalcaemia	1	1 (3.57)	1	1 (3.57)
Malnutrition	1	1 (3.57)	1	1 (3.57)
Musculoskeletal and connective tissue disorders				
- Total	23	13 (46.43)	1	1 (3.57)
Back pain	6	5 (17.86)	1	1 (3.57)
Pain in extremity	6	6 (21.43)	0	0 (0.00)
Arthralgia	5	4 (14.29)	0	0 (0.00)
Growth retardation	1	1 (3.57)	0	0 (0.00)
Muscular weakness	1	1 (3.57)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (3.57)	0	0 (0.00)
Myalgia	1	1 (3.57)	0	0 (0.00)
Osteonecrosis	1	1 (3.57)	0	0 (0.00)
Pain in jaw	1	1 (3.57)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	5	4 (14.29)	2	2 (7.14)
Bone giant cell tumour benign	2	1 (3.57)	1	1 (3.57)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Skin papilloma	2	2 (7.14)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (3.57)	1	1 (3.57)
Nervous system disorders				
- Total	34	17 (60.71)	9	5 (17.86)
Headache	14	10 (35.71)	1	1 (3.57)
Encephalopathy	3	3 (10.71)	1	1 (3.57)
Hydrocephalus	3	1 (3.57)	3	1 (3.57)
Tremor	3	2 (7.14)	0	0 (0.00)
Hyperaesthesia	2	1 (3.57)	0	0 (0.00)
Seizure	2	2 (7.14)	2	2 (7.14)
Amnesia	1	1 (3.57)	0	0 (0.00)
Autonomic neuropathy	1	1 (3.57)	1	1 (3.57)
Cerebral haemorrhage	1	1 (3.57)	1	1 (3.57)
Dysarthria	1	1 (3.57)	0	0 (0.00)
Dysgeusia	1	1 (3.57)	0	0 (0.00)
Memory impairment	1	1 (3.57)	0	0 (0.00)
Neuralgia	1	1 (3.57)	0	0 (0.00)
Psychiatric disorders				

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
- Total	14	11 (39.29)	1	1 (3.57)
Anxiety	4	4 (14.29)	1	1 (3.57)
Sleep disorder	3	2 (7.14)	0	0 (0.00)
Confusional state	2	2 (7.14)	0	0 (0.00)
Hallucination	2	2 (7.14)	0	0 (0.00)
Insomnia	2	2 (7.14)	0	0 (0.00)
Hallucination, visual	1	1 (3.57)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	6 (21.43)	2	2 (7.14)
Dysuria	2	2 (7.14)	0	0 (0.00)
Anuria	1	1 (3.57)	1	1 (3.57)
Renal failure	1	1 (3.57)	0	0 (0.00)
Renal tubular disorder	1	1 (3.57)	1	1 (3.57)
Urinary tract disorder	1	1 (3.57)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (3.57)	0	0 (0.00)
Female genital tract fistula	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	37	17 (60.71)	7	5 (17.86)
Cough	12	10 (35.71)	0	0 (0.00)
Oropharyngeal pain	4	3 (10.71)	0	0 (0.00)
Pulmonary oedema	4	4 (14.29)	3	3 (10.71)
Hypoxia	3	3 (10.71)	0	0 (0.00)
Tachypnoea	2	1 (3.57)	2	1 (3.57)
Bronchial oedema	1	1 (3.57)	0	0 (0.00)
Bronchospasm	1	1 (3.57)	0	0 (0.00)
Dyspnoea	1	1 (3.57)	1	1 (3.57)
Dyspnoea exertional	1	1 (3.57)	0	0 (0.00)
Epistaxis	1	1 (3.57)	0	0 (0.00)
Lung disorder	1	1 (3.57)	0	0 (0.00)
Painful respiration	1	1 (3.57)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.57)	0	0 (0.00)
Pleural effusion	1	1 (3.57)	0	0 (0.00)
Productive cough	1	1 (3.57)	0	0 (0.00)
Respiratory disorder	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Respiratory failure	1	1 (3.57)	1	1 (3.57)
Skin and subcutaneous tissue disorders				
- Total	28	13 (46.43)	4	3 (10.71)
Rash	5	2 (7.14)	0	0 (0.00)
Dermatitis atopic	4	3 (10.71)	1	1 (3.57)
Pruritus	3	2 (7.14)	0	0 (0.00)
Dry skin	2	2 (7.14)	0	0 (0.00)
Erythema	2	2 (7.14)	0	0 (0.00)
Rash macular	2	1 (3.57)	2	1 (3.57)
Rash vesicular	2	1 (3.57)	0	0 (0.00)
Decubitus ulcer	1	1 (3.57)	1	1 (3.57)
Dermatitis allergic	1	1 (3.57)	0	0 (0.00)
Hangnail	1	1 (3.57)	0	0 (0.00)
Papule	1	1 (3.57)	0	0 (0.00)
Photosensitivity reaction	1	1 (3.57)	0	0 (0.00)
Pruritus allergic	1	1 (3.57)	0	0 (0.00)
Rash maculo-papular	1	1 (3.57)	0	0 (0.00)
Urticaria	1	1 (3.57)	0	0 (0.00)

Timing: At anytime, Region: Europe

Primary system organ class Preferred term	All grades Total events	All patients N=28 n (%)[1]	Grade >= 3 Total events	All patients N=28 n (%)[2]
Vascular disorders				
- Total	8	8 (28.57)	4	4 (14.29)
Hypotension	4	4 (14.29)	1	1 (3.57)
Hypertension	3	3 (10.71)	2	2 (7.14)
Venoocclusive disease	1	1 (3.57)	1	1 (3.57)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Total number of AE per patient	1743	45 (100.00)	556	40 (88.89)
Blood and lymphatic system disorders				
- Total	97	31 (68.89)	55	25 (55.56)
Anaemia	47	16 (35.56)	16	5 (11.11)
Febrile neutropenia	26	20 (44.44)	26	20 (44.44)
Thrombocytopenia	6	5 (11.11)	6	5 (11.11)
Coagulopathy	3	3 (6.67)	1	1 (2.22)
Disseminated intravascular coagulation	3	3 (6.67)	2	2 (4.44)
Neutropenia	3	3 (6.67)	2	2 (4.44)
Splenomegaly	3	3 (6.67)	0	0 (0.00)
Leukopenia	2	1 (2.22)	0	0 (0.00)
Lymphopenia	2	2 (4.44)	2	2 (4.44)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Leukocytosis	1	1 (2.22)	0	0 (0.00)
Lymphocytosis	1	1 (2.22)	0	0 (0.00)
Cardiac disorders				
- Total	46	22 (48.89)	13	10 (22.22)
Tachycardia	24	17 (37.78)	3	3 (6.67)
Cardiac failure	5	2 (4.44)	3	2 (4.44)
Bradycardia	3	3 (6.67)	0	0 (0.00)
Cardiac arrest	3	3 (6.67)	3	3 (6.67)
Left ventricular dysfunction	3	3 (6.67)	3	3 (6.67)
Sinus tachycardia	2	2 (4.44)	0	0 (0.00)
Atrioventricular block first degree	1	1 (2.22)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.22)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.22)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.22)	0	0 (0.00)
Sinus bradycardia	1	1 (2.22)	1	1 (2.22)
Tricuspid valve incompetence	1	1 (2.22)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Cerebral cavernous malformation	1	1 (2.22)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (6.67)	0	0 (0.00)
Deafness unilateral	1	1 (2.22)	0	0 (0.00)
Ear pain	1	1 (2.22)	0	0 (0.00)
Ear pruritus	1	1 (2.22)	0	0 (0.00)
Endocrine disorders				
- Total	6	5 (11.11)	0	0 (0.00)
Adrenal insufficiency	3	3 (6.67)	0	0 (0.00)
Hypothyroidism	2	2 (4.44)	0	0 (0.00)
Delayed puberty	1	1 (2.22)	0	0 (0.00)
Eye disorders				
- Total	15	11 (24.44)	0	0 (0.00)
Ocular hyperaemia	3	3 (6.67)	0	0 (0.00)
Cataract	2	2 (4.44)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (4.44)	0	0 (0.00)
Visual impairment	2	2 (4.44)	0	0 (0.00)
Dry eye	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Eyelid oedema	1	1 (2.22)	0	0 (0.00)
Hypermetropia	1	1 (2.22)	0	0 (0.00)
Mydriasis	1	1 (2.22)	0	0 (0.00)
Periorbital oedema	1	1 (2.22)	0	0 (0.00)
Periorbital swelling	1	1 (2.22)	0	0 (0.00)
Gastrointestinal disorders				
- Total	114	33 (73.33)	14	12 (26.67)
Vomiting	24	18 (40.00)	1	1 (2.22)
Diarrhoea	19	17 (37.78)	1	1 (2.22)
Nausea	18	16 (35.56)	1	1 (2.22)
Abdominal pain	8	5 (11.11)	2	2 (4.44)
Constipation	8	7 (15.56)	0	0 (0.00)
Mouth haemorrhage	4	4 (8.89)	2	2 (4.44)
Abdominal distension	3	3 (6.67)	0	0 (0.00)
Ascites	2	2 (4.44)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.44)	0	0 (0.00)
Pancreatitis	2	2 (4.44)	1	1 (2.22)
Proctalgia	2	2 (4.44)	1	1 (2.22)
Abdominal compartment syndrome	1	1 (2.22)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Abdominal pain upper	1	1 (2.22)	0	0 (0.00)
Anal fissure	1	1 (2.22)	0	0 (0.00)
Anal haemorrhage	1	1 (2.22)	0	0 (0.00)
Dry mouth	1	1 (2.22)	0	0 (0.00)
Dysphagia	1	1 (2.22)	1	1 (2.22)
Gastrointestinal haemorrhage	1	1 (2.22)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.22)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.22)	0	0 (0.00)
Gingival bleeding	1	1 (2.22)	0	0 (0.00)
Gingival erythema	1	1 (2.22)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.22)	1	1 (2.22)
Haematemesis	1	1 (2.22)	0	0 (0.00)
Ileus	1	1 (2.22)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.22)	0	0 (0.00)
Lip dry	1	1 (2.22)	0	0 (0.00)
Lip oedema	1	1 (2.22)	0	0 (0.00)
Melaena	1	1 (2.22)	1	1 (2.22)
Neutropenic colitis	1	1 (2.22)	1	1 (2.22)
Stomatitis	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Trichoglossia	1	1 (2.22)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.22)	0	0 (0.00)
General disorders and administration site conditions				
- Total	116	37 (82.22)	19	12 (26.67)
Pyrexia	48	25 (55.56)	11	10 (22.22)
Fatigue	18	16 (35.56)	0	0 (0.00)
Chills	10	7 (15.56)	0	0 (0.00)
Oedema peripheral	6	5 (11.11)	0	0 (0.00)
Catheter site pain	4	2 (4.44)	2	1 (2.22)
Face oedema	4	4 (8.89)	0	0 (0.00)
Generalised oedema	4	4 (8.89)	0	0 (0.00)
Pain	4	4 (8.89)	2	2 (4.44)
Drug withdrawal syndrome	2	2 (4.44)	0	0 (0.00)
Malaise	2	2 (4.44)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (4.44)	2	2 (4.44)
Catheter site haemorrhage	1	1 (2.22)	0	0 (0.00)
Chest discomfort	1	1 (2.22)	1	1 (2.22)
Crying	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Facial pain	1	1 (2.22)	0	0 (0.00)
Localised oedema	1	1 (2.22)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.22)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.22)	0	0 (0.00)
Sluggishness	1	1 (2.22)	0	0 (0.00)
Swelling face	1	1 (2.22)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (2.22)	1	1 (2.22)
Vascular device occlusion	1	1 (2.22)	0	0 (0.00)
Xerosis	1	1 (2.22)	0	0 (0.00)
Hepatobiliary disorders				
- Total	17	10 (22.22)	3	3 (6.67)
Hyperbilirubinaemia	5	4 (8.89)	1	1 (2.22)
Hypertransaminasaemia	3	2 (4.44)	0	0 (0.00)
Gallbladder enlargement	2	2 (4.44)	0	0 (0.00)
Hepatomegaly	2	2 (4.44)	1	1 (2.22)
Biliary tract disorder	1	1 (2.22)	0	0 (0.00)
Cholelithiasis	1	1 (2.22)	0	0 (0.00)
Cholestasis	1	1 (2.22)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hepatic function abnormal	1	1 (2.22)	0	0 (0.00)
Ocular icterus	1	1 (2.22)	0	0 (0.00)
Immune system disorders				
- Total	117	42 (93.33)	41	22 (48.89)
Cytokine release syndrome	78	36 (80.00)	32	20 (44.44)
Hypogammaglobulinaemia	26	19 (42.22)	3	3 (6.67)
Haemophagocytic lymphohistiocytosis	4	4 (8.89)	3	3 (6.67)
Seasonal allergy	4	4 (8.89)	0	0 (0.00)
Allergy to immunoglobulin therapy	1	1 (2.22)	1	1 (2.22)
Drug hypersensitivity	1	1 (2.22)	0	0 (0.00)
Engraftment syndrome	1	1 (2.22)	1	1 (2.22)
Graft versus host disease	1	1 (2.22)	1	1 (2.22)
Selective IgG subclass deficiency	1	1 (2.22)	0	0 (0.00)
Infections and infestations				
- Total	140	29 (64.44)	55	20 (44.44)
Sinusitis	10	5 (11.11)	1	1 (2.22)
Upper respiratory tract infection	9	8 (17.78)	1	1 (2.22)
Rhinovirus infection	7	6 (13.33)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Staphylococcal bacteraemia	5	4 (8.89)	5	4 (8.89)
Candida infection	4	3 (6.67)	2	1 (2.22)
Clostridium difficile infection	4	4 (8.89)	3	3 (6.67)
Conjunctivitis	4	3 (6.67)	0	0 (0.00)
Oral herpes	4	3 (6.67)	1	1 (2.22)
Gastroenteritis viral	3	2 (4.44)	0	0 (0.00)
Klebsiella infection	3	1 (2.22)	3	1 (2.22)
Metapneumovirus infection	3	3 (6.67)	3	3 (6.67)
Oral candidiasis	3	2 (4.44)	0	0 (0.00)
Otitis media	3	3 (6.67)	1	1 (2.22)
Parainfluenzae virus infection	3	2 (4.44)	1	1 (2.22)
Staphylococcal infection	3	3 (6.67)	1	1 (2.22)
Acute sinusitis	2	2 (4.44)	0	0 (0.00)
Ear infection	2	2 (4.44)	1	1 (2.22)
Gastroenteritis	2	2 (4.44)	0	0 (0.00)
Herpes simplex	2	2 (4.44)	1	1 (2.22)
Human herpesvirus 6 infection	2	2 (4.44)	2	2 (4.44)
Influenza	2	2 (4.44)	0	0 (0.00)
Otitis externa	2	2 (4.44)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pneumonia	2	2 (4.44)	1	1 (2.22)
Respiratory syncytial virus infection	2	2 (4.44)	1	1 (2.22)
Septic shock	2	2 (4.44)	2	2 (4.44)
Skin infection	2	2 (4.44)	0	0 (0.00)
Varicella zoster virus infection	2	2 (4.44)	1	1 (2.22)
Adenovirus infection	1	1 (2.22)	1	1 (2.22)
Anal abscess	1	1 (2.22)	1	1 (2.22)
Atypical pneumonia	1	1 (2.22)	0	0 (0.00)
BK virus infection	1	1 (2.22)	1	1 (2.22)
Bacteraemia	1	1 (2.22)	0	0 (0.00)
Bronchiolitis	1	1 (2.22)	1	1 (2.22)
Bronchitis	1	1 (2.22)	0	0 (0.00)
COVID-19	1	1 (2.22)	0	0 (0.00)
Cellulitis	1	1 (2.22)	0	0 (0.00)
Cholecystitis infective	1	1 (2.22)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.22)	1	1 (2.22)
Coronavirus infection	1	1 (2.22)	1	1 (2.22)
Cytomegalovirus infection reactivation	1	1 (2.22)	1	1 (2.22)
Encephalitis	1	1 (2.22)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Enterobacter infection	1	1 (2.22)	1	1 (2.22)
Folliculitis	1	1 (2.22)	0	0 (0.00)
Fungal infection	1	1 (2.22)	0	0 (0.00)
Fungal skin infection	1	1 (2.22)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.22)	1	1 (2.22)
Gastroenteritis clostridial	1	1 (2.22)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.22)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (2.22)	1	1 (2.22)
Gastrointestinal infection	1	1 (2.22)	0	0 (0.00)
Gingivitis	1	1 (2.22)	0	0 (0.00)
Granulicatella infection	1	1 (2.22)	1	1 (2.22)
Herpes zoster	1	1 (2.22)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (2.22)	0	0 (0.00)
Localised infection	1	1 (2.22)	0	0 (0.00)
Mastoiditis	1	1 (2.22)	1	1 (2.22)
Meningitis pneumococcal	1	1 (2.22)	1	1 (2.22)
Nail infection	1	1 (2.22)	0	0 (0.00)
Otitis media acute	1	1 (2.22)	0	0 (0.00)
Paronychia	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pharyngitis streptococcal	1	1 (2.22)	1	1 (2.22)
Pneumocystis jirovecii pneumonia	1	1 (2.22)	1	1 (2.22)
Pneumonia respiratory syncytial viral	1	1 (2.22)	1	1 (2.22)
Salmonellosis	1	1 (2.22)	0	0 (0.00)
Sinusitis fungal	1	1 (2.22)	1	1 (2.22)
Soft tissue infection	1	1 (2.22)	1	1 (2.22)
Staphylococcal abscess	1	1 (2.22)	1	1 (2.22)
Stomatococcal infection	1	1 (2.22)	0	0 (0.00)
Syphilis	1	1 (2.22)	0	0 (0.00)
Systemic candida	1	1 (2.22)	1	1 (2.22)
Tinea pedis	1	1 (2.22)	0	0 (0.00)
Urinary tract infection	1	1 (2.22)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.22)	0	0 (0.00)
Viral infection	1	1 (2.22)	1	1 (2.22)
Viral upper respiratory tract infection	1	1 (2.22)	1	1 (2.22)
Injury, poisoning and procedural complications				
- Total	26	17 (37.78)	4	3 (6.67)
Infusion related reaction	4	4 (8.89)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Contusion	3	2 (4.44)	0	0 (0.00)
Wound	3	2 (4.44)	1	1 (2.22)
Skin abrasion	2	2 (4.44)	0	0 (0.00)
Transfusion reaction	2	2 (4.44)	0	0 (0.00)
Abdominal injury	1	1 (2.22)	0	0 (0.00)
Fall	1	1 (2.22)	0	0 (0.00)
Fibula fracture	1	1 (2.22)	0	0 (0.00)
Ligament sprain	1	1 (2.22)	0	0 (0.00)
Limb injury	1	1 (2.22)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.22)	0	0 (0.00)
Procedural pain	1	1 (2.22)	0	0 (0.00)
Scratch	1	1 (2.22)	0	0 (0.00)
Skin injury	1	1 (2.22)	0	0 (0.00)
Skin wound	1	1 (2.22)	0	0 (0.00)
Transplant failure	1	1 (2.22)	1	1 (2.22)
Vasoplegia syndrome	1	1 (2.22)	1	1 (2.22)
Investigations				
- Total	368	37 (82.22)	164	31 (68.89)
Platelet count decreased	71	16 (35.56)	42	10 (22.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Neutrophil count decreased	50	15 (33.33)	32	12 (26.67)
White blood cell count decreased	38	15 (33.33)	19	9 (20.00)
Aspartate aminotransferase increased	31	18 (40.00)	12	10 (22.22)
Blood bilirubin increased	24	12 (26.67)	9	8 (17.78)
Alanine aminotransferase increased	23	16 (35.56)	5	5 (11.11)
Lymphocyte count decreased	18	10 (22.22)	11	9 (20.00)
International normalised ratio increased	12	9 (20.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (13.33)	1	1 (2.22)
Blood creatinine increased	7	5 (11.11)	5	3 (6.67)
Blood immunoglobulin A decreased	7	7 (15.56)	1	1 (2.22)
Blood immunoglobulin M decreased	7	7 (15.56)	2	2 (4.44)
Weight increased	7	4 (8.89)	2	2 (4.44)
Electrocardiogram QT prolonged	6	5 (11.11)	2	2 (4.44)
Blood fibrinogen decreased	4	4 (8.89)	1	1 (2.22)
Blood lactate dehydrogenase increased	4	4 (8.89)	1	1 (2.22)
C-reactive protein increased	4	4 (8.89)	2	2 (4.44)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Lipase increased	4	2 (4.44)	2	1 (2.22)
Serum ferritin increased	4	4 (8.89)	2	2 (4.44)
Blood immunoglobulin G decreased	3	3 (6.67)	0	0 (0.00)
Blood uric acid increased	3	3 (6.67)	1	1 (2.22)
Fibrin D dimer increased	3	3 (6.67)	1	1 (2.22)
Urine output decreased	3	2 (4.44)	3	2 (4.44)
Blood glucose increased	2	1 (2.22)	2	1 (2.22)
Haemoglobin decreased	2	1 (2.22)	1	1 (2.22)
Oxygen saturation decreased	2	2 (4.44)	0	0 (0.00)
Amylase increased	1	1 (2.22)	0	0 (0.00)
Bacterial test positive	1	1 (2.22)	1	1 (2.22)
Blood alkaline phosphatase increased	1	1 (2.22)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (2.22)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.22)	1	1 (2.22)
Blood phosphorus increased	1	1 (2.22)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.22)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Blood urea increased	1	1 (2.22)	1	1 (2.22)
Breath sounds abnormal	1	1 (2.22)	0	0 (0.00)
Cardiac murmur	1	1 (2.22)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.22)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.22)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.22)	0	0 (0.00)
Enterovirus test positive	1	1 (2.22)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (2.22)	1	1 (2.22)
Haptoglobin decreased	1	1 (2.22)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.22)	0	0 (0.00)
Staphylococcus test positive	1	1 (2.22)	0	0 (0.00)
Troponin increased	1	1 (2.22)	1	1 (2.22)
Weight decreased	1	1 (2.22)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	211	39 (86.67)	71	24 (53.33)
Hypokalaemia	41	15 (33.33)	21	8 (17.78)
Hypophosphataemia	26	14 (31.11)	6	6 (13.33)
Decreased appetite	25	25 (55.56)	10	10 (22.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hypocalcaemia	23	15 (33.33)	5	4 (8.89)
Hypoalbuminaemia	17	9 (20.00)	1	1 (2.22)
Hyperuricaemia	11	8 (17.78)	1	1 (2.22)
Hyperglycaemia	9	6 (13.33)	3	3 (6.67)
Hypervolaemia	7	7 (15.56)	5	5 (11.11)
Hyperphosphataemia	5	5 (11.11)	1	1 (2.22)
Hypercalcaemia	4	3 (6.67)	2	2 (4.44)
Acidosis	3	2 (4.44)	2	2 (4.44)
Hyperkalaemia	3	3 (6.67)	2	2 (4.44)
Hypermagnesaemia	3	2 (4.44)	0	0 (0.00)
Hypertriglyceridaemia	3	3 (6.67)	2	2 (4.44)
Hypomagnesaemia	3	3 (6.67)	0	0 (0.00)
Hyponatraemia	3	3 (6.67)	0	0 (0.00)
Iron overload	3	2 (4.44)	0	0 (0.00)
Metabolic acidosis	3	3 (6.67)	2	2 (4.44)
Tumour lysis syndrome	3	3 (6.67)	3	3 (6.67)
Hyperchloraemia	2	2 (4.44)	0	0 (0.00)
Hypernatraemia	2	2 (4.44)	2	2 (4.44)
Calcium deficiency	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Dehydration	1	1 (2.22)	0	0 (0.00)
Haemosiderosis	1	1 (2.22)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.22)	0	0 (0.00)
Hyperlactacidaemia	1	1 (2.22)	0	0 (0.00)
Hyperlipidaemia	1	1 (2.22)	0	0 (0.00)
Hypoglycaemia	1	1 (2.22)	0	0 (0.00)
Hypophagia	1	1 (2.22)	0	0 (0.00)
Malnutrition	1	1 (2.22)	1	1 (2.22)
Metabolic syndrome	1	1 (2.22)	0	0 (0.00)
Obesity	1	1 (2.22)	1	1 (2.22)
Polydipsia	1	1 (2.22)	1	1 (2.22)
Musculoskeletal and connective tissue disorders				
- Total	59	30 (66.67)	8	7 (15.56)
Pain in extremity	11	10 (22.22)	1	1 (2.22)
Myalgia	10	9 (20.00)	0	0 (0.00)
Arthralgia	9	8 (17.78)	1	1 (2.22)
Back pain	8	5 (11.11)	2	2 (4.44)
Bone pain	6	4 (8.89)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Neck pain	2	2 (4.44)	0	0 (0.00)
Growth retardation	1	1 (2.22)	0	0 (0.00)
Haemarthrosis	1	1 (2.22)	1	1 (2.22)
Joint effusion	1	1 (2.22)	0	0 (0.00)
Muscle rigidity	1	1 (2.22)	0	0 (0.00)
Muscle spasms	1	1 (2.22)	0	0 (0.00)
Muscular weakness	1	1 (2.22)	1	1 (2.22)
Musculoskeletal chest pain	1	1 (2.22)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.22)	0	0 (0.00)
Myositis	1	1 (2.22)	0	0 (0.00)
Osteopenia	1	1 (2.22)	0	0 (0.00)
Pain in jaw	1	1 (2.22)	1	1 (2.22)
Rhabdomyolysis	1	1 (2.22)	1	1 (2.22)
Synovitis	1	1 (2.22)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.22)	0	0 (0.00)
Cancer pain	1	1 (2.22)	0	0 (0.00)
Nervous system disorders				

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
- Total	71	28 (62.22)	14	9 (20.00)
Headache	24	16 (35.56)	2	2 (4.44)
Cognitive disorder	5	3 (6.67)	1	1 (2.22)
Dizziness	5	4 (8.89)	0	0 (0.00)
Encephalopathy	5	5 (11.11)	3	3 (6.67)
Somnolence	5	5 (11.11)	2	2 (4.44)
Tremor	4	4 (8.89)	0	0 (0.00)
Lethargy	3	3 (6.67)	0	0 (0.00)
Seizure	3	1 (2.22)	1	1 (2.22)
Dysgeusia	2	2 (4.44)	0	0 (0.00)
Migraine	2	1 (2.22)	0	0 (0.00)
Nervous system disorder	2	1 (2.22)	1	1 (2.22)
Aphasia	1	1 (2.22)	0	0 (0.00)
Cerebral haemorrhage	1	1 (2.22)	1	1 (2.22)
Depressed level of consciousness	1	1 (2.22)	1	1 (2.22)
Disturbance in attention	1	1 (2.22)	0	0 (0.00)
Dysarthria	1	1 (2.22)	1	1 (2.22)
Extrapyramidal disorder	1	1 (2.22)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Hypoaesthesia	1	1 (2.22)	0	0 (0.00)
Monoparesis	1	1 (2.22)	0	0 (0.00)
Neurological decompensation	1	1 (2.22)	1	1 (2.22)
Paraesthesia	1	1 (2.22)	0	0 (0.00)
Psychiatric disorders				
- Total	50	27 (60.00)	6	6 (13.33)
Anxiety	9	9 (20.00)	1	1 (2.22)
Delirium	8	8 (17.78)	3	3 (6.67)
Agitation	7	6 (13.33)	0	0 (0.00)
Confusional state	5	5 (11.11)	0	0 (0.00)
Mental status changes	5	5 (11.11)	2	2 (4.44)
Irritability	3	3 (6.67)	0	0 (0.00)
Insomnia	2	2 (4.44)	0	0 (0.00)
Affect lability	1	1 (2.22)	0	0 (0.00)
Automatism	1	1 (2.22)	0	0 (0.00)
Hallucination	1	1 (2.22)	0	0 (0.00)
Mood altered	1	1 (2.22)	0	0 (0.00)
Nightmare	1	1 (2.22)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Restlessness	1	1 (2.22)	0	0 (0.00)
Sleep disorder	1	1 (2.22)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.22)	0	0 (0.00)
Tearfulness	1	1 (2.22)	0	0 (0.00)
Tic	1	1 (2.22)	0	0 (0.00)
Renal and urinary disorders				
- Total	36	15 (33.33)	11	8 (17.78)
Acute kidney injury	14	10 (22.22)	6	6 (13.33)
Renal failure	3	1 (2.22)	3	1 (2.22)
Dysuria	2	2 (4.44)	0	0 (0.00)
Haematuria	2	2 (4.44)	1	1 (2.22)
Pollakiuria	2	2 (4.44)	0	0 (0.00)
Urinary incontinence	2	1 (2.22)	0	0 (0.00)
Urinary retention	2	2 (4.44)	0	0 (0.00)
Anuria	1	1 (2.22)	0	0 (0.00)
Azotaemia	1	1 (2.22)	0	0 (0.00)
Bladder dilatation	1	1 (2.22)	0	0 (0.00)
Incontinence	1	1 (2.22)	0	0 (0.00)
Kidney enlargement	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Micturition urgency	1	1 (2.22)	0	0 (0.00)
Renal mass	1	1 (2.22)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.22)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.22)	1	1 (2.22)
Reproductive system and breast disorders				
- Total	8	4 (8.89)	2	2 (4.44)
Dysmenorrhoea	2	1 (2.22)	0	0 (0.00)
Endometriosis	2	1 (2.22)	1	1 (2.22)
Vaginal haemorrhage	2	1 (2.22)	0	0 (0.00)
Perineal rash	1	1 (2.22)	0	0 (0.00)
Vaginal ulceration	1	1 (2.22)	1	1 (2.22)
Respiratory, thoracic and mediastinal disorders				
- Total	134	32 (71.11)	48	21 (46.67)
Cough	17	13 (28.89)	0	0 (0.00)
Hypoxia	17	14 (31.11)	15	13 (28.89)
Nasal congestion	10	9 (20.00)	0	0 (0.00)
Tachypnoea	9	8 (17.78)	4	4 (8.89)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Pulmonary oedema	8	8 (17.78)	4	4 (8.89)
Rhinorrhoea	8	6 (13.33)	0	0 (0.00)
Dyspnoea	7	6 (13.33)	3	3 (6.67)
Pleural effusion	7	6 (13.33)	3	3 (6.67)
Epistaxis	6	5 (11.11)	1	1 (2.22)
Atelectasis	5	3 (6.67)	2	2 (4.44)
Respiratory distress	5	4 (8.89)	3	2 (4.44)
Respiratory failure	5	5 (11.11)	5	5 (11.11)
Oropharyngeal pain	4	4 (8.89)	0	0 (0.00)
Acute respiratory distress syndrome	3	3 (6.67)	3	3 (6.67)
Lung infiltration	2	1 (2.22)	1	1 (2.22)
Rhinitis allergic	2	2 (4.44)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.44)	0	0 (0.00)
Wheezing	2	2 (4.44)	0	0 (0.00)
Acute respiratory failure	1	1 (2.22)	1	1 (2.22)
Bradypnoea	1	1 (2.22)	1	1 (2.22)
Haemoptysis	1	1 (2.22)	0	0 (0.00)
Laryngeal oedema	1	1 (2.22)	1	1 (2.22)
Nasal discomfort	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Nasal dryness	1	1 (2.22)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.22)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.22)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.22)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.22)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.22)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.22)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.22)	0	0 (0.00)
Pulmonary mass	1	1 (2.22)	0	0 (0.00)
Respiratory acidosis	1	1 (2.22)	1	1 (2.22)
Skin and subcutaneous tissue disorders				
- Total	61	23 (51.11)	5	4 (8.89)
Rash	8	6 (13.33)	0	0 (0.00)
Blister	6	3 (6.67)	0	0 (0.00)
Dry skin	6	5 (11.11)	0	0 (0.00)
Pruritus	5	4 (8.89)	0	0 (0.00)
Rash papular	4	3 (6.67)	0	0 (0.00)
Eczema	3	3 (6.67)	1	1 (2.22)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Erythema	3	3 (6.67)	0	0 (0.00)
Hyperhidrosis	3	3 (6.67)	0	0 (0.00)
Rash maculo-papular	3	2 (4.44)	1	1 (2.22)
Ingrowing nail	2	2 (4.44)	0	0 (0.00)
Petechiae	2	2 (4.44)	1	1 (2.22)
Skin discolouration	2	2 (4.44)	0	0 (0.00)
Decubitus ulcer	1	1 (2.22)	0	0 (0.00)
Dermatitis	1	1 (2.22)	0	0 (0.00)
Dermatitis diaper	1	1 (2.22)	0	0 (0.00)
Miliaria	1	1 (2.22)	0	0 (0.00)
Night sweats	1	1 (2.22)	0	0 (0.00)
Purpura	1	1 (2.22)	0	0 (0.00)
Rash erythematous	1	1 (2.22)	0	0 (0.00)
Rash pruritic	1	1 (2.22)	0	0 (0.00)
Scab	1	1 (2.22)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.22)	0	0 (0.00)
Skin lesion	1	1 (2.22)	0	0 (0.00)
Skin necrosis	1	1 (2.22)	1	1 (2.22)
Skin ulcer	1	1 (2.22)	0	0 (0.00)

Timing: At anytime, Region: US

Primary system organ class Preferred term	All grades Total events	All patients N=45 n (%)[1]	Grade >= 3 Total events	All patients N=45 n (%)[2]
Vancomycin infusion reaction	1	1 (2.22)	1	1 (2.22)
Social circumstances				
- Total	1	1 (2.22)	0	0 (0.00)
Patient uncooperative	1	1 (2.22)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (2.22)	1	1 (2.22)
Thrombolysis	1	1 (2.22)	1	1 (2.22)
Vascular disorders				
- Total	44	24 (53.33)	22	16 (35.56)
Hypotension	24	19 (42.22)	17	14 (31.11)
Hypertension	13	12 (26.67)	3	3 (6.67)
Capillary leak syndrome	2	2 (4.44)	1	1 (2.22)
Flushing	1	1 (2.22)	0	0 (0.00)
Hot flush	1	1 (2.22)	0	0 (0.00)
Peripheral ischaemia	1	1 (2.22)	0	0 (0.00)
Thrombosis	1	1 (2.22)	0	0 (0.00)
Venoocclusive disease	1	1 (2.22)	1	1 (2.22)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

/vob/CCTL019/haq/haq_eu_7/pgm/saf/t250_gd_b2202.sas@@/main/1 15AUG23:06:01 **Final**

Table 250k
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Region
Safety Set

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Total number of AE per patient	160	7 (100.00)	70	7 (100.00)
Blood and lymphatic system disorders				
- Total	19	6 (85.71)	11	4 (57.14)
Neutropenia	8	3 (42.86)	8	3 (42.86)
B-cell aplasia	3	1 (14.29)	0	0 (0.00)
Anaemia	2	1 (14.29)	0	0 (0.00)
Disseminated intravascular coagulation	2	2 (28.57)	0	0 (0.00)
Leukopenia	2	1 (14.29)	2	1 (14.29)
Hypofibrinogenaemia	1	1 (14.29)	0	0 (0.00)
Thrombocytopenia	1	1 (14.29)	1	1 (14.29)
Cardiac disorders				

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
- Total	3	3 (42.86)	1	1 (14.29)
Cardiac dysfunction	2	2 (28.57)	0	0 (0.00)
Cardiac failure	1	1 (14.29)	1	1 (14.29)
Gastrointestinal disorders				
- Total	12	6 (85.71)	0	0 (0.00)
Constipation	2	2 (28.57)	0	0 (0.00)
Nausea	2	2 (28.57)	0	0 (0.00)
Pancreatitis	2	2 (28.57)	0	0 (0.00)
Abdominal pain	1	1 (14.29)	0	0 (0.00)
Diarrhoea	1	1 (14.29)	0	0 (0.00)
Enteritis	1	1 (14.29)	0	0 (0.00)
Enterocolitis	1	1 (14.29)	0	0 (0.00)
Stomatitis	1	1 (14.29)	0	0 (0.00)
Trichoglossia	1	1 (14.29)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	1 (14.29)	0	0 (0.00)
Pyrexia	5	1 (14.29)	0	0 (0.00)
Face oedema	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Influenza like illness	1	1 (14.29)	0	0 (0.00)
Pain	1	1 (14.29)	0	0 (0.00)
Hepatobiliary disorders				
- Total	10	4 (57.14)	4	3 (42.86)
Hepatic function abnormal	10	4 (57.14)	4	3 (42.86)
Immune system disorders				
- Total	16	7 (100.00)	6	5 (71.43)
Cytokine release syndrome	12	6 (85.71)	6	5 (71.43)
Hypogammaglobulinaemia	4	4 (57.14)	0	0 (0.00)
Infections and infestations				
- Total	22	6 (85.71)	9	4 (57.14)
Upper respiratory tract infection	5	2 (28.57)	2	2 (28.57)
Nasopharyngitis	2	1 (14.29)	0	0 (0.00)
Otitis media	2	1 (14.29)	0	0 (0.00)
Rhinovirus infection	2	1 (14.29)	1	1 (14.29)
BK virus infection	1	1 (14.29)	0	0 (0.00)
Bacteraemia	1	1 (14.29)	1	1 (14.29)
Encephalitis viral	1	1 (14.29)	1	1 (14.29)

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Meningitis bacterial	1	1 (14.29)	1	1 (14.29)
Otitis externa	1	1 (14.29)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (14.29)	1	1 (14.29)
Pneumonia	1	1 (14.29)	1	1 (14.29)
Respiratory syncytial virus infection	1	1 (14.29)	1	1 (14.29)
Sinusitis	1	1 (14.29)	0	0 (0.00)
Urinary tract infection	1	1 (14.29)	0	0 (0.00)
Urinary tract infection viral	1	1 (14.29)	0	0 (0.00)
Investigations				
- Total	33	5 (71.43)	25	5 (71.43)
Neutrophil count decreased	13	3 (42.86)	12	3 (42.86)
White blood cell count decreased	10	4 (57.14)	10	4 (57.14)
Blood creatine phosphokinase increased	3	1 (14.29)	1	1 (14.29)
Serum ferritin increased	3	3 (42.86)	0	0 (0.00)
Blood fibrinogen decreased	2	2 (28.57)	0	0 (0.00)
Platelet count decreased	2	2 (28.57)	2	2 (28.57)
Metabolism and nutrition disorders				
- Total	4	2 (28.57)	3	2 (28.57)

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Tumour lysis syndrome	2	2 (28.57)	2	2 (28.57)
Hypoalbuminaemia	1	1 (14.29)	0	0 (0.00)
Metabolic acidosis	1	1 (14.29)	1	1 (14.29)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Pain in extremity	1	1 (14.29)	0	0 (0.00)
Nervous system disorders				
- Total	4	2 (28.57)	0	0 (0.00)
Headache	2	1 (14.29)	0	0 (0.00)
Seizure	2	1 (14.29)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Anxiety	1	1 (14.29)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	4 (57.14)	3	2 (28.57)
Acute kidney injury	3	2 (28.57)	3	2 (28.57)
Cystitis haemorrhagic	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Haematuria	1	1 (14.29)	0	0 (0.00)
Proteinuria	1	1 (14.29)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (14.29)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (14.29)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	12	6 (85.71)	7	3 (42.86)
Hypoxia	7	3 (42.86)	7	3 (42.86)
Pleural effusion	2	2 (28.57)	0	0 (0.00)
Epistaxis	1	1 (14.29)	0	0 (0.00)
Oropharyngeal pain	1	1 (14.29)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (14.29)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	4 (57.14)	0	0 (0.00)
Dry skin	1	1 (14.29)	0	0 (0.00)
Erythema nodosum	1	1 (14.29)	0	0 (0.00)

Timing: At anytime, Region: Rest of World

Primary system organ class Preferred term	All grades Total events	All patients N=7 n (%)[1]	Grade >= 3 Total events	All patients N=7 n (%)[2]
Palmar-plantar erythrodysaesthesia syndrome	1	1 (14.29)	0	0 (0.00)
Pruritus	1	1 (14.29)	0	0 (0.00)
Skin swelling	1	1 (14.29)	0	0 (0.00)
Skin ulcer	1	1 (14.29)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (28.57)	1	1 (14.29)
Hypertension	1	1 (14.29)	0	0 (0.00)
Hypotension	1	1 (14.29)	1	1 (14.29)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Total number of AE per patient	963	48 (100.00)	321	42 (87.50)
Blood and lymphatic system disorders				
- Total	75	29 (60.42)	49	22 (45.83)
Anaemia	33	13 (27.08)	18	7 (14.58)
Febrile neutropenia	15	14 (29.17)	15	14 (29.17)
Neutropenia	6	5 (10.42)	5	4 (8.33)
Leukopenia	4	3 (6.25)	3	2 (4.17)
Thrombocytopenia	4	4 (8.33)	4	4 (8.33)
Disseminated intravascular coagulation	3	3 (6.25)	0	0 (0.00)
Coagulopathy	2	2 (4.17)	1	1 (2.08)
Eosinophilia	2	1 (2.08)	0	0 (0.00)
Pancytopenia	2	2 (4.17)	2	2 (4.17)
Splenomegaly	2	2 (4.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
B-cell aplasia	1	1 (2.08)	0	0 (0.00)
Lymphopenia	1	1 (2.08)	1	1 (2.08)
Cardiac disorders				
- Total	17	10 (20.83)	3	3 (6.25)
Tachycardia	7	7 (14.58)	1	1 (2.08)
Left ventricular dysfunction	2	2 (4.17)	2	2 (4.17)
Sinus tachycardia	2	1 (2.08)	0	0 (0.00)
Bradycardia	1	1 (2.08)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.08)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.08)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.08)	0	0 (0.00)
Pericardial effusion	1	1 (2.08)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.08)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.08)	0	0 (0.00)
Ear pain	1	1 (2.08)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (4.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Adrenal insufficiency	1	1 (2.08)	0	0 (0.00)
Hypothyroidism	1	1 (2.08)	0	0 (0.00)
Eye disorders				
- Total	9	5 (10.42)	0	0 (0.00)
Eyelid oedema	2	1 (2.08)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.08)	0	0 (0.00)
Eye oedema	1	1 (2.08)	0	0 (0.00)
Eye pain	1	1 (2.08)	0	0 (0.00)
Periorbital swelling	1	1 (2.08)	0	0 (0.00)
Visual field defect	1	1 (2.08)	0	0 (0.00)
Visual impairment	1	1 (2.08)	0	0 (0.00)
Gastrointestinal disorders				
- Total	94	32 (66.67)	9	7 (14.58)
Vomiting	22	14 (29.17)	0	0 (0.00)
Nausea	15	12 (25.00)	1	1 (2.08)
Diarrhoea	13	12 (25.00)	1	1 (2.08)
Abdominal pain	11	9 (18.75)	2	2 (4.17)
Constipation	5	5 (10.42)	0	0 (0.00)
Abdominal pain upper	3	3 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Abdominal distension	2	2 (4.17)	0	0 (0.00)
Ascites	2	2 (4.17)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.17)	0	0 (0.00)
Mouth haemorrhage	2	2 (4.17)	1	1 (2.08)
Stomatitis	2	2 (4.17)	1	1 (2.08)
Anal haemorrhage	1	1 (2.08)	0	0 (0.00)
Enterocolitis	1	1 (2.08)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.08)	0	0 (0.00)
Gingival bleeding	1	1 (2.08)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.08)	1	1 (2.08)
Haematemesis	1	1 (2.08)	0	0 (0.00)
Lip dry	1	1 (2.08)	0	0 (0.00)
Lip oedema	1	1 (2.08)	0	0 (0.00)
Mouth swelling	1	1 (2.08)	0	0 (0.00)
Neutropenic colitis	1	1 (2.08)	1	1 (2.08)
Odynophagia	1	1 (2.08)	0	0 (0.00)
Pancreatitis	1	1 (2.08)	0	0 (0.00)
Proctalgia	1	1 (2.08)	1	1 (2.08)
Trichoglossia	1	1 (2.08)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
General disorders and administration site conditions				
- Total	65	20 (41.67)	8	3 (6.25)
Pyrexia	24	11 (22.92)	4	3 (6.25)
Chills	7	4 (8.33)	0	0 (0.00)
Fatigue	6	6 (12.50)	0	0 (0.00)
Face oedema	5	4 (8.33)	0	0 (0.00)
Catheter site pain	3	1 (2.08)	2	1 (2.08)
Asthenia	2	2 (4.17)	0	0 (0.00)
Catheter site erythema	2	1 (2.08)	0	0 (0.00)
Generalised oedema	2	2 (4.17)	0	0 (0.00)
Influenza like illness	2	2 (4.17)	0	0 (0.00)
Oedema peripheral	2	2 (4.17)	0	0 (0.00)
Chest discomfort	1	1 (2.08)	1	1 (2.08)
Crying	1	1 (2.08)	0	0 (0.00)
Facial pain	1	1 (2.08)	0	0 (0.00)
Localised oedema	1	1 (2.08)	0	0 (0.00)
Malaise	1	1 (2.08)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.08)	0	0 (0.00)
Pain	1	1 (2.08)	1	1 (2.08)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Sluggishness	1	1 (2.08)	0	0 (0.00)
Swelling face	1	1 (2.08)	0	0 (0.00)
Vascular device occlusion	1	1 (2.08)	0	0 (0.00)
Hepatobiliary disorders				
- Total	11	7 (14.58)	3	2 (4.17)
Hepatic function abnormal	6	2 (4.17)	3	2 (4.17)
Hepatomegaly	2	2 (4.17)	0	0 (0.00)
Hyperbilirubinaemia	2	2 (4.17)	0	0 (0.00)
Cholelithiasis	1	1 (2.08)	0	0 (0.00)
Immune system disorders				
- Total	91	41 (85.42)	36	27 (56.25)
Cytokine release syndrome	72	37 (77.08)	28	23 (47.92)
Hypogammaglobulinaemia	14	14 (29.17)	5	5 (10.42)
Haemophagocytic lymphohistiocytosis	2	2 (4.17)	1	1 (2.08)
Immunodeficiency	2	2 (4.17)	2	2 (4.17)
Hypersensitivity	1	1 (2.08)	0	0 (0.00)
Infections and infestations				
- Total	42	23 (47.92)	22	13 (27.08)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Candida infection	3	2 (4.17)	2	1 (2.08)
Conjunctivitis	3	3 (6.25)	0	0 (0.00)
Nail infection	2	2 (4.17)	0	0 (0.00)
Oral candidiasis	2	1 (2.08)	0	0 (0.00)
Oral herpes	2	2 (4.17)	1	1 (2.08)
Oral infection	2	2 (4.17)	0	0 (0.00)
Staphylococcal infection	2	2 (4.17)	2	2 (4.17)
Adenovirus infection	1	1 (2.08)	1	1 (2.08)
Anal abscess	1	1 (2.08)	1	1 (2.08)
BK virus infection	1	1 (2.08)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (2.08)	1	1 (2.08)
Cholecystitis infective	1	1 (2.08)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.08)	1	1 (2.08)
Encephalitis viral	1	1 (2.08)	1	1 (2.08)
Gastroenteritis norovirus	1	1 (2.08)	0	0 (0.00)
Gingivitis	1	1 (2.08)	0	0 (0.00)
Granulicatella infection	1	1 (2.08)	1	1 (2.08)
Herpes simplex	1	1 (2.08)	1	1 (2.08)
Human herpesvirus 6 infection	1	1 (2.08)	1	1 (2.08)
Klebsiella infection	1	1 (2.08)	1	1 (2.08)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Myringitis	1	1 (2.08)	0	0 (0.00)
Otitis externa	1	1 (2.08)	0	0 (0.00)
Paronychia	1	1 (2.08)	0	0 (0.00)
Pneumonia	1	1 (2.08)	1	1 (2.08)
Pneumonia fungal	1	1 (2.08)	1	1 (2.08)
Pneumonia viral	1	1 (2.08)	1	1 (2.08)
Rhinovirus infection	1	1 (2.08)	0	0 (0.00)
Sinusitis	1	1 (2.08)	1	1 (2.08)
Soft tissue infection	1	1 (2.08)	1	1 (2.08)
Staphylococcal bacteraemia	1	1 (2.08)	1	1 (2.08)
Stomatococcal infection	1	1 (2.08)	0	0 (0.00)
Systemic candida	1	1 (2.08)	1	1 (2.08)
Varicella zoster virus infection	1	1 (2.08)	1	1 (2.08)
Injury, poisoning and procedural complications				
- Total	7	5 (10.42)	1	1 (2.08)
Fall	2	2 (4.17)	0	0 (0.00)
Infusion related reaction	2	1 (2.08)	0	0 (0.00)
Procedural pain	1	1 (2.08)	0	0 (0.00)
Transfusion reaction	1	1 (2.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Transplant failure	1	1 (2.08)	1	1 (2.08)
Investigations				
- Total	217	36 (75.00)	118	24 (50.00)
Platelet count decreased	46	13 (27.08)	30	10 (20.83)
White blood cell count decreased	26	13 (27.08)	21	10 (20.83)
Lymphocyte count decreased	25	10 (20.83)	20	9 (18.75)
Neutrophil count decreased	23	13 (27.08)	20	11 (22.92)
Alanine aminotransferase increased	19	13 (27.08)	4	4 (8.33)
Aspartate aminotransferase increased	17	10 (20.83)	6	4 (8.33)
Blood bilirubin increased	6	5 (10.42)	4	4 (8.33)
Immunoglobulins decreased	5	2 (4.17)	0	0 (0.00)
Activated partial thromboplastin time prolonged	4	3 (6.25)	1	1 (2.08)
Blood fibrinogen decreased	4	4 (8.33)	1	1 (2.08)
Blood immunoglobulin A decreased	4	4 (8.33)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (8.33)	0	0 (0.00)
International normalised ratio increased	4	3 (6.25)	0	0 (0.00)
Serum ferritin increased	4	4 (8.33)	1	1 (2.08)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Blood creatine phosphokinase increased	3	1 (2.08)	1	1 (2.08)
Blood lactate dehydrogenase increased	3	3 (6.25)	0	0 (0.00)
C-reactive protein increased	3	3 (6.25)	2	2 (4.17)
Blood glucose increased	2	1 (2.08)	2	1 (2.08)
Haemoglobin decreased	2	1 (2.08)	1	1 (2.08)
Weight increased	2	2 (4.17)	1	1 (2.08)
Blood creatinine increased	1	1 (2.08)	1	1 (2.08)
Blood testosterone decreased	1	1 (2.08)	0	0 (0.00)
Blood uric acid increased	1	1 (2.08)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.08)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.08)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (2.08)	1	1 (2.08)
Enterovirus test positive	1	1 (2.08)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.08)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (2.08)	1	1 (2.08)
Prothrombin time prolonged	1	1 (2.08)	0	0 (0.00)
Weight decreased	1	1 (2.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Metabolism and nutrition disorders				
- Total	93	25 (52.08)	33	16 (33.33)
Hypokalaemia	22	11 (22.92)	10	7 (14.58)
Hypophosphataemia	20	10 (20.83)	7	5 (10.42)
Decreased appetite	14	14 (29.17)	7	7 (14.58)
Hypoalbuminaemia	11	5 (10.42)	0	0 (0.00)
Hypocalcaemia	8	6 (12.50)	2	2 (4.17)
Hypomagnesaemia	4	3 (6.25)	0	0 (0.00)
Hyperglycaemia	3	3 (6.25)	2	2 (4.17)
Hypermagnesaemia	2	1 (2.08)	0	0 (0.00)
Tumour lysis syndrome	2	2 (4.17)	2	2 (4.17)
Hypernatraemia	1	1 (2.08)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (2.08)	1	1 (2.08)
Hyperuricaemia	1	1 (2.08)	0	0 (0.00)
Hypervolaemia	1	1 (2.08)	0	0 (0.00)
Hyponatraemia	1	1 (2.08)	0	0 (0.00)
Malnutrition	1	1 (2.08)	1	1 (2.08)
Polydipsia	1	1 (2.08)	1	1 (2.08)
Musculoskeletal and connective tissue disorders				

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
- Total	35	20 (41.67)	2	2 (4.17)
Pain in extremity	9	9 (18.75)	0	0 (0.00)
Arthralgia	8	8 (16.67)	0	0 (0.00)
Myalgia	6	5 (10.42)	0	0 (0.00)
Back pain	5	5 (10.42)	1	1 (2.08)
Bone pain	3	1 (2.08)	0	0 (0.00)
Pain in jaw	2	2 (4.17)	1	1 (2.08)
Musculoskeletal chest pain	1	1 (2.08)	0	0 (0.00)
Neck pain	1	1 (2.08)	0	0 (0.00)
Nervous system disorders				
- Total	39	21 (43.75)	5	4 (8.33)
Headache	12	12 (25.00)	2	2 (4.17)
Encephalopathy	4	4 (8.33)	1	1 (2.08)
Tremor	4	3 (6.25)	0	0 (0.00)
Dizziness	3	3 (6.25)	0	0 (0.00)
Dysgeusia	2	2 (4.17)	0	0 (0.00)
Hyperaesthesia	2	1 (2.08)	0	0 (0.00)
Lethargy	2	2 (4.17)	0	0 (0.00)
Somnolence	2	2 (4.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Amnesia	1	1 (2.08)	0	0 (0.00)
Aphasia	1	1 (2.08)	0	0 (0.00)
Cognitive disorder	1	1 (2.08)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.08)	1	1 (2.08)
Disturbance in attention	1	1 (2.08)	0	0 (0.00)
Hypoaesthesia	1	1 (2.08)	0	0 (0.00)
Neuralgia	1	1 (2.08)	0	0 (0.00)
Seizure	1	1 (2.08)	1	1 (2.08)
Psychiatric disorders				
- Total	27	17 (35.42)	1	1 (2.08)
Anxiety	5	5 (10.42)	1	1 (2.08)
Confusional state	4	4 (8.33)	0	0 (0.00)
Hallucination	3	3 (6.25)	0	0 (0.00)
Insomnia	3	3 (6.25)	0	0 (0.00)
Agitation	2	2 (4.17)	0	0 (0.00)
Delirium	2	2 (4.17)	0	0 (0.00)
Irritability	2	2 (4.17)	0	0 (0.00)
Sleep disorder	2	1 (2.08)	0	0 (0.00)
Affect lability	1	1 (2.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hallucination, visual	1	1 (2.08)	0	0 (0.00)
Restlessness	1	1 (2.08)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.08)	0	0 (0.00)
Renal and urinary disorders				
- Total	16	10 (20.83)	2	2 (4.17)
Acute kidney injury	3	3 (6.25)	1	1 (2.08)
Dysuria	2	2 (4.17)	0	0 (0.00)
Haematuria	2	2 (4.17)	0	0 (0.00)
Urinary incontinence	2	1 (2.08)	0	0 (0.00)
Anuria	1	1 (2.08)	1	1 (2.08)
Incontinence	1	1 (2.08)	0	0 (0.00)
Pollakiuria	1	1 (2.08)	0	0 (0.00)
Proteinuria	1	1 (2.08)	0	0 (0.00)
Renal failure	1	1 (2.08)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.08)	0	0 (0.00)
Urinary tract disorder	1	1 (2.08)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Vaginal haemorrhage	2	1 (2.08)	0	0 (0.00)
Female genital tract fistula	1	1 (2.08)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.08)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	64	24 (50.00)	20	10 (20.83)
Hypoxia	11	8 (16.67)	8	5 (10.42)
Cough	8	7 (14.58)	0	0 (0.00)
Pulmonary oedema	6	6 (12.50)	4	4 (8.33)
Tachypnoea	5	5 (10.42)	1	1 (2.08)
Oropharyngeal pain	4	3 (6.25)	0	0 (0.00)
Pleural effusion	4	4 (8.33)	1	1 (2.08)
Epistaxis	3	3 (6.25)	1	1 (2.08)
Atelectasis	2	2 (4.17)	1	1 (2.08)
Dyspnoea	2	2 (4.17)	2	2 (4.17)
Lung infiltration	2	1 (2.08)	1	1 (2.08)
Nasal congestion	2	2 (4.17)	0	0 (0.00)
Rhinorrhoea	2	2 (4.17)	0	0 (0.00)
Bradypnoea	1	1 (2.08)	1	1 (2.08)
Nasal dryness	1	1 (2.08)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Oropharyngeal plaque	1	1 (2.08)	0	0 (0.00)
Painful respiration	1	1 (2.08)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.08)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.08)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.08)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.08)	0	0 (0.00)
Productive cough	1	1 (2.08)	0	0 (0.00)
Pulmonary mass	1	1 (2.08)	0	0 (0.00)
Respiratory disorder	1	1 (2.08)	0	0 (0.00)
Respiratory distress	1	1 (2.08)	0	0 (0.00)
Wheezing	1	1 (2.08)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	33	17 (35.42)	2	2 (4.17)
Pruritus	4	3 (6.25)	0	0 (0.00)
Rash papular	4	3 (6.25)	0	0 (0.00)
Rash	3	3 (6.25)	0	0 (0.00)
Rash maculo-papular	3	2 (4.17)	1	1 (2.08)
Dermatitis atopic	2	2 (4.17)	0	0 (0.00)
Erythema	2	2 (4.17)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=48** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=48** **n (%)[2]**
Rash vesicular	2	1 (2.08)	0	0 (0.00)
Blister	1	1 (2.08)	0	0 (0.00)
Dry skin	1	1 (2.08)	0	0 (0.00)
Eczema	1	1 (2.08)	0	0 (0.00)
Erythema nodosum	1	1 (2.08)	0	0 (0.00)
Hyperhidrosis	1	1 (2.08)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.08)	0	0 (0.00)
Pruritus allergic	1	1 (2.08)	0	0 (0.00)
Purpura	1	1 (2.08)	0	0 (0.00)
Rash pruritic	1	1 (2.08)	0	0 (0.00)
Skin lesion	1	1 (2.08)	0	0 (0.00)
Skin ulcer	1	1 (2.08)	0	0 (0.00)
Urticaria	1	1 (2.08)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.08)	1	1 (2.08)
Social circumstances				
- Total	1	1 (2.08)	0	0 (0.00)
Patient uncooperative	1	1 (2.08)	0	0 (0.00)
Vascular disorders				

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
- Total	20	15 (31.25)	7	7 (14.58)
Hypotension	10	9 (18.75)	5	5 (10.42)
Hypertension	6	6 (12.50)	1	1 (2.08)
Capillary leak syndrome	2	2 (4.17)	1	1 (2.08)
Flushing	1	1 (2.08)	0	0 (0.00)
Hot flush	1	1 (2.08)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	788	31 (96.88)	298	25 (78.13)
Blood and lymphatic system disorders				
- Total	50	21 (65.63)	27	17 (53.13)
Anaemia	17	8 (25.00)	2	1 (3.13)
Febrile neutropenia	14	12 (37.50)	14	12 (37.50)
Neutropenia	5	4 (12.50)	4	3 (9.38)
Disseminated intravascular coagulation	4	4 (12.50)	2	2 (6.25)
Thrombocytopenia	4	4 (12.50)	4	4 (12.50)
Coagulopathy	3	3 (9.38)	1	1 (3.13)
Splenomegaly	2	2 (6.25)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (3.13)	0	0 (0.00)
Cardiac disorders				
- Total	28	14 (43.75)	7	5 (15.63)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Tachycardia	15	10 (31.25)	2	2 (6.25)
Cardiac failure	4	1 (3.13)	2	1 (3.13)
Bradycardia	2	2 (6.25)	0	0 (0.00)
Sinus tachycardia	2	2 (6.25)	0	0 (0.00)
Atrioventricular block first degree	1	1 (3.13)	0	0 (0.00)
Cardiac arrest	1	1 (3.13)	1	1 (3.13)
Cardiac dysfunction	1	1 (3.13)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.13)	1	1 (3.13)
Sinus bradycardia	1	1 (3.13)	1	1 (3.13)
Ear and labyrinth disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Ear pruritus	1	1 (3.13)	0	0 (0.00)
Endocrine disorders				
- Total	3	3 (9.38)	0	0 (0.00)
Adrenal insufficiency	3	3 (9.38)	0	0 (0.00)
Eye disorders				
- Total	6	4 (12.50)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (6.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Ocular hyperaemia	2	2 (6.25)	0	0 (0.00)
Eyelid oedema	1	1 (3.13)	0	0 (0.00)
Periorbital oedema	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	41	19 (59.38)	7	7 (21.88)
Vomiting	8	7 (21.88)	1	1 (3.13)
Constipation	6	6 (18.75)	0	0 (0.00)
Nausea	6	6 (18.75)	1	1 (3.13)
Diarrhoea	5	3 (9.38)	0	0 (0.00)
Pancreatitis	3	3 (9.38)	1	1 (3.13)
Abdominal pain	2	2 (6.25)	0	0 (0.00)
Mouth haemorrhage	2	2 (6.25)	1	1 (3.13)
Abdominal compartment syndrome	1	1 (3.13)	1	1 (3.13)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Anal fissure	1	1 (3.13)	0	0 (0.00)
Ascites	1	1 (3.13)	0	0 (0.00)
Dry mouth	1	1 (3.13)	0	0 (0.00)
Dysphagia	1	1 (3.13)	1	1 (3.13)
Gingival erythema	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Ileus	1	1 (3.13)	0	0 (0.00)
Melaena	1	1 (3.13)	1	1 (3.13)
General disorders and administration site conditions				
- Total	47	20 (62.50)	11	8 (25.00)
Pyrexia	20	13 (40.63)	5	5 (15.63)
Fatigue	5	5 (15.63)	0	0 (0.00)
Oedema peripheral	5	4 (12.50)	2	1 (3.13)
Face oedema	4	4 (12.50)	1	1 (3.13)
Generalised oedema	3	3 (9.38)	0	0 (0.00)
Chills	2	2 (6.25)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (6.25)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (6.25)	2	2 (6.25)
Catheter site haemorrhage	1	1 (3.13)	0	0 (0.00)
Catheter site pain	1	1 (3.13)	0	0 (0.00)
Localised oedema	1	1 (3.13)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.13)	1	1 (3.13)
Hepatobiliary disorders				
- Total	18	10 (31.25)	4	4 (12.50)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hepatic function abnormal	5	3 (9.38)	1	1 (3.13)
Hyperbilirubinaemia	4	3 (9.38)	1	1 (3.13)
Gallbladder enlargement	2	2 (6.25)	0	0 (0.00)
Hypertransaminasaemia	2	2 (6.25)	0	0 (0.00)
Biliary tract disorder	1	1 (3.13)	0	0 (0.00)
Cholelithiasis	1	1 (3.13)	0	0 (0.00)
Cholestasis	1	1 (3.13)	1	1 (3.13)
Hepatomegaly	1	1 (3.13)	1	1 (3.13)
Ocular icterus	1	1 (3.13)	0	0 (0.00)
Immune system disorders				
- Total	73	26 (81.25)	32	16 (50.00)
Cytokine release syndrome	56	24 (75.00)	27	15 (46.88)
Hypogammaglobulinaemia	11	9 (28.13)	2	2 (6.25)
Haemophagocytic lymphohistiocytosis	3	3 (9.38)	2	2 (6.25)
Immunodeficiency	1	1 (3.13)	1	1 (3.13)
Seasonal allergy	1	1 (3.13)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (3.13)	0	0 (0.00)
Infections and infestations				

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	22	12 (37.50)	9	6 (18.75)
Clostridium difficile infection	3	3 (9.38)	2	2 (6.25)
Conjunctivitis	3	2 (6.25)	0	0 (0.00)
Staphylococcal bacteraemia	3	2 (6.25)	3	2 (6.25)
Staphylococcal infection	3	3 (9.38)	0	0 (0.00)
Atypical pneumonia	1	1 (3.13)	0	0 (0.00)
Bacteraemia	1	1 (3.13)	1	1 (3.13)
Candida infection	1	1 (3.13)	0	0 (0.00)
Encephalitis	1	1 (3.13)	1	1 (3.13)
Encephalitis viral	1	1 (3.13)	1	1 (3.13)
Klebsiella bacteraemia	1	1 (3.13)	0	0 (0.00)
Localised infection	1	1 (3.13)	0	0 (0.00)
Meningitis bacterial	1	1 (3.13)	1	1 (3.13)
Rhinovirus infection	1	1 (3.13)	0	0 (0.00)
Urinary tract infection viral	1	1 (3.13)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	13	6 (18.75)	2	1 (3.13)
Wound	3	2 (6.25)	1	1 (3.13)
Contusion	2	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Infusion related reaction	1	1 (3.13)	0	0 (0.00)
Procedural pain	1	1 (3.13)	0	0 (0.00)
Scratch	1	1 (3.13)	0	0 (0.00)
Skin abrasion	1	1 (3.13)	0	0 (0.00)
Skin injury	1	1 (3.13)	0	0 (0.00)
Skin wound	1	1 (3.13)	0	0 (0.00)
Transfusion reaction	1	1 (3.13)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.13)	1	1 (3.13)
Investigations				
- Total	169	21 (65.63)	79	21 (65.63)
Neutrophil count decreased	25	7 (21.88)	18	6 (18.75)
White blood cell count decreased	24	11 (34.38)	15	8 (25.00)
Platelet count decreased	19	8 (25.00)	8	4 (12.50)
Aspartate aminotransferase increased	16	9 (28.13)	7	7 (21.88)
Blood bilirubin increased	12	7 (21.88)	5	5 (15.63)
International normalised ratio increased	8	6 (18.75)	0	0 (0.00)
Alanine aminotransferase increased	7	5 (15.63)	2	2 (6.25)
Blood creatinine increased	5	3 (9.38)	4	2 (6.25)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Electrocardiogram QT prolonged	5	4 (12.50)	1	1 (3.13)
Lymphocyte count decreased	5	5 (15.63)	4	4 (12.50)
Activated partial thromboplastin time prolonged	4	3 (9.38)	0	0 (0.00)
Lipase increased	4	2 (6.25)	2	1 (3.13)
Serum ferritin increased	4	4 (12.50)	1	1 (3.13)
Blood fibrinogen decreased	3	3 (9.38)	1	1 (3.13)
Urine output decreased	3	2 (6.25)	3	2 (6.25)
Blood immunoglobulin G decreased	2	2 (6.25)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (6.25)	1	1 (3.13)
Fibrin D dimer increased	2	2 (6.25)	1	1 (3.13)
Weight increased	2	2 (6.25)	0	0 (0.00)
Amylase increased	1	1 (3.13)	0	0 (0.00)
Bacterial test positive	1	1 (3.13)	1	1 (3.13)
Blood alkaline phosphatase increased	1	1 (3.13)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.13)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (3.13)	1	1 (3.13)
Blood immunoglobulin A decreased	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (3.13)	1	1 (3.13)
Blood phosphorus increased	1	1 (3.13)	0	0 (0.00)
Blood uric acid increased	1	1 (3.13)	0	0 (0.00)
C-reactive protein increased	1	1 (3.13)	1	1 (3.13)
Cardiac murmur	1	1 (3.13)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (3.13)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (3.13)	1	1 (3.13)
Haptoglobin decreased	1	1 (3.13)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.13)	0	0 (0.00)
Staphylococcus test positive	1	1 (3.13)	0	0 (0.00)
Troponin increased	1	1 (3.13)	1	1 (3.13)
Metabolism and nutrition disorders				
- Total	117	21 (65.63)	43	13 (40.63)
Hypokalaemia	18	8 (25.00)	10	4 (12.50)
Hypocalcaemia	16	10 (31.25)	4	3 (9.38)
Hypophosphataemia	11	7 (21.88)	4	4 (12.50)
Decreased appetite	10	10 (31.25)	4	4 (12.50)
Hyperglycaemia	8	5 (15.63)	2	2 (6.25)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Hyperuricaemia	8	6 (18.75)	1	1 (3.13)
Hypoalbuminaemia	8	6 (18.75)	1	1 (3.13)
Hyperphosphataemia	5	5 (15.63)	1	1 (3.13)
Hypervolaemia	5	5 (15.63)	4	4 (12.50)
Hypercalcaemia	4	3 (9.38)	2	2 (6.25)
Acidosis	3	2 (6.25)	2	2 (6.25)
Hypomagnesaemia	3	3 (9.38)	0	0 (0.00)
Metabolic acidosis	3	3 (9.38)	2	2 (6.25)
Hyperkalaemia	2	2 (6.25)	2	2 (6.25)
Hyponatraemia	2	2 (6.25)	0	0 (0.00)
Tumour lysis syndrome	2	2 (6.25)	2	2 (6.25)
Calcium deficiency	1	1 (3.13)	0	0 (0.00)
Dehydration	1	1 (3.13)	0	0 (0.00)
Haemosiderosis	1	1 (3.13)	0	0 (0.00)
Hyperchloraemia	1	1 (3.13)	0	0 (0.00)
Hyperlactacidaemia	1	1 (3.13)	0	0 (0.00)
Hypermagnesaemia	1	1 (3.13)	0	0 (0.00)
Hypernatraemia	1	1 (3.13)	1	1 (3.13)
Hypertriglyceridaemia	1	1 (3.13)	1	1 (3.13)
Hypoglycaemia	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	18	13 (40.63)	4	3 (9.38)
Myalgia	4	4 (12.50)	0	0 (0.00)
Arthralgia	2	2 (6.25)	1	1 (3.13)
Back pain	2	1 (3.13)	0	0 (0.00)
Muscular weakness	2	2 (6.25)	1	1 (3.13)
Pain in extremity	2	2 (6.25)	0	0 (0.00)
Bone pain	1	1 (3.13)	0	0 (0.00)
Haemarthrosis	1	1 (3.13)	1	1 (3.13)
Muscle rigidity	1	1 (3.13)	0	0 (0.00)
Muscle spasms	1	1 (3.13)	0	0 (0.00)
Myositis	1	1 (3.13)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.13)	1	1 (3.13)
Nervous system disorders				
- Total	38	19 (59.38)	9	6 (18.75)
Headache	14	11 (34.38)	0	0 (0.00)
Cognitive disorder	4	2 (6.25)	1	1 (3.13)
Encephalopathy	4	4 (12.50)	3	3 (9.38)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Somnolence	3	3 (9.38)	2	2 (6.25)
Tremor	3	3 (9.38)	0	0 (0.00)
Seizure	2	1 (3.13)	0	0 (0.00)
Cerebral haemorrhage	1	1 (3.13)	1	1 (3.13)
Dysarthria	1	1 (3.13)	1	1 (3.13)
Dysgeusia	1	1 (3.13)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (3.13)	0	0 (0.00)
Lethargy	1	1 (3.13)	0	0 (0.00)
Monoparesis	1	1 (3.13)	0	0 (0.00)
Neurological decompensation	1	1 (3.13)	1	1 (3.13)
Paraesthesia	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	20	11 (34.38)	5	5 (15.63)
Delirium	5	5 (15.63)	3	3 (9.38)
Agitation	4	3 (9.38)	0	0 (0.00)
Confusional state	3	3 (9.38)	0	0 (0.00)
Mental status changes	3	3 (9.38)	1	1 (3.13)
Anxiety	1	1 (3.13)	1	1 (3.13)
Automatism	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Insomnia	1	1 (3.13)	0	0 (0.00)
Irritability	1	1 (3.13)	0	0 (0.00)
Sleep disorder	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				
- Total	23	10 (31.25)	11	7 (21.88)
Acute kidney injury	11	6 (18.75)	7	6 (18.75)
Renal failure	3	1 (3.13)	3	1 (3.13)
Urinary retention	2	2 (6.25)	0	0 (0.00)
Anuria	1	1 (3.13)	0	0 (0.00)
Azotaemia	1	1 (3.13)	0	0 (0.00)
Bladder dilatation	1	1 (3.13)	0	0 (0.00)
Dysuria	1	1 (3.13)	0	0 (0.00)
Micturition urgency	1	1 (3.13)	0	0 (0.00)
Pollakiuria	1	1 (3.13)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.13)	1	1 (3.13)
Reproductive system and breast disorders				
- Total	2	2 (6.25)	1	1 (3.13)
Perineal rash	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Vaginal ulceration	1	1 (3.13)	1	1 (3.13)
Respiratory, thoracic and mediastinal disorders				
- Total	50	17 (53.13)	30	13 (40.63)
Hypoxia	12	9 (28.13)	10	7 (21.88)
Pulmonary oedema	6	6 (18.75)	3	3 (9.38)
Respiratory failure	4	4 (12.50)	4	4 (12.50)
Tachypnoea	4	3 (9.38)	3	3 (9.38)
Atelectasis	3	1 (3.13)	1	1 (3.13)
Cough	3	3 (9.38)	0	0 (0.00)
Pleural effusion	3	3 (9.38)	2	2 (6.25)
Respiratory distress	3	2 (6.25)	2	1 (3.13)
Acute respiratory distress syndrome	2	2 (6.25)	2	2 (6.25)
Oropharyngeal pain	2	2 (6.25)	0	0 (0.00)
Acute respiratory failure	1	1 (3.13)	1	1 (3.13)
Dyspnoea	1	1 (3.13)	1	1 (3.13)
Epistaxis	1	1 (3.13)	0	0 (0.00)
Haemoptysis	1	1 (3.13)	0	0 (0.00)
Nasal congestion	1	1 (3.13)	0	0 (0.00)
Nasal discomfort	1	1 (3.13)	0	0 (0.00)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Pharyngeal haemorrhage	1	1 (3.13)	0	0 (0.00)
Respiratory acidosis	1	1 (3.13)	1	1 (3.13)
Skin and subcutaneous tissue disorders				
- Total	23	10 (31.25)	2	1 (3.13)
Blister	5	2 (6.25)	0	0 (0.00)
Pruritus	3	3 (9.38)	0	0 (0.00)
Erythema	2	2 (6.25)	0	0 (0.00)
Hyperhidrosis	2	2 (6.25)	0	0 (0.00)
Petechiae	2	2 (6.25)	1	1 (3.13)
Rash	2	2 (6.25)	0	0 (0.00)
Decubitus ulcer	1	1 (3.13)	0	0 (0.00)
Dermatitis	1	1 (3.13)	0	0 (0.00)
Dermatitis diaper	1	1 (3.13)	0	0 (0.00)
Scab	1	1 (3.13)	0	0 (0.00)
Skin discolouration	1	1 (3.13)	0	0 (0.00)
Skin necrosis	1	1 (3.13)	1	1 (3.13)
Skin ulcer	1	1 (3.13)	0	0 (0.00)
Surgical and medical procedures				

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
- Total	1	1 (3.13)	1	1 (3.13)
Thrombolysis	1	1 (3.13)	1	1 (3.13)
Vascular disorders				
- Total	25	13 (40.63)	14	10 (31.25)
Hypotension	15	12 (37.50)	11	9 (28.13)
Hypertension	8	7 (21.88)	3	3 (9.38)
Peripheral ischaemia	1	1 (3.13)	0	0 (0.00)
Thrombosis	1	1 (3.13)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Total number of AE per patient	368	46 (95.83)	115	24 (50.00)
Blood and lymphatic system disorders				
- Total	27	12 (25.00)	14	7 (14.58)
Anaemia	11	5 (10.42)	3	1 (2.08)
Febrile neutropenia	4	3 (6.25)	4	3 (6.25)
Neutropenia	3	3 (6.25)	3	3 (6.25)
B-cell aplasia	2	1 (2.08)	0	0 (0.00)
Thrombocytopenia	2	2 (4.17)	2	2 (4.17)
Disseminated intravascular coagulation	1	1 (2.08)	1	1 (2.08)
Eosinophilia	1	1 (2.08)	0	0 (0.00)
Leukocytosis	1	1 (2.08)	0	0 (0.00)
Leukopenia	1	1 (2.08)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Lymphopenia	1	1 (2.08)	1	1 (2.08)
Cardiac disorders				
- Total	5	5 (10.42)	1	1 (2.08)
Tachycardia	2	2 (4.17)	0	0 (0.00)
Cardiac arrest	1	1 (2.08)	1	1 (2.08)
Left ventricular dysfunction	1	1 (2.08)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.08)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.25)	0	0 (0.00)
Cataract	2	2 (4.17)	0	0 (0.00)
Hypermetropia	1	1 (2.08)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.08)	0	0 (0.00)
Gastrointestinal disorders				
- Total	27	13 (27.08)	1	1 (2.08)
Vomiting	5	4 (8.33)	0	0 (0.00)
Constipation	4	3 (6.25)	0	0 (0.00)
Nausea	4	4 (8.33)	0	0 (0.00)
Diarrhoea	3	3 (6.25)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Pancreatitis	2	2 (4.17)	1	1 (2.08)
Abdominal pain	1	1 (2.08)	0	0 (0.00)
Abdominal pain upper	1	1 (2.08)	0	0 (0.00)
Abdominal rigidity	1	1 (2.08)	0	0 (0.00)
Dyspepsia	1	1 (2.08)	0	0 (0.00)
Enteritis	1	1 (2.08)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.08)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.08)	0	0 (0.00)
Proctalgia	1	1 (2.08)	0	0 (0.00)
Trichoglossia	1	1 (2.08)	0	0 (0.00)
General disorders and administration site conditions				
- Total	19	15 (31.25)	3	3 (6.25)
Pyrexia	11	10 (20.83)	2	2 (4.17)
Fatigue	4	4 (8.33)	0	0 (0.00)
Asthenia	1	1 (2.08)	0	0 (0.00)
Chills	1	1 (2.08)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.08)	0	0 (0.00)
Pain	1	1 (2.08)	1	1 (2.08)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hepatobiliary disorders				
- Total	2	2 (4.17)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.08)	0	0 (0.00)
Liver disorder	1	1 (2.08)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (27.08)	3	2 (4.17)
Hypogammaglobulinaemia	11	9 (18.75)	0	0 (0.00)
Graft versus host disease	2	2 (4.17)	2	2 (4.17)
Allergy to immunoglobulin therapy	1	1 (2.08)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.08)	0	0 (0.00)
Engraftment syndrome	1	1 (2.08)	1	1 (2.08)
Infections and infestations				
- Total	77	28 (58.33)	37	16 (33.33)
Nasopharyngitis	6	5 (10.42)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (2.08)	3	1 (2.08)
Upper respiratory tract infection	5	4 (8.33)	2	2 (4.17)
Gastroenteritis	4	4 (8.33)	2	2 (4.17)
Rhinovirus infection	4	4 (8.33)	1	1 (2.08)
Metapneumovirus infection	3	3 (6.25)	3	3 (6.25)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Parainfluenzae virus infection	3	2 (4.17)	2	2 (4.17)
Respiratory syncytial virus infection	3	3 (6.25)	2	2 (4.17)
Sinusitis	3	2 (4.17)	1	1 (2.08)
Bacteraemia	2	1 (2.08)	2	1 (2.08)
Klebsiella infection	2	1 (2.08)	2	1 (2.08)
Otitis media	2	2 (4.17)	1	1 (2.08)
Pneumocystis jirovecii pneumonia	2	2 (4.17)	2	2 (4.17)
Pneumonia	2	2 (4.17)	0	0 (0.00)
Respiratory tract infection	2	2 (4.17)	0	0 (0.00)
Rhinitis	2	2 (4.17)	0	0 (0.00)
Urinary tract infection	2	1 (2.08)	2	1 (2.08)
Viral infection	2	2 (4.17)	1	1 (2.08)
Coronavirus infection	1	1 (2.08)	1	1 (2.08)
Cystitis	1	1 (2.08)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.08)	1	1 (2.08)
Device related infection	1	1 (2.08)	1	1 (2.08)
Ear, nose and throat infection	1	1 (2.08)	0	0 (0.00)
Encephalitis	1	1 (2.08)	1	1 (2.08)
Enterobacter infection	1	1 (2.08)	1	1 (2.08)
Gastroenteritis viral	1	1 (2.08)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Gingivitis	1	1 (2.08)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.08)	1	1 (2.08)
Influenza	1	1 (2.08)	0	0 (0.00)
Mastoiditis	1	1 (2.08)	1	1 (2.08)
Oral candidiasis	1	1 (2.08)	0	0 (0.00)
Oral herpes	1	1 (2.08)	0	0 (0.00)
Otitis externa	1	1 (2.08)	1	1 (2.08)
Paronychia	1	1 (2.08)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.08)	0	0 (0.00)
Salmonellosis	1	1 (2.08)	0	0 (0.00)
Septic shock	1	1 (2.08)	1	1 (2.08)
Staphylococcal sepsis	1	1 (2.08)	1	1 (2.08)
Staphylococcal skin infection	1	1 (2.08)	0	0 (0.00)
Tinea pedis	1	1 (2.08)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (2.08)	1	1 (2.08)
Injury, poisoning and procedural complications				
- Total	8	7 (14.58)	0	0 (0.00)
Infusion related reaction	4	3 (6.25)	0	0 (0.00)
Contusion	1	1 (2.08)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Ligament sprain	1	1 (2.08)	0	0 (0.00)
Limb injury	1	1 (2.08)	0	0 (0.00)
Skin abrasion	1	1 (2.08)	0	0 (0.00)
Investigations				
- Total	61	19 (39.58)	28	11 (22.92)
Platelet count decreased	14	4 (8.33)	9	2 (4.17)
Neutrophil count decreased	12	7 (14.58)	8	5 (10.42)
White blood cell count decreased	10	6 (12.50)	2	2 (4.17)
Immunoglobulins decreased	5	1 (2.08)	0	0 (0.00)
Blood bilirubin increased	4	2 (4.17)	1	1 (2.08)
Alanine aminotransferase increased	3	2 (4.17)	1	1 (2.08)
Blood immunoglobulin A decreased	2	2 (4.17)	1	1 (2.08)
Blood uric acid increased	2	2 (4.17)	2	2 (4.17)
Lymphocyte count decreased	2	2 (4.17)	1	1 (2.08)
Blood creatinine increased	1	1 (2.08)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.08)	1	1 (2.08)
Blood urea increased	1	1 (2.08)	1	1 (2.08)
Bone density decreased	1	1 (2.08)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.08)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Oxygen saturation decreased	1	1 (2.08)	0	0 (0.00)
Weight decreased	1	1 (2.08)	1	1 (2.08)
Metabolism and nutrition disorders				
- Total	21	10 (20.83)	9	6 (12.50)
Hypokalaemia	6	3 (6.25)	4	2 (4.17)
Decreased appetite	4	4 (8.33)	1	1 (2.08)
Hyperuricaemia	2	2 (4.17)	0	0 (0.00)
Haemochromatosis	1	1 (2.08)	1	1 (2.08)
Hyperchloraemia	1	1 (2.08)	0	0 (0.00)
Hyperkalaemia	1	1 (2.08)	0	0 (0.00)
Hypervolaemia	1	1 (2.08)	1	1 (2.08)
Hypophagia	1	1 (2.08)	0	0 (0.00)
Hypophosphataemia	1	1 (2.08)	0	0 (0.00)
Iron overload	1	1 (2.08)	0	0 (0.00)
Malnutrition	1	1 (2.08)	1	1 (2.08)
Tumour lysis syndrome	1	1 (2.08)	1	1 (2.08)
Musculoskeletal and connective tissue disorders				
- Total	13	10 (20.83)	2	2 (4.17)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Back pain	4	4 (8.33)	1	1 (2.08)
Pain in extremity	3	3 (6.25)	1	1 (2.08)
Arthralgia	2	2 (4.17)	0	0 (0.00)
Bone pain	1	1 (2.08)	0	0 (0.00)
Growth retardation	1	1 (2.08)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.08)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.08)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (6.25)	1	1 (2.08)
Skin papilloma	2	2 (4.17)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.08)	1	1 (2.08)
Nervous system disorders				
- Total	16	9 (18.75)	6	2 (4.17)
Headache	7	6 (12.50)	0	0 (0.00)
Hydrocephalus	3	1 (2.08)	3	1 (2.08)
Dizziness	2	1 (2.08)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.08)	1	1 (2.08)
Cerebral haemorrhage	1	1 (2.08)	1	1 (2.08)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Memory impairment	1	1 (2.08)	0	0 (0.00)
Seizure	1	1 (2.08)	1	1 (2.08)
Psychiatric disorders				
- Total	11	6 (12.50)	1	1 (2.08)
Anxiety	3	3 (6.25)	0	0 (0.00)
Mental status changes	2	2 (4.17)	1	1 (2.08)
Agitation	1	1 (2.08)	0	0 (0.00)
Delirium	1	1 (2.08)	0	0 (0.00)
Mood altered	1	1 (2.08)	0	0 (0.00)
Nightmare	1	1 (2.08)	0	0 (0.00)
Sleep disorder	1	1 (2.08)	0	0 (0.00)
Tearfulness	1	1 (2.08)	0	0 (0.00)
Renal and urinary disorders				
- Total	4	4 (8.33)	2	2 (4.17)
Acute kidney injury	2	2 (4.17)	1	1 (2.08)
Cystitis haemorrhagic	1	1 (2.08)	0	0 (0.00)
Renal tubular disorder	1	1 (2.08)	1	1 (2.08)
Respiratory, thoracic and mediastinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
- Total	33	17 (35.42)	4	4 (8.33)
Cough	12	9 (18.75)	0	0 (0.00)
Nasal congestion	4	4 (8.33)	0	0 (0.00)
Rhinorrhoea	3	3 (6.25)	0	0 (0.00)
Dyspnoea	2	1 (2.08)	0	0 (0.00)
Epistaxis	2	2 (4.17)	0	0 (0.00)
Hypoxia	2	2 (4.17)	2	2 (4.17)
Pleural effusion	2	2 (4.17)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (2.08)	1	1 (2.08)
Bronchial oedema	1	1 (2.08)	0	0 (0.00)
Lung disorder	1	1 (2.08)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.08)	0	0 (0.00)
Respiratory distress	1	1 (2.08)	1	1 (2.08)
Rhinitis allergic	1	1 (2.08)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	17	11 (22.92)	1	1 (2.08)
Rash	5	3 (6.25)	0	0 (0.00)
Dry skin	4	3 (6.25)	0	0 (0.00)
Decubitus ulcer	1	1 (2.08)	1	1 (2.08)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Dermatitis allergic	1	1 (2.08)	0	0 (0.00)
Dermatitis atopic	1	1 (2.08)	0	0 (0.00)
Hangnail	1	1 (2.08)	0	0 (0.00)
Ingrowing nail	1	1 (2.08)	0	0 (0.00)
Night sweats	1	1 (2.08)	0	0 (0.00)
Skin discolouration	1	1 (2.08)	0	0 (0.00)
Skin swelling	1	1 (2.08)	0	0 (0.00)
Vascular disorders				
- Total	4	3 (6.25)	2	2 (4.17)
Hypotension	2	2 (4.17)	1	1 (2.08)
Hypertension	1	1 (2.08)	0	0 (0.00)
Venoocclusive disease	1	1 (2.08)	1	1 (2.08)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Total number of AE per patient	166	23 (85.19)	31	12 (44.44)
Blood and lymphatic system disorders				
- Total	5	5 (18.52)	3	3 (11.11)
Neutropenia	2	2 (7.41)	2	2 (7.41)
Anaemia	1	1 (3.70)	1	1 (3.70)
Lymphadenopathy	1	1 (3.70)	0	0 (0.00)
Lymphocytosis	1	1 (3.70)	0	0 (0.00)
Cardiac disorders				
- Total	3	2 (7.41)	3	2 (7.41)
Cardiac failure	2	2 (7.41)	2	2 (7.41)
Cardiac arrest	1	1 (3.70)	1	1 (3.70)
Endocrine disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	1	1 (3.70)	0	0 (0.00)
Hypothyroidism	1	1 (3.70)	0	0 (0.00)
Eye disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Visual impairment	1	1 (3.70)	0	0 (0.00)
Gastrointestinal disorders				
- Total	11	7 (25.93)	0	0 (0.00)
Diarrhoea	4	4 (14.81)	0	0 (0.00)
Vomiting	2	2 (7.41)	0	0 (0.00)
Abdominal pain	1	1 (3.70)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (3.70)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (3.70)	0	0 (0.00)
Nausea	1	1 (3.70)	0	0 (0.00)
Stomatitis	1	1 (3.70)	0	0 (0.00)
General disorders and administration site conditions				
- Total	12	9 (33.33)	0	0 (0.00)
Pyrexia	5	5 (18.52)	0	0 (0.00)
Fatigue	3	2 (7.41)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Oedema peripheral	2	1 (3.70)	0	0 (0.00)
Malaise	1	1 (3.70)	0	0 (0.00)
Pain	1	1 (3.70)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (3.70)	0	0 (0.00)
Hypertransaminasaemia	1	1 (3.70)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (11.11)	2	2 (7.41)
Allergy to immunoglobulin therapy	1	1 (3.70)	1	1 (3.70)
Hypogammaglobulinaemia	1	1 (3.70)	0	0 (0.00)
Immunodeficiency	1	1 (3.70)	1	1 (3.70)
Infections and infestations				
- Total	36	11 (40.74)	8	4 (14.81)
Upper respiratory tract infection	5	4 (14.81)	0	0 (0.00)
Ear infection	3	2 (7.41)	0	0 (0.00)
Nasopharyngitis	3	2 (7.41)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (7.41)	0	0 (0.00)
Acute sinusitis	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Adenovirus infection	1	1 (3.70)	1	1 (3.70)
BK virus infection	1	1 (3.70)	1	1 (3.70)
Bacteraemia	1	1 (3.70)	0	0 (0.00)
Cellulitis	1	1 (3.70)	0	0 (0.00)
Conjunctivitis	1	1 (3.70)	0	0 (0.00)
Gastroenteritis	1	1 (3.70)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (3.70)	0	0 (0.00)
Gastrointestinal infection	1	1 (3.70)	0	0 (0.00)
Herpes simplex	1	1 (3.70)	0	0 (0.00)
Herpes zoster	1	1 (3.70)	1	1 (3.70)
Molluscum contagiosum	1	1 (3.70)	0	0 (0.00)
Nail infection	1	1 (3.70)	0	0 (0.00)
Otitis externa	1	1 (3.70)	0	0 (0.00)
Otitis media	1	1 (3.70)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (3.70)	1	1 (3.70)
Pneumonia	1	1 (3.70)	1	1 (3.70)
Respiratory tract infection	1	1 (3.70)	0	0 (0.00)
Rhinovirus infection	1	1 (3.70)	0	0 (0.00)
Sinusitis	1	1 (3.70)	0	0 (0.00)
Sinusitis fungal	1	1 (3.70)	1	1 (3.70)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Staphylococcal bacteraemia	1	1 (3.70)	1	1 (3.70)
Viral upper respiratory tract infection	1	1 (3.70)	1	1 (3.70)
Injury, poisoning and procedural complications				
- Total	2	2 (7.41)	0	0 (0.00)
Fibula fracture	1	1 (3.70)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (3.70)	0	0 (0.00)
Investigations				
- Total	30	11 (40.74)	7	5 (18.52)
White blood cell count decreased	8	4 (14.81)	2	2 (7.41)
Neutrophil count decreased	7	3 (11.11)	3	2 (7.41)
Lymphocyte count decreased	4	2 (7.41)	1	1 (3.70)
Weight increased	3	1 (3.70)	1	1 (3.70)
Platelet count decreased	2	1 (3.70)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (3.70)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.70)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (3.70)	0	0 (0.00)
C-reactive protein increased	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Ejection fraction decreased	1	1 (3.70)	0	0 (0.00)
Heart sounds abnormal	1	1 (3.70)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	5	5 (18.52)	1	1 (3.70)
Decreased appetite	2	2 (7.41)	0	0 (0.00)
Hyperuricaemia	1	1 (3.70)	0	0 (0.00)
Metabolic acidosis	1	1 (3.70)	1	1 (3.70)
Metabolic syndrome	1	1 (3.70)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	9	5 (18.52)	1	1 (3.70)
Back pain	3	2 (7.41)	1	1 (3.70)
Pain in extremity	2	2 (7.41)	0	0 (0.00)
Arthralgia	1	1 (3.70)	0	0 (0.00)
Bone pain	1	1 (3.70)	0	0 (0.00)
Myalgia	1	1 (3.70)	0	0 (0.00)
Neck pain	1	1 (3.70)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
- Total	1	1 (3.70)	0	0 (0.00)
Cancer pain	1	1 (3.70)	0	0 (0.00)
Nervous system disorders				
- Total	7	5 (18.52)	0	0 (0.00)
Headache	4	4 (14.81)	0	0 (0.00)
Migraine	2	1 (3.70)	0	0 (0.00)
Extrapyramidal disorder	1	1 (3.70)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (14.81)	0	0 (0.00)
Anxiety	3	3 (11.11)	0	0 (0.00)
Persistent depressive disorder	1	1 (3.70)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	1 (3.70)	1	1 (3.70)
Acute kidney injury	1	1 (3.70)	0	0 (0.00)
Dysuria	1	1 (3.70)	0	0 (0.00)
Haematuria	1	1 (3.70)	1	1 (3.70)
Kidney enlargement	1	1 (3.70)	0	0 (0.00)
Renal mass	1	1 (3.70)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (3.70)	0	0 (0.00)
Dysmenorrhoea	2	1 (3.70)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	7 (25.93)	2	2 (7.41)
Nasal congestion	3	2 (7.41)	0	0 (0.00)
Cough	2	2 (7.41)	0	0 (0.00)
Oropharyngeal pain	2	2 (7.41)	0	0 (0.00)
Bronchospasm	1	1 (3.70)	0	0 (0.00)
Epistaxis	1	1 (3.70)	0	0 (0.00)
Hypoxia	1	1 (3.70)	1	1 (3.70)
Respiratory failure	1	1 (3.70)	1	1 (3.70)
Rhinitis allergic	1	1 (3.70)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (3.70)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	12	9 (33.33)	0	0 (0.00)
Dry skin	3	3 (11.11)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=27 n (%)[1]	Grade >= 3 Total events	All patients N=27 n (%)[2]
Pruritus	2	1 (3.70)	0	0 (0.00)
Eczema	1	1 (3.70)	0	0 (0.00)
Erythema	1	1 (3.70)	0	0 (0.00)
Ingrowing nail	1	1 (3.70)	0	0 (0.00)
Miliaria	1	1 (3.70)	0	0 (0.00)
Photosensitivity reaction	1	1 (3.70)	0	0 (0.00)
Rash	1	1 (3.70)	0	0 (0.00)
Skin hypopigmentation	1	1 (3.70)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (11.11)	3	3 (11.11)
Hypotension	2	2 (7.41)	2	2 (7.41)
Venoocclusive disease	1	1 (3.70)	1	1 (3.70)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Total number of AE per patient	154	24 (72.73)	38	14 (42.42)
Blood and lymphatic system disorders				
- Total	5	3 (9.09)	2	2 (6.06)
Agranulocytosis	1	1 (3.03)	1	1 (3.03)
Anaemia	1	1 (3.03)	0	0 (0.00)
Lymphadenopathy	1	1 (3.03)	0	0 (0.00)
Neutropenia	1	1 (3.03)	1	1 (3.03)
Thrombocytopenia	1	1 (3.03)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Deafness unilateral	1	1 (3.03)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (3.03)	0	0 (0.00)
Delayed puberty	1	1 (3.03)	0	0 (0.00)
Hypothyroidism	1	1 (3.03)	0	0 (0.00)
Eye disorders				
- Total	4	3 (9.09)	1	1 (3.03)
Dry eye	1	1 (3.03)	0	0 (0.00)
Eye pain	1	1 (3.03)	1	1 (3.03)
Eyelid oedema	1	1 (3.03)	0	0 (0.00)
Mydriasis	1	1 (3.03)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	4 (12.12)	1	1 (3.03)
Diarrhoea	4	4 (12.12)	1	1 (3.03)
Nausea	1	1 (3.03)	0	0 (0.00)
Vomiting	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=33** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=33** **n (%)[2]**
General disorders and administration site conditions				
- Total	10	7 (21.21)	1	1 (3.03)
Pyrexia	5	3 (9.09)	1	1 (3.03)
Pain	2	2 (6.06)	0	0 (0.00)
Fatigue	1	1 (3.03)	0	0 (0.00)
Non-cardiac chest pain	1	1 (3.03)	0	0 (0.00)
Xerosis	1	1 (3.03)	0	0 (0.00)
Immune system disorders				
- Total	5	5 (15.15)	1	1 (3.03)
Hypogammaglobulinaemia	2	2 (6.06)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.03)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.03)	1	1 (3.03)
Seasonal allergy	1	1 (3.03)	0	0 (0.00)
Infections and infestations				
- Total	57	17 (51.52)	13	10 (30.30)
Sinusitis	7	4 (12.12)	0	0 (0.00)
Upper respiratory tract infection	5	3 (9.09)	1	1 (3.03)
Conjunctivitis	4	3 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Fungal infection	3	2 (6.06)	0	0 (0.00)
Sepsis	3	3 (9.09)	3	3 (9.09)
COVID-19	2	1 (3.03)	1	1 (3.03)
Device related sepsis	2	1 (3.03)	2	1 (3.03)
Herpes zoster	2	2 (6.06)	1	1 (3.03)
Oral herpes	2	2 (6.06)	0	0 (0.00)
Otitis media	2	1 (3.03)	0	0 (0.00)
Skin infection	2	2 (6.06)	0	0 (0.00)
Urinary tract infection	2	2 (6.06)	0	0 (0.00)
Acute sinusitis	1	1 (3.03)	0	0 (0.00)
Bronchitis	1	1 (3.03)	0	0 (0.00)
Candida infection	1	1 (3.03)	0	0 (0.00)
Ear infection	1	1 (3.03)	1	1 (3.03)
Fungal skin infection	1	1 (3.03)	0	0 (0.00)
Gastroenteritis	1	1 (3.03)	0	0 (0.00)
Herpes virus infection	1	1 (3.03)	0	0 (0.00)
Influenza	1	1 (3.03)	0	0 (0.00)
Meningitis pneumococcal	1	1 (3.03)	1	1 (3.03)
Neutropenic infection	1	1 (3.03)	1	1 (3.03)
Ophthalmic herpes zoster	1	1 (3.03)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Oral candidiasis	1	1 (3.03)	0	0 (0.00)
Otitis media acute	1	1 (3.03)	0	0 (0.00)
Rhinitis	1	1 (3.03)	0	0 (0.00)
Rhinovirus infection	1	1 (3.03)	0	0 (0.00)
Septic shock	1	1 (3.03)	1	1 (3.03)
Staphylococcal abscess	1	1 (3.03)	1	1 (3.03)
Streptococcal sepsis	1	1 (3.03)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (3.03)	0	0 (0.00)
Varicella zoster virus infection	1	1 (3.03)	0	0 (0.00)
Viral skin infection	1	1 (3.03)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.03)	0	0 (0.00)
Ligament sprain	1	1 (3.03)	0	0 (0.00)
Investigations				
- Total	13	4 (12.12)	5	1 (3.03)
Neutrophil count decreased	8	3 (9.09)	5	1 (3.03)
Blood bilirubin increased	3	1 (3.03)	0	0 (0.00)
Platelet count decreased	2	2 (6.06)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=33 n (%)[1]	Grade >= 3 Total events	All patients N=33 n (%)[2]
Metabolism and nutrition disorders				
- Total	7	3 (9.09)	3	2 (6.06)
Decreased appetite	2	1 (3.03)	2	1 (3.03)
Iron overload	2	1 (3.03)	0	0 (0.00)
Hypercholesterolaemia	1	1 (3.03)	0	0 (0.00)
Hypernatraemia	1	1 (3.03)	1	1 (3.03)
Hypertriglyceridaemia	1	1 (3.03)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	7	6 (18.18)	0	0 (0.00)
Pain in extremity	2	2 (6.06)	0	0 (0.00)
Growth retardation	1	1 (3.03)	0	0 (0.00)
Joint effusion	1	1 (3.03)	0	0 (0.00)
Osteonecrosis	1	1 (3.03)	0	0 (0.00)
Osteopenia	1	1 (3.03)	0	0 (0.00)
Synovitis	1	1 (3.03)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (3.03)	1	1 (3.03)
Bone giant cell tumour benign	2	1 (3.03)	1	1 (3.03)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=33** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=33** **n (%)[2]**
Nervous system disorders				
- Total	8	3 (9.09)	3	2 (6.06)
Seizure	3	1 (3.03)	1	1 (3.03)
Headache	2	1 (3.03)	1	1 (3.03)
Nervous system disorder	2	1 (3.03)	1	1 (3.03)
Dysarthria	1	1 (3.03)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (9.09)	0	0 (0.00)
Anxiety	2	2 (6.06)	0	0 (0.00)
Tic	1	1 (3.03)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (3.03)	1	1 (3.03)
Endometriosis	2	1 (3.03)	1	1 (3.03)
Respiratory, thoracic and mediastinal disorders				
- Total	13	7 (21.21)	2	2 (6.06)
Cough	3	3 (9.09)	0	0 (0.00)
Rhinorrhoea	2	2 (6.06)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=33** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=33** **n (%)[2]**
Dyspnoea	1	1 (3.03)	0	0 (0.00)
Dyspnoea exertional	1	1 (3.03)	0	0 (0.00)
Epistaxis	1	1 (3.03)	0	0 (0.00)
Laryngeal oedema	1	1 (3.03)	1	1 (3.03)
Oropharyngeal pain	1	1 (3.03)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.03)	0	0 (0.00)
Respiratory failure	1	1 (3.03)	1	1 (3.03)
Sleep apnoea syndrome	1	1 (3.03)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	5 (15.15)	4	3 (9.09)
Rash macular	2	1 (3.03)	2	1 (3.03)
Dermatitis atopic	1	1 (3.03)	1	1 (3.03)
Dry skin	1	1 (3.03)	0	0 (0.00)
Eczema	1	1 (3.03)	1	1 (3.03)
Papule	1	1 (3.03)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (3.03)	0	0 (0.00)
Hypertension	1	1 (3.03)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Total number of AE per patient	66	8 (47.06)	25	5 (29.41)
Blood and lymphatic system disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Hypercoagulation	1	1 (5.88)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	3 (17.65)	0	0 (0.00)
Constipation	1	1 (5.88)	0	0 (0.00)
Diarrhoea	1	1 (5.88)	0	0 (0.00)
Irritable bowel syndrome	1	1 (5.88)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	2 (11.76)	1	1 (5.88)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Pyrexia	2	2 (11.76)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.88)	1	1 (5.88)
Immune system disorders				
- Total	5	4 (23.53)	2	1 (5.88)
Seasonal allergy	2	2 (11.76)	0	0 (0.00)
Chronic graft versus host disease	1	1 (5.88)	1	1 (5.88)
Haemophagocytic lymphohistiocytosis	1	1 (5.88)	1	1 (5.88)
Hypogammaglobulinaemia	1	1 (5.88)	0	0 (0.00)
Infections and infestations				
- Total	29	6 (35.29)	13	4 (23.53)
Rhinovirus infection	3	3 (17.65)	1	1 (5.88)
Gastroenteritis viral	2	1 (5.88)	0	0 (0.00)
Pneumonia	2	2 (11.76)	2	2 (11.76)
Sinusitis	2	2 (11.76)	0	0 (0.00)
Upper respiratory tract infection	2	2 (11.76)	0	0 (0.00)
Bronchiolitis	1	1 (5.88)	1	1 (5.88)
Bronchitis	1	1 (5.88)	0	0 (0.00)
COVID-19	1	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
COVID-19 pneumonia	1	1 (5.88)	1	1 (5.88)
Clostridium difficile colitis	1	1 (5.88)	1	1 (5.88)
Conjunctivitis	1	1 (5.88)	0	0 (0.00)
Enterovirus infection	1	1 (5.88)	1	1 (5.88)
Folliculitis	1	1 (5.88)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (5.88)	1	1 (5.88)
Gastroenteritis salmonella	1	1 (5.88)	1	1 (5.88)
Influenza	1	1 (5.88)	1	1 (5.88)
Nail infection	1	1 (5.88)	0	0 (0.00)
Otitis media	1	1 (5.88)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.88)	1	1 (5.88)
Pneumonia respiratory syncytial viral	1	1 (5.88)	1	1 (5.88)
Skin infection	1	1 (5.88)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (5.88)	1	1 (5.88)
Syphilis	1	1 (5.88)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (11.76)	1	1 (5.88)
Abdominal injury	1	1 (5.88)	0	0 (0.00)
Infusion related reaction	1	1 (5.88)	1	1 (5.88)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Investigations				
- Total	3	2 (11.76)	1	1 (5.88)
Blood immunoglobulin G decreased	1	1 (5.88)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.88)	1	1 (5.88)
SARS-CoV-2 test positive	1	1 (5.88)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	3 (17.65)	2	2 (11.76)
Hyperglycaemia	1	1 (5.88)	1	1 (5.88)
Hyperlipidaemia	1	1 (5.88)	0	0 (0.00)
Obesity	1	1 (5.88)	1	1 (5.88)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Arthralgia	1	1 (5.88)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Headache	1	1 (5.88)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	10	3 (17.65)	4	2 (11.76)
Dyspnoea	2	2 (11.76)	1	1 (5.88)
Tachypnoea	2	1 (5.88)	2	1 (5.88)
Cough	1	1 (5.88)	0	0 (0.00)
Hypoxia	1	1 (5.88)	1	1 (5.88)
Pleural effusion	1	1 (5.88)	0	0 (0.00)
Rhinorrhoea	1	1 (5.88)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (5.88)	0	0 (0.00)
Wheezing	1	1 (5.88)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	2 (11.76)	0	0 (0.00)
Rash	2	2 (11.76)	0	0 (0.00)
Rash erythematous	1	1 (5.88)	0	0 (0.00)
Rash maculo-papular	1	1 (5.88)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (5.88)	1	1 (5.88)
Hypertension	1	1 (5.88)	1	1 (5.88)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Total number of AE per patient	1485	48 (100.00)	474	44 (91.67)
Blood and lymphatic system disorders				
- Total	107	32 (66.67)	65	25 (52.08)
Anaemia	45	16 (33.33)	21	7 (14.58)
Febrile neutropenia	19	15 (31.25)	19	15 (31.25)
Neutropenia	10	7 (14.58)	9	6 (12.50)
Thrombocytopenia	7	5 (10.42)	6	5 (10.42)
Leukopenia	5	3 (6.25)	3	2 (4.17)
Disseminated intravascular coagulation	4	4 (8.33)	1	1 (2.08)
B-cell aplasia	3	1 (2.08)	0	0 (0.00)
Eosinophilia	3	1 (2.08)	0	0 (0.00)
Coagulopathy	2	2 (4.17)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Lymphopenia	2	2 (4.17)	2	2 (4.17)
Pancytopenia	2	2 (4.17)	2	2 (4.17)
Splenomegaly	2	2 (4.17)	0	0 (0.00)
Agranulocytosis	1	1 (2.08)	1	1 (2.08)
Leukocytosis	1	1 (2.08)	0	0 (0.00)
Lymphadenopathy	1	1 (2.08)	0	0 (0.00)
Cardiac disorders				
- Total	22	12 (25.00)	4	4 (8.33)
Tachycardia	9	7 (14.58)	1	1 (2.08)
Left ventricular dysfunction	3	3 (6.25)	2	2 (4.17)
Sinus tachycardia	2	1 (2.08)	0	0 (0.00)
Bradycardia	1	1 (2.08)	0	0 (0.00)
Cardiac arrest	1	1 (2.08)	1	1 (2.08)
Cardiac dysfunction	1	1 (2.08)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.08)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.08)	0	0 (0.00)
Pericardial effusion	1	1 (2.08)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.08)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Congenital, familial and genetic disorders				
- Total	1	1 (2.08)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.08)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (4.17)	0	0 (0.00)
Deafness unilateral	1	1 (2.08)	0	0 (0.00)
Ear pain	1	1 (2.08)	0	0 (0.00)
Endocrine disorders				
- Total	4	3 (6.25)	0	0 (0.00)
Hypothyroidism	2	2 (4.17)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.08)	0	0 (0.00)
Delayed puberty	1	1 (2.08)	0	0 (0.00)
Eye disorders				
- Total	17	10 (20.83)	1	1 (2.08)
Eyelid oedema	3	2 (4.17)	0	0 (0.00)
Cataract	2	2 (4.17)	0	0 (0.00)
Eye pain	2	2 (4.17)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Retinal haemorrhage	2	1 (2.08)	0	0 (0.00)
Dry eye	1	1 (2.08)	0	0 (0.00)
Eye oedema	1	1 (2.08)	0	0 (0.00)
Hypermetropia	1	1 (2.08)	0	0 (0.00)
Mydriasis	1	1 (2.08)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.08)	0	0 (0.00)
Periorbital swelling	1	1 (2.08)	0	0 (0.00)
Visual field defect	1	1 (2.08)	0	0 (0.00)
Visual impairment	1	1 (2.08)	0	0 (0.00)
Gastrointestinal disorders				
- Total	127	39 (81.25)	11	9 (18.75)
Vomiting	28	17 (35.42)	0	0 (0.00)
Diarrhoea	20	19 (39.58)	2	2 (4.17)
Nausea	20	15 (31.25)	1	1 (2.08)
Abdominal pain	12	9 (18.75)	2	2 (4.17)
Constipation	9	8 (16.67)	0	0 (0.00)
Abdominal pain upper	4	4 (8.33)	0	0 (0.00)
Mouth haemorrhage	3	3 (6.25)	1	1 (2.08)
Pancreatitis	3	3 (6.25)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Abdominal distension	2	2 (4.17)	0	0 (0.00)
Ascites	2	2 (4.17)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (4.17)	0	0 (0.00)
Proctalgia	2	2 (4.17)	1	1 (2.08)
Stomatitis	2	2 (4.17)	1	1 (2.08)
Trichoglossia	2	2 (4.17)	0	0 (0.00)
Abdominal rigidity	1	1 (2.08)	0	0 (0.00)
Anal haemorrhage	1	1 (2.08)	0	0 (0.00)
Dyspepsia	1	1 (2.08)	0	0 (0.00)
Enteritis	1	1 (2.08)	0	0 (0.00)
Enterocolitis	1	1 (2.08)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.08)	0	0 (0.00)
Gingival bleeding	1	1 (2.08)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.08)	1	1 (2.08)
Haematemesis	1	1 (2.08)	0	0 (0.00)
Lip dry	1	1 (2.08)	0	0 (0.00)
Lip oedema	1	1 (2.08)	0	0 (0.00)
Mouth swelling	1	1 (2.08)	0	0 (0.00)
Neutropenic colitis	1	1 (2.08)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Odynophagia	1	1 (2.08)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.08)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.08)	0	0 (0.00)
General disorders and administration site conditions				
- Total	94	29 (60.42)	12	6 (12.50)
Pyrexia	40	18 (37.50)	7	6 (12.50)
Fatigue	11	10 (20.83)	0	0 (0.00)
Chills	8	5 (10.42)	0	0 (0.00)
Face oedema	5	4 (8.33)	0	0 (0.00)
Pain	4	4 (8.33)	2	2 (4.17)
Asthenia	3	3 (6.25)	0	0 (0.00)
Catheter site pain	3	1 (2.08)	2	1 (2.08)
Catheter site erythema	2	1 (2.08)	0	0 (0.00)
Generalised oedema	2	2 (4.17)	0	0 (0.00)
Influenza like illness	2	2 (4.17)	0	0 (0.00)
Non-cardiac chest pain	2	2 (4.17)	0	0 (0.00)
Oedema peripheral	2	2 (4.17)	0	0 (0.00)
Chest discomfort	1	1 (2.08)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Crying	1	1 (2.08)	0	0 (0.00)
Facial pain	1	1 (2.08)	0	0 (0.00)
Localised oedema	1	1 (2.08)	0	0 (0.00)
Malaise	1	1 (2.08)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.08)	0	0 (0.00)
Sluggishness	1	1 (2.08)	0	0 (0.00)
Swelling face	1	1 (2.08)	0	0 (0.00)
Vascular device occlusion	1	1 (2.08)	0	0 (0.00)
Xerosis	1	1 (2.08)	0	0 (0.00)
Hepatobiliary disorders				
- Total	13	9 (18.75)	3	2 (4.17)
Hepatic function abnormal	6	2 (4.17)	3	2 (4.17)
Hepatomegaly	2	2 (4.17)	0	0 (0.00)
Hyperbilirubinaemia	2	2 (4.17)	0	0 (0.00)
Cholelithiasis	1	1 (2.08)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.08)	0	0 (0.00)
Liver disorder	1	1 (2.08)	0	0 (0.00)
Immune system disorders				

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
- Total	112	44 (91.67)	40	28 (58.33)
Cytokine release syndrome	72	37 (77.08)	28	23 (47.92)
Hypogammaglobulinaemia	27	22 (45.83)	5	5 (10.42)
Drug hypersensitivity	2	2 (4.17)	1	1 (2.08)
Graft versus host disease	2	2 (4.17)	2	2 (4.17)
Haemophagocytic lymphohistiocytosis	2	2 (4.17)	1	1 (2.08)
Immunodeficiency	2	2 (4.17)	2	2 (4.17)
Allergy to immunoglobulin therapy	1	1 (2.08)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.08)	0	0 (0.00)
Engraftment syndrome	1	1 (2.08)	1	1 (2.08)
Hypersensitivity	1	1 (2.08)	0	0 (0.00)
Seasonal allergy	1	1 (2.08)	0	0 (0.00)
Infections and infestations				
- Total	176	39 (81.25)	72	28 (58.33)
Sinusitis	11	5 (10.42)	2	2 (4.17)
Upper respiratory tract infection	10	7 (14.58)	3	3 (6.25)
Conjunctivitis	7	6 (12.50)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (4.17)	4	2 (4.17)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Nasopharyngitis	6	5 (10.42)	0	0 (0.00)
Rhinovirus infection	6	5 (10.42)	1	1 (2.08)
Gastroenteritis	5	5 (10.42)	2	2 (4.17)
Oral herpes	5	4 (8.33)	1	1 (2.08)
Candida infection	4	3 (6.25)	2	1 (2.08)
Oral candidiasis	4	3 (6.25)	0	0 (0.00)
Otitis media	4	3 (6.25)	1	1 (2.08)
Urinary tract infection	4	3 (6.25)	2	1 (2.08)
Fungal infection	3	2 (4.17)	0	0 (0.00)
Klebsiella infection	3	1 (2.08)	3	1 (2.08)
Metapneumovirus infection	3	3 (6.25)	3	3 (6.25)
Parainfluenzae virus infection	3	2 (4.17)	2	2 (4.17)
Pneumonia	3	3 (6.25)	1	1 (2.08)
Respiratory syncytial virus infection	3	3 (6.25)	2	2 (4.17)
Rhinitis	3	3 (6.25)	0	0 (0.00)
Sepsis	3	3 (6.25)	3	3 (6.25)
Bacteraemia	2	1 (2.08)	2	1 (2.08)
COVID-19	2	1 (2.08)	1	1 (2.08)
Device related sepsis	2	1 (2.08)	2	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Gingivitis	2	2 (4.17)	0	0 (0.00)
Herpes zoster	2	2 (4.17)	1	1 (2.08)
Human herpesvirus 6 infection	2	2 (4.17)	2	2 (4.17)
Influenza	2	2 (4.17)	0	0 (0.00)
Nail infection	2	2 (4.17)	0	0 (0.00)
Oral infection	2	2 (4.17)	0	0 (0.00)
Otitis externa	2	2 (4.17)	1	1 (2.08)
Paronychia	2	2 (4.17)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (4.17)	2	2 (4.17)
Respiratory tract infection	2	2 (4.17)	0	0 (0.00)
Septic shock	2	2 (4.17)	2	2 (4.17)
Skin infection	2	2 (4.17)	0	0 (0.00)
Staphylococcal infection	2	2 (4.17)	2	2 (4.17)
Varicella zoster virus infection	2	2 (4.17)	1	1 (2.08)
Viral infection	2	2 (4.17)	1	1 (2.08)
Acute sinusitis	1	1 (2.08)	0	0 (0.00)
Adenovirus infection	1	1 (2.08)	1	1 (2.08)
Anal abscess	1	1 (2.08)	1	1 (2.08)
BK virus infection	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Bronchitis	1	1 (2.08)	0	0 (0.00)
Cholecystitis infective	1	1 (2.08)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.08)	1	1 (2.08)
Coronavirus infection	1	1 (2.08)	1	1 (2.08)
Cystitis	1	1 (2.08)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.08)	1	1 (2.08)
Device related infection	1	1 (2.08)	1	1 (2.08)
Ear infection	1	1 (2.08)	1	1 (2.08)
Ear, nose and throat infection	1	1 (2.08)	0	0 (0.00)
Encephalitis	1	1 (2.08)	1	1 (2.08)
Encephalitis viral	1	1 (2.08)	1	1 (2.08)
Enterobacter infection	1	1 (2.08)	1	1 (2.08)
Fungal skin infection	1	1 (2.08)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.08)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.08)	0	0 (0.00)
Granulicatella infection	1	1 (2.08)	1	1 (2.08)
Herpes simplex	1	1 (2.08)	1	1 (2.08)
Herpes virus infection	1	1 (2.08)	0	0 (0.00)
Mastoiditis	1	1 (2.08)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Meningitis pneumococcal	1	1 (2.08)	1	1 (2.08)
Myringitis	1	1 (2.08)	0	0 (0.00)
Neutropenic infection	1	1 (2.08)	1	1 (2.08)
Ophthalmic herpes zoster	1	1 (2.08)	0	0 (0.00)
Otitis media acute	1	1 (2.08)	0	0 (0.00)
Pneumonia fungal	1	1 (2.08)	1	1 (2.08)
Pneumonia viral	1	1 (2.08)	1	1 (2.08)
Respiratory tract infection viral	1	1 (2.08)	0	0 (0.00)
Salmonellosis	1	1 (2.08)	0	0 (0.00)
Soft tissue infection	1	1 (2.08)	1	1 (2.08)
Staphylococcal abscess	1	1 (2.08)	1	1 (2.08)
Staphylococcal bacteraemia	1	1 (2.08)	1	1 (2.08)
Staphylococcal sepsis	1	1 (2.08)	1	1 (2.08)
Staphylococcal skin infection	1	1 (2.08)	0	0 (0.00)
Stomatococcal infection	1	1 (2.08)	0	0 (0.00)
Streptococcal sepsis	1	1 (2.08)	0	0 (0.00)
Systemic candida	1	1 (2.08)	1	1 (2.08)
Tinea pedis	1	1 (2.08)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Viral haemorrhagic cystitis	1	1 (2.08)	1	1 (2.08)
Viral skin infection	1	1 (2.08)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	16	11 (22.92)	1	1 (2.08)
Infusion related reaction	6	3 (6.25)	0	0 (0.00)
Fall	2	2 (4.17)	0	0 (0.00)
Ligament sprain	2	2 (4.17)	0	0 (0.00)
Contusion	1	1 (2.08)	0	0 (0.00)
Limb injury	1	1 (2.08)	0	0 (0.00)
Procedural pain	1	1 (2.08)	0	0 (0.00)
Skin abrasion	1	1 (2.08)	0	0 (0.00)
Transfusion reaction	1	1 (2.08)	0	0 (0.00)
Transplant failure	1	1 (2.08)	1	1 (2.08)
Investigations				
- Total	291	37 (77.08)	151	27 (56.25)
Platelet count decreased	62	16 (33.33)	39	11 (22.92)
Neutrophil count decreased	43	16 (33.33)	33	14 (29.17)
White blood cell count decreased	36	14 (29.17)	23	10 (20.83)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Lymphocyte count decreased	27	11 (22.92)	21	10 (20.83)
Alanine aminotransferase increased	22	13 (27.08)	5	5 (10.42)
Aspartate aminotransferase increased	17	10 (20.83)	6	4 (8.33)
Blood bilirubin increased	13	6 (12.50)	5	4 (8.33)
Immunoglobulins decreased	10	2 (4.17)	0	0 (0.00)
Blood immunoglobulin A decreased	6	6 (12.50)	1	1 (2.08)
Blood immunoglobulin M decreased	5	5 (10.42)	1	1 (2.08)
Activated partial thromboplastin time prolonged	4	3 (6.25)	1	1 (2.08)
Blood fibrinogen decreased	4	4 (8.33)	1	1 (2.08)
International normalised ratio increased	4	3 (6.25)	0	0 (0.00)
Serum ferritin increased	4	4 (8.33)	1	1 (2.08)
Blood creatine phosphokinase increased	3	1 (2.08)	1	1 (2.08)
Blood lactate dehydrogenase increased	3	3 (6.25)	0	0 (0.00)
Blood uric acid increased	3	3 (6.25)	2	2 (4.17)
C-reactive protein increased	3	3 (6.25)	2	2 (4.17)
Blood creatinine increased	2	2 (4.17)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Blood glucose increased	2	1 (2.08)	2	1 (2.08)
Haemoglobin decreased	2	1 (2.08)	1	1 (2.08)
Weight decreased	2	2 (4.17)	1	1 (2.08)
Weight increased	2	2 (4.17)	1	1 (2.08)
Blood testosterone decreased	1	1 (2.08)	0	0 (0.00)
Blood urea increased	1	1 (2.08)	1	1 (2.08)
Bone density decreased	1	1 (2.08)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.08)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.08)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (2.08)	1	1 (2.08)
Enterovirus test positive	1	1 (2.08)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.08)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (2.08)	1	1 (2.08)
Hepatitis B virus test positive	1	1 (2.08)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.08)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.08)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	121	30 (62.50)	45	18 (37.50)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hypokalaemia	28	12 (25.00)	14	7 (14.58)
Hypophosphataemia	21	11 (22.92)	7	5 (10.42)
Decreased appetite	20	18 (37.50)	10	8 (16.67)
Hypoalbuminaemia	11	5 (10.42)	0	0 (0.00)
Hypocalcaemia	8	6 (12.50)	2	2 (4.17)
Hypomagnesaemia	4	3 (6.25)	0	0 (0.00)
Hyperglycaemia	3	3 (6.25)	2	2 (4.17)
Hyperuricaemia	3	3 (6.25)	0	0 (0.00)
Iron overload	3	2 (4.17)	0	0 (0.00)
Tumour lysis syndrome	3	3 (6.25)	3	3 (6.25)
Hypermagnesaemia	2	1 (2.08)	0	0 (0.00)
Hypernatraemia	2	2 (4.17)	1	1 (2.08)
Hypertriglyceridaemia	2	2 (4.17)	1	1 (2.08)
Hypervolaemia	2	2 (4.17)	1	1 (2.08)
Malnutrition	2	2 (4.17)	2	2 (4.17)
Haemochromatosis	1	1 (2.08)	1	1 (2.08)
Hyperchloraemia	1	1 (2.08)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.08)	0	0 (0.00)
Hyperkalaemia	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hyponatraemia	1	1 (2.08)	0	0 (0.00)
Hypophagia	1	1 (2.08)	0	0 (0.00)
Polydipsia	1	1 (2.08)	1	1 (2.08)
Musculoskeletal and connective tissue disorders				
- Total	55	28 (58.33)	4	4 (8.33)
Pain in extremity	14	13 (27.08)	1	1 (2.08)
Arthralgia	10	9 (18.75)	0	0 (0.00)
Back pain	9	8 (16.67)	2	2 (4.17)
Myalgia	6	5 (10.42)	0	0 (0.00)
Bone pain	4	2 (4.17)	0	0 (0.00)
Growth retardation	2	2 (4.17)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (4.17)	0	0 (0.00)
Pain in jaw	2	2 (4.17)	1	1 (2.08)
Joint effusion	1	1 (2.08)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.08)	0	0 (0.00)
Neck pain	1	1 (2.08)	0	0 (0.00)
Osteonecrosis	1	1 (2.08)	0	0 (0.00)
Osteopenia	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Synovitis	1	1 (2.08)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	5	4 (8.33)	2	2 (4.17)
Bone giant cell tumour benign	2	1 (2.08)	1	1 (2.08)
Skin papilloma	2	2 (4.17)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.08)	1	1 (2.08)
Nervous system disorders				
- Total	63	26 (54.17)	14	8 (16.67)
Headache	21	15 (31.25)	3	3 (6.25)
Dizziness	5	4 (8.33)	0	0 (0.00)
Seizure	5	3 (6.25)	3	3 (6.25)
Encephalopathy	4	4 (8.33)	1	1 (2.08)
Tremor	4	3 (6.25)	0	0 (0.00)
Hydrocephalus	3	1 (2.08)	3	1 (2.08)
Dysgeusia	2	2 (4.17)	0	0 (0.00)
Hyperaesthesia	2	1 (2.08)	0	0 (0.00)
Lethargy	2	2 (4.17)	0	0 (0.00)
Nervous system disorder	2	1 (2.08)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Somnolence	2	2 (4.17)	0	0 (0.00)
Amnesia	1	1 (2.08)	0	0 (0.00)
Aphasia	1	1 (2.08)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.08)	1	1 (2.08)
Cerebral haemorrhage	1	1 (2.08)	1	1 (2.08)
Cognitive disorder	1	1 (2.08)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.08)	1	1 (2.08)
Disturbance in attention	1	1 (2.08)	0	0 (0.00)
Dysarthria	1	1 (2.08)	0	0 (0.00)
Hypoaesthesia	1	1 (2.08)	0	0 (0.00)
Memory impairment	1	1 (2.08)	0	0 (0.00)
Neuralgia	1	1 (2.08)	0	0 (0.00)
Psychiatric disorders				
- Total	41	24 (50.00)	2	2 (4.17)
Anxiety	10	10 (20.83)	1	1 (2.08)
Confusional state	4	4 (8.33)	0	0 (0.00)
Agitation	3	3 (6.25)	0	0 (0.00)
Delirium	3	3 (6.25)	0	0 (0.00)
Hallucination	3	3 (6.25)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Insomnia	3	3 (6.25)	0	0 (0.00)
Sleep disorder	3	2 (4.17)	0	0 (0.00)
Irritability	2	2 (4.17)	0	0 (0.00)
Mental status changes	2	2 (4.17)	1	1 (2.08)
Affect lability	1	1 (2.08)	0	0 (0.00)
Hallucination, visual	1	1 (2.08)	0	0 (0.00)
Mood altered	1	1 (2.08)	0	0 (0.00)
Nightmare	1	1 (2.08)	0	0 (0.00)
Restlessness	1	1 (2.08)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.08)	0	0 (0.00)
Tearfulness	1	1 (2.08)	0	0 (0.00)
Tic	1	1 (2.08)	0	0 (0.00)
Renal and urinary disorders				
- Total	20	14 (29.17)	4	4 (8.33)
Acute kidney injury	5	5 (10.42)	2	2 (4.17)
Dysuria	2	2 (4.17)	0	0 (0.00)
Haematuria	2	2 (4.17)	0	0 (0.00)
Urinary incontinence	2	1 (2.08)	0	0 (0.00)
Anuria	1	1 (2.08)	1	1 (2.08)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Cystitis haemorrhagic	1	1 (2.08)	0	0 (0.00)
Incontinence	1	1 (2.08)	0	0 (0.00)
Pollakiuria	1	1 (2.08)	0	0 (0.00)
Proteinuria	1	1 (2.08)	0	0 (0.00)
Renal failure	1	1 (2.08)	0	0 (0.00)
Renal tubular disorder	1	1 (2.08)	1	1 (2.08)
Renal tubular dysfunction	1	1 (2.08)	0	0 (0.00)
Urinary tract disorder	1	1 (2.08)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	4 (8.33)	1	1 (2.08)
Endometriosis	2	1 (2.08)	1	1 (2.08)
Vaginal haemorrhage	2	1 (2.08)	0	0 (0.00)
Female genital tract fistula	1	1 (2.08)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.08)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	110	36 (75.00)	26	14 (29.17)
Cough	23	17 (35.42)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hypoxia	13	10 (20.83)	10	7 (14.58)
Rhinorrhoea	7	5 (10.42)	0	0 (0.00)
Epistaxis	6	5 (10.42)	1	1 (2.08)
Nasal congestion	6	6 (12.50)	0	0 (0.00)
Pleural effusion	6	5 (10.42)	1	1 (2.08)
Pulmonary oedema	6	6 (12.50)	4	4 (8.33)
Dyspnoea	5	4 (8.33)	2	2 (4.17)
Oropharyngeal pain	5	4 (8.33)	0	0 (0.00)
Tachypnoea	5	5 (10.42)	1	1 (2.08)
Atelectasis	2	2 (4.17)	1	1 (2.08)
Lung infiltration	2	1 (2.08)	1	1 (2.08)
Pharyngeal erythema	2	2 (4.17)	0	0 (0.00)
Respiratory distress	2	2 (4.17)	1	1 (2.08)
Acute respiratory distress syndrome	1	1 (2.08)	1	1 (2.08)
Bradypnoea	1	1 (2.08)	1	1 (2.08)
Bronchial oedema	1	1 (2.08)	0	0 (0.00)
Dyspnoea exertional	1	1 (2.08)	0	0 (0.00)
Laryngeal oedema	1	1 (2.08)	1	1 (2.08)
Lung disorder	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Nasal dryness	1	1 (2.08)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.08)	0	0 (0.00)
Painful respiration	1	1 (2.08)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.08)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.08)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.08)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.08)	0	0 (0.00)
Productive cough	1	1 (2.08)	0	0 (0.00)
Pulmonary mass	1	1 (2.08)	0	0 (0.00)
Respiratory disorder	1	1 (2.08)	0	0 (0.00)
Respiratory failure	1	1 (2.08)	1	1 (2.08)
Rhinitis allergic	1	1 (2.08)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (2.08)	0	0 (0.00)
Wheezing	1	1 (2.08)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	56	24 (50.00)	7	6 (12.50)
Rash	8	4 (8.33)	0	0 (0.00)
Dry skin	6	5 (10.42)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Dermatitis atopic	4	3 (6.25)	1	1 (2.08)
Pruritus	4	3 (6.25)	0	0 (0.00)
Rash papular	4	3 (6.25)	0	0 (0.00)
Rash maculo-papular	3	2 (4.17)	1	1 (2.08)
Eczema	2	2 (4.17)	1	1 (2.08)
Erythema	2	2 (4.17)	0	0 (0.00)
Rash macular	2	1 (2.08)	2	1 (2.08)
Rash vesicular	2	1 (2.08)	0	0 (0.00)
Blister	1	1 (2.08)	0	0 (0.00)
Decubitus ulcer	1	1 (2.08)	1	1 (2.08)
Dermatitis allergic	1	1 (2.08)	0	0 (0.00)
Erythema nodosum	1	1 (2.08)	0	0 (0.00)
Hangnail	1	1 (2.08)	0	0 (0.00)
Hyperhidrosis	1	1 (2.08)	0	0 (0.00)
Ingrowing nail	1	1 (2.08)	0	0 (0.00)
Night sweats	1	1 (2.08)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.08)	0	0 (0.00)
Papule	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Pruritus allergic	1	1 (2.08)	0	0 (0.00)
Purpura	1	1 (2.08)	0	0 (0.00)
Rash pruritic	1	1 (2.08)	0	0 (0.00)
Skin discolouration	1	1 (2.08)	0	0 (0.00)
Skin lesion	1	1 (2.08)	0	0 (0.00)
Skin swelling	1	1 (2.08)	0	0 (0.00)
Skin ulcer	1	1 (2.08)	0	0 (0.00)
Urticaria	1	1 (2.08)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.08)	1	1 (2.08)
Social circumstances				
- Total	1	1 (2.08)	0	0 (0.00)
Patient uncooperative	1	1 (2.08)	0	0 (0.00)
Vascular disorders				
- Total	25	17 (35.42)	9	7 (14.58)
Hypotension	12	10 (20.83)	6	5 (10.42)
Hypertension	8	8 (16.67)	1	1 (2.08)
Capillary leak syndrome	2	2 (4.17)	1	1 (2.08)
Flushing	1	1 (2.08)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=48 n (%)[1]	Grade >= 3 Total events	All patients N=48 n (%)[2]
Hot flush	1	1 (2.08)	0	0 (0.00)
Venoocclusive disease	1	1 (2.08)	1	1 (2.08)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250l
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Prior SCT therapy
Safety Set

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Total number of AE per patient	1020	32 (100.00)	354	29 (90.63)
Blood and lymphatic system disorders				
- Total	56	23 (71.88)	30	18 (56.25)
Anaemia	18	9 (28.13)	3	2 (6.25)
Febrile neutropenia	14	12 (37.50)	14	12 (37.50)
Neutropenia	7	4 (12.50)	6	3 (9.38)
Disseminated intravascular coagulation	4	4 (12.50)	2	2 (6.25)
Thrombocytopenia	4	4 (12.50)	4	4 (12.50)
Coagulopathy	3	3 (9.38)	1	1 (3.13)
Splenomegaly	2	2 (6.25)	0	0 (0.00)
Hypercoagulation	1	1 (3.13)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Lymphadenopathy	1	1 (3.13)	0	0 (0.00)
Lymphocytosis	1	1 (3.13)	0	0 (0.00)
Cardiac disorders				
- Total	31	16 (50.00)	10	7 (21.88)
Tachycardia	15	10 (31.25)	2	2 (6.25)
Cardiac failure	6	3 (9.38)	4	3 (9.38)
Bradycardia	2	2 (6.25)	0	0 (0.00)
Cardiac arrest	2	2 (6.25)	2	2 (6.25)
Sinus tachycardia	2	2 (6.25)	0	0 (0.00)
Atrioventricular block first degree	1	1 (3.13)	0	0 (0.00)
Cardiac dysfunction	1	1 (3.13)	0	0 (0.00)
Left ventricular dysfunction	1	1 (3.13)	1	1 (3.13)
Sinus bradycardia	1	1 (3.13)	1	1 (3.13)
Ear and labyrinth disorders				
- Total	1	1 (3.13)	0	0 (0.00)
Ear pruritus	1	1 (3.13)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (12.50)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Adrenal insufficiency	3	3 (9.38)	0	0 (0.00)
Hypothyroidism	1	1 (3.13)	0	0 (0.00)
Eye disorders				
- Total	7	5 (15.63)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (6.25)	0	0 (0.00)
Ocular hyperaemia	2	2 (6.25)	0	0 (0.00)
Eyelid oedema	1	1 (3.13)	0	0 (0.00)
Periorbital oedema	1	1 (3.13)	0	0 (0.00)
Visual impairment	1	1 (3.13)	0	0 (0.00)
Gastrointestinal disorders				
- Total	55	21 (65.63)	7	7 (21.88)
Diarrhoea	10	7 (21.88)	0	0 (0.00)
Vomiting	10	9 (28.13)	1	1 (3.13)
Constipation	7	6 (18.75)	0	0 (0.00)
Nausea	7	7 (21.88)	1	1 (3.13)
Abdominal pain	3	2 (6.25)	0	0 (0.00)
Pancreatitis	3	3 (9.38)	1	1 (3.13)
Mouth haemorrhage	2	2 (6.25)	1	1 (3.13)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Abdominal compartment syndrome	1	1 (3.13)	1	1 (3.13)
Abdominal distension	1	1 (3.13)	0	0 (0.00)
Anal fissure	1	1 (3.13)	0	0 (0.00)
Ascites	1	1 (3.13)	0	0 (0.00)
Dry mouth	1	1 (3.13)	0	0 (0.00)
Dysphagia	1	1 (3.13)	1	1 (3.13)
Gastrointestinal haemorrhage	1	1 (3.13)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (3.13)	0	0 (0.00)
Gingival erythema	1	1 (3.13)	0	0 (0.00)
Ileus	1	1 (3.13)	0	0 (0.00)
Irritable bowel syndrome	1	1 (3.13)	0	0 (0.00)
Melaena	1	1 (3.13)	1	1 (3.13)
Stomatitis	1	1 (3.13)	0	0 (0.00)
General disorders and administration site conditions				
- Total	62	24 (75.00)	12	9 (28.13)
Pyrexia	27	17 (53.13)	5	5 (15.63)
Fatigue	8	7 (21.88)	0	0 (0.00)
Oedema peripheral	7	5 (15.63)	2	1 (3.13)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Face oedema	4	4 (12.50)	1	1 (3.13)
Generalised oedema	3	3 (9.38)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (9.38)	3	3 (9.38)
Chills	2	2 (6.25)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (6.25)	0	0 (0.00)
Catheter site haemorrhage	1	1 (3.13)	0	0 (0.00)
Catheter site pain	1	1 (3.13)	0	0 (0.00)
Localised oedema	1	1 (3.13)	0	0 (0.00)
Malaise	1	1 (3.13)	0	0 (0.00)
Pain	1	1 (3.13)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.13)	1	1 (3.13)
Hepatobiliary disorders				
- Total	19	10 (31.25)	4	4 (12.50)
Hepatic function abnormal	5	3 (9.38)	1	1 (3.13)
Hyperbilirubinaemia	4	3 (9.38)	1	1 (3.13)
Hypertransaminasaemia	3	2 (6.25)	0	0 (0.00)
Gallbladder enlargement	2	2 (6.25)	0	0 (0.00)
Biliary tract disorder	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Cholelithiasis	1	1 (3.13)	0	0 (0.00)
Cholestasis	1	1 (3.13)	1	1 (3.13)
Hepatomegaly	1	1 (3.13)	1	1 (3.13)
Ocular icterus	1	1 (3.13)	0	0 (0.00)
Immune system disorders				
- Total	81	27 (84.38)	36	18 (56.25)
Cytokine release syndrome	56	24 (75.00)	27	15 (46.88)
Hypogammaglobulinaemia	13	11 (34.38)	2	2 (6.25)
Haemophagocytic lymphohistiocytosis	4	4 (12.50)	3	3 (9.38)
Seasonal allergy	3	3 (9.38)	0	0 (0.00)
Immunodeficiency	2	2 (6.25)	2	2 (6.25)
Allergy to immunoglobulin therapy	1	1 (3.13)	1	1 (3.13)
Chronic graft versus host disease	1	1 (3.13)	1	1 (3.13)
Selective IgG subclass deficiency	1	1 (3.13)	0	0 (0.00)
Infections and infestations				
- Total	87	21 (65.63)	30	11 (34.38)
Upper respiratory tract infection	7	6 (18.75)	0	0 (0.00)
Conjunctivitis	5	2 (6.25)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Rhinovirus infection	5	4 (12.50)	1	1 (3.13)
Staphylococcal bacteraemia	5	4 (12.50)	5	4 (12.50)
Clostridium difficile infection	3	3 (9.38)	2	2 (6.25)
Ear infection	3	2 (6.25)	0	0 (0.00)
Nasopharyngitis	3	2 (6.25)	0	0 (0.00)
Parainfluenzae virus infection	3	3 (9.38)	1	1 (3.13)
Pneumonia	3	3 (9.38)	3	3 (9.38)
Sinusitis	3	2 (6.25)	0	0 (0.00)
Staphylococcal infection	3	3 (9.38)	0	0 (0.00)
Bacteraemia	2	2 (6.25)	1	1 (3.13)
Gastroenteritis viral	2	1 (3.13)	0	0 (0.00)
Nail infection	2	2 (6.25)	0	0 (0.00)
Otitis media	2	2 (6.25)	0	0 (0.00)
Acute sinusitis	1	1 (3.13)	0	0 (0.00)
Adenovirus infection	1	1 (3.13)	1	1 (3.13)
Atypical pneumonia	1	1 (3.13)	0	0 (0.00)
BK virus infection	1	1 (3.13)	1	1 (3.13)
Bronchiolitis	1	1 (3.13)	1	1 (3.13)
Bronchitis	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
COVID-19	1	1 (3.13)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.13)	1	1 (3.13)
Candida infection	1	1 (3.13)	0	0 (0.00)
Cellulitis	1	1 (3.13)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.13)	1	1 (3.13)
Encephalitis	1	1 (3.13)	1	1 (3.13)
Encephalitis viral	1	1 (3.13)	1	1 (3.13)
Enterovirus infection	1	1 (3.13)	1	1 (3.13)
Folliculitis	1	1 (3.13)	0	0 (0.00)
Gastroenteritis	1	1 (3.13)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (3.13)	1	1 (3.13)
Gastroenteritis clostridial	1	1 (3.13)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (3.13)	1	1 (3.13)
Gastrointestinal infection	1	1 (3.13)	0	0 (0.00)
Herpes simplex	1	1 (3.13)	0	0 (0.00)
Herpes zoster	1	1 (3.13)	1	1 (3.13)
Influenza	1	1 (3.13)	1	1 (3.13)
Klebsiella bacteraemia	1	1 (3.13)	0	0 (0.00)
Localised infection	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Meningitis bacterial	1	1 (3.13)	1	1 (3.13)
Molluscum contagiosum	1	1 (3.13)	0	0 (0.00)
Otitis externa	1	1 (3.13)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (3.13)	1	1 (3.13)
Pneumonia respiratory syncytial viral	1	1 (3.13)	1	1 (3.13)
Respiratory tract infection	1	1 (3.13)	0	0 (0.00)
Sinusitis fungal	1	1 (3.13)	1	1 (3.13)
Skin infection	1	1 (3.13)	0	0 (0.00)
Syphilis	1	1 (3.13)	0	0 (0.00)
Urinary tract infection viral	1	1 (3.13)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (3.13)	1	1 (3.13)
Injury, poisoning and procedural complications				
- Total	17	10 (31.25)	3	2 (6.25)
Wound	3	2 (6.25)	1	1 (3.13)
Contusion	2	1 (3.13)	0	0 (0.00)
Infusion related reaction	2	2 (6.25)	1	1 (3.13)
Abdominal injury	1	1 (3.13)	0	0 (0.00)
Fibula fracture	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Post-traumatic neck syndrome	1	1 (3.13)	0	0 (0.00)
Procedural pain	1	1 (3.13)	0	0 (0.00)
Scratch	1	1 (3.13)	0	0 (0.00)
Skin abrasion	1	1 (3.13)	0	0 (0.00)
Skin injury	1	1 (3.13)	0	0 (0.00)
Skin wound	1	1 (3.13)	0	0 (0.00)
Transfusion reaction	1	1 (3.13)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.13)	1	1 (3.13)
Investigations				
- Total	202	23 (71.88)	87	21 (65.63)
Neutrophil count decreased	32	8 (25.00)	21	7 (21.88)
White blood cell count decreased	32	11 (34.38)	17	8 (25.00)
Platelet count decreased	21	8 (25.00)	8	4 (12.50)
Aspartate aminotransferase increased	16	9 (28.13)	7	7 (21.88)
Blood bilirubin increased	12	7 (21.88)	5	5 (15.63)
Lymphocyte count decreased	9	6 (18.75)	5	5 (15.63)
International normalised ratio increased	8	6 (18.75)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Alanine aminotransferase increased	7	5 (15.63)	2	2 (6.25)
Blood creatinine increased	5	3 (9.38)	4	2 (6.25)
Electrocardiogram QT prolonged	5	4 (12.50)	1	1 (3.13)
Weight increased	5	2 (6.25)	1	1 (3.13)
Activated partial thromboplastin time prolonged	4	3 (9.38)	0	0 (0.00)
Blood immunoglobulin G decreased	4	4 (12.50)	0	0 (0.00)
Lipase increased	4	2 (6.25)	2	1 (3.13)
Serum ferritin increased	4	4 (12.50)	1	1 (3.13)
Blood fibrinogen decreased	3	3 (9.38)	1	1 (3.13)
Urine output decreased	3	2 (6.25)	3	2 (6.25)
Blood immunoglobulin M decreased	2	2 (6.25)	1	1 (3.13)
Blood lactate dehydrogenase increased	2	2 (6.25)	1	1 (3.13)
C-reactive protein increased	2	2 (6.25)	1	1 (3.13)
Fibrin D dimer increased	2	2 (6.25)	1	1 (3.13)
Oxygen saturation decreased	2	2 (6.25)	1	1 (3.13)
Amylase increased	1	1 (3.13)	0	0 (0.00)
Bacterial test positive	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Blood alkaline phosphatase increased	1	1 (3.13)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (3.13)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (3.13)	1	1 (3.13)
Blood immunoglobulin A decreased	1	1 (3.13)	0	0 (0.00)
Blood phosphorus increased	1	1 (3.13)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (3.13)	0	0 (0.00)
Blood uric acid increased	1	1 (3.13)	0	0 (0.00)
Cardiac murmur	1	1 (3.13)	0	0 (0.00)
Ejection fraction decreased	1	1 (3.13)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (3.13)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (3.13)	1	1 (3.13)
Haptoglobin decreased	1	1 (3.13)	0	0 (0.00)
Heart sounds abnormal	1	1 (3.13)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (3.13)	0	0 (0.00)
Staphylococcus test positive	1	1 (3.13)	0	0 (0.00)
Troponin increased	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Metabolism and nutrition disorders				
- Total	125	22 (68.75)	46	15 (46.88)
Hypokalaemia	18	8 (25.00)	10	4 (12.50)
Hypocalcaemia	16	10 (31.25)	4	3 (9.38)
Decreased appetite	12	12 (37.50)	4	4 (12.50)
Hypophosphataemia	11	7 (21.88)	4	4 (12.50)
Hyperglycaemia	9	6 (18.75)	3	3 (9.38)
Hyperuricaemia	9	6 (18.75)	1	1 (3.13)
Hypoalbuminaemia	8	6 (18.75)	1	1 (3.13)
Hyperphosphataemia	5	5 (15.63)	1	1 (3.13)
Hypervolaemia	5	5 (15.63)	4	4 (12.50)
Hypercalcaemia	4	3 (9.38)	2	2 (6.25)
Metabolic acidosis	4	4 (12.50)	3	3 (9.38)
Acidosis	3	2 (6.25)	2	2 (6.25)
Hypomagnesaemia	3	3 (9.38)	0	0 (0.00)
Hyperkalaemia	2	2 (6.25)	2	2 (6.25)
Hyponatraemia	2	2 (6.25)	0	0 (0.00)
Tumour lysis syndrome	2	2 (6.25)	2	2 (6.25)
Calcium deficiency	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Dehydration	1	1 (3.13)	0	0 (0.00)
Haemosiderosis	1	1 (3.13)	0	0 (0.00)
Hyperchloraemia	1	1 (3.13)	0	0 (0.00)
Hyperlactacidaemia	1	1 (3.13)	0	0 (0.00)
Hyperlipidaemia	1	1 (3.13)	0	0 (0.00)
Hypermagnesaemia	1	1 (3.13)	0	0 (0.00)
Hypernatraemia	1	1 (3.13)	1	1 (3.13)
Hypertriglyceridaemia	1	1 (3.13)	1	1 (3.13)
Hypoglycaemia	1	1 (3.13)	0	0 (0.00)
Metabolic syndrome	1	1 (3.13)	0	0 (0.00)
Obesity	1	1 (3.13)	1	1 (3.13)
Musculoskeletal and connective tissue disorders				
- Total	28	16 (50.00)	5	4 (12.50)
Back pain	5	2 (6.25)	1	1 (3.13)
Myalgia	5	5 (15.63)	0	0 (0.00)
Arthralgia	4	3 (9.38)	1	1 (3.13)
Pain in extremity	4	4 (12.50)	0	0 (0.00)
Bone pain	2	2 (6.25)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Muscular weakness	2	2 (6.25)	1	1 (3.13)
Haemarthrosis	1	1 (3.13)	1	1 (3.13)
Muscle rigidity	1	1 (3.13)	0	0 (0.00)
Muscle spasms	1	1 (3.13)	0	0 (0.00)
Myositis	1	1 (3.13)	0	0 (0.00)
Neck pain	1	1 (3.13)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.13)	1	1 (3.13)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (3.13)	0	0 (0.00)
Cancer pain	1	1 (3.13)	0	0 (0.00)
Nervous system disorders				
- Total	46	21 (65.63)	9	6 (18.75)
Headache	19	12 (37.50)	0	0 (0.00)
Cognitive disorder	4	2 (6.25)	1	1 (3.13)
Encephalopathy	4	4 (12.50)	3	3 (9.38)
Somnolence	3	3 (9.38)	2	2 (6.25)
Tremor	3	3 (9.38)	0	0 (0.00)
Migraine	2	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Seizure	2	1 (3.13)	0	0 (0.00)
Cerebral haemorrhage	1	1 (3.13)	1	1 (3.13)
Dysarthria	1	1 (3.13)	1	1 (3.13)
Dysgeusia	1	1 (3.13)	0	0 (0.00)
Extrapyramidal disorder	1	1 (3.13)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (3.13)	0	0 (0.00)
Lethargy	1	1 (3.13)	0	0 (0.00)
Monoparesis	1	1 (3.13)	0	0 (0.00)
Neurological decompensation	1	1 (3.13)	1	1 (3.13)
Paraesthesia	1	1 (3.13)	0	0 (0.00)
Psychiatric disorders				
- Total	24	15 (46.88)	5	5 (15.63)
Delirium	5	5 (15.63)	3	3 (9.38)
Agitation	4	3 (9.38)	0	0 (0.00)
Anxiety	4	4 (12.50)	1	1 (3.13)
Confusional state	3	3 (9.38)	0	0 (0.00)
Mental status changes	3	3 (9.38)	1	1 (3.13)
Automatism	1	1 (3.13)	0	0 (0.00)
Insomnia	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Irritability	1	1 (3.13)	0	0 (0.00)
Persistent depressive disorder	1	1 (3.13)	0	0 (0.00)
Sleep disorder	1	1 (3.13)	0	0 (0.00)
Renal and urinary disorders				
- Total	28	11 (34.38)	12	8 (25.00)
Acute kidney injury	12	7 (21.88)	7	6 (18.75)
Renal failure	3	1 (3.13)	3	1 (3.13)
Dysuria	2	2 (6.25)	0	0 (0.00)
Urinary retention	2	2 (6.25)	0	0 (0.00)
Anuria	1	1 (3.13)	0	0 (0.00)
Azotaemia	1	1 (3.13)	0	0 (0.00)
Bladder dilatation	1	1 (3.13)	0	0 (0.00)
Haematuria	1	1 (3.13)	1	1 (3.13)
Kidney enlargement	1	1 (3.13)	0	0 (0.00)
Micturition urgency	1	1 (3.13)	0	0 (0.00)
Pollakiuria	1	1 (3.13)	0	0 (0.00)
Renal mass	1	1 (3.13)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.13)	1	1 (3.13)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Reproductive system and breast disorders				
- Total	4	2 (6.25)	1	1 (3.13)
Dysmenorrhoea	2	1 (3.13)	0	0 (0.00)
Perineal rash	1	1 (3.13)	0	0 (0.00)
Vaginal ulceration	1	1 (3.13)	1	1 (3.13)
Respiratory, thoracic and mediastinal disorders				
- Total	73	19 (59.38)	36	15 (46.88)
Hypoxia	14	10 (31.25)	12	9 (28.13)
Cough	6	6 (18.75)	0	0 (0.00)
Pulmonary oedema	6	6 (18.75)	3	3 (9.38)
Tachypnoea	6	4 (12.50)	5	4 (12.50)
Respiratory failure	5	5 (15.63)	5	5 (15.63)
Nasal congestion	4	3 (9.38)	0	0 (0.00)
Oropharyngeal pain	4	4 (12.50)	0	0 (0.00)
Pleural effusion	4	4 (12.50)	2	2 (6.25)
Atelectasis	3	1 (3.13)	1	1 (3.13)
Dyspnoea	3	3 (9.38)	2	2 (6.25)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Respiratory distress	3	2 (6.25)	2	1 (3.13)
Acute respiratory distress syndrome	2	2 (6.25)	2	2 (6.25)
Epistaxis	2	2 (6.25)	0	0 (0.00)
Acute respiratory failure	1	1 (3.13)	1	1 (3.13)
Bronchospasm	1	1 (3.13)	0	0 (0.00)
Haemoptysis	1	1 (3.13)	0	0 (0.00)
Nasal discomfort	1	1 (3.13)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (3.13)	0	0 (0.00)
Respiratory acidosis	1	1 (3.13)	1	1 (3.13)
Rhinitis allergic	1	1 (3.13)	0	0 (0.00)
Rhinorrhoea	1	1 (3.13)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (3.13)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (3.13)	0	0 (0.00)
Wheezing	1	1 (3.13)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	39	16 (50.00)	2	1 (3.13)
Blister	5	2 (6.25)	0	0 (0.00)
Pruritus	5	4 (12.50)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Rash	5	4 (12.50)	0	0 (0.00)
Dry skin	3	3 (9.38)	0	0 (0.00)
Erythema	3	3 (9.38)	0	0 (0.00)
Hyperhidrosis	2	2 (6.25)	0	0 (0.00)
Petechiae	2	2 (6.25)	1	1 (3.13)
Decubitus ulcer	1	1 (3.13)	0	0 (0.00)
Dermatitis	1	1 (3.13)	0	0 (0.00)
Dermatitis diaper	1	1 (3.13)	0	0 (0.00)
Eczema	1	1 (3.13)	0	0 (0.00)
Ingrowing nail	1	1 (3.13)	0	0 (0.00)
Miliaria	1	1 (3.13)	0	0 (0.00)
Photosensitivity reaction	1	1 (3.13)	0	0 (0.00)
Rash erythematous	1	1 (3.13)	0	0 (0.00)
Rash maculo-papular	1	1 (3.13)	0	0 (0.00)
Scab	1	1 (3.13)	0	0 (0.00)
Skin discolouration	1	1 (3.13)	0	0 (0.00)
Skin hypopigmentation	1	1 (3.13)	0	0 (0.00)
Skin necrosis	1	1 (3.13)	1	1 (3.13)
Skin ulcer	1	1 (3.13)	0	0 (0.00)

Timing: At anytime, Prior SCT therapy: No

Primary system organ class Preferred term	All grades Total events	All patients N=32 n (%)[1]	Grade >= 3 Total events	All patients N=32 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (3.13)	1	1 (3.13)
Thrombolysis	1	1 (3.13)	1	1 (3.13)
Vascular disorders				
- Total	29	17 (53.13)	18	14 (43.75)
Hypotension	17	14 (43.75)	13	11 (34.38)
Hypertension	9	8 (25.00)	4	4 (12.50)
Peripheral ischaemia	1	1 (3.13)	0	0 (0.00)
Thrombosis	1	1 (3.13)	0	0 (0.00)
Venoocclusive disease	1	1 (3.13)	1	1 (3.13)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Total number of AE per patient	305	13 (100.00)	84	12 (92.31)
Blood and lymphatic system disorders				
- Total	25	11 (84.62)	13	8 (61.54)
Anaemia	9	8 (61.54)	0	0 (0.00)
Febrile neutropenia	7	6 (46.15)	7	6 (46.15)
Neutropenia	4	2 (15.38)	4	2 (15.38)
Leukopenia	2	1 (7.69)	2	1 (7.69)
Disseminated intravascular coagulation	1	1 (7.69)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (7.69)	0	0 (0.00)
Splenomegaly	1	1 (7.69)	0	0 (0.00)
Cardiac disorders				
- Total	9	7 (53.85)	1	1 (7.69)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Tachycardia	7	6 (46.15)	0	0 (0.00)
Cardiac dysfunction	1	1 (7.69)	0	0 (0.00)
Left ventricular dysfunction	1	1 (7.69)	1	1 (7.69)
Ear and labyrinth disorders				
- Total	1	1 (7.69)	0	0 (0.00)
Ear pain	1	1 (7.69)	0	0 (0.00)
Eye disorders				
- Total	1	1 (7.69)	0	0 (0.00)
Ocular hyperaemia	1	1 (7.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	32	10 (76.92)	3	2 (15.38)
Vomiting	8	5 (38.46)	0	0 (0.00)
Nausea	7	6 (46.15)	0	0 (0.00)
Diarrhoea	4	4 (30.77)	0	0 (0.00)
Abdominal pain	3	3 (23.08)	1	1 (7.69)
Constipation	2	2 (15.38)	0	0 (0.00)
Anal haemorrhage	1	1 (7.69)	0	0 (0.00)
Enterocolitis	1	1 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Gastrointestinal sounds abnormal	1	1 (7.69)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (7.69)	0	0 (0.00)
Haematemesis	1	1 (7.69)	0	0 (0.00)
Lip oedema	1	1 (7.69)	0	0 (0.00)
Neutropenic colitis	1	1 (7.69)	1	1 (7.69)
Proctalgia	1	1 (7.69)	1	1 (7.69)
General disorders and administration site conditions				
- Total	14	6 (46.15)	0	0 (0.00)
Fatigue	5	5 (38.46)	0	0 (0.00)
Pyrexia	4	3 (23.08)	0	0 (0.00)
Chills	2	1 (7.69)	0	0 (0.00)
Catheter site haemorrhage	1	1 (7.69)	0	0 (0.00)
Generalised oedema	1	1 (7.69)	0	0 (0.00)
Vascular device occlusion	1	1 (7.69)	0	0 (0.00)
Hepatobiliary disorders				
- Total	7	4 (30.77)	2	1 (7.69)
Hepatic function abnormal	5	2 (15.38)	2	1 (7.69)
Hepatomegaly	1	1 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Ocular icterus	1	1 (7.69)	0	0 (0.00)
Immune system disorders				
- Total	21	12 (92.31)	6	6 (46.15)
Cytokine release syndrome	18	11 (84.62)	6	6 (46.15)
Hypogammaglobulinaemia	3	2 (15.38)	0	0 (0.00)
Infections and infestations				
- Total	6	5 (38.46)	3	3 (23.08)
Anal abscess	1	1 (7.69)	1	1 (7.69)
Otitis externa	1	1 (7.69)	0	0 (0.00)
Paronychia	1	1 (7.69)	0	0 (0.00)
Pneumonia	1	1 (7.69)	1	1 (7.69)
Urinary tract infection viral	1	1 (7.69)	0	0 (0.00)
Varicella zoster virus infection	1	1 (7.69)	1	1 (7.69)
Injury, poisoning and procedural complications				
- Total	2	2 (15.38)	0	0 (0.00)
Procedural pain	1	1 (7.69)	0	0 (0.00)
Transfusion reaction	1	1 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Investigations				
- Total	102	11 (84.62)	42	9 (69.23)
Platelet count decreased	15	8 (61.54)	6	4 (30.77)
Neutrophil count decreased	14	7 (53.85)	11	5 (38.46)
Lymphocyte count decreased	11	7 (53.85)	8	6 (46.15)
White blood cell count decreased	10	8 (61.54)	7	5 (38.46)
International normalised ratio increased	9	6 (46.15)	0	0 (0.00)
Activated partial thromboplastin time prolonged	5	3 (23.08)	0	0 (0.00)
Alanine aminotransferase increased	5	4 (30.77)	2	2 (15.38)
Aspartate aminotransferase increased	5	4 (30.77)	3	3 (23.08)
Blood bilirubin increased	5	3 (23.08)	2	2 (15.38)
Blood immunoglobulin A decreased	4	4 (30.77)	0	0 (0.00)
Blood immunoglobulin M decreased	4	4 (30.77)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (7.69)	1	1 (7.69)
Blood fibrinogen decreased	3	3 (23.08)	0	0 (0.00)
Haemoglobin decreased	2	1 (7.69)	1	1 (7.69)
Serum ferritin increased	2	2 (15.38)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (7.69)	0	0 (0.00)
Blood uric acid increased	1	1 (7.69)	0	0 (0.00)
C-reactive protein increased	1	1 (7.69)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (7.69)	0	0 (0.00)
Weight increased	1	1 (7.69)	1	1 (7.69)
Metabolism and nutrition disorders				
- Total	23	9 (69.23)	8	5 (38.46)
Decreased appetite	7	7 (53.85)	2	2 (15.38)
Hypokalaemia	3	3 (23.08)	2	2 (15.38)
Hyperphosphataemia	2	2 (15.38)	0	0 (0.00)
Hyperuricaemia	2	1 (7.69)	0	0 (0.00)
Hypoalbuminaemia	2	1 (7.69)	0	0 (0.00)
Hypophosphataemia	2	2 (15.38)	2	2 (15.38)
Dehydration	1	1 (7.69)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (7.69)	1	1 (7.69)
Hypomagnesaemia	1	1 (7.69)	0	0 (0.00)
Metabolic acidosis	1	1 (7.69)	0	0 (0.00)
Tumour lysis syndrome	1	1 (7.69)	1	1 (7.69)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	12	8 (61.54)	0	0 (0.00)
Myalgia	5	4 (30.77)	0	0 (0.00)
Pain in extremity	5	5 (38.46)	0	0 (0.00)
Arthralgia	2	2 (15.38)	0	0 (0.00)
Nervous system disorders				
- Total	8	5 (38.46)	0	0 (0.00)
Headache	4	3 (23.08)	0	0 (0.00)
Dizziness	1	1 (7.69)	0	0 (0.00)
Hypoaesthesia	1	1 (7.69)	0	0 (0.00)
Lethargy	1	1 (7.69)	0	0 (0.00)
Tremor	1	1 (7.69)	0	0 (0.00)
Psychiatric disorders				
- Total	7	5 (38.46)	0	0 (0.00)
Anxiety	2	2 (15.38)	0	0 (0.00)
Confusional state	2	2 (15.38)	0	0 (0.00)
Agitation	1	1 (7.69)	0	0 (0.00)
Irritability	1	1 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Mental status changes	1	1 (7.69)	0	0 (0.00)
Renal and urinary disorders				
- Total	5	4 (30.77)	1	1 (7.69)
Acute kidney injury	1	1 (7.69)	1	1 (7.69)
Dysuria	1	1 (7.69)	0	0 (0.00)
Micturition urgency	1	1 (7.69)	0	0 (0.00)
Pollakiuria	1	1 (7.69)	0	0 (0.00)
Renal tubular dysfunction	1	1 (7.69)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	14	8 (61.54)	3	2 (15.38)
Hypoxia	3	2 (15.38)	3	2 (15.38)
Oropharyngeal pain	3	3 (23.08)	0	0 (0.00)
Cough	2	2 (15.38)	0	0 (0.00)
Rhinorrhoea	2	2 (15.38)	0	0 (0.00)
Tachypnoea	2	2 (15.38)	0	0 (0.00)
Pleural effusion	1	1 (7.69)	0	0 (0.00)
Respiratory distress	1	1 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	11	7 (53.85)	0	0 (0.00)
Pruritus	2	2 (15.38)	0	0 (0.00)
Rash papular	2	2 (15.38)	0	0 (0.00)
Blister	1	1 (7.69)	0	0 (0.00)
Dermatitis	1	1 (7.69)	0	0 (0.00)
Dry skin	1	1 (7.69)	0	0 (0.00)
Eczema	1	1 (7.69)	0	0 (0.00)
Erythema nodosum	1	1 (7.69)	0	0 (0.00)
Rash pruritic	1	1 (7.69)	0	0 (0.00)
Skin ulcer	1	1 (7.69)	0	0 (0.00)
Vascular disorders				
- Total	5	4 (30.77)	2	2 (15.38)
Hypotension	4	3 (23.08)	2	2 (15.38)
Hypertension	1	1 (7.69)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Total number of AE per patient	1446	66 (98.51)	535	55 (82.09)
Blood and lymphatic system disorders				
- Total	100	39 (58.21)	63	31 (46.27)
Anaemia	41	13 (19.40)	20	8 (11.94)
Febrile neutropenia	22	20 (29.85)	22	20 (29.85)
Thrombocytopenia	8	8 (11.94)	8	8 (11.94)
Neutropenia	7	7 (10.45)	5	5 (7.46)
Disseminated intravascular coagulation	6	6 (8.96)	2	2 (2.99)
Coagulopathy	5	5 (7.46)	2	2 (2.99)
Splenomegaly	3	3 (4.48)	0	0 (0.00)
Eosinophilia	2	1 (1.49)	0	0 (0.00)
Leukopenia	2	2 (2.99)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Pancytopenia	2	2 (2.99)	2	2 (2.99)
B-cell aplasia	1	1 (1.49)	0	0 (0.00)
Lymphopenia	1	1 (1.49)	1	1 (1.49)
Cardiac disorders				
- Total	36	17 (25.37)	9	7 (10.45)
Tachycardia	15	11 (16.42)	3	3 (4.48)
Cardiac failure	4	1 (1.49)	2	1 (1.49)
Sinus tachycardia	4	3 (4.48)	0	0 (0.00)
Bradycardia	3	3 (4.48)	0	0 (0.00)
Left ventricular dysfunction	2	2 (2.99)	2	2 (2.99)
Atrioventricular block first degree	1	1 (1.49)	0	0 (0.00)
Cardiac arrest	1	1 (1.49)	1	1 (1.49)
Cardiac dysfunction	1	1 (1.49)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.49)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.49)	0	0 (0.00)
Pericardial effusion	1	1 (1.49)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.49)	0	0 (0.00)
Sinus bradycardia	1	1 (1.49)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (1.49)	0	0 (0.00)
Ear pruritus	1	1 (1.49)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (7.46)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.97)	0	0 (0.00)
Hypothyroidism	1	1 (1.49)	0	0 (0.00)
Eye disorders				
- Total	14	8 (11.94)	0	0 (0.00)
Eyelid oedema	3	2 (2.99)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.99)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.49)	0	0 (0.00)
Eye oedema	1	1 (1.49)	0	0 (0.00)
Eye pain	1	1 (1.49)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.49)	0	0 (0.00)
Periorbital oedema	1	1 (1.49)	0	0 (0.00)
Periorbital swelling	1	1 (1.49)	0	0 (0.00)
Visual field defect	1	1 (1.49)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Visual impairment	1	1 (1.49)	0	0 (0.00)
Gastrointestinal disorders				
- Total	103	41 (61.19)	13	12 (17.91)
Vomiting	22	16 (23.88)	1	1 (1.49)
Diarrhoea	14	11 (16.42)	1	1 (1.49)
Nausea	14	12 (17.91)	2	2 (2.99)
Abdominal pain	10	8 (11.94)	1	1 (1.49)
Constipation	9	9 (13.43)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.97)	2	2 (2.99)
Pancreatitis	4	4 (5.97)	1	1 (1.49)
Abdominal distension	3	3 (4.48)	0	0 (0.00)
Abdominal pain upper	3	3 (4.48)	0	0 (0.00)
Ascites	3	3 (4.48)	0	0 (0.00)
Stomatitis	2	2 (2.99)	1	1 (1.49)
Abdominal compartment syndrome	1	1 (1.49)	1	1 (1.49)
Anal fissure	1	1 (1.49)	0	0 (0.00)
Dry mouth	1	1 (1.49)	0	0 (0.00)
Dysphagia	1	1 (1.49)	1	1 (1.49)
Gastrointestinal sounds abnormal	1	1 (1.49)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Gingival bleeding	1	1 (1.49)	0	0 (0.00)
Gingival erythema	1	1 (1.49)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.49)	1	1 (1.49)
Ileus	1	1 (1.49)	0	0 (0.00)
Lip dry	1	1 (1.49)	0	0 (0.00)
Melaena	1	1 (1.49)	1	1 (1.49)
Mouth swelling	1	1 (1.49)	0	0 (0.00)
Odynophagia	1	1 (1.49)	0	0 (0.00)
Trichoglossia	1	1 (1.49)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.49)	0	0 (0.00)
General disorders and administration site conditions				
- Total	98	34 (50.75)	19	11 (16.42)
Pyrexia	40	21 (31.34)	9	8 (11.94)
Face oedema	9	8 (11.94)	1	1 (1.49)
Chills	7	5 (7.46)	0	0 (0.00)
Oedema peripheral	7	6 (8.96)	2	1 (1.49)
Fatigue	6	6 (8.96)	0	0 (0.00)
Catheter site pain	4	2 (2.99)	2	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Generalised oedema	4	4 (5.97)	0	0 (0.00)
Asthenia	2	2 (2.99)	0	0 (0.00)
Catheter site erythema	2	1 (1.49)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.99)	0	0 (0.00)
Influenza like illness	2	2 (2.99)	0	0 (0.00)
Localised oedema	2	2 (2.99)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.99)	2	2 (2.99)
Chest discomfort	1	1 (1.49)	1	1 (1.49)
Crying	1	1 (1.49)	0	0 (0.00)
Facial pain	1	1 (1.49)	0	0 (0.00)
Malaise	1	1 (1.49)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.49)	0	0 (0.00)
Pain	1	1 (1.49)	1	1 (1.49)
Sluggishness	1	1 (1.49)	0	0 (0.00)
Swelling face	1	1 (1.49)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.49)	1	1 (1.49)
Hepatobiliary disorders				
- Total	22	13 (19.40)	5	5 (7.46)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Hepatic function abnormal	6	3 (4.48)	2	2 (2.99)
Hyperbilirubinaemia	6	5 (7.46)	1	1 (1.49)
Cholelithiasis	2	2 (2.99)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.99)	0	0 (0.00)
Hepatomegaly	2	2 (2.99)	1	1 (1.49)
Hypertransaminasaemia	2	2 (2.99)	0	0 (0.00)
Biliary tract disorder	1	1 (1.49)	0	0 (0.00)
Cholestasis	1	1 (1.49)	1	1 (1.49)
Immune system disorders				
- Total	143	55 (82.09)	62	37 (55.22)
Cytokine release syndrome	110	50 (74.63)	49	32 (47.76)
Hypogammaglobulinaemia	22	21 (31.34)	7	7 (10.45)
Haemophagocytic lymphohistiocytosis	5	5 (7.46)	3	3 (4.48)
Immunodeficiency	3	3 (4.48)	3	3 (4.48)
Hypersensitivity	1	1 (1.49)	0	0 (0.00)
Seasonal allergy	1	1 (1.49)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.49)	0	0 (0.00)
Infections and infestations				

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
- Total	58	30 (44.78)	28	16 (23.88)
Conjunctivitis	6	5 (7.46)	0	0 (0.00)
Staphylococcal infection	5	5 (7.46)	2	2 (2.99)
Candida infection	4	3 (4.48)	2	1 (1.49)
Clostridium difficile infection	4	4 (5.97)	3	3 (4.48)
Staphylococcal bacteraemia	4	3 (4.48)	4	3 (4.48)
Encephalitis viral	2	2 (2.99)	2	2 (2.99)
Nail infection	2	2 (2.99)	0	0 (0.00)
Oral candidiasis	2	1 (1.49)	0	0 (0.00)
Oral herpes	2	2 (2.99)	1	1 (1.49)
Oral infection	2	2 (2.99)	0	0 (0.00)
Rhinovirus infection	2	2 (2.99)	0	0 (0.00)
Adenovirus infection	1	1 (1.49)	1	1 (1.49)
Atypical pneumonia	1	1 (1.49)	0	0 (0.00)
BK virus infection	1	1 (1.49)	0	0 (0.00)
Bacteraemia	1	1 (1.49)	1	1 (1.49)
Bronchopulmonary aspergillosis	1	1 (1.49)	1	1 (1.49)
Cholecystitis infective	1	1 (1.49)	0	0 (0.00)
Encephalitis	1	1 (1.49)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Gastroenteritis norovirus	1	1 (1.49)	0	0 (0.00)
Gingivitis	1	1 (1.49)	0	0 (0.00)
Granulicatella infection	1	1 (1.49)	1	1 (1.49)
Herpes simplex	1	1 (1.49)	1	1 (1.49)
Human herpesvirus 6 infection	1	1 (1.49)	1	1 (1.49)
Klebsiella bacteraemia	1	1 (1.49)	0	0 (0.00)
Klebsiella infection	1	1 (1.49)	1	1 (1.49)
Localised infection	1	1 (1.49)	0	0 (0.00)
Meningitis bacterial	1	1 (1.49)	1	1 (1.49)
Myringitis	1	1 (1.49)	0	0 (0.00)
Pneumonia fungal	1	1 (1.49)	1	1 (1.49)
Pneumonia viral	1	1 (1.49)	1	1 (1.49)
Sinusitis	1	1 (1.49)	1	1 (1.49)
Soft tissue infection	1	1 (1.49)	1	1 (1.49)
Stomatococcal infection	1	1 (1.49)	0	0 (0.00)
Systemic candida	1	1 (1.49)	1	1 (1.49)
Injury, poisoning and procedural complications				
- Total	18	9 (13.43)	3	2 (2.99)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Infusion related reaction	3	2 (2.99)	0	0 (0.00)
Wound	3	2 (2.99)	1	1 (1.49)
Contusion	2	1 (1.49)	0	0 (0.00)
Fall	2	2 (2.99)	0	0 (0.00)
Procedural pain	1	1 (1.49)	0	0 (0.00)
Scratch	1	1 (1.49)	0	0 (0.00)
Skin abrasion	1	1 (1.49)	0	0 (0.00)
Skin injury	1	1 (1.49)	0	0 (0.00)
Skin wound	1	1 (1.49)	0	0 (0.00)
Transfusion reaction	1	1 (1.49)	0	0 (0.00)
Transplant failure	1	1 (1.49)	1	1 (1.49)
Vasoplegia syndrome	1	1 (1.49)	1	1 (1.49)
Investigations				
- Total	284	46 (68.66)	155	36 (53.73)
Platelet count decreased	50	13 (19.40)	32	10 (14.93)
White blood cell count decreased	40	16 (23.88)	29	13 (19.40)
Neutrophil count decreased	34	13 (19.40)	27	12 (17.91)
Aspartate aminotransferase increased	28	15 (22.39)	10	8 (11.94)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Alanine aminotransferase increased	21	14 (20.90)	4	4 (5.97)
Lymphocyte count decreased	19	8 (11.94)	16	7 (10.45)
Blood bilirubin increased	13	9 (13.43)	7	7 (10.45)
Blood creatinine increased	6	4 (5.97)	5	3 (4.48)
Serum ferritin increased	6	6 (8.96)	2	2 (2.99)
Electrocardiogram QT prolonged	5	4 (5.97)	2	2 (2.99)
Immunoglobulins decreased	5	2 (2.99)	0	0 (0.00)
Blood fibrinogen decreased	4	4 (5.97)	2	2 (2.99)
Lipase increased	4	2 (2.99)	2	1 (1.49)
Activated partial thromboplastin time prolonged	3	3 (4.48)	1	1 (1.49)
Blood lactate dehydrogenase increased	3	3 (4.48)	1	1 (1.49)
C-reactive protein increased	3	3 (4.48)	3	3 (4.48)
Fibrin D dimer increased	3	3 (4.48)	1	1 (1.49)
International normalised ratio increased	3	3 (4.48)	0	0 (0.00)
Urine output decreased	3	2 (2.99)	3	2 (2.99)
Weight increased	3	3 (4.48)	0	0 (0.00)
Blood glucose increased	2	1 (1.49)	2	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Blood immunoglobulin G decreased	2	2 (2.99)	0	0 (0.00)
Blood immunoglobulin M decreased	2	2 (2.99)	1	1 (1.49)
Gamma-glutamyltransferase increased	2	2 (2.99)	2	2 (2.99)
Amylase increased	1	1 (1.49)	0	0 (0.00)
Bacterial test positive	1	1 (1.49)	1	1 (1.49)
Blood alkaline phosphatase increased	1	1 (1.49)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.49)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.49)	1	1 (1.49)
Blood immunoglobulin A decreased	1	1 (1.49)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.49)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.49)	0	0 (0.00)
Blood uric acid increased	1	1 (1.49)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.49)	0	0 (0.00)
Cardiac murmur	1	1 (1.49)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.49)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.49)	0	0 (0.00)
Enterovirus test positive	1	1 (1.49)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Haptoglobin decreased	1	1 (1.49)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.49)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.49)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.49)	0	0 (0.00)
Troponin increased	1	1 (1.49)	1	1 (1.49)
Weight decreased	1	1 (1.49)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	187	37 (55.22)	68	24 (35.82)
Hypokalaemia	37	16 (23.88)	18	9 (13.43)
Hypophosphataemia	29	15 (22.39)	9	7 (10.45)
Hypocalcaemia	24	16 (23.88)	6	5 (7.46)
Decreased appetite	17	17 (25.37)	9	9 (13.43)
Hypoalbuminaemia	17	10 (14.93)	1	1 (1.49)
Hyperglycaemia	11	8 (11.94)	4	4 (5.97)
Hyperuricaemia	7	6 (8.96)	1	1 (1.49)
Hypervolaemia	6	6 (8.96)	4	4 (5.97)
Hypomagnesaemia	6	5 (7.46)	0	0 (0.00)
Hypercalcaemia	4	3 (4.48)	2	2 (2.99)
Acidosis	3	2 (2.99)	2	2 (2.99)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Hypermagnesaemia	3	2 (2.99)	0	0 (0.00)
Hyperphosphataemia	3	3 (4.48)	1	1 (1.49)
Hyponatraemia	3	3 (4.48)	0	0 (0.00)
Tumour lysis syndrome	3	3 (4.48)	3	3 (4.48)
Hyperkalaemia	2	2 (2.99)	2	2 (2.99)
Hypernatraemia	2	2 (2.99)	1	1 (1.49)
Metabolic acidosis	2	2 (2.99)	2	2 (2.99)
Calcium deficiency	1	1 (1.49)	0	0 (0.00)
Haemosiderosis	1	1 (1.49)	0	0 (0.00)
Hyperchloraemia	1	1 (1.49)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.49)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (1.49)	1	1 (1.49)
Hypoglycaemia	1	1 (1.49)	0	0 (0.00)
Malnutrition	1	1 (1.49)	1	1 (1.49)
Polydipsia	1	1 (1.49)	1	1 (1.49)
Musculoskeletal and connective tissue disorders				
- Total	41	25 (37.31)	6	5 (7.46)
Arthralgia	8	8 (11.94)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Back pain	7	6 (8.96)	1	1 (1.49)
Pain in extremity	6	6 (8.96)	0	0 (0.00)
Myalgia	5	5 (7.46)	0	0 (0.00)
Bone pain	4	2 (2.99)	0	0 (0.00)
Muscular weakness	2	2 (2.99)	1	1 (1.49)
Pain in jaw	2	2 (2.99)	1	1 (1.49)
Haemarthrosis	1	1 (1.49)	1	1 (1.49)
Muscle rigidity	1	1 (1.49)	0	0 (0.00)
Muscle spasms	1	1 (1.49)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.49)	0	0 (0.00)
Myositis	1	1 (1.49)	0	0 (0.00)
Neck pain	1	1 (1.49)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.49)	1	1 (1.49)
Nervous system disorders				
- Total	69	35 (52.24)	14	10 (14.93)
Headache	22	20 (29.85)	2	2 (2.99)
Encephalopathy	8	8 (11.94)	4	4 (5.97)
Tremor	6	5 (7.46)	0	0 (0.00)
Cognitive disorder	5	3 (4.48)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Somnolence	5	5 (7.46)	2	2 (2.99)
Dysgeusia	3	3 (4.48)	0	0 (0.00)
Seizure	3	2 (2.99)	1	1 (1.49)
Dizziness	2	2 (2.99)	0	0 (0.00)
Hyperaesthesia	2	1 (1.49)	0	0 (0.00)
Lethargy	2	2 (2.99)	0	0 (0.00)
Amnesia	1	1 (1.49)	0	0 (0.00)
Aphasia	1	1 (1.49)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.49)	1	1 (1.49)
Depressed level of consciousness	1	1 (1.49)	1	1 (1.49)
Disturbance in attention	1	1 (1.49)	0	0 (0.00)
Dysarthria	1	1 (1.49)	1	1 (1.49)
Generalised tonic-clonic seizure	1	1 (1.49)	0	0 (0.00)
Monoparesis	1	1 (1.49)	0	0 (0.00)
Neuralgia	1	1 (1.49)	0	0 (0.00)
Neurological decompensation	1	1 (1.49)	1	1 (1.49)
Paraesthesia	1	1 (1.49)	0	0 (0.00)
Psychiatric disorders				
- Total	40	23 (34.33)	6	6 (8.96)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Delirium	7	7 (10.45)	3	3 (4.48)
Agitation	5	4 (5.97)	0	0 (0.00)
Confusional state	5	5 (7.46)	0	0 (0.00)
Anxiety	4	4 (5.97)	2	2 (2.99)
Insomnia	4	4 (5.97)	0	0 (0.00)
Hallucination	3	3 (4.48)	0	0 (0.00)
Sleep disorder	3	2 (2.99)	0	0 (0.00)
Irritability	2	2 (2.99)	0	0 (0.00)
Mental status changes	2	2 (2.99)	1	1 (1.49)
Affect lability	1	1 (1.49)	0	0 (0.00)
Automatism	1	1 (1.49)	0	0 (0.00)
Hallucination, visual	1	1 (1.49)	0	0 (0.00)
Restlessness	1	1 (1.49)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.49)	0	0 (0.00)
Renal and urinary disorders				
- Total	34	16 (23.88)	12	8 (11.94)
Acute kidney injury	13	8 (11.94)	7	6 (8.96)
Renal failure	4	2 (2.99)	3	1 (1.49)
Anuria	2	2 (2.99)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Dysuria	2	2 (2.99)	0	0 (0.00)
Haematuria	2	2 (2.99)	0	0 (0.00)
Urinary incontinence	2	1 (1.49)	0	0 (0.00)
Urinary retention	2	2 (2.99)	0	0 (0.00)
Azotaemia	1	1 (1.49)	0	0 (0.00)
Bladder dilatation	1	1 (1.49)	0	0 (0.00)
Incontinence	1	1 (1.49)	0	0 (0.00)
Pollakiuria	1	1 (1.49)	0	0 (0.00)
Proteinuria	1	1 (1.49)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.49)	1	1 (1.49)
Urinary tract disorder	1	1 (1.49)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	5 (7.46)	1	1 (1.49)
Vaginal haemorrhage	2	1 (1.49)	0	0 (0.00)
Female genital tract fistula	1	1 (1.49)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.49)	0	0 (0.00)
Perineal rash	1	1 (1.49)	0	0 (0.00)
Vaginal ulceration	1	1 (1.49)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	100	33 (49.25)	47	21 (31.34)
Hypoxia	20	15 (22.39)	15	10 (14.93)
Pulmonary oedema	12	12 (17.91)	7	7 (10.45)
Cough	9	8 (11.94)	0	0 (0.00)
Tachypnoea	7	6 (8.96)	4	4 (5.97)
Pleural effusion	6	6 (8.96)	3	3 (4.48)
Atelectasis	5	3 (4.48)	2	2 (2.99)
Epistaxis	4	4 (5.97)	1	1 (1.49)
Respiratory failure	4	4 (5.97)	4	4 (5.97)
Dyspnoea	3	3 (4.48)	3	3 (4.48)
Nasal congestion	3	3 (4.48)	0	0 (0.00)
Oropharyngeal pain	3	2 (2.99)	0	0 (0.00)
Respiratory distress	3	2 (2.99)	2	1 (1.49)
Acute respiratory distress syndrome	2	2 (2.99)	2	2 (2.99)
Lung infiltration	2	1 (1.49)	1	1 (1.49)
Acute respiratory failure	1	1 (1.49)	1	1 (1.49)
Bradypnoea	1	1 (1.49)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Haemoptysis	1	1 (1.49)	0	0 (0.00)
Nasal discomfort	1	1 (1.49)	0	0 (0.00)
Nasal dryness	1	1 (1.49)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.49)	0	0 (0.00)
Painful respiration	1	1 (1.49)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.49)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.49)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.49)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.49)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.49)	0	0 (0.00)
Productive cough	1	1 (1.49)	0	0 (0.00)
Pulmonary mass	1	1 (1.49)	0	0 (0.00)
Respiratory acidosis	1	1 (1.49)	1	1 (1.49)
Respiratory disorder	1	1 (1.49)	0	0 (0.00)
Wheezing	1	1 (1.49)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	45	20 (29.85)	4	3 (4.48)
Blister	5	2 (2.99)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Pruritus	5	4 (5.97)	0	0 (0.00)
Rash	5	5 (7.46)	0	0 (0.00)
Erythema	4	4 (5.97)	0	0 (0.00)
Hyperhidrosis	3	3 (4.48)	0	0 (0.00)
Rash maculo-papular	3	2 (2.99)	1	1 (1.49)
Dermatitis atopic	2	2 (2.99)	0	0 (0.00)
Petechiae	2	2 (2.99)	1	1 (1.49)
Rash papular	2	1 (1.49)	0	0 (0.00)
Rash vesicular	2	1 (1.49)	0	0 (0.00)
Decubitus ulcer	1	1 (1.49)	0	0 (0.00)
Dermatitis diaper	1	1 (1.49)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.49)	0	0 (0.00)
Pruritus allergic	1	1 (1.49)	0	0 (0.00)
Purpura	1	1 (1.49)	0	0 (0.00)
Scab	1	1 (1.49)	0	0 (0.00)
Skin discolouration	1	1 (1.49)	0	0 (0.00)
Skin lesion	1	1 (1.49)	0	0 (0.00)
Skin necrosis	1	1 (1.49)	1	1 (1.49)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Skin ulcer	1	1 (1.49)	0	0 (0.00)
Urticaria	1	1 (1.49)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.49)	1	1 (1.49)
Social circumstances				
- Total	1	1 (1.49)	0	0 (0.00)
Patient uncooperative	1	1 (1.49)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.49)	1	1 (1.49)
Thrombolysis	1	1 (1.49)	1	1 (1.49)
Vascular disorders				
- Total	40	24 (35.82)	19	15 (22.39)
Hypotension	21	18 (26.87)	14	12 (17.91)
Hypertension	13	12 (17.91)	4	4 (5.97)
Capillary leak syndrome	2	2 (2.99)	1	1 (1.49)
Flushing	1	1 (1.49)	0	0 (0.00)
Hot flush	1	1 (1.49)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.49)	0	0 (0.00)
Thrombosis	1	1 (1.49)	0	0 (0.00)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Total number of AE per patient	69	13 (100.00)	8	5 (38.46)
Blood and lymphatic system disorders				
- Total	3	3 (23.08)	2	2 (15.38)
Neutropenia	2	2 (15.38)	2	2 (15.38)
Anaemia	1	1 (7.69)	0	0 (0.00)
Eye disorders				
- Total	2	2 (15.38)	0	0 (0.00)
Cataract	1	1 (7.69)	0	0 (0.00)
Ocular hyperaemia	1	1 (7.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	10	5 (38.46)	0	0 (0.00)
Vomiting	2	2 (15.38)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Abdominal pain	1	1 (7.69)	0	0 (0.00)
Constipation	1	1 (7.69)	0	0 (0.00)
Diarrhoea	1	1 (7.69)	0	0 (0.00)
Enteritis	1	1 (7.69)	0	0 (0.00)
Nausea	1	1 (7.69)	0	0 (0.00)
Proctalgia	1	1 (7.69)	0	0 (0.00)
Stomatitis	1	1 (7.69)	0	0 (0.00)
Trichoglossia	1	1 (7.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	3 (23.08)	0	0 (0.00)
Fatigue	2	2 (15.38)	0	0 (0.00)
Oedema peripheral	2	1 (7.69)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (23.08)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (23.08)	0	0 (0.00)
Infections and infestations				
- Total	5	2 (15.38)	0	0 (0.00)
Nasopharyngitis	2	1 (7.69)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Gastroenteritis	1	1 (7.69)	0	0 (0.00)
Sinusitis	1	1 (7.69)	0	0 (0.00)
Tinea pedis	1	1 (7.69)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (15.38)	0	0 (0.00)
Contusion	1	1 (7.69)	0	0 (0.00)
Infusion related reaction	1	1 (7.69)	0	0 (0.00)
Investigations				
- Total	18	10 (76.92)	6	4 (30.77)
Neutrophil count decreased	5	4 (30.77)	3	2 (15.38)
White blood cell count decreased	3	3 (23.08)	1	1 (7.69)
Blood bilirubin increased	2	1 (7.69)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (15.38)	1	1 (7.69)
Lymphocyte count decreased	2	2 (15.38)	0	0 (0.00)
Platelet count decreased	2	1 (7.69)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (7.69)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (7.69)	1	1 (7.69)
Metabolism and nutrition disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
- Total	2	2 (15.38)	0	0 (0.00)
Decreased appetite	1	1 (7.69)	0	0 (0.00)
Hyperuricaemia	1	1 (7.69)	0	0 (0.00)
Nervous system disorders				
- Total	2	2 (15.38)	0	0 (0.00)
Headache	2	2 (15.38)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (7.69)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (7.69)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	6 (46.15)	0	0 (0.00)
Cough	4	3 (23.08)	0	0 (0.00)
Rhinorrhoea	3	3 (23.08)	0	0 (0.00)
Nasal congestion	2	2 (15.38)	0	0 (0.00)
Epistaxis	1	1 (7.69)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (7.69)	0	0 (0.00)
Pleural effusion	1	1 (7.69)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (7.69)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	4	3 (23.08)	0	0 (0.00)
Dry skin	3	2 (15.38)	0	0 (0.00)
Skin swelling	1	1 (7.69)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Total number of AE per patient	465	56 (90.32)	138	31 (50.00)
Blood and lymphatic system disorders				
- Total	29	14 (22.58)	15	8 (12.90)
Anaemia	11	5 (8.06)	4	2 (3.23)
Febrile neutropenia	4	3 (4.84)	4	3 (4.84)
Neutropenia	3	3 (4.84)	3	3 (4.84)
B-cell aplasia	2	1 (1.61)	0	0 (0.00)
Thrombocytopenia	2	2 (3.23)	2	2 (3.23)
Disseminated intravascular coagulation	1	1 (1.61)	1	1 (1.61)
Eosinophilia	1	1 (1.61)	0	0 (0.00)
Leukocytosis	1	1 (1.61)	0	0 (0.00)
Leukopenia	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Lymphadenopathy	1	1 (1.61)	0	0 (0.00)
Lymphocytosis	1	1 (1.61)	0	0 (0.00)
Lymphopenia	1	1 (1.61)	1	1 (1.61)
Cardiac disorders				
- Total	8	7 (11.29)	4	3 (4.84)
Cardiac arrest	2	2 (3.23)	2	2 (3.23)
Cardiac failure	2	2 (3.23)	2	2 (3.23)
Tachycardia	2	2 (3.23)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.61)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.61)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.61)	0	0 (0.00)
Hypothyroidism	1	1 (1.61)	0	0 (0.00)
Eye disorders				
- Total	3	2 (3.23)	0	0 (0.00)
Cataract	1	1 (1.61)	0	0 (0.00)
Hypermetropia	1	1 (1.61)	0	0 (0.00)
Visual impairment	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Gastrointestinal disorders				
- Total	28	15 (24.19)	1	1 (1.61)
Diarrhoea	6	6 (9.68)	0	0 (0.00)
Vomiting	5	4 (6.45)	0	0 (0.00)
Nausea	4	4 (6.45)	0	0 (0.00)
Constipation	3	2 (3.23)	0	0 (0.00)
Pancreatitis	2	2 (3.23)	1	1 (1.61)
Abdominal pain	1	1 (1.61)	0	0 (0.00)
Abdominal pain upper	1	1 (1.61)	0	0 (0.00)
Abdominal rigidity	1	1 (1.61)	0	0 (0.00)
Dyspepsia	1	1 (1.61)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.61)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.61)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.61)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.61)	0	0 (0.00)
General disorders and administration site conditions				
- Total	27	21 (33.87)	3	3 (4.84)
Pyrexia	16	15 (24.19)	2	2 (3.23)
Fatigue	5	4 (6.45)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Pain	2	2 (3.23)	1	1 (1.61)
Asthenia	1	1 (1.61)	0	0 (0.00)
Chills	1	1 (1.61)	0	0 (0.00)
Malaise	1	1 (1.61)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.61)	0	0 (0.00)
Hepatobiliary disorders				
- Total	3	3 (4.84)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.61)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.61)	0	0 (0.00)
Liver disorder	1	1 (1.61)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (20.97)	5	4 (6.45)
Hypogammaglobulinaemia	9	7 (11.29)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (3.23)	1	1 (1.61)
Graft versus host disease	2	2 (3.23)	2	2 (3.23)
Drug hypersensitivity	1	1 (1.61)	0	0 (0.00)
Engraftment syndrome	1	1 (1.61)	1	1 (1.61)
Immunodeficiency	1	1 (1.61)	1	1 (1.61)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Infections and infestations				
- Total	108	37 (59.68)	45	20 (32.26)
Upper respiratory tract infection	10	8 (12.90)	2	2 (3.23)
Nasopharyngitis	7	6 (9.68)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (1.61)	3	1 (1.61)
Parainfluenzae virus infection	5	4 (6.45)	2	2 (3.23)
Rhinovirus infection	5	5 (8.06)	1	1 (1.61)
Gastroenteritis	4	4 (6.45)	2	2 (3.23)
Bacteraemia	3	2 (3.23)	2	1 (1.61)
Ear infection	3	2 (3.23)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.84)	3	3 (4.84)
Otitis media	3	3 (4.84)	1	1 (1.61)
Pneumonia	3	3 (4.84)	1	1 (1.61)
Respiratory syncytial virus infection	3	3 (4.84)	2	2 (3.23)
Respiratory tract infection	3	3 (4.84)	0	0 (0.00)
Sinusitis	3	2 (3.23)	1	1 (1.61)
Klebsiella infection	2	1 (1.61)	2	1 (1.61)
Otitis externa	2	2 (3.23)	1	1 (1.61)
Pneumocystis jirovecii pneumonia	2	2 (3.23)	2	2 (3.23)
Rhinitis	2	2 (3.23)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Urinary tract infection	2	1 (1.61)	2	1 (1.61)
Viral infection	2	2 (3.23)	1	1 (1.61)
Acute sinusitis	1	1 (1.61)	0	0 (0.00)
Adenovirus infection	1	1 (1.61)	1	1 (1.61)
BK virus infection	1	1 (1.61)	1	1 (1.61)
Cellulitis	1	1 (1.61)	0	0 (0.00)
Conjunctivitis	1	1 (1.61)	0	0 (0.00)
Coronavirus infection	1	1 (1.61)	1	1 (1.61)
Cystitis	1	1 (1.61)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.61)	1	1 (1.61)
Device related infection	1	1 (1.61)	1	1 (1.61)
Ear, nose and throat infection	1	1 (1.61)	0	0 (0.00)
Encephalitis	1	1 (1.61)	1	1 (1.61)
Enterobacter infection	1	1 (1.61)	1	1 (1.61)
Gastroenteritis clostridial	1	1 (1.61)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.61)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.61)	0	0 (0.00)
Gingivitis	1	1 (1.61)	0	0 (0.00)
Herpes simplex	1	1 (1.61)	0	0 (0.00)
Herpes zoster	1	1 (1.61)	1	1 (1.61)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Human herpesvirus 6 infection	1	1 (1.61)	1	1 (1.61)
Influenza	1	1 (1.61)	0	0 (0.00)
Mastoiditis	1	1 (1.61)	1	1 (1.61)
Molluscum contagiosum	1	1 (1.61)	0	0 (0.00)
Nail infection	1	1 (1.61)	0	0 (0.00)
Oral candidiasis	1	1 (1.61)	0	0 (0.00)
Oral herpes	1	1 (1.61)	0	0 (0.00)
Paronychia	1	1 (1.61)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.61)	1	1 (1.61)
Respiratory tract infection viral	1	1 (1.61)	0	0 (0.00)
Salmonellosis	1	1 (1.61)	0	0 (0.00)
Septic shock	1	1 (1.61)	1	1 (1.61)
Sinusitis fungal	1	1 (1.61)	1	1 (1.61)
Staphylococcal bacteraemia	1	1 (1.61)	1	1 (1.61)
Staphylococcal sepsis	1	1 (1.61)	1	1 (1.61)
Staphylococcal skin infection	1	1 (1.61)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.61)	1	1 (1.61)
Viral upper respiratory tract infection	1	1 (1.61)	1	1 (1.61)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
- Total	8	7 (11.29)	0	0 (0.00)
Infusion related reaction	3	2 (3.23)	0	0 (0.00)
Fibula fracture	1	1 (1.61)	0	0 (0.00)
Ligament sprain	1	1 (1.61)	0	0 (0.00)
Limb injury	1	1 (1.61)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.61)	0	0 (0.00)
Skin abrasion	1	1 (1.61)	0	0 (0.00)
Investigations				
- Total	73	20 (32.26)	29	12 (19.35)
White blood cell count decreased	15	7 (11.29)	3	3 (4.84)
Neutrophil count decreased	14	6 (9.68)	8	5 (8.06)
Platelet count decreased	14	4 (6.45)	9	2 (3.23)
Immunoglobulins decreased	5	1 (1.61)	0	0 (0.00)
Lymphocyte count decreased	4	2 (3.23)	2	2 (3.23)
Weight increased	3	1 (1.61)	1	1 (1.61)
Alanine aminotransferase increased	2	1 (1.61)	1	1 (1.61)
Blood bilirubin increased	2	1 (1.61)	1	1 (1.61)
Blood uric acid increased	2	2 (3.23)	2	2 (3.23)
Blood creatinine increased	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Blood immunoglobulin G decreased	1	1 (1.61)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (1.61)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.61)	0	0 (0.00)
Blood urea increased	1	1 (1.61)	1	1 (1.61)
Bone density decreased	1	1 (1.61)	0	0 (0.00)
C-reactive protein increased	1	1 (1.61)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.61)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.61)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.61)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.61)	0	0 (0.00)
Weight decreased	1	1 (1.61)	1	1 (1.61)
Metabolism and nutrition disorders				
- Total	24	13 (20.97)	10	7 (11.29)
Hypokalaemia	6	3 (4.84)	4	2 (3.23)
Decreased appetite	5	5 (8.06)	1	1 (1.61)
Hyperuricaemia	2	2 (3.23)	0	0 (0.00)
Haemochromatosis	1	1 (1.61)	1	1 (1.61)
Hyperchloraemia	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Hyperkalaemia	1	1 (1.61)	0	0 (0.00)
Hypervolaemia	1	1 (1.61)	1	1 (1.61)
Hypophagia	1	1 (1.61)	0	0 (0.00)
Hypophosphataemia	1	1 (1.61)	0	0 (0.00)
Iron overload	1	1 (1.61)	0	0 (0.00)
Malnutrition	1	1 (1.61)	1	1 (1.61)
Metabolic acidosis	1	1 (1.61)	1	1 (1.61)
Metabolic syndrome	1	1 (1.61)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.61)	1	1 (1.61)
Musculoskeletal and connective tissue disorders				
- Total	22	15 (24.19)	3	3 (4.84)
Back pain	7	6 (9.68)	2	2 (3.23)
Pain in extremity	5	5 (8.06)	1	1 (1.61)
Arthralgia	3	3 (4.84)	0	0 (0.00)
Bone pain	2	2 (3.23)	0	0 (0.00)
Growth retardation	1	1 (1.61)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.61)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.61)	0	0 (0.00)
Myalgia	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Neck pain	1	1 (1.61)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (6.45)	1	1 (1.61)
Skin papilloma	2	2 (3.23)	0	0 (0.00)
Cancer pain	1	1 (1.61)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.61)	1	1 (1.61)
Nervous system disorders				
- Total	21	12 (19.35)	6	2 (3.23)
Headache	9	8 (12.90)	0	0 (0.00)
Hydrocephalus	3	1 (1.61)	3	1 (1.61)
Dizziness	2	1 (1.61)	0	0 (0.00)
Migraine	2	1 (1.61)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.61)	1	1 (1.61)
Cerebral haemorrhage	1	1 (1.61)	1	1 (1.61)
Extrapyramidal disorder	1	1 (1.61)	0	0 (0.00)
Memory impairment	1	1 (1.61)	0	0 (0.00)
Seizure	1	1 (1.61)	1	1 (1.61)
Psychiatric disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
- Total	15	10 (16.13)	1	1 (1.61)
Anxiety	6	6 (9.68)	0	0 (0.00)
Mental status changes	2	2 (3.23)	1	1 (1.61)
Agitation	1	1 (1.61)	0	0 (0.00)
Delirium	1	1 (1.61)	0	0 (0.00)
Mood altered	1	1 (1.61)	0	0 (0.00)
Nightmare	1	1 (1.61)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.61)	0	0 (0.00)
Sleep disorder	1	1 (1.61)	0	0 (0.00)
Tearfulness	1	1 (1.61)	0	0 (0.00)
Renal and urinary disorders				
- Total	8	4 (6.45)	3	3 (4.84)
Acute kidney injury	3	3 (4.84)	1	1 (1.61)
Dysuria	1	1 (1.61)	0	0 (0.00)
Haematuria	1	1 (1.61)	1	1 (1.61)
Kidney enlargement	1	1 (1.61)	0	0 (0.00)
Renal mass	1	1 (1.61)	0	0 (0.00)
Renal tubular disorder	1	1 (1.61)	1	1 (1.61)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Reproductive system and breast disorders				
- Total	2	1 (1.61)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.61)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	33	18 (29.03)	6	6 (9.68)
Cough	10	8 (12.90)	0	0 (0.00)
Nasal congestion	5	4 (6.45)	0	0 (0.00)
Hypoxia	3	3 (4.84)	3	3 (4.84)
Dyspnoea	2	1 (1.61)	0	0 (0.00)
Epistaxis	2	2 (3.23)	0	0 (0.00)
Oropharyngeal pain	2	2 (3.23)	0	0 (0.00)
Rhinitis allergic	2	2 (3.23)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.61)	1	1 (1.61)
Bronchial oedema	1	1 (1.61)	0	0 (0.00)
Bronchospasm	1	1 (1.61)	0	0 (0.00)
Lung disorder	1	1 (1.61)	0	0 (0.00)
Pleural effusion	1	1 (1.61)	0	0 (0.00)
Respiratory distress	1	1 (1.61)	1	1 (1.61)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Respiratory failure	1	1 (1.61)	1	1 (1.61)
Skin and subcutaneous tissue disorders				
- Total	25	17 (27.42)	1	1 (1.61)
Rash	6	4 (6.45)	0	0 (0.00)
Dry skin	4	4 (6.45)	0	0 (0.00)
Ingrowing nail	2	2 (3.23)	0	0 (0.00)
Pruritus	2	1 (1.61)	0	0 (0.00)
Decubitus ulcer	1	1 (1.61)	1	1 (1.61)
Dermatitis allergic	1	1 (1.61)	0	0 (0.00)
Dermatitis atopic	1	1 (1.61)	0	0 (0.00)
Eczema	1	1 (1.61)	0	0 (0.00)
Erythema	1	1 (1.61)	0	0 (0.00)
Hangnail	1	1 (1.61)	0	0 (0.00)
Miliaria	1	1 (1.61)	0	0 (0.00)
Night sweats	1	1 (1.61)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.61)	0	0 (0.00)
Skin discolouration	1	1 (1.61)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.61)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=62 n (%)[1]	Grade >= 3 Total events	All patients N=62 n (%)[2]
Vascular disorders				
- Total	7	6 (9.68)	5	5 (8.06)
Hypotension	4	4 (6.45)	3	3 (4.84)
Venoocclusive disease	2	2 (3.23)	2	2 (3.23)
Hypertension	1	1 (1.61)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Total number of AE per patient	37	6 (75.00)	5	3 (37.50)
Congenital, familial and genetic disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (12.50)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (12.50)	0	0 (0.00)
Deafness unilateral	1	1 (12.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	2 (25.00)	0	0 (0.00)
Non-cardiac chest pain	1	1 (12.50)	0	0 (0.00)
Xerosis	1	1 (12.50)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Immune system disorders				
- Total	2	2 (25.00)	0	0 (0.00)
Hypogammaglobulinaemia	2	2 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	19	3 (37.50)	3	3 (37.50)
Sinusitis	4	1 (12.50)	0	0 (0.00)
Upper respiratory tract infection	4	2 (25.00)	1	1 (12.50)
Conjunctivitis	2	1 (12.50)	0	0 (0.00)
Otitis media	2	1 (12.50)	0	0 (0.00)
Acute sinusitis	1	1 (12.50)	0	0 (0.00)
Ear infection	1	1 (12.50)	1	1 (12.50)
Herpes zoster	1	1 (12.50)	0	0 (0.00)
Influenza	1	1 (12.50)	0	0 (0.00)
Oral herpes	1	1 (12.50)	0	0 (0.00)
Skin infection	1	1 (12.50)	0	0 (0.00)
Staphylococcal abscess	1	1 (12.50)	1	1 (12.50)
Investigations				
- Total	6	2 (25.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=8 n (%)[1]	Grade >= 3 Total events	All patients N=8 n (%)[2]
Blood bilirubin increased	3	1 (12.50)	0	0 (0.00)
Neutrophil count decreased	2	2 (25.00)	0	0 (0.00)
Platelet count decreased	1	1 (12.50)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (25.00)	1	1 (12.50)
Cough	1	1 (12.50)	0	0 (0.00)
Dyspnoea	1	1 (12.50)	0	0 (0.00)
Laryngeal oedema	1	1 (12.50)	1	1 (12.50)
Rhinorrhoea	1	1 (12.50)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (12.50)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	1	1 (12.50)	1	1 (12.50)
Eczema	1	1 (12.50)	1	1 (12.50)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Total number of AE per patient	183	26 (61.90)	58	16 (38.10)
Blood and lymphatic system disorders				
- Total	6	4 (9.52)	2	2 (4.76)
Agranulocytosis	1	1 (2.38)	1	1 (2.38)
Anaemia	1	1 (2.38)	0	0 (0.00)
Hypercoagulation	1	1 (2.38)	0	0 (0.00)
Lymphadenopathy	1	1 (2.38)	0	0 (0.00)
Neutropenia	1	1 (2.38)	1	1 (2.38)
Thrombocytopenia	1	1 (2.38)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.38)	0	0 (0.00)
Delayed puberty	1	1 (2.38)	0	0 (0.00)
Hypothyroidism	1	1 (2.38)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Eye disorders				
- Total	4	3 (7.14)	1	1 (2.38)
Dry eye	1	1 (2.38)	0	0 (0.00)
Eye pain	1	1 (2.38)	1	1 (2.38)
Eyelid oedema	1	1 (2.38)	0	0 (0.00)
Mydriasis	1	1 (2.38)	0	0 (0.00)
Gastrointestinal disorders				
- Total	9	7 (16.67)	1	1 (2.38)
Diarrhoea	5	5 (11.90)	1	1 (2.38)
Constipation	1	1 (2.38)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.38)	0	0 (0.00)
Nausea	1	1 (2.38)	0	0 (0.00)
Vomiting	1	1 (2.38)	0	0 (0.00)
General disorders and administration site conditions				
- Total	11	7 (16.67)	2	2 (4.76)
Pyrexia	7	5 (11.90)	1	1 (2.38)
Pain	2	2 (4.76)	0	0 (0.00)
Fatigue	1	1 (2.38)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (2.38)	1	1 (2.38)
Immune system disorders				
- Total	8	7 (16.67)	3	2 (4.76)
Seasonal allergy	3	3 (7.14)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.76)	1	1 (2.38)
Drug hypersensitivity	1	1 (2.38)	1	1 (2.38)
Haemophagocytic lymphohistiocytosis	1	1 (2.38)	1	1 (2.38)
Hypogammaglobulinaemia	1	1 (2.38)	0	0 (0.00)
Infections and infestations				
- Total	67	20 (47.62)	23	11 (26.19)
Sinusitis	5	5 (11.90)	0	0 (0.00)
Rhinovirus infection	4	4 (9.52)	1	1 (2.38)
COVID-19	3	2 (4.76)	1	1 (2.38)
Conjunctivitis	3	3 (7.14)	0	0 (0.00)
Fungal infection	3	2 (4.76)	0	0 (0.00)
Sepsis	3	3 (7.14)	3	3 (7.14)
Upper respiratory tract infection	3	3 (7.14)	0	0 (0.00)
Bronchitis	2	2 (4.76)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Device related sepsis	2	1 (2.38)	2	1 (2.38)
Gastroenteritis viral	2	1 (2.38)	0	0 (0.00)
Pneumonia	2	2 (4.76)	2	2 (4.76)
Skin infection	2	2 (4.76)	0	0 (0.00)
Urinary tract infection	2	2 (4.76)	0	0 (0.00)
Bronchiolitis	1	1 (2.38)	1	1 (2.38)
COVID-19 pneumonia	1	1 (2.38)	1	1 (2.38)
Candida infection	1	1 (2.38)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.38)	1	1 (2.38)
Enterovirus infection	1	1 (2.38)	1	1 (2.38)
Folliculitis	1	1 (2.38)	0	0 (0.00)
Fungal skin infection	1	1 (2.38)	0	0 (0.00)
Gastroenteritis	1	1 (2.38)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.38)	1	1 (2.38)
Gastroenteritis salmonella	1	1 (2.38)	1	1 (2.38)
Herpes virus infection	1	1 (2.38)	0	0 (0.00)
Herpes zoster	1	1 (2.38)	1	1 (2.38)
Influenza	1	1 (2.38)	1	1 (2.38)
Meningitis pneumococcal	1	1 (2.38)	1	1 (2.38)
Nail infection	1	1 (2.38)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Neutropenic infection	1	1 (2.38)	1	1 (2.38)
Ophthalmic herpes zoster	1	1 (2.38)	0	0 (0.00)
Oral candidiasis	1	1 (2.38)	0	0 (0.00)
Oral herpes	1	1 (2.38)	0	0 (0.00)
Otitis media	1	1 (2.38)	0	0 (0.00)
Otitis media acute	1	1 (2.38)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.38)	1	1 (2.38)
Pneumonia respiratory syncytial viral	1	1 (2.38)	1	1 (2.38)
Rhinitis	1	1 (2.38)	0	0 (0.00)
Septic shock	1	1 (2.38)	1	1 (2.38)
Staphylococcal bacteraemia	1	1 (2.38)	1	1 (2.38)
Streptococcal sepsis	1	1 (2.38)	0	0 (0.00)
Syphilis	1	1 (2.38)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.38)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.38)	0	0 (0.00)
Viral skin infection	1	1 (2.38)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (7.14)	1	1 (2.38)
Abdominal injury	1	1 (2.38)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Infusion related reaction	1	1 (2.38)	1	1 (2.38)
Ligament sprain	1	1 (2.38)	0	0 (0.00)
Investigations				
- Total	10	4 (9.52)	6	2 (4.76)
Neutrophil count decreased	6	1 (2.38)	5	1 (2.38)
Blood immunoglobulin G decreased	1	1 (2.38)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.38)	1	1 (2.38)
Platelet count decreased	1	1 (2.38)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (2.38)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	10	6 (14.29)	5	4 (9.52)
Decreased appetite	2	1 (2.38)	2	1 (2.38)
Iron overload	2	1 (2.38)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.38)	0	0 (0.00)
Hyperglycaemia	1	1 (2.38)	1	1 (2.38)
Hyperlipidaemia	1	1 (2.38)	0	0 (0.00)
Hypernatraemia	1	1 (2.38)	1	1 (2.38)
Hypertriglyceridaemia	1	1 (2.38)	0	0 (0.00)
Obesity	1	1 (2.38)	1	1 (2.38)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	8	7 (16.67)	0	0 (0.00)
Pain in extremity	2	2 (4.76)	0	0 (0.00)
Arthralgia	1	1 (2.38)	0	0 (0.00)
Growth retardation	1	1 (2.38)	0	0 (0.00)
Joint effusion	1	1 (2.38)	0	0 (0.00)
Osteonecrosis	1	1 (2.38)	0	0 (0.00)
Osteopenia	1	1 (2.38)	0	0 (0.00)
Synovitis	1	1 (2.38)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.38)	1	1 (2.38)
Bone giant cell tumour benign	2	1 (2.38)	1	1 (2.38)
Nervous system disorders				
- Total	9	4 (9.52)	3	2 (4.76)
Headache	3	2 (4.76)	1	1 (2.38)
Seizure	3	1 (2.38)	1	1 (2.38)
Nervous system disorder	2	1 (2.38)	1	1 (2.38)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Dysarthria	1	1 (2.38)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (7.14)	0	0 (0.00)
Anxiety	2	2 (4.76)	0	0 (0.00)
Tic	1	1 (2.38)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.38)	1	1 (2.38)
Endometriosis	2	1 (2.38)	1	1 (2.38)
Respiratory, thoracic and mediastinal disorders				
- Total	18	8 (19.05)	5	3 (7.14)
Cough	3	3 (7.14)	0	0 (0.00)
Dyspnoea	2	2 (4.76)	1	1 (2.38)
Rhinorrhoea	2	2 (4.76)	0	0 (0.00)
Tachypnoea	2	1 (2.38)	2	1 (2.38)
Dyspnoea exertional	1	1 (2.38)	0	0 (0.00)
Epistaxis	1	1 (2.38)	0	0 (0.00)
Hypoxia	1	1 (2.38)	1	1 (2.38)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=42 n (%)[1]	Grade >= 3 Total events	All patients N=42 n (%)[2]
Oropharyngeal pain	1	1 (2.38)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.38)	0	0 (0.00)
Pleural effusion	1	1 (2.38)	0	0 (0.00)
Respiratory failure	1	1 (2.38)	1	1 (2.38)
Sleep apnoea syndrome	1	1 (2.38)	0	0 (0.00)
Wheezing	1	1 (2.38)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	9	6 (14.29)	3	2 (4.76)
Rash	2	2 (4.76)	0	0 (0.00)
Rash macular	2	1 (2.38)	2	1 (2.38)
Dermatitis atopic	1	1 (2.38)	1	1 (2.38)
Dry skin	1	1 (2.38)	0	0 (0.00)
Papule	1	1 (2.38)	0	0 (0.00)
Rash erythematous	1	1 (2.38)	0	0 (0.00)
Rash maculo-papular	1	1 (2.38)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.76)	1	1 (2.38)
Hypertension	2	2 (4.76)	1	1 (2.38)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Total number of AE per patient	411	13 (100.00)	97	12 (92.31)
Blood and lymphatic system disorders				
- Total	28	11 (84.62)	15	8 (61.54)
Anaemia	10	8 (61.54)	0	0 (0.00)
Febrile neutropenia	7	6 (46.15)	7	6 (46.15)
Neutropenia	6	2 (15.38)	6	2 (15.38)
Leukopenia	2	1 (7.69)	2	1 (7.69)
Disseminated intravascular coagulation	1	1 (7.69)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (7.69)	0	0 (0.00)
Splenomegaly	1	1 (7.69)	0	0 (0.00)
Cardiac disorders				

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
- Total	9	7 (53.85)	1	1 (7.69)
Tachycardia	7	6 (46.15)	0	0 (0.00)
Cardiac dysfunction	1	1 (7.69)	0	0 (0.00)
Left ventricular dysfunction	1	1 (7.69)	1	1 (7.69)
Congenital, familial and genetic disorders				
- Total	1	1 (7.69)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (7.69)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (15.38)	0	0 (0.00)
Deafness unilateral	1	1 (7.69)	0	0 (0.00)
Ear pain	1	1 (7.69)	0	0 (0.00)
Eye disorders				
- Total	3	3 (23.08)	0	0 (0.00)
Ocular hyperaemia	2	2 (15.38)	0	0 (0.00)
Cataract	1	1 (7.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	42	10 (76.92)	3	2 (15.38)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Vomiting	10	6 (46.15)	0	0 (0.00)
Nausea	8	7 (53.85)	0	0 (0.00)
Diarrhoea	5	5 (38.46)	0	0 (0.00)
Abdominal pain	4	3 (23.08)	1	1 (7.69)
Constipation	3	3 (23.08)	0	0 (0.00)
Proctalgia	2	2 (15.38)	1	1 (7.69)
Anal haemorrhage	1	1 (7.69)	0	0 (0.00)
Enteritis	1	1 (7.69)	0	0 (0.00)
Enterocolitis	1	1 (7.69)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (7.69)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (7.69)	0	0 (0.00)
Haematemesis	1	1 (7.69)	0	0 (0.00)
Lip oedema	1	1 (7.69)	0	0 (0.00)
Neutropenic colitis	1	1 (7.69)	1	1 (7.69)
Stomatitis	1	1 (7.69)	0	0 (0.00)
Trichoglossia	1	1 (7.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	20	8 (61.54)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Fatigue	7	6 (46.15)	0	0 (0.00)
Pyrexia	4	3 (23.08)	0	0 (0.00)
Chills	2	1 (7.69)	0	0 (0.00)
Oedema peripheral	2	1 (7.69)	0	0 (0.00)
Catheter site haemorrhage	1	1 (7.69)	0	0 (0.00)
Generalised oedema	1	1 (7.69)	0	0 (0.00)
Non-cardiac chest pain	1	1 (7.69)	0	0 (0.00)
Vascular device occlusion	1	1 (7.69)	0	0 (0.00)
Xerosis	1	1 (7.69)	0	0 (0.00)
Hepatobiliary disorders				
- Total	7	4 (30.77)	2	1 (7.69)
Hepatic function abnormal	5	2 (15.38)	2	1 (7.69)
Hepatomegaly	1	1 (7.69)	0	0 (0.00)
Ocular icterus	1	1 (7.69)	0	0 (0.00)
Immune system disorders				
- Total	26	13 (100.00)	6	6 (46.15)
Cytokine release syndrome	18	11 (84.62)	6	6 (46.15)
Hypogammaglobulinaemia	8	6 (46.15)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Infections and infestations				
- Total	30	5 (38.46)	6	4 (30.77)
Sinusitis	5	1 (7.69)	0	0 (0.00)
Upper respiratory tract infection	4	2 (15.38)	1	1 (7.69)
Conjunctivitis	2	1 (7.69)	0	0 (0.00)
Nasopharyngitis	2	1 (7.69)	0	0 (0.00)
Otitis media	2	1 (7.69)	0	0 (0.00)
Acute sinusitis	1	1 (7.69)	0	0 (0.00)
Anal abscess	1	1 (7.69)	1	1 (7.69)
Ear infection	1	1 (7.69)	1	1 (7.69)
Gastroenteritis	1	1 (7.69)	0	0 (0.00)
Herpes zoster	1	1 (7.69)	0	0 (0.00)
Influenza	1	1 (7.69)	0	0 (0.00)
Oral herpes	1	1 (7.69)	0	0 (0.00)
Otitis externa	1	1 (7.69)	0	0 (0.00)
Paronychia	1	1 (7.69)	0	0 (0.00)
Pneumonia	1	1 (7.69)	1	1 (7.69)
Skin infection	1	1 (7.69)	0	0 (0.00)
Staphylococcal abscess	1	1 (7.69)	1	1 (7.69)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Tinea pedis	1	1 (7.69)	0	0 (0.00)
Urinary tract infection viral	1	1 (7.69)	0	0 (0.00)
Varicella zoster virus infection	1	1 (7.69)	1	1 (7.69)
Injury, poisoning and procedural complications				
- Total	4	3 (23.08)	0	0 (0.00)
Contusion	1	1 (7.69)	0	0 (0.00)
Infusion related reaction	1	1 (7.69)	0	0 (0.00)
Procedural pain	1	1 (7.69)	0	0 (0.00)
Transfusion reaction	1	1 (7.69)	0	0 (0.00)
Investigations				
- Total	126	11 (84.62)	48	9 (69.23)
Neutrophil count decreased	21	9 (69.23)	14	6 (46.15)
Platelet count decreased	18	9 (69.23)	6	4 (30.77)
Lymphocyte count decreased	13	7 (53.85)	8	6 (46.15)
White blood cell count decreased	13	9 (69.23)	8	5 (38.46)
Blood bilirubin increased	10	4 (30.77)	2	2 (15.38)
International normalised ratio increased	9	6 (46.15)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Alanine aminotransferase increased	6	4 (30.77)	2	2 (15.38)
Blood immunoglobulin A decreased	6	6 (46.15)	1	1 (7.69)
Activated partial thromboplastin time prolonged	5	3 (23.08)	0	0 (0.00)
Aspartate aminotransferase increased	5	4 (30.77)	3	3 (23.08)
Blood immunoglobulin M decreased	5	5 (38.46)	1	1 (7.69)
Blood creatine phosphokinase increased	3	1 (7.69)	1	1 (7.69)
Blood fibrinogen decreased	3	3 (23.08)	0	0 (0.00)
Haemoglobin decreased	2	1 (7.69)	1	1 (7.69)
Serum ferritin increased	2	2 (15.38)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (7.69)	0	0 (0.00)
Blood uric acid increased	1	1 (7.69)	0	0 (0.00)
C-reactive protein increased	1	1 (7.69)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (7.69)	0	0 (0.00)
Weight increased	1	1 (7.69)	1	1 (7.69)
Metabolism and nutrition disorders				
- Total	25	10 (76.92)	8	5 (38.46)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Decreased appetite	8	8 (61.54)	2	2 (15.38)
Hyperuricaemia	3	2 (15.38)	0	0 (0.00)
Hypokalaemia	3	3 (23.08)	2	2 (15.38)
Hyperphosphataemia	2	2 (15.38)	0	0 (0.00)
Hypoalbuminaemia	2	1 (7.69)	0	0 (0.00)
Hypophosphataemia	2	2 (15.38)	2	2 (15.38)
Dehydration	1	1 (7.69)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (7.69)	1	1 (7.69)
Hypomagnesaemia	1	1 (7.69)	0	0 (0.00)
Metabolic acidosis	1	1 (7.69)	0	0 (0.00)
Tumour lysis syndrome	1	1 (7.69)	1	1 (7.69)
Musculoskeletal and connective tissue disorders				
- Total	12	8 (61.54)	0	0 (0.00)
Myalgia	5	4 (30.77)	0	0 (0.00)
Pain in extremity	5	5 (38.46)	0	0 (0.00)
Arthralgia	2	2 (15.38)	0	0 (0.00)
Nervous system disorders				
- Total	10	6 (46.15)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Headache	6	4 (30.77)	0	0 (0.00)
Dizziness	1	1 (7.69)	0	0 (0.00)
Hypoaesthesia	1	1 (7.69)	0	0 (0.00)
Lethargy	1	1 (7.69)	0	0 (0.00)
Tremor	1	1 (7.69)	0	0 (0.00)
Psychiatric disorders				
- Total	7	5 (38.46)	0	0 (0.00)
Anxiety	2	2 (15.38)	0	0 (0.00)
Confusional state	2	2 (15.38)	0	0 (0.00)
Agitation	1	1 (7.69)	0	0 (0.00)
Irritability	1	1 (7.69)	0	0 (0.00)
Mental status changes	1	1 (7.69)	0	0 (0.00)
Renal and urinary disorders				
- Total	6	5 (38.46)	1	1 (7.69)
Acute kidney injury	1	1 (7.69)	1	1 (7.69)
Cystitis haemorrhagic	1	1 (7.69)	0	0 (0.00)
Dysuria	1	1 (7.69)	0	0 (0.00)
Micturition urgency	1	1 (7.69)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Pollakiuria	1	1 (7.69)	0	0 (0.00)
Renal tubular dysfunction	1	1 (7.69)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	32	10 (76.92)	4	3 (23.08)
Cough	7	4 (30.77)	0	0 (0.00)
Rhinorrhoea	6	4 (30.77)	0	0 (0.00)
Hypoxia	3	2 (15.38)	3	2 (15.38)
Oropharyngeal pain	3	3 (23.08)	0	0 (0.00)
Nasal congestion	2	2 (15.38)	0	0 (0.00)
Pleural effusion	2	2 (15.38)	0	0 (0.00)
Tachypnoea	2	2 (15.38)	0	0 (0.00)
Dyspnoea	1	1 (7.69)	0	0 (0.00)
Epistaxis	1	1 (7.69)	0	0 (0.00)
Laryngeal oedema	1	1 (7.69)	1	1 (7.69)
Paranasal sinus inflammation	1	1 (7.69)	0	0 (0.00)
Respiratory distress	1	1 (7.69)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (7.69)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (7.69)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	16	8 (61.54)	1	1 (7.69)
Dry skin	4	3 (23.08)	0	0 (0.00)
Eczema	2	2 (15.38)	1	1 (7.69)
Pruritus	2	2 (15.38)	0	0 (0.00)
Rash papular	2	2 (15.38)	0	0 (0.00)
Blister	1	1 (7.69)	0	0 (0.00)
Dermatitis	1	1 (7.69)	0	0 (0.00)
Erythema nodosum	1	1 (7.69)	0	0 (0.00)
Rash pruritic	1	1 (7.69)	0	0 (0.00)
Skin swelling	1	1 (7.69)	0	0 (0.00)
Skin ulcer	1	1 (7.69)	0	0 (0.00)
Vascular disorders				
- Total	5	4 (30.77)	2	2 (15.38)
Hypotension	4	3 (23.08)	2	2 (15.38)
Hypertension	1	1 (7.69)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250m
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Eligibility for SCT
Safety Set

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Total number of AE per patient	2094	67 (100.00)	731	61 (91.04)
Blood and lymphatic system disorders				
- Total	135	44 (65.67)	80	35 (52.24)
Anaemia	53	17 (25.37)	24	9 (13.43)
Febrile neutropenia	26	21 (31.34)	26	21 (31.34)
Neutropenia	11	9 (13.43)	9	7 (10.45)
Thrombocytopenia	11	9 (13.43)	10	9 (13.43)
Disseminated intravascular coagulation	7	7 (10.45)	3	3 (4.48)
Coagulopathy	5	5 (7.46)	2	2 (2.99)
B-cell aplasia	3	1 (1.49)	0	0 (0.00)
Eosinophilia	3	1 (1.49)	0	0 (0.00)
Leukopenia	3	2 (2.99)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Splenomegaly	3	3 (4.48)	0	0 (0.00)
Lymphadenopathy	2	2 (2.99)	0	0 (0.00)
Lymphopenia	2	2 (2.99)	2	2 (2.99)
Pancytopenia	2	2 (2.99)	2	2 (2.99)
Agranulocytosis	1	1 (1.49)	1	1 (1.49)
Hypercoagulation	1	1 (1.49)	0	0 (0.00)
Leukocytosis	1	1 (1.49)	0	0 (0.00)
Lymphocytosis	1	1 (1.49)	0	0 (0.00)
Cardiac disorders				
- Total	44	21 (31.34)	13	10 (14.93)
Tachycardia	17	11 (16.42)	3	3 (4.48)
Cardiac failure	6	3 (4.48)	4	3 (4.48)
Sinus tachycardia	4	3 (4.48)	0	0 (0.00)
Bradycardia	3	3 (4.48)	0	0 (0.00)
Cardiac arrest	3	3 (4.48)	3	3 (4.48)
Left ventricular dysfunction	3	3 (4.48)	2	2 (2.99)
Atrioventricular block first degree	1	1 (1.49)	0	0 (0.00)
Cardiac dysfunction	1	1 (1.49)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Mitral valve incompetence	1	1 (1.49)	0	0 (0.00)
Pericardial effusion	1	1 (1.49)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.49)	0	0 (0.00)
Sinus bradycardia	1	1 (1.49)	1	1 (1.49)
Tricuspid valve incompetence	1	1 (1.49)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (1.49)	0	0 (0.00)
Ear pruritus	1	1 (1.49)	0	0 (0.00)
Endocrine disorders				
- Total	8	7 (10.45)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.97)	0	0 (0.00)
Hypothyroidism	3	3 (4.48)	0	0 (0.00)
Delayed puberty	1	1 (1.49)	0	0 (0.00)
Eye disorders				
- Total	21	12 (17.91)	1	1 (1.49)
Eyelid oedema	4	3 (4.48)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.99)	0	0 (0.00)
Eye pain	2	2 (2.99)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Retinal haemorrhage	2	1 (1.49)	0	0 (0.00)
Visual impairment	2	2 (2.99)	0	0 (0.00)
Cataract	1	1 (1.49)	0	0 (0.00)
Dry eye	1	1 (1.49)	0	0 (0.00)
Eye oedema	1	1 (1.49)	0	0 (0.00)
Hypermetropia	1	1 (1.49)	0	0 (0.00)
Mydriasis	1	1 (1.49)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.49)	0	0 (0.00)
Periorbital oedema	1	1 (1.49)	0	0 (0.00)
Periorbital swelling	1	1 (1.49)	0	0 (0.00)
Visual field defect	1	1 (1.49)	0	0 (0.00)
Gastrointestinal disorders				
- Total	140	50 (74.63)	15	14 (20.90)
Vomiting	28	20 (29.85)	1	1 (1.49)
Diarrhoea	25	21 (31.34)	2	2 (2.99)
Nausea	19	15 (22.39)	2	2 (2.99)
Constipation	13	11 (16.42)	0	0 (0.00)
Abdominal pain	11	8 (11.94)	1	1 (1.49)
Pancreatitis	6	6 (8.96)	2	2 (2.99)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Mouth haemorrhage	5	5 (7.46)	2	2 (2.99)
Abdominal pain upper	4	4 (5.97)	0	0 (0.00)
Abdominal distension	3	3 (4.48)	0	0 (0.00)
Ascites	3	3 (4.48)	0	0 (0.00)
Stomatitis	2	2 (2.99)	1	1 (1.49)
Abdominal compartment syndrome	1	1 (1.49)	1	1 (1.49)
Abdominal rigidity	1	1 (1.49)	0	0 (0.00)
Anal fissure	1	1 (1.49)	0	0 (0.00)
Dry mouth	1	1 (1.49)	0	0 (0.00)
Dyspepsia	1	1 (1.49)	0	0 (0.00)
Dysphagia	1	1 (1.49)	1	1 (1.49)
Gastrointestinal haemorrhage	1	1 (1.49)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.49)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (1.49)	0	0 (0.00)
Gingival bleeding	1	1 (1.49)	0	0 (0.00)
Gingival erythema	1	1 (1.49)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.49)	1	1 (1.49)
Ileus	1	1 (1.49)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Lip dry	1	1 (1.49)	0	0 (0.00)
Melaena	1	1 (1.49)	1	1 (1.49)
Mouth swelling	1	1 (1.49)	0	0 (0.00)
Odynophagia	1	1 (1.49)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.49)	0	0 (0.00)
Trichoglossia	1	1 (1.49)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.49)	0	0 (0.00)
General disorders and administration site conditions				
- Total	136	45 (67.16)	24	15 (22.39)
Pyrexia	63	32 (47.76)	12	11 (16.42)
Fatigue	12	11 (16.42)	0	0 (0.00)
Face oedema	9	8 (11.94)	1	1 (1.49)
Chills	8	6 (8.96)	0	0 (0.00)
Oedema peripheral	7	6 (8.96)	2	1 (1.49)
Pain	5	5 (7.46)	2	2 (2.99)
Catheter site pain	4	2 (2.99)	2	1 (1.49)
Generalised oedema	4	4 (5.97)	0	0 (0.00)
Asthenia	3	3 (4.48)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Multiple organ dysfunction syndrome	3	3 (4.48)	3	3 (4.48)
Catheter site erythema	2	1 (1.49)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.99)	0	0 (0.00)
Influenza like illness	2	2 (2.99)	0	0 (0.00)
Localised oedema	2	2 (2.99)	0	0 (0.00)
Malaise	2	2 (2.99)	0	0 (0.00)
Chest discomfort	1	1 (1.49)	1	1 (1.49)
Crying	1	1 (1.49)	0	0 (0.00)
Facial pain	1	1 (1.49)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.49)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.49)	0	0 (0.00)
Sluggishness	1	1 (1.49)	0	0 (0.00)
Swelling face	1	1 (1.49)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.49)	1	1 (1.49)
Hepatobiliary disorders				
- Total	25	15 (22.39)	5	5 (7.46)
Hepatic function abnormal	6	3 (4.48)	2	2 (2.99)
Hyperbilirubinaemia	6	5 (7.46)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Hypertransaminasaemia	3	2 (2.99)	0	0 (0.00)
Cholelithiasis	2	2 (2.99)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.99)	0	0 (0.00)
Hepatomegaly	2	2 (2.99)	1	1 (1.49)
Biliary tract disorder	1	1 (1.49)	0	0 (0.00)
Cholestasis	1	1 (1.49)	1	1 (1.49)
Hepatic cytolysis	1	1 (1.49)	0	0 (0.00)
Liver disorder	1	1 (1.49)	0	0 (0.00)
Immune system disorders				
- Total	167	58 (86.57)	70	40 (59.70)
Cytokine release syndrome	110	50 (74.63)	49	32 (47.76)
Hypogammaglobulinaemia	32	27 (40.30)	7	7 (10.45)
Haemophagocytic lymphohistiocytosis	6	6 (8.96)	4	4 (5.97)
Immunodeficiency	4	4 (5.97)	4	4 (5.97)
Seasonal allergy	4	4 (5.97)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.99)	1	1 (1.49)
Chronic graft versus host disease	2	2 (2.99)	1	1 (1.49)
Drug hypersensitivity	2	2 (2.99)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Graft versus host disease	2	2 (2.99)	2	2 (2.99)
Engraftment syndrome	1	1 (1.49)	1	1 (1.49)
Hypersensitivity	1	1 (1.49)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.49)	0	0 (0.00)
Infections and infestations				
- Total	233	55 (82.09)	96	35 (52.24)
Upper respiratory tract infection	13	11 (16.42)	2	2 (2.99)
Rhinovirus infection	11	9 (13.43)	2	2 (2.99)
Conjunctivitis	10	7 (10.45)	0	0 (0.00)
Sinusitis	9	6 (8.96)	2	2 (2.99)
Nasopharyngitis	7	6 (8.96)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.99)	4	2 (2.99)
Parainfluenzae virus infection	6	5 (7.46)	3	3 (4.48)
Staphylococcal bacteraemia	6	5 (7.46)	6	5 (7.46)
Candida infection	5	4 (5.97)	2	1 (1.49)
Gastroenteritis	5	5 (7.46)	2	2 (2.99)
Pneumonia	5	5 (7.46)	3	3 (4.48)
Staphylococcal infection	5	5 (7.46)	2	2 (2.99)
Bacteraemia	4	3 (4.48)	3	2 (2.99)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Clostridium difficile infection	4	4 (5.97)	3	3 (4.48)
Nail infection	4	4 (5.97)	0	0 (0.00)
Oral candidiasis	4	3 (4.48)	0	0 (0.00)
Oral herpes	4	3 (4.48)	1	1 (1.49)
Otitis media	4	4 (5.97)	1	1 (1.49)
Urinary tract infection	4	3 (4.48)	2	1 (1.49)
COVID-19	3	2 (2.99)	1	1 (1.49)
Ear infection	3	2 (2.99)	0	0 (0.00)
Fungal infection	3	2 (2.99)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.99)	0	0 (0.00)
Klebsiella infection	3	1 (1.49)	3	1 (1.49)
Metapneumovirus infection	3	3 (4.48)	3	3 (4.48)
Respiratory syncytial virus infection	3	3 (4.48)	2	2 (2.99)
Respiratory tract infection	3	3 (4.48)	0	0 (0.00)
Rhinitis	3	3 (4.48)	0	0 (0.00)
Sepsis	3	3 (4.48)	3	3 (4.48)
Adenovirus infection	2	2 (2.99)	2	2 (2.99)
BK virus infection	2	2 (2.99)	1	1 (1.49)
Bronchitis	2	2 (2.99)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Device related sepsis	2	1 (1.49)	2	1 (1.49)
Encephalitis	2	2 (2.99)	2	2 (2.99)
Encephalitis viral	2	2 (2.99)	2	2 (2.99)
Gingivitis	2	2 (2.99)	0	0 (0.00)
Herpes simplex	2	2 (2.99)	1	1 (1.49)
Herpes zoster	2	2 (2.99)	2	2 (2.99)
Human herpesvirus 6 infection	2	2 (2.99)	2	2 (2.99)
Influenza	2	2 (2.99)	1	1 (1.49)
Oral infection	2	2 (2.99)	0	0 (0.00)
Otitis externa	2	2 (2.99)	1	1 (1.49)
Pneumocystis jirovecii pneumonia	2	2 (2.99)	2	2 (2.99)
Septic shock	2	2 (2.99)	2	2 (2.99)
Skin infection	2	2 (2.99)	0	0 (0.00)
Viral infection	2	2 (2.99)	1	1 (1.49)
Acute sinusitis	1	1 (1.49)	0	0 (0.00)
Atypical pneumonia	1	1 (1.49)	0	0 (0.00)
Bronchiolitis	1	1 (1.49)	1	1 (1.49)
COVID-19 pneumonia	1	1 (1.49)	1	1 (1.49)
Cellulitis	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Cholecystitis infective	1	1 (1.49)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.49)	1	1 (1.49)
Coronavirus infection	1	1 (1.49)	1	1 (1.49)
Cystitis	1	1 (1.49)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.49)	1	1 (1.49)
Device related infection	1	1 (1.49)	1	1 (1.49)
Ear, nose and throat infection	1	1 (1.49)	0	0 (0.00)
Enterobacter infection	1	1 (1.49)	1	1 (1.49)
Enterovirus infection	1	1 (1.49)	1	1 (1.49)
Folliculitis	1	1 (1.49)	0	0 (0.00)
Fungal skin infection	1	1 (1.49)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.49)	1	1 (1.49)
Gastroenteritis clostridial	1	1 (1.49)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.49)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.49)	1	1 (1.49)
Gastrointestinal infection	1	1 (1.49)	0	0 (0.00)
Granulicatella infection	1	1 (1.49)	1	1 (1.49)
Herpes virus infection	1	1 (1.49)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Localised infection	1	1 (1.49)	0	0 (0.00)
Mastoiditis	1	1 (1.49)	1	1 (1.49)
Meningitis bacterial	1	1 (1.49)	1	1 (1.49)
Meningitis pneumococcal	1	1 (1.49)	1	1 (1.49)
Molluscum contagiosum	1	1 (1.49)	0	0 (0.00)
Myringitis	1	1 (1.49)	0	0 (0.00)
Neutropenic infection	1	1 (1.49)	1	1 (1.49)
Ophthalmic herpes zoster	1	1 (1.49)	0	0 (0.00)
Otitis media acute	1	1 (1.49)	0	0 (0.00)
Paronychia	1	1 (1.49)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.49)	1	1 (1.49)
Pneumonia fungal	1	1 (1.49)	1	1 (1.49)
Pneumonia respiratory syncytial viral	1	1 (1.49)	1	1 (1.49)
Pneumonia viral	1	1 (1.49)	1	1 (1.49)
Respiratory tract infection viral	1	1 (1.49)	0	0 (0.00)
Salmonellosis	1	1 (1.49)	0	0 (0.00)
Sinusitis fungal	1	1 (1.49)	1	1 (1.49)
Soft tissue infection	1	1 (1.49)	1	1 (1.49)
Staphylococcal sepsis	1	1 (1.49)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Staphylococcal skin infection	1	1 (1.49)	0	0 (0.00)
Stomatococcal infection	1	1 (1.49)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.49)	0	0 (0.00)
Syphilis	1	1 (1.49)	0	0 (0.00)
Systemic candida	1	1 (1.49)	1	1 (1.49)
Urinary tract infection pseudomonal	1	1 (1.49)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.49)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.49)	1	1 (1.49)
Viral skin infection	1	1 (1.49)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.49)	1	1 (1.49)
Injury, poisoning and procedural complications				
- Total	29	18 (26.87)	4	3 (4.48)
Infusion related reaction	7	4 (5.97)	1	1 (1.49)
Wound	3	2 (2.99)	1	1 (1.49)
Contusion	2	1 (1.49)	0	0 (0.00)
Fall	2	2 (2.99)	0	0 (0.00)
Ligament sprain	2	2 (2.99)	0	0 (0.00)
Skin abrasion	2	2 (2.99)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Abdominal injury	1	1 (1.49)	0	0 (0.00)
Fibula fracture	1	1 (1.49)	0	0 (0.00)
Limb injury	1	1 (1.49)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.49)	0	0 (0.00)
Procedural pain	1	1 (1.49)	0	0 (0.00)
Scratch	1	1 (1.49)	0	0 (0.00)
Skin injury	1	1 (1.49)	0	0 (0.00)
Skin wound	1	1 (1.49)	0	0 (0.00)
Transfusion reaction	1	1 (1.49)	0	0 (0.00)
Transplant failure	1	1 (1.49)	1	1 (1.49)
Vasoplegia syndrome	1	1 (1.49)	1	1 (1.49)
Investigations				
- Total	367	49 (73.13)	190	39 (58.21)
Platelet count decreased	65	15 (22.39)	41	11 (16.42)
White blood cell count decreased	55	16 (23.88)	32	13 (19.40)
Neutrophil count decreased	54	15 (22.39)	40	15 (22.39)
Aspartate aminotransferase increased	28	15 (22.39)	10	8 (11.94)
Alanine aminotransferase increased	23	14 (20.90)	5	5 (7.46)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Lymphocyte count decreased	23	10 (14.93)	18	9 (13.43)
Blood bilirubin increased	15	9 (13.43)	8	7 (10.45)
Immunoglobulins decreased	10	2 (2.99)	0	0 (0.00)
Blood creatinine increased	7	5 (7.46)	5	3 (4.48)
Serum ferritin increased	6	6 (8.96)	2	2 (2.99)
Weight increased	6	3 (4.48)	1	1 (1.49)
Electrocardiogram QT prolonged	5	4 (5.97)	2	2 (2.99)
Blood fibrinogen decreased	4	4 (5.97)	2	2 (2.99)
Blood immunoglobulin G decreased	4	4 (5.97)	0	0 (0.00)
Blood lactate dehydrogenase increased	4	4 (5.97)	1	1 (1.49)
C-reactive protein increased	4	4 (5.97)	3	3 (4.48)
Lipase increased	4	2 (2.99)	2	1 (1.49)
Activated partial thromboplastin time prolonged	3	3 (4.48)	1	1 (1.49)
Blood uric acid increased	3	3 (4.48)	2	2 (2.99)
Fibrin D dimer increased	3	3 (4.48)	1	1 (1.49)
International normalised ratio increased	3	3 (4.48)	0	0 (0.00)
Oxygen saturation decreased	3	3 (4.48)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Urine output decreased	3	2 (2.99)	3	2 (2.99)
Blood glucose increased	2	1 (1.49)	2	1 (1.49)
Blood immunoglobulin M decreased	2	2 (2.99)	1	1 (1.49)
Gamma-glutamyltransferase increased	2	2 (2.99)	2	2 (2.99)
Weight decreased	2	2 (2.99)	1	1 (1.49)
Amylase increased	1	1 (1.49)	0	0 (0.00)
Bacterial test positive	1	1 (1.49)	1	1 (1.49)
Blood alkaline phosphatase increased	1	1 (1.49)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.49)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.49)	1	1 (1.49)
Blood immunoglobulin A decreased	1	1 (1.49)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.49)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.49)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.49)	0	0 (0.00)
Blood urea increased	1	1 (1.49)	1	1 (1.49)
Bone density decreased	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Breath sounds abnormal	1	1 (1.49)	0	0 (0.00)
Cardiac murmur	1	1 (1.49)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.49)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.49)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.49)	0	0 (0.00)
Enterovirus test positive	1	1 (1.49)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.49)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.49)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.49)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.49)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.49)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.49)	0	0 (0.00)
Troponin increased	1	1 (1.49)	1	1 (1.49)
Metabolism and nutrition disorders				
- Total	221	42 (62.69)	83	28 (41.79)
Hypokalaemia	43	17 (25.37)	22	9 (13.43)
Hypophosphataemia	30	16 (23.88)	9	7 (10.45)
Decreased appetite	24	22 (32.84)	12	10 (14.93)
Hypocalcaemia	24	16 (23.88)	6	5 (7.46)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Hypoalbuminaemia	17	10 (14.93)	1	1 (1.49)
Hyperglycaemia	12	9 (13.43)	5	5 (7.46)
Hyperuricaemia	9	7 (10.45)	1	1 (1.49)
Hypervolaemia	7	7 (10.45)	5	5 (7.46)
Hypomagnesaemia	6	5 (7.46)	0	0 (0.00)
Hypercalcaemia	4	3 (4.48)	2	2 (2.99)
Tumour lysis syndrome	4	4 (5.97)	4	4 (5.97)
Acidosis	3	2 (2.99)	2	2 (2.99)
Hyperkalaemia	3	3 (4.48)	2	2 (2.99)
Hypermagnesaemia	3	2 (2.99)	0	0 (0.00)
Hypernatraemia	3	3 (4.48)	2	2 (2.99)
Hyperphosphataemia	3	3 (4.48)	1	1 (1.49)
Hyponatraemia	3	3 (4.48)	0	0 (0.00)
Iron overload	3	2 (2.99)	0	0 (0.00)
Metabolic acidosis	3	3 (4.48)	3	3 (4.48)
Hyperchloraemia	2	2 (2.99)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (2.99)	1	1 (1.49)
Malnutrition	2	2 (2.99)	2	2 (2.99)
Calcium deficiency	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Haemochromatosis	1	1 (1.49)	1	1 (1.49)
Haemosiderosis	1	1 (1.49)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.49)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.49)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.49)	0	0 (0.00)
Hypoglycaemia	1	1 (1.49)	0	0 (0.00)
Hypophagia	1	1 (1.49)	0	0 (0.00)
Metabolic syndrome	1	1 (1.49)	0	0 (0.00)
Obesity	1	1 (1.49)	1	1 (1.49)
Polydipsia	1	1 (1.49)	1	1 (1.49)
Musculoskeletal and connective tissue disorders				
- Total	71	36 (53.73)	9	8 (11.94)
Back pain	14	10 (14.93)	3	3 (4.48)
Pain in extremity	13	12 (17.91)	1	1 (1.49)
Arthralgia	12	10 (14.93)	1	1 (1.49)
Bone pain	6	4 (5.97)	0	0 (0.00)
Myalgia	6	6 (8.96)	0	0 (0.00)
Growth retardation	2	2 (2.99)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Muscular weakness	2	2 (2.99)	1	1 (1.49)
Musculoskeletal chest pain	2	2 (2.99)	0	0 (0.00)
Neck pain	2	2 (2.99)	0	0 (0.00)
Pain in jaw	2	2 (2.99)	1	1 (1.49)
Haemarthrosis	1	1 (1.49)	1	1 (1.49)
Joint effusion	1	1 (1.49)	0	0 (0.00)
Muscle rigidity	1	1 (1.49)	0	0 (0.00)
Muscle spasms	1	1 (1.49)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.49)	0	0 (0.00)
Myositis	1	1 (1.49)	0	0 (0.00)
Osteonecrosis	1	1 (1.49)	0	0 (0.00)
Osteopenia	1	1 (1.49)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.49)	1	1 (1.49)
Synovitis	1	1 (1.49)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (7.46)	2	2 (2.99)
Bone giant cell tumour benign	2	1 (1.49)	1	1 (1.49)
Skin papilloma	2	2 (2.99)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Cancer pain	1	1 (1.49)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.49)	1	1 (1.49)
Nervous system disorders				
- Total	99	41 (61.19)	23	14 (20.90)
Headache	34	23 (34.33)	3	3 (4.48)
Encephalopathy	8	8 (11.94)	4	4 (5.97)
Seizure	7	4 (5.97)	3	3 (4.48)
Tremor	6	5 (7.46)	0	0 (0.00)
Cognitive disorder	5	3 (4.48)	1	1 (1.49)
Somnolence	5	5 (7.46)	2	2 (2.99)
Dizziness	4	3 (4.48)	0	0 (0.00)
Dysgeusia	3	3 (4.48)	0	0 (0.00)
Hydrocephalus	3	1 (1.49)	3	1 (1.49)
Cerebral haemorrhage	2	2 (2.99)	2	2 (2.99)
Dysarthria	2	2 (2.99)	1	1 (1.49)
Hyperaesthesia	2	1 (1.49)	0	0 (0.00)
Lethargy	2	2 (2.99)	0	0 (0.00)
Migraine	2	1 (1.49)	0	0 (0.00)
Nervous system disorder	2	1 (1.49)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Amnesia	1	1 (1.49)	0	0 (0.00)
Aphasia	1	1 (1.49)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.49)	1	1 (1.49)
Depressed level of consciousness	1	1 (1.49)	1	1 (1.49)
Disturbance in attention	1	1 (1.49)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.49)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.49)	0	0 (0.00)
Memory impairment	1	1 (1.49)	0	0 (0.00)
Monoparesis	1	1 (1.49)	0	0 (0.00)
Neuralgia	1	1 (1.49)	0	0 (0.00)
Neurological decompensation	1	1 (1.49)	1	1 (1.49)
Paraesthesia	1	1 (1.49)	0	0 (0.00)
Psychiatric disorders				
- Total	58	34 (50.75)	7	7 (10.45)
Anxiety	12	12 (17.91)	2	2 (2.99)
Delirium	8	8 (11.94)	3	3 (4.48)
Agitation	6	5 (7.46)	0	0 (0.00)
Confusional state	5	5 (7.46)	0	0 (0.00)
Insomnia	4	4 (5.97)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Mental status changes	4	4 (5.97)	2	2 (2.99)
Sleep disorder	4	3 (4.48)	0	0 (0.00)
Hallucination	3	3 (4.48)	0	0 (0.00)
Irritability	2	2 (2.99)	0	0 (0.00)
Affect lability	1	1 (1.49)	0	0 (0.00)
Automatism	1	1 (1.49)	0	0 (0.00)
Hallucination, visual	1	1 (1.49)	0	0 (0.00)
Mood altered	1	1 (1.49)	0	0 (0.00)
Nightmare	1	1 (1.49)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.49)	0	0 (0.00)
Restlessness	1	1 (1.49)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.49)	0	0 (0.00)
Tearfulness	1	1 (1.49)	0	0 (0.00)
Tic	1	1 (1.49)	0	0 (0.00)
Renal and urinary disorders				
- Total	42	20 (29.85)	15	11 (16.42)
Acute kidney injury	16	11 (16.42)	8	7 (10.45)
Renal failure	4	2 (2.99)	3	1 (1.49)
Dysuria	3	3 (4.48)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Haematuria	3	3 (4.48)	1	1 (1.49)
Anuria	2	2 (2.99)	1	1 (1.49)
Urinary incontinence	2	1 (1.49)	0	0 (0.00)
Urinary retention	2	2 (2.99)	0	0 (0.00)
Azotaemia	1	1 (1.49)	0	0 (0.00)
Bladder dilatation	1	1 (1.49)	0	0 (0.00)
Incontinence	1	1 (1.49)	0	0 (0.00)
Kidney enlargement	1	1 (1.49)	0	0 (0.00)
Pollakiuria	1	1 (1.49)	0	0 (0.00)
Proteinuria	1	1 (1.49)	0	0 (0.00)
Renal mass	1	1 (1.49)	0	0 (0.00)
Renal tubular disorder	1	1 (1.49)	1	1 (1.49)
Renal tubular necrosis	1	1 (1.49)	1	1 (1.49)
Urinary tract disorder	1	1 (1.49)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	10	6 (8.96)	2	2 (2.99)
Dysmenorrhoea	2	1 (1.49)	0	0 (0.00)
Endometriosis	2	1 (1.49)	1	1 (1.49)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Vaginal haemorrhage	2	1 (1.49)	0	0 (0.00)
Female genital tract fistula	1	1 (1.49)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.49)	0	0 (0.00)
Perineal rash	1	1 (1.49)	0	0 (0.00)
Vaginal ulceration	1	1 (1.49)	1	1 (1.49)
Respiratory, thoracic and mediastinal disorders				
- Total	151	45 (67.16)	58	26 (38.81)
Hypoxia	24	18 (26.87)	19	14 (20.90)
Cough	22	19 (28.36)	0	0 (0.00)
Pulmonary oedema	12	12 (17.91)	7	7 (10.45)
Tachypnoea	9	7 (10.45)	6	5 (7.46)
Nasal congestion	8	7 (10.45)	0	0 (0.00)
Pleural effusion	8	7 (10.45)	3	3 (4.48)
Dyspnoea	7	6 (8.96)	4	4 (5.97)
Epistaxis	7	6 (8.96)	1	1 (1.49)
Oropharyngeal pain	6	5 (7.46)	0	0 (0.00)
Respiratory failure	6	6 (8.96)	6	6 (8.96)
Atelectasis	5	3 (4.48)	2	2 (2.99)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Respiratory distress	4	3 (4.48)	3	2 (2.99)
Acute respiratory distress syndrome	3	3 (4.48)	3	3 (4.48)
Lung infiltration	2	1 (1.49)	1	1 (1.49)
Pharyngeal erythema	2	2 (2.99)	0	0 (0.00)
Rhinitis allergic	2	2 (2.99)	0	0 (0.00)
Rhinorrhoea	2	2 (2.99)	0	0 (0.00)
Wheezing	2	2 (2.99)	0	0 (0.00)
Acute respiratory failure	1	1 (1.49)	1	1 (1.49)
Bradypnoea	1	1 (1.49)	1	1 (1.49)
Bronchial oedema	1	1 (1.49)	0	0 (0.00)
Bronchospasm	1	1 (1.49)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.49)	0	0 (0.00)
Haemoptysis	1	1 (1.49)	0	0 (0.00)
Lung disorder	1	1 (1.49)	0	0 (0.00)
Nasal discomfort	1	1 (1.49)	0	0 (0.00)
Nasal dryness	1	1 (1.49)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.49)	0	0 (0.00)
Painful respiration	1	1 (1.49)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Pharyngeal exudate	1	1 (1.49)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.49)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.49)	0	0 (0.00)
Productive cough	1	1 (1.49)	0	0 (0.00)
Pulmonary mass	1	1 (1.49)	0	0 (0.00)
Respiratory acidosis	1	1 (1.49)	1	1 (1.49)
Respiratory disorder	1	1 (1.49)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.49)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	79	32 (47.76)	8	6 (8.96)
Rash	13	8 (11.94)	0	0 (0.00)
Pruritus	7	5 (7.46)	0	0 (0.00)
Blister	5	2 (2.99)	0	0 (0.00)
Dry skin	5	5 (7.46)	0	0 (0.00)
Erythema	5	5 (7.46)	0	0 (0.00)
Dermatitis atopic	4	3 (4.48)	1	1 (1.49)
Rash maculo-papular	4	3 (4.48)	1	1 (1.49)
Hyperhidrosis	3	3 (4.48)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Decubitus ulcer	2	2 (2.99)	1	1 (1.49)
Ingrowing nail	2	2 (2.99)	0	0 (0.00)
Petechiae	2	2 (2.99)	1	1 (1.49)
Rash macular	2	1 (1.49)	2	1 (1.49)
Rash papular	2	1 (1.49)	0	0 (0.00)
Rash vesicular	2	1 (1.49)	0	0 (0.00)
Skin discolouration	2	2 (2.99)	0	0 (0.00)
Dermatitis allergic	1	1 (1.49)	0	0 (0.00)
Dermatitis diaper	1	1 (1.49)	0	0 (0.00)
Eczema	1	1 (1.49)	0	0 (0.00)
Hangnail	1	1 (1.49)	0	0 (0.00)
Miliaria	1	1 (1.49)	0	0 (0.00)
Night sweats	1	1 (1.49)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.49)	0	0 (0.00)
Papule	1	1 (1.49)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.49)	0	0 (0.00)
Pruritus allergic	1	1 (1.49)	0	0 (0.00)
Purpura	1	1 (1.49)	0	0 (0.00)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Rash erythematous	1	1 (1.49)	0	0 (0.00)
Scab	1	1 (1.49)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.49)	0	0 (0.00)
Skin lesion	1	1 (1.49)	0	0 (0.00)
Skin necrosis	1	1 (1.49)	1	1 (1.49)
Skin ulcer	1	1 (1.49)	0	0 (0.00)
Urticaria	1	1 (1.49)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.49)	1	1 (1.49)
Social circumstances				
- Total	1	1 (1.49)	0	0 (0.00)
Patient uncooperative	1	1 (1.49)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.49)	1	1 (1.49)
Thrombolysis	1	1 (1.49)	1	1 (1.49)
Vascular disorders				
- Total	49	30 (44.78)	25	19 (28.36)
Hypotension	25	21 (31.34)	17	14 (20.90)
Hypertension	16	15 (22.39)	5	5 (7.46)

Timing: At anytime, Eligibility for SCT: No

Primary system organ class Preferred term	All grades Total events	All patients N=67 n (%)[1]	Grade >= 3 Total events	All patients N=67 n (%)[2]
Capillary leak syndrome	2	2 (2.99)	1	1 (1.49)
Venoocclusive disease	2	2 (2.99)	2	2 (2.99)
Flushing	1	1 (1.49)	0	0 (0.00)
Hot flush	1	1 (1.49)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.49)	0	0 (0.00)
Thrombosis	1	1 (1.49)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Total number of AE per patient	473	26 (100.00)	190	22 (84.62)
Blood and lymphatic system disorders				
- Total	47	19 (73.08)	34	15 (57.69)
Anaemia	15	8 (30.77)	6	3 (11.54)
Febrile neutropenia	13	10 (38.46)	13	10 (38.46)
Neutropenia	5	4 (15.38)	4	3 (11.54)
Leukopenia	4	3 (11.54)	3	2 (7.69)
Thrombocytopenia	4	4 (15.38)	4	4 (15.38)
Disseminated intravascular coagulation	2	2 (7.69)	1	1 (3.85)
Pancytopenia	2	2 (7.69)	2	2 (7.69)
B-cell aplasia	1	1 (3.85)	0	0 (0.00)
Coagulopathy	1	1 (3.85)	1	1 (3.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Cardiac disorders				
- Total	11	7 (26.92)	4	3 (11.54)
Tachycardia	9	6 (23.08)	2	2 (7.69)
Left ventricular dysfunction	1	1 (3.85)	1	1 (3.85)
Sinus bradycardia	1	1 (3.85)	1	1 (3.85)
Endocrine disorders				
- Total	2	2 (7.69)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.85)	0	0 (0.00)
Hypothyroidism	1	1 (3.85)	0	0 (0.00)
Eye disorders				
- Total	4	3 (11.54)	0	0 (0.00)
Ocular hyperaemia	2	2 (7.69)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.85)	0	0 (0.00)
Eyelid oedema	1	1 (3.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	37	14 (53.85)	5	5 (19.23)
Vomiting	8	5 (19.23)	1	1 (3.85)
Nausea	6	5 (19.23)	1	1 (3.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Constipation	5	5 (19.23)	0	0 (0.00)
Diarrhoea	5	4 (15.38)	0	0 (0.00)
Abdominal pain	4	3 (11.54)	0	0 (0.00)
Ascites	2	2 (7.69)	0	0 (0.00)
Abdominal distension	1	1 (3.85)	0	0 (0.00)
Anal fissure	1	1 (3.85)	0	0 (0.00)
Melaena	1	1 (3.85)	1	1 (3.85)
Mouth haemorrhage	1	1 (3.85)	0	0 (0.00)
Pancreatitis	1	1 (3.85)	1	1 (3.85)
Stomatitis	1	1 (3.85)	1	1 (3.85)
Trichoglossia	1	1 (3.85)	0	0 (0.00)
General disorders and administration site conditions				
- Total	28	13 (50.00)	6	3 (11.54)
Pyrexia	12	9 (34.62)	1	1 (3.85)
Face oedema	4	4 (15.38)	1	1 (3.85)
Fatigue	3	3 (11.54)	0	0 (0.00)
Influenza like illness	2	2 (7.69)	0	0 (0.00)
Oedema peripheral	2	1 (3.85)	2	1 (3.85)
Catheter site pain	1	1 (3.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Drug withdrawal syndrome	1	1 (3.85)	0	0 (0.00)
Generalised oedema	1	1 (3.85)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.85)	1	1 (3.85)
Systemic inflammatory response syndrome	1	1 (3.85)	1	1 (3.85)
Hepatobiliary disorders				
- Total	5	3 (11.54)	1	1 (3.85)
Cholelithiasis	2	2 (7.69)	0	0 (0.00)
Cholestasis	1	1 (3.85)	1	1 (3.85)
Gallbladder enlargement	1	1 (3.85)	0	0 (0.00)
Ocular icterus	1	1 (3.85)	0	0 (0.00)
Immune system disorders				
- Total	47	22 (84.62)	16	10 (38.46)
Cytokine release syndrome	33	18 (69.23)	11	7 (26.92)
Hypogammaglobulinaemia	11	9 (34.62)	2	2 (7.69)
Immunodeficiency	2	2 (7.69)	2	2 (7.69)
Haemophagocytic lymphohistiocytosis	1	1 (3.85)	1	1 (3.85)
Infections and infestations				

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
- Total	11	7 (26.92)	3	3 (11.54)
Conjunctivitis	5	4 (15.38)	0	0 (0.00)
Clostridium difficile infection	2	2 (7.69)	1	1 (3.85)
Encephalitis	1	1 (3.85)	1	1 (3.85)
Localised infection	1	1 (3.85)	0	0 (0.00)
Nail infection	1	1 (3.85)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (3.85)	1	1 (3.85)
Injury, poisoning and procedural complications				
- Total	8	3 (11.54)	2	1 (3.85)
Infusion related reaction	2	1 (3.85)	0	0 (0.00)
Wound	2	1 (3.85)	1	1 (3.85)
Scratch	1	1 (3.85)	0	0 (0.00)
Skin injury	1	1 (3.85)	0	0 (0.00)
Skin wound	1	1 (3.85)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.85)	1	1 (3.85)
Investigations				
- Total	115	16 (61.54)	63	15 (57.69)
Platelet count decreased	23	7 (26.92)	13	4 (15.38)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Neutrophil count decreased	18	6 (23.08)	14	5 (19.23)
White blood cell count decreased	17	8 (30.77)	11	5 (19.23)
Alanine aminotransferase increased	6	6 (23.08)	1	1 (3.85)
Aspartate aminotransferase increased	5	5 (19.23)	2	2 (7.69)
Lipase increased	4	2 (7.69)	2	1 (3.85)
Lymphocyte count decreased	4	4 (15.38)	4	4 (15.38)
Serum ferritin increased	4	4 (15.38)	2	2 (7.69)
Blood bilirubin increased	3	3 (11.54)	2	2 (7.69)
Blood immunoglobulin M decreased	3	3 (11.54)	1	1 (3.85)
C-reactive protein increased	3	3 (11.54)	3	3 (11.54)
Electrocardiogram QT prolonged	3	2 (7.69)	1	1 (3.85)
International normalised ratio increased	3	3 (11.54)	0	0 (0.00)
Activated partial thromboplastin time prolonged	2	2 (7.69)	1	1 (3.85)
Blood immunoglobulin A decreased	2	2 (7.69)	0	0 (0.00)
Blood immunoglobulin G decreased	2	2 (7.69)	0	0 (0.00)
Fibrin D dimer increased	2	2 (7.69)	1	1 (3.85)
Amylase increased	1	1 (3.85)	0	0 (0.00)
Bacterial test positive	1	1 (3.85)	1	1 (3.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Blood creatine phosphokinase increased	1	1 (3.85)	1	1 (3.85)
Blood creatinine increased	1	1 (3.85)	1	1 (3.85)
Blood fibrinogen decreased	1	1 (3.85)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (3.85)	1	1 (3.85)
Blood phosphorus increased	1	1 (3.85)	0	0 (0.00)
Blood testosterone decreased	1	1 (3.85)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (3.85)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.85)	0	0 (0.00)
Troponin increased	1	1 (3.85)	1	1 (3.85)
Metabolism and nutrition disorders				
- Total	67	12 (46.15)	24	6 (23.08)
Hypokalaemia	19	5 (19.23)	12	4 (15.38)
Hypophosphataemia	12	4 (15.38)	2	2 (7.69)
Hypocalcaemia	11	6 (23.08)	3	2 (7.69)
Decreased appetite	4	4 (15.38)	1	1 (3.85)
Hyperuricaemia	4	3 (11.54)	0	0 (0.00)
Hypoalbuminaemia	3	2 (7.69)	0	0 (0.00)
Calcium deficiency	1	1 (3.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Dehydration	1	1 (3.85)	0	0 (0.00)
Haemosiderosis	1	1 (3.85)	0	0 (0.00)
Hypercalcaemia	1	1 (3.85)	0	0 (0.00)
Hyperglycaemia	1	1 (3.85)	1	1 (3.85)
Hyperlactacidaemia	1	1 (3.85)	0	0 (0.00)
Hypernatraemia	1	1 (3.85)	1	1 (3.85)
Hyperphosphataemia	1	1 (3.85)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (3.85)	1	1 (3.85)
Hypervolaemia	1	1 (3.85)	1	1 (3.85)
Hypomagnesaemia	1	1 (3.85)	0	0 (0.00)
Malnutrition	1	1 (3.85)	1	1 (3.85)
Metabolic acidosis	1	1 (3.85)	0	0 (0.00)
Tumour lysis syndrome	1	1 (3.85)	1	1 (3.85)
Musculoskeletal and connective tissue disorders				
- Total	11	8 (30.77)	4	3 (11.54)
Arthralgia	2	2 (7.69)	1	1 (3.85)
Back pain	2	2 (7.69)	1	1 (3.85)
Myalgia	2	2 (7.69)	0	0 (0.00)
Pain in extremity	2	2 (7.69)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Haemarthrosis	1	1 (3.85)	1	1 (3.85)
Myositis	1	1 (3.85)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.85)	1	1 (3.85)
Nervous system disorders				
- Total	14	11 (42.31)	4	4 (15.38)
Headache	5	5 (19.23)	1	1 (3.85)
Cognitive disorder	2	2 (7.69)	0	0 (0.00)
Encephalopathy	2	2 (7.69)	2	2 (7.69)
Dysgeusia	1	1 (3.85)	0	0 (0.00)
Lethargy	1	1 (3.85)	0	0 (0.00)
Monoparesis	1	1 (3.85)	0	0 (0.00)
Seizure	1	1 (3.85)	1	1 (3.85)
Tremor	1	1 (3.85)	0	0 (0.00)
Psychiatric disorders				
- Total	8	8 (30.77)	1	1 (3.85)
Anxiety	3	3 (11.54)	1	1 (3.85)
Confusional state	2	2 (7.69)	0	0 (0.00)
Insomnia	1	1 (3.85)	0	0 (0.00)
Irritability	1	1 (3.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Sleep disorder	1	1 (3.85)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	4 (15.38)	3	2 (7.69)
Dysuria	2	2 (7.69)	0	0 (0.00)
Acute kidney injury	1	1 (3.85)	1	1 (3.85)
Anuria	1	1 (3.85)	1	1 (3.85)
Bladder dilatation	1	1 (3.85)	0	0 (0.00)
Renal tubular necrosis	1	1 (3.85)	1	1 (3.85)
Urinary retention	1	1 (3.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	2 (7.69)	1	1 (3.85)
Heavy menstrual bleeding	1	1 (3.85)	0	0 (0.00)
Vaginal ulceration	1	1 (3.85)	1	1 (3.85)
Respiratory, thoracic and mediastinal disorders				
- Total	23	11 (42.31)	11	5 (19.23)
Atelectasis	3	1 (3.85)	1	1 (3.85)
Cough	3	3 (11.54)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Acute respiratory distress syndrome	2	2 (7.69)	2	2 (7.69)
Hypoxia	2	2 (7.69)	1	1 (3.85)
Nasal congestion	2	2 (7.69)	0	0 (0.00)
Pleural effusion	2	2 (7.69)	2	2 (7.69)
Pulmonary oedema	2	2 (7.69)	2	2 (7.69)
Dyspnoea	1	1 (3.85)	1	1 (3.85)
Epistaxis	1	1 (3.85)	0	0 (0.00)
Nasal dryness	1	1 (3.85)	0	0 (0.00)
Respiratory acidosis	1	1 (3.85)	1	1 (3.85)
Rhinorrhoea	1	1 (3.85)	0	0 (0.00)
Tachypnoea	1	1 (3.85)	1	1 (3.85)
Wheezing	1	1 (3.85)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	16	8 (30.77)	2	1 (3.85)
Rash	3	3 (11.54)	0	0 (0.00)
Erythema	2	2 (7.69)	0	0 (0.00)
Decubitus ulcer	1	1 (3.85)	0	0 (0.00)
Dermatitis	1	1 (3.85)	0	0 (0.00)
Eczema	1	1 (3.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Palmar-plantar erythrodysaesthesia syndrome	1	1 (3.85)	0	0 (0.00)
Petechiae	1	1 (3.85)	1	1 (3.85)
Pruritus	1	1 (3.85)	0	0 (0.00)
Rash maculo-papular	1	1 (3.85)	0	0 (0.00)
Rash papular	1	1 (3.85)	0	0 (0.00)
Skin discolouration	1	1 (3.85)	0	0 (0.00)
Skin necrosis	1	1 (3.85)	1	1 (3.85)
Skin ulcer	1	1 (3.85)	0	0 (0.00)
Vascular disorders				
- Total	10	7 (26.92)	6	4 (15.38)
Hypotension	7	6 (23.08)	4	3 (11.54)
Hypertension	2	1 (3.85)	1	1 (3.85)
Capillary leak syndrome	1	1 (3.85)	1	1 (3.85)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Total number of AE per patient	1278	53 (98.15)	429	45 (83.33)
Blood and lymphatic system disorders				
- Total	78	31 (57.41)	42	24 (44.44)
Anaemia	35	13 (24.07)	14	5 (9.26)
Febrile neutropenia	16	16 (29.63)	16	16 (29.63)
Neutropenia	6	5 (9.26)	5	4 (7.41)
Disseminated intravascular coagulation	5	5 (9.26)	1	1 (1.85)
Coagulopathy	4	4 (7.41)	1	1 (1.85)
Splenomegaly	4	4 (7.41)	0	0 (0.00)
Thrombocytopenia	4	4 (7.41)	4	4 (7.41)
Eosinophilia	2	1 (1.85)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.85)	0	0 (0.00)
Lymphopenia	1	1 (1.85)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Cardiac disorders				
- Total	34	17 (31.48)	6	5 (9.26)
Tachycardia	13	11 (20.37)	1	1 (1.85)
Cardiac failure	4	1 (1.85)	2	1 (1.85)
Sinus tachycardia	4	3 (5.56)	0	0 (0.00)
Bradycardia	3	3 (5.56)	0	0 (0.00)
Cardiac dysfunction	2	2 (3.70)	0	0 (0.00)
Left ventricular dysfunction	2	2 (3.70)	2	2 (3.70)
Atrioventricular block first degree	1	1 (1.85)	0	0 (0.00)
Cardiac arrest	1	1 (1.85)	1	1 (1.85)
Cardiac failure congestive	1	1 (1.85)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.85)	0	0 (0.00)
Pericardial effusion	1	1 (1.85)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.85)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (3.70)	0	0 (0.00)
Ear pain	1	1 (1.85)	0	0 (0.00)
Ear pruritus	1	1 (1.85)	0	0 (0.00)
Endocrine disorders				

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
- Total	3	3 (5.56)	0	0 (0.00)
Adrenal insufficiency	3	3 (5.56)	0	0 (0.00)
Eye disorders				
- Total	11	6 (11.11)	0	0 (0.00)
Eyelid oedema	2	1 (1.85)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.85)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (1.85)	0	0 (0.00)
Eye oedema	1	1 (1.85)	0	0 (0.00)
Eye pain	1	1 (1.85)	0	0 (0.00)
Periorbital oedema	1	1 (1.85)	0	0 (0.00)
Periorbital swelling	1	1 (1.85)	0	0 (0.00)
Visual field defect	1	1 (1.85)	0	0 (0.00)
Visual impairment	1	1 (1.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	98	37 (68.52)	11	9 (16.67)
Vomiting	22	16 (29.63)	0	0 (0.00)
Nausea	15	13 (24.07)	1	1 (1.85)
Diarrhoea	13	11 (20.37)	1	1 (1.85)
Abdominal pain	9	8 (14.81)	2	2 (3.70)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Constipation	6	6 (11.11)	0	0 (0.00)
Abdominal pain upper	3	3 (5.56)	0	0 (0.00)
Mouth haemorrhage	3	3 (5.56)	2	2 (3.70)
Pancreatitis	3	3 (5.56)	0	0 (0.00)
Abdominal distension	2	2 (3.70)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (3.70)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.85)	1	1 (1.85)
Anal haemorrhage	1	1 (1.85)	0	0 (0.00)
Ascites	1	1 (1.85)	0	0 (0.00)
Dry mouth	1	1 (1.85)	0	0 (0.00)
Dysphagia	1	1 (1.85)	1	1 (1.85)
Enterocolitis	1	1 (1.85)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.85)	0	0 (0.00)
Gingival bleeding	1	1 (1.85)	0	0 (0.00)
Gingival erythema	1	1 (1.85)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.85)	1	1 (1.85)
Haematemesis	1	1 (1.85)	0	0 (0.00)
Ileus	1	1 (1.85)	0	0 (0.00)
Lip dry	1	1 (1.85)	0	0 (0.00)
Lip oedema	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Mouth swelling	1	1 (1.85)	0	0 (0.00)
Neutropenic colitis	1	1 (1.85)	1	1 (1.85)
Odynophagia	1	1 (1.85)	0	0 (0.00)
Proctalgia	1	1 (1.85)	1	1 (1.85)
Stomatitis	1	1 (1.85)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.85)	0	0 (0.00)
General disorders and administration site conditions				
- Total	84	27 (50.00)	13	8 (14.81)
Pyrexia	32	15 (27.78)	8	7 (12.96)
Chills	9	6 (11.11)	0	0 (0.00)
Fatigue	8	8 (14.81)	0	0 (0.00)
Face oedema	5	4 (7.41)	0	0 (0.00)
Oedema peripheral	5	5 (9.26)	0	0 (0.00)
Generalised oedema	4	4 (7.41)	0	0 (0.00)
Catheter site pain	3	1 (1.85)	2	1 (1.85)
Asthenia	2	2 (3.70)	0	0 (0.00)
Catheter site erythema	2	1 (1.85)	0	0 (0.00)
Localised oedema	2	2 (3.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Chest discomfort	1	1 (1.85)	1	1 (1.85)
Crying	1	1 (1.85)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.85)	0	0 (0.00)
Facial pain	1	1 (1.85)	0	0 (0.00)
Malaise	1	1 (1.85)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.85)	1	1 (1.85)
Oedema due to hepatic disease	1	1 (1.85)	0	0 (0.00)
Pain	1	1 (1.85)	1	1 (1.85)
Sluggishness	1	1 (1.85)	0	0 (0.00)
Swelling face	1	1 (1.85)	0	0 (0.00)
Vascular device occlusion	1	1 (1.85)	0	0 (0.00)
Hepatobiliary disorders				
- Total	24	14 (25.93)	6	5 (9.26)
Hepatic function abnormal	11	5 (9.26)	4	3 (5.56)
Hyperbilirubinaemia	6	5 (9.26)	1	1 (1.85)
Hepatomegaly	3	3 (5.56)	1	1 (1.85)
Hypertransaminasaemia	2	2 (3.70)	0	0 (0.00)
Biliary tract disorder	1	1 (1.85)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Immune system disorders				
- Total	117	45 (83.33)	52	33 (61.11)
Cytokine release syndrome	95	43 (79.63)	44	31 (57.41)
Hypogammaglobulinaemia	14	14 (25.93)	5	5 (9.26)
Haemophagocytic lymphohistiocytosis	4	4 (7.41)	2	2 (3.70)
Hypersensitivity	1	1 (1.85)	0	0 (0.00)
Immunodeficiency	1	1 (1.85)	1	1 (1.85)
Seasonal allergy	1	1 (1.85)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.85)	0	0 (0.00)
Infections and infestations				
- Total	53	28 (51.85)	28	16 (29.63)
Staphylococcal infection	5	5 (9.26)	2	2 (3.70)
Candida infection	4	3 (5.56)	2	1 (1.85)
Staphylococcal bacteraemia	3	2 (3.70)	3	2 (3.70)
Clostridium difficile infection	2	2 (3.70)	2	2 (3.70)
Encephalitis viral	2	2 (3.70)	2	2 (3.70)
Oral candidiasis	2	1 (1.85)	0	0 (0.00)
Oral herpes	2	2 (3.70)	1	1 (1.85)
Oral infection	2	2 (3.70)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Rhinovirus infection	2	2 (3.70)	0	0 (0.00)
Adenovirus infection	1	1 (1.85)	1	1 (1.85)
Anal abscess	1	1 (1.85)	1	1 (1.85)
Atypical pneumonia	1	1 (1.85)	0	0 (0.00)
BK virus infection	1	1 (1.85)	0	0 (0.00)
Bacteraemia	1	1 (1.85)	1	1 (1.85)
Bronchopulmonary aspergillosis	1	1 (1.85)	1	1 (1.85)
Cholecystitis infective	1	1 (1.85)	0	0 (0.00)
Conjunctivitis	1	1 (1.85)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.85)	0	0 (0.00)
Gingivitis	1	1 (1.85)	0	0 (0.00)
Granulicatella infection	1	1 (1.85)	1	1 (1.85)
Herpes simplex	1	1 (1.85)	1	1 (1.85)
Human herpesvirus 6 infection	1	1 (1.85)	1	1 (1.85)
Klebsiella bacteraemia	1	1 (1.85)	0	0 (0.00)
Klebsiella infection	1	1 (1.85)	1	1 (1.85)
Meningitis bacterial	1	1 (1.85)	1	1 (1.85)
Myringitis	1	1 (1.85)	0	0 (0.00)
Nail infection	1	1 (1.85)	0	0 (0.00)
Otitis externa	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Paronychia	1	1 (1.85)	0	0 (0.00)
Pneumonia	1	1 (1.85)	1	1 (1.85)
Pneumonia fungal	1	1 (1.85)	1	1 (1.85)
Pneumonia viral	1	1 (1.85)	1	1 (1.85)
Sinusitis	1	1 (1.85)	1	1 (1.85)
Soft tissue infection	1	1 (1.85)	1	1 (1.85)
Stomatococcal infection	1	1 (1.85)	0	0 (0.00)
Systemic candida	1	1 (1.85)	1	1 (1.85)
Urinary tract infection viral	1	1 (1.85)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.85)	1	1 (1.85)
Injury, poisoning and procedural complications				
- Total	12	8 (14.81)	1	1 (1.85)
Contusion	2	1 (1.85)	0	0 (0.00)
Fall	2	2 (3.70)	0	0 (0.00)
Procedural pain	2	2 (3.70)	0	0 (0.00)
Transfusion reaction	2	2 (3.70)	0	0 (0.00)
Infusion related reaction	1	1 (1.85)	0	0 (0.00)
Skin abrasion	1	1 (1.85)	0	0 (0.00)
Transplant failure	1	1 (1.85)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Wound	1	1 (1.85)	0	0 (0.00)
Investigations				
- Total	271	41 (75.93)	134	30 (55.56)
Platelet count decreased	42	14 (25.93)	25	10 (18.52)
White blood cell count decreased	33	16 (29.63)	25	13 (24.07)
Neutrophil count decreased	30	14 (25.93)	24	12 (22.22)
Aspartate aminotransferase increased	28	14 (25.93)	11	9 (16.67)
Lymphocyte count decreased	26	11 (20.37)	20	9 (16.67)
Alanine aminotransferase increased	20	12 (22.22)	5	5 (9.26)
Blood bilirubin increased	15	9 (16.67)	7	7 (12.96)
International normalised ratio increased	9	6 (11.11)	0	0 (0.00)
Activated partial thromboplastin time prolonged	6	4 (7.41)	0	0 (0.00)
Blood fibrinogen decreased	6	6 (11.11)	2	2 (3.70)
Blood creatinine increased	5	3 (5.56)	4	2 (3.70)
Immunoglobulins decreased	5	2 (3.70)	0	0 (0.00)
Serum ferritin increased	4	4 (7.41)	0	0 (0.00)
Weight increased	4	4 (7.41)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Blood creatine phosphokinase increased	3	1 (1.85)	1	1 (1.85)
Blood immunoglobulin A decreased	3	3 (5.56)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (5.56)	0	0 (0.00)
Blood lactate dehydrogenase increased	3	3 (5.56)	0	0 (0.00)
Electrocardiogram QT prolonged	3	3 (5.56)	1	1 (1.85)
Urine output decreased	3	2 (3.70)	3	2 (3.70)
Blood glucose increased	2	1 (1.85)	2	1 (1.85)
Blood uric acid increased	2	2 (3.70)	0	0 (0.00)
Gamma-glutamyltransferase increased	2	2 (3.70)	2	2 (3.70)
Haemoglobin decreased	2	1 (1.85)	1	1 (1.85)
Blood alkaline phosphatase increased	1	1 (1.85)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.85)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.85)	0	0 (0.00)
C-reactive protein increased	1	1 (1.85)	0	0 (0.00)
Cardiac murmur	1	1 (1.85)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.85)	0	0 (0.00)
Enterovirus test positive	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Fibrin D dimer increased	1	1 (1.85)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.85)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.85)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.85)	0	0 (0.00)
Weight decreased	1	1 (1.85)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	143	34 (62.96)	52	23 (42.59)
Hypokalaemia	21	14 (25.93)	8	7 (12.96)
Decreased appetite	20	20 (37.04)	10	10 (18.52)
Hypophosphataemia	19	13 (24.07)	9	7 (12.96)
Hypoalbuminaemia	16	9 (16.67)	1	1 (1.85)
Hypocalcaemia	13	10 (18.52)	3	3 (5.56)
Hyperglycaemia	10	7 (12.96)	3	3 (5.56)
Hypomagnesaemia	6	5 (9.26)	0	0 (0.00)
Hyperuricaemia	5	4 (7.41)	1	1 (1.85)
Hypervolaemia	5	5 (9.26)	3	3 (5.56)
Hyperphosphataemia	4	4 (7.41)	1	1 (1.85)
Acidosis	3	2 (3.70)	2	2 (3.70)
Hypercalcaemia	3	2 (3.70)	2	2 (3.70)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Hypermagnesaemia	3	2 (3.70)	0	0 (0.00)
Hyponatraemia	3	3 (5.56)	0	0 (0.00)
Tumour lysis syndrome	3	3 (5.56)	3	3 (5.56)
Hyperkalaemia	2	2 (3.70)	2	2 (3.70)
Metabolic acidosis	2	2 (3.70)	2	2 (3.70)
Hyperchloraemia	1	1 (1.85)	0	0 (0.00)
Hypernatraemia	1	1 (1.85)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (1.85)	1	1 (1.85)
Hypoglycaemia	1	1 (1.85)	0	0 (0.00)
Polydipsia	1	1 (1.85)	1	1 (1.85)
Musculoskeletal and connective tissue disorders				
- Total	42	25 (46.30)	2	2 (3.70)
Pain in extremity	9	9 (16.67)	0	0 (0.00)
Arthralgia	8	8 (14.81)	0	0 (0.00)
Myalgia	8	7 (12.96)	0	0 (0.00)
Back pain	5	4 (7.41)	0	0 (0.00)
Bone pain	4	2 (3.70)	0	0 (0.00)
Muscular weakness	2	2 (3.70)	1	1 (1.85)
Pain in jaw	2	2 (3.70)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Muscle rigidity	1	1 (1.85)	0	0 (0.00)
Muscle spasms	1	1 (1.85)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.85)	0	0 (0.00)
Neck pain	1	1 (1.85)	0	0 (0.00)
Nervous system disorders				
- Total	63	29 (53.70)	10	6 (11.11)
Headache	21	18 (33.33)	1	1 (1.85)
Encephalopathy	6	6 (11.11)	2	2 (3.70)
Tremor	6	5 (9.26)	0	0 (0.00)
Somnolence	5	5 (9.26)	2	2 (3.70)
Cognitive disorder	3	1 (1.85)	1	1 (1.85)
Dizziness	3	3 (5.56)	0	0 (0.00)
Dysgeusia	2	2 (3.70)	0	0 (0.00)
Hyperaesthesia	2	1 (1.85)	0	0 (0.00)
Lethargy	2	2 (3.70)	0	0 (0.00)
Seizure	2	1 (1.85)	0	0 (0.00)
Amnesia	1	1 (1.85)	0	0 (0.00)
Aphasia	1	1 (1.85)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.85)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Depressed level of consciousness	1	1 (1.85)	1	1 (1.85)
Disturbance in attention	1	1 (1.85)	0	0 (0.00)
Dysarthria	1	1 (1.85)	1	1 (1.85)
Generalised tonic-clonic seizure	1	1 (1.85)	0	0 (0.00)
Hypoaesthesia	1	1 (1.85)	0	0 (0.00)
Neuralgia	1	1 (1.85)	0	0 (0.00)
Neurological decompensation	1	1 (1.85)	1	1 (1.85)
Paraesthesia	1	1 (1.85)	0	0 (0.00)
Psychiatric disorders				
- Total	39	20 (37.04)	5	5 (9.26)
Delirium	7	7 (12.96)	3	3 (5.56)
Agitation	6	5 (9.26)	0	0 (0.00)
Confusional state	5	5 (9.26)	0	0 (0.00)
Anxiety	3	3 (5.56)	1	1 (1.85)
Hallucination	3	3 (5.56)	0	0 (0.00)
Insomnia	3	3 (5.56)	0	0 (0.00)
Mental status changes	3	3 (5.56)	1	1 (1.85)
Irritability	2	2 (3.70)	0	0 (0.00)
Sleep disorder	2	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Affect lability	1	1 (1.85)	0	0 (0.00)
Automatism	1	1 (1.85)	0	0 (0.00)
Hallucination, visual	1	1 (1.85)	0	0 (0.00)
Restlessness	1	1 (1.85)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.85)	0	0 (0.00)
Renal and urinary disorders				
- Total	32	16 (29.63)	10	7 (12.96)
Acute kidney injury	13	8 (14.81)	7	6 (11.11)
Renal failure	4	2 (3.70)	3	1 (1.85)
Haematuria	2	2 (3.70)	0	0 (0.00)
Pollakiuria	2	2 (3.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.85)	0	0 (0.00)
Anuria	1	1 (1.85)	0	0 (0.00)
Azotaemia	1	1 (1.85)	0	0 (0.00)
Dysuria	1	1 (1.85)	0	0 (0.00)
Incontinence	1	1 (1.85)	0	0 (0.00)
Micturition urgency	1	1 (1.85)	0	0 (0.00)
Proteinuria	1	1 (1.85)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Urinary retention	1	1 (1.85)	0	0 (0.00)
Urinary tract disorder	1	1 (1.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (5.56)	0	0 (0.00)
Vaginal haemorrhage	2	1 (1.85)	0	0 (0.00)
Female genital tract fistula	1	1 (1.85)	0	0 (0.00)
Perineal rash	1	1 (1.85)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	91	30 (55.56)	39	18 (33.33)
Hypoxia	21	15 (27.78)	17	11 (20.37)
Pulmonary oedema	10	10 (18.52)	5	5 (9.26)
Cough	8	7 (12.96)	0	0 (0.00)
Tachypnoea	8	7 (12.96)	3	3 (5.56)
Oropharyngeal pain	6	5 (9.26)	0	0 (0.00)
Pleural effusion	5	5 (9.26)	1	1 (1.85)
Respiratory distress	4	3 (5.56)	2	1 (1.85)
Respiratory failure	4	4 (7.41)	4	4 (7.41)
Epistaxis	3	3 (5.56)	1	1 (1.85)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Atelectasis	2	2 (3.70)	1	1 (1.85)
Dyspnoea	2	2 (3.70)	2	2 (3.70)
Lung infiltration	2	1 (1.85)	1	1 (1.85)
Acute respiratory failure	1	1 (1.85)	1	1 (1.85)
Bradypnoea	1	1 (1.85)	1	1 (1.85)
Haemoptysis	1	1 (1.85)	0	0 (0.00)
Nasal congestion	1	1 (1.85)	0	0 (0.00)
Nasal discomfort	1	1 (1.85)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.85)	0	0 (0.00)
Painful respiration	1	1 (1.85)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.85)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.85)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.85)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.85)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.85)	0	0 (0.00)
Productive cough	1	1 (1.85)	0	0 (0.00)
Pulmonary mass	1	1 (1.85)	0	0 (0.00)
Respiratory disorder	1	1 (1.85)	0	0 (0.00)
Rhinorrhoea	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	40	19 (35.19)	2	2 (3.70)
Blister	6	3 (5.56)	0	0 (0.00)
Pruritus	6	5 (9.26)	0	0 (0.00)
Hyperhidrosis	3	3 (5.56)	0	0 (0.00)
Rash papular	3	2 (3.70)	0	0 (0.00)
Dermatitis atopic	2	2 (3.70)	0	0 (0.00)
Erythema	2	2 (3.70)	0	0 (0.00)
Rash	2	2 (3.70)	0	0 (0.00)
Rash maculo-papular	2	1 (1.85)	1	1 (1.85)
Rash vesicular	2	1 (1.85)	0	0 (0.00)
Dermatitis diaper	1	1 (1.85)	0	0 (0.00)
Dry skin	1	1 (1.85)	0	0 (0.00)
Erythema nodosum	1	1 (1.85)	0	0 (0.00)
Petechiae	1	1 (1.85)	0	0 (0.00)
Pruritus allergic	1	1 (1.85)	0	0 (0.00)
Purpura	1	1 (1.85)	0	0 (0.00)
Rash pruritic	1	1 (1.85)	0	0 (0.00)
Scab	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Skin lesion	1	1 (1.85)	0	0 (0.00)
Skin ulcer	1	1 (1.85)	0	0 (0.00)
Urticaria	1	1 (1.85)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.85)	1	1 (1.85)
Social circumstances				
- Total	1	1 (1.85)	0	0 (0.00)
Patient uncooperative	1	1 (1.85)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.85)	1	1 (1.85)
Thrombolysis	1	1 (1.85)	1	1 (1.85)
Vascular disorders				
- Total	35	21 (38.89)	15	13 (24.07)
Hypotension	18	15 (27.78)	12	11 (20.37)
Hypertension	12	12 (22.22)	3	3 (5.56)
Capillary leak syndrome	1	1 (1.85)	0	0 (0.00)
Flushing	1	1 (1.85)	0	0 (0.00)
Hot flush	1	1 (1.85)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.85)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Thrombosis	1	1 (1.85)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Total number of AE per patient	172	22 (88.00)	47	10 (40.00)
Blood and lymphatic system disorders				
- Total	17	8 (32.00)	6	3 (12.00)
Anaemia	8	3 (12.00)	3	1 (4.00)
B-cell aplasia	2	1 (4.00)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (4.00)	1	1 (4.00)
Febrile neutropenia	1	1 (4.00)	1	1 (4.00)
Leukocytosis	1	1 (4.00)	0	0 (0.00)
Leukopenia	1	1 (4.00)	0	0 (0.00)
Lymphadenopathy	1	1 (4.00)	0	0 (0.00)
Lymphocytosis	1	1 (4.00)	0	0 (0.00)
Neutropenia	1	1 (4.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cardiac disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Left ventricular dysfunction	1	1 (4.00)	0	0 (0.00)
Tachycardia	1	1 (4.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Ocular hyperaemia	1	1 (4.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	7 (28.00)	0	0 (0.00)
Diarrhoea	4	4 (16.00)	0	0 (0.00)
Vomiting	4	3 (12.00)	0	0 (0.00)
Abdominal pain upper	1	1 (4.00)	0	0 (0.00)
Dyspepsia	1	1 (4.00)	0	0 (0.00)
Nausea	1	1 (4.00)	0	0 (0.00)
Pancreatitis	1	1 (4.00)	0	0 (0.00)
Peritoneal haematoma	1	1 (4.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	7 (28.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Pyrexia	6	5 (20.00)	1	1 (4.00)
Fatigue	2	2 (8.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Hepatic cytolysis	1	1 (4.00)	0	0 (0.00)
Immune system disorders				
- Total	5	5 (20.00)	0	0 (0.00)
Hypogammaglobulinaemia	5	5 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	41	12 (48.00)	16	6 (24.00)
Bronchopulmonary aspergillosis	5	1 (4.00)	3	1 (4.00)
Upper respiratory tract infection	5	4 (16.00)	2	2 (8.00)
Respiratory syncytial virus infection	3	3 (12.00)	2	2 (8.00)
Ear infection	2	1 (4.00)	0	0 (0.00)
Nasopharyngitis	2	1 (4.00)	0	0 (0.00)
Otitis media	2	2 (8.00)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (8.00)	1	1 (4.00)
Rhinovirus infection	2	2 (8.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Cellulitis	1	1 (4.00)	0	0 (0.00)
Conjunctivitis	1	1 (4.00)	0	0 (0.00)
Ear, nose and throat infection	1	1 (4.00)	0	0 (0.00)
Encephalitis	1	1 (4.00)	1	1 (4.00)
Gastroenteritis	1	1 (4.00)	1	1 (4.00)
Gastrointestinal infection	1	1 (4.00)	0	0 (0.00)
Herpes zoster	1	1 (4.00)	1	1 (4.00)
Metapneumovirus infection	1	1 (4.00)	1	1 (4.00)
Molluscum contagiosum	1	1 (4.00)	0	0 (0.00)
Otitis externa	1	1 (4.00)	0	0 (0.00)
Paronychia	1	1 (4.00)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (4.00)	1	1 (4.00)
Pneumonia	1	1 (4.00)	0	0 (0.00)
Respiratory tract infection	1	1 (4.00)	0	0 (0.00)
Respiratory tract infection viral	1	1 (4.00)	0	0 (0.00)
Rhinitis	1	1 (4.00)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (4.00)	1	1 (4.00)
Viral haemorrhagic cystitis	1	1 (4.00)	1	1 (4.00)
Injury, poisoning and procedural complications				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
- Total	5	4 (16.00)	0	0 (0.00)
Infusion related reaction	3	2 (8.00)	0	0 (0.00)
Fibula fracture	1	1 (4.00)	0	0 (0.00)
Skin abrasion	1	1 (4.00)	0	0 (0.00)
Investigations				
- Total	29	7 (28.00)	14	4 (16.00)
Platelet count decreased	12	2 (8.00)	8	1 (4.00)
Neutrophil count decreased	5	4 (16.00)	3	2 (8.00)
White blood cell count decreased	5	4 (16.00)	1	1 (4.00)
Lymphocyte count decreased	4	2 (8.00)	1	1 (4.00)
Blood lactate dehydrogenase increased	1	1 (4.00)	0	0 (0.00)
C-reactive protein increased	1	1 (4.00)	0	0 (0.00)
Weight decreased	1	1 (4.00)	1	1 (4.00)
Metabolism and nutrition disorders				
- Total	11	4 (16.00)	5	2 (8.00)
Decreased appetite	4	4 (16.00)	1	1 (4.00)
Hypokalaemia	4	1 (4.00)	3	1 (4.00)
Haemochromatosis	1	1 (4.00)	1	1 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Hyperkalaemia	1	1 (4.00)	0	0 (0.00)
Hypophosphataemia	1	1 (4.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (12.00)	0	0 (0.00)
Back pain	1	1 (4.00)	0	0 (0.00)
Growth retardation	1	1 (4.00)	0	0 (0.00)
Pain in extremity	1	1 (4.00)	0	0 (0.00)
Nervous system disorders				
- Total	10	6 (24.00)	3	1 (4.00)
Headache	6	5 (20.00)	0	0 (0.00)
Autonomic neuropathy	1	1 (4.00)	1	1 (4.00)
Cerebral haemorrhage	1	1 (4.00)	1	1 (4.00)
Memory impairment	1	1 (4.00)	0	0 (0.00)
Seizure	1	1 (4.00)	1	1 (4.00)
Psychiatric disorders				
- Total	2	2 (8.00)	0	0 (0.00)
Persistent depressive disorder	1	1 (4.00)	0	0 (0.00)
Sleep disorder	1	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Renal and urinary disorders				
- Total	1	1 (4.00)	1	1 (4.00)
Renal tubular disorder	1	1 (4.00)	1	1 (4.00)
Respiratory, thoracic and mediastinal disorders				
- Total	15	7 (28.00)	1	1 (4.00)
Cough	4	2 (8.00)	0	0 (0.00)
Epistaxis	2	2 (8.00)	0	0 (0.00)
Nasal congestion	2	2 (8.00)	0	0 (0.00)
Rhinitis allergic	2	2 (8.00)	0	0 (0.00)
Bronchospasm	1	1 (4.00)	0	0 (0.00)
Hypoxia	1	1 (4.00)	1	1 (4.00)
Lung disorder	1	1 (4.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.00)	0	0 (0.00)
Rhinorrhoea	1	1 (4.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	6 (24.00)	0	0 (0.00)
Dry skin	2	1 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=25 n (%)[1]	Grade >= 3 Total events	All patients N=25 n (%)[2]
Dermatitis allergic	1	1 (4.00)	0	0 (0.00)
Erythema	1	1 (4.00)	0	0 (0.00)
Ingrowing nail	1	1 (4.00)	0	0 (0.00)
Miliaria	1	1 (4.00)	0	0 (0.00)
Rash	1	1 (4.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (4.00)	0	0 (0.00)
Hypotension	1	1 (4.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Total number of AE per patient	362	47 (94.00)	99	26 (52.00)
Blood and lymphatic system disorders				
- Total	15	9 (18.00)	11	7 (14.00)
Anaemia	4	3 (6.00)	1	1 (2.00)
Neutropenia	4	4 (8.00)	4	4 (8.00)
Febrile neutropenia	3	2 (4.00)	3	2 (4.00)
Thrombocytopenia	2	2 (4.00)	2	2 (4.00)
Eosinophilia	1	1 (2.00)	0	0 (0.00)
Lymphopenia	1	1 (2.00)	1	1 (2.00)
Cardiac disorders				
- Total	6	5 (10.00)	4	3 (6.00)
Cardiac arrest	2	2 (4.00)	2	2 (4.00)
Cardiac failure	2	2 (4.00)	2	2 (4.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Tachycardia	1	1 (2.00)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.00)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.00)	0	0 (0.00)
Hypothyroidism	1	1 (2.00)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.00)	0	0 (0.00)
Cataract	2	2 (4.00)	0	0 (0.00)
Hypermetropia	1	1 (2.00)	0	0 (0.00)
Visual impairment	1	1 (2.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	25	13 (26.00)	1	1 (2.00)
Constipation	4	3 (6.00)	0	0 (0.00)
Nausea	4	4 (8.00)	0	0 (0.00)
Diarrhoea	3	3 (6.00)	0	0 (0.00)
Vomiting	3	3 (6.00)	0	0 (0.00)
Abdominal pain	2	2 (4.00)	0	0 (0.00)
Abdominal rigidity	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Enteritis	1	1 (2.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.00)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.00)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.00)	0	0 (0.00)
Pancreatitis	1	1 (2.00)	1	1 (2.00)
Proctalgia	1	1 (2.00)	0	0 (0.00)
Stomatitis	1	1 (2.00)	0	0 (0.00)
Trichoglossia	1	1 (2.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	23	17 (34.00)	2	2 (4.00)
Pyrexia	10	10 (20.00)	1	1 (2.00)
Fatigue	5	4 (8.00)	0	0 (0.00)
Oedema peripheral	2	1 (2.00)	0	0 (0.00)
Pain	2	2 (4.00)	1	1 (2.00)
Asthenia	1	1 (2.00)	0	0 (0.00)
Chills	1	1 (2.00)	0	0 (0.00)
Malaise	1	1 (2.00)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Hepatobiliary disorders				
- Total	2	2 (4.00)	0	0 (0.00)
Hypertransaminasaemia	1	1 (2.00)	0	0 (0.00)
Liver disorder	1	1 (2.00)	0	0 (0.00)
Immune system disorders				
- Total	14	11 (22.00)	5	4 (8.00)
Hypogammaglobulinaemia	7	5 (10.00)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (4.00)	1	1 (2.00)
Graft versus host disease	2	2 (4.00)	2	2 (4.00)
Drug hypersensitivity	1	1 (2.00)	0	0 (0.00)
Engraftment syndrome	1	1 (2.00)	1	1 (2.00)
Immunodeficiency	1	1 (2.00)	1	1 (2.00)
Infections and infestations				
- Total	72	27 (54.00)	29	14 (28.00)
Nasopharyngitis	7	6 (12.00)	0	0 (0.00)
Upper respiratory tract infection	5	4 (8.00)	0	0 (0.00)
Gastroenteritis	4	4 (8.00)	1	1 (2.00)
Sinusitis	4	3 (6.00)	1	1 (2.00)
Bacteraemia	3	2 (4.00)	2	1 (2.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Parainfluenzae virus infection	3	2 (4.00)	1	1 (2.00)
Rhinovirus infection	3	3 (6.00)	0	0 (0.00)
Klebsiella infection	2	1 (2.00)	2	1 (2.00)
Metapneumovirus infection	2	2 (4.00)	2	2 (4.00)
Pneumonia	2	2 (4.00)	1	1 (2.00)
Respiratory tract infection	2	2 (4.00)	0	0 (0.00)
Urinary tract infection	2	1 (2.00)	2	1 (2.00)
Viral infection	2	2 (4.00)	1	1 (2.00)
Acute sinusitis	1	1 (2.00)	0	0 (0.00)
Adenovirus infection	1	1 (2.00)	1	1 (2.00)
BK virus infection	1	1 (2.00)	1	1 (2.00)
Coronavirus infection	1	1 (2.00)	1	1 (2.00)
Cystitis	1	1 (2.00)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.00)	1	1 (2.00)
Device related infection	1	1 (2.00)	1	1 (2.00)
Ear infection	1	1 (2.00)	0	0 (0.00)
Enterobacter infection	1	1 (2.00)	1	1 (2.00)
Gastroenteritis clostridial	1	1 (2.00)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.00)	0	0 (0.00)
Gingivitis	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Herpes simplex	1	1 (2.00)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.00)	1	1 (2.00)
Influenza	1	1 (2.00)	0	0 (0.00)
Mastoiditis	1	1 (2.00)	1	1 (2.00)
Nail infection	1	1 (2.00)	0	0 (0.00)
Oral candidiasis	1	1 (2.00)	0	0 (0.00)
Oral herpes	1	1 (2.00)	0	0 (0.00)
Otitis externa	1	1 (2.00)	1	1 (2.00)
Otitis media	1	1 (2.00)	1	1 (2.00)
Pharyngitis streptococcal	1	1 (2.00)	1	1 (2.00)
Pneumocystis jirovecii pneumonia	1	1 (2.00)	1	1 (2.00)
Rhinitis	1	1 (2.00)	0	0 (0.00)
Salmonellosis	1	1 (2.00)	0	0 (0.00)
Septic shock	1	1 (2.00)	1	1 (2.00)
Sinusitis fungal	1	1 (2.00)	1	1 (2.00)
Staphylococcal sepsis	1	1 (2.00)	1	1 (2.00)
Staphylococcal skin infection	1	1 (2.00)	0	0 (0.00)
Tinea pedis	1	1 (2.00)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.00)	1	1 (2.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Injury, poisoning and procedural complications				
- Total	5	5 (10.00)	0	0 (0.00)
Contusion	1	1 (2.00)	0	0 (0.00)
Infusion related reaction	1	1 (2.00)	0	0 (0.00)
Ligament sprain	1	1 (2.00)	0	0 (0.00)
Limb injury	1	1 (2.00)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.00)	0	0 (0.00)
Investigations				
- Total	62	23 (46.00)	21	12 (24.00)
Neutrophil count decreased	14	6 (12.00)	8	5 (10.00)
White blood cell count decreased	13	6 (12.00)	3	3 (6.00)
Immunoglobulins decreased	5	1 (2.00)	0	0 (0.00)
Blood bilirubin increased	4	2 (4.00)	1	1 (2.00)
Platelet count decreased	4	3 (6.00)	1	1 (2.00)
Alanine aminotransferase increased	3	2 (4.00)	1	1 (2.00)
Weight increased	3	1 (2.00)	1	1 (2.00)
Blood immunoglobulin A decreased	2	2 (4.00)	1	1 (2.00)
Blood uric acid increased	2	2 (4.00)	2	2 (4.00)
Lymphocyte count decreased	2	2 (4.00)	1	1 (2.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Blood creatinine increased	1	1 (2.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.00)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.00)	1	1 (2.00)
Blood thyroid stimulating hormone increased	1	1 (2.00)	0	0 (0.00)
Blood urea increased	1	1 (2.00)	1	1 (2.00)
Bone density decreased	1	1 (2.00)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.00)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.00)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	15	11 (22.00)	5	5 (10.00)
Hyperuricaemia	3	3 (6.00)	0	0 (0.00)
Decreased appetite	2	2 (4.00)	0	0 (0.00)
Hypokalaemia	2	2 (4.00)	1	1 (2.00)
Hyperchloraemia	1	1 (2.00)	0	0 (0.00)
Hypervolaemia	1	1 (2.00)	1	1 (2.00)
Hypophagia	1	1 (2.00)	0	0 (0.00)
Iron overload	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Malnutrition	1	1 (2.00)	1	1 (2.00)
Metabolic acidosis	1	1 (2.00)	1	1 (2.00)
Metabolic syndrome	1	1 (2.00)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.00)	1	1 (2.00)
Musculoskeletal and connective tissue disorders				
- Total	19	12 (24.00)	3	3 (6.00)
Back pain	6	5 (10.00)	2	2 (4.00)
Pain in extremity	4	4 (8.00)	1	1 (2.00)
Arthralgia	3	3 (6.00)	0	0 (0.00)
Bone pain	2	2 (4.00)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.00)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.00)	0	0 (0.00)
Myalgia	1	1 (2.00)	0	0 (0.00)
Neck pain	1	1 (2.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (8.00)	1	1 (2.00)
Skin papilloma	2	2 (4.00)	0	0 (0.00)
Cancer pain	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Myelodysplastic syndrome	1	1 (2.00)	1	1 (2.00)
Nervous system disorders				
- Total	13	8 (16.00)	3	1 (2.00)
Headache	5	5 (10.00)	0	0 (0.00)
Hydrocephalus	3	1 (2.00)	3	1 (2.00)
Dizziness	2	1 (2.00)	0	0 (0.00)
Migraine	2	1 (2.00)	0	0 (0.00)
Extrapyramidal disorder	1	1 (2.00)	0	0 (0.00)
Psychiatric disorders				
- Total	13	8 (16.00)	1	1 (2.00)
Anxiety	6	6 (12.00)	0	0 (0.00)
Mental status changes	2	2 (4.00)	1	1 (2.00)
Agitation	1	1 (2.00)	0	0 (0.00)
Delirium	1	1 (2.00)	0	0 (0.00)
Mood altered	1	1 (2.00)	0	0 (0.00)
Nightmare	1	1 (2.00)	0	0 (0.00)
Tearfulness	1	1 (2.00)	0	0 (0.00)
Renal and urinary disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
- Total	8	4 (8.00)	2	2 (4.00)
Acute kidney injury	3	3 (6.00)	1	1 (2.00)
Cystitis haemorrhagic	1	1 (2.00)	0	0 (0.00)
Dysuria	1	1 (2.00)	0	0 (0.00)
Haematuria	1	1 (2.00)	1	1 (2.00)
Kidney enlargement	1	1 (2.00)	0	0 (0.00)
Renal mass	1	1 (2.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.00)	0	0 (0.00)
Dysmenorrhoea	2	1 (2.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	31	17 (34.00)	5	5 (10.00)
Cough	10	9 (18.00)	0	0 (0.00)
Nasal congestion	5	4 (8.00)	0	0 (0.00)
Dyspnoea	2	1 (2.00)	0	0 (0.00)
Hypoxia	2	2 (4.00)	2	2 (4.00)
Pleural effusion	2	2 (4.00)	0	0 (0.00)
Rhinorrhoea	2	2 (4.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Acute respiratory distress syndrome	1	1 (2.00)	1	1 (2.00)
Bronchial oedema	1	1 (2.00)	0	0 (0.00)
Epistaxis	1	1 (2.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.00)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.00)	0	0 (0.00)
Respiratory distress	1	1 (2.00)	1	1 (2.00)
Respiratory failure	1	1 (2.00)	1	1 (2.00)
Upper respiratory tract inflammation	1	1 (2.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	22	14 (28.00)	1	1 (2.00)
Dry skin	5	5 (10.00)	0	0 (0.00)
Rash	5	3 (6.00)	0	0 (0.00)
Pruritus	2	1 (2.00)	0	0 (0.00)
Decubitus ulcer	1	1 (2.00)	1	1 (2.00)
Dermatitis atopic	1	1 (2.00)	0	0 (0.00)
Eczema	1	1 (2.00)	0	0 (0.00)
Hangnail	1	1 (2.00)	0	0 (0.00)
Ingrowing nail	1	1 (2.00)	0	0 (0.00)
Night sweats	1	1 (2.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=50 n (%)[1]	Grade >= 3 Total events	All patients N=50 n (%)[2]
Photosensitivity reaction	1	1 (2.00)	0	0 (0.00)
Skin discolouration	1	1 (2.00)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.00)	0	0 (0.00)
Skin swelling	1	1 (2.00)	0	0 (0.00)
Vascular disorders				
- Total	6	5 (10.00)	5	5 (10.00)
Hypotension	3	3 (6.00)	3	3 (6.00)
Venoocclusive disease	2	2 (4.00)	2	2 (4.00)
Hypertension	1	1 (2.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	98	14 (70.00)	33	9 (45.00)
Blood and lymphatic system disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Hypercoagulation	1	1 (5.00)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (5.00)	0	0 (0.00)
Delayed puberty	1	1 (5.00)	0	0 (0.00)
Hypothyroidism	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Dry eye	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	7	5 (25.00)	0	0 (0.00)
Diarrhoea	3	3 (15.00)	0	0 (0.00)
Constipation	1	1 (5.00)	0	0 (0.00)
Irritable bowel syndrome	1	1 (5.00)	0	0 (0.00)
Nausea	1	1 (5.00)	0	0 (0.00)
Vomiting	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	9	5 (25.00)	1	1 (5.00)
Pyrexia	5	3 (15.00)	0	0 (0.00)
Pain	2	2 (10.00)	0	0 (0.00)
Fatigue	1	1 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (5.00)	1	1 (5.00)
Immune system disorders				
- Total	4	3 (15.00)	2	1 (5.00)
Chronic graft versus host disease	1	1 (5.00)	1	1 (5.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.00)	1	1 (5.00)
Hypogammaglobulinaemia	1	1 (5.00)	0	0 (0.00)
Seasonal allergy	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Infections and infestations				
- Total	28	10 (50.00)	13	5 (25.00)
Rhinovirus infection	3	3 (15.00)	1	1 (5.00)
Sinusitis	3	3 (15.00)	0	0 (0.00)
Fungal infection	2	1 (5.00)	0	0 (0.00)
Pneumonia	2	2 (10.00)	2	2 (10.00)
Upper respiratory tract infection	2	2 (10.00)	0	0 (0.00)
COVID-19 pneumonia	1	1 (5.00)	1	1 (5.00)
Clostridium difficile colitis	1	1 (5.00)	1	1 (5.00)
Conjunctivitis	1	1 (5.00)	0	0 (0.00)
Enterovirus infection	1	1 (5.00)	1	1 (5.00)
Fungal skin infection	1	1 (5.00)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (5.00)	1	1 (5.00)
Gastroenteritis salmonella	1	1 (5.00)	1	1 (5.00)
Influenza	1	1 (5.00)	1	1 (5.00)
Neutropenic infection	1	1 (5.00)	1	1 (5.00)
Otitis media acute	1	1 (5.00)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (5.00)	1	1 (5.00)
Sepsis	1	1 (5.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Skin infection	1	1 (5.00)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (5.00)	1	1 (5.00)
Urinary tract infection	1	1 (5.00)	0	0 (0.00)
Varicella zoster virus infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (10.00)	1	1 (5.00)
Abdominal injury	1	1 (5.00)	0	0 (0.00)
Infusion related reaction	1	1 (5.00)	1	1 (5.00)
Investigations				
- Total	9	3 (15.00)	6	2 (10.00)
Neutrophil count decreased	6	1 (5.00)	5	1 (5.00)
Blood immunoglobulin G decreased	1	1 (5.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.00)	1	1 (5.00)
SARS-CoV-2 test positive	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	4 (20.00)	4	3 (15.00)
Decreased appetite	2	1 (5.00)	2	1 (5.00)
Iron overload	2	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Hypercholesterolaemia	1	1 (5.00)	0	0 (0.00)
Hyperglycaemia	1	1 (5.00)	1	1 (5.00)
Hypertriglyceridaemia	1	1 (5.00)	0	0 (0.00)
Obesity	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				
- Total	5	4 (20.00)	0	0 (0.00)
Growth retardation	1	1 (5.00)	0	0 (0.00)
Joint effusion	1	1 (5.00)	0	0 (0.00)
Osteopenia	1	1 (5.00)	0	0 (0.00)
Pain in extremity	1	1 (5.00)	0	0 (0.00)
Synovitis	1	1 (5.00)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (5.00)	1	1 (5.00)
Bone giant cell tumour benign	2	1 (5.00)	1	1 (5.00)
Nervous system disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Dysarthria	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Psychiatric disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Anxiety	2	2 (10.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (5.00)	1	1 (5.00)
Endometriosis	2	1 (5.00)	1	1 (5.00)
Respiratory, thoracic and mediastinal disorders				
- Total	10	4 (20.00)	3	1 (5.00)
Cough	2	2 (10.00)	0	0 (0.00)
Tachypnoea	2	1 (5.00)	2	1 (5.00)
Dyspnoea	1	1 (5.00)	1	1 (5.00)
Dyspnoea exertional	1	1 (5.00)	0	0 (0.00)
Pharyngeal erythema	1	1 (5.00)	0	0 (0.00)
Pleural effusion	1	1 (5.00)	0	0 (0.00)
Rhinorrhoea	1	1 (5.00)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	3	2 (10.00)	0	0 (0.00)
Dry skin	1	1 (5.00)	0	0 (0.00)
Rash	1	1 (5.00)	0	0 (0.00)
Rash maculo-papular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Hypertension	2	2 (10.00)	1	1 (5.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Total number of AE per patient	122	18 (60.00)	30	10 (33.33)
Blood and lymphatic system disorders				
- Total	5	3 (10.00)	2	2 (6.67)
Agranulocytosis	1	1 (3.33)	1	1 (3.33)
Anaemia	1	1 (3.33)	0	0 (0.00)
Lymphadenopathy	1	1 (3.33)	0	0 (0.00)
Neutropenia	1	1 (3.33)	1	1 (3.33)
Thrombocytopenia	1	1 (3.33)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (3.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Deafness unilateral	1	1 (3.33)	0	0 (0.00)
Eye disorders				
- Total	3	2 (6.67)	1	1 (3.33)
Eye pain	1	1 (3.33)	1	1 (3.33)
Eyelid oedema	1	1 (3.33)	0	0 (0.00)
Mydriasis	1	1 (3.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	2 (6.67)	1	1 (3.33)
Diarrhoea	2	2 (6.67)	1	1 (3.33)
General disorders and administration site conditions				
- Total	4	4 (13.33)	1	1 (3.33)
Pyrexia	2	2 (6.67)	1	1 (3.33)
Non-cardiac chest pain	1	1 (3.33)	0	0 (0.00)
Xerosis	1	1 (3.33)	0	0 (0.00)
Immune system disorders				

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
- Total	6	6 (20.00)	1	1 (3.33)
Hypogammaglobulinaemia	2	2 (6.67)	0	0 (0.00)
Seasonal allergy	2	2 (6.67)	0	0 (0.00)
Chronic graft versus host disease	1	1 (3.33)	0	0 (0.00)
Drug hypersensitivity	1	1 (3.33)	1	1 (3.33)
Infections and infestations				
- Total	58	13 (43.33)	13	9 (30.00)
Sinusitis	6	3 (10.00)	0	0 (0.00)
Upper respiratory tract infection	5	3 (10.00)	1	1 (3.33)
Conjunctivitis	4	3 (10.00)	0	0 (0.00)
COVID-19	3	2 (6.67)	1	1 (3.33)
Otitis media	3	2 (6.67)	0	0 (0.00)
Bronchitis	2	2 (6.67)	0	0 (0.00)
Device related sepsis	2	1 (3.33)	2	1 (3.33)
Gastroenteritis viral	2	1 (3.33)	0	0 (0.00)
Herpes zoster	2	2 (6.67)	1	1 (3.33)
Oral herpes	2	2 (6.67)	0	0 (0.00)
Sepsis	2	2 (6.67)	2	2 (6.67)
Skin infection	2	2 (6.67)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Acute sinusitis	1	1 (3.33)	0	0 (0.00)
Bronchiolitis	1	1 (3.33)	1	1 (3.33)
Candida infection	1	1 (3.33)	0	0 (0.00)
Ear infection	1	1 (3.33)	1	1 (3.33)
Folliculitis	1	1 (3.33)	0	0 (0.00)
Fungal infection	1	1 (3.33)	0	0 (0.00)
Gastroenteritis	1	1 (3.33)	0	0 (0.00)
Herpes virus infection	1	1 (3.33)	0	0 (0.00)
Influenza	1	1 (3.33)	0	0 (0.00)
Meningitis pneumococcal	1	1 (3.33)	1	1 (3.33)
Nail infection	1	1 (3.33)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (3.33)	0	0 (0.00)
Oral candidiasis	1	1 (3.33)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (3.33)	1	1 (3.33)
Rhinitis	1	1 (3.33)	0	0 (0.00)
Rhinovirus infection	1	1 (3.33)	0	0 (0.00)
Septic shock	1	1 (3.33)	1	1 (3.33)
Staphylococcal abscess	1	1 (3.33)	1	1 (3.33)
Streptococcal sepsis	1	1 (3.33)	0	0 (0.00)
Syphilis	1	1 (3.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Urinary tract infection	1	1 (3.33)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (3.33)	0	0 (0.00)
Viral skin infection	1	1 (3.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.33)	0	0 (0.00)
Ligament sprain	1	1 (3.33)	0	0 (0.00)
Investigations				
- Total	7	3 (10.00)	0	0 (0.00)
Blood bilirubin increased	3	1 (3.33)	0	0 (0.00)
Neutrophil count decreased	2	2 (6.67)	0	0 (0.00)
Platelet count decreased	2	2 (6.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (6.67)	1	1 (3.33)
Hyperlipidaemia	1	1 (3.33)	0	0 (0.00)
Hypernatraemia	1	1 (3.33)	1	1 (3.33)
Musculoskeletal and connective tissue disorders				
- Total	3	3 (10.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Arthralgia	1	1 (3.33)	0	0 (0.00)
Osteonecrosis	1	1 (3.33)	0	0 (0.00)
Pain in extremity	1	1 (3.33)	0	0 (0.00)
Nervous system disorders				
- Total	8	3 (10.00)	3	2 (6.67)
Headache	3	2 (6.67)	1	1 (3.33)
Seizure	3	1 (3.33)	1	1 (3.33)
Nervous system disorder	2	1 (3.33)	1	1 (3.33)
Psychiatric disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Tic	1	1 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	6 (20.00)	3	3 (10.00)
Cough	2	2 (6.67)	0	0 (0.00)
Dyspnoea	2	2 (6.67)	0	0 (0.00)
Rhinorrhoea	2	2 (6.67)	0	0 (0.00)
Epistaxis	1	1 (3.33)	0	0 (0.00)
Hypoxia	1	1 (3.33)	1	1 (3.33)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Laryngeal oedema	1	1 (3.33)	1	1 (3.33)
Oropharyngeal pain	1	1 (3.33)	0	0 (0.00)
Respiratory failure	1	1 (3.33)	1	1 (3.33)
Sleep apnoea syndrome	1	1 (3.33)	0	0 (0.00)
Wheezing	1	1 (3.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	5 (16.67)	4	3 (10.00)
Rash macular	2	1 (3.33)	2	1 (3.33)
Dermatitis atopic	1	1 (3.33)	1	1 (3.33)
Eczema	1	1 (3.33)	1	1 (3.33)
Papule	1	1 (3.33)	0	0 (0.00)
Rash	1	1 (3.33)	0	0 (0.00)
Rash erythematous	1	1 (3.33)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Total number of AE per patient	743	26 (100.00)	270	23 (88.46)
Blood and lymphatic system disorders				
- Total	65	20 (76.92)	40	15 (57.69)
Anaemia	23	8 (30.77)	9	3 (11.54)
Febrile neutropenia	14	10 (38.46)	14	10 (38.46)
Neutropenia	6	4 (15.38)	5	3 (11.54)
Leukopenia	5	3 (11.54)	3	2 (7.69)
Thrombocytopenia	4	4 (15.38)	4	4 (15.38)
B-cell aplasia	3	1 (3.85)	0	0 (0.00)
Disseminated intravascular coagulation	3	3 (11.54)	2	2 (7.69)
Pancytopenia	2	2 (7.69)	2	2 (7.69)
Coagulopathy	1	1 (3.85)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Hypercoagulation	1	1 (3.85)	0	0 (0.00)
Leukocytosis	1	1 (3.85)	0	0 (0.00)
Lymphadenopathy	1	1 (3.85)	0	0 (0.00)
Lymphocytosis	1	1 (3.85)	0	0 (0.00)
Cardiac disorders				
- Total	13	8 (30.77)	4	3 (11.54)
Tachycardia	10	6 (23.08)	2	2 (7.69)
Left ventricular dysfunction	2	2 (7.69)	1	1 (3.85)
Sinus bradycardia	1	1 (3.85)	1	1 (3.85)
Endocrine disorders				
- Total	4	3 (11.54)	0	0 (0.00)
Hypothyroidism	2	2 (7.69)	0	0 (0.00)
Adrenal insufficiency	1	1 (3.85)	0	0 (0.00)
Delayed puberty	1	1 (3.85)	0	0 (0.00)
Eye disorders				
- Total	6	5 (19.23)	0	0 (0.00)
Ocular hyperaemia	3	3 (11.54)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (3.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Dry eye	1	1 (3.85)	0	0 (0.00)
Eyelid oedema	1	1 (3.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	57	19 (73.08)	5	5 (19.23)
Vomiting	13	8 (30.77)	1	1 (3.85)
Diarrhoea	12	10 (38.46)	0	0 (0.00)
Nausea	8	6 (23.08)	1	1 (3.85)
Constipation	6	5 (19.23)	0	0 (0.00)
Abdominal pain	4	3 (11.54)	0	0 (0.00)
Ascites	2	2 (7.69)	0	0 (0.00)
Pancreatitis	2	2 (7.69)	1	1 (3.85)
Abdominal distension	1	1 (3.85)	0	0 (0.00)
Abdominal pain upper	1	1 (3.85)	0	0 (0.00)
Anal fissure	1	1 (3.85)	0	0 (0.00)
Dyspepsia	1	1 (3.85)	0	0 (0.00)
Irritable bowel syndrome	1	1 (3.85)	0	0 (0.00)
Melaena	1	1 (3.85)	1	1 (3.85)
Mouth haemorrhage	1	1 (3.85)	0	0 (0.00)
Peritoneal haematoma	1	1 (3.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Stomatitis	1	1 (3.85)	1	1 (3.85)
Trichoglossia	1	1 (3.85)	0	0 (0.00)
General disorders and administration site conditions				
- Total	45	18 (69.23)	8	5 (19.23)
Pyrexia	23	12 (46.15)	2	2 (7.69)
Fatigue	6	5 (19.23)	0	0 (0.00)
Face oedema	4	4 (15.38)	1	1 (3.85)
Influenza like illness	2	2 (7.69)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (7.69)	2	2 (7.69)
Oedema peripheral	2	1 (3.85)	2	1 (3.85)
Pain	2	2 (7.69)	0	0 (0.00)
Catheter site pain	1	1 (3.85)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (3.85)	0	0 (0.00)
Generalised oedema	1	1 (3.85)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (3.85)	1	1 (3.85)
Hepatobiliary disorders				
- Total	6	4 (15.38)	1	1 (3.85)
Cholelithiasis	2	2 (7.69)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Cholestasis	1	1 (3.85)	1	1 (3.85)
Gallbladder enlargement	1	1 (3.85)	0	0 (0.00)
Hepatic cytolysis	1	1 (3.85)	0	0 (0.00)
Ocular icterus	1	1 (3.85)	0	0 (0.00)
Immune system disorders				
- Total	56	23 (88.46)	18	11 (42.31)
Cytokine release syndrome	33	18 (69.23)	11	7 (26.92)
Hypogammaglobulinaemia	17	14 (53.85)	2	2 (7.69)
Haemophagocytic lymphohistiocytosis	2	2 (7.69)	2	2 (7.69)
Immunodeficiency	2	2 (7.69)	2	2 (7.69)
Chronic graft versus host disease	1	1 (3.85)	1	1 (3.85)
Seasonal allergy	1	1 (3.85)	0	0 (0.00)
Infections and infestations				
- Total	80	19 (73.08)	32	10 (38.46)
Conjunctivitis	7	4 (15.38)	0	0 (0.00)
Upper respiratory tract infection	7	6 (23.08)	2	2 (7.69)
Bronchopulmonary aspergillosis	5	1 (3.85)	3	1 (3.85)
Rhinovirus infection	5	4 (15.38)	2	2 (7.69)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Parainfluenzae virus infection	3	3 (11.54)	2	2 (7.69)
Pneumonia	3	3 (11.54)	2	2 (7.69)
Respiratory syncytial virus infection	3	3 (11.54)	2	2 (7.69)
Sinusitis	3	3 (11.54)	0	0 (0.00)
Staphylococcal bacteraemia	3	3 (11.54)	3	3 (11.54)
Clostridium difficile infection	2	2 (7.69)	1	1 (3.85)
Ear infection	2	1 (3.85)	0	0 (0.00)
Encephalitis	2	2 (7.69)	2	2 (7.69)
Fungal infection	2	1 (3.85)	0	0 (0.00)
Nasopharyngitis	2	1 (3.85)	0	0 (0.00)
Otitis media	2	2 (7.69)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.85)	1	1 (3.85)
Cellulitis	1	1 (3.85)	0	0 (0.00)
Clostridium difficile colitis	1	1 (3.85)	1	1 (3.85)
Ear, nose and throat infection	1	1 (3.85)	0	0 (0.00)
Enterovirus infection	1	1 (3.85)	1	1 (3.85)
Fungal skin infection	1	1 (3.85)	0	0 (0.00)
Gastroenteritis	1	1 (3.85)	1	1 (3.85)
Gastroenteritis Escherichia coli	1	1 (3.85)	1	1 (3.85)
Gastroenteritis salmonella	1	1 (3.85)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Gastrointestinal infection	1	1 (3.85)	0	0 (0.00)
Herpes zoster	1	1 (3.85)	1	1 (3.85)
Influenza	1	1 (3.85)	1	1 (3.85)
Localised infection	1	1 (3.85)	0	0 (0.00)
Metapneumovirus infection	1	1 (3.85)	1	1 (3.85)
Molluscum contagiosum	1	1 (3.85)	0	0 (0.00)
Nail infection	1	1 (3.85)	0	0 (0.00)
Neutropenic infection	1	1 (3.85)	1	1 (3.85)
Otitis externa	1	1 (3.85)	0	0 (0.00)
Otitis media acute	1	1 (3.85)	0	0 (0.00)
Paronychia	1	1 (3.85)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (3.85)	1	1 (3.85)
Respiratory tract infection	1	1 (3.85)	0	0 (0.00)
Respiratory tract infection viral	1	1 (3.85)	0	0 (0.00)
Rhinitis	1	1 (3.85)	0	0 (0.00)
Sepsis	1	1 (3.85)	1	1 (3.85)
Skin infection	1	1 (3.85)	0	0 (0.00)
Urinary tract infection	1	1 (3.85)	0	0 (0.00)
Varicella zoster virus infection	1	1 (3.85)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (3.85)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Injury, poisoning and procedural complications				
- Total	15	8 (30.77)	3	2 (7.69)
Infusion related reaction	6	3 (11.54)	1	1 (3.85)
Wound	2	1 (3.85)	1	1 (3.85)
Abdominal injury	1	1 (3.85)	0	0 (0.00)
Fibula fracture	1	1 (3.85)	0	0 (0.00)
Scratch	1	1 (3.85)	0	0 (0.00)
Skin abrasion	1	1 (3.85)	0	0 (0.00)
Skin injury	1	1 (3.85)	0	0 (0.00)
Skin wound	1	1 (3.85)	0	0 (0.00)
Vasoplegia syndrome	1	1 (3.85)	1	1 (3.85)
Investigations				
- Total	153	18 (69.23)	83	16 (61.54)
Platelet count decreased	35	7 (26.92)	21	4 (15.38)
Neutrophil count decreased	29	8 (30.77)	22	7 (26.92)
White blood cell count decreased	22	8 (30.77)	12	5 (19.23)
Lymphocyte count decreased	8	5 (19.23)	5	5 (19.23)
Alanine aminotransferase increased	6	6 (23.08)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Aspartate aminotransferase increased	5	5 (19.23)	2	2 (7.69)
C-reactive protein increased	4	4 (15.38)	3	3 (11.54)
Lipase increased	4	2 (7.69)	2	1 (3.85)
Serum ferritin increased	4	4 (15.38)	2	2 (7.69)
Blood bilirubin increased	3	3 (11.54)	2	2 (7.69)
Blood immunoglobulin G decreased	3	3 (11.54)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (11.54)	1	1 (3.85)
Electrocardiogram QT prolonged	3	2 (7.69)	1	1 (3.85)
International normalised ratio increased	3	3 (11.54)	0	0 (0.00)
Activated partial thromboplastin time prolonged	2	2 (7.69)	1	1 (3.85)
Blood immunoglobulin A decreased	2	2 (7.69)	0	0 (0.00)
Blood lactate dehydrogenase increased	2	2 (7.69)	1	1 (3.85)
Fibrin D dimer increased	2	2 (7.69)	1	1 (3.85)
Oxygen saturation decreased	2	2 (7.69)	1	1 (3.85)
Amylase increased	1	1 (3.85)	0	0 (0.00)
Bacterial test positive	1	1 (3.85)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Blood creatine phosphokinase increased	1	1 (3.85)	1	1 (3.85)
Blood creatinine increased	1	1 (3.85)	1	1 (3.85)
Blood fibrinogen decreased	1	1 (3.85)	0	0 (0.00)
Blood phosphorus increased	1	1 (3.85)	0	0 (0.00)
Blood testosterone decreased	1	1 (3.85)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (3.85)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (3.85)	0	0 (0.00)
Troponin increased	1	1 (3.85)	1	1 (3.85)
Weight decreased	1	1 (3.85)	1	1 (3.85)
Metabolism and nutrition disorders				
- Total	86	15 (57.69)	33	9 (34.62)
Hypokalaemia	23	5 (19.23)	15	4 (15.38)
Hypophosphataemia	13	5 (19.23)	2	2 (7.69)
Hypocalcaemia	11	6 (23.08)	3	2 (7.69)
Decreased appetite	10	8 (30.77)	4	2 (7.69)
Hyperuricaemia	4	3 (11.54)	0	0 (0.00)
Hypoalbuminaemia	3	2 (7.69)	0	0 (0.00)
Hyperglycaemia	2	2 (7.69)	2	2 (7.69)
Hypertriglyceridaemia	2	2 (7.69)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Iron overload	2	1 (3.85)	0	0 (0.00)
Calcium deficiency	1	1 (3.85)	0	0 (0.00)
Dehydration	1	1 (3.85)	0	0 (0.00)
Haemochromatosis	1	1 (3.85)	1	1 (3.85)
Haemosiderosis	1	1 (3.85)	0	0 (0.00)
Hypercalcaemia	1	1 (3.85)	0	0 (0.00)
Hypercholesterolaemia	1	1 (3.85)	0	0 (0.00)
Hyperkalaemia	1	1 (3.85)	0	0 (0.00)
Hyperlactacidaemia	1	1 (3.85)	0	0 (0.00)
Hypernatraemia	1	1 (3.85)	1	1 (3.85)
Hyperphosphataemia	1	1 (3.85)	0	0 (0.00)
Hypervolaemia	1	1 (3.85)	1	1 (3.85)
Hypomagnesaemia	1	1 (3.85)	0	0 (0.00)
Malnutrition	1	1 (3.85)	1	1 (3.85)
Metabolic acidosis	1	1 (3.85)	0	0 (0.00)
Obesity	1	1 (3.85)	1	1 (3.85)
Tumour lysis syndrome	1	1 (3.85)	1	1 (3.85)
Musculoskeletal and connective tissue disorders				
- Total	19	11 (42.31)	4	3 (11.54)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Pain in extremity	4	4 (15.38)	0	0 (0.00)
Back pain	3	3 (11.54)	1	1 (3.85)
Arthralgia	2	2 (7.69)	1	1 (3.85)
Growth retardation	2	2 (7.69)	0	0 (0.00)
Myalgia	2	2 (7.69)	0	0 (0.00)
Haemarthrosis	1	1 (3.85)	1	1 (3.85)
Joint effusion	1	1 (3.85)	0	0 (0.00)
Myositis	1	1 (3.85)	0	0 (0.00)
Osteopenia	1	1 (3.85)	0	0 (0.00)
Rhabdomyolysis	1	1 (3.85)	1	1 (3.85)
Synovitis	1	1 (3.85)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (3.85)	1	1 (3.85)
Bone giant cell tumour benign	2	1 (3.85)	1	1 (3.85)
Nervous system disorders				
- Total	25	15 (57.69)	7	5 (19.23)
Headache	11	8 (30.77)	1	1 (3.85)
Cognitive disorder	2	2 (7.69)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Encephalopathy	2	2 (7.69)	2	2 (7.69)
Seizure	2	2 (7.69)	2	2 (7.69)
Autonomic neuropathy	1	1 (3.85)	1	1 (3.85)
Cerebral haemorrhage	1	1 (3.85)	1	1 (3.85)
Dysarthria	1	1 (3.85)	0	0 (0.00)
Dysgeusia	1	1 (3.85)	0	0 (0.00)
Lethargy	1	1 (3.85)	0	0 (0.00)
Memory impairment	1	1 (3.85)	0	0 (0.00)
Monoparesis	1	1 (3.85)	0	0 (0.00)
Tremor	1	1 (3.85)	0	0 (0.00)
Psychiatric disorders				
- Total	12	12 (46.15)	1	1 (3.85)
Anxiety	5	5 (19.23)	1	1 (3.85)
Confusional state	2	2 (7.69)	0	0 (0.00)
Sleep disorder	2	2 (7.69)	0	0 (0.00)
Insomnia	1	1 (3.85)	0	0 (0.00)
Irritability	1	1 (3.85)	0	0 (0.00)
Persistent depressive disorder	1	1 (3.85)	0	0 (0.00)
Renal and urinary disorders				

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
- Total	8	5 (19.23)	4	3 (11.54)
Dysuria	2	2 (7.69)	0	0 (0.00)
Acute kidney injury	1	1 (3.85)	1	1 (3.85)
Anuria	1	1 (3.85)	1	1 (3.85)
Bladder dilatation	1	1 (3.85)	0	0 (0.00)
Renal tubular disorder	1	1 (3.85)	1	1 (3.85)
Renal tubular necrosis	1	1 (3.85)	1	1 (3.85)
Urinary retention	1	1 (3.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (11.54)	2	2 (7.69)
Endometriosis	2	1 (3.85)	1	1 (3.85)
Heavy menstrual bleeding	1	1 (3.85)	0	0 (0.00)
Vaginal ulceration	1	1 (3.85)	1	1 (3.85)
Respiratory, thoracic and mediastinal disorders				
- Total	48	16 (61.54)	15	6 (23.08)
Cough	9	6 (23.08)	0	0 (0.00)
Nasal congestion	4	4 (15.38)	0	0 (0.00)
Atelectasis	3	1 (3.85)	1	1 (3.85)

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
Epistaxis	3	3 (11.54)	0	0 (0.00)
Hypoxia	3	3 (11.54)	2	2 (7.69)
Pleural effusion	3	3 (11.54)	2	2 (7.69)
Rhinorrhoea	3	2 (7.69)	0	0 (0.00)
Tachypnoea	3	2 (7.69)	3	2 (7.69)
Acute respiratory distress syndrome	2	2 (7.69)	2	2 (7.69)
Dyspnoea	2	2 (7.69)	2	2 (7.69)
Pulmonary oedema	2	2 (7.69)	2	2 (7.69)
Rhinitis allergic	2	2 (7.69)	0	0 (0.00)
Bronchospasm	1	1 (3.85)	0	0 (0.00)
Dyspnoea exertional	1	1 (3.85)	0	0 (0.00)
Lung disorder	1	1 (3.85)	0	0 (0.00)
Nasal dryness	1	1 (3.85)	0	0 (0.00)
Oropharyngeal pain	1	1 (3.85)	0	0 (0.00)
Pharyngeal erythema	1	1 (3.85)	0	0 (0.00)
Respiratory acidosis	1	1 (3.85)	1	1 (3.85)
Sleep apnoea syndrome	1	1 (3.85)	0	0 (0.00)
Wheezing	1	1 (3.85)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
- Total	26	12 (46.15)	2	1 (3.85)
Rash	5	4 (15.38)	0	0 (0.00)
Dry skin	3	2 (7.69)	0	0 (0.00)
Erythema	3	3 (11.54)	0	0 (0.00)
Rash maculo-papular	2	2 (7.69)	0	0 (0.00)
Decubitus ulcer	1	1 (3.85)	0	0 (0.00)
Dermatitis	1	1 (3.85)	0	0 (0.00)
Dermatitis allergic	1	1 (3.85)	0	0 (0.00)
Eczema	1	1 (3.85)	0	0 (0.00)
Ingrowing nail	1	1 (3.85)	0	0 (0.00)
Miliaria	1	1 (3.85)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (3.85)	0	0 (0.00)
Petechiae	1	1 (3.85)	1	1 (3.85)
Pruritus	1	1 (3.85)	0	0 (0.00)
Rash papular	1	1 (3.85)	0	0 (0.00)
Skin discolouration	1	1 (3.85)	0	0 (0.00)
Skin necrosis	1	1 (3.85)	1	1 (3.85)
Skin ulcer	1	1 (3.85)	0	0 (0.00)
Vascular disorders				

Timing: At anytime, Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All grades Total events	All patients N=26 n (%)[1]	Grade >= 3 Total events	All patients N=26 n (%)[2]
- Total	13	10 (38.46)	7	5 (19.23)
Hypotension	8	7 (26.92)	4	3 (11.54)
Hypertension	4	3 (11.54)	2	2 (7.69)
Capillary leak syndrome	1	1 (3.85)	1	1 (3.85)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250n
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline bone marrow tumor burden
Safety Set

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Total number of AE per patient	1762	54 (100.00)	558	50 (92.59)
Blood and lymphatic system disorders				
- Total	98	35 (64.81)	55	28 (51.85)
Anaemia	40	17 (31.48)	15	6 (11.11)
Febrile neutropenia	19	17 (31.48)	19	17 (31.48)
Neutropenia	11	7 (12.96)	10	6 (11.11)
Thrombocytopenia	7	5 (9.26)	6	5 (9.26)
Disseminated intravascular coagulation	5	5 (9.26)	1	1 (1.85)
Coagulopathy	4	4 (7.41)	1	1 (1.85)
Splenomegaly	4	4 (7.41)	0	0 (0.00)
Eosinophilia	3	1 (1.85)	0	0 (0.00)
Lymphopenia	2	2 (3.70)	2	2 (3.70)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Agranulocytosis	1	1 (1.85)	1	1 (1.85)
Hypofibrinogenaemia	1	1 (1.85)	0	0 (0.00)
Lymphadenopathy	1	1 (1.85)	0	0 (0.00)
Cardiac disorders				
- Total	40	20 (37.04)	10	8 (14.81)
Tachycardia	14	11 (20.37)	1	1 (1.85)
Cardiac failure	6	3 (5.56)	4	3 (5.56)
Sinus tachycardia	4	3 (5.56)	0	0 (0.00)
Bradycardia	3	3 (5.56)	0	0 (0.00)
Cardiac arrest	3	3 (5.56)	3	3 (5.56)
Cardiac dysfunction	2	2 (3.70)	0	0 (0.00)
Left ventricular dysfunction	2	2 (3.70)	2	2 (3.70)
Atrioventricular block first degree	1	1 (1.85)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.85)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.85)	0	0 (0.00)
Pericardial effusion	1	1 (1.85)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.85)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Congenital, familial and genetic disorders				
- Total	1	1 (1.85)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.85)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (5.56)	0	0 (0.00)
Deafness unilateral	1	1 (1.85)	0	0 (0.00)
Ear pain	1	1 (1.85)	0	0 (0.00)
Ear pruritus	1	1 (1.85)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (7.41)	0	0 (0.00)
Adrenal insufficiency	3	3 (5.56)	0	0 (0.00)
Hypothyroidism	1	1 (1.85)	0	0 (0.00)
Eye disorders				
- Total	18	10 (18.52)	1	1 (1.85)
Eyelid oedema	3	2 (3.70)	0	0 (0.00)
Cataract	2	2 (3.70)	0	0 (0.00)
Eye pain	2	2 (3.70)	1	1 (1.85)
Retinal haemorrhage	2	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Visual impairment	2	2 (3.70)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (1.85)	0	0 (0.00)
Eye oedema	1	1 (1.85)	0	0 (0.00)
Hypermetropia	1	1 (1.85)	0	0 (0.00)
Mydriasis	1	1 (1.85)	0	0 (0.00)
Periorbital oedema	1	1 (1.85)	0	0 (0.00)
Periorbital swelling	1	1 (1.85)	0	0 (0.00)
Visual field defect	1	1 (1.85)	0	0 (0.00)
Gastrointestinal disorders				
- Total	125	41 (75.93)	13	11 (20.37)
Vomiting	25	18 (33.33)	0	0 (0.00)
Nausea	19	16 (29.63)	1	1 (1.85)
Diarrhoea	18	16 (29.63)	2	2 (3.70)
Abdominal pain	11	8 (14.81)	2	2 (3.70)
Constipation	10	9 (16.67)	0	0 (0.00)
Mouth haemorrhage	4	4 (7.41)	2	2 (3.70)
Pancreatitis	4	4 (7.41)	1	1 (1.85)
Abdominal pain upper	3	3 (5.56)	0	0 (0.00)
Abdominal distension	2	2 (3.70)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Gastrointestinal sounds abnormal	2	2 (3.70)	0	0 (0.00)
Proctalgia	2	2 (3.70)	1	1 (1.85)
Stomatitis	2	2 (3.70)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (1.85)	1	1 (1.85)
Abdominal rigidity	1	1 (1.85)	0	0 (0.00)
Anal haemorrhage	1	1 (1.85)	0	0 (0.00)
Ascites	1	1 (1.85)	0	0 (0.00)
Dry mouth	1	1 (1.85)	0	0 (0.00)
Dysphagia	1	1 (1.85)	1	1 (1.85)
Enteritis	1	1 (1.85)	0	0 (0.00)
Enterocolitis	1	1 (1.85)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.85)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.85)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.85)	0	0 (0.00)
Gingival bleeding	1	1 (1.85)	0	0 (0.00)
Gingival erythema	1	1 (1.85)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.85)	1	1 (1.85)
Haematemesis	1	1 (1.85)	0	0 (0.00)
Ileus	1	1 (1.85)	0	0 (0.00)
Lip dry	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Lip oedema	1	1 (1.85)	0	0 (0.00)
Mouth swelling	1	1 (1.85)	0	0 (0.00)
Neutropenic colitis	1	1 (1.85)	1	1 (1.85)
Odynophagia	1	1 (1.85)	0	0 (0.00)
Trichoglossia	1	1 (1.85)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.85)	0	0 (0.00)
General disorders and administration site conditions				
- Total	111	35 (64.81)	16	10 (18.52)
Pyrexia	44	23 (42.59)	10	9 (16.67)
Fatigue	13	12 (22.22)	0	0 (0.00)
Chills	10	7 (12.96)	0	0 (0.00)
Oedema peripheral	7	6 (11.11)	0	0 (0.00)
Face oedema	5	4 (7.41)	0	0 (0.00)
Generalised oedema	4	4 (7.41)	0	0 (0.00)
Asthenia	3	3 (5.56)	0	0 (0.00)
Catheter site pain	3	1 (1.85)	2	1 (1.85)
Pain	3	3 (5.56)	2	2 (3.70)
Catheter site erythema	2	1 (1.85)	0	0 (0.00)
Localised oedema	2	2 (3.70)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Malaise	2	2 (3.70)	0	0 (0.00)
Non-cardiac chest pain	2	2 (3.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.85)	0	0 (0.00)
Chest discomfort	1	1 (1.85)	1	1 (1.85)
Crying	1	1 (1.85)	0	0 (0.00)
Drug withdrawal syndrome	1	1 (1.85)	0	0 (0.00)
Facial pain	1	1 (1.85)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (1.85)	1	1 (1.85)
Oedema due to hepatic disease	1	1 (1.85)	0	0 (0.00)
Sluggishness	1	1 (1.85)	0	0 (0.00)
Swelling face	1	1 (1.85)	0	0 (0.00)
Vascular device occlusion	1	1 (1.85)	0	0 (0.00)
Xerosis	1	1 (1.85)	0	0 (0.00)
Hepatobiliary disorders				
- Total	26	15 (27.78)	6	5 (9.26)
Hepatic function abnormal	11	5 (9.26)	4	3 (5.56)
Hyperbilirubinaemia	6	5 (9.26)	1	1 (1.85)
Hepatomegaly	3	3 (5.56)	1	1 (1.85)
Hypertransaminasaemia	3	2 (3.70)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Biliary tract disorder	1	1 (1.85)	0	0 (0.00)
Gallbladder enlargement	1	1 (1.85)	0	0 (0.00)
Liver disorder	1	1 (1.85)	0	0 (0.00)
Immune system disorders				
- Total	137	48 (88.89)	58	35 (64.81)
Cytokine release syndrome	95	43 (79.63)	44	31 (57.41)
Hypogammaglobulinaemia	23	19 (35.19)	5	5 (9.26)
Haemophagocytic lymphohistiocytosis	4	4 (7.41)	2	2 (3.70)
Seasonal allergy	3	3 (5.56)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (3.70)	1	1 (1.85)
Drug hypersensitivity	2	2 (3.70)	1	1 (1.85)
Graft versus host disease	2	2 (3.70)	2	2 (3.70)
Immunodeficiency	2	2 (3.70)	2	2 (3.70)
Chronic graft versus host disease	1	1 (1.85)	0	0 (0.00)
Engraftment syndrome	1	1 (1.85)	1	1 (1.85)
Hypersensitivity	1	1 (1.85)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.85)	0	0 (0.00)
Infections and infestations				

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
- Total	183	41 (75.93)	70	29 (53.70)
Sinusitis	11	4 (7.41)	2	2 (3.70)
Upper respiratory tract infection	10	7 (12.96)	1	1 (1.85)
Nasopharyngitis	7	6 (11.11)	0	0 (0.00)
Rhinovirus infection	6	5 (9.26)	0	0 (0.00)
Candida infection	5	4 (7.41)	2	1 (1.85)
Conjunctivitis	5	4 (7.41)	0	0 (0.00)
Gastroenteritis	5	5 (9.26)	1	1 (1.85)
Oral herpes	5	4 (7.41)	1	1 (1.85)
Staphylococcal infection	5	5 (9.26)	2	2 (3.70)
Bacteraemia	4	3 (5.56)	3	2 (3.70)
Oral candidiasis	4	3 (5.56)	0	0 (0.00)
Otitis media	4	3 (5.56)	1	1 (1.85)
COVID-19	3	2 (3.70)	1	1 (1.85)
Gastroenteritis viral	3	2 (3.70)	0	0 (0.00)
Klebsiella infection	3	1 (1.85)	3	1 (1.85)
Nail infection	3	3 (5.56)	0	0 (0.00)
Parainfluenzae virus infection	3	2 (3.70)	1	1 (1.85)
Pneumonia	3	3 (5.56)	2	2 (3.70)
Staphylococcal bacteraemia	3	2 (3.70)	3	2 (3.70)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Urinary tract infection	3	2 (3.70)	2	1 (1.85)
Acute sinusitis	2	2 (3.70)	0	0 (0.00)
Adenovirus infection	2	2 (3.70)	2	2 (3.70)
BK virus infection	2	2 (3.70)	1	1 (1.85)
Bronchitis	2	2 (3.70)	0	0 (0.00)
Clostridium difficile infection	2	2 (3.70)	2	2 (3.70)
Device related sepsis	2	1 (1.85)	2	1 (1.85)
Ear infection	2	2 (3.70)	1	1 (1.85)
Encephalitis viral	2	2 (3.70)	2	2 (3.70)
Gingivitis	2	2 (3.70)	0	0 (0.00)
Herpes simplex	2	2 (3.70)	1	1 (1.85)
Herpes zoster	2	2 (3.70)	1	1 (1.85)
Human herpesvirus 6 infection	2	2 (3.70)	2	2 (3.70)
Influenza	2	2 (3.70)	0	0 (0.00)
Metapneumovirus infection	2	2 (3.70)	2	2 (3.70)
Oral infection	2	2 (3.70)	0	0 (0.00)
Otitis externa	2	2 (3.70)	1	1 (1.85)
Respiratory tract infection	2	2 (3.70)	0	0 (0.00)
Rhinitis	2	2 (3.70)	0	0 (0.00)
Sepsis	2	2 (3.70)	2	2 (3.70)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Septic shock	2	2 (3.70)	2	2 (3.70)
Skin infection	2	2 (3.70)	0	0 (0.00)
Viral infection	2	2 (3.70)	1	1 (1.85)
Anal abscess	1	1 (1.85)	1	1 (1.85)
Atypical pneumonia	1	1 (1.85)	0	0 (0.00)
Bronchiolitis	1	1 (1.85)	1	1 (1.85)
Bronchopulmonary aspergillosis	1	1 (1.85)	1	1 (1.85)
Cholecystitis infective	1	1 (1.85)	0	0 (0.00)
Coronavirus infection	1	1 (1.85)	1	1 (1.85)
Cystitis	1	1 (1.85)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.85)	1	1 (1.85)
Device related infection	1	1 (1.85)	1	1 (1.85)
Enterobacter infection	1	1 (1.85)	1	1 (1.85)
Folliculitis	1	1 (1.85)	0	0 (0.00)
Fungal infection	1	1 (1.85)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (1.85)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.85)	0	0 (0.00)
Granulicatella infection	1	1 (1.85)	1	1 (1.85)
Herpes virus infection	1	1 (1.85)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Mastoiditis	1	1 (1.85)	1	1 (1.85)
Meningitis bacterial	1	1 (1.85)	1	1 (1.85)
Meningitis pneumococcal	1	1 (1.85)	1	1 (1.85)
Myringitis	1	1 (1.85)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (1.85)	0	0 (0.00)
Paronychia	1	1 (1.85)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.85)	1	1 (1.85)
Pneumocystis jirovecii pneumonia	1	1 (1.85)	1	1 (1.85)
Pneumonia fungal	1	1 (1.85)	1	1 (1.85)
Pneumonia respiratory syncytial viral	1	1 (1.85)	1	1 (1.85)
Pneumonia viral	1	1 (1.85)	1	1 (1.85)
Salmonellosis	1	1 (1.85)	0	0 (0.00)
Sinusitis fungal	1	1 (1.85)	1	1 (1.85)
Soft tissue infection	1	1 (1.85)	1	1 (1.85)
Staphylococcal abscess	1	1 (1.85)	1	1 (1.85)
Staphylococcal sepsis	1	1 (1.85)	1	1 (1.85)
Staphylococcal skin infection	1	1 (1.85)	0	0 (0.00)
Stomatococcal infection	1	1 (1.85)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.85)	0	0 (0.00)
Syphilis	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Systemic candida	1	1 (1.85)	1	1 (1.85)
Tinea pedis	1	1 (1.85)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.85)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.85)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.85)	1	1 (1.85)
Viral skin infection	1	1 (1.85)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.85)	1	1 (1.85)
Injury, poisoning and procedural complications				
- Total	18	13 (24.07)	1	1 (1.85)
Contusion	3	2 (3.70)	0	0 (0.00)
Fall	2	2 (3.70)	0	0 (0.00)
Infusion related reaction	2	2 (3.70)	0	0 (0.00)
Ligament sprain	2	2 (3.70)	0	0 (0.00)
Procedural pain	2	2 (3.70)	0	0 (0.00)
Transfusion reaction	2	2 (3.70)	0	0 (0.00)
Limb injury	1	1 (1.85)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.85)	0	0 (0.00)
Skin abrasion	1	1 (1.85)	0	0 (0.00)
Transplant failure	1	1 (1.85)	1	1 (1.85)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Wound	1	1 (1.85)	0	0 (0.00)
Investigations				
- Total	340	42 (77.78)	155	32 (59.26)
Platelet count decreased	48	17 (31.48)	26	11 (20.37)
Neutrophil count decreased	46	16 (29.63)	32	14 (25.93)
White blood cell count decreased	46	17 (31.48)	28	13 (24.07)
Aspartate aminotransferase increased	28	14 (25.93)	11	9 (16.67)
Lymphocyte count decreased	28	12 (22.22)	21	10 (18.52)
Alanine aminotransferase increased	23	12 (22.22)	6	6 (11.11)
Blood bilirubin increased	22	10 (18.52)	8	7 (12.96)
Immunoglobulins decreased	10	2 (3.70)	0	0 (0.00)
International normalised ratio increased	9	6 (11.11)	0	0 (0.00)
Weight increased	7	4 (7.41)	2	2 (3.70)
Activated partial thromboplastin time prolonged	6	4 (7.41)	0	0 (0.00)
Blood creatinine increased	6	4 (7.41)	4	2 (3.70)
Blood fibrinogen decreased	6	6 (11.11)	2	2 (3.70)
Blood immunoglobulin A decreased	5	5 (9.26)	1	1 (1.85)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Blood immunoglobulin M decreased	4	4 (7.41)	1	1 (1.85)
Blood uric acid increased	4	4 (7.41)	2	2 (3.70)
Serum ferritin increased	4	4 (7.41)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (1.85)	1	1 (1.85)
Blood lactate dehydrogenase increased	3	3 (5.56)	0	0 (0.00)
Electrocardiogram QT prolonged	3	3 (5.56)	1	1 (1.85)
Urine output decreased	3	2 (3.70)	3	2 (3.70)
Blood glucose increased	2	1 (1.85)	2	1 (1.85)
Gamma-glutamyltransferase increased	2	2 (3.70)	2	2 (3.70)
Haemoglobin decreased	2	1 (1.85)	1	1 (1.85)
Blood alkaline phosphatase increased	1	1 (1.85)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.85)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.85)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.85)	0	0 (0.00)
Blood urea increased	1	1 (1.85)	1	1 (1.85)
Bone density decreased	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Breath sounds abnormal	1	1 (1.85)	0	0 (0.00)
C-reactive protein increased	1	1 (1.85)	0	0 (0.00)
Cardiac murmur	1	1 (1.85)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.85)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.85)	0	0 (0.00)
Enterovirus test positive	1	1 (1.85)	0	0 (0.00)
Fibrin D dimer increased	1	1 (1.85)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.85)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.85)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.85)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.85)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.85)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.85)	0	0 (0.00)
Weight decreased	1	1 (1.85)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	160	37 (68.52)	58	24 (44.44)
Hypokalaemia	23	15 (27.78)	9	7 (12.96)
Decreased appetite	22	22 (40.74)	10	10 (18.52)
Hypophosphataemia	19	13 (24.07)	9	7 (12.96)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Hypoalbuminaemia	16	9 (16.67)	1	1 (1.85)
Hypocalcaemia	13	10 (18.52)	3	3 (5.56)
Hyperglycaemia	10	7 (12.96)	3	3 (5.56)
Hyperuricaemia	8	6 (11.11)	1	1 (1.85)
Hypervolaemia	6	6 (11.11)	4	4 (7.41)
Hypomagnesaemia	6	5 (9.26)	0	0 (0.00)
Hyperphosphataemia	4	4 (7.41)	1	1 (1.85)
Tumour lysis syndrome	4	4 (7.41)	4	4 (7.41)
Acidosis	3	2 (3.70)	2	2 (3.70)
Hypercalcaemia	3	2 (3.70)	2	2 (3.70)
Hypermagnesaemia	3	2 (3.70)	0	0 (0.00)
Hyponatraemia	3	3 (5.56)	0	0 (0.00)
Metabolic acidosis	3	3 (5.56)	3	3 (5.56)
Hyperchloraemia	2	2 (3.70)	0	0 (0.00)
Hyperkalaemia	2	2 (3.70)	2	2 (3.70)
Hypernatraemia	2	2 (3.70)	1	1 (1.85)
Hyperlipidaemia	1	1 (1.85)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (1.85)	1	1 (1.85)
Hypoglycaemia	1	1 (1.85)	0	0 (0.00)
Hypophagia	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Iron overload	1	1 (1.85)	0	0 (0.00)
Malnutrition	1	1 (1.85)	1	1 (1.85)
Metabolic syndrome	1	1 (1.85)	0	0 (0.00)
Polydipsia	1	1 (1.85)	1	1 (1.85)
Musculoskeletal and connective tissue disorders				
- Total	64	33 (61.11)	5	5 (9.26)
Pain in extremity	14	13 (24.07)	1	1 (1.85)
Arthralgia	12	10 (18.52)	0	0 (0.00)
Back pain	11	7 (12.96)	2	2 (3.70)
Myalgia	9	8 (14.81)	0	0 (0.00)
Bone pain	6	4 (7.41)	0	0 (0.00)
Muscular weakness	2	2 (3.70)	1	1 (1.85)
Musculoskeletal chest pain	2	2 (3.70)	0	0 (0.00)
Neck pain	2	2 (3.70)	0	0 (0.00)
Pain in jaw	2	2 (3.70)	1	1 (1.85)
Muscle rigidity	1	1 (1.85)	0	0 (0.00)
Muscle spasms	1	1 (1.85)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.85)	0	0 (0.00)
Osteonecrosis	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (7.41)	1	1 (1.85)
Skin papilloma	2	2 (3.70)	0	0 (0.00)
Cancer pain	1	1 (1.85)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.85)	1	1 (1.85)
Nervous system disorders				
- Total	84	32 (59.26)	16	9 (16.67)
Headache	29	19 (35.19)	2	2 (3.70)
Encephalopathy	6	6 (11.11)	2	2 (3.70)
Tremor	6	5 (9.26)	0	0 (0.00)
Dizziness	5	4 (7.41)	0	0 (0.00)
Seizure	5	2 (3.70)	1	1 (1.85)
Somnolence	5	5 (9.26)	2	2 (3.70)
Cognitive disorder	3	1 (1.85)	1	1 (1.85)
Hydrocephalus	3	1 (1.85)	3	1 (1.85)
Dysgeusia	2	2 (3.70)	0	0 (0.00)
Hyperaesthesia	2	1 (1.85)	0	0 (0.00)
Lethargy	2	2 (3.70)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Migraine	2	1 (1.85)	0	0 (0.00)
Nervous system disorder	2	1 (1.85)	1	1 (1.85)
Amnesia	1	1 (1.85)	0	0 (0.00)
Aphasia	1	1 (1.85)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.85)	1	1 (1.85)
Depressed level of consciousness	1	1 (1.85)	1	1 (1.85)
Disturbance in attention	1	1 (1.85)	0	0 (0.00)
Dysarthria	1	1 (1.85)	1	1 (1.85)
Extrapyramidal disorder	1	1 (1.85)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.85)	0	0 (0.00)
Hypoaesthesia	1	1 (1.85)	0	0 (0.00)
Neuralgia	1	1 (1.85)	0	0 (0.00)
Neurological decompensation	1	1 (1.85)	1	1 (1.85)
Paraesthesia	1	1 (1.85)	0	0 (0.00)
Psychiatric disorders				
- Total	53	27 (50.00)	6	6 (11.11)
Anxiety	9	9 (16.67)	1	1 (1.85)
Delirium	8	8 (14.81)	3	3 (5.56)
Agitation	7	6 (11.11)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Confusional state	5	5 (9.26)	0	0 (0.00)
Mental status changes	5	5 (9.26)	2	2 (3.70)
Hallucination	3	3 (5.56)	0	0 (0.00)
Insomnia	3	3 (5.56)	0	0 (0.00)
Irritability	2	2 (3.70)	0	0 (0.00)
Sleep disorder	2	1 (1.85)	0	0 (0.00)
Affect lability	1	1 (1.85)	0	0 (0.00)
Automatism	1	1 (1.85)	0	0 (0.00)
Hallucination, visual	1	1 (1.85)	0	0 (0.00)
Mood altered	1	1 (1.85)	0	0 (0.00)
Nightmare	1	1 (1.85)	0	0 (0.00)
Restlessness	1	1 (1.85)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.85)	0	0 (0.00)
Tearfulness	1	1 (1.85)	0	0 (0.00)
Tic	1	1 (1.85)	0	0 (0.00)
Renal and urinary disorders				
- Total	40	20 (37.04)	12	9 (16.67)
Acute kidney injury	16	11 (20.37)	8	7 (12.96)
Renal failure	4	2 (3.70)	3	1 (1.85)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Haematuria	3	3 (5.56)	1	1 (1.85)
Dysuria	2	2 (3.70)	0	0 (0.00)
Pollakiuria	2	2 (3.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.85)	0	0 (0.00)
Anuria	1	1 (1.85)	0	0 (0.00)
Azotaemia	1	1 (1.85)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.85)	0	0 (0.00)
Incontinence	1	1 (1.85)	0	0 (0.00)
Kidney enlargement	1	1 (1.85)	0	0 (0.00)
Micturition urgency	1	1 (1.85)	0	0 (0.00)
Proteinuria	1	1 (1.85)	0	0 (0.00)
Renal mass	1	1 (1.85)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.85)	0	0 (0.00)
Urinary retention	1	1 (1.85)	0	0 (0.00)
Urinary tract disorder	1	1 (1.85)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	6	3 (5.56)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.85)	0	0 (0.00)
Vaginal haemorrhage	2	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Female genital tract fistula	1	1 (1.85)	0	0 (0.00)
Perineal rash	1	1 (1.85)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	135	39 (72.22)	47	23 (42.59)
Hypoxia	24	17 (31.48)	20	14 (25.93)
Cough	20	17 (31.48)	0	0 (0.00)
Pulmonary oedema	10	10 (18.52)	5	5 (9.26)
Oropharyngeal pain	8	7 (12.96)	0	0 (0.00)
Tachypnoea	8	7 (12.96)	3	3 (5.56)
Pleural effusion	7	6 (11.11)	1	1 (1.85)
Dyspnoea	6	5 (9.26)	2	2 (3.70)
Nasal congestion	6	5 (9.26)	0	0 (0.00)
Respiratory failure	6	6 (11.11)	6	6 (11.11)
Epistaxis	5	4 (7.41)	1	1 (1.85)
Respiratory distress	5	4 (7.41)	3	2 (3.70)
Rhinorrhoea	5	4 (7.41)	0	0 (0.00)
Atelectasis	2	2 (3.70)	1	1 (1.85)
Lung infiltration	2	1 (1.85)	1	1 (1.85)
Acute respiratory distress syndrome	1	1 (1.85)	1	1 (1.85)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Acute respiratory failure	1	1 (1.85)	1	1 (1.85)
Bradypnoea	1	1 (1.85)	1	1 (1.85)
Bronchial oedema	1	1 (1.85)	0	0 (0.00)
Haemoptysis	1	1 (1.85)	0	0 (0.00)
Laryngeal oedema	1	1 (1.85)	1	1 (1.85)
Nasal discomfort	1	1 (1.85)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.85)	0	0 (0.00)
Painful respiration	1	1 (1.85)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.85)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.85)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.85)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.85)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.85)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.85)	0	0 (0.00)
Productive cough	1	1 (1.85)	0	0 (0.00)
Pulmonary mass	1	1 (1.85)	0	0 (0.00)
Respiratory disorder	1	1 (1.85)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.85)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.85)	0	0 (0.00)
Wheezing	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	69	28 (51.85)	7	6 (11.11)
Pruritus	8	6 (11.11)	0	0 (0.00)
Rash	8	4 (7.41)	0	0 (0.00)
Blister	6	3 (5.56)	0	0 (0.00)
Dry skin	6	6 (11.11)	0	0 (0.00)
Dermatitis atopic	4	3 (5.56)	1	1 (1.85)
Hyperhidrosis	3	3 (5.56)	0	0 (0.00)
Rash papular	3	2 (3.70)	0	0 (0.00)
Eczema	2	2 (3.70)	1	1 (1.85)
Erythema	2	2 (3.70)	0	0 (0.00)
Rash macular	2	1 (1.85)	2	1 (1.85)
Rash maculo-papular	2	1 (1.85)	1	1 (1.85)
Rash vesicular	2	1 (1.85)	0	0 (0.00)
Decubitus ulcer	1	1 (1.85)	1	1 (1.85)
Dermatitis diaper	1	1 (1.85)	0	0 (0.00)
Erythema nodosum	1	1 (1.85)	0	0 (0.00)
Hangnail	1	1 (1.85)	0	0 (0.00)
Ingrowing nail	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Night sweats	1	1 (1.85)	0	0 (0.00)
Papule	1	1 (1.85)	0	0 (0.00)
Petechiae	1	1 (1.85)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.85)	0	0 (0.00)
Pruritus allergic	1	1 (1.85)	0	0 (0.00)
Purpura	1	1 (1.85)	0	0 (0.00)
Rash erythematous	1	1 (1.85)	0	0 (0.00)
Rash pruritic	1	1 (1.85)	0	0 (0.00)
Scab	1	1 (1.85)	0	0 (0.00)
Skin discolouration	1	1 (1.85)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.85)	0	0 (0.00)
Skin lesion	1	1 (1.85)	0	0 (0.00)
Skin swelling	1	1 (1.85)	0	0 (0.00)
Skin ulcer	1	1 (1.85)	0	0 (0.00)
Urticaria	1	1 (1.85)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.85)	1	1 (1.85)
Social circumstances				
- Total	1	1 (1.85)	0	0 (0.00)
Patient uncooperative	1	1 (1.85)	0	0 (0.00)

Timing: At anytime, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All grades Total events	All patients N=54 n (%)[1]	Grade >= 3 Total events	All patients N=54 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (1.85)	1	1 (1.85)
Thrombolysis	1	1 (1.85)	1	1 (1.85)
Vascular disorders				
- Total	41	24 (44.44)	20	16 (29.63)
Hypotension	21	17 (31.48)	15	13 (24.07)
Hypertension	13	13 (24.07)	3	3 (5.56)
Venoocclusive disease	2	2 (3.70)	2	2 (3.70)
Capillary leak syndrome	1	1 (1.85)	0	0 (0.00)
Flushing	1	1 (1.85)	0	0 (0.00)
Hot flush	1	1 (1.85)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.85)	0	0 (0.00)
Thrombosis	1	1 (1.85)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	73	11 (100.00)	27	8 (72.73)
Blood and lymphatic system disorders				
- Total	6	5 (45.45)	3	3 (27.27)
Anaemia	1	1 (9.09)	0	0 (0.00)
B-cell aplasia	1	1 (9.09)	0	0 (0.00)
Febrile neutropenia	1	1 (9.09)	1	1 (9.09)
Leukopenia	1	1 (9.09)	0	0 (0.00)
Neutropenia	1	1 (9.09)	1	1 (9.09)
Pancytopenia	1	1 (9.09)	1	1 (9.09)
Cardiac disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Sinus tachycardia	1	1 (9.09)	0	0 (0.00)
Endocrine disorders				

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	1	1 (9.09)	0	0 (0.00)
Hypothyroidism	1	1 (9.09)	0	0 (0.00)
Eye disorders				
- Total	3	1 (9.09)	0	0 (0.00)
Retinal haemorrhage	2	1 (9.09)	0	0 (0.00)
Visual field defect	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	4 (36.36)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Constipation	1	1 (9.09)	0	0 (0.00)
Trichoglossia	1	1 (9.09)	0	0 (0.00)
Vomiting	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	6	4 (36.36)	0	0 (0.00)
Pyrexia	4	4 (36.36)	0	0 (0.00)
Face oedema	1	1 (9.09)	0	0 (0.00)
Influenza like illness	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Immune system disorders				
- Total	15	7 (63.64)	6	4 (36.36)
Cytokine release syndrome	12	6 (54.55)	4	2 (18.18)
Hypogammaglobulinaemia	3	3 (27.27)	2	2 (18.18)
Infections and infestations				
- Total	2	2 (18.18)	0	0 (0.00)
Conjunctivitis	1	1 (9.09)	0	0 (0.00)
Staphylococcal infection	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	21	6 (54.55)	15	5 (45.45)
Alanine aminotransferase increased	5	3 (27.27)	1	1 (9.09)
Lymphocyte count decreased	3	2 (18.18)	3	2 (18.18)
Platelet count decreased	3	3 (27.27)	3	3 (27.27)
Neutrophil count decreased	2	2 (18.18)	2	2 (18.18)
Aspartate aminotransferase increased	1	1 (9.09)	0	0 (0.00)
Blood bilirubin increased	1	1 (9.09)	1	1 (9.09)
Blood fibrinogen decreased	1	1 (9.09)	1	1 (9.09)
Blood testosterone decreased	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
C-reactive protein increased	1	1 (9.09)	1	1 (9.09)
Gamma-glutamyltransferase increased	1	1 (9.09)	1	1 (9.09)
Serum ferritin increased	1	1 (9.09)	1	1 (9.09)
White blood cell count decreased	1	1 (9.09)	1	1 (9.09)
Metabolism and nutrition disorders				
- Total	2	2 (18.18)	1	1 (9.09)
Decreased appetite	1	1 (9.09)	0	0 (0.00)
Hypophosphataemia	1	1 (9.09)	1	1 (9.09)
Musculoskeletal and connective tissue disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Arthralgia	1	1 (9.09)	0	0 (0.00)
Nervous system disorders				
- Total	4	4 (36.36)	1	1 (9.09)
Headache	3	3 (27.27)	1	1 (9.09)
Neuralgia	1	1 (9.09)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (9.09)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Confusional state	1	1 (9.09)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (9.09)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	2	2 (18.18)	0	0 (0.00)
Epistaxis	1	1 (9.09)	0	0 (0.00)
Nasal dryness	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	2 (18.18)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (9.09)	0	0 (0.00)
Rash	1	1 (9.09)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Hypertension	1	1 (9.09)	1	1 (9.09)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Total number of AE per patient	1678	68 (98.55)	592	59 (85.51)
Blood and lymphatic system disorders				
- Total	119	45 (65.22)	73	36 (52.17)
Anaemia	49	20 (28.99)	20	8 (11.59)
Febrile neutropenia	28	25 (36.23)	28	25 (36.23)
Neutropenia	10	8 (11.59)	8	6 (8.70)
Thrombocytopenia	8	8 (11.59)	8	8 (11.59)
Disseminated intravascular coagulation	7	7 (10.14)	2	2 (2.90)
Coagulopathy	5	5 (7.25)	2	2 (2.90)
Splenomegaly	4	4 (5.80)	0	0 (0.00)
Leukopenia	3	2 (2.90)	3	2 (2.90)
Eosinophilia	2	1 (1.45)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Lymphopenia	1	1 (1.45)	1	1 (1.45)
Pancytopenia	1	1 (1.45)	1	1 (1.45)
Cardiac disorders				
- Total	44	23 (33.33)	10	8 (11.59)
Tachycardia	22	17 (24.64)	3	3 (4.35)
Cardiac failure	4	1 (1.45)	2	1 (1.45)
Bradycardia	3	3 (4.35)	0	0 (0.00)
Left ventricular dysfunction	3	3 (4.35)	3	3 (4.35)
Sinus tachycardia	3	2 (2.90)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.90)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.45)	0	0 (0.00)
Cardiac arrest	1	1 (1.45)	1	1 (1.45)
Cardiac failure congestive	1	1 (1.45)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.45)	0	0 (0.00)
Pericardial effusion	1	1 (1.45)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.45)	0	0 (0.00)
Sinus bradycardia	1	1 (1.45)	1	1 (1.45)
Ear and labyrinth disorders				
- Total	2	2 (2.90)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Ear pain	1	1 (1.45)	0	0 (0.00)
Ear pruritus	1	1 (1.45)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (5.80)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.80)	0	0 (0.00)
Eye disorders				
- Total	12	8 (11.59)	0	0 (0.00)
Eyelid oedema	3	2 (2.90)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.90)	0	0 (0.00)
Ocular hyperaemia	2	2 (2.90)	0	0 (0.00)
Eye oedema	1	1 (1.45)	0	0 (0.00)
Eye pain	1	1 (1.45)	0	0 (0.00)
Periorbital oedema	1	1 (1.45)	0	0 (0.00)
Periorbital swelling	1	1 (1.45)	0	0 (0.00)
Visual impairment	1	1 (1.45)	0	0 (0.00)
Gastrointestinal disorders				
- Total	131	47 (68.12)	16	14 (20.29)
Vomiting	29	20 (28.99)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Nausea	21	18 (26.09)	2	2 (2.90)
Diarrhoea	18	15 (21.74)	1	1 (1.45)
Abdominal pain	12	10 (14.49)	2	2 (2.90)
Constipation	10	10 (14.49)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.80)	2	2 (2.90)
Pancreatitis	4	4 (5.80)	1	1 (1.45)
Abdominal distension	3	3 (4.35)	0	0 (0.00)
Abdominal pain upper	3	3 (4.35)	0	0 (0.00)
Ascites	3	3 (4.35)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.90)	0	0 (0.00)
Stomatitis	2	2 (2.90)	1	1 (1.45)
Abdominal compartment syndrome	1	1 (1.45)	1	1 (1.45)
Anal fissure	1	1 (1.45)	0	0 (0.00)
Anal haemorrhage	1	1 (1.45)	0	0 (0.00)
Dry mouth	1	1 (1.45)	0	0 (0.00)
Dysphagia	1	1 (1.45)	1	1 (1.45)
Enterocolitis	1	1 (1.45)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.45)	0	0 (0.00)
Gingival bleeding	1	1 (1.45)	0	0 (0.00)
Gingival erythema	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Gingivitis ulcerative	1	1 (1.45)	1	1 (1.45)
Haematemesis	1	1 (1.45)	0	0 (0.00)
Ileus	1	1 (1.45)	0	0 (0.00)
Lip dry	1	1 (1.45)	0	0 (0.00)
Lip oedema	1	1 (1.45)	0	0 (0.00)
Melaena	1	1 (1.45)	1	1 (1.45)
Mouth swelling	1	1 (1.45)	0	0 (0.00)
Neutropenic colitis	1	1 (1.45)	1	1 (1.45)
Odynophagia	1	1 (1.45)	0	0 (0.00)
Proctalgia	1	1 (1.45)	1	1 (1.45)
Upper gastrointestinal haemorrhage	1	1 (1.45)	0	0 (0.00)
General disorders and administration site conditions				
- Total	106	36 (52.17)	19	11 (15.94)
Pyrexia	40	20 (28.99)	9	8 (11.59)
Fatigue	11	11 (15.94)	0	0 (0.00)
Chills	9	6 (8.70)	0	0 (0.00)
Face oedema	8	7 (10.14)	1	1 (1.45)
Oedema peripheral	7	6 (8.70)	2	1 (1.45)
Generalised oedema	5	5 (7.25)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Catheter site pain	4	2 (2.90)	2	1 (1.45)
Asthenia	2	2 (2.90)	0	0 (0.00)
Catheter site erythema	2	1 (1.45)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.90)	0	0 (0.00)
Localised oedema	2	2 (2.90)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.90)	2	2 (2.90)
Catheter site haemorrhage	1	1 (1.45)	0	0 (0.00)
Chest discomfort	1	1 (1.45)	1	1 (1.45)
Crying	1	1 (1.45)	0	0 (0.00)
Facial pain	1	1 (1.45)	0	0 (0.00)
Influenza like illness	1	1 (1.45)	0	0 (0.00)
Malaise	1	1 (1.45)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.45)	0	0 (0.00)
Pain	1	1 (1.45)	1	1 (1.45)
Sluggishness	1	1 (1.45)	0	0 (0.00)
Swelling face	1	1 (1.45)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.45)	1	1 (1.45)
Vascular device occlusion	1	1 (1.45)	0	0 (0.00)
Hepatobiliary disorders				

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
- Total	29	17 (24.64)	7	6 (8.70)
Hepatic function abnormal	11	5 (7.25)	4	3 (4.35)
Hyperbilirubinaemia	6	5 (7.25)	1	1 (1.45)
Hepatomegaly	3	3 (4.35)	1	1 (1.45)
Cholelithiasis	2	2 (2.90)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.90)	0	0 (0.00)
Hypertransaminasaemia	2	2 (2.90)	0	0 (0.00)
Biliary tract disorder	1	1 (1.45)	0	0 (0.00)
Cholestasis	1	1 (1.45)	1	1 (1.45)
Ocular icterus	1	1 (1.45)	0	0 (0.00)
Immune system disorders				
- Total	149	60 (86.96)	62	39 (56.52)
Cytokine release syndrome	116	55 (79.71)	51	36 (52.17)
Hypogammaglobulinaemia	22	20 (28.99)	5	5 (7.25)
Haemophagocytic lymphohistiocytosis	5	5 (7.25)	3	3 (4.35)
Immunodeficiency	3	3 (4.35)	3	3 (4.35)
Hypersensitivity	1	1 (1.45)	0	0 (0.00)
Seasonal allergy	1	1 (1.45)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Infections and infestations				
- Total	62	33 (47.83)	31	19 (27.54)
Conjunctivitis	5	4 (5.80)	0	0 (0.00)
Candida infection	4	3 (4.35)	2	1 (1.45)
Clostridium difficile infection	4	4 (5.80)	3	3 (4.35)
Staphylococcal bacteraemia	4	3 (4.35)	4	3 (4.35)
Staphylococcal infection	4	4 (5.80)	2	2 (2.90)
Encephalitis viral	2	2 (2.90)	2	2 (2.90)
Nail infection	2	2 (2.90)	0	0 (0.00)
Oral candidiasis	2	1 (1.45)	0	0 (0.00)
Oral herpes	2	2 (2.90)	1	1 (1.45)
Oral infection	2	2 (2.90)	0	0 (0.00)
Rhinovirus infection	2	2 (2.90)	0	0 (0.00)
Adenovirus infection	1	1 (1.45)	1	1 (1.45)
Anal abscess	1	1 (1.45)	1	1 (1.45)
Atypical pneumonia	1	1 (1.45)	0	0 (0.00)
BK virus infection	1	1 (1.45)	0	0 (0.00)
Bacteraemia	1	1 (1.45)	1	1 (1.45)
Bronchopulmonary aspergillosis	1	1 (1.45)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Cholecystitis infective	1	1 (1.45)	0	0 (0.00)
Encephalitis	1	1 (1.45)	1	1 (1.45)
Gastroenteritis norovirus	1	1 (1.45)	0	0 (0.00)
Gingivitis	1	1 (1.45)	0	0 (0.00)
Granulicatella infection	1	1 (1.45)	1	1 (1.45)
Herpes simplex	1	1 (1.45)	1	1 (1.45)
Human herpesvirus 6 infection	1	1 (1.45)	1	1 (1.45)
Klebsiella bacteraemia	1	1 (1.45)	0	0 (0.00)
Klebsiella infection	1	1 (1.45)	1	1 (1.45)
Localised infection	1	1 (1.45)	0	0 (0.00)
Meningitis bacterial	1	1 (1.45)	1	1 (1.45)
Myringitis	1	1 (1.45)	0	0 (0.00)
Otitis externa	1	1 (1.45)	0	0 (0.00)
Paronychia	1	1 (1.45)	0	0 (0.00)
Pneumonia	1	1 (1.45)	1	1 (1.45)
Pneumonia fungal	1	1 (1.45)	1	1 (1.45)
Pneumonia viral	1	1 (1.45)	1	1 (1.45)
Sinusitis	1	1 (1.45)	1	1 (1.45)
Soft tissue infection	1	1 (1.45)	1	1 (1.45)
Stomatococcal infection	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Systemic candida	1	1 (1.45)	1	1 (1.45)
Urinary tract infection viral	1	1 (1.45)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.45)	1	1 (1.45)
Injury, poisoning and procedural complications				
- Total	20	11 (15.94)	3	2 (2.90)
Infusion related reaction	3	2 (2.90)	0	0 (0.00)
Wound	3	2 (2.90)	1	1 (1.45)
Contusion	2	1 (1.45)	0	0 (0.00)
Fall	2	2 (2.90)	0	0 (0.00)
Procedural pain	2	2 (2.90)	0	0 (0.00)
Transfusion reaction	2	2 (2.90)	0	0 (0.00)
Scratch	1	1 (1.45)	0	0 (0.00)
Skin abrasion	1	1 (1.45)	0	0 (0.00)
Skin injury	1	1 (1.45)	0	0 (0.00)
Skin wound	1	1 (1.45)	0	0 (0.00)
Transplant failure	1	1 (1.45)	1	1 (1.45)
Vasoplegia syndrome	1	1 (1.45)	1	1 (1.45)
Investigations				

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
- Total	365	51 (73.91)	182	40 (57.97)
Platelet count decreased	62	18 (26.09)	35	11 (15.94)
White blood cell count decreased	49	23 (33.33)	35	17 (24.64)
Neutrophil count decreased	46	18 (26.09)	36	15 (21.74)
Aspartate aminotransferase increased	32	18 (26.09)	13	11 (15.94)
Lymphocyte count decreased	27	13 (18.84)	21	11 (15.94)
Alanine aminotransferase increased	21	15 (21.74)	5	5 (7.25)
Blood bilirubin increased	17	11 (15.94)	8	8 (11.59)
International normalised ratio increased	12	9 (13.04)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (8.70)	1	1 (1.45)
Serum ferritin increased	7	7 (10.14)	1	1 (1.45)
Blood creatinine increased	6	4 (5.80)	5	3 (4.35)
Blood fibrinogen decreased	6	6 (8.70)	1	1 (1.45)
Blood immunoglobulin M decreased	6	6 (8.70)	1	1 (1.45)
Electrocardiogram QT prolonged	6	5 (7.25)	2	2 (2.90)
Blood immunoglobulin A decreased	5	5 (7.25)	0	0 (0.00)
Immunoglobulins decreased	5	2 (2.90)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Blood creatine phosphokinase increased	4	2 (2.90)	2	2 (2.90)
Blood lactate dehydrogenase increased	4	4 (5.80)	1	1 (1.45)
Lipase increased	4	2 (2.90)	2	1 (1.45)
Weight increased	4	4 (5.80)	1	1 (1.45)
C-reactive protein increased	3	3 (4.35)	2	2 (2.90)
Fibrin D dimer increased	3	3 (4.35)	1	1 (1.45)
Urine output decreased	3	2 (2.90)	3	2 (2.90)
Blood glucose increased	2	1 (1.45)	2	1 (1.45)
Blood immunoglobulin G decreased	2	2 (2.90)	0	0 (0.00)
Blood uric acid increased	2	2 (2.90)	0	0 (0.00)
Haemoglobin decreased	2	1 (1.45)	1	1 (1.45)
Amylase increased	1	1 (1.45)	0	0 (0.00)
Bacterial test positive	1	1 (1.45)	1	1 (1.45)
Blood alkaline phosphatase increased	1	1 (1.45)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.45)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.45)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.45)	0	0 (0.00)
Cardiac murmur	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Coagulation test abnormal	1	1 (1.45)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.45)	0	0 (0.00)
Enterovirus test positive	1	1 (1.45)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.45)	1	1 (1.45)
Haptoglobin decreased	1	1 (1.45)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.45)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.45)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.45)	0	0 (0.00)
Troponin increased	1	1 (1.45)	1	1 (1.45)
Weight decreased	1	1 (1.45)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	208	44 (63.77)	75	28 (40.58)
Hypokalaemia	40	19 (27.54)	20	11 (15.94)
Hypophosphataemia	30	16 (23.19)	10	8 (11.59)
Hypocalcaemia	24	16 (23.19)	6	5 (7.25)
Decreased appetite	23	23 (33.33)	11	11 (15.94)
Hypoalbuminaemia	19	11 (15.94)	1	1 (1.45)
Hyperglycaemia	11	8 (11.59)	4	4 (5.80)
Hyperuricaemia	9	7 (10.14)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Hypomagnesaemia	7	6 (8.70)	0	0 (0.00)
Hypervolaemia	6	6 (8.70)	4	4 (5.80)
Hyperphosphataemia	5	5 (7.25)	1	1 (1.45)
Hypercalcaemia	4	3 (4.35)	2	2 (2.90)
Tumour lysis syndrome	4	4 (5.80)	4	4 (5.80)
Acidosis	3	2 (2.90)	2	2 (2.90)
Hypermagnesaemia	3	2 (2.90)	0	0 (0.00)
Hyponatraemia	3	3 (4.35)	0	0 (0.00)
Metabolic acidosis	3	3 (4.35)	2	2 (2.90)
Hyperkalaemia	2	2 (2.90)	2	2 (2.90)
Hypernatraemia	2	2 (2.90)	1	1 (1.45)
Hypertriglyceridaemia	2	2 (2.90)	2	2 (2.90)
Calcium deficiency	1	1 (1.45)	0	0 (0.00)
Dehydration	1	1 (1.45)	0	0 (0.00)
Haemosiderosis	1	1 (1.45)	0	0 (0.00)
Hyperchloraemia	1	1 (1.45)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.45)	0	0 (0.00)
Hypoglycaemia	1	1 (1.45)	0	0 (0.00)
Malnutrition	1	1 (1.45)	1	1 (1.45)
Polydipsia	1	1 (1.45)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	52	32 (46.38)	6	5 (7.25)
Pain in extremity	11	11 (15.94)	0	0 (0.00)
Myalgia	10	9 (13.04)	0	0 (0.00)
Arthralgia	9	9 (13.04)	1	1 (1.45)
Back pain	7	6 (8.70)	1	1 (1.45)
Bone pain	4	2 (2.90)	0	0 (0.00)
Muscular weakness	2	2 (2.90)	1	1 (1.45)
Pain in jaw	2	2 (2.90)	1	1 (1.45)
Haemarthrosis	1	1 (1.45)	1	1 (1.45)
Muscle rigidity	1	1 (1.45)	0	0 (0.00)
Muscle spasms	1	1 (1.45)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.45)	0	0 (0.00)
Myositis	1	1 (1.45)	0	0 (0.00)
Neck pain	1	1 (1.45)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.45)	1	1 (1.45)
Nervous system disorders				
- Total	73	36 (52.17)	13	9 (13.04)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Headache	23	20 (28.99)	1	1 (1.45)
Encephalopathy	8	8 (11.59)	4	4 (5.80)
Tremor	7	6 (8.70)	0	0 (0.00)
Cognitive disorder	5	3 (4.35)	1	1 (1.45)
Somnolence	5	5 (7.25)	2	2 (2.90)
Dizziness	3	3 (4.35)	0	0 (0.00)
Dysgeusia	3	3 (4.35)	0	0 (0.00)
Lethargy	3	3 (4.35)	0	0 (0.00)
Seizure	3	2 (2.90)	1	1 (1.45)
Hyperaesthesia	2	1 (1.45)	0	0 (0.00)
Amnesia	1	1 (1.45)	0	0 (0.00)
Aphasia	1	1 (1.45)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.45)	1	1 (1.45)
Depressed level of consciousness	1	1 (1.45)	1	1 (1.45)
Disturbance in attention	1	1 (1.45)	0	0 (0.00)
Dysarthria	1	1 (1.45)	1	1 (1.45)
Generalised tonic-clonic seizure	1	1 (1.45)	0	0 (0.00)
Hypoaesthesia	1	1 (1.45)	0	0 (0.00)
Monoparesis	1	1 (1.45)	0	0 (0.00)
Neurological decompensation	1	1 (1.45)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Paraesthesia	1	1 (1.45)	0	0 (0.00)
Psychiatric disorders				
- Total	46	27 (39.13)	6	6 (8.70)
Delirium	7	7 (10.14)	3	3 (4.35)
Agitation	6	5 (7.25)	0	0 (0.00)
Anxiety	6	6 (8.70)	2	2 (2.90)
Confusional state	6	6 (8.70)	0	0 (0.00)
Insomnia	4	4 (5.80)	0	0 (0.00)
Hallucination	3	3 (4.35)	0	0 (0.00)
Irritability	3	3 (4.35)	0	0 (0.00)
Mental status changes	3	3 (4.35)	1	1 (1.45)
Sleep disorder	3	2 (2.90)	0	0 (0.00)
Affect lability	1	1 (1.45)	0	0 (0.00)
Automatism	1	1 (1.45)	0	0 (0.00)
Hallucination, visual	1	1 (1.45)	0	0 (0.00)
Restlessness	1	1 (1.45)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.45)	0	0 (0.00)
Renal and urinary disorders				
- Total	39	20 (28.99)	13	9 (13.04)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Acute kidney injury	14	9 (13.04)	8	7 (10.14)
Renal failure	4	2 (2.90)	3	1 (1.45)
Dysuria	3	3 (4.35)	0	0 (0.00)
Anuria	2	2 (2.90)	1	1 (1.45)
Haematuria	2	2 (2.90)	0	0 (0.00)
Pollakiuria	2	2 (2.90)	0	0 (0.00)
Urinary incontinence	2	1 (1.45)	0	0 (0.00)
Urinary retention	2	2 (2.90)	0	0 (0.00)
Azotaemia	1	1 (1.45)	0	0 (0.00)
Bladder dilatation	1	1 (1.45)	0	0 (0.00)
Incontinence	1	1 (1.45)	0	0 (0.00)
Micturition urgency	1	1 (1.45)	0	0 (0.00)
Proteinuria	1	1 (1.45)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.45)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.45)	1	1 (1.45)
Urinary tract disorder	1	1 (1.45)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (5.80)	1	1 (1.45)
Vaginal haemorrhage	2	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Female genital tract fistula	1	1 (1.45)	0	0 (0.00)
Perineal rash	1	1 (1.45)	0	0 (0.00)
Vaginal ulceration	1	1 (1.45)	1	1 (1.45)
Respiratory, thoracic and mediastinal disorders				
- Total	112	39 (56.52)	50	23 (33.33)
Hypoxia	23	17 (24.64)	18	12 (17.39)
Pulmonary oedema	12	12 (17.39)	7	7 (10.14)
Cough	11	10 (14.49)	0	0 (0.00)
Tachypnoea	9	8 (11.59)	4	4 (5.80)
Pleural effusion	7	7 (10.14)	3	3 (4.35)
Oropharyngeal pain	6	5 (7.25)	0	0 (0.00)
Atelectasis	5	3 (4.35)	2	2 (2.90)
Respiratory distress	4	3 (4.35)	2	1 (1.45)
Respiratory failure	4	4 (5.80)	4	4 (5.80)
Dyspnoea	3	3 (4.35)	3	3 (4.35)
Epistaxis	3	3 (4.35)	1	1 (1.45)
Nasal congestion	3	3 (4.35)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (2.90)	2	2 (2.90)
Lung infiltration	2	1 (1.45)	1	1 (1.45)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Rhinorrhoea	2	2 (2.90)	0	0 (0.00)
Acute respiratory failure	1	1 (1.45)	1	1 (1.45)
Bradypnoea	1	1 (1.45)	1	1 (1.45)
Haemoptysis	1	1 (1.45)	0	0 (0.00)
Nasal discomfort	1	1 (1.45)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.45)	0	0 (0.00)
Painful respiration	1	1 (1.45)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.45)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.45)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.45)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.45)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.45)	0	0 (0.00)
Productive cough	1	1 (1.45)	0	0 (0.00)
Pulmonary mass	1	1 (1.45)	0	0 (0.00)
Respiratory acidosis	1	1 (1.45)	1	1 (1.45)
Respiratory disorder	1	1 (1.45)	0	0 (0.00)
Wheezing	1	1 (1.45)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	54	25 (36.23)	4	3 (4.35)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Pruritus	7	6 (8.70)	0	0 (0.00)
Blister	6	3 (4.35)	0	0 (0.00)
Erythema	4	4 (5.80)	0	0 (0.00)
Rash	4	4 (5.80)	0	0 (0.00)
Rash papular	4	3 (4.35)	0	0 (0.00)
Hyperhidrosis	3	3 (4.35)	0	0 (0.00)
Rash maculo-papular	3	2 (2.90)	1	1 (1.45)
Dermatitis atopic	2	2 (2.90)	0	0 (0.00)
Petechiae	2	2 (2.90)	1	1 (1.45)
Rash vesicular	2	1 (1.45)	0	0 (0.00)
Skin ulcer	2	2 (2.90)	0	0 (0.00)
Decubitus ulcer	1	1 (1.45)	0	0 (0.00)
Dermatitis	1	1 (1.45)	0	0 (0.00)
Dermatitis diaper	1	1 (1.45)	0	0 (0.00)
Dry skin	1	1 (1.45)	0	0 (0.00)
Eczema	1	1 (1.45)	0	0 (0.00)
Erythema nodosum	1	1 (1.45)	0	0 (0.00)
Pruritus allergic	1	1 (1.45)	0	0 (0.00)
Purpura	1	1 (1.45)	0	0 (0.00)
Rash pruritic	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Scab	1	1 (1.45)	0	0 (0.00)
Skin discolouration	1	1 (1.45)	0	0 (0.00)
Skin lesion	1	1 (1.45)	0	0 (0.00)
Skin necrosis	1	1 (1.45)	1	1 (1.45)
Urticaria	1	1 (1.45)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.45)	1	1 (1.45)
Social circumstances				
- Total	1	1 (1.45)	0	0 (0.00)
Patient uncooperative	1	1 (1.45)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.45)	1	1 (1.45)
Thrombolysis	1	1 (1.45)	1	1 (1.45)
Vascular disorders				
- Total	44	27 (39.13)	20	16 (23.19)
Hypotension	25	21 (30.43)	16	14 (20.29)
Hypertension	13	12 (17.39)	3	3 (4.35)
Capillary leak syndrome	2	2 (2.90)	1	1 (1.45)
Flushing	1	1 (1.45)	0	0 (0.00)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Hot flush	1	1 (1.45)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.45)	0	0 (0.00)
Thrombosis	1	1 (1.45)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	52	10 (90.91)	16	3 (27.27)
Blood and lymphatic system disorders				
- Total	5	3 (27.27)	1	1 (9.09)
B-cell aplasia	2	1 (9.09)	0	0 (0.00)
Anaemia	1	1 (9.09)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (9.09)	1	1 (9.09)
Leukopenia	1	1 (9.09)	0	0 (0.00)
Cardiac disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Left ventricular dysfunction	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	6	3 (27.27)	1	1 (9.09)
Constipation	3	2 (18.18)	0	0 (0.00)
Abdominal rigidity	1	1 (9.09)	0	0 (0.00)
Pancreatitis	1	1 (9.09)	1	1 (9.09)
Peritoneal haematoma	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	2 (18.18)	0	0 (0.00)
Pyrexia	2	2 (18.18)	0	0 (0.00)
Asthenia	1	1 (9.09)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Hepatic cytolysis	1	1 (9.09)	0	0 (0.00)
Immune system disorders				
- Total	3	3 (27.27)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (27.27)	0	0 (0.00)
Infections and infestations				
- Total	10	3 (27.27)	6	2 (18.18)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Upper respiratory tract infection	2	1 (9.09)	1	1 (9.09)
Encephalitis	1	1 (9.09)	1	1 (9.09)
Parainfluenzae virus infection	1	1 (9.09)	1	1 (9.09)
Paronychia	1	1 (9.09)	0	0 (0.00)
Pneumonia	1	1 (9.09)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection	1	1 (9.09)	0	0 (0.00)
Rhinovirus infection	1	1 (9.09)	1	1 (9.09)
Viral haemorrhagic cystitis	1	1 (9.09)	1	1 (9.09)
Injury, poisoning and procedural complications				
- Total	1	1 (9.09)	0	0 (0.00)
Infusion related reaction	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	2	2 (18.18)	2	2 (18.18)
Blood uric acid increased	1	1 (9.09)	1	1 (9.09)
Weight decreased	1	1 (9.09)	1	1 (9.09)
Metabolism and nutrition disorders				
- Total	3	1 (9.09)	2	1 (9.09)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Decreased appetite	1	1 (9.09)	1	1 (9.09)
Haemochromatosis	1	1 (9.09)	1	1 (9.09)
Hypophosphataemia	1	1 (9.09)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (18.18)	0	0 (0.00)
Back pain	2	2 (18.18)	0	0 (0.00)
Nervous system disorders				
- Total	6	3 (27.27)	3	1 (9.09)
Headache	2	2 (18.18)	0	0 (0.00)
Autonomic neuropathy	1	1 (9.09)	1	1 (9.09)
Cerebral haemorrhage	1	1 (9.09)	1	1 (9.09)
Memory impairment	1	1 (9.09)	0	0 (0.00)
Seizure	1	1 (9.09)	1	1 (9.09)
Psychiatric disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Sleep disorder	1	1 (9.09)	0	0 (0.00)
Renal and urinary disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	1	1 (9.09)	1	1 (9.09)
Renal tubular disorder	1	1 (9.09)	1	1 (9.09)
Respiratory, thoracic and mediastinal disorders				
- Total	3	2 (18.18)	0	0 (0.00)
Cough	2	1 (9.09)	0	0 (0.00)
Lung disorder	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	3 (27.27)	0	0 (0.00)
Dermatitis allergic	1	1 (9.09)	0	0 (0.00)
Photosensitivity reaction	1	1 (9.09)	0	0 (0.00)
Rash	1	1 (9.09)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Hypotension	1	1 (9.09)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Total number of AE per patient	482	59 (92.19)	130	33 (51.56)
Blood and lymphatic system disorders				
- Total	27	14 (21.88)	16	9 (14.06)
Anaemia	11	5 (7.81)	4	2 (3.13)
Neutropenia	5	5 (7.81)	5	5 (7.81)
Febrile neutropenia	4	3 (4.69)	4	3 (4.69)
Thrombocytopenia	2	2 (3.13)	2	2 (3.13)
Eosinophilia	1	1 (1.56)	0	0 (0.00)
Leukocytosis	1	1 (1.56)	0	0 (0.00)
Lymphadenopathy	1	1 (1.56)	0	0 (0.00)
Lymphocytosis	1	1 (1.56)	0	0 (0.00)
Lymphopenia	1	1 (1.56)	1	1 (1.56)
Cardiac disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
- Total	7	6 (9.38)	4	3 (4.69)
Cardiac arrest	2	2 (3.13)	2	2 (3.13)
Cardiac failure	2	2 (3.13)	2	2 (3.13)
Tachycardia	2	2 (3.13)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.56)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (1.56)	0	0 (0.00)
Hypothyroidism	1	1 (1.56)	0	0 (0.00)
Eye disorders				
- Total	5	4 (6.25)	0	0 (0.00)
Cataract	2	2 (3.13)	0	0 (0.00)
Hypermetropia	1	1 (1.56)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.56)	0	0 (0.00)
Visual impairment	1	1 (1.56)	0	0 (0.00)
Gastrointestinal disorders				
- Total	32	17 (26.56)	0	0 (0.00)
Diarrhoea	7	7 (10.94)	0	0 (0.00)
Vomiting	7	6 (9.38)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Nausea	5	5 (7.81)	0	0 (0.00)
Abdominal pain	2	2 (3.13)	0	0 (0.00)
Abdominal pain upper	1	1 (1.56)	0	0 (0.00)
Constipation	1	1 (1.56)	0	0 (0.00)
Dyspepsia	1	1 (1.56)	0	0 (0.00)
Enteritis	1	1 (1.56)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.56)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.56)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.56)	0	0 (0.00)
Pancreatitis	1	1 (1.56)	0	0 (0.00)
Proctalgia	1	1 (1.56)	0	0 (0.00)
Stomatitis	1	1 (1.56)	0	0 (0.00)
Trichoglossia	1	1 (1.56)	0	0 (0.00)
General disorders and administration site conditions				
- Total	28	22 (34.38)	3	3 (4.69)
Pyrexia	14	13 (20.31)	2	2 (3.13)
Fatigue	7	6 (9.38)	0	0 (0.00)
Oedema peripheral	2	1 (1.56)	0	0 (0.00)
Pain	2	2 (3.13)	1	1 (1.56)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Chills	1	1 (1.56)	0	0 (0.00)
Malaise	1	1 (1.56)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.56)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (3.13)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.56)	0	0 (0.00)
Liver disorder	1	1 (1.56)	0	0 (0.00)
Immune system disorders				
- Total	16	13 (20.31)	5	4 (6.25)
Hypogammaglobulinaemia	9	7 (10.94)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (3.13)	1	1 (1.56)
Graft versus host disease	2	2 (3.13)	2	2 (3.13)
Drug hypersensitivity	1	1 (1.56)	0	0 (0.00)
Engraftment syndrome	1	1 (1.56)	1	1 (1.56)
Immunodeficiency	1	1 (1.56)	1	1 (1.56)
Infections and infestations				
- Total	103	36 (56.25)	39	18 (28.13)
Nasopharyngitis	9	7 (10.94)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Upper respiratory tract infection	8	7 (10.94)	1	1 (1.56)
Bronchopulmonary aspergillosis	5	1 (1.56)	3	1 (1.56)
Gastroenteritis	5	5 (7.81)	2	2 (3.13)
Parainfluenzae virus infection	4	3 (4.69)	1	1 (1.56)
Rhinovirus infection	4	4 (6.25)	0	0 (0.00)
Sinusitis	4	3 (4.69)	1	1 (1.56)
Bacteraemia	3	2 (3.13)	2	1 (1.56)
Ear infection	3	2 (3.13)	0	0 (0.00)
Metapneumovirus infection	3	3 (4.69)	3	3 (4.69)
Otitis media	3	3 (4.69)	1	1 (1.56)
Klebsiella infection	2	1 (1.56)	2	1 (1.56)
Otitis externa	2	2 (3.13)	1	1 (1.56)
Pneumocystis jirovecii pneumonia	2	2 (3.13)	2	2 (3.13)
Pneumonia	2	2 (3.13)	1	1 (1.56)
Respiratory syncytial virus infection	2	2 (3.13)	1	1 (1.56)
Respiratory tract infection	2	2 (3.13)	0	0 (0.00)
Rhinitis	2	2 (3.13)	0	0 (0.00)
Urinary tract infection	2	1 (1.56)	2	1 (1.56)
Viral infection	2	2 (3.13)	1	1 (1.56)
Acute sinusitis	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Adenovirus infection	1	1 (1.56)	1	1 (1.56)
BK virus infection	1	1 (1.56)	1	1 (1.56)
Cellulitis	1	1 (1.56)	0	0 (0.00)
Conjunctivitis	1	1 (1.56)	0	0 (0.00)
Coronavirus infection	1	1 (1.56)	1	1 (1.56)
Cystitis	1	1 (1.56)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.56)	1	1 (1.56)
Device related infection	1	1 (1.56)	1	1 (1.56)
Ear, nose and throat infection	1	1 (1.56)	0	0 (0.00)
Enterobacter infection	1	1 (1.56)	1	1 (1.56)
Gastroenteritis clostridial	1	1 (1.56)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.56)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.56)	0	0 (0.00)
Gingivitis	1	1 (1.56)	0	0 (0.00)
Herpes simplex	1	1 (1.56)	0	0 (0.00)
Herpes zoster	1	1 (1.56)	1	1 (1.56)
Human herpesvirus 6 infection	1	1 (1.56)	1	1 (1.56)
Influenza	1	1 (1.56)	0	0 (0.00)
Mastoiditis	1	1 (1.56)	1	1 (1.56)
Molluscum contagiosum	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Nail infection	1	1 (1.56)	0	0 (0.00)
Oral candidiasis	1	1 (1.56)	0	0 (0.00)
Oral herpes	1	1 (1.56)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.56)	1	1 (1.56)
Respiratory tract infection viral	1	1 (1.56)	0	0 (0.00)
Salmonellosis	1	1 (1.56)	0	0 (0.00)
Septic shock	1	1 (1.56)	1	1 (1.56)
Sinusitis fungal	1	1 (1.56)	1	1 (1.56)
Staphylococcal bacteraemia	1	1 (1.56)	1	1 (1.56)
Staphylococcal sepsis	1	1 (1.56)	1	1 (1.56)
Staphylococcal skin infection	1	1 (1.56)	0	0 (0.00)
Tinea pedis	1	1 (1.56)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.56)	1	1 (1.56)
Injury, poisoning and procedural complications				
- Total	9	8 (12.50)	0	0 (0.00)
Infusion related reaction	3	2 (3.13)	0	0 (0.00)
Contusion	1	1 (1.56)	0	0 (0.00)
Fibula fracture	1	1 (1.56)	0	0 (0.00)
Ligament sprain	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Limb injury	1	1 (1.56)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.56)	0	0 (0.00)
Skin abrasion	1	1 (1.56)	0	0 (0.00)
Investigations				
- Total	89	28 (43.75)	33	14 (21.88)
Neutrophil count decreased	19	10 (15.63)	11	7 (10.94)
White blood cell count decreased	18	10 (15.63)	4	4 (6.25)
Platelet count decreased	16	5 (7.81)	9	2 (3.13)
Lymphocyte count decreased	6	4 (6.25)	2	2 (3.13)
Immunoglobulins decreased	5	1 (1.56)	0	0 (0.00)
Blood bilirubin increased	4	2 (3.13)	1	1 (1.56)
Alanine aminotransferase increased	3	2 (3.13)	1	1 (1.56)
Weight increased	3	1 (1.56)	1	1 (1.56)
Blood immunoglobulin A decreased	2	2 (3.13)	1	1 (1.56)
Blood creatinine increased	1	1 (1.56)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.56)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.56)	1	1 (1.56)
Blood lactate dehydrogenase increased	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Blood thyroid stimulating hormone increased	1	1 (1.56)	0	0 (0.00)
Blood urea increased	1	1 (1.56)	1	1 (1.56)
Blood uric acid increased	1	1 (1.56)	1	1 (1.56)
Bone density decreased	1	1 (1.56)	0	0 (0.00)
C-reactive protein increased	1	1 (1.56)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.56)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.56)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.56)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.56)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	23	14 (21.88)	8	6 (9.38)
Hypokalaemia	6	3 (4.69)	4	2 (3.13)
Decreased appetite	5	5 (7.81)	0	0 (0.00)
Hyperuricaemia	3	3 (4.69)	0	0 (0.00)
Hyperchloraemia	1	1 (1.56)	0	0 (0.00)
Hyperkalaemia	1	1 (1.56)	0	0 (0.00)
Hypervolaemia	1	1 (1.56)	1	1 (1.56)
Hypophagia	1	1 (1.56)	0	0 (0.00)
Iron overload	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Malnutrition	1	1 (1.56)	1	1 (1.56)
Metabolic acidosis	1	1 (1.56)	1	1 (1.56)
Metabolic syndrome	1	1 (1.56)	0	0 (0.00)
Tumour lysis syndrome	1	1 (1.56)	1	1 (1.56)
Musculoskeletal and connective tissue disorders				
- Total	20	13 (20.31)	3	3 (4.69)
Back pain	5	4 (6.25)	2	2 (3.13)
Pain in extremity	5	5 (7.81)	1	1 (1.56)
Arthralgia	3	3 (4.69)	0	0 (0.00)
Bone pain	2	2 (3.13)	0	0 (0.00)
Growth retardation	1	1 (1.56)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.56)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.56)	0	0 (0.00)
Myalgia	1	1 (1.56)	0	0 (0.00)
Neck pain	1	1 (1.56)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (6.25)	1	1 (1.56)
Skin papilloma	2	2 (3.13)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Cancer pain	1	1 (1.56)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.56)	1	1 (1.56)
Nervous system disorders				
- Total	17	11 (17.19)	3	1 (1.56)
Headache	9	8 (12.50)	0	0 (0.00)
Hydrocephalus	3	1 (1.56)	3	1 (1.56)
Dizziness	2	1 (1.56)	0	0 (0.00)
Migraine	2	1 (1.56)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.56)	0	0 (0.00)
Psychiatric disorders				
- Total	14	9 (14.06)	1	1 (1.56)
Anxiety	6	6 (9.38)	0	0 (0.00)
Mental status changes	2	2 (3.13)	1	1 (1.56)
Agitation	1	1 (1.56)	0	0 (0.00)
Delirium	1	1 (1.56)	0	0 (0.00)
Mood altered	1	1 (1.56)	0	0 (0.00)
Nightmare	1	1 (1.56)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.56)	0	0 (0.00)
Tearfulness	1	1 (1.56)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Renal and urinary disorders				
- Total	8	4 (6.25)	2	2 (3.13)
Acute kidney injury	3	3 (4.69)	1	1 (1.56)
Cystitis haemorrhagic	1	1 (1.56)	0	0 (0.00)
Dysuria	1	1 (1.56)	0	0 (0.00)
Haematuria	1	1 (1.56)	1	1 (1.56)
Kidney enlargement	1	1 (1.56)	0	0 (0.00)
Renal mass	1	1 (1.56)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (1.56)	0	0 (0.00)
Dysmenorrhoea	2	1 (1.56)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	43	22 (34.38)	6	6 (9.38)
Cough	12	10 (15.63)	0	0 (0.00)
Nasal congestion	7	6 (9.38)	0	0 (0.00)
Epistaxis	3	3 (4.69)	0	0 (0.00)
Hypoxia	3	3 (4.69)	3	3 (4.69)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Rhinorrhoea	3	3 (4.69)	0	0 (0.00)
Dyspnoea	2	1 (1.56)	0	0 (0.00)
Oropharyngeal pain	2	2 (3.13)	0	0 (0.00)
Pleural effusion	2	2 (3.13)	0	0 (0.00)
Rhinitis allergic	2	2 (3.13)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.56)	1	1 (1.56)
Bronchial oedema	1	1 (1.56)	0	0 (0.00)
Bronchospasm	1	1 (1.56)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.56)	0	0 (0.00)
Respiratory distress	1	1 (1.56)	1	1 (1.56)
Respiratory failure	1	1 (1.56)	1	1 (1.56)
Upper respiratory tract inflammation	1	1 (1.56)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	26	17 (26.56)	1	1 (1.56)
Dry skin	7	6 (9.38)	0	0 (0.00)
Rash	5	3 (4.69)	0	0 (0.00)
Ingrowing nail	2	2 (3.13)	0	0 (0.00)
Pruritus	2	1 (1.56)	0	0 (0.00)
Decubitus ulcer	1	1 (1.56)	1	1 (1.56)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=64 n (%)[1]	Grade >= 3 Total events	All patients N=64 n (%)[2]
Dermatitis atopic	1	1 (1.56)	0	0 (0.00)
Eczema	1	1 (1.56)	0	0 (0.00)
Erythema	1	1 (1.56)	0	0 (0.00)
Hangnail	1	1 (1.56)	0	0 (0.00)
Miliaria	1	1 (1.56)	0	0 (0.00)
Night sweats	1	1 (1.56)	0	0 (0.00)
Skin discolouration	1	1 (1.56)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.56)	0	0 (0.00)
Skin swelling	1	1 (1.56)	0	0 (0.00)
Vascular disorders				
- Total	6	5 (7.81)	5	5 (7.81)
Hypotension	3	3 (4.69)	3	3 (4.69)
Venoocclusive disease	2	2 (3.13)	2	2 (3.13)
Hypertension	1	1 (1.56)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Total number of AE per patient	34	5 (55.56)	9	3 (33.33)
Gastrointestinal disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Diarrhoea	1	1 (11.11)	0	0 (0.00)
General disorders and administration site conditions				
- Total	5	2 (22.22)	0	0 (0.00)
Pyrexia	3	1 (11.11)	0	0 (0.00)
Pain	2	2 (22.22)	0	0 (0.00)
Infections and infestations				
- Total	8	4 (44.44)	1	1 (11.11)
Sinusitis	2	2 (22.22)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Fungal skin infection	1	1 (11.11)	0	0 (0.00)
Rhinitis	1	1 (11.11)	0	0 (0.00)
Rhinovirus infection	1	1 (11.11)	0	0 (0.00)
Sepsis	1	1 (11.11)	1	1 (11.11)
Urinary tract infection	1	1 (11.11)	0	0 (0.00)
Varicella zoster virus infection	1	1 (11.11)	0	0 (0.00)
Investigations				
- Total	6	1 (11.11)	5	1 (11.11)
Neutrophil count decreased	6	1 (11.11)	5	1 (11.11)
Metabolism and nutrition disorders				
- Total	6	2 (22.22)	2	1 (11.11)
Decreased appetite	2	1 (11.11)	2	1 (11.11)
Iron overload	2	1 (11.11)	0	0 (0.00)
Hypercholesterolaemia	1	1 (11.11)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (11.11)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	1 (11.11)	0	0 (0.00)
Joint effusion	1	1 (11.11)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=9 n (%)[1]	Grade >= 3 Total events	All patients N=9 n (%)[2]
Synovitis	1	1 (11.11)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Dysarthria	1	1 (11.11)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (22.22)	0	0 (0.00)
Anxiety	2	2 (22.22)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (11.11)	1	1 (11.11)
Endometriosis	2	1 (11.11)	1	1 (11.11)
Vascular disorders				
- Total	1	1 (11.11)	0	0 (0.00)
Hypertension	1	1 (11.11)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Total number of AE per patient	186	27 (65.85)	54	16 (39.02)
Blood and lymphatic system disorders				
- Total	6	4 (9.76)	2	2 (4.88)
Agranulocytosis	1	1 (2.44)	1	1 (2.44)
Anaemia	1	1 (2.44)	0	0 (0.00)
Hypercoagulation	1	1 (2.44)	0	0 (0.00)
Lymphadenopathy	1	1 (2.44)	0	0 (0.00)
Neutropenia	1	1 (2.44)	1	1 (2.44)
Thrombocytopenia	1	1 (2.44)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.44)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.44)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.44)	0	0 (0.00)
Deafness unilateral	1	1 (2.44)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.44)	0	0 (0.00)
Delayed puberty	1	1 (2.44)	0	0 (0.00)
Hypothyroidism	1	1 (2.44)	0	0 (0.00)
Eye disorders				
- Total	4	3 (7.32)	1	1 (2.44)
Dry eye	1	1 (2.44)	0	0 (0.00)
Eye pain	1	1 (2.44)	1	1 (2.44)
Eyelid oedema	1	1 (2.44)	0	0 (0.00)
Mydriasis	1	1 (2.44)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	6 (14.63)	1	1 (2.44)
Diarrhoea	4	4 (9.76)	1	1 (2.44)
Constipation	1	1 (2.44)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.44)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Nausea	1	1 (2.44)	0	0 (0.00)
Vomiting	1	1 (2.44)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	7 (17.07)	2	2 (4.88)
Pyrexia	4	4 (9.76)	1	1 (2.44)
Fatigue	1	1 (2.44)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.44)	1	1 (2.44)
Non-cardiac chest pain	1	1 (2.44)	0	0 (0.00)
Xerosis	1	1 (2.44)	0	0 (0.00)
Immune system disorders				
- Total	10	9 (21.95)	3	2 (4.88)
Hypogammaglobulinaemia	3	3 (7.32)	0	0 (0.00)
Seasonal allergy	3	3 (7.32)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.88)	1	1 (2.44)
Drug hypersensitivity	1	1 (2.44)	1	1 (2.44)
Haemophagocytic lymphohistiocytosis	1	1 (2.44)	1	1 (2.44)
Infections and infestations				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
- Total	78	19 (46.34)	25	13 (31.71)
Sinusitis	7	4 (9.76)	0	0 (0.00)
Upper respiratory tract infection	7	5 (12.20)	1	1 (2.44)
Conjunctivitis	5	4 (9.76)	0	0 (0.00)
COVID-19	3	2 (4.88)	1	1 (2.44)
Fungal infection	3	2 (4.88)	0	0 (0.00)
Otitis media	3	2 (4.88)	0	0 (0.00)
Rhinovirus infection	3	3 (7.32)	1	1 (2.44)
Skin infection	3	3 (7.32)	0	0 (0.00)
Bronchitis	2	2 (4.88)	0	0 (0.00)
Device related sepsis	2	1 (2.44)	2	1 (2.44)
Gastroenteritis viral	2	1 (2.44)	0	0 (0.00)
Herpes zoster	2	2 (4.88)	1	1 (2.44)
Influenza	2	2 (4.88)	1	1 (2.44)
Oral herpes	2	2 (4.88)	0	0 (0.00)
Pneumonia	2	2 (4.88)	2	2 (4.88)
Sepsis	2	2 (4.88)	2	2 (4.88)
Acute sinusitis	1	1 (2.44)	0	0 (0.00)
Bronchiolitis	1	1 (2.44)	1	1 (2.44)
COVID-19 pneumonia	1	1 (2.44)	1	1 (2.44)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Candida infection	1	1 (2.44)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.44)	1	1 (2.44)
Ear infection	1	1 (2.44)	1	1 (2.44)
Enterovirus infection	1	1 (2.44)	1	1 (2.44)
Folliculitis	1	1 (2.44)	0	0 (0.00)
Gastroenteritis	1	1 (2.44)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.44)	1	1 (2.44)
Gastroenteritis salmonella	1	1 (2.44)	1	1 (2.44)
Herpes virus infection	1	1 (2.44)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.44)	1	1 (2.44)
Nail infection	1	1 (2.44)	0	0 (0.00)
Neutropenic infection	1	1 (2.44)	1	1 (2.44)
Ophthalmic herpes zoster	1	1 (2.44)	0	0 (0.00)
Oral candidiasis	1	1 (2.44)	0	0 (0.00)
Otitis media acute	1	1 (2.44)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.44)	1	1 (2.44)
Pneumonia respiratory syncytial viral	1	1 (2.44)	1	1 (2.44)
Septic shock	1	1 (2.44)	1	1 (2.44)
Staphylococcal abscess	1	1 (2.44)	1	1 (2.44)
Staphylococcal bacteraemia	1	1 (2.44)	1	1 (2.44)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Streptococcal sepsis	1	1 (2.44)	0	0 (0.00)
Syphilis	1	1 (2.44)	0	0 (0.00)
Urinary tract infection	1	1 (2.44)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.44)	0	0 (0.00)
Viral skin infection	1	1 (2.44)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	3	3 (7.32)	1	1 (2.44)
Abdominal injury	1	1 (2.44)	0	0 (0.00)
Infusion related reaction	1	1 (2.44)	1	1 (2.44)
Ligament sprain	1	1 (2.44)	0	0 (0.00)
Investigations				
- Total	10	5 (12.20)	1	1 (2.44)
Blood bilirubin increased	3	1 (2.44)	0	0 (0.00)
Neutrophil count decreased	2	2 (4.88)	0	0 (0.00)
Platelet count decreased	2	2 (4.88)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.44)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.44)	1	1 (2.44)
SARS-CoV-2 test positive	1	1 (2.44)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Metabolism and nutrition disorders				
- Total	4	4 (9.76)	3	3 (7.32)
Hyperglycaemia	1	1 (2.44)	1	1 (2.44)
Hyperlipidaemia	1	1 (2.44)	0	0 (0.00)
Hypernatraemia	1	1 (2.44)	1	1 (2.44)
Obesity	1	1 (2.44)	1	1 (2.44)
Musculoskeletal and connective tissue disorders				
- Total	6	6 (14.63)	0	0 (0.00)
Pain in extremity	2	2 (4.88)	0	0 (0.00)
Arthralgia	1	1 (2.44)	0	0 (0.00)
Growth retardation	1	1 (2.44)	0	0 (0.00)
Osteonecrosis	1	1 (2.44)	0	0 (0.00)
Osteopenia	1	1 (2.44)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.44)	1	1 (2.44)
Bone giant cell tumour benign	2	1 (2.44)	1	1 (2.44)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
- Total	8	3 (7.32)	3	2 (4.88)
Headache	3	2 (4.88)	1	1 (2.44)
Seizure	3	1 (2.44)	1	1 (2.44)
Nervous system disorder	2	1 (2.44)	1	1 (2.44)
Psychiatric disorders				
- Total	1	1 (2.44)	0	0 (0.00)
Tic	1	1 (2.44)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	23	10 (24.39)	6	4 (9.76)
Cough	4	4 (9.76)	0	0 (0.00)
Dyspnoea	3	3 (7.32)	1	1 (2.44)
Rhinorrhoea	3	3 (7.32)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (4.88)	0	0 (0.00)
Tachypnoea	2	1 (2.44)	2	1 (2.44)
Dyspnoea exertional	1	1 (2.44)	0	0 (0.00)
Epistaxis	1	1 (2.44)	0	0 (0.00)
Hypoxia	1	1 (2.44)	1	1 (2.44)
Laryngeal oedema	1	1 (2.44)	1	1 (2.44)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=41 n (%)[1]	Grade >= 3 Total events	All patients N=41 n (%)[2]
Oropharyngeal pain	1	1 (2.44)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.44)	0	0 (0.00)
Pleural effusion	1	1 (2.44)	0	0 (0.00)
Respiratory failure	1	1 (2.44)	1	1 (2.44)
Wheezing	1	1 (2.44)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	10	7 (17.07)	4	3 (7.32)
Rash	2	2 (4.88)	0	0 (0.00)
Rash macular	2	1 (2.44)	2	1 (2.44)
Dermatitis atopic	1	1 (2.44)	1	1 (2.44)
Dry skin	1	1 (2.44)	0	0 (0.00)
Eczema	1	1 (2.44)	1	1 (2.44)
Papule	1	1 (2.44)	0	0 (0.00)
Rash erythematous	1	1 (2.44)	0	0 (0.00)
Rash maculo-papular	1	1 (2.44)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (2.44)	1	1 (2.44)
Hypertension	1	1 (2.44)	1	1 (2.44)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	159	11 (100.00)	52	8 (72.73)
Blood and lymphatic system disorders				
- Total	11	5 (45.45)	4	3 (27.27)
B-cell aplasia	3	1 (9.09)	0	0 (0.00)
Anaemia	2	1 (9.09)	0	0 (0.00)
Leukopenia	2	1 (9.09)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (9.09)	1	1 (9.09)
Febrile neutropenia	1	1 (9.09)	1	1 (9.09)
Neutropenia	1	1 (9.09)	1	1 (9.09)
Pancytopenia	1	1 (9.09)	1	1 (9.09)
Cardiac disorders				
- Total	2	2 (18.18)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Left ventricular dysfunction	1	1 (9.09)	0	0 (0.00)
Sinus tachycardia	1	1 (9.09)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Hypothyroidism	1	1 (9.09)	0	0 (0.00)
Eye disorders				
- Total	3	1 (9.09)	0	0 (0.00)
Retinal haemorrhage	2	1 (9.09)	0	0 (0.00)
Visual field defect	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				
- Total	11	7 (63.64)	1	1 (9.09)
Constipation	4	3 (27.27)	0	0 (0.00)
Abdominal pain	1	1 (9.09)	0	0 (0.00)
Abdominal rigidity	1	1 (9.09)	0	0 (0.00)
Diarrhoea	1	1 (9.09)	0	0 (0.00)
Pancreatitis	1	1 (9.09)	1	1 (9.09)
Peritoneal haematoma	1	1 (9.09)	0	0 (0.00)
Trichoglossia	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Vomiting	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	5 (45.45)	0	0 (0.00)
Pyrexia	9	4 (36.36)	0	0 (0.00)
Pain	2	2 (18.18)	0	0 (0.00)
Asthenia	1	1 (9.09)	0	0 (0.00)
Face oedema	1	1 (9.09)	0	0 (0.00)
Influenza like illness	1	1 (9.09)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Hepatic cytolysis	1	1 (9.09)	0	0 (0.00)
Immune system disorders				
- Total	18	8 (72.73)	6	4 (36.36)
Cytokine release syndrome	12	6 (54.55)	4	2 (18.18)
Hypogammaglobulinaemia	6	6 (54.55)	2	2 (18.18)
Infections and infestations				
- Total	20	7 (63.64)	7	2 (18.18)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Rhinovirus infection	2	1 (9.09)	1	1 (9.09)
Sinusitis	2	2 (18.18)	0	0 (0.00)
Upper respiratory tract infection	2	1 (9.09)	1	1 (9.09)
Conjunctivitis	1	1 (9.09)	0	0 (0.00)
Encephalitis	1	1 (9.09)	1	1 (9.09)
Fungal skin infection	1	1 (9.09)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (9.09)	1	1 (9.09)
Paronychia	1	1 (9.09)	0	0 (0.00)
Pneumonia	1	1 (9.09)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (9.09)	1	1 (9.09)
Respiratory tract infection	1	1 (9.09)	0	0 (0.00)
Rhinitis	1	1 (9.09)	0	0 (0.00)
Sepsis	1	1 (9.09)	1	1 (9.09)
Staphylococcal infection	1	1 (9.09)	0	0 (0.00)
Urinary tract infection	1	1 (9.09)	0	0 (0.00)
Varicella zoster virus infection	1	1 (9.09)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (9.09)	1	1 (9.09)
Injury, poisoning and procedural complications				
- Total	1	1 (9.09)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Infusion related reaction	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	29	7 (63.64)	22	6 (54.55)
Neutrophil count decreased	8	2 (18.18)	7	2 (18.18)
Alanine aminotransferase increased	5	3 (27.27)	1	1 (9.09)
Lymphocyte count decreased	3	2 (18.18)	3	2 (18.18)
Platelet count decreased	3	3 (27.27)	3	3 (27.27)
Aspartate aminotransferase increased	1	1 (9.09)	0	0 (0.00)
Blood bilirubin increased	1	1 (9.09)	1	1 (9.09)
Blood fibrinogen decreased	1	1 (9.09)	1	1 (9.09)
Blood testosterone decreased	1	1 (9.09)	0	0 (0.00)
Blood uric acid increased	1	1 (9.09)	1	1 (9.09)
C-reactive protein increased	1	1 (9.09)	1	1 (9.09)
Gamma-glutamyltransferase increased	1	1 (9.09)	1	1 (9.09)
Serum ferritin increased	1	1 (9.09)	1	1 (9.09)
Weight decreased	1	1 (9.09)	1	1 (9.09)
White blood cell count decreased	1	1 (9.09)	1	1 (9.09)
Metabolism and nutrition disorders				

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	11	4 (36.36)	5	2 (18.18)
Decreased appetite	4	2 (18.18)	3	1 (9.09)
Hypophosphataemia	2	2 (18.18)	1	1 (9.09)
Iron overload	2	1 (9.09)	0	0 (0.00)
Haemochromatosis	1	1 (9.09)	1	1 (9.09)
Hypercholesterolaemia	1	1 (9.09)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (9.09)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	5	3 (27.27)	0	0 (0.00)
Back pain	2	2 (18.18)	0	0 (0.00)
Arthralgia	1	1 (9.09)	0	0 (0.00)
Joint effusion	1	1 (9.09)	0	0 (0.00)
Synovitis	1	1 (9.09)	0	0 (0.00)
Nervous system disorders				
- Total	11	5 (45.45)	4	2 (18.18)
Headache	5	3 (27.27)	1	1 (9.09)
Autonomic neuropathy	1	1 (9.09)	1	1 (9.09)
Cerebral haemorrhage	1	1 (9.09)	1	1 (9.09)

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Dysarthria	1	1 (9.09)	0	0 (0.00)
Memory impairment	1	1 (9.09)	0	0 (0.00)
Neuralgia	1	1 (9.09)	0	0 (0.00)
Seizure	1	1 (9.09)	1	1 (9.09)
Psychiatric disorders				
- Total	4	4 (36.36)	0	0 (0.00)
Anxiety	2	2 (18.18)	0	0 (0.00)
Confusional state	1	1 (9.09)	0	0 (0.00)
Sleep disorder	1	1 (9.09)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (9.09)	1	1 (9.09)
Renal tubular disorder	1	1 (9.09)	1	1 (9.09)
Reproductive system and breast disorders				
- Total	3	2 (18.18)	1	1 (9.09)
Endometriosis	2	1 (9.09)	1	1 (9.09)
Heavy menstrual bleeding	1	1 (9.09)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				

Timing: At anytime, Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	5	4 (36.36)	0	0 (0.00)
Cough	2	1 (9.09)	0	0 (0.00)
Epistaxis	1	1 (9.09)	0	0 (0.00)
Lung disorder	1	1 (9.09)	0	0 (0.00)
Nasal dryness	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	4 (36.36)	0	0 (0.00)
Rash	2	1 (9.09)	0	0 (0.00)
Dermatitis allergic	1	1 (9.09)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (9.09)	0	0 (0.00)
Photosensitivity reaction	1	1 (9.09)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (27.27)	1	1 (9.09)
Hypertension	2	2 (18.18)	1	1 (9.09)
Hypotension	1	1 (9.09)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse

events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250o
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Baseline extramedullary disease presence
Safety Set

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Total number of AE per patient	2346	69 (100.00)	776	65 (94.20)
Blood and lymphatic system disorders				
- Total	152	50 (72.46)	91	40 (57.97)
Anaemia	61	24 (34.78)	24	9 (13.04)
Febrile neutropenia	32	26 (37.68)	32	26 (37.68)
Neutropenia	16	10 (14.49)	14	8 (11.59)
Thrombocytopenia	11	9 (13.04)	10	9 (13.04)
Disseminated intravascular coagulation	7	7 (10.14)	2	2 (2.90)
Coagulopathy	5	5 (7.25)	2	2 (2.90)
Splenomegaly	4	4 (5.80)	0	0 (0.00)
Eosinophilia	3	1 (1.45)	0	0 (0.00)
Leukopenia	3	2 (2.90)	3	2 (2.90)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Lymphadenopathy	2	2 (2.90)	0	0 (0.00)
Lymphopenia	2	2 (2.90)	2	2 (2.90)
Agranulocytosis	1	1 (1.45)	1	1 (1.45)
Hypercoagulation	1	1 (1.45)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.45)	0	0 (0.00)
Leukocytosis	1	1 (1.45)	0	0 (0.00)
Lymphocytosis	1	1 (1.45)	0	0 (0.00)
Pancytopenia	1	1 (1.45)	1	1 (1.45)
Cardiac disorders				
- Total	51	26 (37.68)	14	11 (15.94)
Tachycardia	24	17 (24.64)	3	3 (4.35)
Cardiac failure	6	3 (4.35)	4	3 (4.35)
Bradycardia	3	3 (4.35)	0	0 (0.00)
Cardiac arrest	3	3 (4.35)	3	3 (4.35)
Left ventricular dysfunction	3	3 (4.35)	3	3 (4.35)
Sinus tachycardia	3	2 (2.90)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.90)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.45)	0	0 (0.00)
Cardiac failure congestive	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Mitral valve incompetence	1	1 (1.45)	0	0 (0.00)
Pericardial effusion	1	1 (1.45)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.45)	0	0 (0.00)
Sinus bradycardia	1	1 (1.45)	1	1 (1.45)
Tricuspid valve incompetence	1	1 (1.45)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.45)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.45)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	3	3 (4.35)	0	0 (0.00)
Deafness unilateral	1	1 (1.45)	0	0 (0.00)
Ear pain	1	1 (1.45)	0	0 (0.00)
Ear pruritus	1	1 (1.45)	0	0 (0.00)
Endocrine disorders				
- Total	7	6 (8.70)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.80)	0	0 (0.00)
Hypothyroidism	2	2 (2.90)	0	0 (0.00)
Delayed puberty	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Eye disorders				
- Total	21	14 (20.29)	1	1 (1.45)
Eyelid oedema	4	3 (4.35)	0	0 (0.00)
Ocular hyperaemia	3	3 (4.35)	0	0 (0.00)
Cataract	2	2 (2.90)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (2.90)	0	0 (0.00)
Eye pain	2	2 (2.90)	1	1 (1.45)
Visual impairment	2	2 (2.90)	0	0 (0.00)
Dry eye	1	1 (1.45)	0	0 (0.00)
Eye oedema	1	1 (1.45)	0	0 (0.00)
Hypermetropia	1	1 (1.45)	0	0 (0.00)
Mydriasis	1	1 (1.45)	0	0 (0.00)
Periorbital oedema	1	1 (1.45)	0	0 (0.00)
Periorbital swelling	1	1 (1.45)	0	0 (0.00)
Gastrointestinal disorders				
- Total	171	53 (76.81)	17	15 (21.74)
Vomiting	37	25 (36.23)	1	1 (1.45)
Diarrhoea	29	25 (36.23)	2	2 (2.90)
Nausea	27	22 (31.88)	2	2 (2.90)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Abdominal pain	14	10 (14.49)	2	2 (2.90)
Constipation	12	11 (15.94)	0	0 (0.00)
Mouth haemorrhage	5	5 (7.25)	2	2 (2.90)
Pancreatitis	5	5 (7.25)	1	1 (1.45)
Abdominal pain upper	4	4 (5.80)	0	0 (0.00)
Abdominal distension	3	3 (4.35)	0	0 (0.00)
Ascites	3	3 (4.35)	0	0 (0.00)
Stomatitis	3	3 (4.35)	1	1 (1.45)
Gastrointestinal sounds abnormal	2	2 (2.90)	0	0 (0.00)
Proctalgia	2	2 (2.90)	1	1 (1.45)
Abdominal compartment syndrome	1	1 (1.45)	1	1 (1.45)
Anal fissure	1	1 (1.45)	0	0 (0.00)
Anal haemorrhage	1	1 (1.45)	0	0 (0.00)
Dry mouth	1	1 (1.45)	0	0 (0.00)
Dyspepsia	1	1 (1.45)	0	0 (0.00)
Dysphagia	1	1 (1.45)	1	1 (1.45)
Enteritis	1	1 (1.45)	0	0 (0.00)
Enterocolitis	1	1 (1.45)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.45)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Gastrooesophageal reflux disease	1	1 (1.45)	0	0 (0.00)
Gingival bleeding	1	1 (1.45)	0	0 (0.00)
Gingival erythema	1	1 (1.45)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.45)	1	1 (1.45)
Haematemesis	1	1 (1.45)	0	0 (0.00)
Ileus	1	1 (1.45)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.45)	0	0 (0.00)
Lip dry	1	1 (1.45)	0	0 (0.00)
Lip oedema	1	1 (1.45)	0	0 (0.00)
Melaena	1	1 (1.45)	1	1 (1.45)
Mouth swelling	1	1 (1.45)	0	0 (0.00)
Neutropenic colitis	1	1 (1.45)	1	1 (1.45)
Odynophagia	1	1 (1.45)	0	0 (0.00)
Trichoglossia	1	1 (1.45)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.45)	0	0 (0.00)
General disorders and administration site conditions				
- Total	142	48 (69.57)	24	15 (21.74)
Pyrexia	58	31 (44.93)	12	11 (15.94)
Fatigue	19	17 (24.64)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Chills	10	7 (10.14)	0	0 (0.00)
Oedema peripheral	9	7 (10.14)	2	1 (1.45)
Face oedema	8	7 (10.14)	1	1 (1.45)
Generalised oedema	5	5 (7.25)	0	0 (0.00)
Catheter site pain	4	2 (2.90)	2	1 (1.45)
Multiple organ dysfunction syndrome	3	3 (4.35)	3	3 (4.35)
Pain	3	3 (4.35)	2	2 (2.90)
Asthenia	2	2 (2.90)	0	0 (0.00)
Catheter site erythema	2	1 (1.45)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.90)	0	0 (0.00)
Localised oedema	2	2 (2.90)	0	0 (0.00)
Malaise	2	2 (2.90)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.90)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.45)	0	0 (0.00)
Chest discomfort	1	1 (1.45)	1	1 (1.45)
Crying	1	1 (1.45)	0	0 (0.00)
Facial pain	1	1 (1.45)	0	0 (0.00)
Influenza like illness	1	1 (1.45)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.45)	0	0 (0.00)
Sluggishness	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Swelling face	1	1 (1.45)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.45)	1	1 (1.45)
Vascular device occlusion	1	1 (1.45)	0	0 (0.00)
Xerosis	1	1 (1.45)	0	0 (0.00)
Hepatobiliary disorders				
- Total	31	18 (26.09)	7	6 (8.70)
Hepatic function abnormal	11	5 (7.25)	4	3 (4.35)
Hyperbilirubinaemia	6	5 (7.25)	1	1 (1.45)
Hepatomegaly	3	3 (4.35)	1	1 (1.45)
Hypertransaminasaemia	3	2 (2.90)	0	0 (0.00)
Cholelithiasis	2	2 (2.90)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.90)	0	0 (0.00)
Biliary tract disorder	1	1 (1.45)	0	0 (0.00)
Cholestasis	1	1 (1.45)	1	1 (1.45)
Liver disorder	1	1 (1.45)	0	0 (0.00)
Ocular icterus	1	1 (1.45)	0	0 (0.00)
Immune system disorders				
- Total	175	63 (91.30)	70	42 (60.87)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Cytokine release syndrome	116	55 (79.71)	51	36 (52.17)
Hypogammaglobulinaemia	34	27 (39.13)	5	5 (7.25)
Haemophagocytic lymphohistiocytosis	6	6 (8.70)	4	4 (5.80)
Immunodeficiency	4	4 (5.80)	4	4 (5.80)
Seasonal allergy	4	4 (5.80)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.90)	1	1 (1.45)
Chronic graft versus host disease	2	2 (2.90)	1	1 (1.45)
Drug hypersensitivity	2	2 (2.90)	1	1 (1.45)
Graft versus host disease	2	2 (2.90)	2	2 (2.90)
Engraftment syndrome	1	1 (1.45)	1	1 (1.45)
Hypersensitivity	1	1 (1.45)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.45)	0	0 (0.00)
Infections and infestations				
- Total	243	53 (76.81)	95	37 (53.62)
Upper respiratory tract infection	15	12 (17.39)	2	2 (2.90)
Sinusitis	12	5 (7.25)	2	2 (2.90)
Conjunctivitis	11	7 (10.14)	0	0 (0.00)
Nasopharyngitis	9	7 (10.14)	0	0 (0.00)
Rhinovirus infection	9	8 (11.59)	1	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Bronchopulmonary aspergillosis	6	2 (2.90)	4	2 (2.90)
Gastroenteritis	6	6 (8.70)	2	2 (2.90)
Otitis media	6	5 (7.25)	1	1 (1.45)
Staphylococcal bacteraemia	6	5 (7.25)	6	5 (7.25)
Candida infection	5	4 (5.80)	2	1 (1.45)
Oral herpes	5	4 (5.80)	1	1 (1.45)
Parainfluenzae virus infection	5	4 (5.80)	2	2 (2.90)
Pneumonia	5	5 (7.25)	4	4 (5.80)
Bacteraemia	4	3 (4.35)	3	2 (2.90)
Clostridium difficile infection	4	4 (5.80)	3	3 (4.35)
Ear infection	4	3 (4.35)	1	1 (1.45)
Nail infection	4	4 (5.80)	0	0 (0.00)
Oral candidiasis	4	3 (4.35)	0	0 (0.00)
Staphylococcal infection	4	4 (5.80)	2	2 (2.90)
COVID-19	3	2 (2.90)	1	1 (1.45)
Fungal infection	3	2 (2.90)	0	0 (0.00)
Gastroenteritis viral	3	2 (2.90)	0	0 (0.00)
Herpes zoster	3	3 (4.35)	2	2 (2.90)
Influenza	3	3 (4.35)	1	1 (1.45)
Klebsiella infection	3	1 (1.45)	3	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Metapneumovirus infection	3	3 (4.35)	3	3 (4.35)
Otitis externa	3	3 (4.35)	1	1 (1.45)
Skin infection	3	3 (4.35)	0	0 (0.00)
Urinary tract infection	3	2 (2.90)	2	1 (1.45)
Acute sinusitis	2	2 (2.90)	0	0 (0.00)
Adenovirus infection	2	2 (2.90)	2	2 (2.90)
BK virus infection	2	2 (2.90)	1	1 (1.45)
Bronchitis	2	2 (2.90)	0	0 (0.00)
Device related sepsis	2	1 (1.45)	2	1 (1.45)
Encephalitis viral	2	2 (2.90)	2	2 (2.90)
Gingivitis	2	2 (2.90)	0	0 (0.00)
Herpes simplex	2	2 (2.90)	1	1 (1.45)
Human herpesvirus 6 infection	2	2 (2.90)	2	2 (2.90)
Oral infection	2	2 (2.90)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.90)	2	2 (2.90)
Respiratory syncytial virus infection	2	2 (2.90)	1	1 (1.45)
Respiratory tract infection	2	2 (2.90)	0	0 (0.00)
Rhinitis	2	2 (2.90)	0	0 (0.00)
Sepsis	2	2 (2.90)	2	2 (2.90)
Septic shock	2	2 (2.90)	2	2 (2.90)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Viral infection	2	2 (2.90)	1	1 (1.45)
Anal abscess	1	1 (1.45)	1	1 (1.45)
Atypical pneumonia	1	1 (1.45)	0	0 (0.00)
Bronchiolitis	1	1 (1.45)	1	1 (1.45)
COVID-19 pneumonia	1	1 (1.45)	1	1 (1.45)
Cellulitis	1	1 (1.45)	0	0 (0.00)
Cholecystitis infective	1	1 (1.45)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.45)	1	1 (1.45)
Coronavirus infection	1	1 (1.45)	1	1 (1.45)
Cystitis	1	1 (1.45)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.45)	1	1 (1.45)
Device related infection	1	1 (1.45)	1	1 (1.45)
Ear, nose and throat infection	1	1 (1.45)	0	0 (0.00)
Encephalitis	1	1 (1.45)	1	1 (1.45)
Enterobacter infection	1	1 (1.45)	1	1 (1.45)
Enterovirus infection	1	1 (1.45)	1	1 (1.45)
Folliculitis	1	1 (1.45)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.45)	1	1 (1.45)
Gastroenteritis clostridial	1	1 (1.45)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Gastroenteritis salmonella	1	1 (1.45)	1	1 (1.45)
Gastrointestinal infection	1	1 (1.45)	0	0 (0.00)
Granulicatella infection	1	1 (1.45)	1	1 (1.45)
Herpes virus infection	1	1 (1.45)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.45)	0	0 (0.00)
Localised infection	1	1 (1.45)	0	0 (0.00)
Mastoiditis	1	1 (1.45)	1	1 (1.45)
Meningitis bacterial	1	1 (1.45)	1	1 (1.45)
Meningitis pneumococcal	1	1 (1.45)	1	1 (1.45)
Molluscum contagiosum	1	1 (1.45)	0	0 (0.00)
Myringitis	1	1 (1.45)	0	0 (0.00)
Neutropenic infection	1	1 (1.45)	1	1 (1.45)
Ophthalmic herpes zoster	1	1 (1.45)	0	0 (0.00)
Otitis media acute	1	1 (1.45)	0	0 (0.00)
Paronychia	1	1 (1.45)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.45)	1	1 (1.45)
Pneumonia fungal	1	1 (1.45)	1	1 (1.45)
Pneumonia respiratory syncytial viral	1	1 (1.45)	1	1 (1.45)
Pneumonia viral	1	1 (1.45)	1	1 (1.45)
Respiratory tract infection viral	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Salmonellosis	1	1 (1.45)	0	0 (0.00)
Sinusitis fungal	1	1 (1.45)	1	1 (1.45)
Soft tissue infection	1	1 (1.45)	1	1 (1.45)
Staphylococcal abscess	1	1 (1.45)	1	1 (1.45)
Staphylococcal sepsis	1	1 (1.45)	1	1 (1.45)
Staphylococcal skin infection	1	1 (1.45)	0	0 (0.00)
Stomatococcal infection	1	1 (1.45)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.45)	0	0 (0.00)
Syphilis	1	1 (1.45)	0	0 (0.00)
Systemic candida	1	1 (1.45)	1	1 (1.45)
Tinea pedis	1	1 (1.45)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.45)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.45)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.45)	1	1 (1.45)
Viral skin infection	1	1 (1.45)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.45)	1	1 (1.45)
Injury, poisoning and procedural complications				
- Total	32	20 (28.99)	4	3 (4.35)
Infusion related reaction	7	4 (5.80)	1	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Contusion	3	2 (2.90)	0	0 (0.00)
Wound	3	2 (2.90)	1	1 (1.45)
Fall	2	2 (2.90)	0	0 (0.00)
Ligament sprain	2	2 (2.90)	0	0 (0.00)
Procedural pain	2	2 (2.90)	0	0 (0.00)
Skin abrasion	2	2 (2.90)	0	0 (0.00)
Transfusion reaction	2	2 (2.90)	0	0 (0.00)
Abdominal injury	1	1 (1.45)	0	0 (0.00)
Fibula fracture	1	1 (1.45)	0	0 (0.00)
Limb injury	1	1 (1.45)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.45)	0	0 (0.00)
Scratch	1	1 (1.45)	0	0 (0.00)
Skin injury	1	1 (1.45)	0	0 (0.00)
Skin wound	1	1 (1.45)	0	0 (0.00)
Transplant failure	1	1 (1.45)	1	1 (1.45)
Vasoplegia syndrome	1	1 (1.45)	1	1 (1.45)
Investigations				
- Total	464	53 (76.81)	216	42 (60.87)
Platelet count decreased	80	21 (30.43)	44	12 (17.39)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Neutrophil count decreased	67	22 (31.88)	47	19 (27.54)
White blood cell count decreased	67	24 (34.78)	39	17 (24.64)
Lymphocyte count decreased	33	15 (21.74)	23	13 (18.84)
Aspartate aminotransferase increased	32	18 (26.09)	13	11 (15.94)
Alanine aminotransferase increased	24	15 (21.74)	6	6 (8.70)
Blood bilirubin increased	24	12 (17.39)	9	8 (11.59)
International normalised ratio increased	12	9 (13.04)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.90)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (8.70)	1	1 (1.45)
Blood creatinine increased	7	5 (7.25)	5	3 (4.35)
Blood immunoglobulin A decreased	7	7 (10.14)	1	1 (1.45)
Blood immunoglobulin M decreased	7	7 (10.14)	2	2 (2.90)
Serum ferritin increased	7	7 (10.14)	1	1 (1.45)
Weight increased	7	4 (5.80)	2	2 (2.90)
Blood fibrinogen decreased	6	6 (8.70)	1	1 (1.45)
Electrocardiogram QT prolonged	6	5 (7.25)	2	2 (2.90)
Blood lactate dehydrogenase increased	5	5 (7.25)	1	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Blood creatine phosphokinase increased	4	2 (2.90)	2	2 (2.90)
Blood immunoglobulin G decreased	4	4 (5.80)	0	0 (0.00)
C-reactive protein increased	4	4 (5.80)	2	2 (2.90)
Lipase increased	4	2 (2.90)	2	1 (1.45)
Blood uric acid increased	3	3 (4.35)	1	1 (1.45)
Fibrin D dimer increased	3	3 (4.35)	1	1 (1.45)
Oxygen saturation decreased	3	3 (4.35)	1	1 (1.45)
Urine output decreased	3	2 (2.90)	3	2 (2.90)
Blood glucose increased	2	1 (1.45)	2	1 (1.45)
Haemoglobin decreased	2	1 (1.45)	1	1 (1.45)
Amylase increased	1	1 (1.45)	0	0 (0.00)
Bacterial test positive	1	1 (1.45)	1	1 (1.45)
Blood alkaline phosphatase increased	1	1 (1.45)	0	0 (0.00)
Blood bicarbonate decreased	1	1 (1.45)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.45)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (1.45)	0	0 (0.00)
Blood urea increased	1	1 (1.45)	1	1 (1.45)
Bone density decreased	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Breath sounds abnormal	1	1 (1.45)	0	0 (0.00)
Cardiac murmur	1	1 (1.45)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.45)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.45)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.45)	0	0 (0.00)
Enterovirus test positive	1	1 (1.45)	0	0 (0.00)
Gamma-glutamyltransferase increased	1	1 (1.45)	1	1 (1.45)
Haptoglobin decreased	1	1 (1.45)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.45)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.45)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.45)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.45)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.45)	0	0 (0.00)
Troponin increased	1	1 (1.45)	1	1 (1.45)
Weight decreased	1	1 (1.45)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	235	48 (69.57)	86	31 (44.93)
Hypokalaemia	46	20 (28.99)	24	11 (15.94)
Hypophosphataemia	30	16 (23.19)	10	8 (11.59)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Decreased appetite	28	28 (40.58)	11	11 (15.94)
Hypocalcaemia	24	16 (23.19)	6	5 (7.25)
Hypoalbuminaemia	19	11 (15.94)	1	1 (1.45)
Hyperglycaemia	12	9 (13.04)	5	5 (7.25)
Hyperuricaemia	12	9 (13.04)	1	1 (1.45)
Hypervolaemia	7	7 (10.14)	5	5 (7.25)
Hypomagnesaemia	7	6 (8.70)	0	0 (0.00)
Hyperphosphataemia	5	5 (7.25)	1	1 (1.45)
Tumour lysis syndrome	5	5 (7.25)	5	5 (7.25)
Hypercalcaemia	4	3 (4.35)	2	2 (2.90)
Metabolic acidosis	4	4 (5.80)	3	3 (4.35)
Acidosis	3	2 (2.90)	2	2 (2.90)
Hyperkalaemia	3	3 (4.35)	2	2 (2.90)
Hypermagnesaemia	3	2 (2.90)	0	0 (0.00)
Hypernatraemia	3	3 (4.35)	2	2 (2.90)
Hyponatraemia	3	3 (4.35)	0	0 (0.00)
Hyperchloraemia	2	2 (2.90)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (2.90)	2	2 (2.90)
Malnutrition	2	2 (2.90)	2	2 (2.90)
Calcium deficiency	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Dehydration	1	1 (1.45)	0	0 (0.00)
Haemosiderosis	1	1 (1.45)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.45)	0	0 (0.00)
Hyperlipidaemia	1	1 (1.45)	0	0 (0.00)
Hypoglycaemia	1	1 (1.45)	0	0 (0.00)
Hypophagia	1	1 (1.45)	0	0 (0.00)
Iron overload	1	1 (1.45)	0	0 (0.00)
Metabolic syndrome	1	1 (1.45)	0	0 (0.00)
Obesity	1	1 (1.45)	1	1 (1.45)
Polydipsia	1	1 (1.45)	1	1 (1.45)
Musculoskeletal and connective tissue disorders				
- Total	78	41 (59.42)	9	8 (11.59)
Pain in extremity	18	17 (24.64)	1	1 (1.45)
Arthralgia	13	11 (15.94)	1	1 (1.45)
Back pain	12	8 (11.59)	3	3 (4.35)
Myalgia	11	10 (14.49)	0	0 (0.00)
Bone pain	6	4 (5.80)	0	0 (0.00)
Growth retardation	2	2 (2.90)	0	0 (0.00)
Muscular weakness	2	2 (2.90)	1	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Musculoskeletal chest pain	2	2 (2.90)	0	0 (0.00)
Neck pain	2	2 (2.90)	0	0 (0.00)
Pain in jaw	2	2 (2.90)	1	1 (1.45)
Haemarthrosis	1	1 (1.45)	1	1 (1.45)
Muscle rigidity	1	1 (1.45)	0	0 (0.00)
Muscle spasms	1	1 (1.45)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.45)	0	0 (0.00)
Myositis	1	1 (1.45)	0	0 (0.00)
Osteonecrosis	1	1 (1.45)	0	0 (0.00)
Osteopenia	1	1 (1.45)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.45)	1	1 (1.45)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	6	5 (7.25)	2	2 (2.90)
Bone giant cell tumour benign	2	1 (1.45)	1	1 (1.45)
Skin papilloma	2	2 (2.90)	0	0 (0.00)
Cancer pain	1	1 (1.45)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.45)	1	1 (1.45)
Nervous system disorders				

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
- Total	98	42 (60.87)	19	12 (17.39)
Headache	35	24 (34.78)	2	2 (2.90)
Encephalopathy	8	8 (11.59)	4	4 (5.80)
Tremor	7	6 (8.70)	0	0 (0.00)
Seizure	6	3 (4.35)	2	2 (2.90)
Cognitive disorder	5	3 (4.35)	1	1 (1.45)
Dizziness	5	4 (5.80)	0	0 (0.00)
Somnolence	5	5 (7.25)	2	2 (2.90)
Dysgeusia	3	3 (4.35)	0	0 (0.00)
Hydrocephalus	3	1 (1.45)	3	1 (1.45)
Lethargy	3	3 (4.35)	0	0 (0.00)
Hyperaesthesia	2	1 (1.45)	0	0 (0.00)
Migraine	2	1 (1.45)	0	0 (0.00)
Nervous system disorder	2	1 (1.45)	1	1 (1.45)
Amnesia	1	1 (1.45)	0	0 (0.00)
Aphasia	1	1 (1.45)	0	0 (0.00)
Cerebral haemorrhage	1	1 (1.45)	1	1 (1.45)
Depressed level of consciousness	1	1 (1.45)	1	1 (1.45)
Disturbance in attention	1	1 (1.45)	0	0 (0.00)
Dysarthria	1	1 (1.45)	1	1 (1.45)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Extrapyramidal disorder	1	1 (1.45)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (1.45)	0	0 (0.00)
Hypoaesthesia	1	1 (1.45)	0	0 (0.00)
Monoparesis	1	1 (1.45)	0	0 (0.00)
Neurological decompensation	1	1 (1.45)	1	1 (1.45)
Paraesthesia	1	1 (1.45)	0	0 (0.00)
Psychiatric disorders				
- Total	61	35 (50.72)	7	7 (10.14)
Anxiety	12	12 (17.39)	2	2 (2.90)
Delirium	8	8 (11.59)	3	3 (4.35)
Agitation	7	6 (8.70)	0	0 (0.00)
Confusional state	6	6 (8.70)	0	0 (0.00)
Mental status changes	5	5 (7.25)	2	2 (2.90)
Insomnia	4	4 (5.80)	0	0 (0.00)
Hallucination	3	3 (4.35)	0	0 (0.00)
Irritability	3	3 (4.35)	0	0 (0.00)
Sleep disorder	3	2 (2.90)	0	0 (0.00)
Affect lability	1	1 (1.45)	0	0 (0.00)
Automatism	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Hallucination, visual	1	1 (1.45)	0	0 (0.00)
Mood altered	1	1 (1.45)	0	0 (0.00)
Nightmare	1	1 (1.45)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.45)	0	0 (0.00)
Restlessness	1	1 (1.45)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.45)	0	0 (0.00)
Tearfulness	1	1 (1.45)	0	0 (0.00)
Tic	1	1 (1.45)	0	0 (0.00)
Renal and urinary disorders				
- Total	47	24 (34.78)	15	11 (15.94)
Acute kidney injury	17	12 (17.39)	9	8 (11.59)
Dysuria	4	4 (5.80)	0	0 (0.00)
Renal failure	4	2 (2.90)	3	1 (1.45)
Haematuria	3	3 (4.35)	1	1 (1.45)
Anuria	2	2 (2.90)	1	1 (1.45)
Pollakiuria	2	2 (2.90)	0	0 (0.00)
Urinary incontinence	2	1 (1.45)	0	0 (0.00)
Urinary retention	2	2 (2.90)	0	0 (0.00)
Azotaemia	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Bladder dilatation	1	1 (1.45)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.45)	0	0 (0.00)
Incontinence	1	1 (1.45)	0	0 (0.00)
Kidney enlargement	1	1 (1.45)	0	0 (0.00)
Micturition urgency	1	1 (1.45)	0	0 (0.00)
Proteinuria	1	1 (1.45)	0	0 (0.00)
Renal mass	1	1 (1.45)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.45)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.45)	1	1 (1.45)
Urinary tract disorder	1	1 (1.45)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	7	4 (5.80)	1	1 (1.45)
Dysmenorrhoea	2	1 (1.45)	0	0 (0.00)
Vaginal haemorrhage	2	1 (1.45)	0	0 (0.00)
Female genital tract fistula	1	1 (1.45)	0	0 (0.00)
Perineal rash	1	1 (1.45)	0	0 (0.00)
Vaginal ulceration	1	1 (1.45)	1	1 (1.45)
Respiratory, thoracic and mediastinal disorders				

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
- Total	178	51 (73.91)	62	29 (42.03)
Cough	27	22 (31.88)	0	0 (0.00)
Hypoxia	27	20 (28.99)	22	16 (23.19)
Pulmonary oedema	12	12 (17.39)	7	7 (10.14)
Tachypnoea	11	9 (13.04)	6	5 (7.25)
Nasal congestion	10	9 (13.04)	0	0 (0.00)
Pleural effusion	10	9 (13.04)	3	3 (4.35)
Oropharyngeal pain	9	8 (11.59)	0	0 (0.00)
Dyspnoea	8	7 (10.14)	4	4 (5.80)
Rhinorrhoea	8	6 (8.70)	0	0 (0.00)
Epistaxis	7	6 (8.70)	1	1 (1.45)
Respiratory failure	6	6 (8.70)	6	6 (8.70)
Atelectasis	5	3 (4.35)	2	2 (2.90)
Respiratory distress	5	4 (5.80)	3	2 (2.90)
Acute respiratory distress syndrome	3	3 (4.35)	3	3 (4.35)
Lung infiltration	2	1 (1.45)	1	1 (1.45)
Pharyngeal erythema	2	2 (2.90)	0	0 (0.00)
Rhinitis allergic	2	2 (2.90)	0	0 (0.00)
Sleep apnoea syndrome	2	2 (2.90)	0	0 (0.00)
Wheezing	2	2 (2.90)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Acute respiratory failure	1	1 (1.45)	1	1 (1.45)
Bradypnoea	1	1 (1.45)	1	1 (1.45)
Bronchial oedema	1	1 (1.45)	0	0 (0.00)
Bronchospasm	1	1 (1.45)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.45)	0	0 (0.00)
Haemoptysis	1	1 (1.45)	0	0 (0.00)
Laryngeal oedema	1	1 (1.45)	1	1 (1.45)
Nasal discomfort	1	1 (1.45)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.45)	0	0 (0.00)
Painful respiration	1	1 (1.45)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.45)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.45)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.45)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (1.45)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.45)	0	0 (0.00)
Productive cough	1	1 (1.45)	0	0 (0.00)
Pulmonary mass	1	1 (1.45)	0	0 (0.00)
Respiratory acidosis	1	1 (1.45)	1	1 (1.45)
Respiratory disorder	1	1 (1.45)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.45)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	90	36 (52.17)	9	7 (10.14)
Rash	11	7 (10.14)	0	0 (0.00)
Dry skin	9	8 (11.59)	0	0 (0.00)
Pruritus	9	7 (10.14)	0	0 (0.00)
Blister	6	3 (4.35)	0	0 (0.00)
Erythema	5	5 (7.25)	0	0 (0.00)
Dermatitis atopic	4	3 (4.35)	1	1 (1.45)
Rash maculo-papular	4	3 (4.35)	1	1 (1.45)
Rash papular	4	3 (4.35)	0	0 (0.00)
Eczema	3	3 (4.35)	1	1 (1.45)
Hyperhidrosis	3	3 (4.35)	0	0 (0.00)
Decubitus ulcer	2	2 (2.90)	1	1 (1.45)
Ingrowing nail	2	2 (2.90)	0	0 (0.00)
Petechiae	2	2 (2.90)	1	1 (1.45)
Rash macular	2	1 (1.45)	2	1 (1.45)
Rash vesicular	2	1 (1.45)	0	0 (0.00)
Skin discolouration	2	2 (2.90)	0	0 (0.00)
Skin ulcer	2	2 (2.90)	0	0 (0.00)

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
Dermatitis	1	1 (1.45)	0	0 (0.00)
Dermatitis diaper	1	1 (1.45)	0	0 (0.00)
Erythema nodosum	1	1 (1.45)	0	0 (0.00)
Hangnail	1	1 (1.45)	0	0 (0.00)
Miliaria	1	1 (1.45)	0	0 (0.00)
Night sweats	1	1 (1.45)	0	0 (0.00)
Papule	1	1 (1.45)	0	0 (0.00)
Pruritus allergic	1	1 (1.45)	0	0 (0.00)
Purpura	1	1 (1.45)	0	0 (0.00)
Rash erythematous	1	1 (1.45)	0	0 (0.00)
Rash pruritic	1	1 (1.45)	0	0 (0.00)
Scab	1	1 (1.45)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.45)	0	0 (0.00)
Skin lesion	1	1 (1.45)	0	0 (0.00)
Skin necrosis	1	1 (1.45)	1	1 (1.45)
Skin swelling	1	1 (1.45)	0	0 (0.00)
Urticaria	1	1 (1.45)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.45)	1	1 (1.45)
Social circumstances				

Timing: At anytime, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All grades Total events	All patients N=69 n (%)[1]	Grade >= 3 Total events	All patients N=69 n (%)[2]
- Total	1	1 (1.45)	0	0 (0.00)
Patient uncooperative	1	1 (1.45)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.45)	1	1 (1.45)
Thrombolysis	1	1 (1.45)	1	1 (1.45)
Vascular disorders				
- Total	51	31 (44.93)	26	20 (28.99)
Hypotension	28	23 (33.33)	19	16 (23.19)
Hypertension	15	14 (20.29)	4	4 (5.80)
Capillary leak syndrome	2	2 (2.90)	1	1 (1.45)
Venoocclusive disease	2	2 (2.90)	2	2 (2.90)
Flushing	1	1 (1.45)	0	0 (0.00)
Hot flush	1	1 (1.45)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.45)	0	0 (0.00)
Thrombosis	1	1 (1.45)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	214	6 (100.00)	66	6 (100.00)
Blood and lymphatic system disorders				
- Total	11	4 (66.67)	5	3 (50.00)
Anaemia	5	2 (33.33)	2	1 (16.67)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Disseminated intravascular coagulation	2	2 (33.33)	0	0 (0.00)
Splenomegaly	1	1 (16.67)	0	0 (0.00)
Cardiac disorders				
- Total	4	3 (50.00)	1	1 (16.67)
Tachycardia	3	2 (33.33)	1	1 (16.67)
Bradycardia	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Ear pruritus	1	1 (16.67)	0	0 (0.00)
Eye disorders				
- Total	4	2 (33.33)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (33.33)	0	0 (0.00)
Ocular hyperaemia	1	1 (16.67)	0	0 (0.00)
Periorbital oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	12	5 (83.33)	2	2 (33.33)
Diarrhoea	4	2 (33.33)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (16.67)	1	1 (16.67)
Anal fissure	1	1 (16.67)	0	0 (0.00)
Constipation	1	1 (16.67)	0	0 (0.00)
Dysphagia	1	1 (16.67)	1	1 (16.67)
Enterocolitis	1	1 (16.67)	0	0 (0.00)
Gingival erythema	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Vomiting	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	8	2 (33.33)	0	0 (0.00)
Face oedema	2	2 (33.33)	0	0 (0.00)
Generalised oedema	2	2 (33.33)	0	0 (0.00)
Chills	1	1 (16.67)	0	0 (0.00)
Fatigue	1	1 (16.67)	0	0 (0.00)
Localised oedema	1	1 (16.67)	0	0 (0.00)
Pyrexia	1	1 (16.67)	0	0 (0.00)
Hepatobiliary disorders				
- Total	7	2 (33.33)	2	1 (16.67)
Hepatic function abnormal	4	1 (16.67)	2	1 (16.67)
Hyperbilirubinaemia	2	1 (16.67)	0	0 (0.00)
Hypertransaminasaemia	1	1 (16.67)	0	0 (0.00)
Immune system disorders				
- Total	13	6 (100.00)	6	4 (66.67)
Cytokine release syndrome	10	6 (100.00)	5	3 (50.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=6** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=6** **n (%)[2]**
Hypogammaglobulinaemia	2	2 (33.33)	1	1 (16.67)
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	2	2 (33.33)	0	0 (0.00)
Otitis externa	1	1 (16.67)	0	0 (0.00)
Staphylococcal infection	1	1 (16.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	5	2 (33.33)	0	0 (0.00)
Contusion	2	1 (16.67)	0	0 (0.00)
Skin abrasion	1	1 (16.67)	0	0 (0.00)
Transfusion reaction	1	1 (16.67)	0	0 (0.00)
Wound	1	1 (16.67)	0	0 (0.00)
Investigations				
- Total	50	6 (100.00)	26	6 (100.00)
Platelet count decreased	11	3 (50.00)	5	2 (33.33)
White blood cell count decreased	9	4 (66.67)	7	3 (50.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Blood creatinine increased	4	2 (33.33)	4	2 (33.33)
Blood creatine phosphokinase increased	3	1 (16.67)	1	1 (16.67)
Neutrophil count decreased	3	2 (33.33)	3	2 (33.33)
Urine output decreased	3	2 (33.33)	3	2 (33.33)
Alanine aminotransferase increased	2	2 (33.33)	0	0 (0.00)
Serum ferritin increased	2	2 (33.33)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (16.67)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (16.67)	1	1 (16.67)
Blood bicarbonate decreased	1	1 (16.67)	0	0 (0.00)
Blood bilirubin increased	1	1 (16.67)	1	1 (16.67)
Blood fibrinogen decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (16.67)	1	1 (16.67)
Blood uric acid increased	1	1 (16.67)	0	0 (0.00)
Cardiac murmur	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Oxygen saturation decreased	1	1 (16.67)	0	0 (0.00)
Weight increased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	36	6 (100.00)	8	3 (50.00)
Hypocalcaemia	7	4 (66.67)	0	0 (0.00)
Hypoalbuminaemia	6	2 (33.33)	0	0 (0.00)
Hypophosphataemia	5	3 (50.00)	0	0 (0.00)
Hypokalaemia	4	3 (50.00)	1	1 (16.67)
Decreased appetite	2	2 (33.33)	2	2 (33.33)
Hypermagnesaemia	2	1 (16.67)	0	0 (0.00)
Hyperphosphataemia	2	2 (33.33)	0	0 (0.00)
Hypercalcaemia	1	1 (16.67)	1	1 (16.67)
Hyperchloraemia	1	1 (16.67)	0	0 (0.00)
Hyperglycaemia	1	1 (16.67)	1	1 (16.67)
Hyperkalaemia	1	1 (16.67)	1	1 (16.67)
Hypervolaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Metabolic acidosis	1	1 (16.67)	1	1 (16.67)
Tumour lysis syndrome	1	1 (16.67)	1	1 (16.67)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (33.33)	0	0 (0.00)
Muscle rigidity	1	1 (16.67)	0	0 (0.00)
Myalgia	1	1 (16.67)	0	0 (0.00)
Nervous system disorders				
- Total	7	2 (33.33)	3	2 (33.33)
Headache	2	1 (16.67)	0	0 (0.00)
Cerebral haemorrhage	1	1 (16.67)	1	1 (16.67)
Encephalopathy	1	1 (16.67)	1	1 (16.67)
Generalised tonic-clonic seizure	1	1 (16.67)	0	0 (0.00)
Somnolence	1	1 (16.67)	1	1 (16.67)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	8	2 (33.33)	1	1 (16.67)
Agitation	2	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Automatism	1	1 (16.67)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Delirium	1	1 (16.67)	0	0 (0.00)
Insomnia	1	1 (16.67)	0	0 (0.00)
Irritability	1	1 (16.67)	0	0 (0.00)
Mental status changes	1	1 (16.67)	1	1 (16.67)
Renal and urinary disorders				
- Total	7	3 (50.00)	3	3 (50.00)
Acute kidney injury	5	3 (50.00)	3	3 (50.00)
Anuria	1	1 (16.67)	0	0 (0.00)
Azotaemia	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Perineal rash	1	1 (16.67)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	17	5 (83.33)	5	3 (50.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Hypoxia	4	3 (50.00)	3	2 (33.33)
Pleural effusion	3	3 (50.00)	1	1 (16.67)
Epistaxis	2	2 (33.33)	0	0 (0.00)
Pulmonary oedema	2	2 (33.33)	0	0 (0.00)
Tachypnoea	2	1 (16.67)	1	1 (16.67)
Cough	1	1 (16.67)	0	0 (0.00)
Nasal discomfort	1	1 (16.67)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (16.67)	0	0 (0.00)
Respiratory distress	1	1 (16.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	11	4 (66.67)	0	0 (0.00)
Blister	5	2 (33.33)	0	0 (0.00)
Dermatitis diaper	1	1 (16.67)	0	0 (0.00)
Erythema	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	0	0 (0.00)
Scab	1	1 (16.67)	0	0 (0.00)
Skin discolouration	1	1 (16.67)	0	0 (0.00)
Skin ulcer	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Vascular disorders				
- Total	8	4 (66.67)	4	3 (50.00)
Hypotension	4	3 (50.00)	4	3 (50.00)
Hypertension	3	3 (50.00)	0	0 (0.00)
Thrombosis	1	1 (16.67)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	1537	73 (98.65)	553	61 (82.43)
Blood and lymphatic system disorders				
- Total	114	46 (62.16)	71	36 (48.65)
Anaemia	45	19 (25.68)	18	7 (9.46)
Febrile neutropenia	26	23 (31.08)	26	23 (31.08)
Neutropenia	11	9 (12.16)	9	7 (9.46)
Thrombocytopenia	8	8 (10.81)	8	8 (10.81)
Coagulopathy	5	5 (6.76)	2	2 (2.70)
Disseminated intravascular coagulation	5	5 (6.76)	2	2 (2.70)
Leukopenia	4	3 (4.05)	3	2 (2.70)
Splenomegaly	3	3 (4.05)	0	0 (0.00)
Eosinophilia	2	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Pancytopenia	2	2 (2.70)	2	2 (2.70)
B-cell aplasia	1	1 (1.35)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.35)	0	0 (0.00)
Lymphopenia	1	1 (1.35)	1	1 (1.35)
Cardiac disorders				
- Total	41	21 (28.38)	9	7 (9.46)
Tachycardia	19	15 (20.27)	2	2 (2.70)
Cardiac failure	4	1 (1.35)	2	1 (1.35)
Sinus tachycardia	4	3 (4.05)	0	0 (0.00)
Left ventricular dysfunction	3	3 (4.05)	3	3 (4.05)
Bradycardia	2	2 (2.70)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.70)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.35)	0	0 (0.00)
Cardiac arrest	1	1 (1.35)	1	1 (1.35)
Cardiac failure congestive	1	1 (1.35)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.35)	0	0 (0.00)
Pericardial effusion	1	1 (1.35)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Sinus bradycardia	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Ear pain	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	5	5 (6.76)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.41)	0	0 (0.00)
Hypothyroidism	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	11	7 (9.46)	0	0 (0.00)
Eyelid oedema	3	2 (2.70)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.35)	0	0 (0.00)
Eye oedema	1	1 (1.35)	0	0 (0.00)
Eye pain	1	1 (1.35)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.35)	0	0 (0.00)
Periorbital swelling	1	1 (1.35)	0	0 (0.00)
Visual field defect	1	1 (1.35)	0	0 (0.00)
Visual impairment	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastrointestinal disorders				
- Total	123	46 (62.16)	14	12 (16.22)
Vomiting	29	20 (27.03)	1	1 (1.35)
Nausea	20	17 (22.97)	2	2 (2.70)
Diarrhoea	14	13 (17.57)	1	1 (1.35)
Abdominal pain	13	11 (14.86)	2	2 (2.70)
Constipation	10	10 (13.51)	0	0 (0.00)
Mouth haemorrhage	4	4 (5.41)	2	2 (2.70)
Pancreatitis	4	4 (5.41)	1	1 (1.35)
Abdominal distension	3	3 (4.05)	0	0 (0.00)
Abdominal pain upper	3	3 (4.05)	0	0 (0.00)
Ascites	3	3 (4.05)	0	0 (0.00)
Gastrointestinal sounds abnormal	2	2 (2.70)	0	0 (0.00)
Stomatitis	2	2 (2.70)	1	1 (1.35)
Anal haemorrhage	1	1 (1.35)	0	0 (0.00)
Dry mouth	1	1 (1.35)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.35)	0	0 (0.00)
Gingival bleeding	1	1 (1.35)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Haematemesis	1	1 (1.35)	0	0 (0.00)
Ileus	1	1 (1.35)	0	0 (0.00)
Lip dry	1	1 (1.35)	0	0 (0.00)
Lip oedema	1	1 (1.35)	0	0 (0.00)
Melaena	1	1 (1.35)	1	1 (1.35)
Mouth swelling	1	1 (1.35)	0	0 (0.00)
Neutropenic colitis	1	1 (1.35)	1	1 (1.35)
Odynophagia	1	1 (1.35)	0	0 (0.00)
Proctalgia	1	1 (1.35)	1	1 (1.35)
Trichoglossia	1	1 (1.35)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	104	38 (51.35)	19	11 (14.86)
Pyrexia	43	23 (31.08)	9	8 (10.81)
Fatigue	10	10 (13.51)	0	0 (0.00)
Chills	8	5 (6.76)	0	0 (0.00)
Face oedema	7	6 (8.11)	1	1 (1.35)
Oedema peripheral	7	6 (8.11)	2	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Catheter site pain	4	2 (2.70)	2	1 (1.35)
Generalised oedema	3	3 (4.05)	0	0 (0.00)
Asthenia	2	2 (2.70)	0	0 (0.00)
Catheter site erythema	2	1 (1.35)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.70)	0	0 (0.00)
Influenza like illness	2	2 (2.70)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (2.70)	2	2 (2.70)
Catheter site haemorrhage	1	1 (1.35)	0	0 (0.00)
Chest discomfort	1	1 (1.35)	1	1 (1.35)
Crying	1	1 (1.35)	0	0 (0.00)
Facial pain	1	1 (1.35)	0	0 (0.00)
Localised oedema	1	1 (1.35)	0	0 (0.00)
Malaise	1	1 (1.35)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (1.35)	0	0 (0.00)
Pain	1	1 (1.35)	1	1 (1.35)
Sluggishness	1	1 (1.35)	0	0 (0.00)
Swelling face	1	1 (1.35)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Vascular device occlusion	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	22	15 (20.27)	5	5 (6.76)
Hepatic function abnormal	7	4 (5.41)	2	2 (2.70)
Hyperbilirubinaemia	4	4 (5.41)	1	1 (1.35)
Hepatomegaly	3	3 (4.05)	1	1 (1.35)
Cholelithiasis	2	2 (2.70)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.70)	0	0 (0.00)
Biliary tract disorder	1	1 (1.35)	0	0 (0.00)
Cholestasis	1	1 (1.35)	1	1 (1.35)
Hypertransaminasaemia	1	1 (1.35)	0	0 (0.00)
Ocular icterus	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	151	61 (82.43)	62	39 (52.70)
Cytokine release syndrome	118	55 (74.32)	50	35 (47.30)
Hypogammaglobulinaemia	23	21 (28.38)	6	6 (8.11)
Haemophagocytic lymphohistiocytosis	4	4 (5.41)	3	3 (4.05)
Immunodeficiency	3	3 (4.05)	3	3 (4.05)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypersensitivity	1	1 (1.35)	0	0 (0.00)
Seasonal allergy	1	1 (1.35)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.35)	0	0 (0.00)
Infections and infestations				
- Total	62	33 (44.59)	31	19 (25.68)
Conjunctivitis	6	5 (6.76)	0	0 (0.00)
Candida infection	4	3 (4.05)	2	1 (1.35)
Clostridium difficile infection	4	4 (5.41)	3	3 (4.05)
Staphylococcal bacteraemia	4	3 (4.05)	4	3 (4.05)
Staphylococcal infection	4	4 (5.41)	2	2 (2.70)
Encephalitis viral	2	2 (2.70)	2	2 (2.70)
Nail infection	2	2 (2.70)	0	0 (0.00)
Oral candidiasis	2	1 (1.35)	0	0 (0.00)
Oral herpes	2	2 (2.70)	1	1 (1.35)
Oral infection	2	2 (2.70)	0	0 (0.00)
Rhinovirus infection	2	2 (2.70)	0	0 (0.00)
Adenovirus infection	1	1 (1.35)	1	1 (1.35)
Anal abscess	1	1 (1.35)	1	1 (1.35)
Atypical pneumonia	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
BK virus infection	1	1 (1.35)	0	0 (0.00)
Bacteraemia	1	1 (1.35)	1	1 (1.35)
Bronchopulmonary aspergillosis	1	1 (1.35)	1	1 (1.35)
Cholecystitis infective	1	1 (1.35)	0	0 (0.00)
Encephalitis	1	1 (1.35)	1	1 (1.35)
Gastroenteritis norovirus	1	1 (1.35)	0	0 (0.00)
Gingivitis	1	1 (1.35)	0	0 (0.00)
Granulicatella infection	1	1 (1.35)	1	1 (1.35)
Herpes simplex	1	1 (1.35)	1	1 (1.35)
Human herpesvirus 6 infection	1	1 (1.35)	1	1 (1.35)
Klebsiella bacteraemia	1	1 (1.35)	0	0 (0.00)
Klebsiella infection	1	1 (1.35)	1	1 (1.35)
Localised infection	1	1 (1.35)	0	0 (0.00)
Meningitis bacterial	1	1 (1.35)	1	1 (1.35)
Myringitis	1	1 (1.35)	0	0 (0.00)
Paronychia	1	1 (1.35)	0	0 (0.00)
Pneumonia	1	1 (1.35)	1	1 (1.35)
Pneumonia fungal	1	1 (1.35)	1	1 (1.35)
Pneumonia viral	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Sinusitis	1	1 (1.35)	1	1 (1.35)
Soft tissue infection	1	1 (1.35)	1	1 (1.35)
Stomatococcal infection	1	1 (1.35)	0	0 (0.00)
Systemic candida	1	1 (1.35)	1	1 (1.35)
Urinary tract infection viral	1	1 (1.35)	0	0 (0.00)
Varicella zoster virus infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	15	9 (12.16)	3	2 (2.70)
Infusion related reaction	3	2 (2.70)	0	0 (0.00)
Fall	2	2 (2.70)	0	0 (0.00)
Procedural pain	2	2 (2.70)	0	0 (0.00)
Wound	2	1 (1.35)	1	1 (1.35)
Scratch	1	1 (1.35)	0	0 (0.00)
Skin injury	1	1 (1.35)	0	0 (0.00)
Skin wound	1	1 (1.35)	0	0 (0.00)
Transfusion reaction	1	1 (1.35)	0	0 (0.00)
Transplant failure	1	1 (1.35)	1	1 (1.35)
Vasoplegia syndrome	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Investigations				
- Total	336	51 (68.92)	171	39 (52.70)
Platelet count decreased	54	18 (24.32)	33	12 (16.22)
Neutrophil count decreased	45	18 (24.32)	35	15 (20.27)
White blood cell count decreased	41	20 (27.03)	29	15 (20.27)
Aspartate aminotransferase increased	32	18 (24.32)	12	10 (13.51)
Lymphocyte count decreased	30	15 (20.27)	24	13 (17.57)
Alanine aminotransferase increased	24	16 (21.62)	6	6 (8.11)
Blood bilirubin increased	17	11 (14.86)	8	8 (10.81)
International normalised ratio increased	11	8 (10.81)	0	0 (0.00)
Activated partial thromboplastin time prolonged	7	5 (6.76)	1	1 (1.35)
Blood fibrinogen decreased	6	6 (8.11)	2	2 (2.70)
Electrocardiogram QT prolonged	6	5 (6.76)	2	2 (2.70)
Serum ferritin increased	6	6 (8.11)	2	2 (2.70)
Blood immunoglobulin M decreased	5	5 (6.76)	0	0 (0.00)
Immunoglobulins decreased	5	2 (2.70)	0	0 (0.00)
Blood immunoglobulin A decreased	4	4 (5.41)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Blood lactate dehydrogenase increased	4	4 (5.41)	1	1 (1.35)
C-reactive protein increased	4	4 (5.41)	3	3 (4.05)
Lipase increased	4	2 (2.70)	2	1 (1.35)
Fibrin D dimer increased	3	3 (4.05)	1	1 (1.35)
Weight increased	3	3 (4.05)	1	1 (1.35)
Blood creatinine increased	2	2 (2.70)	1	1 (1.35)
Blood glucose increased	2	1 (1.35)	2	1 (1.35)
Gamma-glutamyltransferase increased	2	2 (2.70)	2	2 (2.70)
Haemoglobin decreased	2	1 (1.35)	1	1 (1.35)
Amylase increased	1	1 (1.35)	0	0 (0.00)
Bacterial test positive	1	1 (1.35)	1	1 (1.35)
Blood alkaline phosphatase increased	1	1 (1.35)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.35)	1	1 (1.35)
Blood immunoglobulin G decreased	1	1 (1.35)	0	0 (0.00)
Blood phosphorus increased	1	1 (1.35)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Blood uric acid increased	1	1 (1.35)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.35)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.35)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.35)	0	0 (0.00)
Enterovirus test positive	1	1 (1.35)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.35)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.35)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.35)	0	0 (0.00)
Troponin increased	1	1 (1.35)	1	1 (1.35)
Weight decreased	1	1 (1.35)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	174	40 (54.05)	68	26 (35.14)
Hypokalaemia	36	16 (21.62)	19	10 (13.51)
Hypophosphataemia	26	14 (18.92)	11	9 (12.16)
Decreased appetite	22	22 (29.73)	9	9 (12.16)
Hypocalcaemia	17	12 (16.22)	6	5 (6.76)
Hypoalbuminaemia	13	9 (12.16)	1	1 (1.35)
Hyperglycaemia	10	7 (9.46)	3	3 (4.05)
Hyperuricaemia	9	7 (9.46)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hypomagnesaemia	7	6 (8.11)	0	0 (0.00)
Hypervolaemia	5	5 (6.76)	4	4 (5.41)
Acidosis	3	2 (2.70)	2	2 (2.70)
Hypercalcaemia	3	2 (2.70)	1	1 (1.35)
Hyperphosphataemia	3	3 (4.05)	1	1 (1.35)
Tumour lysis syndrome	3	3 (4.05)	3	3 (4.05)
Hypernatraemia	2	2 (2.70)	1	1 (1.35)
Hypertriglyceridaemia	2	2 (2.70)	2	2 (2.70)
Hyponatraemia	2	2 (2.70)	0	0 (0.00)
Metabolic acidosis	2	2 (2.70)	1	1 (1.35)
Calcium deficiency	1	1 (1.35)	0	0 (0.00)
Dehydration	1	1 (1.35)	0	0 (0.00)
Haemosiderosis	1	1 (1.35)	0	0 (0.00)
Hyperkalaemia	1	1 (1.35)	1	1 (1.35)
Hyperlactacidaemia	1	1 (1.35)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.35)	0	0 (0.00)
Hypoglycaemia	1	1 (1.35)	0	0 (0.00)
Malnutrition	1	1 (1.35)	1	1 (1.35)
Polydipsia	1	1 (1.35)	1	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	51	31 (41.89)	6	5 (6.76)
Pain in extremity	11	11 (14.86)	0	0 (0.00)
Arthralgia	10	10 (13.51)	1	1 (1.35)
Myalgia	9	8 (10.81)	0	0 (0.00)
Back pain	7	6 (8.11)	1	1 (1.35)
Bone pain	4	2 (2.70)	0	0 (0.00)
Muscular weakness	2	2 (2.70)	1	1 (1.35)
Pain in jaw	2	2 (2.70)	1	1 (1.35)
Haemarthrosis	1	1 (1.35)	1	1 (1.35)
Muscle spasms	1	1 (1.35)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.35)	0	0 (0.00)
Myositis	1	1 (1.35)	0	0 (0.00)
Neck pain	1	1 (1.35)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.35)	1	1 (1.35)
Nervous system disorders				
- Total	70	38 (51.35)	11	8 (10.81)
Headache	24	22 (29.73)	2	2 (2.70)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Encephalopathy	7	7 (9.46)	3	3 (4.05)
Tremor	6	5 (6.76)	0	0 (0.00)
Cognitive disorder	5	3 (4.05)	1	1 (1.35)
Somnolence	4	4 (5.41)	1	1 (1.35)
Dizziness	3	3 (4.05)	0	0 (0.00)
Dysgeusia	3	3 (4.05)	0	0 (0.00)
Lethargy	3	3 (4.05)	0	0 (0.00)
Seizure	3	2 (2.70)	1	1 (1.35)
Hyperaesthesia	2	1 (1.35)	0	0 (0.00)
Amnesia	1	1 (1.35)	0	0 (0.00)
Aphasia	1	1 (1.35)	0	0 (0.00)
Depressed level of consciousness	1	1 (1.35)	1	1 (1.35)
Disturbance in attention	1	1 (1.35)	0	0 (0.00)
Dysarthria	1	1 (1.35)	1	1 (1.35)
Hypoaesthesia	1	1 (1.35)	0	0 (0.00)
Monoparesis	1	1 (1.35)	0	0 (0.00)
Neuralgia	1	1 (1.35)	0	0 (0.00)
Neurological decompensation	1	1 (1.35)	1	1 (1.35)
Paraesthesia	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Psychiatric disorders				
- Total	39	26 (35.14)	5	5 (6.76)
Anxiety	6	6 (8.11)	2	2 (2.70)
Confusional state	6	6 (8.11)	0	0 (0.00)
Delirium	6	6 (8.11)	3	3 (4.05)
Agitation	4	4 (5.41)	0	0 (0.00)
Hallucination	3	3 (4.05)	0	0 (0.00)
Insomnia	3	3 (4.05)	0	0 (0.00)
Sleep disorder	3	2 (2.70)	0	0 (0.00)
Irritability	2	2 (2.70)	0	0 (0.00)
Mental status changes	2	2 (2.70)	0	0 (0.00)
Affect lability	1	1 (1.35)	0	0 (0.00)
Hallucination, visual	1	1 (1.35)	0	0 (0.00)
Restlessness	1	1 (1.35)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	32	17 (22.97)	10	6 (8.11)
Acute kidney injury	9	6 (8.11)	5	4 (5.41)
Renal failure	4	2 (2.70)	3	1 (1.35)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dysuria	3	3 (4.05)	0	0 (0.00)
Haematuria	2	2 (2.70)	0	0 (0.00)
Pollakiuria	2	2 (2.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.35)	0	0 (0.00)
Urinary retention	2	2 (2.70)	0	0 (0.00)
Anuria	1	1 (1.35)	1	1 (1.35)
Bladder dilatation	1	1 (1.35)	0	0 (0.00)
Incontinence	1	1 (1.35)	0	0 (0.00)
Micturition urgency	1	1 (1.35)	0	0 (0.00)
Proteinuria	1	1 (1.35)	0	0 (0.00)
Renal tubular dysfunction	1	1 (1.35)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.35)	1	1 (1.35)
Urinary tract disorder	1	1 (1.35)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	5	4 (5.41)	1	1 (1.35)
Vaginal haemorrhage	2	1 (1.35)	0	0 (0.00)
Female genital tract fistula	1	1 (1.35)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Vaginal ulceration	1	1 (1.35)	1	1 (1.35)
Respiratory, thoracic and mediastinal disorders				
- Total	97	36 (48.65)	45	20 (27.03)
Hypoxia	19	14 (18.92)	15	10 (13.51)
Cough	10	9 (12.16)	0	0 (0.00)
Pulmonary oedema	10	10 (13.51)	7	7 (9.46)
Tachypnoea	7	7 (9.46)	3	3 (4.05)
Oropharyngeal pain	6	5 (6.76)	0	0 (0.00)
Atelectasis	5	3 (4.05)	2	2 (2.70)
Pleural effusion	4	4 (5.41)	2	2 (2.70)
Respiratory failure	4	4 (5.41)	4	4 (5.41)
Dyspnoea	3	3 (4.05)	3	3 (4.05)
Nasal congestion	3	3 (4.05)	0	0 (0.00)
Respiratory distress	3	2 (2.70)	2	1 (1.35)
Acute respiratory distress syndrome	2	2 (2.70)	2	2 (2.70)
Epistaxis	2	2 (2.70)	1	1 (1.35)
Lung infiltration	2	1 (1.35)	1	1 (1.35)
Rhinorrhoea	2	2 (2.70)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Acute respiratory failure	1	1 (1.35)	1	1 (1.35)
Bradypnoea	1	1 (1.35)	1	1 (1.35)
Haemoptysis	1	1 (1.35)	0	0 (0.00)
Nasal dryness	1	1 (1.35)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.35)	0	0 (0.00)
Painful respiration	1	1 (1.35)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (1.35)	0	0 (0.00)
Pharyngeal erythema	1	1 (1.35)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.35)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.35)	0	0 (0.00)
Productive cough	1	1 (1.35)	0	0 (0.00)
Pulmonary mass	1	1 (1.35)	0	0 (0.00)
Respiratory acidosis	1	1 (1.35)	1	1 (1.35)
Respiratory disorder	1	1 (1.35)	0	0 (0.00)
Wheezing	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	45	23 (31.08)	4	3 (4.05)
Pruritus	7	6 (8.11)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Rash	5	5 (6.76)	0	0 (0.00)
Rash papular	4	3 (4.05)	0	0 (0.00)
Erythema	3	3 (4.05)	0	0 (0.00)
Hyperhidrosis	3	3 (4.05)	0	0 (0.00)
Rash maculo-papular	3	2 (2.70)	1	1 (1.35)
Dermatitis atopic	2	2 (2.70)	0	0 (0.00)
Rash vesicular	2	1 (1.35)	0	0 (0.00)
Blister	1	1 (1.35)	0	0 (0.00)
Decubitus ulcer	1	1 (1.35)	0	0 (0.00)
Dermatitis	1	1 (1.35)	0	0 (0.00)
Dry skin	1	1 (1.35)	0	0 (0.00)
Eczema	1	1 (1.35)	0	0 (0.00)
Erythema nodosum	1	1 (1.35)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.35)	0	0 (0.00)
Petechiae	1	1 (1.35)	1	1 (1.35)
Pruritus allergic	1	1 (1.35)	0	0 (0.00)
Purpura	1	1 (1.35)	0	0 (0.00)
Rash pruritic	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Skin lesion	1	1 (1.35)	0	0 (0.00)
Skin necrosis	1	1 (1.35)	1	1 (1.35)
Skin ulcer	1	1 (1.35)	0	0 (0.00)
Urticaria	1	1 (1.35)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.35)	1	1 (1.35)
Social circumstances				
- Total	1	1 (1.35)	0	0 (0.00)
Patient uncooperative	1	1 (1.35)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.35)	1	1 (1.35)
Thrombolysis	1	1 (1.35)	1	1 (1.35)
Vascular disorders				
- Total	37	24 (32.43)	17	14 (18.92)
Hypotension	21	18 (24.32)	12	11 (14.86)
Hypertension	11	10 (13.51)	4	4 (5.41)
Capillary leak syndrome	2	2 (2.70)	1	1 (1.35)
Flushing	1	1 (1.35)	0	0 (0.00)
Hot flush	1	1 (1.35)	0	0 (0.00)

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Peripheral ischaemia	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	50	5 (100.00)	9	4 (80.00)
Endocrine disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hypothyroidism	1	1 (20.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Constipation	1	1 (20.00)	0	0 (0.00)
Diarrhoea	1	1 (20.00)	0	0 (0.00)
Vomiting	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	3	3 (60.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Pyrexia	2	2 (40.00)	0	0 (0.00)
Fatigue	1	1 (20.00)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hypertransaminasaemia	1	1 (20.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	7	4 (80.00)	1	1 (20.00)
Nasopharyngitis	2	1 (20.00)	0	0 (0.00)
Cellulitis	1	1 (20.00)	0	0 (0.00)
Ear infection	1	1 (20.00)	0	0 (0.00)
Metapneumovirus infection	1	1 (20.00)	1	1 (20.00)
Sinusitis	1	1 (20.00)	0	0 (0.00)
Upper respiratory tract infection	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	19	4 (80.00)	7	4 (80.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Lymphocyte count decreased	4	2 (40.00)	2	2 (40.00)
Neutrophil count decreased	4	2 (40.00)	3	2 (40.00)
Weight increased	3	1 (20.00)	1	1 (20.00)
White blood cell count decreased	3	2 (40.00)	0	0 (0.00)
Alanine aminotransferase increased	2	1 (20.00)	1	1 (20.00)
Blood lactate dehydrogenase increased	1	1 (20.00)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (20.00)	0	0 (0.00)
C-reactive protein increased	1	1 (20.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Metabolic syndrome	1	1 (20.00)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (40.00)	0	0 (0.00)
Bone pain	1	1 (20.00)	0	0 (0.00)
Pain in extremity	1	1 (20.00)	0	0 (0.00)
Reproductive system and breast disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
- Total	2	1 (20.00)	0	0 (0.00)
Dysmenorrhoea	2	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	6	3 (60.00)	1	1 (20.00)
Cough	2	2 (40.00)	0	0 (0.00)
Nasal congestion	2	2 (40.00)	0	0 (0.00)
Hypoxia	1	1 (20.00)	1	1 (20.00)
Rhinitis allergic	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	3 (60.00)	0	0 (0.00)
Eczema	1	1 (20.00)	0	0 (0.00)
Miliaria	1	1 (20.00)	0	0 (0.00)
Rash	1	1 (20.00)	0	0 (0.00)
Skin swelling	1	1 (20.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Total number of AE per patient	484	64 (91.43)	137	32 (45.71)
Blood and lymphatic system disorders				
- Total	32	17 (24.29)	17	10 (14.29)
Anaemia	12	6 (8.57)	4	2 (2.86)
Neutropenia	5	5 (7.14)	5	5 (7.14)
Febrile neutropenia	4	3 (4.29)	4	3 (4.29)
B-cell aplasia	2	1 (1.43)	0	0 (0.00)
Thrombocytopenia	2	2 (2.86)	2	2 (2.86)
Disseminated intravascular coagulation	1	1 (1.43)	1	1 (1.43)
Eosinophilia	1	1 (1.43)	0	0 (0.00)
Leukocytosis	1	1 (1.43)	0	0 (0.00)
Leukopenia	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Lymphadenopathy	1	1 (1.43)	0	0 (0.00)
Lymphocytosis	1	1 (1.43)	0	0 (0.00)
Lymphopenia	1	1 (1.43)	1	1 (1.43)
Cardiac disorders				
- Total	8	7 (10.00)	4	3 (4.29)
Cardiac arrest	2	2 (2.86)	2	2 (2.86)
Cardiac failure	2	2 (2.86)	2	2 (2.86)
Tachycardia	2	2 (2.86)	0	0 (0.00)
Left ventricular dysfunction	1	1 (1.43)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (1.43)	0	0 (0.00)
Eye disorders				
- Total	5	4 (5.71)	0	0 (0.00)
Cataract	2	2 (2.86)	0	0 (0.00)
Hypermetropia	1	1 (1.43)	0	0 (0.00)
Ocular hyperaemia	1	1 (1.43)	0	0 (0.00)
Visual impairment	1	1 (1.43)	0	0 (0.00)
Gastrointestinal disorders				
- Total	35	18 (25.71)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Diarrhoea	6	6 (8.57)	0	0 (0.00)
Vomiting	6	5 (7.14)	0	0 (0.00)
Nausea	5	5 (7.14)	0	0 (0.00)
Constipation	3	2 (2.86)	0	0 (0.00)
Abdominal pain	2	2 (2.86)	0	0 (0.00)
Pancreatitis	2	2 (2.86)	1	1 (1.43)
Abdominal pain upper	1	1 (1.43)	0	0 (0.00)
Abdominal rigidity	1	1 (1.43)	0	0 (0.00)
Dyspepsia	1	1 (1.43)	0	0 (0.00)
Enteritis	1	1 (1.43)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.43)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (1.43)	0	0 (0.00)
Mouth haemorrhage	1	1 (1.43)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.43)	0	0 (0.00)
Proctalgia	1	1 (1.43)	0	0 (0.00)
Stomatitis	1	1 (1.43)	0	0 (0.00)
Trichoglossia	1	1 (1.43)	0	0 (0.00)
General disorders and administration site conditions				
- Total	28	21 (30.00)	3	3 (4.29)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Pyrexia	14	13 (18.57)	2	2 (2.86)
Fatigue	6	5 (7.14)	0	0 (0.00)
Oedema peripheral	2	1 (1.43)	0	0 (0.00)
Pain	2	2 (2.86)	1	1 (1.43)
Asthenia	1	1 (1.43)	0	0 (0.00)
Chills	1	1 (1.43)	0	0 (0.00)
Malaise	1	1 (1.43)	0	0 (0.00)
Non-cardiac chest pain	1	1 (1.43)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (2.86)	0	0 (0.00)
Hepatic cytolysis	1	1 (1.43)	0	0 (0.00)
Liver disorder	1	1 (1.43)	0	0 (0.00)
Immune system disorders				
- Total	18	15 (21.43)	5	4 (5.71)
Hypogammaglobulinaemia	11	9 (12.86)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.86)	1	1 (1.43)
Graft versus host disease	2	2 (2.86)	2	2 (2.86)
Drug hypersensitivity	1	1 (1.43)	0	0 (0.00)
Engraftment syndrome	1	1 (1.43)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Immunodeficiency	1	1 (1.43)	1	1 (1.43)
Infections and infestations				
- Total	106	35 (50.00)	44	19 (27.14)
Upper respiratory tract infection	9	7 (10.00)	2	2 (2.86)
Nasopharyngitis	7	6 (8.57)	0	0 (0.00)
Bronchopulmonary aspergillosis	5	1 (1.43)	3	1 (1.43)
Gastroenteritis	5	5 (7.14)	2	2 (2.86)
Parainfluenzae virus infection	5	4 (5.71)	2	2 (2.86)
Rhinovirus infection	5	5 (7.14)	1	1 (1.43)
Bacteraemia	3	2 (2.86)	2	1 (1.43)
Otitis media	3	3 (4.29)	1	1 (1.43)
Pneumonia	3	3 (4.29)	1	1 (1.43)
Respiratory syncytial virus infection	3	3 (4.29)	2	2 (2.86)
Respiratory tract infection	3	3 (4.29)	0	0 (0.00)
Sinusitis	3	2 (2.86)	1	1 (1.43)
Ear infection	2	1 (1.43)	0	0 (0.00)
Klebsiella infection	2	1 (1.43)	2	1 (1.43)
Metapneumovirus infection	2	2 (2.86)	2	2 (2.86)
Otitis externa	2	2 (2.86)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Pneumocystis jirovecii pneumonia	2	2 (2.86)	2	2 (2.86)
Rhinitis	2	2 (2.86)	0	0 (0.00)
Urinary tract infection	2	1 (1.43)	2	1 (1.43)
Viral infection	2	2 (2.86)	1	1 (1.43)
Acute sinusitis	1	1 (1.43)	0	0 (0.00)
Adenovirus infection	1	1 (1.43)	1	1 (1.43)
BK virus infection	1	1 (1.43)	1	1 (1.43)
Conjunctivitis	1	1 (1.43)	0	0 (0.00)
Coronavirus infection	1	1 (1.43)	1	1 (1.43)
Cystitis	1	1 (1.43)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.43)	1	1 (1.43)
Device related infection	1	1 (1.43)	1	1 (1.43)
Ear, nose and throat infection	1	1 (1.43)	0	0 (0.00)
Encephalitis	1	1 (1.43)	1	1 (1.43)
Enterobacter infection	1	1 (1.43)	1	1 (1.43)
Gastroenteritis clostridial	1	1 (1.43)	0	0 (0.00)
Gastroenteritis viral	1	1 (1.43)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.43)	0	0 (0.00)
Gingivitis	1	1 (1.43)	0	0 (0.00)
Herpes simplex	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Herpes zoster	1	1 (1.43)	1	1 (1.43)
Human herpesvirus 6 infection	1	1 (1.43)	1	1 (1.43)
Influenza	1	1 (1.43)	0	0 (0.00)
Mastoiditis	1	1 (1.43)	1	1 (1.43)
Molluscum contagiosum	1	1 (1.43)	0	0 (0.00)
Nail infection	1	1 (1.43)	0	0 (0.00)
Oral candidiasis	1	1 (1.43)	0	0 (0.00)
Oral herpes	1	1 (1.43)	0	0 (0.00)
Paronychia	1	1 (1.43)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.43)	1	1 (1.43)
Respiratory tract infection viral	1	1 (1.43)	0	0 (0.00)
Salmonellosis	1	1 (1.43)	0	0 (0.00)
Septic shock	1	1 (1.43)	1	1 (1.43)
Sinusitis fungal	1	1 (1.43)	1	1 (1.43)
Staphylococcal bacteraemia	1	1 (1.43)	1	1 (1.43)
Staphylococcal sepsis	1	1 (1.43)	1	1 (1.43)
Staphylococcal skin infection	1	1 (1.43)	0	0 (0.00)
Tinea pedis	1	1 (1.43)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (1.43)	1	1 (1.43)
Viral upper respiratory tract infection	1	1 (1.43)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Injury, poisoning and procedural complications				
- Total	10	9 (12.86)	0	0 (0.00)
Infusion related reaction	4	3 (4.29)	0	0 (0.00)
Contusion	1	1 (1.43)	0	0 (0.00)
Fibula fracture	1	1 (1.43)	0	0 (0.00)
Ligament sprain	1	1 (1.43)	0	0 (0.00)
Limb injury	1	1 (1.43)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.43)	0	0 (0.00)
Skin abrasion	1	1 (1.43)	0	0 (0.00)
Investigations				
- Total	72	26 (37.14)	28	12 (17.14)
Platelet count decreased	16	5 (7.14)	9	2 (2.86)
Neutrophil count decreased	15	8 (11.43)	8	5 (7.14)
White blood cell count decreased	15	8 (11.43)	4	4 (5.71)
Immunoglobulins decreased	5	1 (1.43)	0	0 (0.00)
Blood bilirubin increased	4	2 (2.86)	1	1 (1.43)
Blood immunoglobulin A decreased	2	2 (2.86)	1	1 (1.43)
Blood uric acid increased	2	2 (2.86)	2	2 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Lymphocyte count decreased	2	2 (2.86)	0	0 (0.00)
Alanine aminotransferase increased	1	1 (1.43)	0	0 (0.00)
Blood creatinine increased	1	1 (1.43)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (1.43)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (1.43)	1	1 (1.43)
Blood urea increased	1	1 (1.43)	1	1 (1.43)
Bone density decreased	1	1 (1.43)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.43)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.43)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.43)	0	0 (0.00)
Oxygen saturation decreased	1	1 (1.43)	0	0 (0.00)
Weight decreased	1	1 (1.43)	1	1 (1.43)
Metabolism and nutrition disorders				
- Total	25	14 (20.00)	10	7 (10.00)
Decreased appetite	6	6 (8.57)	1	1 (1.43)
Hypokalaemia	6	3 (4.29)	4	2 (2.86)
Hyperuricaemia	3	3 (4.29)	0	0 (0.00)
Haemochromatosis	1	1 (1.43)	1	1 (1.43)
Hyperchloraemia	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Hyperkalaemia	1	1 (1.43)	0	0 (0.00)
Hypervolaemia	1	1 (1.43)	1	1 (1.43)
Hypophagia	1	1 (1.43)	0	0 (0.00)
Hypophosphataemia	1	1 (1.43)	0	0 (0.00)
Iron overload	1	1 (1.43)	0	0 (0.00)
Malnutrition	1	1 (1.43)	1	1 (1.43)
Metabolic acidosis	1	1 (1.43)	1	1 (1.43)
Tumour lysis syndrome	1	1 (1.43)	1	1 (1.43)
Musculoskeletal and connective tissue disorders				
- Total	20	13 (18.57)	3	3 (4.29)
Back pain	7	6 (8.57)	2	2 (2.86)
Pain in extremity	4	4 (5.71)	1	1 (1.43)
Arthralgia	3	3 (4.29)	0	0 (0.00)
Bone pain	1	1 (1.43)	0	0 (0.00)
Growth retardation	1	1 (1.43)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (1.43)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.43)	0	0 (0.00)
Myalgia	1	1 (1.43)	0	0 (0.00)
Neck pain	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	4	4 (5.71)	1	1 (1.43)
Skin papilloma	2	2 (2.86)	0	0 (0.00)
Cancer pain	1	1 (1.43)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.43)	1	1 (1.43)
Nervous system disorders				
- Total	23	14 (20.00)	6	2 (2.86)
Headache	11	10 (14.29)	0	0 (0.00)
Hydrocephalus	3	1 (1.43)	3	1 (1.43)
Dizziness	2	1 (1.43)	0	0 (0.00)
Migraine	2	1 (1.43)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.43)	1	1 (1.43)
Cerebral haemorrhage	1	1 (1.43)	1	1 (1.43)
Extrapyramidal disorder	1	1 (1.43)	0	0 (0.00)
Memory impairment	1	1 (1.43)	0	0 (0.00)
Seizure	1	1 (1.43)	1	1 (1.43)
Psychiatric disorders				
- Total	15	10 (14.29)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Anxiety	6	6 (8.57)	0	0 (0.00)
Mental status changes	2	2 (2.86)	1	1 (1.43)
Agitation	1	1 (1.43)	0	0 (0.00)
Delirium	1	1 (1.43)	0	0 (0.00)
Mood altered	1	1 (1.43)	0	0 (0.00)
Nightmare	1	1 (1.43)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.43)	0	0 (0.00)
Sleep disorder	1	1 (1.43)	0	0 (0.00)
Tearfulness	1	1 (1.43)	0	0 (0.00)
Renal and urinary disorders				
- Total	9	5 (7.14)	3	3 (4.29)
Acute kidney injury	3	3 (4.29)	1	1 (1.43)
Cystitis haemorrhagic	1	1 (1.43)	0	0 (0.00)
Dysuria	1	1 (1.43)	0	0 (0.00)
Haematuria	1	1 (1.43)	1	1 (1.43)
Kidney enlargement	1	1 (1.43)	0	0 (0.00)
Renal mass	1	1 (1.43)	0	0 (0.00)
Renal tubular disorder	1	1 (1.43)	1	1 (1.43)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	40	21 (30.00)	5	5 (7.14)
Cough	12	9 (12.86)	0	0 (0.00)
Nasal congestion	5	4 (5.71)	0	0 (0.00)
Epistaxis	3	3 (4.29)	0	0 (0.00)
Rhinorrhoea	3	3 (4.29)	0	0 (0.00)
Dyspnoea	2	1 (1.43)	0	0 (0.00)
Hypoxia	2	2 (2.86)	2	2 (2.86)
Oropharyngeal pain	2	2 (2.86)	0	0 (0.00)
Pleural effusion	2	2 (2.86)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (1.43)	1	1 (1.43)
Bronchial oedema	1	1 (1.43)	0	0 (0.00)
Bronchospasm	1	1 (1.43)	0	0 (0.00)
Lung disorder	1	1 (1.43)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.43)	0	0 (0.00)
Respiratory distress	1	1 (1.43)	1	1 (1.43)
Respiratory failure	1	1 (1.43)	1	1 (1.43)
Rhinitis allergic	1	1 (1.43)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.43)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	25	17 (24.29)	1	1 (1.43)
Dry skin	7	6 (8.57)	0	0 (0.00)
Rash	5	3 (4.29)	0	0 (0.00)
Ingrowing nail	2	2 (2.86)	0	0 (0.00)
Pruritus	2	1 (1.43)	0	0 (0.00)
Decubitus ulcer	1	1 (1.43)	1	1 (1.43)
Dermatitis allergic	1	1 (1.43)	0	0 (0.00)
Dermatitis atopic	1	1 (1.43)	0	0 (0.00)
Erythema	1	1 (1.43)	0	0 (0.00)
Hangnail	1	1 (1.43)	0	0 (0.00)
Night sweats	1	1 (1.43)	0	0 (0.00)
Photosensitivity reaction	1	1 (1.43)	0	0 (0.00)
Skin discolouration	1	1 (1.43)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.43)	0	0 (0.00)
Vascular disorders				
- Total	7	6 (8.57)	5	5 (7.14)
Hypotension	4	4 (5.71)	3	3 (4.29)
Venoocclusive disease	2	2 (2.86)	2	2 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=70 n (%)[1]	Grade >= 3 Total events	All patients N=70 n (%)[2]
Hypertension	1	1 (1.43)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Total number of AE per patient	33	3 (75.00)	5	3 (75.00)
Gastrointestinal disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Constipation	1	1 (25.00)	0	0 (0.00)
Immune system disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Seasonal allergy	1	1 (25.00)	0	0 (0.00)
Infections and infestations				
- Total	18	3 (75.00)	3	2 (50.00)
Upper respiratory tract infection	5	3 (75.00)	1	1 (25.00)
Otitis media	3	2 (50.00)	0	0 (0.00)
Gastroenteritis viral	2	1 (25.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Bronchiolitis	1	1 (25.00)	1	1 (25.00)
Bronchitis	1	1 (25.00)	0	0 (0.00)
Folliculitis	1	1 (25.00)	0	0 (0.00)
Nail infection	1	1 (25.00)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (25.00)	1	1 (25.00)
Rhinovirus infection	1	1 (25.00)	0	0 (0.00)
Sinusitis	1	1 (25.00)	0	0 (0.00)
Skin infection	1	1 (25.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (25.00)	0	0 (0.00)
Abdominal injury	1	1 (25.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (50.00)	1	1 (25.00)
Hyperlipidaemia	1	1 (25.00)	0	0 (0.00)
Obesity	1	1 (25.00)	1	1 (25.00)
Nervous system disorders				
- Total	1	1 (25.00)	0	0 (0.00)
Headache	1	1 (25.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=4 n (%)[1]	Grade >= 3 Total events	All patients N=4 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	5	2 (50.00)	1	1 (25.00)
Dyspnoea	1	1 (25.00)	0	0 (0.00)
Hypoxia	1	1 (25.00)	1	1 (25.00)
Rhinorrhoea	1	1 (25.00)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (25.00)	0	0 (0.00)
Wheezing	1	1 (25.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	4	2 (50.00)	0	0 (0.00)
Rash	2	2 (50.00)	0	0 (0.00)
Rash erythematous	1	1 (25.00)	0	0 (0.00)
Rash maculo-papular	1	1 (25.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Total number of AE per patient	187	29 (63.04)	58	16 (34.78)
Blood and lymphatic system disorders				
- Total	6	4 (8.70)	2	2 (4.35)
Agranulocytosis	1	1 (2.17)	1	1 (2.17)
Anaemia	1	1 (2.17)	0	0 (0.00)
Hypercoagulation	1	1 (2.17)	0	0 (0.00)
Lymphadenopathy	1	1 (2.17)	0	0 (0.00)
Neutropenia	1	1 (2.17)	1	1 (2.17)
Thrombocytopenia	1	1 (2.17)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.17)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (2.17)	0	0 (0.00)
Deafness unilateral	1	1 (2.17)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (2.17)	0	0 (0.00)
Delayed puberty	1	1 (2.17)	0	0 (0.00)
Hypothyroidism	1	1 (2.17)	0	0 (0.00)
Eye disorders				
- Total	4	3 (6.52)	1	1 (2.17)
Dry eye	1	1 (2.17)	0	0 (0.00)
Eye pain	1	1 (2.17)	1	1 (2.17)
Eyelid oedema	1	1 (2.17)	0	0 (0.00)
Mydriasis	1	1 (2.17)	0	0 (0.00)
Gastrointestinal disorders				
- Total	8	6 (13.04)	1	1 (2.17)
Diarrhoea	5	5 (10.87)	1	1 (2.17)
Irritable bowel syndrome	1	1 (2.17)	0	0 (0.00)
Nausea	1	1 (2.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Vomiting	1	1 (2.17)	0	0 (0.00)
General disorders and administration site conditions				
- Total	13	9 (19.57)	2	2 (4.35)
Pyrexia	7	5 (10.87)	1	1 (2.17)
Pain	2	2 (4.35)	0	0 (0.00)
Fatigue	1	1 (2.17)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.17)	1	1 (2.17)
Non-cardiac chest pain	1	1 (2.17)	0	0 (0.00)
Xerosis	1	1 (2.17)	0	0 (0.00)
Immune system disorders				
- Total	9	8 (17.39)	3	2 (4.35)
Hypogammaglobulinaemia	3	3 (6.52)	0	0 (0.00)
Chronic graft versus host disease	2	2 (4.35)	1	1 (2.17)
Seasonal allergy	2	2 (4.35)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.17)	1	1 (2.17)
Haemophagocytic lymphohistiocytosis	1	1 (2.17)	1	1 (2.17)
Infections and infestations				

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
- Total	68	20 (43.48)	23	12 (26.09)
Sinusitis	8	5 (10.87)	0	0 (0.00)
Conjunctivitis	5	4 (8.70)	0	0 (0.00)
COVID-19	3	2 (4.35)	1	1 (2.17)
Fungal infection	3	2 (4.35)	0	0 (0.00)
Rhinovirus infection	3	3 (6.52)	1	1 (2.17)
Sepsis	3	3 (6.52)	3	3 (6.52)
Device related sepsis	2	1 (2.17)	2	1 (2.17)
Herpes zoster	2	2 (4.35)	1	1 (2.17)
Influenza	2	2 (4.35)	1	1 (2.17)
Oral herpes	2	2 (4.35)	0	0 (0.00)
Pneumonia	2	2 (4.35)	2	2 (4.35)
Skin infection	2	2 (4.35)	0	0 (0.00)
Upper respiratory tract infection	2	2 (4.35)	0	0 (0.00)
Urinary tract infection	2	2 (4.35)	0	0 (0.00)
Acute sinusitis	1	1 (2.17)	0	0 (0.00)
Bronchitis	1	1 (2.17)	0	0 (0.00)
COVID-19 pneumonia	1	1 (2.17)	1	1 (2.17)
Candida infection	1	1 (2.17)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.17)	1	1 (2.17)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Ear infection	1	1 (2.17)	1	1 (2.17)
Enterovirus infection	1	1 (2.17)	1	1 (2.17)
Fungal skin infection	1	1 (2.17)	0	0 (0.00)
Gastroenteritis	1	1 (2.17)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.17)	1	1 (2.17)
Gastroenteritis salmonella	1	1 (2.17)	1	1 (2.17)
Herpes virus infection	1	1 (2.17)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.17)	1	1 (2.17)
Neutropenic infection	1	1 (2.17)	1	1 (2.17)
Ophthalmic herpes zoster	1	1 (2.17)	0	0 (0.00)
Oral candidiasis	1	1 (2.17)	0	0 (0.00)
Otitis media acute	1	1 (2.17)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.17)	1	1 (2.17)
Rhinitis	1	1 (2.17)	0	0 (0.00)
Septic shock	1	1 (2.17)	1	1 (2.17)
Staphylococcal abscess	1	1 (2.17)	1	1 (2.17)
Staphylococcal bacteraemia	1	1 (2.17)	1	1 (2.17)
Streptococcal sepsis	1	1 (2.17)	0	0 (0.00)
Syphilis	1	1 (2.17)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Varicella zoster virus infection	1	1 (2.17)	0	0 (0.00)
Viral skin infection	1	1 (2.17)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (4.35)	1	1 (2.17)
Infusion related reaction	1	1 (2.17)	1	1 (2.17)
Ligament sprain	1	1 (2.17)	0	0 (0.00)
Investigations				
- Total	16	6 (13.04)	6	2 (4.35)
Neutrophil count decreased	8	3 (6.52)	5	1 (2.17)
Blood bilirubin increased	3	1 (2.17)	0	0 (0.00)
Platelet count decreased	2	2 (4.35)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.17)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.17)	1	1 (2.17)
SARS-CoV-2 test positive	1	1 (2.17)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	8	4 (8.70)	4	3 (6.52)
Decreased appetite	2	1 (2.17)	2	1 (2.17)
Iron overload	2	1 (2.17)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Hypercholesterolaemia	1	1 (2.17)	0	0 (0.00)
Hyperglycaemia	1	1 (2.17)	1	1 (2.17)
Hypernatraemia	1	1 (2.17)	1	1 (2.17)
Hypertriglyceridaemia	1	1 (2.17)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (15.22)	0	0 (0.00)
Pain in extremity	2	2 (4.35)	0	0 (0.00)
Arthralgia	1	1 (2.17)	0	0 (0.00)
Growth retardation	1	1 (2.17)	0	0 (0.00)
Joint effusion	1	1 (2.17)	0	0 (0.00)
Osteonecrosis	1	1 (2.17)	0	0 (0.00)
Osteopenia	1	1 (2.17)	0	0 (0.00)
Synovitis	1	1 (2.17)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (2.17)	1	1 (2.17)
Bone giant cell tumour benign	2	1 (2.17)	1	1 (2.17)
Nervous system disorders				

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
- Total	8	3 (6.52)	3	2 (4.35)
Seizure	3	1 (2.17)	1	1 (2.17)
Headache	2	1 (2.17)	1	1 (2.17)
Nervous system disorder	2	1 (2.17)	1	1 (2.17)
Dysarthria	1	1 (2.17)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (6.52)	0	0 (0.00)
Anxiety	2	2 (4.35)	0	0 (0.00)
Tic	1	1 (2.17)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.17)	1	1 (2.17)
Endometriosis	2	1 (2.17)	1	1 (2.17)
Respiratory, thoracic and mediastinal disorders				
- Total	18	8 (17.39)	5	3 (6.52)
Cough	4	4 (8.70)	0	0 (0.00)
Dyspnoea	2	2 (4.35)	1	1 (2.17)
Rhinorrhoea	2	2 (4.35)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Tachypnoea	2	1 (2.17)	2	1 (2.17)
Dyspnoea exertional	1	1 (2.17)	0	0 (0.00)
Epistaxis	1	1 (2.17)	0	0 (0.00)
Laryngeal oedema	1	1 (2.17)	1	1 (2.17)
Oropharyngeal pain	1	1 (2.17)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.17)	0	0 (0.00)
Pleural effusion	1	1 (2.17)	0	0 (0.00)
Respiratory failure	1	1 (2.17)	1	1 (2.17)
Sleep apnoea syndrome	1	1 (2.17)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	5 (10.87)	4	3 (6.52)
Rash macular	2	1 (2.17)	2	1 (2.17)
Dermatitis atopic	1	1 (2.17)	1	1 (2.17)
Dry skin	1	1 (2.17)	0	0 (0.00)
Eczema	1	1 (2.17)	1	1 (2.17)
Papule	1	1 (2.17)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (4.35)	1	1 (2.17)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=46 n (%)[1]	Grade >= 3 Total events	All patients N=46 n (%)[2]
Hypertension	2	2 (4.35)	1	1 (2.17)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	297	6 (100.00)	80	6 (100.00)
Blood and lymphatic system disorders				
- Total	11	4 (66.67)	5	3 (50.00)
Anaemia	5	2 (33.33)	2	1 (16.67)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Disseminated intravascular coagulation	2	2 (33.33)	0	0 (0.00)
Splenomegaly	1	1 (16.67)	0	0 (0.00)
Cardiac disorders				
- Total	4	3 (50.00)	1	1 (16.67)
Tachycardia	3	2 (33.33)	1	1 (16.67)
Bradycardia	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Ear and labyrinth disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Ear pruritus	1	1 (16.67)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Hypothyroidism	1	1 (16.67)	0	0 (0.00)
Eye disorders				
- Total	4	2 (33.33)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (33.33)	0	0 (0.00)
Ocular hyperaemia	1	1 (16.67)	0	0 (0.00)
Periorbital oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	16	5 (83.33)	2	2 (33.33)
Diarrhoea	5	3 (50.00)	0	0 (0.00)
Constipation	3	2 (33.33)	0	0 (0.00)
Vomiting	2	2 (33.33)	0	0 (0.00)
Abdominal compartment syndrome	1	1 (16.67)	1	1 (16.67)
Anal fissure	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Dysphagia	1	1 (16.67)	1	1 (16.67)
Enterocolitis	1	1 (16.67)	0	0 (0.00)
Gingival erythema	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	11	4 (66.67)	0	0 (0.00)
Pyrexia	3	3 (50.00)	0	0 (0.00)
Face oedema	2	2 (33.33)	0	0 (0.00)
Fatigue	2	2 (33.33)	0	0 (0.00)
Generalised oedema	2	2 (33.33)	0	0 (0.00)
Chills	1	1 (16.67)	0	0 (0.00)
Localised oedema	1	1 (16.67)	0	0 (0.00)
Hepatobiliary disorders				
- Total	8	2 (33.33)	2	1 (16.67)
Hepatic function abnormal	4	1 (16.67)	2	1 (16.67)
Hyperbilirubinaemia	2	1 (16.67)	0	0 (0.00)
Hypertransaminasaemia	2	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Immune system disorders				
- Total	15	6 (100.00)	6	4 (66.67)
Cytokine release syndrome	10	6 (100.00)	5	3 (50.00)
Hypogammaglobulinaemia	3	3 (50.00)	1	1 (16.67)
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	0	0 (0.00)
Seasonal allergy	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	27	5 (83.33)	4	3 (50.00)
Upper respiratory tract infection	6	4 (66.67)	1	1 (16.67)
Otitis media	3	2 (33.33)	0	0 (0.00)
Gastroenteritis viral	2	1 (16.67)	0	0 (0.00)
Nasopharyngitis	2	1 (16.67)	0	0 (0.00)
Sinusitis	2	1 (16.67)	0	0 (0.00)
Bronchiolitis	1	1 (16.67)	1	1 (16.67)
Bronchitis	1	1 (16.67)	0	0 (0.00)
Cellulitis	1	1 (16.67)	0	0 (0.00)
Ear infection	1	1 (16.67)	0	0 (0.00)
Folliculitis	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Metapneumovirus infection	1	1 (16.67)	1	1 (16.67)
Nail infection	1	1 (16.67)	0	0 (0.00)
Otitis externa	1	1 (16.67)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (16.67)	1	1 (16.67)
Rhinovirus infection	1	1 (16.67)	0	0 (0.00)
Skin infection	1	1 (16.67)	0	0 (0.00)
Staphylococcal infection	1	1 (16.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	3 (50.00)	0	0 (0.00)
Contusion	2	1 (16.67)	0	0 (0.00)
Abdominal injury	1	1 (16.67)	0	0 (0.00)
Skin abrasion	1	1 (16.67)	0	0 (0.00)
Transfusion reaction	1	1 (16.67)	0	0 (0.00)
Wound	1	1 (16.67)	0	0 (0.00)
Investigations				
- Total	69	6 (100.00)	33	6 (100.00)
White blood cell count decreased	12	4 (66.67)	7	3 (50.00)
Platelet count decreased	11	3 (50.00)	5	2 (33.33)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Neutrophil count decreased	7	3 (50.00)	6	3 (50.00)
Alanine aminotransferase increased	4	2 (33.33)	1	1 (16.67)
Blood creatinine increased	4	2 (33.33)	4	2 (33.33)
Lymphocyte count decreased	4	2 (33.33)	2	2 (33.33)
Weight increased	4	1 (16.67)	1	1 (16.67)
Blood creatine phosphokinase increased	3	1 (16.67)	1	1 (16.67)
Urine output decreased	3	2 (33.33)	3	2 (33.33)
Serum ferritin increased	2	2 (33.33)	0	0 (0.00)
Activated partial thromboplastin time prolonged	1	1 (16.67)	0	0 (0.00)
Aspartate aminotransferase increased	1	1 (16.67)	1	1 (16.67)
Blood bicarbonate decreased	1	1 (16.67)	0	0 (0.00)
Blood bilirubin increased	1	1 (16.67)	1	1 (16.67)
Blood fibrinogen decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (16.67)	1	1 (16.67)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Blood lactate dehydrogenase increased	1	1 (16.67)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (16.67)	0	0 (0.00)
Blood uric acid increased	1	1 (16.67)	0	0 (0.00)
C-reactive protein increased	1	1 (16.67)	0	0 (0.00)
Cardiac murmur	1	1 (16.67)	0	0 (0.00)
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Oxygen saturation decreased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	39	6 (100.00)	9	4 (66.67)
Hypocalcaemia	7	4 (66.67)	0	0 (0.00)
Hypoalbuminaemia	6	2 (33.33)	0	0 (0.00)
Hypophosphataemia	5	3 (50.00)	0	0 (0.00)
Hypokalaemia	4	3 (50.00)	1	1 (16.67)
Decreased appetite	2	2 (33.33)	2	2 (33.33)
Hypermagnesaemia	2	1 (16.67)	0	0 (0.00)
Hyperphosphataemia	2	2 (33.33)	0	0 (0.00)
Hypercalcaemia	1	1 (16.67)	1	1 (16.67)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Hyperchloraemia	1	1 (16.67)	0	0 (0.00)
Hyperglycaemia	1	1 (16.67)	1	1 (16.67)
Hyperkalaemia	1	1 (16.67)	1	1 (16.67)
Hyperlipidaemia	1	1 (16.67)	0	0 (0.00)
Hypervolaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)
Metabolic acidosis	1	1 (16.67)	1	1 (16.67)
Metabolic syndrome	1	1 (16.67)	0	0 (0.00)
Obesity	1	1 (16.67)	1	1 (16.67)
Tumour lysis syndrome	1	1 (16.67)	1	1 (16.67)
Musculoskeletal and connective tissue disorders				
- Total	4	3 (50.00)	0	0 (0.00)
Bone pain	1	1 (16.67)	0	0 (0.00)
Muscle rigidity	1	1 (16.67)	0	0 (0.00)
Myalgia	1	1 (16.67)	0	0 (0.00)
Pain in extremity	1	1 (16.67)	0	0 (0.00)
Nervous system disorders				
- Total	8	2 (33.33)	3	2 (33.33)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Headache	3	1 (16.67)	0	0 (0.00)
Cerebral haemorrhage	1	1 (16.67)	1	1 (16.67)
Encephalopathy	1	1 (16.67)	1	1 (16.67)
Generalised tonic-clonic seizure	1	1 (16.67)	0	0 (0.00)
Somnolence	1	1 (16.67)	1	1 (16.67)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	8	2 (33.33)	1	1 (16.67)
Agitation	2	1 (16.67)	0	0 (0.00)
Automatism	1	1 (16.67)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Delirium	1	1 (16.67)	0	0 (0.00)
Insomnia	1	1 (16.67)	0	0 (0.00)
Irritability	1	1 (16.67)	0	0 (0.00)
Mental status changes	1	1 (16.67)	1	1 (16.67)
Renal and urinary disorders				
- Total	7	3 (50.00)	3	3 (50.00)
Acute kidney injury	5	3 (50.00)	3	3 (50.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Anuria	1	1 (16.67)	0	0 (0.00)
Azotaemia	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	3	1 (16.67)	0	0 (0.00)
Dysmenorrhoea	2	1 (16.67)	0	0 (0.00)
Perineal rash	1	1 (16.67)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	28	6 (100.00)	7	4 (66.67)
Hypoxia	6	4 (66.67)	5	4 (66.67)
Cough	3	3 (50.00)	0	0 (0.00)
Pleural effusion	3	3 (50.00)	1	1 (16.67)
Epistaxis	2	2 (33.33)	0	0 (0.00)
Nasal congestion	2	2 (33.33)	0	0 (0.00)
Pulmonary oedema	2	2 (33.33)	0	0 (0.00)
Tachypnoea	2	1 (16.67)	1	1 (16.67)
Dyspnoea	1	1 (16.67)	0	0 (0.00)
Nasal discomfort	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Pharyngeal haemorrhage	1	1 (16.67)	0	0 (0.00)
Respiratory distress	1	1 (16.67)	0	0 (0.00)
Rhinitis allergic	1	1 (16.67)	0	0 (0.00)
Rhinorrhoea	1	1 (16.67)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (16.67)	0	0 (0.00)
Wheezing	1	1 (16.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	19	5 (83.33)	0	0 (0.00)
Blister	5	2 (33.33)	0	0 (0.00)
Rash	3	2 (33.33)	0	0 (0.00)
Dermatitis diaper	1	1 (16.67)	0	0 (0.00)
Eczema	1	1 (16.67)	0	0 (0.00)
Erythema	1	1 (16.67)	0	0 (0.00)
Miliaria	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	0	0 (0.00)
Rash erythematous	1	1 (16.67)	0	0 (0.00)
Rash maculo-papular	1	1 (16.67)	0	0 (0.00)
Scab	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Down syndrome: Yes

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Skin discolouration	1	1 (16.67)	0	0 (0.00)
Skin swelling	1	1 (16.67)	0	0 (0.00)
Skin ulcer	1	1 (16.67)	0	0 (0.00)
Vascular disorders				
- Total	8	4 (66.67)	4	3 (50.00)
Hypotension	4	3 (50.00)	4	3 (50.00)
Hypertension	3	3 (50.00)	0	0 (0.00)
Thrombosis	1	1 (16.67)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250p
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Down syndrome
Safety Set

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Total number of AE per patient	2208	74 (100.00)	748	67 (90.54)
Blood and lymphatic system disorders				
- Total	152	51 (68.92)	90	40 (54.05)
Anaemia	58	23 (31.08)	22	8 (10.81)
Febrile neutropenia	30	24 (32.43)	30	24 (32.43)
Neutropenia	17	11 (14.86)	15	9 (12.16)
Thrombocytopenia	11	9 (12.16)	10	9 (12.16)
Disseminated intravascular coagulation	6	6 (8.11)	3	3 (4.05)
Coagulopathy	5	5 (6.76)	2	2 (2.70)
Leukopenia	5	3 (4.05)	3	2 (2.70)
B-cell aplasia	3	1 (1.35)	0	0 (0.00)
Eosinophilia	3	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Splenomegaly	3	3 (4.05)	0	0 (0.00)
Lymphadenopathy	2	2 (2.70)	0	0 (0.00)
Lymphopenia	2	2 (2.70)	2	2 (2.70)
Pancytopenia	2	2 (2.70)	2	2 (2.70)
Agranulocytosis	1	1 (1.35)	1	1 (1.35)
Hypercoagulation	1	1 (1.35)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (1.35)	0	0 (0.00)
Leukocytosis	1	1 (1.35)	0	0 (0.00)
Lymphocytosis	1	1 (1.35)	0	0 (0.00)
Cardiac disorders				
- Total	49	25 (33.78)	13	10 (13.51)
Tachycardia	21	15 (20.27)	2	2 (2.70)
Cardiac failure	6	3 (4.05)	4	3 (4.05)
Left ventricular dysfunction	4	4 (5.41)	3	3 (4.05)
Sinus tachycardia	4	3 (4.05)	0	0 (0.00)
Cardiac arrest	3	3 (4.05)	3	3 (4.05)
Bradycardia	2	2 (2.70)	0	0 (0.00)
Cardiac dysfunction	2	2 (2.70)	0	0 (0.00)
Atrioventricular block first degree	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Cardiac failure congestive	1	1 (1.35)	0	0 (0.00)
Mitral valve incompetence	1	1 (1.35)	0	0 (0.00)
Pericardial effusion	1	1 (1.35)	0	0 (0.00)
Right ventricular dysfunction	1	1 (1.35)	0	0 (0.00)
Sinus bradycardia	1	1 (1.35)	1	1 (1.35)
Tricuspid valve incompetence	1	1 (1.35)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (1.35)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (1.35)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (2.70)	0	0 (0.00)
Deafness unilateral	1	1 (1.35)	0	0 (0.00)
Ear pain	1	1 (1.35)	0	0 (0.00)
Endocrine disorders				
- Total	7	6 (8.11)	0	0 (0.00)
Adrenal insufficiency	4	4 (5.41)	0	0 (0.00)
Hypothyroidism	2	2 (2.70)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Delayed puberty	1	1 (1.35)	0	0 (0.00)
Eye disorders				
- Total	20	13 (17.57)	1	1 (1.35)
Eyelid oedema	4	3 (4.05)	0	0 (0.00)
Cataract	2	2 (2.70)	0	0 (0.00)
Eye pain	2	2 (2.70)	1	1 (1.35)
Ocular hyperaemia	2	2 (2.70)	0	0 (0.00)
Retinal haemorrhage	2	1 (1.35)	0	0 (0.00)
Visual impairment	2	2 (2.70)	0	0 (0.00)
Dry eye	1	1 (1.35)	0	0 (0.00)
Eye oedema	1	1 (1.35)	0	0 (0.00)
Hypermetropia	1	1 (1.35)	0	0 (0.00)
Mydriasis	1	1 (1.35)	0	0 (0.00)
Periorbital swelling	1	1 (1.35)	0	0 (0.00)
Visual field defect	1	1 (1.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	166	55 (74.32)	16	14 (18.92)
Vomiting	36	24 (32.43)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Nausea	26	21 (28.38)	2	2 (2.70)
Diarrhoea	25	23 (31.08)	2	2 (2.70)
Abdominal pain	15	11 (14.86)	2	2 (2.70)
Constipation	13	12 (16.22)	0	0 (0.00)
Pancreatitis	6	6 (8.11)	2	2 (2.70)
Mouth haemorrhage	5	5 (6.76)	2	2 (2.70)
Abdominal pain upper	4	4 (5.41)	0	0 (0.00)
Abdominal distension	3	3 (4.05)	0	0 (0.00)
Ascites	3	3 (4.05)	0	0 (0.00)
Stomatitis	3	3 (4.05)	1	1 (1.35)
Gastrointestinal sounds abnormal	2	2 (2.70)	0	0 (0.00)
Proctalgia	2	2 (2.70)	1	1 (1.35)
Trichoglossia	2	2 (2.70)	0	0 (0.00)
Abdominal rigidity	1	1 (1.35)	0	0 (0.00)
Anal haemorrhage	1	1 (1.35)	0	0 (0.00)
Dry mouth	1	1 (1.35)	0	0 (0.00)
Dyspepsia	1	1 (1.35)	0	0 (0.00)
Enteritis	1	1 (1.35)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Gastrointestinal inflammation	1	1 (1.35)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (1.35)	0	0 (0.00)
Gingival bleeding	1	1 (1.35)	0	0 (0.00)
Gingivitis ulcerative	1	1 (1.35)	1	1 (1.35)
Haematemesis	1	1 (1.35)	0	0 (0.00)
Ileus	1	1 (1.35)	0	0 (0.00)
Irritable bowel syndrome	1	1 (1.35)	0	0 (0.00)
Lip dry	1	1 (1.35)	0	0 (0.00)
Lip oedema	1	1 (1.35)	0	0 (0.00)
Melaena	1	1 (1.35)	1	1 (1.35)
Mouth swelling	1	1 (1.35)	0	0 (0.00)
Neutropenic colitis	1	1 (1.35)	1	1 (1.35)
Odynophagia	1	1 (1.35)	0	0 (0.00)
Peritoneal haematoma	1	1 (1.35)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (1.35)	0	0 (0.00)
General disorders and administration site conditions				
- Total	145	49 (66.22)	24	15 (20.27)
Pyrexia	64	32 (43.24)	12	11 (14.86)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Fatigue	17	15 (20.27)	0	0 (0.00)
Chills	9	6 (8.11)	0	0 (0.00)
Oedema peripheral	9	7 (9.46)	2	1 (1.35)
Face oedema	7	6 (8.11)	1	1 (1.35)
Pain	5	5 (6.76)	2	2 (2.70)
Catheter site pain	4	2 (2.70)	2	1 (1.35)
Asthenia	3	3 (4.05)	0	0 (0.00)
Generalised oedema	3	3 (4.05)	0	0 (0.00)
Multiple organ dysfunction syndrome	3	3 (4.05)	3	3 (4.05)
Catheter site erythema	2	1 (1.35)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (2.70)	0	0 (0.00)
Influenza like illness	2	2 (2.70)	0	0 (0.00)
Malaise	2	2 (2.70)	0	0 (0.00)
Non-cardiac chest pain	2	2 (2.70)	0	0 (0.00)
Catheter site haemorrhage	1	1 (1.35)	0	0 (0.00)
Chest discomfort	1	1 (1.35)	1	1 (1.35)
Crying	1	1 (1.35)	0	0 (0.00)
Facial pain	1	1 (1.35)	0	0 (0.00)
Localised oedema	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Oedema due to hepatic disease	1	1 (1.35)	0	0 (0.00)
Sluggishness	1	1 (1.35)	0	0 (0.00)
Swelling face	1	1 (1.35)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (1.35)	1	1 (1.35)
Vascular device occlusion	1	1 (1.35)	0	0 (0.00)
Xerosis	1	1 (1.35)	0	0 (0.00)
Hepatobiliary disorders				
- Total	24	17 (22.97)	5	5 (6.76)
Hepatic function abnormal	7	4 (5.41)	2	2 (2.70)
Hyperbilirubinaemia	4	4 (5.41)	1	1 (1.35)
Hepatomegaly	3	3 (4.05)	1	1 (1.35)
Cholelithiasis	2	2 (2.70)	0	0 (0.00)
Gallbladder enlargement	2	2 (2.70)	0	0 (0.00)
Biliary tract disorder	1	1 (1.35)	0	0 (0.00)
Cholestasis	1	1 (1.35)	1	1 (1.35)
Hepatic cytolysis	1	1 (1.35)	0	0 (0.00)
Hypertransaminasaemia	1	1 (1.35)	0	0 (0.00)
Liver disorder	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Ocular icterus	1	1 (1.35)	0	0 (0.00)
Immune system disorders				
- Total	178	65 (87.84)	70	42 (56.76)
Cytokine release syndrome	118	55 (74.32)	50	35 (47.30)
Hypogammaglobulinaemia	37	30 (40.54)	6	6 (8.11)
Haemophagocytic lymphohistiocytosis	5	5 (6.76)	4	4 (5.41)
Immunodeficiency	4	4 (5.41)	4	4 (5.41)
Seasonal allergy	3	3 (4.05)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (2.70)	1	1 (1.35)
Chronic graft versus host disease	2	2 (2.70)	1	1 (1.35)
Drug hypersensitivity	2	2 (2.70)	1	1 (1.35)
Graft versus host disease	2	2 (2.70)	2	2 (2.70)
Engraftment syndrome	1	1 (1.35)	1	1 (1.35)
Hypersensitivity	1	1 (1.35)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (1.35)	0	0 (0.00)
Infections and infestations				
- Total	236	55 (74.32)	98	36 (48.65)
Conjunctivitis	12	8 (10.81)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Sinusitis	12	6 (8.11)	2	2 (2.70)
Upper respiratory tract infection	11	9 (12.16)	2	2 (2.70)
Rhinovirus infection	10	8 (10.81)	2	2 (2.70)
Nasopharyngitis	7	6 (8.11)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (2.70)	4	2 (2.70)
Gastroenteritis	6	6 (8.11)	2	2 (2.70)
Parainfluenzae virus infection	6	5 (6.76)	3	3 (4.05)
Pneumonia	6	6 (8.11)	4	4 (5.41)
Staphylococcal bacteraemia	6	5 (6.76)	6	5 (6.76)
Candida infection	5	4 (5.41)	2	1 (1.35)
Oral herpes	5	4 (5.41)	1	1 (1.35)
Bacteraemia	4	3 (4.05)	3	2 (2.70)
Clostridium difficile infection	4	4 (5.41)	3	3 (4.05)
Oral candidiasis	4	3 (4.05)	0	0 (0.00)
Staphylococcal infection	4	4 (5.41)	2	2 (2.70)
Urinary tract infection	4	3 (4.05)	2	1 (1.35)
COVID-19	3	2 (2.70)	1	1 (1.35)
Ear infection	3	2 (2.70)	1	1 (1.35)
Fungal infection	3	2 (2.70)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Herpes zoster	3	3 (4.05)	2	2 (2.70)
Influenza	3	3 (4.05)	1	1 (1.35)
Klebsiella infection	3	1 (1.35)	3	1 (1.35)
Nail infection	3	3 (4.05)	0	0 (0.00)
Otitis media	3	3 (4.05)	1	1 (1.35)
Respiratory syncytial virus infection	3	3 (4.05)	2	2 (2.70)
Respiratory tract infection	3	3 (4.05)	0	0 (0.00)
Rhinitis	3	3 (4.05)	0	0 (0.00)
Sepsis	3	3 (4.05)	3	3 (4.05)
Acute sinusitis	2	2 (2.70)	0	0 (0.00)
Adenovirus infection	2	2 (2.70)	2	2 (2.70)
BK virus infection	2	2 (2.70)	1	1 (1.35)
Device related sepsis	2	1 (1.35)	2	1 (1.35)
Encephalitis	2	2 (2.70)	2	2 (2.70)
Encephalitis viral	2	2 (2.70)	2	2 (2.70)
Gingivitis	2	2 (2.70)	0	0 (0.00)
Herpes simplex	2	2 (2.70)	1	1 (1.35)
Human herpesvirus 6 infection	2	2 (2.70)	2	2 (2.70)
Metapneumovirus infection	2	2 (2.70)	2	2 (2.70)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Oral infection	2	2 (2.70)	0	0 (0.00)
Otitis externa	2	2 (2.70)	1	1 (1.35)
Paronychia	2	2 (2.70)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	2	2 (2.70)	2	2 (2.70)
Septic shock	2	2 (2.70)	2	2 (2.70)
Skin infection	2	2 (2.70)	0	0 (0.00)
Varicella zoster virus infection	2	2 (2.70)	1	1 (1.35)
Viral infection	2	2 (2.70)	1	1 (1.35)
Anal abscess	1	1 (1.35)	1	1 (1.35)
Atypical pneumonia	1	1 (1.35)	0	0 (0.00)
Bronchitis	1	1 (1.35)	0	0 (0.00)
COVID-19 pneumonia	1	1 (1.35)	1	1 (1.35)
Cholecystitis infective	1	1 (1.35)	0	0 (0.00)
Clostridium difficile colitis	1	1 (1.35)	1	1 (1.35)
Coronavirus infection	1	1 (1.35)	1	1 (1.35)
Cystitis	1	1 (1.35)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (1.35)	1	1 (1.35)
Device related infection	1	1 (1.35)	1	1 (1.35)
Ear, nose and throat infection	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Enterobacter infection	1	1 (1.35)	1	1 (1.35)
Enterovirus infection	1	1 (1.35)	1	1 (1.35)
Fungal skin infection	1	1 (1.35)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (1.35)	1	1 (1.35)
Gastroenteritis clostridial	1	1 (1.35)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (1.35)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (1.35)	1	1 (1.35)
Gastroenteritis viral	1	1 (1.35)	0	0 (0.00)
Gastrointestinal infection	1	1 (1.35)	0	0 (0.00)
Granulicatella infection	1	1 (1.35)	1	1 (1.35)
Herpes virus infection	1	1 (1.35)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (1.35)	0	0 (0.00)
Localised infection	1	1 (1.35)	0	0 (0.00)
Mastoiditis	1	1 (1.35)	1	1 (1.35)
Meningitis bacterial	1	1 (1.35)	1	1 (1.35)
Meningitis pneumococcal	1	1 (1.35)	1	1 (1.35)
Molluscum contagiosum	1	1 (1.35)	0	0 (0.00)
Myringitis	1	1 (1.35)	0	0 (0.00)
Neutropenic infection	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Ophthalmic herpes zoster	1	1 (1.35)	0	0 (0.00)
Otitis media acute	1	1 (1.35)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (1.35)	1	1 (1.35)
Pneumonia fungal	1	1 (1.35)	1	1 (1.35)
Pneumonia viral	1	1 (1.35)	1	1 (1.35)
Respiratory tract infection viral	1	1 (1.35)	0	0 (0.00)
Salmonellosis	1	1 (1.35)	0	0 (0.00)
Sinusitis fungal	1	1 (1.35)	1	1 (1.35)
Soft tissue infection	1	1 (1.35)	1	1 (1.35)
Staphylococcal abscess	1	1 (1.35)	1	1 (1.35)
Staphylococcal sepsis	1	1 (1.35)	1	1 (1.35)
Staphylococcal skin infection	1	1 (1.35)	0	0 (0.00)
Stomatococcal infection	1	1 (1.35)	0	0 (0.00)
Streptococcal sepsis	1	1 (1.35)	0	0 (0.00)
Syphilis	1	1 (1.35)	0	0 (0.00)
Systemic candida	1	1 (1.35)	1	1 (1.35)
Tinea pedis	1	1 (1.35)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (1.35)	0	0 (0.00)
Urinary tract infection viral	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Viral haemorrhagic cystitis	1	1 (1.35)	1	1 (1.35)
Viral skin infection	1	1 (1.35)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (1.35)	1	1 (1.35)
Injury, poisoning and procedural complications				
- Total	27	18 (24.32)	4	3 (4.05)
Infusion related reaction	8	5 (6.76)	1	1 (1.35)
Fall	2	2 (2.70)	0	0 (0.00)
Ligament sprain	2	2 (2.70)	0	0 (0.00)
Procedural pain	2	2 (2.70)	0	0 (0.00)
Wound	2	1 (1.35)	1	1 (1.35)
Contusion	1	1 (1.35)	0	0 (0.00)
Fibula fracture	1	1 (1.35)	0	0 (0.00)
Limb injury	1	1 (1.35)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (1.35)	0	0 (0.00)
Scratch	1	1 (1.35)	0	0 (0.00)
Skin abrasion	1	1 (1.35)	0	0 (0.00)
Skin injury	1	1 (1.35)	0	0 (0.00)
Skin wound	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Transfusion reaction	1	1 (1.35)	0	0 (0.00)
Transplant failure	1	1 (1.35)	1	1 (1.35)
Vasoplegia syndrome	1	1 (1.35)	1	1 (1.35)
Investigations				
- Total	424	54 (72.97)	205	42 (56.76)
Platelet count decreased	72	21 (28.38)	42	13 (17.57)
Neutrophil count decreased	68	21 (28.38)	48	18 (24.32)
White blood cell count decreased	56	21 (28.38)	33	15 (20.27)
Aspartate aminotransferase increased	32	18 (24.32)	12	10 (13.51)
Lymphocyte count decreased	32	15 (20.27)	24	13 (17.57)
Alanine aminotransferase increased	25	16 (21.62)	6	6 (8.11)
Blood bilirubin increased	24	12 (16.22)	9	8 (10.81)
International normalised ratio increased	11	8 (10.81)	0	0 (0.00)
Immunoglobulins decreased	10	2 (2.70)	0	0 (0.00)
Activated partial thromboplastin time prolonged	7	5 (6.76)	1	1 (1.35)
Blood fibrinogen decreased	6	6 (8.11)	2	2 (2.70)
Blood immunoglobulin A decreased	6	6 (8.11)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Blood immunoglobulin M decreased	6	6 (8.11)	1	1 (1.35)
Electrocardiogram QT prolonged	6	5 (6.76)	2	2 (2.70)
Serum ferritin increased	6	6 (8.11)	2	2 (2.70)
Blood lactate dehydrogenase increased	4	4 (5.41)	1	1 (1.35)
C-reactive protein increased	4	4 (5.41)	3	3 (4.05)
Lipase increased	4	2 (2.70)	2	1 (1.35)
Blood creatinine increased	3	3 (4.05)	1	1 (1.35)
Blood immunoglobulin G decreased	3	3 (4.05)	0	0 (0.00)
Blood uric acid increased	3	3 (4.05)	2	2 (2.70)
Fibrin D dimer increased	3	3 (4.05)	1	1 (1.35)
Weight increased	3	3 (4.05)	1	1 (1.35)
Blood glucose increased	2	1 (1.35)	2	1 (1.35)
Gamma-glutamyltransferase increased	2	2 (2.70)	2	2 (2.70)
Haemoglobin decreased	2	1 (1.35)	1	1 (1.35)
Oxygen saturation decreased	2	2 (2.70)	1	1 (1.35)
Weight decreased	2	2 (2.70)	1	1 (1.35)
Amylase increased	1	1 (1.35)	0	0 (0.00)
Bacterial test positive	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Blood alkaline phosphatase increased	1	1 (1.35)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (1.35)	1	1 (1.35)
Blood phosphorus increased	1	1 (1.35)	0	0 (0.00)
Blood testosterone decreased	1	1 (1.35)	0	0 (0.00)
Blood urea increased	1	1 (1.35)	1	1 (1.35)
Bone density decreased	1	1 (1.35)	0	0 (0.00)
Breath sounds abnormal	1	1 (1.35)	0	0 (0.00)
Coagulation test abnormal	1	1 (1.35)	0	0 (0.00)
Ejection fraction decreased	1	1 (1.35)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (1.35)	0	0 (0.00)
Enterovirus test positive	1	1 (1.35)	0	0 (0.00)
Haptoglobin decreased	1	1 (1.35)	0	0 (0.00)
Heart sounds abnormal	1	1 (1.35)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (1.35)	0	0 (0.00)
Prothrombin time prolonged	1	1 (1.35)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (1.35)	0	0 (0.00)
Staphylococcus test positive	1	1 (1.35)	0	0 (0.00)
Troponin increased	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Metabolism and nutrition disorders				
- Total	207	46 (62.16)	82	29 (39.19)
Hypokalaemia	42	17 (22.97)	23	10 (13.51)
Decreased appetite	30	28 (37.84)	12	10 (13.51)
Hypophosphataemia	27	15 (20.27)	11	9 (12.16)
Hypocalcaemia	17	12 (16.22)	6	5 (6.76)
Hypoalbuminaemia	13	9 (12.16)	1	1 (1.35)
Hyperuricaemia	12	9 (12.16)	1	1 (1.35)
Hyperglycaemia	11	8 (10.81)	4	4 (5.41)
Hypomagnesaemia	7	6 (8.11)	0	0 (0.00)
Hypervolaemia	6	6 (8.11)	5	5 (6.76)
Tumour lysis syndrome	4	4 (5.41)	4	4 (5.41)
Acidosis	3	2 (2.70)	2	2 (2.70)
Hypercalcaemia	3	2 (2.70)	1	1 (1.35)
Hypernatraemia	3	3 (4.05)	2	2 (2.70)
Hyperphosphataemia	3	3 (4.05)	1	1 (1.35)
Hypertriglyceridaemia	3	3 (4.05)	2	2 (2.70)
Iron overload	3	2 (2.70)	0	0 (0.00)
Metabolic acidosis	3	3 (4.05)	2	2 (2.70)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Hyperkalaemia	2	2 (2.70)	1	1 (1.35)
Hyponatraemia	2	2 (2.70)	0	0 (0.00)
Malnutrition	2	2 (2.70)	2	2 (2.70)
Calcium deficiency	1	1 (1.35)	0	0 (0.00)
Dehydration	1	1 (1.35)	0	0 (0.00)
Haemochromatosis	1	1 (1.35)	1	1 (1.35)
Haemosiderosis	1	1 (1.35)	0	0 (0.00)
Hyperchloraemia	1	1 (1.35)	0	0 (0.00)
Hypercholesterolaemia	1	1 (1.35)	0	0 (0.00)
Hyperlactacidaemia	1	1 (1.35)	0	0 (0.00)
Hypermagnesaemia	1	1 (1.35)	0	0 (0.00)
Hypoglycaemia	1	1 (1.35)	0	0 (0.00)
Hypophagia	1	1 (1.35)	0	0 (0.00)
Polydipsia	1	1 (1.35)	1	1 (1.35)
Musculoskeletal and connective tissue disorders				
- Total	79	41 (55.41)	9	8 (10.81)
Pain in extremity	17	16 (21.62)	1	1 (1.35)
Arthralgia	14	12 (16.22)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Back pain	14	10 (13.51)	3	3 (4.05)
Myalgia	10	9 (12.16)	0	0 (0.00)
Bone pain	5	3 (4.05)	0	0 (0.00)
Growth retardation	2	2 (2.70)	0	0 (0.00)
Muscular weakness	2	2 (2.70)	1	1 (1.35)
Musculoskeletal chest pain	2	2 (2.70)	0	0 (0.00)
Neck pain	2	2 (2.70)	0	0 (0.00)
Pain in jaw	2	2 (2.70)	1	1 (1.35)
Haemarthrosis	1	1 (1.35)	1	1 (1.35)
Joint effusion	1	1 (1.35)	0	0 (0.00)
Muscle spasms	1	1 (1.35)	0	0 (0.00)
Musculoskeletal pain	1	1 (1.35)	0	0 (0.00)
Myositis	1	1 (1.35)	0	0 (0.00)
Osteonecrosis	1	1 (1.35)	0	0 (0.00)
Osteopenia	1	1 (1.35)	0	0 (0.00)
Rhabdomyolysis	1	1 (1.35)	1	1 (1.35)
Synovitis	1	1 (1.35)	0	0 (0.00)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
- Total	6	5 (6.76)	2	2 (2.70)
Bone giant cell tumour benign	2	1 (1.35)	1	1 (1.35)
Skin papilloma	2	2 (2.70)	0	0 (0.00)
Cancer pain	1	1 (1.35)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (1.35)	1	1 (1.35)
Nervous system disorders				
- Total	101	45 (60.81)	20	12 (16.22)
Headache	37	26 (35.14)	3	3 (4.05)
Encephalopathy	7	7 (9.46)	3	3 (4.05)
Seizure	7	4 (5.41)	3	3 (4.05)
Tremor	6	5 (6.76)	0	0 (0.00)
Cognitive disorder	5	3 (4.05)	1	1 (1.35)
Dizziness	5	4 (5.41)	0	0 (0.00)
Somnolence	4	4 (5.41)	1	1 (1.35)
Dysgeusia	3	3 (4.05)	0	0 (0.00)
Hydrocephalus	3	1 (1.35)	3	1 (1.35)
Lethargy	3	3 (4.05)	0	0 (0.00)
Dysarthria	2	2 (2.70)	1	1 (1.35)
Hyperaesthesia	2	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Migraine	2	1 (1.35)	0	0 (0.00)
Nervous system disorder	2	1 (1.35)	1	1 (1.35)
Amnesia	1	1 (1.35)	0	0 (0.00)
Aphasia	1	1 (1.35)	0	0 (0.00)
Autonomic neuropathy	1	1 (1.35)	1	1 (1.35)
Cerebral haemorrhage	1	1 (1.35)	1	1 (1.35)
Depressed level of consciousness	1	1 (1.35)	1	1 (1.35)
Disturbance in attention	1	1 (1.35)	0	0 (0.00)
Extrapyramidal disorder	1	1 (1.35)	0	0 (0.00)
Hypoaesthesia	1	1 (1.35)	0	0 (0.00)
Memory impairment	1	1 (1.35)	0	0 (0.00)
Monoparesis	1	1 (1.35)	0	0 (0.00)
Neuralgia	1	1 (1.35)	0	0 (0.00)
Neurological decompensation	1	1 (1.35)	1	1 (1.35)
Paraesthesia	1	1 (1.35)	0	0 (0.00)
Psychiatric disorders				
- Total	57	37 (50.00)	6	6 (8.11)
Anxiety	14	14 (18.92)	2	2 (2.70)
Delirium	7	7 (9.46)	3	3 (4.05)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Confusional state	6	6 (8.11)	0	0 (0.00)
Agitation	5	5 (6.76)	0	0 (0.00)
Mental status changes	4	4 (5.41)	1	1 (1.35)
Sleep disorder	4	3 (4.05)	0	0 (0.00)
Hallucination	3	3 (4.05)	0	0 (0.00)
Insomnia	3	3 (4.05)	0	0 (0.00)
Irritability	2	2 (2.70)	0	0 (0.00)
Affect lability	1	1 (1.35)	0	0 (0.00)
Hallucination, visual	1	1 (1.35)	0	0 (0.00)
Mood altered	1	1 (1.35)	0	0 (0.00)
Nightmare	1	1 (1.35)	0	0 (0.00)
Persistent depressive disorder	1	1 (1.35)	0	0 (0.00)
Restlessness	1	1 (1.35)	0	0 (0.00)
Social avoidant behaviour	1	1 (1.35)	0	0 (0.00)
Tearfulness	1	1 (1.35)	0	0 (0.00)
Tic	1	1 (1.35)	0	0 (0.00)
Renal and urinary disorders				
- Total	41	22 (29.73)	13	9 (12.16)
Acute kidney injury	12	9 (12.16)	6	5 (6.76)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Dysuria	4	4 (5.41)	0	0 (0.00)
Renal failure	4	2 (2.70)	3	1 (1.35)
Haematuria	3	3 (4.05)	1	1 (1.35)
Pollakiuria	2	2 (2.70)	0	0 (0.00)
Urinary incontinence	2	1 (1.35)	0	0 (0.00)
Urinary retention	2	2 (2.70)	0	0 (0.00)
Anuria	1	1 (1.35)	1	1 (1.35)
Bladder dilatation	1	1 (1.35)	0	0 (0.00)
Cystitis haemorrhagic	1	1 (1.35)	0	0 (0.00)
Incontinence	1	1 (1.35)	0	0 (0.00)
Kidney enlargement	1	1 (1.35)	0	0 (0.00)
Micturition urgency	1	1 (1.35)	0	0 (0.00)
Proteinuria	1	1 (1.35)	0	0 (0.00)
Renal mass	1	1 (1.35)	0	0 (0.00)
Renal tubular disorder	1	1 (1.35)	1	1 (1.35)
Renal tubular dysfunction	1	1 (1.35)	0	0 (0.00)
Renal tubular necrosis	1	1 (1.35)	1	1 (1.35)
Urinary tract disorder	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Reproductive system and breast disorders				
- Total	7	5 (6.76)	2	2 (2.70)
Endometriosis	2	1 (1.35)	1	1 (1.35)
Vaginal haemorrhage	2	1 (1.35)	0	0 (0.00)
Female genital tract fistula	1	1 (1.35)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (1.35)	0	0 (0.00)
Vaginal ulceration	1	1 (1.35)	1	1 (1.35)
Respiratory, thoracic and mediastinal disorders				
- Total	155	49 (66.22)	55	25 (33.78)
Cough	26	20 (27.03)	0	0 (0.00)
Hypoxia	21	16 (21.62)	17	12 (16.22)
Pulmonary oedema	10	10 (13.51)	7	7 (9.46)
Oropharyngeal pain	9	8 (10.81)	0	0 (0.00)
Tachypnoea	9	8 (10.81)	5	4 (5.41)
Nasal congestion	8	7 (9.46)	0	0 (0.00)
Dyspnoea	7	6 (8.11)	4	4 (5.41)
Pleural effusion	7	6 (8.11)	2	2 (2.70)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Rhinorrhoea	7	5 (6.76)	0	0 (0.00)
Epistaxis	6	5 (6.76)	1	1 (1.35)
Respiratory failure	6	6 (8.11)	6	6 (8.11)
Atelectasis	5	3 (4.05)	2	2 (2.70)
Respiratory distress	4	3 (4.05)	3	2 (2.70)
Acute respiratory distress syndrome	3	3 (4.05)	3	3 (4.05)
Lung infiltration	2	1 (1.35)	1	1 (1.35)
Pharyngeal erythema	2	2 (2.70)	0	0 (0.00)
Acute respiratory failure	1	1 (1.35)	1	1 (1.35)
Bradypnoea	1	1 (1.35)	1	1 (1.35)
Bronchial oedema	1	1 (1.35)	0	0 (0.00)
Bronchospasm	1	1 (1.35)	0	0 (0.00)
Dyspnoea exertional	1	1 (1.35)	0	0 (0.00)
Haemoptysis	1	1 (1.35)	0	0 (0.00)
Laryngeal oedema	1	1 (1.35)	1	1 (1.35)
Lung disorder	1	1 (1.35)	0	0 (0.00)
Nasal dryness	1	1 (1.35)	0	0 (0.00)
Oropharyngeal plaque	1	1 (1.35)	0	0 (0.00)
Painful respiration	1	1 (1.35)	0	0 (0.00)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Paranasal sinus discomfort	1	1 (1.35)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (1.35)	0	0 (0.00)
Pharyngeal exudate	1	1 (1.35)	0	0 (0.00)
Pharyngeal oedema	1	1 (1.35)	0	0 (0.00)
Productive cough	1	1 (1.35)	0	0 (0.00)
Pulmonary mass	1	1 (1.35)	0	0 (0.00)
Respiratory acidosis	1	1 (1.35)	1	1 (1.35)
Respiratory disorder	1	1 (1.35)	0	0 (0.00)
Rhinitis allergic	1	1 (1.35)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (1.35)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (1.35)	0	0 (0.00)
Wheezing	1	1 (1.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	76	35 (47.30)	9	7 (9.46)
Rash	10	6 (8.11)	0	0 (0.00)
Dry skin	9	8 (10.81)	0	0 (0.00)
Pruritus	9	7 (9.46)	0	0 (0.00)
Dermatitis atopic	4	3 (4.05)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Erythema	4	4 (5.41)	0	0 (0.00)
Rash papular	4	3 (4.05)	0	0 (0.00)
Hyperhidrosis	3	3 (4.05)	0	0 (0.00)
Rash maculo-papular	3	2 (2.70)	1	1 (1.35)
Decubitus ulcer	2	2 (2.70)	1	1 (1.35)
Eczema	2	2 (2.70)	1	1 (1.35)
Ingrowing nail	2	2 (2.70)	0	0 (0.00)
Rash macular	2	1 (1.35)	2	1 (1.35)
Rash vesicular	2	1 (1.35)	0	0 (0.00)
Blister	1	1 (1.35)	0	0 (0.00)
Dermatitis	1	1 (1.35)	0	0 (0.00)
Dermatitis allergic	1	1 (1.35)	0	0 (0.00)
Erythema nodosum	1	1 (1.35)	0	0 (0.00)
Hangnail	1	1 (1.35)	0	0 (0.00)
Night sweats	1	1 (1.35)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (1.35)	0	0 (0.00)
Papule	1	1 (1.35)	0	0 (0.00)
Petechiae	1	1 (1.35)	1	1 (1.35)

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
Photosensitivity reaction	1	1 (1.35)	0	0 (0.00)
Pruritus allergic	1	1 (1.35)	0	0 (0.00)
Purpura	1	1 (1.35)	0	0 (0.00)
Rash pruritic	1	1 (1.35)	0	0 (0.00)
Skin discolouration	1	1 (1.35)	0	0 (0.00)
Skin hypopigmentation	1	1 (1.35)	0	0 (0.00)
Skin lesion	1	1 (1.35)	0	0 (0.00)
Skin necrosis	1	1 (1.35)	1	1 (1.35)
Skin ulcer	1	1 (1.35)	0	0 (0.00)
Urticaria	1	1 (1.35)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (1.35)	1	1 (1.35)
Social circumstances				
- Total	1	1 (1.35)	0	0 (0.00)
Patient uncooperative	1	1 (1.35)	0	0 (0.00)
Surgical and medical procedures				
- Total	1	1 (1.35)	1	1 (1.35)
Thrombolysis	1	1 (1.35)	1	1 (1.35)
Vascular disorders				

Timing: At anytime, Down syndrome: No

Primary system organ class Preferred term	All grades Total events	All patients N=74 n (%)[1]	Grade >= 3 Total events	All patients N=74 n (%)[2]
- Total	46	30 (40.54)	23	18 (24.32)
Hypotension	25	21 (28.38)	15	13 (17.57)
Hypertension	14	13 (17.57)	5	5 (6.76)
Capillary leak syndrome	2	2 (2.70)	1	1 (1.35)
Venoocclusive disease	2	2 (2.70)	2	2 (2.70)
Flushing	1	1 (1.35)	0	0 (0.00)
Hot flush	1	1 (1.35)	0	0 (0.00)
Peripheral ischaemia	1	1 (1.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	829	39 (97.50)	291	36 (90.00)
Blood and lymphatic system disorders				
- Total	75	27 (67.50)	47	21 (52.50)
Anaemia	32	10 (25.00)	15	6 (15.00)
Febrile neutropenia	11	11 (27.50)	11	11 (27.50)
Neutropenia	9	7 (17.50)	8	6 (15.00)
Thrombocytopenia	5	5 (12.50)	5	5 (12.50)
Disseminated intravascular coagulation	4	4 (10.00)	0	0 (0.00)
Coagulopathy	3	3 (7.50)	2	2 (5.00)
Leukopenia	3	2 (5.00)	3	2 (5.00)
Eosinophilia	2	1 (2.50)	0	0 (0.00)
Pancytopenia	2	2 (5.00)	2	2 (5.00)
B-cell aplasia	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypofibrinogenaemia	1	1 (2.50)	0	0 (0.00)
Lymphopenia	1	1 (2.50)	1	1 (2.50)
Splenomegaly	1	1 (2.50)	0	0 (0.00)
Cardiac disorders				
- Total	14	7 (17.50)	1	1 (2.50)
Tachycardia	4	3 (7.50)	0	0 (0.00)
Sinus tachycardia	3	2 (5.00)	0	0 (0.00)
Cardiac dysfunction	2	2 (5.00)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.50)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.50)	1	1 (2.50)
Mitral valve incompetence	1	1 (2.50)	0	0 (0.00)
Pericardial effusion	1	1 (2.50)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.50)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.50)	0	0 (0.00)
Hypothyroidism	1	1 (2.50)	0	0 (0.00)
Eye disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
- Total	6	4 (10.00)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.50)	0	0 (0.00)
Eye oedema	1	1 (2.50)	0	0 (0.00)
Periorbital swelling	1	1 (2.50)	0	0 (0.00)
Visual field defect	1	1 (2.50)	0	0 (0.00)
Visual impairment	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	70	24 (60.00)	7	6 (15.00)
Vomiting	16	10 (25.00)	0	0 (0.00)
Diarrhoea	10	9 (22.50)	0	0 (0.00)
Nausea	10	8 (20.00)	2	2 (5.00)
Abdominal pain	9	7 (17.50)	1	1 (2.50)
Constipation	4	4 (10.00)	0	0 (0.00)
Abdominal distension	2	2 (5.00)	0	0 (0.00)
Ascites	2	2 (5.00)	0	0 (0.00)
Mouth haemorrhage	2	2 (5.00)	1	1 (2.50)
Pancreatitis	2	2 (5.00)	0	0 (0.00)
Stomatitis	2	2 (5.00)	1	1 (2.50)
Abdominal pain upper	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Enterocolitis	1	1 (2.50)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (2.50)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.50)	0	0 (0.00)
Gingival bleeding	1	1 (2.50)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.50)	1	1 (2.50)
Lip dry	1	1 (2.50)	0	0 (0.00)
Mouth swelling	1	1 (2.50)	0	0 (0.00)
Odynophagia	1	1 (2.50)	0	0 (0.00)
Proctalgia	1	1 (2.50)	1	1 (2.50)
Upper gastrointestinal haemorrhage	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	63	17 (42.50)	12	5 (12.50)
Pyrexia	26	10 (25.00)	5	4 (10.00)
Chills	8	5 (12.50)	0	0 (0.00)
Face oedema	5	4 (10.00)	1	1 (2.50)
Oedema peripheral	4	3 (7.50)	2	1 (2.50)
Catheter site pain	3	1 (2.50)	2	1 (2.50)
Asthenia	2	2 (5.00)	0	0 (0.00)
Fatigue	2	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Generalised oedema	2	2 (5.00)	0	0 (0.00)
Influenza like illness	2	2 (5.00)	0	0 (0.00)
Chest discomfort	1	1 (2.50)	1	1 (2.50)
Crying	1	1 (2.50)	0	0 (0.00)
Facial pain	1	1 (2.50)	0	0 (0.00)
Localised oedema	1	1 (2.50)	0	0 (0.00)
Malaise	1	1 (2.50)	0	0 (0.00)
Pain	1	1 (2.50)	1	1 (2.50)
Sluggishness	1	1 (2.50)	0	0 (0.00)
Swelling face	1	1 (2.50)	0	0 (0.00)
Vascular device occlusion	1	1 (2.50)	0	0 (0.00)
Hepatobiliary disorders				
- Total	14	8 (20.00)	4	3 (7.50)
Hepatic function abnormal	10	4 (10.00)	4	3 (7.50)
Hyperbilirubinaemia	2	2 (5.00)	0	0 (0.00)
Cholelithiasis	1	1 (2.50)	0	0 (0.00)
Hepatomegaly	1	1 (2.50)	0	0 (0.00)
Immune system disorders				
- Total	81	34 (85.00)	35	24 (60.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Cytokine release syndrome	61	31 (77.50)	26	20 (50.00)
Hypogammaglobulinaemia	14	14 (35.00)	6	6 (15.00)
Immunodeficiency	3	3 (7.50)	3	3 (7.50)
Haemophagocytic lymphohistiocytosis	1	1 (2.50)	0	0 (0.00)
Hypersensitivity	1	1 (2.50)	0	0 (0.00)
Seasonal allergy	1	1 (2.50)	0	0 (0.00)
Infections and infestations				
- Total	42	21 (52.50)	24	13 (32.50)
Conjunctivitis	4	3 (7.50)	0	0 (0.00)
Candida infection	3	2 (5.00)	2	1 (2.50)
Staphylococcal infection	3	3 (7.50)	2	2 (5.00)
Encephalitis viral	2	2 (5.00)	2	2 (5.00)
Oral candidiasis	2	1 (2.50)	0	0 (0.00)
Oral herpes	2	2 (5.00)	1	1 (2.50)
Adenovirus infection	1	1 (2.50)	1	1 (2.50)
Anal abscess	1	1 (2.50)	1	1 (2.50)
BK virus infection	1	1 (2.50)	0	0 (0.00)
Bacteraemia	1	1 (2.50)	1	1 (2.50)
Bronchopulmonary aspergillosis	1	1 (2.50)	1	1 (2.50)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Clostridium difficile infection	1	1 (2.50)	1	1 (2.50)
Gingivitis	1	1 (2.50)	0	0 (0.00)
Granulicatella infection	1	1 (2.50)	1	1 (2.50)
Herpes simplex	1	1 (2.50)	1	1 (2.50)
Human herpesvirus 6 infection	1	1 (2.50)	1	1 (2.50)
Klebsiella infection	1	1 (2.50)	1	1 (2.50)
Meningitis bacterial	1	1 (2.50)	1	1 (2.50)
Myringitis	1	1 (2.50)	0	0 (0.00)
Nail infection	1	1 (2.50)	0	0 (0.00)
Oral infection	1	1 (2.50)	0	0 (0.00)
Otitis externa	1	1 (2.50)	0	0 (0.00)
Paronychia	1	1 (2.50)	0	0 (0.00)
Pneumonia	1	1 (2.50)	1	1 (2.50)
Pneumonia fungal	1	1 (2.50)	1	1 (2.50)
Pneumonia viral	1	1 (2.50)	1	1 (2.50)
Sinusitis	1	1 (2.50)	1	1 (2.50)
Soft tissue infection	1	1 (2.50)	1	1 (2.50)
Stomatococcal infection	1	1 (2.50)	0	0 (0.00)
Systemic candida	1	1 (2.50)	1	1 (2.50)
Urinary tract infection viral	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Varicella zoster virus infection	1	1 (2.50)	1	1 (2.50)
Injury, poisoning and procedural complications				
- Total	6	4 (10.00)	1	1 (2.50)
Infusion related reaction	3	2 (5.00)	0	0 (0.00)
Fall	1	1 (2.50)	0	0 (0.00)
Procedural pain	1	1 (2.50)	0	0 (0.00)
Transplant failure	1	1 (2.50)	1	1 (2.50)
Investigations				
- Total	188	26 (65.00)	101	21 (52.50)
Platelet count decreased	39	11 (27.50)	23	8 (20.00)
White blood cell count decreased	33	12 (30.00)	23	10 (25.00)
Neutrophil count decreased	27	11 (27.50)	22	10 (25.00)
Lymphocyte count decreased	22	7 (17.50)	17	6 (15.00)
Aspartate aminotransferase increased	16	5 (12.50)	5	3 (7.50)
Alanine aminotransferase increased	12	6 (15.00)	3	3 (7.50)
Blood bilirubin increased	6	2 (5.00)	1	1 (2.50)
Serum ferritin increased	5	5 (12.50)	0	0 (0.00)
Immunoglobulins decreased	4	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood creatine phosphokinase increased	3	1 (2.50)	1	1 (2.50)
Blood fibrinogen decreased	2	2 (5.00)	0	0 (0.00)
Blood glucose increased	2	1 (2.50)	2	1 (2.50)
Blood lactate dehydrogenase increased	2	2 (5.00)	0	0 (0.00)
C-reactive protein increased	2	2 (5.00)	1	1 (2.50)
Gamma-glutamyltransferase increased	2	2 (5.00)	2	2 (5.00)
Haemoglobin decreased	2	1 (2.50)	1	1 (2.50)
Weight increased	2	2 (5.00)	0	0 (0.00)
Blood alkaline phosphatase increased	1	1 (2.50)	0	0 (0.00)
Blood creatinine increased	1	1 (2.50)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (2.50)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.50)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.50)	0	0 (0.00)
International normalised ratio increased	1	1 (2.50)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.50)	0	0 (0.00)
Metabolism and nutrition disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
- Total	80	18 (45.00)	22	11 (27.50)
Hypokalaemia	14	8 (20.00)	6	5 (12.50)
Hypoalbuminaemia	13	6 (15.00)	0	0 (0.00)
Hypophosphataemia	12	6 (15.00)	5	3 (7.50)
Decreased appetite	9	9 (22.50)	3	3 (7.50)
Hyperglycaemia	6	4 (10.00)	2	2 (5.00)
Hypocalcaemia	6	4 (10.00)	1	1 (2.50)
Hypomagnesaemia	6	5 (12.50)	0	0 (0.00)
Hypermagnesaemia	3	2 (5.00)	0	0 (0.00)
Acidosis	2	1 (2.50)	1	1 (2.50)
Hyperuricaemia	2	1 (2.50)	1	1 (2.50)
Hyponatraemia	2	2 (5.00)	0	0 (0.00)
Tumour lysis syndrome	2	2 (5.00)	2	2 (5.00)
Hypernatraemia	1	1 (2.50)	0	0 (0.00)
Hypervolaemia	1	1 (2.50)	0	0 (0.00)
Polydipsia	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				
- Total	30	16 (40.00)	2	2 (5.00)
Arthralgia	6	6 (15.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Myalgia	6	5 (12.50)	0	0 (0.00)
Pain in extremity	6	6 (15.00)	0	0 (0.00)
Back pain	4	4 (10.00)	1	1 (2.50)
Bone pain	3	1 (2.50)	0	0 (0.00)
Pain in jaw	2	2 (5.00)	1	1 (2.50)
Muscular weakness	1	1 (2.50)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.50)	0	0 (0.00)
Neck pain	1	1 (2.50)	0	0 (0.00)
Nervous system disorders				
- Total	37	18 (45.00)	4	3 (7.50)
Headache	10	10 (25.00)	1	1 (2.50)
Tremor	4	3 (7.50)	0	0 (0.00)
Dysgeusia	3	3 (7.50)	0	0 (0.00)
Encephalopathy	3	3 (7.50)	1	1 (2.50)
Seizure	3	2 (5.00)	1	1 (2.50)
Somnolence	3	3 (7.50)	0	0 (0.00)
Dizziness	2	2 (5.00)	0	0 (0.00)
Hyperaesthesia	2	1 (2.50)	0	0 (0.00)
Lethargy	2	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Amnesia	1	1 (2.50)	0	0 (0.00)
Aphasia	1	1 (2.50)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.50)	1	1 (2.50)
Disturbance in attention	1	1 (2.50)	0	0 (0.00)
Hypoaesthesia	1	1 (2.50)	0	0 (0.00)
Psychiatric disorders				
- Total	15	8 (20.00)	1	1 (2.50)
Hallucination	3	3 (7.50)	0	0 (0.00)
Confusional state	2	2 (5.00)	0	0 (0.00)
Sleep disorder	2	1 (2.50)	0	0 (0.00)
Affect lability	1	1 (2.50)	0	0 (0.00)
Agitation	1	1 (2.50)	0	0 (0.00)
Anxiety	1	1 (2.50)	1	1 (2.50)
Delirium	1	1 (2.50)	0	0 (0.00)
Hallucination, visual	1	1 (2.50)	0	0 (0.00)
Irritability	1	1 (2.50)	0	0 (0.00)
Restlessness	1	1 (2.50)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
- Total	19	10 (25.00)	5	4 (10.00)
Acute kidney injury	8	5 (12.50)	4	3 (7.50)
Haematuria	2	2 (5.00)	0	0 (0.00)
Urinary incontinence	2	1 (2.50)	0	0 (0.00)
Anuria	1	1 (2.50)	1	1 (2.50)
Dysuria	1	1 (2.50)	0	0 (0.00)
Incontinence	1	1 (2.50)	0	0 (0.00)
Pollakiuria	1	1 (2.50)	0	0 (0.00)
Proteinuria	1	1 (2.50)	0	0 (0.00)
Renal failure	1	1 (2.50)	0	0 (0.00)
Urinary tract disorder	1	1 (2.50)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (7.50)	0	0 (0.00)
Vaginal haemorrhage	2	1 (2.50)	0	0 (0.00)
Female genital tract fistula	1	1 (2.50)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.50)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	49	18 (45.00)	21	10 (25.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypoxia	12	7 (17.50)	10	5 (12.50)
Cough	6	5 (12.50)	0	0 (0.00)
Pulmonary oedema	5	5 (12.50)	4	4 (10.00)
Epistaxis	3	3 (7.50)	1	1 (2.50)
Oropharyngeal pain	3	3 (7.50)	0	0 (0.00)
Tachypnoea	3	3 (7.50)	2	2 (5.00)
Dyspnoea	2	2 (5.00)	2	2 (5.00)
Lung infiltration	2	1 (2.50)	1	1 (2.50)
Pleural effusion	2	2 (5.00)	0	0 (0.00)
Acute respiratory failure	1	1 (2.50)	1	1 (2.50)
Atelectasis	1	1 (2.50)	0	0 (0.00)
Nasal congestion	1	1 (2.50)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.50)	0	0 (0.00)
Painful respiration	1	1 (2.50)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.50)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.50)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.50)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.50)	0	0 (0.00)
Pulmonary mass	1	1 (2.50)	0	0 (0.00)
Respiratory disorder	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	20	12 (30.00)	1	1 (2.50)
Rash maculo-papular	3	2 (5.00)	1	1 (2.50)
Dermatitis atopic	2	2 (5.00)	0	0 (0.00)
Hyperhidrosis	2	2 (5.00)	0	0 (0.00)
Pruritus	2	2 (5.00)	0	0 (0.00)
Rash papular	2	1 (2.50)	0	0 (0.00)
Rash vesicular	2	1 (2.50)	0	0 (0.00)
Erythema	1	1 (2.50)	0	0 (0.00)
Erythema nodosum	1	1 (2.50)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.50)	0	0 (0.00)
Purpura	1	1 (2.50)	0	0 (0.00)
Rash	1	1 (2.50)	0	0 (0.00)
Skin lesion	1	1 (2.50)	0	0 (0.00)
Skin ulcer	1	1 (2.50)	0	0 (0.00)
Social circumstances				
- Total	1	1 (2.50)	0	0 (0.00)
Patient uncooperative	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Vascular disorders				
- Total	13	9 (22.50)	3	3 (7.50)
Hypotension	6	5 (12.50)	3	3 (7.50)
Hypertension	5	5 (12.50)	0	0 (0.00)
Flushing	1	1 (2.50)	0	0 (0.00)
Hot flush	1	1 (2.50)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	922	40 (100.00)	328	31 (77.50)
Blood and lymphatic system disorders				
- Total	50	23 (57.50)	29	18 (45.00)
Anaemia	18	11 (27.50)	5	2 (5.00)
Febrile neutropenia	18	15 (37.50)	18	15 (37.50)
Disseminated intravascular coagulation	3	3 (7.50)	2	2 (5.00)
Splenomegaly	3	3 (7.50)	0	0 (0.00)
Thrombocytopenia	3	3 (7.50)	3	3 (7.50)
Coagulopathy	2	2 (5.00)	0	0 (0.00)
Neutropenia	2	2 (5.00)	1	1 (2.50)
Leukopenia	1	1 (2.50)	0	0 (0.00)
Cardiac disorders				
- Total	31	17 (42.50)	9	7 (17.50)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Tachycardia	18	14 (35.00)	3	3 (7.50)
Cardiac failure	4	1 (2.50)	2	1 (2.50)
Bradycardia	3	3 (7.50)	0	0 (0.00)
Left ventricular dysfunction	2	2 (5.00)	2	2 (5.00)
Atrioventricular block first degree	1	1 (2.50)	0	0 (0.00)
Cardiac arrest	1	1 (2.50)	1	1 (2.50)
Sinus bradycardia	1	1 (2.50)	1	1 (2.50)
Sinus tachycardia	1	1 (2.50)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (5.00)	0	0 (0.00)
Ear pain	1	1 (2.50)	0	0 (0.00)
Ear pruritus	1	1 (2.50)	0	0 (0.00)
Endocrine disorders				
- Total	3	3 (7.50)	0	0 (0.00)
Adrenal insufficiency	3	3 (7.50)	0	0 (0.00)
Eye disorders				
- Total	9	5 (12.50)	0	0 (0.00)
Eyelid oedema	3	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Conjunctival haemorrhage	2	2 (5.00)	0	0 (0.00)
Ocular hyperaemia	2	2 (5.00)	0	0 (0.00)
Eye pain	1	1 (2.50)	0	0 (0.00)
Periorbital oedema	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	65	27 (67.50)	9	8 (20.00)
Vomiting	14	11 (27.50)	1	1 (2.50)
Nausea	11	10 (25.00)	0	0 (0.00)
Diarrhoea	8	6 (15.00)	1	1 (2.50)
Constipation	7	7 (17.50)	0	0 (0.00)
Abdominal pain	4	4 (10.00)	1	1 (2.50)
Abdominal pain upper	2	2 (5.00)	0	0 (0.00)
Mouth haemorrhage	2	2 (5.00)	1	1 (2.50)
Pancreatitis	2	2 (5.00)	1	1 (2.50)
Abdominal compartment syndrome	1	1 (2.50)	1	1 (2.50)
Abdominal distension	1	1 (2.50)	0	0 (0.00)
Anal fissure	1	1 (2.50)	0	0 (0.00)
Anal haemorrhage	1	1 (2.50)	0	0 (0.00)
Ascites	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Dry mouth	1	1 (2.50)	0	0 (0.00)
Dysphagia	1	1 (2.50)	1	1 (2.50)
Gastrointestinal sounds abnormal	1	1 (2.50)	0	0 (0.00)
Gingival erythema	1	1 (2.50)	0	0 (0.00)
Haematemesis	1	1 (2.50)	0	0 (0.00)
Ileus	1	1 (2.50)	0	0 (0.00)
Lip oedema	1	1 (2.50)	0	0 (0.00)
Melaena	1	1 (2.50)	1	1 (2.50)
Neutropenic colitis	1	1 (2.50)	1	1 (2.50)
Trichoglossia	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	49	23 (57.50)	7	6 (15.00)
Pyrexia	18	14 (35.00)	4	4 (10.00)
Fatigue	9	9 (22.50)	0	0 (0.00)
Face oedema	4	4 (10.00)	0	0 (0.00)
Generalised oedema	3	3 (7.50)	0	0 (0.00)
Oedema peripheral	3	3 (7.50)	0	0 (0.00)
Catheter site erythema	2	1 (2.50)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Multiple organ dysfunction syndrome	2	2 (5.00)	2	2 (5.00)
Catheter site haemorrhage	1	1 (2.50)	0	0 (0.00)
Catheter site pain	1	1 (2.50)	0	0 (0.00)
Chills	1	1 (2.50)	0	0 (0.00)
Localised oedema	1	1 (2.50)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.50)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (2.50)	1	1 (2.50)
Hepatobiliary disorders				
- Total	15	9 (22.50)	3	3 (7.50)
Hyperbilirubinaemia	4	3 (7.50)	1	1 (2.50)
Gallbladder enlargement	2	2 (5.00)	0	0 (0.00)
Hepatomegaly	2	2 (5.00)	1	1 (2.50)
Hypertransaminasaemia	2	2 (5.00)	0	0 (0.00)
Biliary tract disorder	1	1 (2.50)	0	0 (0.00)
Cholelithiasis	1	1 (2.50)	0	0 (0.00)
Cholestasis	1	1 (2.50)	1	1 (2.50)
Hepatic function abnormal	1	1 (2.50)	0	0 (0.00)
Ocular icterus	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Immune system disorders				
- Total	83	33 (82.50)	33	19 (47.50)
Cytokine release syndrome	67	30 (75.00)	29	18 (45.00)
Hypogammaglobulinaemia	11	9 (22.50)	1	1 (2.50)
Haemophagocytic lymphohistiocytosis	4	4 (10.00)	3	3 (7.50)
Selective IgG subclass deficiency	1	1 (2.50)	0	0 (0.00)
Infections and infestations				
- Total	22	14 (35.00)	7	6 (15.00)
Staphylococcal bacteraemia	4	3 (7.50)	4	3 (7.50)
Clostridium difficile infection	3	3 (7.50)	2	2 (5.00)
Conjunctivitis	2	2 (5.00)	0	0 (0.00)
Rhinovirus infection	2	2 (5.00)	0	0 (0.00)
Staphylococcal infection	2	2 (5.00)	0	0 (0.00)
Atypical pneumonia	1	1 (2.50)	0	0 (0.00)
Candida infection	1	1 (2.50)	0	0 (0.00)
Cholecystitis infective	1	1 (2.50)	0	0 (0.00)
Encephalitis	1	1 (2.50)	1	1 (2.50)
Gastroenteritis norovirus	1	1 (2.50)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Localised infection	1	1 (2.50)	0	0 (0.00)
Nail infection	1	1 (2.50)	0	0 (0.00)
Oral infection	1	1 (2.50)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	14	7 (17.50)	2	1 (2.50)
Wound	3	2 (5.00)	1	1 (2.50)
Contusion	2	1 (2.50)	0	0 (0.00)
Transfusion reaction	2	2 (5.00)	0	0 (0.00)
Fall	1	1 (2.50)	0	0 (0.00)
Procedural pain	1	1 (2.50)	0	0 (0.00)
Scratch	1	1 (2.50)	0	0 (0.00)
Skin abrasion	1	1 (2.50)	0	0 (0.00)
Skin injury	1	1 (2.50)	0	0 (0.00)
Skin wound	1	1 (2.50)	0	0 (0.00)
Vasoplegia syndrome	1	1 (2.50)	1	1 (2.50)
Investigations				
- Total	198	31 (77.50)	96	24 (60.00)
Platelet count decreased	26	10 (25.00)	15	6 (15.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Neutrophil count decreased	21	9 (22.50)	16	7 (17.50)
Aspartate aminotransferase increased	17	14 (35.00)	8	8 (20.00)
White blood cell count decreased	17	12 (30.00)	13	8 (20.00)
Alanine aminotransferase increased	14	12 (30.00)	3	3 (7.50)
Blood bilirubin increased	12	10 (25.00)	8	8 (20.00)
International normalised ratio increased	11	8 (20.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (15.00)	1	1 (2.50)
Lymphocyte count decreased	8	8 (20.00)	7	7 (17.50)
Blood immunoglobulin M decreased	6	6 (15.00)	1	1 (2.50)
Electrocardiogram QT prolonged	6	5 (12.50)	2	2 (5.00)
Blood creatinine increased	5	3 (7.50)	5	3 (7.50)
Blood fibrinogen decreased	5	5 (12.50)	2	2 (5.00)
Blood immunoglobulin A decreased	4	4 (10.00)	0	0 (0.00)
Lipase increased	4	2 (5.00)	2	1 (2.50)
Serum ferritin increased	3	3 (7.50)	2	2 (5.00)
Urine output decreased	3	2 (5.00)	3	2 (5.00)
Blood immunoglobulin G decreased	2	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood lactate dehydrogenase increased	2	2 (5.00)	1	1 (2.50)
Blood uric acid increased	2	2 (5.00)	0	0 (0.00)
C-reactive protein increased	2	2 (5.00)	2	2 (5.00)
Fibrin D dimer increased	2	2 (5.00)	1	1 (2.50)
Weight increased	2	2 (5.00)	1	1 (2.50)
Amylase increased	1	1 (2.50)	0	0 (0.00)
Bacterial test positive	1	1 (2.50)	1	1 (2.50)
Blood bicarbonate decreased	1	1 (2.50)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.50)	1	1 (2.50)
Blood phosphorus increased	1	1 (2.50)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.50)	0	0 (0.00)
Cardiac murmur	1	1 (2.50)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.50)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.50)	0	0 (0.00)
Enterovirus test positive	1	1 (2.50)	0	0 (0.00)
Haptoglobin decreased	1	1 (2.50)	0	0 (0.00)
Immunoglobulins decreased	1	1 (2.50)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Staphylococcus test positive	1	1 (2.50)	0	0 (0.00)
Troponin increased	1	1 (2.50)	1	1 (2.50)
Weight decreased	1	1 (2.50)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	130	28 (70.00)	54	18 (45.00)
Hypokalaemia	26	11 (27.50)	14	6 (15.00)
Hypophosphataemia	19	11 (27.50)	6	6 (15.00)
Hypocalcaemia	18	12 (30.00)	5	4 (10.00)
Decreased appetite	15	15 (37.50)	8	8 (20.00)
Hyperuricaemia	7	6 (15.00)	0	0 (0.00)
Hypoalbuminaemia	6	5 (12.50)	1	1 (2.50)
Hyperglycaemia	5	4 (10.00)	2	2 (5.00)
Hyperphosphataemia	5	5 (12.50)	1	1 (2.50)
Hypervolaemia	5	5 (12.50)	4	4 (10.00)
Hypercalcaemia	4	3 (7.50)	2	2 (5.00)
Metabolic acidosis	3	3 (7.50)	2	2 (5.00)
Hyperkalaemia	2	2 (5.00)	2	2 (5.00)
Hypertriglyceridaemia	2	2 (5.00)	2	2 (5.00)
Tumour lysis syndrome	2	2 (5.00)	2	2 (5.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Acidosis	1	1 (2.50)	1	1 (2.50)
Calcium deficiency	1	1 (2.50)	0	0 (0.00)
Dehydration	1	1 (2.50)	0	0 (0.00)
Haemosiderosis	1	1 (2.50)	0	0 (0.00)
Hyperchloraemia	1	1 (2.50)	0	0 (0.00)
Hyperlactacidaemia	1	1 (2.50)	0	0 (0.00)
Hypernatraemia	1	1 (2.50)	1	1 (2.50)
Hypoglycaemia	1	1 (2.50)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.50)	0	0 (0.00)
Hyponatraemia	1	1 (2.50)	0	0 (0.00)
Malnutrition	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				
- Total	23	17 (42.50)	4	3 (7.50)
Pain in extremity	5	5 (12.50)	0	0 (0.00)
Arthralgia	4	4 (10.00)	1	1 (2.50)
Myalgia	4	4 (10.00)	0	0 (0.00)
Back pain	3	2 (5.00)	0	0 (0.00)
Bone pain	1	1 (2.50)	0	0 (0.00)
Haemarthrosis	1	1 (2.50)	1	1 (2.50)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Muscle rigidity	1	1 (2.50)	0	0 (0.00)
Muscle spasms	1	1 (2.50)	0	0 (0.00)
Muscular weakness	1	1 (2.50)	1	1 (2.50)
Myositis	1	1 (2.50)	0	0 (0.00)
Rhabdomyolysis	1	1 (2.50)	1	1 (2.50)
Nervous system disorders				
- Total	40	22 (55.00)	10	7 (17.50)
Headache	16	13 (32.50)	1	1 (2.50)
Cognitive disorder	5	3 (7.50)	1	1 (2.50)
Encephalopathy	5	5 (12.50)	3	3 (7.50)
Tremor	3	3 (7.50)	0	0 (0.00)
Somnolence	2	2 (5.00)	2	2 (5.00)
Cerebral haemorrhage	1	1 (2.50)	1	1 (2.50)
Dizziness	1	1 (2.50)	0	0 (0.00)
Dysarthria	1	1 (2.50)	1	1 (2.50)
Generalised tonic-clonic seizure	1	1 (2.50)	0	0 (0.00)
Lethargy	1	1 (2.50)	0	0 (0.00)
Monoparesis	1	1 (2.50)	0	0 (0.00)
Neuralgia	1	1 (2.50)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Neurological decompensation	1	1 (2.50)	1	1 (2.50)
Paraesthesia	1	1 (2.50)	0	0 (0.00)
Psychiatric disorders				
- Total	32	20 (50.00)	5	5 (12.50)
Delirium	6	6 (15.00)	3	3 (7.50)
Agitation	5	4 (10.00)	0	0 (0.00)
Anxiety	5	5 (12.50)	1	1 (2.50)
Confusional state	5	5 (12.50)	0	0 (0.00)
Insomnia	4	4 (10.00)	0	0 (0.00)
Mental status changes	3	3 (7.50)	1	1 (2.50)
Irritability	2	2 (5.00)	0	0 (0.00)
Automatism	1	1 (2.50)	0	0 (0.00)
Sleep disorder	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				
- Total	20	10 (25.00)	8	5 (12.50)
Acute kidney injury	6	4 (10.00)	4	4 (10.00)
Renal failure	3	1 (2.50)	3	1 (2.50)
Dysuria	2	2 (5.00)	0	0 (0.00)
Urinary retention	2	2 (5.00)	0	0 (0.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Anuria	1	1 (2.50)	0	0 (0.00)
Azotaemia	1	1 (2.50)	0	0 (0.00)
Bladder dilatation	1	1 (2.50)	0	0 (0.00)
Micturition urgency	1	1 (2.50)	0	0 (0.00)
Pollakiuria	1	1 (2.50)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.50)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.50)	1	1 (2.50)
Reproductive system and breast disorders				
- Total	2	2 (5.00)	1	1 (2.50)
Perineal rash	1	1 (2.50)	0	0 (0.00)
Vaginal ulceration	1	1 (2.50)	1	1 (2.50)
Respiratory, thoracic and mediastinal disorders				
- Total	65	23 (57.50)	29	13 (32.50)
Hypoxia	11	10 (25.00)	8	7 (17.50)
Pulmonary oedema	7	7 (17.50)	3	3 (7.50)
Tachypnoea	6	5 (12.50)	2	2 (5.00)
Cough	5	5 (12.50)	0	0 (0.00)
Pleural effusion	5	5 (12.50)	3	3 (7.50)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Atelectasis	4	2 (5.00)	2	2 (5.00)
Respiratory distress	4	3 (7.50)	2	1 (2.50)
Respiratory failure	4	4 (10.00)	4	4 (10.00)
Oropharyngeal pain	3	2 (5.00)	0	0 (0.00)
Acute respiratory distress syndrome	2	2 (5.00)	2	2 (5.00)
Nasal congestion	2	2 (5.00)	0	0 (0.00)
Rhinorrhoea	2	2 (5.00)	0	0 (0.00)
Bradypnoea	1	1 (2.50)	1	1 (2.50)
Dyspnoea	1	1 (2.50)	1	1 (2.50)
Epistaxis	1	1 (2.50)	0	0 (0.00)
Haemoptysis	1	1 (2.50)	0	0 (0.00)
Nasal discomfort	1	1 (2.50)	0	0 (0.00)
Nasal dryness	1	1 (2.50)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.50)	0	0 (0.00)
Productive cough	1	1 (2.50)	0	0 (0.00)
Respiratory acidosis	1	1 (2.50)	1	1 (2.50)
Wheezing	1	1 (2.50)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	36	15 (37.50)	3	2 (5.00)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blister	6	3 (7.50)	0	0 (0.00)
Pruritus	5	4 (10.00)	0	0 (0.00)
Rash	4	4 (10.00)	0	0 (0.00)
Erythema	3	3 (7.50)	0	0 (0.00)
Petechiae	2	2 (5.00)	1	1 (2.50)
Rash papular	2	2 (5.00)	0	0 (0.00)
Decubitus ulcer	1	1 (2.50)	0	0 (0.00)
Dermatitis	1	1 (2.50)	0	0 (0.00)
Dermatitis diaper	1	1 (2.50)	0	0 (0.00)
Dry skin	1	1 (2.50)	0	0 (0.00)
Eczema	1	1 (2.50)	0	0 (0.00)
Hyperhidrosis	1	1 (2.50)	0	0 (0.00)
Pruritus allergic	1	1 (2.50)	0	0 (0.00)
Rash pruritic	1	1 (2.50)	0	0 (0.00)
Scab	1	1 (2.50)	0	0 (0.00)
Skin discolouration	1	1 (2.50)	0	0 (0.00)
Skin necrosis	1	1 (2.50)	1	1 (2.50)
Skin ulcer	1	1 (2.50)	0	0 (0.00)
Urticaria	1	1 (2.50)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.50)	1	1 (2.50)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Surgical and medical procedures				
- Total	1	1 (2.50)	1	1 (2.50)
Thrombolysis	1	1 (2.50)	1	1 (2.50)
Vascular disorders				
- Total	32	19 (47.50)	18	14 (35.00)
Hypotension	19	16 (40.00)	13	11 (27.50)
Hypertension	9	8 (20.00)	4	4 (10.00)
Capillary leak syndrome	2	2 (5.00)	1	1 (2.50)
Peripheral ischaemia	1	1 (2.50)	0	0 (0.00)
Thrombosis	1	1 (2.50)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	274	38 (95.00)	80	22 (55.00)
Blood and lymphatic system disorders				
- Total	18	11 (27.50)	10	7 (17.50)
Neutropenia	5	5 (12.50)	5	5 (12.50)
Anaemia	4	3 (7.50)	0	0 (0.00)
B-cell aplasia	2	1 (2.50)	0	0 (0.00)
Febrile neutropenia	2	1 (2.50)	2	1 (2.50)
Disseminated intravascular coagulation	1	1 (2.50)	1	1 (2.50)
Eosinophilia	1	1 (2.50)	0	0 (0.00)
Lymphadenopathy	1	1 (2.50)	0	0 (0.00)
Lymphopenia	1	1 (2.50)	1	1 (2.50)
Thrombocytopenia	1	1 (2.50)	1	1 (2.50)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Cardiac disorders				
- Total	4	4 (10.00)	2	2 (5.00)
Cardiac arrest	1	1 (2.50)	1	1 (2.50)
Cardiac failure	1	1 (2.50)	1	1 (2.50)
Left ventricular dysfunction	1	1 (2.50)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.50)	0	0 (0.00)
Eye disorders				
- Total	3	2 (5.00)	0	0 (0.00)
Cataract	2	2 (5.00)	0	0 (0.00)
Hypermetropia	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	19	10 (25.00)	0	0 (0.00)
Vomiting	4	3 (7.50)	0	0 (0.00)
Constipation	2	2 (5.00)	0	0 (0.00)
Diarrhoea	2	2 (5.00)	0	0 (0.00)
Nausea	2	2 (5.00)	0	0 (0.00)
Abdominal pain upper	1	1 (2.50)	0	0 (0.00)
Abdominal rigidity	1	1 (2.50)	0	0 (0.00)
Dyspepsia	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Enteritis	1	1 (2.50)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.50)	0	0 (0.00)
Pancreatitis	1	1 (2.50)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.50)	0	0 (0.00)
Stomatitis	1	1 (2.50)	0	0 (0.00)
Trichoglossia	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	10 (25.00)	1	1 (2.50)
Pyrexia	8	7 (17.50)	0	0 (0.00)
Fatigue	3	2 (5.00)	0	0 (0.00)
Asthenia	1	1 (2.50)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.50)	0	0 (0.00)
Pain	1	1 (2.50)	1	1 (2.50)
Hepatobiliary disorders				
- Total	1	1 (2.50)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.50)	0	0 (0.00)
Immune system disorders				
- Total	5	5 (12.50)	2	2 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypogammaglobulinaemia	2	2 (5.00)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.50)	0	0 (0.00)
Graft versus host disease	1	1 (2.50)	1	1 (2.50)
Immunodeficiency	1	1 (2.50)	1	1 (2.50)
Infections and infestations				
- Total	76	26 (65.00)	30	12 (30.00)
Nasopharyngitis	9	7 (17.50)	0	0 (0.00)
Upper respiratory tract infection	7	5 (12.50)	1	1 (2.50)
Bronchopulmonary aspergillosis	5	1 (2.50)	3	1 (2.50)
Gastroenteritis	5	5 (12.50)	2	2 (5.00)
Parainfluenzae virus infection	4	3 (7.50)	2	2 (5.00)
Respiratory tract infection	3	3 (7.50)	0	0 (0.00)
Sinusitis	3	2 (5.00)	1	1 (2.50)
Bacteraemia	2	1 (2.50)	2	1 (2.50)
Ear infection	2	1 (2.50)	0	0 (0.00)
Klebsiella infection	2	1 (2.50)	2	1 (2.50)
Otitis media	2	2 (5.00)	1	1 (2.50)
Pneumonia	2	2 (5.00)	1	1 (2.50)
Rhinitis	2	2 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Rhinovirus infection	2	2 (5.00)	1	1 (2.50)
Urinary tract infection	2	1 (2.50)	2	1 (2.50)
Conjunctivitis	1	1 (2.50)	0	0 (0.00)
Cystitis	1	1 (2.50)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.50)	1	1 (2.50)
Ear, nose and throat infection	1	1 (2.50)	0	0 (0.00)
Encephalitis	1	1 (2.50)	1	1 (2.50)
Enterobacter infection	1	1 (2.50)	1	1 (2.50)
Gingivitis	1	1 (2.50)	0	0 (0.00)
Herpes zoster	1	1 (2.50)	1	1 (2.50)
Human herpesvirus 6 infection	1	1 (2.50)	1	1 (2.50)
Mastoiditis	1	1 (2.50)	1	1 (2.50)
Metapneumovirus infection	1	1 (2.50)	1	1 (2.50)
Molluscum contagiosum	1	1 (2.50)	0	0 (0.00)
Nail infection	1	1 (2.50)	0	0 (0.00)
Oral candidiasis	1	1 (2.50)	0	0 (0.00)
Oral herpes	1	1 (2.50)	0	0 (0.00)
Otitis externa	1	1 (2.50)	1	1 (2.50)
Paronychia	1	1 (2.50)	0	0 (0.00)
Respiratory syncytial virus infection	1	1 (2.50)	1	1 (2.50)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class **Preferred term**	**All grades** **Total events**	**All patients** **N=40** **n (%)[1]**	**Grade >= 3** **Total events**	**All patients** **N=40** **n (%)[2]**
Respiratory tract infection viral	1	1 (2.50)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (2.50)	1	1 (2.50)
Staphylococcal skin infection	1	1 (2.50)	0	0 (0.00)
Tinea pedis	1	1 (2.50)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (2.50)	1	1 (2.50)
Viral infection	1	1 (2.50)	1	1 (2.50)
Injury, poisoning and procedural complications				
- Total	3	2 (5.00)	0	0 (0.00)
Infusion related reaction	2	1 (2.50)	0	0 (0.00)
Ligament sprain	1	1 (2.50)	0	0 (0.00)
Investigations				
- Total	45	13 (32.50)	16	8 (20.00)
Neutrophil count decreased	13	5 (12.50)	8	5 (12.50)
White blood cell count decreased	13	6 (15.00)	3	3 (7.50)
Immunoglobulins decreased	5	1 (2.50)	0	0 (0.00)
Alanine aminotransferase increased	3	2 (5.00)	1	1 (2.50)
Platelet count decreased	3	2 (5.00)	0	0 (0.00)
Blood bilirubin increased	2	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood immunoglobulin A decreased	1	1 (2.50)	1	1 (2.50)
Blood immunoglobulin M decreased	1	1 (2.50)	1	1 (2.50)
Bone density decreased	1	1 (2.50)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.50)	0	0 (0.00)
Lymphocyte count decreased	1	1 (2.50)	1	1 (2.50)
Weight decreased	1	1 (2.50)	1	1 (2.50)
Metabolism and nutrition disorders				
- Total	11	8 (20.00)	5	4 (10.00)
Decreased appetite	2	2 (5.00)	1	1 (2.50)
Hyperuricaemia	2	2 (5.00)	0	0 (0.00)
Haemochromatosis	1	1 (2.50)	1	1 (2.50)
Hypokalaemia	1	1 (2.50)	1	1 (2.50)
Hypophagia	1	1 (2.50)	0	0 (0.00)
Hypophosphataemia	1	1 (2.50)	0	0 (0.00)
Iron overload	1	1 (2.50)	0	0 (0.00)
Malnutrition	1	1 (2.50)	1	1 (2.50)
Metabolic acidosis	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
- Total	9	6 (15.00)	2	2 (5.00)
Back pain	3	3 (7.50)	1	1 (2.50)
Arthralgia	2	2 (5.00)	0	0 (0.00)
Pain in extremity	2	2 (5.00)	1	1 (2.50)
Bone pain	1	1 (2.50)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.50)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (7.50)	1	1 (2.50)
Skin papilloma	2	2 (5.00)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.50)	1	1 (2.50)
Nervous system disorders				
- Total	10	5 (12.50)	3	1 (2.50)
Headache	4	3 (7.50)	0	0 (0.00)
Dizziness	2	1 (2.50)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.50)	1	1 (2.50)
Cerebral haemorrhage	1	1 (2.50)	1	1 (2.50)
Memory impairment	1	1 (2.50)	0	0 (0.00)
Seizure	1	1 (2.50)	1	1 (2.50)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Psychiatric disorders				
- Total	11	6 (15.00)	1	1 (2.50)
Anxiety	4	4 (10.00)	0	0 (0.00)
Agitation	1	1 (2.50)	0	0 (0.00)
Delirium	1	1 (2.50)	0	0 (0.00)
Mental status changes	1	1 (2.50)	1	1 (2.50)
Mood altered	1	1 (2.50)	0	0 (0.00)
Nightmare	1	1 (2.50)	0	0 (0.00)
Sleep disorder	1	1 (2.50)	0	0 (0.00)
Tearfulness	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				
- Total	2	2 (5.00)	1	1 (2.50)
Cystitis haemorrhagic	1	1 (2.50)	0	0 (0.00)
Renal tubular disorder	1	1 (2.50)	1	1 (2.50)
Respiratory, thoracic and mediastinal disorders				
- Total	24	14 (35.00)	3	3 (7.50)
Cough	9	7 (17.50)	0	0 (0.00)
Nasal congestion	4	3 (7.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypoxia	2	2 (5.00)	2	2 (5.00)
Bronchial oedema	1	1 (2.50)	0	0 (0.00)
Bronchospasm	1	1 (2.50)	0	0 (0.00)
Epistaxis	1	1 (2.50)	0	0 (0.00)
Lung disorder	1	1 (2.50)	0	0 (0.00)
Oropharyngeal pain	1	1 (2.50)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.50)	0	0 (0.00)
Pleural effusion	1	1 (2.50)	0	0 (0.00)
Respiratory failure	1	1 (2.50)	1	1 (2.50)
Upper respiratory tract inflammation	1	1 (2.50)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	13	11 (27.50)	1	1 (2.50)
Dry skin	3	3 (7.50)	0	0 (0.00)
Decubitus ulcer	1	1 (2.50)	1	1 (2.50)
Dermatitis allergic	1	1 (2.50)	0	0 (0.00)
Dermatitis atopic	1	1 (2.50)	0	0 (0.00)
Erythema	1	1 (2.50)	0	0 (0.00)
Hangnail	1	1 (2.50)	0	0 (0.00)
Night sweats	1	1 (2.50)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Photosensitivity reaction	1	1 (2.50)	0	0 (0.00)
Rash	1	1 (2.50)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.50)	0	0 (0.00)
Skin swelling	1	1 (2.50)	0	0 (0.00)
Vascular disorders				
- Total	3	3 (7.50)	2	2 (5.00)
Hypotension	2	2 (5.00)	1	1 (2.50)
Venoocclusive disease	1	1 (2.50)	1	1 (2.50)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Total number of AE per patient	260	31 (88.57)	66	14 (40.00)
Blood and lymphatic system disorders				
- Total	14	6 (17.14)	7	3 (8.57)
Anaemia	8	3 (8.57)	4	2 (5.71)
Febrile neutropenia	2	2 (5.71)	2	2 (5.71)
Leukocytosis	1	1 (2.86)	0	0 (0.00)
Leukopenia	1	1 (2.86)	0	0 (0.00)
Lymphocytosis	1	1 (2.86)	0	0 (0.00)
Thrombocytopenia	1	1 (2.86)	1	1 (2.86)
Cardiac disorders				
- Total	4	3 (8.57)	2	1 (2.86)
Tachycardia	2	2 (5.71)	0	0 (0.00)
Cardiac arrest	1	1 (2.86)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Cardiac failure	1	1 (2.86)	1	1 (2.86)
Endocrine disorders				
- Total	1	1 (2.86)	0	0 (0.00)
Hypothyroidism	1	1 (2.86)	0	0 (0.00)
Eye disorders				
- Total	2	2 (5.71)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.86)	0	0 (0.00)
Visual impairment	1	1 (2.86)	0	0 (0.00)
Gastrointestinal disorders				
- Total	19	10 (28.57)	1	1 (2.86)
Diarrhoea	5	5 (14.29)	0	0 (0.00)
Nausea	3	3 (8.57)	0	0 (0.00)
Vomiting	3	3 (8.57)	0	0 (0.00)
Abdominal pain	2	2 (5.71)	0	0 (0.00)
Constipation	2	1 (2.86)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (2.86)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.86)	0	0 (0.00)
Pancreatitis	1	1 (2.86)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Proctalgia	1	1 (2.86)	0	0 (0.00)
General disorders and administration site conditions				
- Total	17	14 (40.00)	2	2 (5.71)
Pyrexia	8	8 (22.86)	2	2 (5.71)
Fatigue	4	4 (11.43)	0	0 (0.00)
Oedema peripheral	2	1 (2.86)	0	0 (0.00)
Chills	1	1 (2.86)	0	0 (0.00)
Malaise	1	1 (2.86)	0	0 (0.00)
Pain	1	1 (2.86)	0	0 (0.00)
Hepatobiliary disorders				
- Total	2	2 (5.71)	0	0 (0.00)
Hypertransaminasaemia	1	1 (2.86)	0	0 (0.00)
Liver disorder	1	1 (2.86)	0	0 (0.00)
Immune system disorders				
- Total	14	11 (31.43)	3	2 (5.71)
Hypogammaglobulinaemia	10	8 (22.86)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (5.71)	1	1 (2.86)
Engraftment syndrome	1	1 (2.86)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Graft versus host disease	1	1 (2.86)	1	1 (2.86)
Infections and infestations				
- Total	37	13 (37.14)	15	8 (22.86)
Rhinovirus infection	3	3 (8.57)	0	0 (0.00)
Upper respiratory tract infection	3	3 (8.57)	1	1 (2.86)
Metapneumovirus infection	2	2 (5.71)	2	2 (5.71)
Pneumocystis jirovecii pneumonia	2	2 (5.71)	2	2 (5.71)
Respiratory syncytial virus infection	2	2 (5.71)	1	1 (2.86)
Acute sinusitis	1	1 (2.86)	0	0 (0.00)
Adenovirus infection	1	1 (2.86)	1	1 (2.86)
BK virus infection	1	1 (2.86)	1	1 (2.86)
Bacteraemia	1	1 (2.86)	0	0 (0.00)
Cellulitis	1	1 (2.86)	0	0 (0.00)
Coronavirus infection	1	1 (2.86)	1	1 (2.86)
Device related infection	1	1 (2.86)	1	1 (2.86)
Ear infection	1	1 (2.86)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (2.86)	0	0 (0.00)
Gastroenteritis viral	1	1 (2.86)	0	0 (0.00)
Gastrointestinal infection	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Herpes simplex	1	1 (2.86)	0	0 (0.00)
Influenza	1	1 (2.86)	0	0 (0.00)
Otitis externa	1	1 (2.86)	0	0 (0.00)
Otitis media	1	1 (2.86)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (2.86)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (2.86)	1	1 (2.86)
Pneumonia	1	1 (2.86)	0	0 (0.00)
Salmonellosis	1	1 (2.86)	0	0 (0.00)
Septic shock	1	1 (2.86)	1	1 (2.86)
Sinusitis	1	1 (2.86)	0	0 (0.00)
Sinusitis fungal	1	1 (2.86)	1	1 (2.86)
Staphylococcal sepsis	1	1 (2.86)	1	1 (2.86)
Viral infection	1	1 (2.86)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.86)	1	1 (2.86)
Injury, poisoning and procedural complications				
- Total	7	7 (20.00)	0	0 (0.00)
Infusion related reaction	2	2 (5.71)	0	0 (0.00)
Contusion	1	1 (2.86)	0	0 (0.00)
Fibula fracture	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Limb injury	1	1 (2.86)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.86)	0	0 (0.00)
Skin abrasion	1	1 (2.86)	0	0 (0.00)
Investigations				
- Total	46	17 (48.57)	19	8 (22.86)
Platelet count decreased	13	3 (8.57)	9	2 (5.71)
Neutrophil count decreased	6	5 (14.29)	3	2 (5.71)
Lymphocyte count decreased	5	3 (8.57)	1	1 (2.86)
White blood cell count decreased	5	4 (11.43)	1	1 (2.86)
Weight increased	3	1 (2.86)	1	1 (2.86)
Blood bilirubin increased	2	1 (2.86)	1	1 (2.86)
Blood uric acid increased	2	2 (5.71)	2	2 (5.71)
Blood creatinine increased	1	1 (2.86)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (2.86)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.86)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (2.86)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (2.86)	0	0 (0.00)
Blood urea increased	1	1 (2.86)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
C-reactive protein increased	1	1 (2.86)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.86)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.86)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.86)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	15	7 (20.00)	5	3 (8.57)
Hypokalaemia	5	2 (5.71)	3	1 (2.86)
Decreased appetite	4	4 (11.43)	0	0 (0.00)
Hyperchloraemia	1	1 (2.86)	0	0 (0.00)
Hyperkalaemia	1	1 (2.86)	0	0 (0.00)
Hyperuricaemia	1	1 (2.86)	0	0 (0.00)
Hypervolaemia	1	1 (2.86)	1	1 (2.86)
Metabolic syndrome	1	1 (2.86)	0	0 (0.00)
Tumour lysis syndrome	1	1 (2.86)	1	1 (2.86)
Musculoskeletal and connective tissue disorders				
- Total	13	9 (25.71)	1	1 (2.86)
Back pain	4	3 (8.57)	1	1 (2.86)
Pain in extremity	3	3 (8.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Arthralgia	1	1 (2.86)	0	0 (0.00)
Bone pain	1	1 (2.86)	0	0 (0.00)
Growth retardation	1	1 (2.86)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.86)	0	0 (0.00)
Myalgia	1	1 (2.86)	0	0 (0.00)
Neck pain	1	1 (2.86)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.86)	0	0 (0.00)
Cancer pain	1	1 (2.86)	0	0 (0.00)
Nervous system disorders				
- Total	13	9 (25.71)	3	1 (2.86)
Headache	7	7 (20.00)	0	0 (0.00)
Hydrocephalus	3	1 (2.86)	3	1 (2.86)
Migraine	2	1 (2.86)	0	0 (0.00)
Extrapyramidal disorder	1	1 (2.86)	0	0 (0.00)
Psychiatric disorders				
- Total	4	4 (11.43)	0	0 (0.00)
Anxiety	2	2 (5.71)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Mental status changes	1	1 (2.86)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.86)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	3 (8.57)	2	2 (5.71)
Acute kidney injury	3	3 (8.57)	1	1 (2.86)
Dysuria	1	1 (2.86)	0	0 (0.00)
Haematuria	1	1 (2.86)	1	1 (2.86)
Kidney enlargement	1	1 (2.86)	0	0 (0.00)
Renal mass	1	1 (2.86)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (2.86)	0	0 (0.00)
Dysmenorrhoea	2	1 (2.86)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	22	10 (28.57)	3	3 (8.57)
Cough	5	4 (11.43)	0	0 (0.00)
Nasal congestion	3	3 (8.57)	0	0 (0.00)
Rhinorrhoea	3	3 (8.57)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Dyspnoea	2	1 (2.86)	0	0 (0.00)
Epistaxis	2	2 (5.71)	0	0 (0.00)
Rhinitis allergic	2	2 (5.71)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (2.86)	1	1 (2.86)
Hypoxia	1	1 (2.86)	1	1 (2.86)
Oropharyngeal pain	1	1 (2.86)	0	0 (0.00)
Pleural effusion	1	1 (2.86)	0	0 (0.00)
Respiratory distress	1	1 (2.86)	1	1 (2.86)
Skin and subcutaneous tissue disorders				
- Total	16	9 (25.71)	0	0 (0.00)
Rash	5	3 (8.57)	0	0 (0.00)
Dry skin	4	3 (8.57)	0	0 (0.00)
Ingrowing nail	2	2 (5.71)	0	0 (0.00)
Pruritus	2	1 (2.86)	0	0 (0.00)
Eczema	1	1 (2.86)	0	0 (0.00)
Miliaria	1	1 (2.86)	0	0 (0.00)
Skin discolouration	1	1 (2.86)	0	0 (0.00)
Vascular disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
- Total	4	3 (8.57)	3	3 (8.57)
Hypotension	2	2 (5.71)	2	2 (5.71)
Hypertension	1	1 (2.86)	0	0 (0.00)
Venoocclusive disease	1	1 (2.86)	1	1 (2.86)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Total number of AE per patient	108	17 (56.67)	39	11 (36.67)
Blood and lymphatic system disorders				
- Total	3	3 (10.00)	1	1 (3.33)
Hypercoagulation	1	1 (3.33)	0	0 (0.00)
Lymphadenopathy	1	1 (3.33)	0	0 (0.00)
Neutropenia	1	1 (3.33)	1	1 (3.33)
Congenital, familial and genetic disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (3.33)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (3.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Deafness unilateral	1	1 (3.33)	0	0 (0.00)
Eye disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Mydriasis	1	1 (3.33)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	2 (6.67)	0	0 (0.00)
Diarrhoea	2	2 (6.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	9	5 (16.67)	1	1 (3.33)
Pyrexia	5	3 (10.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (3.33)	1	1 (3.33)
Non-cardiac chest pain	1	1 (3.33)	0	0 (0.00)
Pain	1	1 (3.33)	0	0 (0.00)
Xerosis	1	1 (3.33)	0	0 (0.00)
Immune system disorders				
- Total	4	3 (10.00)	3	2 (6.67)
Chronic graft versus host disease	2	2 (6.67)	1	1 (3.33)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Drug hypersensitivity	1	1 (3.33)	1	1 (3.33)
Haemophagocytic lymphohistiocytosis	1	1 (3.33)	1	1 (3.33)
Infections and infestations				
- Total	43	13 (43.33)	15	8 (26.67)
Sinusitis	6	3 (10.00)	0	0 (0.00)
Upper respiratory tract infection	5	3 (10.00)	1	1 (3.33)
Conjunctivitis	3	2 (6.67)	0	0 (0.00)
Device related sepsis	2	1 (3.33)	2	1 (3.33)
Fungal infection	2	1 (3.33)	0	0 (0.00)
Herpes zoster	2	2 (6.67)	1	1 (3.33)
Influenza	2	2 (6.67)	1	1 (3.33)
Otitis media	2	1 (3.33)	0	0 (0.00)
Rhinovirus infection	2	2 (6.67)	1	1 (3.33)
Sepsis	2	2 (6.67)	2	2 (6.67)
Acute sinusitis	1	1 (3.33)	0	0 (0.00)
Bronchitis	1	1 (3.33)	0	0 (0.00)
COVID-19 pneumonia	1	1 (3.33)	1	1 (3.33)
Ear infection	1	1 (3.33)	1	1 (3.33)
Enterovirus infection	1	1 (3.33)	1	1 (3.33)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Gastroenteritis	1	1 (3.33)	0	0 (0.00)
Neutropenic infection	1	1 (3.33)	1	1 (3.33)
Oral herpes	1	1 (3.33)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (3.33)	1	1 (3.33)
Pneumonia	1	1 (3.33)	1	1 (3.33)
Rhinitis	1	1 (3.33)	0	0 (0.00)
Skin infection	1	1 (3.33)	0	0 (0.00)
Staphylococcal abscess	1	1 (3.33)	1	1 (3.33)
Urinary tract infection	1	1 (3.33)	0	0 (0.00)
Viral skin infection	1	1 (3.33)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (3.33)	0	0 (0.00)
Ligament sprain	1	1 (3.33)	0	0 (0.00)
Investigations				
- Total	15	5 (16.67)	6	2 (6.67)
Neutrophil count decreased	7	2 (6.67)	5	1 (3.33)
Blood bilirubin increased	3	1 (3.33)	0	0 (0.00)
Platelet count decreased	2	2 (6.67)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Blood immunoglobulin G decreased	1	1 (3.33)	0	0 (0.00)
Oxygen saturation decreased	1	1 (3.33)	1	1 (3.33)
SARS-CoV-2 test positive	1	1 (3.33)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (6.67)	3	2 (6.67)
Decreased appetite	2	1 (3.33)	2	1 (3.33)
Hyperglycaemia	1	1 (3.33)	1	1 (3.33)
Musculoskeletal and connective tissue disorders				
- Total	2	2 (6.67)	0	0 (0.00)
Growth retardation	1	1 (3.33)	0	0 (0.00)
Pain in extremity	1	1 (3.33)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (3.33)	1	1 (3.33)
Bone giant cell tumour benign	2	1 (3.33)	1	1 (3.33)
Nervous system disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Dysarthria	1	1 (3.33)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Psychiatric disorders				
- Total	1	1 (3.33)	0	0 (0.00)
Anxiety	1	1 (3.33)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	5 (16.67)	4	2 (6.67)
Cough	2	2 (6.67)	0	0 (0.00)
Dyspnoea	2	2 (6.67)	1	1 (3.33)
Tachypnoea	2	1 (3.33)	2	1 (3.33)
Dyspnoea exertional	1	1 (3.33)	0	0 (0.00)
Epistaxis	1	1 (3.33)	0	0 (0.00)
Laryngeal oedema	1	1 (3.33)	1	1 (3.33)
Pharyngeal erythema	1	1 (3.33)	0	0 (0.00)
Pleural effusion	1	1 (3.33)	0	0 (0.00)
Rhinorrhoea	1	1 (3.33)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (3.33)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	4 (13.33)	4	3 (10.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=30 n (%)[1]	Grade >= 3 Total events	All patients N=30 n (%)[2]
Rash macular	2	1 (3.33)	2	1 (3.33)
Dermatitis atopic	1	1 (3.33)	1	1 (3.33)
Dry skin	1	1 (3.33)	0	0 (0.00)
Eczema	1	1 (3.33)	1	1 (3.33)
Vascular disorders				
- Total	1	1 (3.33)	1	1 (3.33)
Hypertension	1	1 (3.33)	1	1 (3.33)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	112	15 (75.00)	24	8 (40.00)
Blood and lymphatic system disorders				
- Total	3	1 (5.00)	1	1 (5.00)
Agranulocytosis	1	1 (5.00)	1	1 (5.00)
Anaemia	1	1 (5.00)	0	0 (0.00)
Thrombocytopenia	1	1 (5.00)	0	0 (0.00)
Endocrine disorders				
- Total	2	1 (5.00)	0	0 (0.00)
Delayed puberty	1	1 (5.00)	0	0 (0.00)
Hypothyroidism	1	1 (5.00)	0	0 (0.00)
Eye disorders				
- Total	3	2 (10.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Dry eye	1	1 (5.00)	0	0 (0.00)
Eye pain	1	1 (5.00)	1	1 (5.00)
Eyelid oedema	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	7	5 (25.00)	1	1 (5.00)
Diarrhoea	3	3 (15.00)	1	1 (5.00)
Constipation	1	1 (5.00)	0	0 (0.00)
Irritable bowel syndrome	1	1 (5.00)	0	0 (0.00)
Nausea	1	1 (5.00)	0	0 (0.00)
Vomiting	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	4	4 (20.00)	1	1 (5.00)
Pyrexia	2	2 (10.00)	1	1 (5.00)
Fatigue	1	1 (5.00)	0	0 (0.00)
Pain	1	1 (5.00)	0	0 (0.00)
Immune system disorders				
- Total	6	6 (30.00)	0	0 (0.00)
Hypogammaglobulinaemia	3	3 (15.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Seasonal allergy	3	3 (15.00)	0	0 (0.00)
Infections and infestations				
- Total	43	10 (50.00)	11	6 (30.00)
COVID-19	3	2 (10.00)	1	1 (5.00)
Sinusitis	3	3 (15.00)	0	0 (0.00)
Conjunctivitis	2	2 (10.00)	0	0 (0.00)
Gastroenteritis viral	2	1 (5.00)	0	0 (0.00)
Rhinovirus infection	2	2 (10.00)	0	0 (0.00)
Skin infection	2	2 (10.00)	0	0 (0.00)
Upper respiratory tract infection	2	2 (10.00)	0	0 (0.00)
Bronchiolitis	1	1 (5.00)	1	1 (5.00)
Bronchitis	1	1 (5.00)	0	0 (0.00)
Candida infection	1	1 (5.00)	0	0 (0.00)
Clostridium difficile colitis	1	1 (5.00)	1	1 (5.00)
Folliculitis	1	1 (5.00)	0	0 (0.00)
Fungal infection	1	1 (5.00)	0	0 (0.00)
Fungal skin infection	1	1 (5.00)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (5.00)	1	1 (5.00)
Gastroenteritis salmonella	1	1 (5.00)	1	1 (5.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Herpes virus infection	1	1 (5.00)	0	0 (0.00)
Meningitis pneumococcal	1	1 (5.00)	1	1 (5.00)
Nail infection	1	1 (5.00)	0	0 (0.00)
Ophthalmic herpes zoster	1	1 (5.00)	0	0 (0.00)
Oral candidiasis	1	1 (5.00)	0	0 (0.00)
Oral herpes	1	1 (5.00)	0	0 (0.00)
Otitis media	1	1 (5.00)	0	0 (0.00)
Otitis media acute	1	1 (5.00)	0	0 (0.00)
Pneumonia	1	1 (5.00)	1	1 (5.00)
Pneumonia respiratory syncytial viral	1	1 (5.00)	1	1 (5.00)
Sepsis	1	1 (5.00)	1	1 (5.00)
Septic shock	1	1 (5.00)	1	1 (5.00)
Staphylococcal bacteraemia	1	1 (5.00)	1	1 (5.00)
Streptococcal sepsis	1	1 (5.00)	0	0 (0.00)
Syphilis	1	1 (5.00)	0	0 (0.00)
Urinary tract infection	1	1 (5.00)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (5.00)	0	0 (0.00)
Varicella zoster virus infection	1	1 (5.00)	0	0 (0.00)
Injury, poisoning and procedural complications				

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	2	2 (10.00)	1	1 (5.00)
Abdominal injury	1	1 (5.00)	0	0 (0.00)
Infusion related reaction	1	1 (5.00)	1	1 (5.00)
Investigations				
- Total	1	1 (5.00)	0	0 (0.00)
Neutrophil count decreased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	7	4 (20.00)	2	2 (10.00)
Iron overload	2	1 (5.00)	0	0 (0.00)
Hypercholesterolaemia	1	1 (5.00)	0	0 (0.00)
Hyperlipidaemia	1	1 (5.00)	0	0 (0.00)
Hypernatraemia	1	1 (5.00)	1	1 (5.00)
Hypertriglyceridaemia	1	1 (5.00)	0	0 (0.00)
Obesity	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				
- Total	6	5 (25.00)	0	0 (0.00)
Arthralgia	1	1 (5.00)	0	0 (0.00)
Joint effusion	1	1 (5.00)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Osteonecrosis	1	1 (5.00)	0	0 (0.00)
Osteopenia	1	1 (5.00)	0	0 (0.00)
Pain in extremity	1	1 (5.00)	0	0 (0.00)
Synovitis	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	8	3 (15.00)	3	2 (10.00)
Headache	3	2 (10.00)	1	1 (5.00)
Seizure	3	1 (5.00)	1	1 (5.00)
Nervous system disorder	2	1 (5.00)	1	1 (5.00)
Psychiatric disorders				
- Total	2	2 (10.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Tic	1	1 (5.00)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (5.00)	1	1 (5.00)
Endometriosis	2	1 (5.00)	1	1 (5.00)
Respiratory, thoracic and mediastinal disorders				

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	10	5 (25.00)	2	2 (10.00)
Cough	2	2 (10.00)	0	0 (0.00)
Rhinorrhoea	2	2 (10.00)	0	0 (0.00)
Dyspnoea	1	1 (5.00)	0	0 (0.00)
Hypoxia	1	1 (5.00)	1	1 (5.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Sleep apnoea syndrome	1	1 (5.00)	0	0 (0.00)
Wheezing	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	5	3 (15.00)	0	0 (0.00)
Rash	2	2 (10.00)	0	0 (0.00)
Papule	1	1 (5.00)	0	0 (0.00)
Rash erythematous	1	1 (5.00)	0	0 (0.00)
Rash maculo-papular	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Hypertension	1	1 (5.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	1211	40 (100.00)	410	38 (95.00)
Blood and lymphatic system disorders				
- Total	96	29 (72.50)	58	23 (57.50)
Anaemia	36	12 (30.00)	15	6 (15.00)
Neutropenia	15	9 (22.50)	14	8 (20.00)
Febrile neutropenia	13	11 (27.50)	13	11 (27.50)
Thrombocytopenia	6	5 (12.50)	6	5 (12.50)
Disseminated intravascular coagulation	5	5 (12.50)	1	1 (2.50)
B-cell aplasia	3	1 (2.50)	0	0 (0.00)
Coagulopathy	3	3 (7.50)	2	2 (5.00)
Eosinophilia	3	1 (2.50)	0	0 (0.00)
Leukopenia	3	2 (5.00)	3	2 (5.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Lymphadenopathy	2	2 (5.00)	0	0 (0.00)
Lymphopenia	2	2 (5.00)	2	2 (5.00)
Pancytopenia	2	2 (5.00)	2	2 (5.00)
Hypercoagulation	1	1 (2.50)	0	0 (0.00)
Hypofibrinogenaemia	1	1 (2.50)	0	0 (0.00)
Splenomegaly	1	1 (2.50)	0	0 (0.00)
Cardiac disorders				
- Total	18	10 (25.00)	3	3 (7.50)
Tachycardia	4	3 (7.50)	0	0 (0.00)
Sinus tachycardia	3	2 (5.00)	0	0 (0.00)
Cardiac dysfunction	2	2 (5.00)	0	0 (0.00)
Left ventricular dysfunction	2	2 (5.00)	1	1 (2.50)
Cardiac arrest	1	1 (2.50)	1	1 (2.50)
Cardiac failure	1	1 (2.50)	1	1 (2.50)
Cardiac failure congestive	1	1 (2.50)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.50)	0	0 (0.00)
Pericardial effusion	1	1 (2.50)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.50)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Congenital, familial and genetic disorders				
- Total	1	1 (2.50)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (2.50)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.50)	0	0 (0.00)
Deafness unilateral	1	1 (2.50)	0	0 (0.00)
Endocrine disorders				
- Total	2	2 (5.00)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.50)	0	0 (0.00)
Hypothyroidism	1	1 (2.50)	0	0 (0.00)
Eye disorders				
- Total	10	6 (15.00)	0	0 (0.00)
Cataract	2	2 (5.00)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.50)	0	0 (0.00)
Eye oedema	1	1 (2.50)	0	0 (0.00)
Hypermetropia	1	1 (2.50)	0	0 (0.00)
Mydriasis	1	1 (2.50)	0	0 (0.00)
Periorbital swelling	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Visual field defect	1	1 (2.50)	0	0 (0.00)
Visual impairment	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	91	29 (72.50)	7	6 (15.00)
Vomiting	20	12 (30.00)	0	0 (0.00)
Diarrhoea	14	12 (30.00)	0	0 (0.00)
Nausea	12	9 (22.50)	2	2 (5.00)
Abdominal pain	9	7 (17.50)	1	1 (2.50)
Constipation	6	6 (15.00)	0	0 (0.00)
Mouth haemorrhage	3	3 (7.50)	1	1 (2.50)
Pancreatitis	3	3 (7.50)	0	0 (0.00)
Stomatitis	3	3 (7.50)	1	1 (2.50)
Abdominal distension	2	2 (5.00)	0	0 (0.00)
Abdominal pain upper	2	2 (5.00)	0	0 (0.00)
Ascites	2	2 (5.00)	0	0 (0.00)
Abdominal rigidity	1	1 (2.50)	0	0 (0.00)
Dyspepsia	1	1 (2.50)	0	0 (0.00)
Enteritis	1	1 (2.50)	0	0 (0.00)
Enterocolitis	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Gastrointestinal sounds abnormal	1	1 (2.50)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.50)	0	0 (0.00)
Gingival bleeding	1	1 (2.50)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.50)	1	1 (2.50)
Lip dry	1	1 (2.50)	0	0 (0.00)
Mouth swelling	1	1 (2.50)	0	0 (0.00)
Odynophagia	1	1 (2.50)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.50)	0	0 (0.00)
Proctalgia	1	1 (2.50)	1	1 (2.50)
Trichoglossia	1	1 (2.50)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	86	23 (57.50)	14	6 (15.00)
Pyrexia	39	15 (37.50)	5	4 (10.00)
Chills	8	5 (12.50)	0	0 (0.00)
Face oedema	5	4 (10.00)	1	1 (2.50)
Fatigue	5	4 (10.00)	0	0 (0.00)
Oedema peripheral	4	3 (7.50)	2	1 (2.50)
Asthenia	3	3 (7.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Catheter site pain	3	1 (2.50)	2	1 (2.50)
Pain	3	3 (7.50)	2	2 (5.00)
Generalised oedema	2	2 (5.00)	0	0 (0.00)
Influenza like illness	2	2 (5.00)	0	0 (0.00)
Non-cardiac chest pain	2	2 (5.00)	0	0 (0.00)
Chest discomfort	1	1 (2.50)	1	1 (2.50)
Crying	1	1 (2.50)	0	0 (0.00)
Facial pain	1	1 (2.50)	0	0 (0.00)
Localised oedema	1	1 (2.50)	0	0 (0.00)
Malaise	1	1 (2.50)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (2.50)	1	1 (2.50)
Sluggishness	1	1 (2.50)	0	0 (0.00)
Swelling face	1	1 (2.50)	0	0 (0.00)
Vascular device occlusion	1	1 (2.50)	0	0 (0.00)
Xerosis	1	1 (2.50)	0	0 (0.00)
Hepatobiliary disorders				
- Total	15	9 (22.50)	4	3 (7.50)
Hepatic function abnormal	10	4 (10.00)	4	3 (7.50)
Hyperbilirubinaemia	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Cholelithiasis	1	1 (2.50)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.50)	0	0 (0.00)
Hepatomegaly	1	1 (2.50)	0	0 (0.00)
Immune system disorders				
- Total	90	35 (87.50)	40	27 (67.50)
Cytokine release syndrome	61	31 (77.50)	26	20 (50.00)
Hypogammaglobulinaemia	16	16 (40.00)	6	6 (15.00)
Immunodeficiency	4	4 (10.00)	4	4 (10.00)
Chronic graft versus host disease	2	2 (5.00)	1	1 (2.50)
Drug hypersensitivity	2	2 (5.00)	1	1 (2.50)
Haemophagocytic lymphohistiocytosis	2	2 (5.00)	1	1 (2.50)
Graft versus host disease	1	1 (2.50)	1	1 (2.50)
Hypersensitivity	1	1 (2.50)	0	0 (0.00)
Seasonal allergy	1	1 (2.50)	0	0 (0.00)
Infections and infestations				
- Total	161	36 (90.00)	69	23 (57.50)
Upper respiratory tract infection	12	8 (20.00)	2	2 (5.00)
Sinusitis	10	4 (10.00)	2	2 (5.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Nasopharyngitis	9	7 (17.50)	0	0 (0.00)
Conjunctivitis	8	4 (10.00)	0	0 (0.00)
Bronchopulmonary aspergillosis	6	2 (5.00)	4	2 (5.00)
Gastroenteritis	6	6 (15.00)	2	2 (5.00)
Parainfluenzae virus infection	5	4 (10.00)	3	3 (7.50)
Oral herpes	4	3 (7.50)	1	1 (2.50)
Otitis media	4	3 (7.50)	1	1 (2.50)
Pneumonia	4	4 (10.00)	3	3 (7.50)
Rhinovirus infection	4	3 (7.50)	2	2 (5.00)
Bacteraemia	3	2 (5.00)	3	2 (5.00)
Candida infection	3	2 (5.00)	2	1 (2.50)
Ear infection	3	2 (5.00)	1	1 (2.50)
Herpes zoster	3	3 (7.50)	2	2 (5.00)
Klebsiella infection	3	1 (2.50)	3	1 (2.50)
Oral candidiasis	3	2 (5.00)	0	0 (0.00)
Respiratory tract infection	3	3 (7.50)	0	0 (0.00)
Rhinitis	3	3 (7.50)	0	0 (0.00)
Staphylococcal infection	3	3 (7.50)	2	2 (5.00)
Urinary tract infection	3	2 (5.00)	2	1 (2.50)
Device related sepsis	2	1 (2.50)	2	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Encephalitis viral	2	2 (5.00)	2	2 (5.00)
Fungal infection	2	1 (2.50)	0	0 (0.00)
Gingivitis	2	2 (5.00)	0	0 (0.00)
Human herpesvirus 6 infection	2	2 (5.00)	2	2 (5.00)
Influenza	2	2 (5.00)	1	1 (2.50)
Nail infection	2	2 (5.00)	0	0 (0.00)
Otitis externa	2	2 (5.00)	1	1 (2.50)
Paronychia	2	2 (5.00)	0	0 (0.00)
Sepsis	2	2 (5.00)	2	2 (5.00)
Acute sinusitis	1	1 (2.50)	0	0 (0.00)
Adenovirus infection	1	1 (2.50)	1	1 (2.50)
Anal abscess	1	1 (2.50)	1	1 (2.50)
BK virus infection	1	1 (2.50)	0	0 (0.00)
Bronchitis	1	1 (2.50)	0	0 (0.00)
COVID-19 pneumonia	1	1 (2.50)	1	1 (2.50)
Clostridium difficile infection	1	1 (2.50)	1	1 (2.50)
Cystitis	1	1 (2.50)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (2.50)	1	1 (2.50)
Ear, nose and throat infection	1	1 (2.50)	0	0 (0.00)
Encephalitis	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Enterobacter infection	1	1 (2.50)	1	1 (2.50)
Enterovirus infection	1	1 (2.50)	1	1 (2.50)
Granulicatella infection	1	1 (2.50)	1	1 (2.50)
Herpes simplex	1	1 (2.50)	1	1 (2.50)
Mastoiditis	1	1 (2.50)	1	1 (2.50)
Meningitis bacterial	1	1 (2.50)	1	1 (2.50)
Metapneumovirus infection	1	1 (2.50)	1	1 (2.50)
Molluscum contagiosum	1	1 (2.50)	0	0 (0.00)
Myringitis	1	1 (2.50)	0	0 (0.00)
Neutropenic infection	1	1 (2.50)	1	1 (2.50)
Oral infection	1	1 (2.50)	0	0 (0.00)
Pneumonia fungal	1	1 (2.50)	1	1 (2.50)
Pneumonia viral	1	1 (2.50)	1	1 (2.50)
Respiratory syncytial virus infection	1	1 (2.50)	1	1 (2.50)
Respiratory tract infection viral	1	1 (2.50)	0	0 (0.00)
Skin infection	1	1 (2.50)	0	0 (0.00)
Soft tissue infection	1	1 (2.50)	1	1 (2.50)
Staphylococcal abscess	1	1 (2.50)	1	1 (2.50)
Staphylococcal bacteraemia	1	1 (2.50)	1	1 (2.50)
Staphylococcal skin infection	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Stomatococcal infection	1	1 (2.50)	0	0 (0.00)
Systemic candida	1	1 (2.50)	1	1 (2.50)
Tinea pedis	1	1 (2.50)	0	0 (0.00)
Urinary tract infection viral	1	1 (2.50)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.50)	1	1 (2.50)
Viral haemorrhagic cystitis	1	1 (2.50)	1	1 (2.50)
Viral infection	1	1 (2.50)	1	1 (2.50)
Viral skin infection	1	1 (2.50)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	10	6 (15.00)	1	1 (2.50)
Infusion related reaction	5	2 (5.00)	0	0 (0.00)
Ligament sprain	2	2 (5.00)	0	0 (0.00)
Fall	1	1 (2.50)	0	0 (0.00)
Procedural pain	1	1 (2.50)	0	0 (0.00)
Transplant failure	1	1 (2.50)	1	1 (2.50)
Investigations				
- Total	248	28 (70.00)	123	22 (55.00)
Neutrophil count decreased	47	13 (32.50)	35	12 (30.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
White blood cell count decreased	46	12 (30.00)	26	10 (25.00)
Platelet count decreased	44	12 (30.00)	23	8 (20.00)
Lymphocyte count decreased	23	8 (20.00)	18	7 (17.50)
Aspartate aminotransferase increased	16	5 (12.50)	5	3 (7.50)
Alanine aminotransferase increased	15	6 (15.00)	4	4 (10.00)
Blood bilirubin increased	11	3 (7.50)	1	1 (2.50)
Immunoglobulins decreased	9	1 (2.50)	0	0 (0.00)
Serum ferritin increased	5	5 (12.50)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (2.50)	1	1 (2.50)
Blood fibrinogen decreased	2	2 (5.00)	0	0 (0.00)
Blood glucose increased	2	1 (2.50)	2	1 (2.50)
Blood immunoglobulin A decreased	2	2 (5.00)	1	1 (2.50)
Blood lactate dehydrogenase increased	2	2 (5.00)	0	0 (0.00)
C-reactive protein increased	2	2 (5.00)	1	1 (2.50)
Gamma-glutamyltransferase increased	2	2 (5.00)	2	2 (5.00)
Haemoglobin decreased	2	1 (2.50)	1	1 (2.50)
Weight increased	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood alkaline phosphatase increased	1	1 (2.50)	0	0 (0.00)
Blood creatinine increased	1	1 (2.50)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (2.50)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.50)	1	1 (2.50)
Bone density decreased	1	1 (2.50)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.50)	0	0 (0.00)
Fibrin D dimer increased	1	1 (2.50)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.50)	0	0 (0.00)
International normalised ratio increased	1	1 (2.50)	0	0 (0.00)
Oxygen saturation decreased	1	1 (2.50)	1	1 (2.50)
Prothrombin time prolonged	1	1 (2.50)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (2.50)	0	0 (0.00)
Weight decreased	1	1 (2.50)	1	1 (2.50)
Metabolism and nutrition disorders				
- Total	94	20 (50.00)	30	13 (32.50)
Hypokalaemia	15	8 (20.00)	7	5 (12.50)
Decreased appetite	13	11 (27.50)	6	4 (10.00)
Hypoalbuminaemia	13	6 (15.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypophosphataemia	13	7 (17.50)	5	3 (7.50)
Hyperglycaemia	7	5 (12.50)	3	3 (7.50)
Hypocalcaemia	6	4 (10.00)	1	1 (2.50)
Hypomagnesaemia	6	5 (12.50)	0	0 (0.00)
Hyperuricaemia	4	2 (5.00)	1	1 (2.50)
Hypermagnesaemia	3	2 (5.00)	0	0 (0.00)
Acidosis	2	1 (2.50)	1	1 (2.50)
Hyponatraemia	2	2 (5.00)	0	0 (0.00)
Tumour lysis syndrome	2	2 (5.00)	2	2 (5.00)
Haemochromatosis	1	1 (2.50)	1	1 (2.50)
Hypernatraemia	1	1 (2.50)	0	0 (0.00)
Hypervolaemia	1	1 (2.50)	0	0 (0.00)
Hypophagia	1	1 (2.50)	0	0 (0.00)
Iron overload	1	1 (2.50)	0	0 (0.00)
Malnutrition	1	1 (2.50)	1	1 (2.50)
Metabolic acidosis	1	1 (2.50)	1	1 (2.50)
Polydipsia	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				
- Total	41	19 (47.50)	4	4 (10.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Pain in extremity	9	8 (20.00)	1	1 (2.50)
Arthralgia	8	7 (17.50)	0	0 (0.00)
Back pain	7	6 (15.00)	2	2 (5.00)
Myalgia	6	5 (12.50)	0	0 (0.00)
Bone pain	4	2 (5.00)	0	0 (0.00)
Musculoskeletal chest pain	2	2 (5.00)	0	0 (0.00)
Pain in jaw	2	2 (5.00)	1	1 (2.50)
Growth retardation	1	1 (2.50)	0	0 (0.00)
Muscular weakness	1	1 (2.50)	0	0 (0.00)
Neck pain	1	1 (2.50)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	5	4 (10.00)	2	2 (5.00)
Bone giant cell tumour benign	2	1 (2.50)	1	1 (2.50)
Skin papilloma	2	2 (5.00)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.50)	1	1 (2.50)
Nervous system disorders				
- Total	48	20 (50.00)	7	4 (10.00)
Headache	14	11 (27.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Dizziness	4	3 (7.50)	0	0 (0.00)
Seizure	4	3 (7.50)	2	2 (5.00)
Tremor	4	3 (7.50)	0	0 (0.00)
Dysgeusia	3	3 (7.50)	0	0 (0.00)
Encephalopathy	3	3 (7.50)	1	1 (2.50)
Somnolence	3	3 (7.50)	0	0 (0.00)
Hyperaesthesia	2	1 (2.50)	0	0 (0.00)
Lethargy	2	2 (5.00)	0	0 (0.00)
Amnesia	1	1 (2.50)	0	0 (0.00)
Aphasia	1	1 (2.50)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.50)	1	1 (2.50)
Cerebral haemorrhage	1	1 (2.50)	1	1 (2.50)
Depressed level of consciousness	1	1 (2.50)	1	1 (2.50)
Disturbance in attention	1	1 (2.50)	0	0 (0.00)
Dysarthria	1	1 (2.50)	0	0 (0.00)
Hypoaesthesia	1	1 (2.50)	0	0 (0.00)
Memory impairment	1	1 (2.50)	0	0 (0.00)
Psychiatric disorders				
- Total	27	13 (32.50)	2	2 (5.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Anxiety	6	6 (15.00)	1	1 (2.50)
Hallucination	3	3 (7.50)	0	0 (0.00)
Sleep disorder	3	2 (5.00)	0	0 (0.00)
Agitation	2	2 (5.00)	0	0 (0.00)
Confusional state	2	2 (5.00)	0	0 (0.00)
Delirium	2	2 (5.00)	0	0 (0.00)
Affect lability	1	1 (2.50)	0	0 (0.00)
Hallucination, visual	1	1 (2.50)	0	0 (0.00)
Irritability	1	1 (2.50)	0	0 (0.00)
Mental status changes	1	1 (2.50)	1	1 (2.50)
Mood altered	1	1 (2.50)	0	0 (0.00)
Nightmare	1	1 (2.50)	0	0 (0.00)
Restlessness	1	1 (2.50)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.50)	0	0 (0.00)
Tearfulness	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				
- Total	21	12 (30.00)	6	5 (12.50)
Acute kidney injury	8	5 (12.50)	4	3 (7.50)
Haematuria	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Urinary incontinence	2	1 (2.50)	0	0 (0.00)
Anuria	1	1 (2.50)	1	1 (2.50)
Cystitis haemorrhagic	1	1 (2.50)	0	0 (0.00)
Dysuria	1	1 (2.50)	0	0 (0.00)
Incontinence	1	1 (2.50)	0	0 (0.00)
Pollakiuria	1	1 (2.50)	0	0 (0.00)
Proteinuria	1	1 (2.50)	0	0 (0.00)
Renal failure	1	1 (2.50)	0	0 (0.00)
Renal tubular disorder	1	1 (2.50)	1	1 (2.50)
Urinary tract disorder	1	1 (2.50)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (7.50)	0	0 (0.00)
Vaginal haemorrhage	2	1 (2.50)	0	0 (0.00)
Female genital tract fistula	1	1 (2.50)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.50)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	86	27 (67.50)	28	14 (35.00)
Cough	17	14 (35.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypoxia	14	9 (22.50)	12	7 (17.50)
Epistaxis	5	4 (10.00)	1	1 (2.50)
Nasal congestion	5	4 (10.00)	0	0 (0.00)
Pulmonary oedema	5	5 (12.50)	4	4 (10.00)
Tachypnoea	5	4 (10.00)	4	3 (7.50)
Dyspnoea	4	4 (10.00)	3	3 (7.50)
Oropharyngeal pain	4	4 (10.00)	0	0 (0.00)
Pleural effusion	4	4 (10.00)	0	0 (0.00)
Lung infiltration	2	1 (2.50)	1	1 (2.50)
Pharyngeal erythema	2	2 (5.00)	0	0 (0.00)
Acute respiratory failure	1	1 (2.50)	1	1 (2.50)
Atelectasis	1	1 (2.50)	0	0 (0.00)
Bronchial oedema	1	1 (2.50)	0	0 (0.00)
Bronchospasm	1	1 (2.50)	0	0 (0.00)
Dyspnoea exertional	1	1 (2.50)	0	0 (0.00)
Laryngeal oedema	1	1 (2.50)	1	1 (2.50)
Lung disorder	1	1 (2.50)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.50)	0	0 (0.00)
Painful respiration	1	1 (2.50)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Paranasal sinus inflammation	1	1 (2.50)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.50)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.50)	0	0 (0.00)
Pulmonary mass	1	1 (2.50)	0	0 (0.00)
Respiratory disorder	1	1 (2.50)	0	0 (0.00)
Respiratory failure	1	1 (2.50)	1	1 (2.50)
Rhinorrhoea	1	1 (2.50)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (2.50)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (2.50)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	38	21 (52.50)	6	5 (12.50)
Dermatitis atopic	4	3 (7.50)	1	1 (2.50)
Dry skin	4	4 (10.00)	0	0 (0.00)
Rash maculo-papular	3	2 (5.00)	1	1 (2.50)
Erythema	2	2 (5.00)	0	0 (0.00)
Hyperhidrosis	2	2 (5.00)	0	0 (0.00)
Pruritus	2	2 (5.00)	0	0 (0.00)
Rash	2	2 (5.00)	0	0 (0.00)
Rash macular	2	1 (2.50)	2	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Rash papular	2	1 (2.50)	0	0 (0.00)
Rash vesicular	2	1 (2.50)	0	0 (0.00)
Decubitus ulcer	1	1 (2.50)	1	1 (2.50)
Dermatitis allergic	1	1 (2.50)	0	0 (0.00)
Eczema	1	1 (2.50)	1	1 (2.50)
Erythema nodosum	1	1 (2.50)	0	0 (0.00)
Hangnail	1	1 (2.50)	0	0 (0.00)
Night sweats	1	1 (2.50)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.50)	0	0 (0.00)
Photosensitivity reaction	1	1 (2.50)	0	0 (0.00)
Purpura	1	1 (2.50)	0	0 (0.00)
Skin hypopigmentation	1	1 (2.50)	0	0 (0.00)
Skin lesion	1	1 (2.50)	0	0 (0.00)
Skin swelling	1	1 (2.50)	0	0 (0.00)
Skin ulcer	1	1 (2.50)	0	0 (0.00)
Social circumstances				
- Total	1	1 (2.50)	0	0 (0.00)
Patient uncooperative	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Vascular disorders				
- Total	17	13 (32.50)	6	6 (15.00)
Hypotension	8	7 (17.50)	4	4 (10.00)
Hypertension	6	6 (15.00)	1	1 (2.50)
Flushing	1	1 (2.50)	0	0 (0.00)
Hot flush	1	1 (2.50)	0	0 (0.00)
Venoocclusive disease	1	1 (2.50)	1	1 (2.50)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250q
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Time since enrollment to CTL019 infusion
Safety Set

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Total number of AE per patient	1294	40 (100.00)	418	35 (87.50)
Blood and lymphatic system disorders				
- Total	67	26 (65.00)	37	20 (50.00)
Anaemia	27	13 (32.50)	9	3 (7.50)
Febrile neutropenia	20	16 (40.00)	20	16 (40.00)
Thrombocytopenia	5	4 (10.00)	4	4 (10.00)
Disseminated intravascular coagulation	3	3 (7.50)	2	2 (5.00)
Splenomegaly	3	3 (7.50)	0	0 (0.00)
Coagulopathy	2	2 (5.00)	0	0 (0.00)
Leukopenia	2	1 (2.50)	0	0 (0.00)
Neutropenia	2	2 (5.00)	1	1 (2.50)
Agranulocytosis	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Leukocytosis	1	1 (2.50)	0	0 (0.00)
Lymphocytosis	1	1 (2.50)	0	0 (0.00)
Cardiac disorders				
- Total	35	18 (45.00)	11	8 (20.00)
Tachycardia	20	14 (35.00)	3	3 (7.50)
Cardiac failure	5	2 (5.00)	3	2 (5.00)
Bradycardia	3	3 (7.50)	0	0 (0.00)
Cardiac arrest	2	2 (5.00)	2	2 (5.00)
Left ventricular dysfunction	2	2 (5.00)	2	2 (5.00)
Atrioventricular block first degree	1	1 (2.50)	0	0 (0.00)
Sinus bradycardia	1	1 (2.50)	1	1 (2.50)
Sinus tachycardia	1	1 (2.50)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	2	2 (5.00)	0	0 (0.00)
Ear pain	1	1 (2.50)	0	0 (0.00)
Ear pruritus	1	1 (2.50)	0	0 (0.00)
Endocrine disorders				
- Total	6	5 (12.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Adrenal insufficiency	3	3 (7.50)	0	0 (0.00)
Hypothyroidism	2	2 (5.00)	0	0 (0.00)
Delayed puberty	1	1 (2.50)	0	0 (0.00)
Eye disorders				
- Total	14	9 (22.50)	1	1 (2.50)
Eyelid oedema	4	3 (7.50)	0	0 (0.00)
Ocular hyperaemia	3	3 (7.50)	0	0 (0.00)
Conjunctival haemorrhage	2	2 (5.00)	0	0 (0.00)
Eye pain	2	2 (5.00)	1	1 (2.50)
Dry eye	1	1 (2.50)	0	0 (0.00)
Periorbital oedema	1	1 (2.50)	0	0 (0.00)
Visual impairment	1	1 (2.50)	0	0 (0.00)
Gastrointestinal disorders				
- Total	91	31 (77.50)	11	10 (25.00)
Vomiting	18	14 (35.00)	1	1 (2.50)
Diarrhoea	16	14 (35.00)	2	2 (5.00)
Nausea	15	13 (32.50)	0	0 (0.00)
Constipation	10	8 (20.00)	0	0 (0.00)
Abdominal pain	6	4 (10.00)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Pancreatitis	3	3 (7.50)	2	2 (5.00)
Abdominal pain upper	2	2 (5.00)	0	0 (0.00)
Mouth haemorrhage	2	2 (5.00)	1	1 (2.50)
Abdominal compartment syndrome	1	1 (2.50)	1	1 (2.50)
Abdominal distension	1	1 (2.50)	0	0 (0.00)
Anal fissure	1	1 (2.50)	0	0 (0.00)
Anal haemorrhage	1	1 (2.50)	0	0 (0.00)
Ascites	1	1 (2.50)	0	0 (0.00)
Dry mouth	1	1 (2.50)	0	0 (0.00)
Dysphagia	1	1 (2.50)	1	1 (2.50)
Gastrointestinal haemorrhage	1	1 (2.50)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (2.50)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (2.50)	0	0 (0.00)
Gingival erythema	1	1 (2.50)	0	0 (0.00)
Haematemesis	1	1 (2.50)	0	0 (0.00)
Ileus	1	1 (2.50)	0	0 (0.00)
Irritable bowel syndrome	1	1 (2.50)	0	0 (0.00)
Lip oedema	1	1 (2.50)	0	0 (0.00)
Melaena	1	1 (2.50)	1	1 (2.50)
Neutropenic colitis	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Proctalgia	1	1 (2.50)	0	0 (0.00)
Trichoglossia	1	1 (2.50)	0	0 (0.00)
General disorders and administration site conditions				
- Total	70	30 (75.00)	10	9 (22.50)
Pyrexia	28	20 (50.00)	7	7 (17.50)
Fatigue	14	13 (32.50)	0	0 (0.00)
Oedema peripheral	5	4 (10.00)	0	0 (0.00)
Face oedema	4	4 (10.00)	0	0 (0.00)
Generalised oedema	3	3 (7.50)	0	0 (0.00)
Catheter site erythema	2	1 (2.50)	0	0 (0.00)
Chills	2	2 (5.00)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (5.00)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (5.00)	2	2 (5.00)
Pain	2	2 (5.00)	0	0 (0.00)
Catheter site haemorrhage	1	1 (2.50)	0	0 (0.00)
Catheter site pain	1	1 (2.50)	0	0 (0.00)
Localised oedema	1	1 (2.50)	0	0 (0.00)
Malaise	1	1 (2.50)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Systemic inflammatory response syndrome	1	1 (2.50)	1	1 (2.50)
Hepatobiliary disorders				
- Total	17	10 (25.00)	3	3 (7.50)
Hyperbilirubinaemia	4	3 (7.50)	1	1 (2.50)
Hypertransaminasaemia	3	2 (5.00)	0	0 (0.00)
Gallbladder enlargement	2	2 (5.00)	0	0 (0.00)
Hepatomegaly	2	2 (5.00)	1	1 (2.50)
Biliary tract disorder	1	1 (2.50)	0	0 (0.00)
Cholelithiasis	1	1 (2.50)	0	0 (0.00)
Cholestasis	1	1 (2.50)	1	1 (2.50)
Hepatic function abnormal	1	1 (2.50)	0	0 (0.00)
Liver disorder	1	1 (2.50)	0	0 (0.00)
Ocular icterus	1	1 (2.50)	0	0 (0.00)
Immune system disorders				
- Total	103	36 (90.00)	36	19 (47.50)
Cytokine release syndrome	67	30 (75.00)	29	18 (45.00)
Hypogammaglobulinaemia	24	17 (42.50)	1	1 (2.50)
Haemophagocytic lymphohistiocytosis	4	4 (10.00)	3	3 (7.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Seasonal allergy	3	3 (7.50)	0	0 (0.00)
Allergy to immunoglobulin therapy	2	2 (5.00)	1	1 (2.50)
Engraftment syndrome	1	1 (2.50)	1	1 (2.50)
Graft versus host disease	1	1 (2.50)	1	1 (2.50)
Selective IgG subclass deficiency	1	1 (2.50)	0	0 (0.00)
Infections and infestations				
- Total	102	24 (60.00)	33	16 (40.00)
Rhinovirus infection	7	6 (15.00)	0	0 (0.00)
Staphylococcal bacteraemia	5	4 (10.00)	5	4 (10.00)
Upper respiratory tract infection	5	5 (12.50)	1	1 (2.50)
Conjunctivitis	4	4 (10.00)	0	0 (0.00)
Sinusitis	4	3 (7.50)	0	0 (0.00)
COVID-19	3	2 (5.00)	1	1 (2.50)
Clostridium difficile infection	3	3 (7.50)	2	2 (5.00)
Gastroenteritis viral	3	2 (5.00)	0	0 (0.00)
Candida infection	2	2 (5.00)	0	0 (0.00)
Metapneumovirus infection	2	2 (5.00)	2	2 (5.00)
Nail infection	2	2 (5.00)	0	0 (0.00)
Otitis media	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Pneumocystis jirovecii pneumonia	2	2 (5.00)	2	2 (5.00)
Pneumonia	2	2 (5.00)	1	1 (2.50)
Respiratory syncytial virus infection	2	2 (5.00)	1	1 (2.50)
Septic shock	2	2 (5.00)	2	2 (5.00)
Skin infection	2	2 (5.00)	0	0 (0.00)
Staphylococcal infection	2	2 (5.00)	0	0 (0.00)
Acute sinusitis	1	1 (2.50)	0	0 (0.00)
Adenovirus infection	1	1 (2.50)	1	1 (2.50)
Atypical pneumonia	1	1 (2.50)	0	0 (0.00)
BK virus infection	1	1 (2.50)	1	1 (2.50)
Bacteraemia	1	1 (2.50)	0	0 (0.00)
Bronchiolitis	1	1 (2.50)	1	1 (2.50)
Bronchitis	1	1 (2.50)	0	0 (0.00)
Cellulitis	1	1 (2.50)	0	0 (0.00)
Cholecystitis infective	1	1 (2.50)	0	0 (0.00)
Clostridium difficile colitis	1	1 (2.50)	1	1 (2.50)
Coronavirus infection	1	1 (2.50)	1	1 (2.50)
Device related infection	1	1 (2.50)	1	1 (2.50)
Ear infection	1	1 (2.50)	0	0 (0.00)
Encephalitis	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Folliculitis	1	1 (2.50)	0	0 (0.00)
Fungal infection	1	1 (2.50)	0	0 (0.00)
Fungal skin infection	1	1 (2.50)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (2.50)	1	1 (2.50)
Gastroenteritis clostridial	1	1 (2.50)	0	0 (0.00)
Gastroenteritis norovirus	1	1 (2.50)	0	0 (0.00)
Gastroenteritis salmonella	1	1 (2.50)	1	1 (2.50)
Gastrointestinal infection	1	1 (2.50)	0	0 (0.00)
Herpes simplex	1	1 (2.50)	0	0 (0.00)
Herpes virus infection	1	1 (2.50)	0	0 (0.00)
Influenza	1	1 (2.50)	0	0 (0.00)
Klebsiella bacteraemia	1	1 (2.50)	0	0 (0.00)
Localised infection	1	1 (2.50)	0	0 (0.00)
Meningitis pneumococcal	1	1 (2.50)	1	1 (2.50)
Ophthalmic herpes zoster	1	1 (2.50)	0	0 (0.00)
Oral candidiasis	1	1 (2.50)	0	0 (0.00)
Oral herpes	1	1 (2.50)	0	0 (0.00)
Oral infection	1	1 (2.50)	0	0 (0.00)
Otitis externa	1	1 (2.50)	0	0 (0.00)
Otitis media acute	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Parainfluenzae virus infection	1	1 (2.50)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (2.50)	1	1 (2.50)
Pneumonia respiratory syncytial viral	1	1 (2.50)	1	1 (2.50)
Salmonellosis	1	1 (2.50)	0	0 (0.00)
Sepsis	1	1 (2.50)	1	1 (2.50)
Sinusitis fungal	1	1 (2.50)	1	1 (2.50)
Staphylococcal sepsis	1	1 (2.50)	1	1 (2.50)
Streptococcal sepsis	1	1 (2.50)	0	0 (0.00)
Syphilis	1	1 (2.50)	0	0 (0.00)
Urinary tract infection	1	1 (2.50)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.50)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.50)	0	0 (0.00)
Viral infection	1	1 (2.50)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (2.50)	1	1 (2.50)
Injury, poisoning and procedural complications				
- Total	23	15 (37.50)	3	2 (5.00)
Contusion	3	2 (5.00)	0	0 (0.00)
Infusion related reaction	3	3 (7.50)	1	1 (2.50)
Wound	3	2 (5.00)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Skin abrasion	2	2 (5.00)	0	0 (0.00)
Transfusion reaction	2	2 (5.00)	0	0 (0.00)
Abdominal injury	1	1 (2.50)	0	0 (0.00)
Fall	1	1 (2.50)	0	0 (0.00)
Fibula fracture	1	1 (2.50)	0	0 (0.00)
Limb injury	1	1 (2.50)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (2.50)	0	0 (0.00)
Procedural pain	1	1 (2.50)	0	0 (0.00)
Scratch	1	1 (2.50)	0	0 (0.00)
Skin injury	1	1 (2.50)	0	0 (0.00)
Skin wound	1	1 (2.50)	0	0 (0.00)
Vasoplegia syndrome	1	1 (2.50)	1	1 (2.50)
Investigations				
- Total	245	32 (80.00)	115	26 (65.00)
Platelet count decreased	39	12 (30.00)	24	7 (17.50)
Neutrophil count decreased	28	11 (27.50)	19	9 (22.50)
White blood cell count decreased	22	13 (32.50)	14	8 (20.00)
Aspartate aminotransferase increased	17	14 (35.00)	8	8 (20.00)
Alanine aminotransferase increased	14	12 (30.00)	3	3 (7.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Blood bilirubin increased	14	10 (25.00)	9	8 (20.00)
Lymphocyte count decreased	13	9 (22.50)	8	8 (20.00)
International normalised ratio increased	11	8 (20.00)	0	0 (0.00)
Activated partial thromboplastin time prolonged	8	6 (15.00)	1	1 (2.50)
Blood creatinine increased	6	4 (10.00)	5	3 (7.50)
Blood immunoglobulin M decreased	6	6 (15.00)	1	1 (2.50)
Electrocardiogram QT prolonged	6	5 (12.50)	2	2 (5.00)
Blood fibrinogen decreased	5	5 (12.50)	2	2 (5.00)
Blood immunoglobulin A decreased	5	5 (12.50)	0	0 (0.00)
Weight increased	5	2 (5.00)	2	2 (5.00)
Blood uric acid increased	4	4 (10.00)	2	2 (5.00)
Lipase increased	4	2 (5.00)	2	1 (2.50)
Blood immunoglobulin G decreased	3	3 (7.50)	0	0 (0.00)
Blood lactate dehydrogenase increased	3	3 (7.50)	1	1 (2.50)
C-reactive protein increased	3	3 (7.50)	2	2 (5.00)
Serum ferritin increased	3	3 (7.50)	2	2 (5.00)
Urine output decreased	3	2 (5.00)	3	2 (5.00)
Fibrin D dimer increased	2	2 (5.00)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Oxygen saturation decreased	2	2 (5.00)	0	0 (0.00)
Amylase increased	1	1 (2.50)	0	0 (0.00)
Bacterial test positive	1	1 (2.50)	1	1 (2.50)
Blood bicarbonate decreased	1	1 (2.50)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (2.50)	1	1 (2.50)
Blood phosphorus increased	1	1 (2.50)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.50)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (2.50)	0	0 (0.00)
Blood urea increased	1	1 (2.50)	1	1 (2.50)
Cardiac murmur	1	1 (2.50)	0	0 (0.00)
Coagulation test abnormal	1	1 (2.50)	0	0 (0.00)
Ejection fraction decreased	1	1 (2.50)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (2.50)	0	0 (0.00)
Enterovirus test positive	1	1 (2.50)	0	0 (0.00)
Haptoglobin decreased	1	1 (2.50)	0	0 (0.00)
Heart sounds abnormal	1	1 (2.50)	0	0 (0.00)
Immunoglobulins decreased	1	1 (2.50)	0	0 (0.00)
Staphylococcus test positive	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Troponin increased	1	1 (2.50)	1	1 (2.50)
Weight decreased	1	1 (2.50)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	152	32 (80.00)	61	20 (50.00)
Hypokalaemia	31	12 (30.00)	17	6 (15.00)
Decreased appetite	19	19 (47.50)	8	8 (20.00)
Hypophosphataemia	19	11 (27.50)	6	6 (15.00)
Hypocalcaemia	18	12 (30.00)	5	4 (10.00)
Hyperuricaemia	8	7 (17.50)	0	0 (0.00)
Hypervolaemia	6	6 (15.00)	5	5 (12.50)
Hypoalbuminaemia	6	5 (12.50)	1	1 (2.50)
Hyperglycaemia	5	4 (10.00)	2	2 (5.00)
Hyperphosphataemia	5	5 (12.50)	1	1 (2.50)
Hypercalcaemia	4	3 (7.50)	2	2 (5.00)
Hyperkalaemia	3	3 (7.50)	2	2 (5.00)
Hypertriglyceridaemia	3	3 (7.50)	2	2 (5.00)
Metabolic acidosis	3	3 (7.50)	2	2 (5.00)
Tumour lysis syndrome	3	3 (7.50)	3	3 (7.50)
Hyperchloraemia	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Hypernatraemia	2	2 (5.00)	2	2 (5.00)
Iron overload	2	1 (2.50)	0	0 (0.00)
Acidosis	1	1 (2.50)	1	1 (2.50)
Calcium deficiency	1	1 (2.50)	0	0 (0.00)
Dehydration	1	1 (2.50)	0	0 (0.00)
Haemosiderosis	1	1 (2.50)	0	0 (0.00)
Hypercholesterolaemia	1	1 (2.50)	0	0 (0.00)
Hyperlactacidaemia	1	1 (2.50)	0	0 (0.00)
Hyperlipidaemia	1	1 (2.50)	0	0 (0.00)
Hypoglycaemia	1	1 (2.50)	0	0 (0.00)
Hypomagnesaemia	1	1 (2.50)	0	0 (0.00)
Hyponatraemia	1	1 (2.50)	0	0 (0.00)
Malnutrition	1	1 (2.50)	1	1 (2.50)
Metabolic syndrome	1	1 (2.50)	0	0 (0.00)
Obesity	1	1 (2.50)	1	1 (2.50)
Musculoskeletal and connective tissue disorders				
- Total	42	25 (62.50)	5	4 (10.00)
Pain in extremity	9	9 (22.50)	0	0 (0.00)
Back pain	7	4 (10.00)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Arthralgia	6	5 (12.50)	1	1 (2.50)
Myalgia	5	5 (12.50)	0	0 (0.00)
Bone pain	2	2 (5.00)	0	0 (0.00)
Growth retardation	1	1 (2.50)	0	0 (0.00)
Haemarthrosis	1	1 (2.50)	1	1 (2.50)
Joint effusion	1	1 (2.50)	0	0 (0.00)
Muscle rigidity	1	1 (2.50)	0	0 (0.00)
Muscle spasms	1	1 (2.50)	0	0 (0.00)
Muscular weakness	1	1 (2.50)	1	1 (2.50)
Musculoskeletal pain	1	1 (2.50)	0	0 (0.00)
Myositis	1	1 (2.50)	0	0 (0.00)
Neck pain	1	1 (2.50)	0	0 (0.00)
Osteonecrosis	1	1 (2.50)	0	0 (0.00)
Osteopenia	1	1 (2.50)	0	0 (0.00)
Rhabdomyolysis	1	1 (2.50)	1	1 (2.50)
Synovitis	1	1 (2.50)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (2.50)	0	0 (0.00)
Cancer pain	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Nervous system disorders				
- Total	61	27 (67.50)	16	10 (25.00)
Headache	26	16 (40.00)	2	2 (5.00)
Cognitive disorder	5	3 (7.50)	1	1 (2.50)
Encephalopathy	5	5 (12.50)	3	3 (7.50)
Hydrocephalus	3	1 (2.50)	3	1 (2.50)
Seizure	3	1 (2.50)	1	1 (2.50)
Tremor	3	3 (7.50)	0	0 (0.00)
Migraine	2	1 (2.50)	0	0 (0.00)
Nervous system disorder	2	1 (2.50)	1	1 (2.50)
Somnolence	2	2 (5.00)	2	2 (5.00)
Cerebral haemorrhage	1	1 (2.50)	1	1 (2.50)
Dizziness	1	1 (2.50)	0	0 (0.00)
Dysarthria	1	1 (2.50)	1	1 (2.50)
Extrapyramidal disorder	1	1 (2.50)	0	0 (0.00)
Generalised tonic-clonic seizure	1	1 (2.50)	0	0 (0.00)
Lethargy	1	1 (2.50)	0	0 (0.00)
Monoparesis	1	1 (2.50)	0	0 (0.00)
Neuralgia	1	1 (2.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Neurological decompensation	1	1 (2.50)	1	1 (2.50)
Paraesthesia	1	1 (2.50)	0	0 (0.00)
Psychiatric disorders				
- Total	38	26 (65.00)	5	5 (12.50)
Anxiety	8	8 (20.00)	1	1 (2.50)
Delirium	6	6 (15.00)	3	3 (7.50)
Agitation	5	4 (10.00)	0	0 (0.00)
Confusional state	5	5 (12.50)	0	0 (0.00)
Insomnia	4	4 (10.00)	0	0 (0.00)
Mental status changes	4	4 (10.00)	1	1 (2.50)
Irritability	2	2 (5.00)	0	0 (0.00)
Automatism	1	1 (2.50)	0	0 (0.00)
Persistent depressive disorder	1	1 (2.50)	0	0 (0.00)
Sleep disorder	1	1 (2.50)	0	0 (0.00)
Tic	1	1 (2.50)	0	0 (0.00)
Renal and urinary disorders				
- Total	27	13 (32.50)	10	7 (17.50)
Acute kidney injury	9	7 (17.50)	5	5 (12.50)
Dysuria	3	3 (7.50)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Renal failure	3	1 (2.50)	3	1 (2.50)
Urinary retention	2	2 (5.00)	0	0 (0.00)
Anuria	1	1 (2.50)	0	0 (0.00)
Azotaemia	1	1 (2.50)	0	0 (0.00)
Bladder dilatation	1	1 (2.50)	0	0 (0.00)
Haematuria	1	1 (2.50)	1	1 (2.50)
Kidney enlargement	1	1 (2.50)	0	0 (0.00)
Micturition urgency	1	1 (2.50)	0	0 (0.00)
Pollakiuria	1	1 (2.50)	0	0 (0.00)
Renal mass	1	1 (2.50)	0	0 (0.00)
Renal tubular dysfunction	1	1 (2.50)	0	0 (0.00)
Renal tubular necrosis	1	1 (2.50)	1	1 (2.50)
Reproductive system and breast disorders				
- Total	6	3 (7.50)	2	2 (5.00)
Dysmenorrhoea	2	1 (2.50)	0	0 (0.00)
Endometriosis	2	1 (2.50)	1	1 (2.50)
Perineal rash	1	1 (2.50)	0	0 (0.00)
Vaginal ulceration	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	97	28 (70.00)	34	15 (37.50)
Hypoxia	13	11 (27.50)	10	9 (22.50)
Cough	12	9 (22.50)	0	0 (0.00)
Pulmonary oedema	7	7 (17.50)	3	3 (7.50)
Rhinorrhoea	7	5 (12.50)	0	0 (0.00)
Pleural effusion	6	5 (12.50)	3	3 (7.50)
Tachypnoea	6	5 (12.50)	2	2 (5.00)
Nasal congestion	5	5 (12.50)	0	0 (0.00)
Oropharyngeal pain	5	4 (10.00)	0	0 (0.00)
Respiratory distress	5	4 (10.00)	3	2 (5.00)
Respiratory failure	5	5 (12.50)	5	5 (12.50)
Atelectasis	4	2 (5.00)	2	2 (5.00)
Dyspnoea	4	3 (7.50)	1	1 (2.50)
Acute respiratory distress syndrome	3	3 (7.50)	3	3 (7.50)
Epistaxis	3	3 (7.50)	0	0 (0.00)
Rhinitis allergic	2	2 (5.00)	0	0 (0.00)
Wheezing	2	2 (5.00)	0	0 (0.00)
Bradypnoea	1	1 (2.50)	1	1 (2.50)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Haemoptysis	1	1 (2.50)	0	0 (0.00)
Nasal discomfort	1	1 (2.50)	0	0 (0.00)
Nasal dryness	1	1 (2.50)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (2.50)	0	0 (0.00)
Productive cough	1	1 (2.50)	0	0 (0.00)
Respiratory acidosis	1	1 (2.50)	1	1 (2.50)
Sleep apnoea syndrome	1	1 (2.50)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	57	19 (47.50)	3	2 (5.00)
Rash	11	6 (15.00)	0	0 (0.00)
Pruritus	7	5 (12.50)	0	0 (0.00)
Blister	6	3 (7.50)	0	0 (0.00)
Dry skin	5	4 (10.00)	0	0 (0.00)
Erythema	3	3 (7.50)	0	0 (0.00)
Eczema	2	2 (5.00)	0	0 (0.00)
Ingrowing nail	2	2 (5.00)	0	0 (0.00)
Petechiae	2	2 (5.00)	1	1 (2.50)
Rash papular	2	2 (5.00)	0	0 (0.00)
Skin discolouration	2	2 (5.00)	0	0 (0.00)

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
Decubitus ulcer	1	1 (2.50)	0	0 (0.00)
Dermatitis	1	1 (2.50)	0	0 (0.00)
Dermatitis diaper	1	1 (2.50)	0	0 (0.00)
Hyperhidrosis	1	1 (2.50)	0	0 (0.00)
Miliaria	1	1 (2.50)	0	0 (0.00)
Papule	1	1 (2.50)	0	0 (0.00)
Pruritus allergic	1	1 (2.50)	0	0 (0.00)
Rash erythematous	1	1 (2.50)	0	0 (0.00)
Rash maculo-papular	1	1 (2.50)	0	0 (0.00)
Rash pruritic	1	1 (2.50)	0	0 (0.00)
Scab	1	1 (2.50)	0	0 (0.00)
Skin necrosis	1	1 (2.50)	1	1 (2.50)
Skin ulcer	1	1 (2.50)	0	0 (0.00)
Urticaria	1	1 (2.50)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (2.50)	1	1 (2.50)
Surgical and medical procedures				
- Total	1	1 (2.50)	1	1 (2.50)
Thrombolysis	1	1 (2.50)	1	1 (2.50)
Vascular disorders				

Timing: At anytime, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades Total events	All patients N=40 n (%)[1]	Grade >= 3 Total events	All patients N=40 n (%)[2]
- Total	37	21 (52.50)	21	15 (37.50)
Hypotension	21	17 (42.50)	15	12 (30.00)
Hypertension	11	10 (25.00)	4	4 (10.00)
Capillary leak syndrome	2	2 (5.00)	1	1 (2.50)
Peripheral ischaemia	1	1 (2.50)	0	0 (0.00)
Thrombosis	1	1 (2.50)	0	0 (0.00)
Venoocclusive disease	1	1 (2.50)	1	1 (2.50)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	211	6 (100.00)	82	4 (66.67)
Blood and lymphatic system disorders				
- Total	13	4 (66.67)	6	4 (66.67)
Anaemia	7	2 (33.33)	0	0 (0.00)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Coagulopathy	1	1 (16.67)	1	1 (16.67)
Disseminated intravascular coagulation	1	1 (16.67)	1	1 (16.67)
Thrombocytopenia	1	1 (16.67)	1	1 (16.67)
Cardiac disorders				
- Total	7	3 (50.00)	1	1 (16.67)
Tachycardia	6	3 (50.00)	1	1 (16.67)
Sinus tachycardia	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Eye disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Eyelid oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	6	2 (33.33)	1	1 (16.67)
Abdominal distension	1	1 (16.67)	0	0 (0.00)
Ascites	1	1 (16.67)	0	0 (0.00)
Constipation	1	1 (16.67)	0	0 (0.00)
Melaena	1	1 (16.67)	1	1 (16.67)
Mouth haemorrhage	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	16	4 (66.67)	3	2 (33.33)
Pyrexia	8	3 (50.00)	1	1 (16.67)
Catheter site pain	1	1 (16.67)	0	0 (0.00)
Chills	1	1 (16.67)	0	0 (0.00)
Face oedema	1	1 (16.67)	0	0 (0.00)
Fatigue	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Generalised oedema	1	1 (16.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (16.67)	1	1 (16.67)
Oedema peripheral	1	1 (16.67)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (16.67)	1	1 (16.67)
Hepatobiliary disorders				
- Total	3	1 (16.67)	1	1 (16.67)
Cholelithiasis	1	1 (16.67)	0	0 (0.00)
Cholestasis	1	1 (16.67)	1	1 (16.67)
Gallbladder enlargement	1	1 (16.67)	0	0 (0.00)
Immune system disorders				
- Total	14	5 (83.33)	7	2 (33.33)
Cytokine release syndrome	10	5 (83.33)	5	2 (33.33)
Hypogammaglobulinaemia	2	2 (33.33)	1	1 (16.67)
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	1	1 (16.67)
Seasonal allergy	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	3	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Conjunctivitis	1	1 (16.67)	0	0 (0.00)
Encephalitis	1	1 (16.67)	1	1 (16.67)
Localised infection	1	1 (16.67)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	2 (33.33)	2	1 (16.67)
Wound	2	1 (16.67)	1	1 (16.67)
Infusion related reaction	1	1 (16.67)	0	0 (0.00)
Skin injury	1	1 (16.67)	0	0 (0.00)
Skin wound	1	1 (16.67)	0	0 (0.00)
Vasoplegia syndrome	1	1 (16.67)	1	1 (16.67)
Investigations				
- Total	56	3 (50.00)	26	3 (50.00)
Neutrophil count decreased	21	3 (50.00)	15	3 (50.00)
White blood cell count decreased	6	2 (33.33)	2	1 (16.67)
Aspartate aminotransferase increased	5	1 (16.67)	1	1 (16.67)
Blood bilirubin increased	5	1 (16.67)	1	1 (16.67)
Platelet count decreased	4	1 (16.67)	2	1 (16.67)
Alanine aminotransferase increased	3	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Lipase increased	3	1 (16.67)	2	1 (16.67)
Blood alkaline phosphatase increased	1	1 (16.67)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (16.67)	1	1 (16.67)
Blood creatinine increased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (16.67)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (16.67)	0	0 (0.00)
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Lymphocyte count decreased	1	1 (16.67)	1	1 (16.67)
Weight increased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	40	5 (83.33)	14	3 (50.00)
Hypokalaemia	10	1 (16.67)	7	1 (16.67)
Hypocalcaemia	6	2 (33.33)	2	1 (16.67)
Hypophosphataemia	6	3 (50.00)	2	2 (33.33)
Hyperglycaemia	3	1 (16.67)	0	0 (0.00)
Hyperuricaemia	3	2 (33.33)	1	1 (16.67)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Acidosis	2	1 (16.67)	1	1 (16.67)
Decreased appetite	2	2 (33.33)	0	0 (0.00)
Hypoalbuminaemia	2	1 (16.67)	0	0 (0.00)
Haemosiderosis	1	1 (16.67)	0	0 (0.00)
Hyperlactacidaemia	1	1 (16.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (16.67)	0	0 (0.00)
Hypernatraemia	1	1 (16.67)	1	1 (16.67)
Hypomagnesaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (33.33)	1	1 (16.67)
Myalgia	1	1 (16.67)	0	0 (0.00)
Myositis	1	1 (16.67)	0	0 (0.00)
Rhabdomyolysis	1	1 (16.67)	1	1 (16.67)
Nervous system disorders				
- Total	7	4 (66.67)	1	1 (16.67)
Headache	3	3 (50.00)	0	0 (0.00)
Encephalopathy	1	1 (16.67)	1	1 (16.67)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Monoparesis	1	1 (16.67)	0	0 (0.00)
Somnolence	1	1 (16.67)	0	0 (0.00)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	2	2 (33.33)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Sleep disorder	1	1 (16.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	2 (33.33)	3	2 (33.33)
Acute kidney injury	4	2 (33.33)	2	2 (33.33)
Bladder dilatation	1	1 (16.67)	0	0 (0.00)
Renal tubular necrosis	1	1 (16.67)	1	1 (16.67)
Urinary retention	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (16.67)	1	1 (16.67)
Vaginal ulceration	1	1 (16.67)	1	1 (16.67)
Respiratory, thoracic and mediastinal disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
- Total	11	3 (50.00)	8	2 (33.33)
Atelectasis	3	1 (16.67)	1	1 (16.67)
Tachypnoea	2	2 (33.33)	2	2 (33.33)
Acute respiratory distress syndrome	1	1 (16.67)	1	1 (16.67)
Acute respiratory failure	1	1 (16.67)	1	1 (16.67)
Dyspnoea	1	1 (16.67)	1	1 (16.67)
Hypoxia	1	1 (16.67)	1	1 (16.67)
Nasal congestion	1	1 (16.67)	0	0 (0.00)
Respiratory acidosis	1	1 (16.67)	1	1 (16.67)
Skin and subcutaneous tissue disorders				
- Total	9	3 (50.00)	2	1 (16.67)
Rash	2	2 (33.33)	0	0 (0.00)
Decubitus ulcer	1	1 (16.67)	0	0 (0.00)
Erythema	1	1 (16.67)	0	0 (0.00)
Hyperhidrosis	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	1	1 (16.67)
Pruritus	1	1 (16.67)	0	0 (0.00)
Skin necrosis	1	1 (16.67)	1	1 (16.67)
Skin ulcer	1	1 (16.67)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Vascular disorders				
- Total	6	2 (33.33)	4	2 (33.33)
Hypotension	4	2 (33.33)	3	2 (33.33)
Hypertension	2	1 (16.67)	1	1 (16.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Total number of AE per patient	487	22 (100.00)	190	18 (81.82)
Blood and lymphatic system disorders				
- Total	32	13 (59.09)	19	9 (40.91)
Anaemia	10	5 (22.73)	2	1 (4.55)
Febrile neutropenia	8	6 (27.27)	8	6 (27.27)
Neutropenia	4	3 (13.64)	4	3 (13.64)
Thrombocytopenia	3	3 (13.64)	3	3 (13.64)
Coagulopathy	2	2 (9.09)	0	0 (0.00)
Disseminated intravascular coagulation	2	2 (9.09)	0	0 (0.00)
Leukopenia	2	1 (4.55)	2	1 (4.55)
Splenomegaly	1	1 (4.55)	0	0 (0.00)
Cardiac disorders				
- Total	19	8 (36.36)	7	5 (22.73)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Tachycardia	9	7 (31.82)	2	2 (9.09)
Cardiac failure	4	1 (4.55)	2	1 (4.55)
Bradycardia	2	2 (9.09)	0	0 (0.00)
Left ventricular dysfunction	2	2 (9.09)	2	2 (9.09)
Atrioventricular block first degree	1	1 (4.55)	0	0 (0.00)
Sinus bradycardia	1	1 (4.55)	1	1 (4.55)
Ear and labyrinth disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Ear pain	1	1 (4.55)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (18.18)	0	0 (0.00)
Adrenal insufficiency	3	3 (13.64)	0	0 (0.00)
Hypothyroidism	1	1 (4.55)	0	0 (0.00)
Eye disorders				
- Total	3	2 (9.09)	0	0 (0.00)
Ocular hyperaemia	2	2 (9.09)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.55)	0	0 (0.00)
Gastrointestinal disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	37	16 (72.73)	7	6 (27.27)
Vomiting	8	7 (31.82)	1	1 (4.55)
Nausea	6	6 (27.27)	1	1 (4.55)
Constipation	5	5 (22.73)	0	0 (0.00)
Abdominal pain	4	4 (18.18)	1	1 (4.55)
Diarrhoea	2	2 (9.09)	0	0 (0.00)
Pancreatitis	2	2 (9.09)	1	1 (4.55)
Abdominal compartment syndrome	1	1 (4.55)	1	1 (4.55)
Abdominal pain upper	1	1 (4.55)	0	0 (0.00)
Anal fissure	1	1 (4.55)	0	0 (0.00)
Anal haemorrhage	1	1 (4.55)	0	0 (0.00)
Dry mouth	1	1 (4.55)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (4.55)	0	0 (0.00)
Haematemesis	1	1 (4.55)	0	0 (0.00)
Ileus	1	1 (4.55)	0	0 (0.00)
Mouth haemorrhage	1	1 (4.55)	1	1 (4.55)
Neutropenic colitis	1	1 (4.55)	1	1 (4.55)
General disorders and administration site conditions				
- Total	23	10 (45.45)	6	4 (18.18)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Pyrexia	7	5 (22.73)	2	2 (9.09)
Oedema peripheral	5	4 (18.18)	2	1 (4.55)
Face oedema	3	3 (13.64)	1	1 (4.55)
Drug withdrawal syndrome	2	2 (9.09)	0	0 (0.00)
Fatigue	2	2 (9.09)	0	0 (0.00)
Chills	1	1 (4.55)	0	0 (0.00)
Generalised oedema	1	1 (4.55)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (4.55)	1	1 (4.55)
Oedema due to hepatic disease	1	1 (4.55)	0	0 (0.00)
Hepatobiliary disorders				
- Total	11	7 (31.82)	2	2 (9.09)
Hepatic function abnormal	4	2 (9.09)	1	1 (4.55)
Hyperbilirubinaemia	2	2 (9.09)	1	1 (4.55)
Biliary tract disorder	1	1 (4.55)	0	0 (0.00)
Gallbladder enlargement	1	1 (4.55)	0	0 (0.00)
Hepatomegaly	1	1 (4.55)	0	0 (0.00)
Hypertransaminasaemia	1	1 (4.55)	0	0 (0.00)
Ocular icterus	1	1 (4.55)	0	0 (0.00)
Immune system disorders				

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	50	19 (86.36)	19	11 (50.00)
Cytokine release syndrome	36	15 (68.18)	15	10 (45.45)
Hypogammaglobulinaemia	11	9 (40.91)	1	1 (4.55)
Haemophagocytic lymphohistiocytosis	2	2 (9.09)	2	2 (9.09)
Immunodeficiency	1	1 (4.55)	1	1 (4.55)
Infections and infestations				
- Total	17	9 (40.91)	7	4 (18.18)
Clostridium difficile infection	3	3 (13.64)	2	2 (9.09)
Conjunctivitis	3	2 (9.09)	0	0 (0.00)
Staphylococcal bacteraemia	2	1 (4.55)	2	1 (4.55)
Atypical pneumonia	1	1 (4.55)	0	0 (0.00)
Bacteraemia	1	1 (4.55)	1	1 (4.55)
Candida infection	1	1 (4.55)	0	0 (0.00)
Cholecystitis infective	1	1 (4.55)	0	0 (0.00)
Encephalitis viral	1	1 (4.55)	1	1 (4.55)
Klebsiella bacteraemia	1	1 (4.55)	0	0 (0.00)
Meningitis bacterial	1	1 (4.55)	1	1 (4.55)
Rhinovirus infection	1	1 (4.55)	0	0 (0.00)
Staphylococcal infection	1	1 (4.55)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Injury, poisoning and procedural complications				
- Total	3	3 (13.64)	0	0 (0.00)
Transfusion reaction	2	2 (9.09)	0	0 (0.00)
Scratch	1	1 (4.55)	0	0 (0.00)
Investigations				
- Total	106	16 (72.73)	51	15 (68.18)
White blood cell count decreased	17	8 (36.36)	13	7 (31.82)
Platelet count decreased	13	5 (22.73)	6	3 (13.64)
Aspartate aminotransferase increased	10	8 (36.36)	6	6 (27.27)
Blood bilirubin increased	7	6 (27.27)	5	5 (22.73)
Lymphocyte count decreased	6	4 (18.18)	4	4 (18.18)
Alanine aminotransferase increased	5	5 (22.73)	0	0 (0.00)
Neutrophil count decreased	5	4 (18.18)	5	4 (18.18)
Activated partial thromboplastin time prolonged	4	3 (13.64)	0	0 (0.00)
Blood fibrinogen decreased	4	4 (18.18)	0	0 (0.00)
Electrocardiogram QT prolonged	4	3 (13.64)	2	2 (9.09)
Serum ferritin increased	4	4 (18.18)	1	1 (4.55)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Blood immunoglobulin M decreased	3	3 (13.64)	1	1 (4.55)
International normalised ratio increased	3	3 (13.64)	0	0 (0.00)
Blood immunoglobulin A decreased	2	2 (9.09)	0	0 (0.00)
Blood uric acid increased	2	2 (9.09)	0	0 (0.00)
Fibrin D dimer increased	2	2 (9.09)	1	1 (4.55)
Amylase increased	1	1 (4.55)	0	0 (0.00)
Bacterial test positive	1	1 (4.55)	1	1 (4.55)
Blood creatinine increased	1	1 (4.55)	1	1 (4.55)
Blood immunoglobulin G decreased	1	1 (4.55)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (4.55)	1	1 (4.55)
Blood phosphorus increased	1	1 (4.55)	0	0 (0.00)
C-reactive protein increased	1	1 (4.55)	1	1 (4.55)
Coagulation test abnormal	1	1 (4.55)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (4.55)	0	0 (0.00)
Lipase increased	1	1 (4.55)	0	0 (0.00)
Oxygen saturation decreased	1	1 (4.55)	0	0 (0.00)
Staphylococcus test positive	1	1 (4.55)	0	0 (0.00)
Troponin increased	1	1 (4.55)	1	1 (4.55)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Urine output decreased	1	1 (4.55)	1	1 (4.55)
Weight increased	1	1 (4.55)	1	1 (4.55)
Metabolism and nutrition disorders				
- Total	60	14 (63.64)	24	9 (40.91)
Hypocalcaemia	10	7 (31.82)	2	2 (9.09)
Decreased appetite	7	7 (31.82)	5	5 (22.73)
Hyperglycaemia	5	4 (18.18)	2	2 (9.09)
Hypoalbuminaemia	5	4 (18.18)	1	1 (4.55)
Hypokalaemia	5	5 (22.73)	1	1 (4.55)
Hyperuricaemia	4	3 (13.64)	0	0 (0.00)
Hypervolaemia	4	4 (18.18)	4	4 (18.18)
Hypophosphataemia	4	3 (13.64)	1	1 (4.55)
Hypercalcaemia	2	2 (9.09)	1	1 (4.55)
Hyperphosphataemia	2	2 (9.09)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (9.09)	2	2 (9.09)
Metabolic acidosis	2	2 (9.09)	1	1 (4.55)
Tumour lysis syndrome	2	2 (9.09)	2	2 (9.09)
Acidosis	1	1 (4.55)	1	1 (4.55)
Calcium deficiency	1	1 (4.55)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Dehydration	1	1 (4.55)	0	0 (0.00)
Hyperkalaemia	1	1 (4.55)	1	1 (4.55)
Hypoglycaemia	1	1 (4.55)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.55)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	12	9 (40.91)	2	1 (4.55)
Pain in extremity	3	3 (13.64)	0	0 (0.00)
Arthralgia	2	2 (9.09)	1	1 (4.55)
Back pain	2	1 (4.55)	0	0 (0.00)
Bone pain	1	1 (4.55)	0	0 (0.00)
Haemarthrosis	1	1 (4.55)	1	1 (4.55)
Muscle spasms	1	1 (4.55)	0	0 (0.00)
Muscular weakness	1	1 (4.55)	0	0 (0.00)
Myalgia	1	1 (4.55)	0	0 (0.00)
Nervous system disorders				
- Total	21	11 (50.00)	6	4 (18.18)
Cognitive disorder	4	2 (9.09)	1	1 (4.55)
Headache	4	3 (13.64)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Encephalopathy	3	3 (13.64)	1	1 (4.55)
Seizure	2	1 (4.55)	0	0 (0.00)
Cerebral haemorrhage	1	1 (4.55)	1	1 (4.55)
Dizziness	1	1 (4.55)	0	0 (0.00)
Dysarthria	1	1 (4.55)	1	1 (4.55)
Dysgeusia	1	1 (4.55)	0	0 (0.00)
Lethargy	1	1 (4.55)	0	0 (0.00)
Neurological decompensation	1	1 (4.55)	1	1 (4.55)
Paraesthesia	1	1 (4.55)	0	0 (0.00)
Somnolence	1	1 (4.55)	1	1 (4.55)
Psychiatric disorders				
- Total	14	10 (45.45)	4	4 (18.18)
Delirium	4	4 (18.18)	3	3 (13.64)
Agitation	2	2 (9.09)	0	0 (0.00)
Anxiety	2	2 (9.09)	1	1 (4.55)
Confusional state	2	2 (9.09)	0	0 (0.00)
Irritability	2	2 (9.09)	0	0 (0.00)
Insomnia	1	1 (4.55)	0	0 (0.00)
Mental status changes	1	1 (4.55)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Renal and urinary disorders				
- Total	10	7 (31.82)	7	4 (18.18)
Acute kidney injury	4	3 (13.64)	4	3 (13.64)
Renal failure	3	1 (4.55)	3	1 (4.55)
Dysuria	1	1 (4.55)	0	0 (0.00)
Renal tubular dysfunction	1	1 (4.55)	0	0 (0.00)
Urinary retention	1	1 (4.55)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	33	13 (59.09)	20	9 (40.91)
Hypoxia	8	6 (27.27)	7	5 (22.73)
Pulmonary oedema	6	6 (27.27)	3	3 (13.64)
Cough	4	4 (18.18)	0	0 (0.00)
Pleural effusion	3	3 (13.64)	2	2 (9.09)
Respiratory distress	3	2 (9.09)	2	1 (4.55)
Respiratory failure	3	3 (13.64)	3	3 (13.64)
Tachypnoea	2	2 (9.09)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (4.55)	1	1 (4.55)
Atelectasis	1	1 (4.55)	1	1 (4.55)
Bradypnoea	1	1 (4.55)	1	1 (4.55)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Rhinorrhoea	1	1 (4.55)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	16	9 (40.91)	1	1 (4.55)
Blister	2	2 (9.09)	0	0 (0.00)
Pruritus	2	2 (9.09)	0	0 (0.00)
Rash vesicular	2	1 (4.55)	0	0 (0.00)
Dermatitis	1	1 (4.55)	0	0 (0.00)
Dermatitis atopic	1	1 (4.55)	0	0 (0.00)
Dry skin	1	1 (4.55)	0	0 (0.00)
Erythema	1	1 (4.55)	0	0 (0.00)
Hyperhidrosis	1	1 (4.55)	0	0 (0.00)
Rash papular	1	1 (4.55)	0	0 (0.00)
Rash pruritic	1	1 (4.55)	0	0 (0.00)
Scab	1	1 (4.55)	0	0 (0.00)
Skin discolouration	1	1 (4.55)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (4.55)	1	1 (4.55)
Surgical and medical procedures				
- Total	1	1 (4.55)	1	1 (4.55)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Thrombolysis	1	1 (4.55)	1	1 (4.55)
Vascular disorders				
- Total	14	8 (36.36)	7	6 (27.27)
Hypotension	8	8 (36.36)	6	6 (27.27)
Hypertension	4	4 (18.18)	1	1 (4.55)
Capillary leak syndrome	1	1 (4.55)	0	0 (0.00)
Peripheral ischaemia	1	1 (4.55)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Total number of AE per patient	304	16 (94.12)	118	13 (76.47)
Blood and lymphatic system disorders				
- Total	23	11 (64.71)	15	10 (58.82)
Febrile neutropenia	8	8 (47.06)	8	8 (47.06)
Anaemia	7	4 (23.53)	3	1 (5.88)
Neutropenia	3	2 (11.76)	2	1 (5.88)
Splenomegaly	2	2 (11.76)	0	0 (0.00)
Disseminated intravascular coagulation	1	1 (5.88)	1	1 (5.88)
Hypofibrinogenaemia	1	1 (5.88)	0	0 (0.00)
Thrombocytopenia	1	1 (5.88)	1	1 (5.88)
Cardiac disorders				
- Total	8	7 (41.18)	1	1 (5.88)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Tachycardia	4	4 (23.53)	0	0 (0.00)
Bradycardia	1	1 (5.88)	0	0 (0.00)
Cardiac arrest	1	1 (5.88)	1	1 (5.88)
Cardiac dysfunction	1	1 (5.88)	0	0 (0.00)
Sinus tachycardia	1	1 (5.88)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Ear pruritus	1	1 (5.88)	0	0 (0.00)
Eye disorders				
- Total	2	1 (5.88)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (5.88)	0	0 (0.00)
Periorbital oedema	1	1 (5.88)	0	0 (0.00)
Gastrointestinal disorders				
- Total	16	7 (41.18)	1	1 (5.88)
Diarrhoea	4	2 (11.76)	0	0 (0.00)
Vomiting	4	3 (17.65)	0	0 (0.00)
Constipation	2	2 (11.76)	0	0 (0.00)
Nausea	2	2 (11.76)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Dysphagia	1	1 (5.88)	1	1 (5.88)
Gingival erythema	1	1 (5.88)	0	0 (0.00)
Lip oedema	1	1 (5.88)	0	0 (0.00)
Pancreatitis	1	1 (5.88)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	10 (58.82)	2	2 (11.76)
Pyrexia	5	5 (29.41)	2	2 (11.76)
Fatigue	3	3 (17.65)	0	0 (0.00)
Generalised oedema	2	2 (11.76)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.88)	0	0 (0.00)
Face oedema	1	1 (5.88)	0	0 (0.00)
Localised oedema	1	1 (5.88)	0	0 (0.00)
Oedema peripheral	1	1 (5.88)	0	0 (0.00)
Hepatobiliary disorders				
- Total	5	3 (17.65)	1	1 (5.88)
Hyperbilirubinaemia	2	1 (5.88)	0	0 (0.00)
Hepatic function abnormal	1	1 (5.88)	0	0 (0.00)
Hepatomegaly	1	1 (5.88)	1	1 (5.88)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Hypertransaminasaemia	1	1 (5.88)	0	0 (0.00)
Immune system disorders				
- Total	30	13 (76.47)	15	8 (47.06)
Cytokine release syndrome	26	12 (70.59)	14	8 (47.06)
Hypogammaglobulinaemia	2	2 (11.76)	1	1 (5.88)
Haemophagocytic lymphohistiocytosis	1	1 (5.88)	0	0 (0.00)
Selective IgG subclass deficiency	1	1 (5.88)	0	0 (0.00)
Infections and infestations				
- Total	8	7 (41.18)	4	4 (23.53)
Staphylococcal bacteraemia	2	2 (11.76)	2	2 (11.76)
Staphylococcal infection	2	2 (11.76)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (5.88)	1	1 (5.88)
Conjunctivitis	1	1 (5.88)	0	0 (0.00)
Oral herpes	1	1 (5.88)	1	1 (5.88)
Urinary tract infection viral	1	1 (5.88)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	6	3 (17.65)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Contusion	2	1 (5.88)	0	0 (0.00)
Procedural pain	2	2 (11.76)	0	0 (0.00)
Skin abrasion	1	1 (5.88)	0	0 (0.00)
Wound	1	1 (5.88)	0	0 (0.00)
Investigations				
- Total	68	11 (64.71)	41	10 (58.82)
Platelet count decreased	13	5 (29.41)	10	4 (23.53)
White blood cell count decreased	8	5 (29.41)	8	5 (29.41)
Alanine aminotransferase increased	6	4 (23.53)	2	2 (11.76)
Aspartate aminotransferase increased	5	5 (29.41)	1	1 (5.88)
International normalised ratio increased	5	2 (11.76)	0	0 (0.00)
Activated partial thromboplastin time prolonged	4	3 (17.65)	1	1 (5.88)
Blood creatinine increased	4	2 (11.76)	4	2 (11.76)
Blood bilirubin increased	3	3 (17.65)	3	3 (17.65)
Lymphocyte count decreased	3	3 (17.65)	3	3 (17.65)
Neutrophil count decreased	3	3 (17.65)	3	3 (17.65)
Blood fibrinogen decreased	2	2 (11.76)	2	2 (11.76)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Gamma-glutamyltransferase increased	2	2 (11.76)	2	2 (11.76)
Urine output decreased	2	1 (5.88)	2	1 (5.88)
Blood bicarbonate decreased	1	1 (5.88)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (5.88)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.88)	0	0 (0.00)
Cardiac murmur	1	1 (5.88)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (5.88)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.88)	0	0 (0.00)
Haptoglobin decreased	1	1 (5.88)	0	0 (0.00)
Weight increased	1	1 (5.88)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	44	9 (52.94)	20	8 (47.06)
Hypokalaemia	11	5 (29.41)	7	5 (29.41)
Hypophosphataemia	9	5 (29.41)	4	4 (23.53)
Decreased appetite	4	4 (23.53)	2	2 (11.76)
Hypocalcaemia	4	4 (23.53)	1	1 (5.88)
Hypoalbuminaemia	3	3 (17.65)	0	0 (0.00)
Hypercalcaemia	2	1 (5.88)	1	1 (5.88)
Hyperphosphataemia	2	2 (11.76)	1	1 (5.88)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Hyperchloraemia	1	1 (5.88)	0	0 (0.00)
Hyperkalaemia	1	1 (5.88)	1	1 (5.88)
Hyperuricaemia	1	1 (5.88)	0	0 (0.00)
Hypervolaemia	1	1 (5.88)	0	0 (0.00)
Hypomagnesaemia	1	1 (5.88)	0	0 (0.00)
Hyponatraemia	1	1 (5.88)	0	0 (0.00)
Malnutrition	1	1 (5.88)	1	1 (5.88)
Metabolic acidosis	1	1 (5.88)	1	1 (5.88)
Tumour lysis syndrome	1	1 (5.88)	1	1 (5.88)
Musculoskeletal and connective tissue disorders				
- Total	6	5 (29.41)	1	1 (5.88)
Arthralgia	2	2 (11.76)	0	0 (0.00)
Muscle rigidity	1	1 (5.88)	0	0 (0.00)
Muscular weakness	1	1 (5.88)	1	1 (5.88)
Myalgia	1	1 (5.88)	0	0 (0.00)
Pain in extremity	1	1 (5.88)	0	0 (0.00)
Nervous system disorders				
- Total	13	7 (41.18)	2	1 (5.88)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Headache	7	5 (29.41)	0	0 (0.00)
Cognitive disorder	1	1 (5.88)	0	0 (0.00)
Encephalopathy	1	1 (5.88)	1	1 (5.88)
Generalised tonic-clonic seizure	1	1 (5.88)	0	0 (0.00)
Neuralgia	1	1 (5.88)	0	0 (0.00)
Somnolence	1	1 (5.88)	1	1 (5.88)
Tremor	1	1 (5.88)	0	0 (0.00)
Psychiatric disorders				
- Total	12	5 (29.41)	1	1 (5.88)
Agitation	3	2 (11.76)	0	0 (0.00)
Confusional state	3	3 (17.65)	0	0 (0.00)
Delirium	2	2 (11.76)	0	0 (0.00)
Anxiety	1	1 (5.88)	0	0 (0.00)
Automatism	1	1 (5.88)	0	0 (0.00)
Insomnia	1	1 (5.88)	0	0 (0.00)
Mental status changes	1	1 (5.88)	1	1 (5.88)
Renal and urinary disorders				
- Total	5	1 (5.88)	1	1 (5.88)
Acute kidney injury	3	1 (5.88)	1	1 (5.88)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Anuria	1	1 (5.88)	0	0 (0.00)
Azotaemia	1	1 (5.88)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Perineal rash	1	1 (5.88)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	23	9 (52.94)	6	4 (23.53)
Hypoxia	4	3 (17.65)	3	2 (11.76)
Tachypnoea	3	2 (11.76)	1	1 (5.88)
Cough	2	2 (11.76)	0	0 (0.00)
Oropharyngeal pain	2	2 (11.76)	0	0 (0.00)
Pleural effusion	2	2 (11.76)	1	1 (5.88)
Epistaxis	1	1 (5.88)	0	0 (0.00)
Haemoptysis	1	1 (5.88)	0	0 (0.00)
Nasal congestion	1	1 (5.88)	0	0 (0.00)
Nasal discomfort	1	1 (5.88)	0	0 (0.00)
Nasal dryness	1	1 (5.88)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (5.88)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Pulmonary oedema	1	1 (5.88)	0	0 (0.00)
Respiratory distress	1	1 (5.88)	0	0 (0.00)
Respiratory failure	1	1 (5.88)	1	1 (5.88)
Wheezing	1	1 (5.88)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	7	2 (11.76)	0	0 (0.00)
Blister	4	1 (5.88)	0	0 (0.00)
Dermatitis diaper	1	1 (5.88)	0	0 (0.00)
Petechiae	1	1 (5.88)	0	0 (0.00)
Pruritus	1	1 (5.88)	0	0 (0.00)
Vascular disorders				
- Total	12	8 (47.06)	7	6 (35.29)
Hypotension	7	5 (29.41)	4	3 (17.65)
Hypertension	3	3 (17.65)	2	2 (11.76)
Capillary leak syndrome	1	1 (5.88)	1	1 (5.88)
Thrombosis	1	1 (5.88)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse

events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Total number of AE per patient	749	35 (100.00)	229	32 (91.43)
Blood and lymphatic system disorders				
- Total	57	22 (62.86)	36	16 (45.71)
Anaemia	26	10 (28.57)	15	6 (17.14)
Febrile neutropenia	10	9 (25.71)	10	9 (25.71)
Neutropenia	4	4 (11.43)	3	3 (8.57)
Disseminated intravascular coagulation	3	3 (8.57)	0	0 (0.00)
Thrombocytopenia	3	3 (8.57)	3	3 (8.57)
Coagulopathy	2	2 (5.71)	1	1 (2.86)
Eosinophilia	2	1 (2.86)	0	0 (0.00)
Leukopenia	2	2 (5.71)	1	1 (2.86)
Pancytopenia	2	2 (5.71)	2	2 (5.71)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
B-cell aplasia	1	1 (2.86)	0	0 (0.00)
Lymphopenia	1	1 (2.86)	1	1 (2.86)
Splenomegaly	1	1 (2.86)	0	0 (0.00)
Cardiac disorders				
- Total	11	6 (17.14)	1	1 (2.86)
Tachycardia	3	3 (8.57)	0	0 (0.00)
Sinus tachycardia	2	1 (2.86)	0	0 (0.00)
Cardiac dysfunction	1	1 (2.86)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.86)	0	0 (0.00)
Left ventricular dysfunction	1	1 (2.86)	1	1 (2.86)
Mitral valve incompetence	1	1 (2.86)	0	0 (0.00)
Pericardial effusion	1	1 (2.86)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.86)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.86)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.86)	0	0 (0.00)
Eye disorders				
- Total	9	5 (14.29)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Eyelid oedema	2	1 (2.86)	0	0 (0.00)
Retinal haemorrhage	2	1 (2.86)	0	0 (0.00)
Eye oedema	1	1 (2.86)	0	0 (0.00)
Eye pain	1	1 (2.86)	0	0 (0.00)
Periorbital swelling	1	1 (2.86)	0	0 (0.00)
Visual field defect	1	1 (2.86)	0	0 (0.00)
Visual impairment	1	1 (2.86)	0	0 (0.00)
Gastrointestinal disorders				
- Total	76	26 (74.29)	7	6 (17.14)
Vomiting	18	11 (31.43)	0	0 (0.00)
Diarrhoea	12	11 (31.43)	1	1 (2.86)
Nausea	12	9 (25.71)	1	1 (2.86)
Abdominal pain	9	7 (20.00)	1	1 (2.86)
Constipation	3	3 (8.57)	0	0 (0.00)
Abdominal distension	2	2 (5.71)	0	0 (0.00)
Abdominal pain upper	2	2 (5.71)	0	0 (0.00)
Ascites	2	2 (5.71)	0	0 (0.00)
Mouth haemorrhage	2	2 (5.71)	1	1 (2.86)
Stomatitis	2	2 (5.71)	1	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Enterocolitis	1	1 (2.86)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (2.86)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.86)	0	0 (0.00)
Gingival bleeding	1	1 (2.86)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.86)	1	1 (2.86)
Lip dry	1	1 (2.86)	0	0 (0.00)
Mouth swelling	1	1 (2.86)	0	0 (0.00)
Odynophagia	1	1 (2.86)	0	0 (0.00)
Pancreatitis	1	1 (2.86)	0	0 (0.00)
Proctalgia	1	1 (2.86)	1	1 (2.86)
Trichoglossia	1	1 (2.86)	0	0 (0.00)
Upper gastrointestinal haemorrhage	1	1 (2.86)	0	0 (0.00)
General disorders and administration site conditions				
- Total	59	16 (45.71)	8	3 (8.57)
Pyrexia	24	11 (31.43)	4	3 (8.57)
Chills	7	4 (11.43)	0	0 (0.00)
Fatigue	5	5 (14.29)	0	0 (0.00)
Face oedema	4	3 (8.57)	0	0 (0.00)
Catheter site pain	3	1 (2.86)	2	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Asthenia	2	2 (5.71)	0	0 (0.00)
Catheter site erythema	2	1 (2.86)	0	0 (0.00)
Influenza like illness	2	2 (5.71)	0	0 (0.00)
Chest discomfort	1	1 (2.86)	1	1 (2.86)
Crying	1	1 (2.86)	0	0 (0.00)
Facial pain	1	1 (2.86)	0	0 (0.00)
Generalised oedema	1	1 (2.86)	0	0 (0.00)
Localised oedema	1	1 (2.86)	0	0 (0.00)
Malaise	1	1 (2.86)	0	0 (0.00)
Pain	1	1 (2.86)	1	1 (2.86)
Sluggishness	1	1 (2.86)	0	0 (0.00)
Swelling face	1	1 (2.86)	0	0 (0.00)
Vascular device occlusion	1	1 (2.86)	0	0 (0.00)
Hepatobiliary disorders				
- Total	10	6 (17.14)	3	2 (5.71)
Hepatic function abnormal	6	2 (5.71)	3	2 (5.71)
Hyperbilirubinaemia	2	2 (5.71)	0	0 (0.00)
Cholelithiasis	1	1 (2.86)	0	0 (0.00)
Hepatomegaly	1	1 (2.86)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Immune system disorders				
- Total	70	30 (85.71)	27	22 (62.86)
Cytokine release syndrome	56	29 (82.86)	21	18 (51.43)
Hypogammaglobulinaemia	10	10 (28.57)	4	4 (11.43)
Immunodeficiency	2	2 (5.71)	2	2 (5.71)
Haemophagocytic lymphohistiocytosis	1	1 (2.86)	0	0 (0.00)
Hypersensitivity	1	1 (2.86)	0	0 (0.00)
Infections and infestations				
- Total	36	18 (51.43)	19	10 (28.57)
Candida infection	3	2 (5.71)	2	1 (2.86)
Nail infection	2	2 (5.71)	0	0 (0.00)
Oral candidiasis	2	1 (2.86)	0	0 (0.00)
Oral infection	2	2 (5.71)	0	0 (0.00)
Staphylococcal infection	2	2 (5.71)	2	2 (5.71)
Adenovirus infection	1	1 (2.86)	1	1 (2.86)
Anal abscess	1	1 (2.86)	1	1 (2.86)
BK virus infection	1	1 (2.86)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.86)	1	1 (2.86)
Conjunctivitis	1	1 (2.86)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Encephalitis viral	1	1 (2.86)	1	1 (2.86)
Gastroenteritis norovirus	1	1 (2.86)	0	0 (0.00)
Gingivitis	1	1 (2.86)	0	0 (0.00)
Granulicatella infection	1	1 (2.86)	1	1 (2.86)
Herpes simplex	1	1 (2.86)	1	1 (2.86)
Human herpesvirus 6 infection	1	1 (2.86)	1	1 (2.86)
Klebsiella infection	1	1 (2.86)	1	1 (2.86)
Myringitis	1	1 (2.86)	0	0 (0.00)
Oral herpes	1	1 (2.86)	0	0 (0.00)
Otitis externa	1	1 (2.86)	0	0 (0.00)
Paronychia	1	1 (2.86)	0	0 (0.00)
Pneumonia	1	1 (2.86)	1	1 (2.86)
Pneumonia fungal	1	1 (2.86)	1	1 (2.86)
Pneumonia viral	1	1 (2.86)	1	1 (2.86)
Rhinovirus infection	1	1 (2.86)	0	0 (0.00)
Sinusitis	1	1 (2.86)	1	1 (2.86)
Soft tissue infection	1	1 (2.86)	1	1 (2.86)
Stomatococcal infection	1	1 (2.86)	0	0 (0.00)
Systemic candida	1	1 (2.86)	1	1 (2.86)
Varicella zoster virus infection	1	1 (2.86)	1	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Injury, poisoning and procedural complications				
- Total	5	3 (8.57)	1	1 (2.86)
Fall	2	2 (5.71)	0	0 (0.00)
Infusion related reaction	2	1 (2.86)	0	0 (0.00)
Transplant failure	1	1 (2.86)	1	1 (2.86)
Investigations				
- Total	156	27 (77.14)	79	17 (48.57)
Platelet count decreased	35	10 (28.57)	20	6 (17.14)
Lymphocyte count decreased	20	7 (20.00)	16	5 (14.29)
Neutrophil count decreased	19	10 (28.57)	15	7 (20.00)
White blood cell count decreased	19	9 (25.71)	13	5 (14.29)
Aspartate aminotransferase increased	13	5 (14.29)	5	3 (8.57)
Alanine aminotransferase increased	12	8 (22.86)	3	3 (8.57)
Immunoglobulins decreased	5	2 (5.71)	0	0 (0.00)
Serum ferritin increased	4	4 (11.43)	1	1 (2.86)
Blood bilirubin increased	3	2 (5.71)	0	0 (0.00)
Blood creatine phosphokinase increased	3	1 (2.86)	1	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Blood lactate dehydrogenase increased	3	3 (8.57)	0	0 (0.00)
C-reactive protein increased	3	3 (8.57)	2	2 (5.71)
International normalised ratio increased	3	3 (8.57)	0	0 (0.00)
Blood glucose increased	2	1 (2.86)	2	1 (2.86)
Blood immunoglobulin A decreased	2	2 (5.71)	0	0 (0.00)
Haemoglobin decreased	2	1 (2.86)	1	1 (2.86)
Blood fibrinogen decreased	1	1 (2.86)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (2.86)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.86)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.86)	0	0 (0.00)
Enterovirus test positive	1	1 (2.86)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.86)	0	0 (0.00)
Weight decreased	1	1 (2.86)	0	0 (0.00)
Weight increased	1	1 (2.86)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	66	18 (51.43)	18	9 (25.71)
Hypokalaemia	14	8 (22.86)	5	4 (11.43)
Hypophosphataemia	12	6 (17.14)	4	2 (5.71)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Decreased appetite	11	11 (31.43)	4	4 (11.43)
Hypoalbuminaemia	9	3 (8.57)	0	0 (0.00)
Hypocalcaemia	4	3 (8.57)	1	1 (2.86)
Hypomagnesaemia	4	3 (8.57)	0	0 (0.00)
Hyperglycaemia	3	3 (8.57)	2	2 (5.71)
Hypermagnesaemia	2	1 (2.86)	0	0 (0.00)
Hypernatraemia	1	1 (2.86)	0	0 (0.00)
Hyperphosphataemia	1	1 (2.86)	0	0 (0.00)
Hyperuricaemia	1	1 (2.86)	0	0 (0.00)
Hypervolaemia	1	1 (2.86)	0	0 (0.00)
Hyponatraemia	1	1 (2.86)	0	0 (0.00)
Polydipsia	1	1 (2.86)	1	1 (2.86)
Tumour lysis syndrome	1	1 (2.86)	1	1 (2.86)
Musculoskeletal and connective tissue disorders				
- Total	32	17 (48.57)	2	2 (5.71)
Myalgia	7	6 (17.14)	0	0 (0.00)
Pain in extremity	7	7 (20.00)	0	0 (0.00)
Arthralgia	6	6 (17.14)	0	0 (0.00)
Back pain	5	5 (14.29)	1	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Bone pain	3	1 (2.86)	0	0 (0.00)
Pain in jaw	2	2 (5.71)	1	1 (2.86)
Musculoskeletal chest pain	1	1 (2.86)	0	0 (0.00)
Neck pain	1	1 (2.86)	0	0 (0.00)
Nervous system disorders				
- Total	36	18 (51.43)	5	4 (11.43)
Headache	12	12 (34.29)	2	2 (5.71)
Tremor	5	4 (11.43)	0	0 (0.00)
Encephalopathy	3	3 (8.57)	1	1 (2.86)
Dizziness	2	2 (5.71)	0	0 (0.00)
Dysgeusia	2	2 (5.71)	0	0 (0.00)
Hyperaesthesia	2	1 (2.86)	0	0 (0.00)
Lethargy	2	2 (5.71)	0	0 (0.00)
Somnolence	2	2 (5.71)	0	0 (0.00)
Amnesia	1	1 (2.86)	0	0 (0.00)
Aphasia	1	1 (2.86)	0	0 (0.00)
Depressed level of consciousness	1	1 (2.86)	1	1 (2.86)
Disturbance in attention	1	1 (2.86)	0	0 (0.00)
Hypoaesthesia	1	1 (2.86)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Seizure	1	1 (2.86)	1	1 (2.86)
Psychiatric disorders				
- Total	19	11 (31.43)	1	1 (2.86)
Anxiety	3	3 (8.57)	1	1 (2.86)
Hallucination	3	3 (8.57)	0	0 (0.00)
Insomnia	2	2 (5.71)	0	0 (0.00)
Sleep disorder	2	1 (2.86)	0	0 (0.00)
Affect lability	1	1 (2.86)	0	0 (0.00)
Agitation	1	1 (2.86)	0	0 (0.00)
Confusional state	1	1 (2.86)	0	0 (0.00)
Delirium	1	1 (2.86)	0	0 (0.00)
Hallucination, visual	1	1 (2.86)	0	0 (0.00)
Irritability	1	1 (2.86)	0	0 (0.00)
Mental status changes	1	1 (2.86)	0	0 (0.00)
Restlessness	1	1 (2.86)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.86)	0	0 (0.00)
Renal and urinary disorders				
- Total	17	10 (28.57)	2	2 (5.71)
Acute kidney injury	3	3 (8.57)	1	1 (2.86)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Dysuria	2	2 (5.71)	0	0 (0.00)
Haematuria	2	2 (5.71)	0	0 (0.00)
Pollakiuria	2	2 (5.71)	0	0 (0.00)
Urinary incontinence	2	1 (2.86)	0	0 (0.00)
Anuria	1	1 (2.86)	1	1 (2.86)
Incontinence	1	1 (2.86)	0	0 (0.00)
Micturition urgency	1	1 (2.86)	0	0 (0.00)
Proteinuria	1	1 (2.86)	0	0 (0.00)
Renal failure	1	1 (2.86)	0	0 (0.00)
Urinary tract disorder	1	1 (2.86)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	4	3 (8.57)	0	0 (0.00)
Vaginal haemorrhage	2	1 (2.86)	0	0 (0.00)
Female genital tract fistula	1	1 (2.86)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.86)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	47	16 (45.71)	16	8 (22.86)
Hypoxia	10	7 (20.00)	7	4 (11.43)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Cough	5	4 (11.43)	0	0 (0.00)
Pulmonary oedema	5	5 (14.29)	4	4 (11.43)
Oropharyngeal pain	4	3 (8.57)	0	0 (0.00)
Epistaxis	3	3 (8.57)	1	1 (2.86)
Dyspnoea	2	2 (5.71)	2	2 (5.71)
Lung infiltration	2	1 (2.86)	1	1 (2.86)
Pleural effusion	2	2 (5.71)	0	0 (0.00)
Tachypnoea	2	2 (5.71)	1	1 (2.86)
Atelectasis	1	1 (2.86)	0	0 (0.00)
Nasal congestion	1	1 (2.86)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.86)	0	0 (0.00)
Painful respiration	1	1 (2.86)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.86)	0	0 (0.00)
Pharyngeal erythema	1	1 (2.86)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.86)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.86)	0	0 (0.00)
Productive cough	1	1 (2.86)	0	0 (0.00)
Pulmonary mass	1	1 (2.86)	0	0 (0.00)
Respiratory disorder	1	1 (2.86)	0	0 (0.00)
Rhinorrhoea	1	1 (2.86)	0	0 (0.00)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	24	13 (37.14)	1	1 (2.86)
Pruritus	3	2 (5.71)	0	0 (0.00)
Rash	3	3 (8.57)	0	0 (0.00)
Rash maculo-papular	3	2 (5.71)	1	1 (2.86)
Rash papular	3	2 (5.71)	0	0 (0.00)
Erythema	2	2 (5.71)	0	0 (0.00)
Dermatitis atopic	1	1 (2.86)	0	0 (0.00)
Eczema	1	1 (2.86)	0	0 (0.00)
Erythema nodosum	1	1 (2.86)	0	0 (0.00)
Hyperhidrosis	1	1 (2.86)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.86)	0	0 (0.00)
Pruritus allergic	1	1 (2.86)	0	0 (0.00)
Purpura	1	1 (2.86)	0	0 (0.00)
Skin lesion	1	1 (2.86)	0	0 (0.00)
Skin ulcer	1	1 (2.86)	0	0 (0.00)
Urticaria	1	1 (2.86)	0	0 (0.00)
Social circumstances				

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
- Total	1	1 (2.86)	0	0 (0.00)
Patient uncooperative	1	1 (2.86)	0	0 (0.00)
Vascular disorders				
- Total	13	10 (28.57)	3	3 (8.57)
Hypotension	6	6 (17.14)	3	3 (8.57)
Hypertension	5	5 (14.29)	0	0 (0.00)
Flushing	1	1 (2.86)	0	0 (0.00)
Hot flush	1	1 (2.86)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Total number of AE per patient	30	4 (80.00)	3	1 (20.00)
Blood and lymphatic system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Lymphocytosis	1	1 (20.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	1 (20.00)	0	0 (0.00)
Fatigue	2	1 (20.00)	0	0 (0.00)
Infections and infestations				
- Total	5	2 (40.00)	0	0 (0.00)
Upper respiratory tract infection	2	1 (20.00)	0	0 (0.00)
Gastroenteritis	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Gastrointestinal infection	1	1 (20.00)	0	0 (0.00)
Otitis externa	1	1 (20.00)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (20.00)	0	0 (0.00)
Fibula fracture	1	1 (20.00)	0	0 (0.00)
Investigations				
- Total	11	2 (40.00)	3	1 (20.00)
Neutrophil count decreased	6	2 (40.00)	2	1 (20.00)
White blood cell count decreased	5	1 (20.00)	1	1 (20.00)
Metabolism and nutrition disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Hyperuricaemia	1	1 (20.00)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (20.00)	0	0 (0.00)
Headache	1	1 (20.00)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (20.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=5 n (%)[1]	Grade >= 3 Total events	All patients N=5 n (%)[2]
Persistent depressive disorder	1	1 (20.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	1 (20.00)	0	0 (0.00)
Nasal congestion	2	1 (20.00)	0	0 (0.00)
Cough	1	1 (20.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (20.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	3	2 (40.00)	0	0 (0.00)
Dry skin	2	2 (40.00)	0	0 (0.00)
Skin hypopigmentation	1	1 (20.00)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Total number of AE per patient	127	18 (90.00)	29	10 (50.00)
Blood and lymphatic system disorders				
- Total	4	4 (20.00)	3	3 (15.00)
Neutropenia	2	2 (10.00)	2	2 (10.00)
Anaemia	1	1 (5.00)	1	1 (5.00)
Lymphadenopathy	1	1 (5.00)	0	0 (0.00)
Cardiac disorders				
- Total	2	2 (10.00)	1	1 (5.00)
Cardiac failure	1	1 (5.00)	1	1 (5.00)
Tachycardia	1	1 (5.00)	0	0 (0.00)
Gastrointestinal disorders				
- Total	15	8 (40.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Diarrhoea	4	4 (20.00)	0	0 (0.00)
Vomiting	4	4 (20.00)	0	0 (0.00)
Nausea	3	3 (15.00)	0	0 (0.00)
Abdominal pain	2	2 (10.00)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (5.00)	0	0 (0.00)
Proctalgia	1	1 (5.00)	0	0 (0.00)
General disorders and administration site conditions				
- Total	6	6 (30.00)	1	1 (5.00)
Pyrexia	4	4 (20.00)	1	1 (5.00)
Fatigue	1	1 (5.00)	0	0 (0.00)
Pain	1	1 (5.00)	0	0 (0.00)
Immune system disorders				
- Total	4	3 (15.00)	3	2 (10.00)
Allergy to immunoglobulin therapy	1	1 (5.00)	1	1 (5.00)
Engraftment syndrome	1	1 (5.00)	1	1 (5.00)
Graft versus host disease	1	1 (5.00)	1	1 (5.00)
Hypogammaglobulinaemia	1	1 (5.00)	0	0 (0.00)
Infections and infestations				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
- Total	26	8 (40.00)	7	4 (20.00)
Nasopharyngitis	3	2 (10.00)	0	0 (0.00)
Ear infection	2	1 (5.00)	0	0 (0.00)
Parainfluenzae virus infection	2	2 (10.00)	0	0 (0.00)
Rhinovirus infection	2	2 (10.00)	0	0 (0.00)
Upper respiratory tract infection	2	2 (10.00)	0	0 (0.00)
Acute sinusitis	1	1 (5.00)	0	0 (0.00)
Cellulitis	1	1 (5.00)	0	0 (0.00)
Conjunctivitis	1	1 (5.00)	0	0 (0.00)
Coronavirus infection	1	1 (5.00)	1	1 (5.00)
Cystitis	1	1 (5.00)	0	0 (0.00)
Gastroenteritis viral	1	1 (5.00)	0	0 (0.00)
Herpes zoster	1	1 (5.00)	1	1 (5.00)
Influenza	1	1 (5.00)	0	0 (0.00)
Metapneumovirus infection	1	1 (5.00)	1	1 (5.00)
Molluscum contagiosum	1	1 (5.00)	0	0 (0.00)
Otitis media	1	1 (5.00)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (5.00)	1	1 (5.00)
Pneumonia	1	1 (5.00)	1	1 (5.00)
Staphylococcal bacteraemia	1	1 (5.00)	1	1 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Viral upper respiratory tract infection	1	1 (5.00)	1	1 (5.00)
Injury, poisoning and procedural complications				
- Total	3	3 (15.00)	0	0 (0.00)
Contusion	1	1 (5.00)	0	0 (0.00)
Post-traumatic neck syndrome	1	1 (5.00)	0	0 (0.00)
Skin abrasion	1	1 (5.00)	0	0 (0.00)
Investigations				
- Total	27	9 (45.00)	7	4 (20.00)
White blood cell count decreased	6	4 (20.00)	1	1 (5.00)
Platelet count decreased	5	3 (15.00)	0	0 (0.00)
Lymphocyte count decreased	3	1 (5.00)	1	1 (5.00)
Neutrophil count decreased	3	2 (10.00)	3	2 (10.00)
Blood bilirubin increased	2	1 (5.00)	1	1 (5.00)
Blood creatinine increased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (5.00)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (5.00)	0	0 (0.00)
Blood lactate dehydrogenase increased	1	1 (5.00)	0	0 (0.00)
Blood urea increased	1	1 (5.00)	1	1 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
C-reactive protein increased	1	1 (5.00)	0	0 (0.00)
Heart sounds abnormal	1	1 (5.00)	0	0 (0.00)
Oxygen saturation decreased	1	1 (5.00)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	3 (15.00)	2	2 (10.00)
Decreased appetite	1	1 (5.00)	0	0 (0.00)
Hypervolaemia	1	1 (5.00)	1	1 (5.00)
Metabolic acidosis	1	1 (5.00)	1	1 (5.00)
Musculoskeletal and connective tissue disorders				
- Total	5	3 (15.00)	0	0 (0.00)
Back pain	2	1 (5.00)	0	0 (0.00)
Arthralgia	1	1 (5.00)	0	0 (0.00)
Bone pain	1	1 (5.00)	0	0 (0.00)
Neck pain	1	1 (5.00)	0	0 (0.00)
Nervous system disorders				
- Total	5	3 (15.00)	0	0 (0.00)
Headache	2	2 (10.00)	0	0 (0.00)
Migraine	2	1 (5.00)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Extrapyramidal disorder	1	1 (5.00)	0	0 (0.00)
Psychiatric disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Anxiety	1	1 (5.00)	0	0 (0.00)
Renal and urinary disorders				
- Total	1	1 (5.00)	0	0 (0.00)
Acute kidney injury	1	1 (5.00)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	13	8 (40.00)	3	3 (15.00)
Cough	2	2 (10.00)	0	0 (0.00)
Rhinitis allergic	2	2 (10.00)	0	0 (0.00)
Bronchospasm	1	1 (5.00)	0	0 (0.00)
Epistaxis	1	1 (5.00)	0	0 (0.00)
Hypoxia	1	1 (5.00)	1	1 (5.00)
Nasal congestion	1	1 (5.00)	0	0 (0.00)
Oropharyngeal pain	1	1 (5.00)	0	0 (0.00)
Pleural effusion	1	1 (5.00)	0	0 (0.00)
Respiratory distress	1	1 (5.00)	1	1 (5.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=20 n (%)[1]	Grade >= 3 Total events	All patients N=20 n (%)[2]
Respiratory failure	1	1 (5.00)	1	1 (5.00)
Rhinorrhoea	1	1 (5.00)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	9	7 (35.00)	0	0 (0.00)
Pruritus	2	1 (5.00)	0	0 (0.00)
Dermatitis allergic	1	1 (5.00)	0	0 (0.00)
Dermatitis atopic	1	1 (5.00)	0	0 (0.00)
Dry skin	1	1 (5.00)	0	0 (0.00)
Erythema	1	1 (5.00)	0	0 (0.00)
Ingrowing nail	1	1 (5.00)	0	0 (0.00)
Miliaria	1	1 (5.00)	0	0 (0.00)
Skin discolouration	1	1 (5.00)	0	0 (0.00)
Vascular disorders				
- Total	3	2 (10.00)	2	2 (10.00)
Hypertension	1	1 (5.00)	0	0 (0.00)
Hypotension	1	1 (5.00)	1	1 (5.00)
Venoocclusive disease	1	1 (5.00)	1	1 (5.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

/vob/CCTL019/haq/haq_eu_7/pgm/saf/t250_gd_b2202.sas@@/main/1 15AUG23:06:01 **Final**

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Total number of AE per patient	129	14 (93.33)	46	8 (53.33)
Blood and lymphatic system disorders				
- Total	13	3 (20.00)	9	3 (20.00)
Anaemia	6	1 (6.67)	3	1 (6.67)
Febrile neutropenia	3	2 (13.33)	3	2 (13.33)
Leukocytosis	1	1 (6.67)	0	0 (0.00)
Lymphopenia	1	1 (6.67)	1	1 (6.67)
Neutropenia	1	1 (6.67)	1	1 (6.67)
Thrombocytopenia	1	1 (6.67)	1	1 (6.67)
Cardiac disorders				
- Total	3	2 (13.33)	2	1 (6.67)
Cardiac arrest	1	1 (6.67)	1	1 (6.67)
Cardiac failure	1	1 (6.67)	1	1 (6.67)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Tachycardia	1	1 (6.67)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Hypothyroidism	1	1 (6.67)	0	0 (0.00)
Eye disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Visual impairment	1	1 (6.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	10	5 (33.33)	1	1 (6.67)
Diarrhoea	3	3 (20.00)	0	0 (0.00)
Constipation	2	1 (6.67)	0	0 (0.00)
Gastrointestinal inflammation	1	1 (6.67)	0	0 (0.00)
Nausea	1	1 (6.67)	0	0 (0.00)
Pancreatitis	1	1 (6.67)	1	1 (6.67)
Stomatitis	1	1 (6.67)	0	0 (0.00)
Vomiting	1	1 (6.67)	0	0 (0.00)
General disorders and administration site conditions				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
- Total	9	7 (46.67)	1	1 (6.67)
Pyrexia	4	4 (26.67)	1	1 (6.67)
Fatigue	2	2 (13.33)	0	0 (0.00)
Oedema peripheral	2	1 (6.67)	0	0 (0.00)
Malaise	1	1 (6.67)	0	0 (0.00)
Hepatobiliary disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Hypertransaminasaemia	1	1 (6.67)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (26.67)	1	1 (6.67)
Hypogammaglobulinaemia	3	3 (20.00)	0	0 (0.00)
Immunodeficiency	1	1 (6.67)	1	1 (6.67)
Infections and infestations				
- Total	23	7 (46.67)	10	4 (26.67)
Respiratory syncytial virus infection	2	2 (13.33)	1	1 (6.67)
Respiratory tract infection	2	2 (13.33)	0	0 (0.00)
Upper respiratory tract infection	2	2 (13.33)	1	1 (6.67)
Adenovirus infection	1	1 (6.67)	1	1 (6.67)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
BK virus infection	1	1 (6.67)	1	1 (6.67)
Bacteraemia	1	1 (6.67)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (6.67)	1	1 (6.67)
Ear infection	1	1 (6.67)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (6.67)	0	0 (0.00)
Herpes simplex	1	1 (6.67)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (6.67)	1	1 (6.67)
Metapneumovirus infection	1	1 (6.67)	1	1 (6.67)
Nail infection	1	1 (6.67)	0	0 (0.00)
Nasopharyngitis	1	1 (6.67)	0	0 (0.00)
Oral herpes	1	1 (6.67)	0	0 (0.00)
Otitis media	1	1 (6.67)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (6.67)	1	1 (6.67)
Sinusitis	1	1 (6.67)	0	0 (0.00)
Sinusitis fungal	1	1 (6.67)	1	1 (6.67)
Viral infection	1	1 (6.67)	1	1 (6.67)
Injury, poisoning and procedural complications				
- Total	1	1 (6.67)	0	0 (0.00)
Infusion related reaction	1	1 (6.67)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Investigations				
- Total	22	6 (40.00)	14	4 (26.67)
Platelet count decreased	10	1 (6.67)	8	1 (6.67)
Neutrophil count decreased	3	2 (13.33)	2	1 (6.67)
Weight increased	3	1 (6.67)	1	1 (6.67)
White blood cell count decreased	3	2 (13.33)	2	2 (13.33)
Blood thyroid stimulating hormone increased	1	1 (6.67)	0	0 (0.00)
Blood uric acid increased	1	1 (6.67)	1	1 (6.67)
Ejection fraction decreased	1	1 (6.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	9	4 (26.67)	3	1 (6.67)
Hypokalaemia	4	1 (6.67)	3	1 (6.67)
Decreased appetite	3	3 (20.00)	0	0 (0.00)
Hyperkalaemia	1	1 (6.67)	0	0 (0.00)
Metabolic syndrome	1	1 (6.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	9	5 (33.33)	2	2 (13.33)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
Pain in extremity	3	3 (20.00)	0	0 (0.00)
Back pain	2	2 (13.33)	2	2 (13.33)
Arthralgia	1	1 (6.67)	0	0 (0.00)
Growth retardation	1	1 (6.67)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (6.67)	0	0 (0.00)
Myalgia	1	1 (6.67)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (6.67)	0	0 (0.00)
Cancer pain	1	1 (6.67)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (6.67)	0	0 (0.00)
Headache	1	1 (6.67)	0	0 (0.00)
Psychiatric disorders				
- Total	4	3 (20.00)	0	0 (0.00)
Anxiety	3	3 (20.00)	0	0 (0.00)
Delirium	1	1 (6.67)	0	0 (0.00)
Renal and urinary disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
- Total	5	1 (6.67)	1	1 (6.67)
Acute kidney injury	1	1 (6.67)	0	0 (0.00)
Dysuria	1	1 (6.67)	0	0 (0.00)
Haematuria	1	1 (6.67)	1	1 (6.67)
Kidney enlargement	1	1 (6.67)	0	0 (0.00)
Renal mass	1	1 (6.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (6.67)	0	0 (0.00)
Dysmenorrhoea	2	1 (6.67)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	4	3 (20.00)	0	0 (0.00)
Cough	1	1 (6.67)	0	0 (0.00)
Nasal congestion	1	1 (6.67)	0	0 (0.00)
Rhinorrhoea	1	1 (6.67)	0	0 (0.00)
Upper respiratory tract inflammation	1	1 (6.67)	0	0 (0.00)
Skin and subcutaneous tissue disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=15 n (%)[1]	Grade >= 3 Total events	All patients N=15 n (%)[2]
- Total	4	3 (20.00)	0	0 (0.00)
Dry skin	1	1 (6.67)	0	0 (0.00)
Eczema	1	1 (6.67)	0	0 (0.00)
Photosensitivity reaction	1	1 (6.67)	0	0 (0.00)
Rash	1	1 (6.67)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (13.33)	2	2 (13.33)
Hypotension	1	1 (6.67)	1	1 (6.67)
Venoocclusive disease	1	1 (6.67)	1	1 (6.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Total number of AE per patient	248	33 (94.29)	68	17 (48.57)
Blood and lymphatic system disorders				
- Total	14	9 (25.71)	5	4 (11.43)
Anaemia	5	4 (11.43)	0	0 (0.00)
B-cell aplasia	2	1 (2.86)	0	0 (0.00)
Neutropenia	2	2 (5.71)	2	2 (5.71)
Disseminated intravascular coagulation	1	1 (2.86)	1	1 (2.86)
Eosinophilia	1	1 (2.86)	0	0 (0.00)
Febrile neutropenia	1	1 (2.86)	1	1 (2.86)
Leukopenia	1	1 (2.86)	0	0 (0.00)
Thrombocytopenia	1	1 (2.86)	1	1 (2.86)
Cardiac disorders				

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
- Total	3	3 (8.57)	1	1 (2.86)
Cardiac arrest	1	1 (2.86)	1	1 (2.86)
Left ventricular dysfunction	1	1 (2.86)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.86)	0	0 (0.00)
Eye disorders				
- Total	4	3 (8.57)	0	0 (0.00)
Cataract	2	2 (5.71)	0	0 (0.00)
Hypermetropia	1	1 (2.86)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.86)	0	0 (0.00)
Gastrointestinal disorders				
- Total	13	7 (20.00)	0	0 (0.00)
Constipation	2	2 (5.71)	0	0 (0.00)
Vomiting	2	1 (2.86)	0	0 (0.00)
Abdominal pain upper	1	1 (2.86)	0	0 (0.00)
Abdominal rigidity	1	1 (2.86)	0	0 (0.00)
Dyspepsia	1	1 (2.86)	0	0 (0.00)
Enteritis	1	1 (2.86)	0	0 (0.00)
Mouth haemorrhage	1	1 (2.86)	0	0 (0.00)
Nausea	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Pancreatitis	1	1 (2.86)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.86)	0	0 (0.00)
Trichoglossia	1	1 (2.86)	0	0 (0.00)
General disorders and administration site conditions				
- Total	14	10 (28.57)	1	1 (2.86)
Pyrexia	8	7 (20.00)	0	0 (0.00)
Fatigue	2	2 (5.71)	0	0 (0.00)
Asthenia	1	1 (2.86)	0	0 (0.00)
Chills	1	1 (2.86)	0	0 (0.00)
Non-cardiac chest pain	1	1 (2.86)	0	0 (0.00)
Pain	1	1 (2.86)	1	1 (2.86)
Hepatobiliary disorders				
- Total	2	2 (5.71)	0	0 (0.00)
Hepatic cytolysis	1	1 (2.86)	0	0 (0.00)
Liver disorder	1	1 (2.86)	0	0 (0.00)
Immune system disorders				
- Total	11	9 (25.71)	1	1 (2.86)
Hypogammaglobulinaemia	8	6 (17.14)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Allergy to immunoglobulin therapy	1	1 (2.86)	0	0 (0.00)
Drug hypersensitivity	1	1 (2.86)	0	0 (0.00)
Graft versus host disease	1	1 (2.86)	1	1 (2.86)
Infections and infestations				
- Total	59	22 (62.86)	28	12 (34.29)
Bronchopulmonary aspergillosis	5	1 (2.86)	3	1 (2.86)
Nasopharyngitis	5	4 (11.43)	0	0 (0.00)
Gastroenteritis	4	4 (11.43)	2	2 (5.71)
Upper respiratory tract infection	4	3 (8.57)	1	1 (2.86)
Parainfluenzae virus infection	3	2 (5.71)	2	2 (5.71)
Rhinovirus infection	3	3 (8.57)	1	1 (2.86)
Sinusitis	3	2 (5.71)	1	1 (2.86)
Bacteraemia	2	1 (2.86)	2	1 (2.86)
Klebsiella infection	2	1 (2.86)	2	1 (2.86)
Pneumonia	2	2 (5.71)	0	0 (0.00)
Rhinitis	2	2 (5.71)	0	0 (0.00)
Urinary tract infection	2	1 (2.86)	2	1 (2.86)
Device related infection	1	1 (2.86)	1	1 (2.86)
Ear, nose and throat infection	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Encephalitis	1	1 (2.86)	1	1 (2.86)
Enterobacter infection	1	1 (2.86)	1	1 (2.86)
Gingivitis	1	1 (2.86)	0	0 (0.00)
Mastoiditis	1	1 (2.86)	1	1 (2.86)
Metapneumovirus infection	1	1 (2.86)	1	1 (2.86)
Oral candidiasis	1	1 (2.86)	0	0 (0.00)
Otitis externa	1	1 (2.86)	1	1 (2.86)
Otitis media	1	1 (2.86)	1	1 (2.86)
Paronychia	1	1 (2.86)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (2.86)	1	1 (2.86)
Respiratory syncytial virus infection	1	1 (2.86)	1	1 (2.86)
Respiratory tract infection	1	1 (2.86)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.86)	0	0 (0.00)
Salmonellosis	1	1 (2.86)	0	0 (0.00)
Septic shock	1	1 (2.86)	1	1 (2.86)
Staphylococcal sepsis	1	1 (2.86)	1	1 (2.86)
Staphylococcal skin infection	1	1 (2.86)	0	0 (0.00)
Tinea pedis	1	1 (2.86)	0	0 (0.00)
Viral haemorrhagic cystitis	1	1 (2.86)	1	1 (2.86)
Viral infection	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Injury, poisoning and procedural complications				
- Total	5	4 (11.43)	0	0 (0.00)
Infusion related reaction	3	2 (5.71)	0	0 (0.00)
Ligament sprain	1	1 (2.86)	0	0 (0.00)
Limb injury	1	1 (2.86)	0	0 (0.00)
Investigations				
- Total	31	13 (37.14)	11	7 (20.00)
Neutrophil count decreased	7	4 (11.43)	4	3 (8.57)
Immunoglobulins decreased	5	1 (2.86)	0	0 (0.00)
White blood cell count decreased	4	3 (8.57)	0	0 (0.00)
Alanine aminotransferase increased	3	2 (5.71)	1	1 (2.86)
Lymphocyte count decreased	3	3 (8.57)	1	1 (2.86)
Blood bilirubin increased	2	1 (2.86)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (2.86)	1	1 (2.86)
Blood immunoglobulin M decreased	1	1 (2.86)	1	1 (2.86)
Blood uric acid increased	1	1 (2.86)	1	1 (2.86)
Bone density decreased	1	1 (2.86)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.86)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Platelet count decreased	1	1 (2.86)	1	1 (2.86)
Weight decreased	1	1 (2.86)	1	1 (2.86)
Metabolism and nutrition disorders				
- Total	13	7 (20.00)	5	4 (11.43)
Decreased appetite	2	2 (5.71)	1	1 (2.86)
Hyperuricaemia	2	2 (5.71)	0	0 (0.00)
Hypokalaemia	2	2 (5.71)	1	1 (2.86)
Haemochromatosis	1	1 (2.86)	1	1 (2.86)
Hyperchloraemia	1	1 (2.86)	0	0 (0.00)
Hypophagia	1	1 (2.86)	0	0 (0.00)
Hypophosphataemia	1	1 (2.86)	0	0 (0.00)
Iron overload	1	1 (2.86)	0	0 (0.00)
Malnutrition	1	1 (2.86)	1	1 (2.86)
Tumour lysis syndrome	1	1 (2.86)	1	1 (2.86)
Musculoskeletal and connective tissue disorders				
- Total	8	7 (20.00)	1	1 (2.86)
Back pain	3	3 (8.57)	0	0 (0.00)
Pain in extremity	2	2 (5.71)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Arthralgia	1	1 (2.86)	0	0 (0.00)
Bone pain	1	1 (2.86)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.86)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	3	3 (8.57)	1	1 (2.86)
Skin papilloma	2	2 (5.71)	0	0 (0.00)
Myelodysplastic syndrome	1	1 (2.86)	1	1 (2.86)
Nervous system disorders				
- Total	16	9 (25.71)	6	2 (5.71)
Headache	7	6 (17.14)	0	0 (0.00)
Hydrocephalus	3	1 (2.86)	3	1 (2.86)
Dizziness	2	1 (2.86)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.86)	1	1 (2.86)
Cerebral haemorrhage	1	1 (2.86)	1	1 (2.86)
Memory impairment	1	1 (2.86)	0	0 (0.00)
Seizure	1	1 (2.86)	1	1 (2.86)
Psychiatric disorders				
- Total	9	5 (14.29)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Anxiety	2	2 (5.71)	0	0 (0.00)
Mental status changes	2	2 (5.71)	1	1 (2.86)
Agitation	1	1 (2.86)	0	0 (0.00)
Mood altered	1	1 (2.86)	0	0 (0.00)
Nightmare	1	1 (2.86)	0	0 (0.00)
Sleep disorder	1	1 (2.86)	0	0 (0.00)
Tearfulness	1	1 (2.86)	0	0 (0.00)
Renal and urinary disorders				
- Total	3	3 (8.57)	2	2 (5.71)
Acute kidney injury	1	1 (2.86)	1	1 (2.86)
Cystitis haemorrhagic	1	1 (2.86)	0	0 (0.00)
Renal tubular disorder	1	1 (2.86)	1	1 (2.86)
Respiratory, thoracic and mediastinal disorders				
- Total	25	12 (34.29)	3	3 (8.57)
Cough	10	7 (20.00)	0	0 (0.00)
Nasal congestion	3	3 (8.57)	0	0 (0.00)
Dyspnoea	2	1 (2.86)	0	0 (0.00)
Epistaxis	2	2 (5.71)	0	0 (0.00)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Hypoxia	2	2 (5.71)	2	2 (5.71)
Acute respiratory distress syndrome	1	1 (2.86)	1	1 (2.86)
Bronchial oedema	1	1 (2.86)	0	0 (0.00)
Lung disorder	1	1 (2.86)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.86)	0	0 (0.00)
Pleural effusion	1	1 (2.86)	0	0 (0.00)
Rhinorrhoea	1	1 (2.86)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	13	8 (22.86)	1	1 (2.86)
Rash	5	3 (8.57)	0	0 (0.00)
Dry skin	3	2 (5.71)	0	0 (0.00)
Decubitus ulcer	1	1 (2.86)	1	1 (2.86)
Hangnail	1	1 (2.86)	0	0 (0.00)
Ingrowing nail	1	1 (2.86)	0	0 (0.00)
Night sweats	1	1 (2.86)	0	0 (0.00)
Skin swelling	1	1 (2.86)	0	0 (0.00)
Vascular disorders				
- Total	2	2 (5.71)	1	1 (2.86)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Hypotension	2	2 (5.71)	1	1 (2.86)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Total number of AE per patient	8	1 (33.33)	4	1 (33.33)
Gastrointestinal disorders				
- Total	1	1 (33.33)	0	0 (0.00)
Irritable bowel syndrome	1	1 (33.33)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (33.33)	0	0 (0.00)
Pyrexia	1	1 (33.33)	0	0 (0.00)
Infections and infestations				
- Total	6	1 (33.33)	4	1 (33.33)
Clostridium difficile colitis	1	1 (33.33)	1	1 (33.33)
Gastroenteritis Escherichia coli	1	1 (33.33)	1	1 (33.33)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=3 n (%)[1]	Grade >= 3 Total events	All patients N=3 n (%)[2]
Gastroenteritis salmonella	1	1 (33.33)	1	1 (33.33)
Pneumonia	1	1 (33.33)	1	1 (33.33)
Rhinovirus infection	1	1 (33.33)	0	0 (0.00)
Sinusitis	1	1 (33.33)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Total number of AE per patient	38	6 (46.15)	18	3 (23.08)
Blood and lymphatic system disorders				
- Total	2	2 (15.38)	0	0 (0.00)
Hypercoagulation	1	1 (7.69)	0	0 (0.00)
Lymphadenopathy	1	1 (7.69)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	2 (15.38)	0	0 (0.00)
Constipation	1	1 (7.69)	0	0 (0.00)
Diarrhoea	1	1 (7.69)	0	0 (0.00)
General disorders and administration site conditions				
- Total	2	1 (7.69)	1	1 (7.69)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Multiple organ dysfunction syndrome	1	1 (7.69)	1	1 (7.69)
Pyrexia	1	1 (7.69)	0	0 (0.00)
Immune system disorders				
- Total	2	1 (7.69)	2	1 (7.69)
Chronic graft versus host disease	1	1 (7.69)	1	1 (7.69)
Haemophagocytic lymphohistiocytosis	1	1 (7.69)	1	1 (7.69)
Infections and infestations				
- Total	13	5 (38.46)	7	2 (15.38)
Bronchitis	1	1 (7.69)	0	0 (0.00)
COVID-19 pneumonia	1	1 (7.69)	1	1 (7.69)
Conjunctivitis	1	1 (7.69)	0	0 (0.00)
Enterovirus infection	1	1 (7.69)	1	1 (7.69)
Gastroenteritis	1	1 (7.69)	0	0 (0.00)
Influenza	1	1 (7.69)	1	1 (7.69)
Otitis media acute	1	1 (7.69)	0	0 (0.00)
Parainfluenzae virus infection	1	1 (7.69)	1	1 (7.69)
Pneumonia	1	1 (7.69)	1	1 (7.69)
Rhinovirus infection	1	1 (7.69)	1	1 (7.69)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Skin infection	1	1 (7.69)	0	0 (0.00)
Staphylococcal bacteraemia	1	1 (7.69)	1	1 (7.69)
Upper respiratory tract infection	1	1 (7.69)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	2	2 (15.38)	1	1 (7.69)
Abdominal injury	1	1 (7.69)	0	0 (0.00)
Infusion related reaction	1	1 (7.69)	1	1 (7.69)
Investigations				
- Total	4	3 (23.08)	1	1 (7.69)
Blood immunoglobulin G decreased	1	1 (7.69)	0	0 (0.00)
Oxygen saturation decreased	1	1 (7.69)	1	1 (7.69)
Platelet count decreased	1	1 (7.69)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (7.69)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	2	2 (15.38)	2	2 (15.38)
Hyperglycaemia	1	1 (7.69)	1	1 (7.69)
Obesity	1	1 (7.69)	1	1 (7.69)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=13 n (%)[1]	Grade >= 3 Total events	All patients N=13 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	6	2 (15.38)	3	1 (7.69)
Tachypnoea	2	1 (7.69)	2	1 (7.69)
Cough	1	1 (7.69)	0	0 (0.00)
Dyspnoea	1	1 (7.69)	1	1 (7.69)
Pleural effusion	1	1 (7.69)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (7.69)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (7.69)	0	0 (0.00)
Rash	1	1 (7.69)	0	0 (0.00)
Rash maculo-papular	1	1 (7.69)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (7.69)	1	1 (7.69)
Hypertension	1	1 (7.69)	1	1 (7.69)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Total number of AE per patient	53	8 (72.73)	6	3 (27.27)
Endocrine disorders				
- Total	2	1 (9.09)	0	0 (0.00)
Delayed puberty	1	1 (9.09)	0	0 (0.00)
Hypothyroidism	1	1 (9.09)	0	0 (0.00)
Eye disorders				
- Total	2	2 (18.18)	0	0 (0.00)
Dry eye	1	1 (9.09)	0	0 (0.00)
Mydriasis	1	1 (9.09)	0	0 (0.00)
Gastrointestinal disorders				
- Total	4	2 (18.18)	0	0 (0.00)
Diarrhoea	2	2 (18.18)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Nausea	1	1 (9.09)	0	0 (0.00)
Vomiting	1	1 (9.09)	0	0 (0.00)
General disorders and administration site conditions				
- Total	1	1 (9.09)	0	0 (0.00)
Fatigue	1	1 (9.09)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (36.36)	0	0 (0.00)
Seasonal allergy	3	3 (27.27)	0	0 (0.00)
Hypogammaglobulinaemia	1	1 (9.09)	0	0 (0.00)
Infections and infestations				
- Total	18	4 (36.36)	4	2 (18.18)
Device related sepsis	2	1 (9.09)	2	1 (9.09)
Gastroenteritis viral	2	1 (9.09)	0	0 (0.00)
Sinusitis	2	2 (18.18)	0	0 (0.00)
Bronchiolitis	1	1 (9.09)	1	1 (9.09)
Bronchitis	1	1 (9.09)	0	0 (0.00)
COVID-19	1	1 (9.09)	0	0 (0.00)
Folliculitis	1	1 (9.09)	0	0 (0.00)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Fungal skin infection	1	1 (9.09)	0	0 (0.00)
Nail infection	1	1 (9.09)	0	0 (0.00)
Otitis media	1	1 (9.09)	0	0 (0.00)
Pneumonia respiratory syncytial viral	1	1 (9.09)	1	1 (9.09)
Rhinovirus infection	1	1 (9.09)	0	0 (0.00)
Syphilis	1	1 (9.09)	0	0 (0.00)
Upper respiratory tract infection	1	1 (9.09)	0	0 (0.00)
Varicella zoster virus infection	1	1 (9.09)	0	0 (0.00)
Investigations				
- Total	1	1 (9.09)	0	0 (0.00)
Neutrophil count decreased	1	1 (9.09)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	5	2 (18.18)	0	0 (0.00)
Iron overload	2	1 (9.09)	0	0 (0.00)
Hypercholesterolaemia	1	1 (9.09)	0	0 (0.00)
Hyperlipidaemia	1	1 (9.09)	0	0 (0.00)
Hypertriglyceridaemia	1	1 (9.09)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
- Total	4	3 (27.27)	0	0 (0.00)
Arthralgia	1	1 (9.09)	0	0 (0.00)
Joint effusion	1	1 (9.09)	0	0 (0.00)
Osteopenia	1	1 (9.09)	0	0 (0.00)
Synovitis	1	1 (9.09)	0	0 (0.00)
Nervous system disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Headache	1	1 (9.09)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	2	1 (9.09)	1	1 (9.09)
Endometriosis	2	1 (9.09)	1	1 (9.09)
Respiratory, thoracic and mediastinal disorders				
- Total	6	2 (18.18)	1	1 (9.09)
Rhinorrhoea	2	2 (18.18)	0	0 (0.00)
Cough	1	1 (9.09)	0	0 (0.00)
Dyspnoea	1	1 (9.09)	0	0 (0.00)
Hypoxia	1	1 (9.09)	1	1 (9.09)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=11 n (%)[1]	Grade >= 3 Total events	All patients N=11 n (%)[2]
Wheezing	1	1 (9.09)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	2	1 (9.09)	0	0 (0.00)
Rash	1	1 (9.09)	0	0 (0.00)
Rash erythematous	1	1 (9.09)	0	0 (0.00)
Vascular disorders				
- Total	1	1 (9.09)	0	0 (0.00)
Hypertension	1	1 (9.09)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Total number of AE per patient	121	17 (73.91)	35	12 (52.17)
Blood and lymphatic system disorders				
- Total	4	2 (8.70)	2	2 (8.70)
Agranulocytosis	1	1 (4.35)	1	1 (4.35)
Anaemia	1	1 (4.35)	0	0 (0.00)
Neutropenia	1	1 (4.35)	1	1 (4.35)
Thrombocytopenia	1	1 (4.35)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (4.35)	0	0 (0.00)
Cerebral cavernous malformation	1	1 (4.35)	0	0 (0.00)
Ear and labyrinth disorders				

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
- Total	1	1 (4.35)	0	0 (0.00)
Deafness unilateral	1	1 (4.35)	0	0 (0.00)
Eye disorders				
- Total	2	1 (4.35)	1	1 (4.35)
Eye pain	1	1 (4.35)	1	1 (4.35)
Eyelid oedema	1	1 (4.35)	0	0 (0.00)
Gastrointestinal disorders				
- Total	2	2 (8.70)	1	1 (4.35)
Diarrhoea	2	2 (8.70)	1	1 (4.35)
General disorders and administration site conditions				
- Total	9	6 (26.09)	1	1 (4.35)
Pyrexia	5	3 (13.04)	1	1 (4.35)
Pain	2	2 (8.70)	0	0 (0.00)
Non-cardiac chest pain	1	1 (4.35)	0	0 (0.00)
Xerosis	1	1 (4.35)	0	0 (0.00)
Immune system disorders				
- Total	4	4 (17.39)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Hypogammaglobulinaemia	2	2 (8.70)	0	0 (0.00)
Chronic graft versus host disease	1	1 (4.35)	0	0 (0.00)
Drug hypersensitivity	1	1 (4.35)	1	1 (4.35)
Infections and infestations				
- Total	49	13 (56.52)	11	9 (39.13)
Sinusitis	6	3 (13.04)	0	0 (0.00)
Upper respiratory tract infection	5	3 (13.04)	1	1 (4.35)
Conjunctivitis	4	3 (13.04)	0	0 (0.00)
Fungal infection	3	2 (8.70)	0	0 (0.00)
Sepsis	3	3 (13.04)	3	3 (13.04)
COVID-19	2	1 (4.35)	1	1 (4.35)
Herpes zoster	2	2 (8.70)	1	1 (4.35)
Oral herpes	2	2 (8.70)	0	0 (0.00)
Otitis media	2	1 (4.35)	0	0 (0.00)
Skin infection	2	2 (8.70)	0	0 (0.00)
Urinary tract infection	2	2 (8.70)	0	0 (0.00)
Acute sinusitis	1	1 (4.35)	0	0 (0.00)
Candida infection	1	1 (4.35)	0	0 (0.00)
Ear infection	1	1 (4.35)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Herpes virus infection	1	1 (4.35)	0	0 (0.00)
Influenza	1	1 (4.35)	0	0 (0.00)
Meningitis pneumococcal	1	1 (4.35)	1	1 (4.35)
Neutropenic infection	1	1 (4.35)	1	1 (4.35)
Ophthalmic herpes zoster	1	1 (4.35)	0	0 (0.00)
Oral candidiasis	1	1 (4.35)	0	0 (0.00)
Rhinitis	1	1 (4.35)	0	0 (0.00)
Rhinovirus infection	1	1 (4.35)	0	0 (0.00)
Septic shock	1	1 (4.35)	1	1 (4.35)
Staphylococcal abscess	1	1 (4.35)	1	1 (4.35)
Streptococcal sepsis	1	1 (4.35)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (4.35)	0	0 (0.00)
Viral skin infection	1	1 (4.35)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	1	1 (4.35)	0	0 (0.00)
Ligament sprain	1	1 (4.35)	0	0 (0.00)
Investigations				
- Total	11	2 (8.70)	5	1 (4.35)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Neutrophil count decreased	7	2 (8.70)	5	1 (4.35)
Blood bilirubin increased	3	1 (4.35)	0	0 (0.00)
Platelet count decreased	1	1 (4.35)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	3	2 (8.70)	3	2 (8.70)
Decreased appetite	2	1 (4.35)	2	1 (4.35)
Hypernatraemia	1	1 (4.35)	1	1 (4.35)
Musculoskeletal and connective tissue disorders				
- Total	4	4 (17.39)	0	0 (0.00)
Pain in extremity	2	2 (8.70)	0	0 (0.00)
Growth retardation	1	1 (4.35)	0	0 (0.00)
Osteonecrosis	1	1 (4.35)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	2	1 (4.35)	1	1 (4.35)
Bone giant cell tumour benign	2	1 (4.35)	1	1 (4.35)
Nervous system disorders				
- Total	8	3 (13.04)	3	2 (8.70)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Seizure	3	1 (4.35)	1	1 (4.35)
Headache	2	1 (4.35)	1	1 (4.35)
Nervous system disorder	2	1 (4.35)	1	1 (4.35)
Dysarthria	1	1 (4.35)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (13.04)	0	0 (0.00)
Anxiety	2	2 (8.70)	0	0 (0.00)
Tic	1	1 (4.35)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	11	6 (26.09)	2	2 (8.70)
Cough	2	2 (8.70)	0	0 (0.00)
Dyspnoea	1	1 (4.35)	0	0 (0.00)
Dyspnoea exertional	1	1 (4.35)	0	0 (0.00)
Epistaxis	1	1 (4.35)	0	0 (0.00)
Laryngeal oedema	1	1 (4.35)	1	1 (4.35)
Oropharyngeal pain	1	1 (4.35)	0	0 (0.00)
Pharyngeal erythema	1	1 (4.35)	0	0 (0.00)
Respiratory failure	1	1 (4.35)	1	1 (4.35)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=23 n (%)[1]	Grade >= 3 Total events	All patients N=23 n (%)[2]
Rhinorrhoea	1	1 (4.35)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (4.35)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	6	5 (21.74)	4	3 (13.04)
Rash macular	2	1 (4.35)	2	1 (4.35)
Dermatitis atopic	1	1 (4.35)	1	1 (4.35)
Dry skin	1	1 (4.35)	0	0 (0.00)
Eczema	1	1 (4.35)	1	1 (4.35)
Papule	1	1 (4.35)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Total number of AE per patient	249	6 (100.00)	89	5 (83.33)
Blood and lymphatic system disorders				
- Total	14	5 (83.33)	6	4 (66.67)
Anaemia	7	2 (33.33)	0	0 (0.00)
Febrile neutropenia	3	3 (50.00)	3	3 (50.00)
Coagulopathy	1	1 (16.67)	1	1 (16.67)
Disseminated intravascular coagulation	1	1 (16.67)	1	1 (16.67)
Lymphocytosis	1	1 (16.67)	0	0 (0.00)
Thrombocytopenia	1	1 (16.67)	1	1 (16.67)
Cardiac disorders				
- Total	7	3 (50.00)	1	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Tachycardia	6	3 (50.00)	1	1 (16.67)
Sinus tachycardia	1	1 (16.67)	0	0 (0.00)
Eye disorders				
- Total	1	1 (16.67)	0	0 (0.00)
Eyelid oedema	1	1 (16.67)	0	0 (0.00)
Gastrointestinal disorders				
- Total	7	2 (33.33)	1	1 (16.67)
Abdominal distension	1	1 (16.67)	0	0 (0.00)
Ascites	1	1 (16.67)	0	0 (0.00)
Constipation	1	1 (16.67)	0	0 (0.00)
Irritable bowel syndrome	1	1 (16.67)	0	0 (0.00)
Melaena	1	1 (16.67)	1	1 (16.67)
Mouth haemorrhage	1	1 (16.67)	0	0 (0.00)
Nausea	1	1 (16.67)	0	0 (0.00)
General disorders and administration site conditions				
- Total	19	4 (66.67)	3	2 (33.33)
Pyrexia	9	3 (50.00)	1	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Fatigue	3	2 (33.33)	0	0 (0.00)
Catheter site pain	1	1 (16.67)	0	0 (0.00)
Chills	1	1 (16.67)	0	0 (0.00)
Face oedema	1	1 (16.67)	0	0 (0.00)
Generalised oedema	1	1 (16.67)	0	0 (0.00)
Multiple organ dysfunction syndrome	1	1 (16.67)	1	1 (16.67)
Oedema peripheral	1	1 (16.67)	0	0 (0.00)
Systemic inflammatory response syndrome	1	1 (16.67)	1	1 (16.67)
Hepatobiliary disorders				
- Total	3	1 (16.67)	1	1 (16.67)
Cholelithiasis	1	1 (16.67)	0	0 (0.00)
Cholestasis	1	1 (16.67)	1	1 (16.67)
Gallbladder enlargement	1	1 (16.67)	0	0 (0.00)
Immune system disorders				
- Total	14	5 (83.33)	7	2 (33.33)
Cytokine release syndrome	10	5 (83.33)	5	2 (33.33)
Hypogammaglobulinaemia	2	2 (33.33)	1	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Haemophagocytic lymphohistiocytosis	1	1 (16.67)	1	1 (16.67)
Seasonal allergy	1	1 (16.67)	0	0 (0.00)
Infections and infestations				
- Total	14	3 (50.00)	5	2 (33.33)
Upper respiratory tract infection	2	1 (16.67)	0	0 (0.00)
Clostridium difficile colitis	1	1 (16.67)	1	1 (16.67)
Conjunctivitis	1	1 (16.67)	0	0 (0.00)
Encephalitis	1	1 (16.67)	1	1 (16.67)
Gastroenteritis	1	1 (16.67)	0	0 (0.00)
Gastroenteritis Escherichia coli	1	1 (16.67)	1	1 (16.67)
Gastroenteritis salmonella	1	1 (16.67)	1	1 (16.67)
Gastrointestinal infection	1	1 (16.67)	0	0 (0.00)
Localised infection	1	1 (16.67)	0	0 (0.00)
Otitis externa	1	1 (16.67)	0	0 (0.00)
Pneumonia	1	1 (16.67)	1	1 (16.67)
Rhinovirus infection	1	1 (16.67)	0	0 (0.00)
Sinusitis	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Injury, poisoning and procedural complications				
- Total	7	3 (50.00)	2	1 (16.67)
Wound	2	1 (16.67)	1	1 (16.67)
Fibula fracture	1	1 (16.67)	0	0 (0.00)
Infusion related reaction	1	1 (16.67)	0	0 (0.00)
Skin injury	1	1 (16.67)	0	0 (0.00)
Skin wound	1	1 (16.67)	0	0 (0.00)
Vasoplegia syndrome	1	1 (16.67)	1	1 (16.67)
Investigations				
- Total	67	3 (50.00)	29	3 (50.00)
Neutrophil count decreased	27	3 (50.00)	17	3 (50.00)
White blood cell count decreased	11	2 (33.33)	3	1 (16.67)
Aspartate aminotransferase increased	5	1 (16.67)	1	1 (16.67)
Blood bilirubin increased	5	1 (16.67)	1	1 (16.67)
Platelet count decreased	4	1 (16.67)	2	1 (16.67)
Alanine aminotransferase increased	3	1 (16.67)	1	1 (16.67)
Lipase increased	3	1 (16.67)	2	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Blood alkaline phosphatase increased	1	1 (16.67)	0	0 (0.00)
Blood creatine phosphokinase increased	1	1 (16.67)	1	1 (16.67)
Blood creatinine increased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin G decreased	1	1 (16.67)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (16.67)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (16.67)	0	0 (0.00)
International normalised ratio increased	1	1 (16.67)	0	0 (0.00)
Lymphocyte count decreased	1	1 (16.67)	1	1 (16.67)
Weight increased	1	1 (16.67)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	41	5 (83.33)	14	3 (50.00)
Hypokalaemia	10	1 (16.67)	7	1 (16.67)
Hypocalcaemia	6	2 (33.33)	2	1 (16.67)
Hypophosphataemia	6	3 (50.00)	2	2 (33.33)
Hyperuricaemia	4	2 (33.33)	1	1 (16.67)
Hyperglycaemia	3	1 (16.67)	0	0 (0.00)
Acidosis	2	1 (16.67)	1	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Decreased appetite	2	2 (33.33)	0	0 (0.00)
Hypoalbuminaemia	2	1 (16.67)	0	0 (0.00)
Haemosiderosis	1	1 (16.67)	0	0 (0.00)
Hyperlactacidaemia	1	1 (16.67)	0	0 (0.00)
Hypermagnesaemia	1	1 (16.67)	0	0 (0.00)
Hypernatraemia	1	1 (16.67)	1	1 (16.67)
Hypomagnesaemia	1	1 (16.67)	0	0 (0.00)
Hyponatraemia	1	1 (16.67)	0	0 (0.00)
Musculoskeletal and connective tissue disorders				
- Total	3	2 (33.33)	1	1 (16.67)
Myalgia	1	1 (16.67)	0	0 (0.00)
Myositis	1	1 (16.67)	0	0 (0.00)
Rhabdomyolysis	1	1 (16.67)	1	1 (16.67)
Nervous system disorders				
- Total	8	4 (66.67)	1	1 (16.67)
Headache	4	3 (50.00)	0	0 (0.00)
Encephalopathy	1	1 (16.67)	1	1 (16.67)
Monoparesis	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Somnolence	1	1 (16.67)	0	0 (0.00)
Tremor	1	1 (16.67)	0	0 (0.00)
Psychiatric disorders				
- Total	3	3 (50.00)	0	0 (0.00)
Confusional state	1	1 (16.67)	0	0 (0.00)
Persistent depressive disorder	1	1 (16.67)	0	0 (0.00)
Sleep disorder	1	1 (16.67)	0	0 (0.00)
Renal and urinary disorders				
- Total	7	2 (33.33)	3	2 (33.33)
Acute kidney injury	4	2 (33.33)	2	2 (33.33)
Bladder dilatation	1	1 (16.67)	0	0 (0.00)
Renal tubular necrosis	1	1 (16.67)	1	1 (16.67)
Urinary retention	1	1 (16.67)	0	0 (0.00)
Reproductive system and breast disorders				
- Total	1	1 (16.67)	1	1 (16.67)
Vaginal ulceration	1	1 (16.67)	1	1 (16.67)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Respiratory, thoracic and mediastinal disorders				
- Total	15	3 (50.00)	8	2 (33.33)
Atelectasis	3	1 (16.67)	1	1 (16.67)
Nasal congestion	3	2 (33.33)	0	0 (0.00)
Tachypnoea	2	2 (33.33)	2	2 (33.33)
Acute respiratory distress syndrome	1	1 (16.67)	1	1 (16.67)
Acute respiratory failure	1	1 (16.67)	1	1 (16.67)
Cough	1	1 (16.67)	0	0 (0.00)
Dyspnoea	1	1 (16.67)	1	1 (16.67)
Hypoxia	1	1 (16.67)	1	1 (16.67)
Oropharyngeal pain	1	1 (16.67)	0	0 (0.00)
Respiratory acidosis	1	1 (16.67)	1	1 (16.67)
Skin and subcutaneous tissue disorders				
- Total	12	4 (66.67)	2	1 (16.67)
Dry skin	2	2 (33.33)	0	0 (0.00)
Rash	2	2 (33.33)	0	0 (0.00)
Decubitus ulcer	1	1 (16.67)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 0

Primary system organ class Preferred term	All grades Total events	All patients N=6 n (%)[1]	Grade >= 3 Total events	All patients N=6 n (%)[2]
Erythema	1	1 (16.67)	0	0 (0.00)
Hyperhidrosis	1	1 (16.67)	0	0 (0.00)
Petechiae	1	1 (16.67)	1	1 (16.67)
Pruritus	1	1 (16.67)	0	0 (0.00)
Skin hypopigmentation	1	1 (16.67)	0	0 (0.00)
Skin necrosis	1	1 (16.67)	1	1 (16.67)
Skin ulcer	1	1 (16.67)	0	0 (0.00)
Vascular disorders				
- Total	6	2 (33.33)	4	2 (33.33)
Hypotension	4	2 (33.33)	3	2 (33.33)
Hypertension	2	1 (16.67)	1	1 (16.67)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Total number of AE per patient	652	22 (100.00)	237	19 (86.36)
Blood and lymphatic system disorders				
- Total	38	15 (68.18)	22	10 (45.45)
Anaemia	11	6 (27.27)	3	2 (9.09)
Febrile neutropenia	8	6 (27.27)	8	6 (27.27)
Neutropenia	6	3 (13.64)	6	3 (13.64)
Thrombocytopenia	3	3 (13.64)	3	3 (13.64)
Coagulopathy	2	2 (9.09)	0	0 (0.00)
Disseminated intravascular coagulation	2	2 (9.09)	0	0 (0.00)
Leukopenia	2	1 (4.55)	2	1 (4.55)
Lymphadenopathy	2	2 (9.09)	0	0 (0.00)
Hypercoagulation	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Splenomegaly	1	1 (4.55)	0	0 (0.00)
Cardiac disorders				
- Total	21	9 (40.91)	8	6 (27.27)
Tachycardia	10	7 (31.82)	2	2 (9.09)
Cardiac failure	5	2 (9.09)	3	2 (9.09)
Bradycardia	2	2 (9.09)	0	0 (0.00)
Left ventricular dysfunction	2	2 (9.09)	2	2 (9.09)
Atrioventricular block first degree	1	1 (4.55)	0	0 (0.00)
Sinus bradycardia	1	1 (4.55)	1	1 (4.55)
Ear and labyrinth disorders				
- Total	1	1 (4.55)	0	0 (0.00)
Ear pain	1	1 (4.55)	0	0 (0.00)
Endocrine disorders				
- Total	4	4 (18.18)	0	0 (0.00)
Adrenal insufficiency	3	3 (13.64)	0	0 (0.00)
Hypothyroidism	1	1 (4.55)	0	0 (0.00)
Eye disorders				

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	3	2 (9.09)	0	0 (0.00)
Ocular hyperaemia	2	2 (9.09)	0	0 (0.00)
Conjunctival haemorrhage	1	1 (4.55)	0	0 (0.00)
Gastrointestinal disorders				
- Total	54	17 (77.27)	7	6 (27.27)
Vomiting	12	10 (45.45)	1	1 (4.55)
Nausea	9	8 (36.36)	1	1 (4.55)
Diarrhoea	7	6 (27.27)	0	0 (0.00)
Abdominal pain	6	4 (18.18)	1	1 (4.55)
Constipation	6	5 (22.73)	0	0 (0.00)
Pancreatitis	2	2 (9.09)	1	1 (4.55)
Abdominal compartment syndrome	1	1 (4.55)	1	1 (4.55)
Abdominal pain upper	1	1 (4.55)	0	0 (0.00)
Anal fissure	1	1 (4.55)	0	0 (0.00)
Anal haemorrhage	1	1 (4.55)	0	0 (0.00)
Dry mouth	1	1 (4.55)	0	0 (0.00)
Gastrointestinal haemorrhage	1	1 (4.55)	0	0 (0.00)
Gastrointestinal sounds abnormal	1	1 (4.55)	0	0 (0.00)
Haematemesis	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Ileus	1	1 (4.55)	0	0 (0.00)
Mouth haemorrhage	1	1 (4.55)	1	1 (4.55)
Neutropenic colitis	1	1 (4.55)	1	1 (4.55)
Proctalgia	1	1 (4.55)	0	0 (0.00)
General disorders and administration site conditions				
- Total	31	13 (59.09)	8	6 (27.27)
Pyrexia	12	8 (36.36)	3	3 (13.64)
Oedema peripheral	5	4 (18.18)	2	1 (4.55)
Face oedema	3	3 (13.64)	1	1 (4.55)
Fatigue	3	3 (13.64)	0	0 (0.00)
Drug withdrawal syndrome	2	2 (9.09)	0	0 (0.00)
Multiple organ dysfunction syndrome	2	2 (9.09)	2	2 (9.09)
Chills	1	1 (4.55)	0	0 (0.00)
Generalised oedema	1	1 (4.55)	0	0 (0.00)
Oedema due to hepatic disease	1	1 (4.55)	0	0 (0.00)
Pain	1	1 (4.55)	0	0 (0.00)
Hepatobiliary disorders				
- Total	11	7 (31.82)	2	2 (9.09)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Hepatic function abnormal	4	2 (9.09)	1	1 (4.55)
Hyperbilirubinaemia	2	2 (9.09)	1	1 (4.55)
Biliary tract disorder	1	1 (4.55)	0	0 (0.00)
Gallbladder enlargement	1	1 (4.55)	0	0 (0.00)
Hepatomegaly	1	1 (4.55)	0	0 (0.00)
Hypertransaminasaemia	1	1 (4.55)	0	0 (0.00)
Ocular icterus	1	1 (4.55)	0	0 (0.00)
Immune system disorders				
- Total	56	20 (90.91)	24	12 (54.55)
Cytokine release syndrome	36	15 (68.18)	15	10 (45.45)
Hypogammaglobulinaemia	12	10 (45.45)	1	1 (4.55)
Haemophagocytic lymphohistiocytosis	3	3 (13.64)	3	3 (13.64)
Allergy to immunoglobulin therapy	1	1 (4.55)	1	1 (4.55)
Chronic graft versus host disease	1	1 (4.55)	1	1 (4.55)
Engraftment syndrome	1	1 (4.55)	1	1 (4.55)
Graft versus host disease	1	1 (4.55)	1	1 (4.55)
Immunodeficiency	1	1 (4.55)	1	1 (4.55)
Infections and infestations				

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	56	15 (68.18)	21	7 (31.82)
Conjunctivitis	5	2 (9.09)	0	0 (0.00)
Rhinovirus infection	4	3 (13.64)	1	1 (4.55)
Staphylococcal bacteraemia	4	3 (13.64)	4	3 (13.64)
Clostridium difficile infection	3	3 (13.64)	2	2 (9.09)
Nasopharyngitis	3	2 (9.09)	0	0 (0.00)
Parainfluenzae virus infection	3	3 (13.64)	1	1 (4.55)
Upper respiratory tract infection	3	3 (13.64)	0	0 (0.00)
Ear infection	2	1 (4.55)	0	0 (0.00)
Influenza	2	2 (9.09)	1	1 (4.55)
Pneumonia	2	2 (9.09)	2	2 (9.09)
Acute sinusitis	1	1 (4.55)	0	0 (0.00)
Atypical pneumonia	1	1 (4.55)	0	0 (0.00)
Bacteraemia	1	1 (4.55)	1	1 (4.55)
Bronchitis	1	1 (4.55)	0	0 (0.00)
COVID-19 pneumonia	1	1 (4.55)	1	1 (4.55)
Candida infection	1	1 (4.55)	0	0 (0.00)
Cellulitis	1	1 (4.55)	0	0 (0.00)
Cholecystitis infective	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Coronavirus infection	1	1 (4.55)	1	1 (4.55)
Cystitis	1	1 (4.55)	0	0 (0.00)
Encephalitis viral	1	1 (4.55)	1	1 (4.55)
Enterovirus infection	1	1 (4.55)	1	1 (4.55)
Gastroenteritis	1	1 (4.55)	0	0 (0.00)
Gastroenteritis viral	1	1 (4.55)	0	0 (0.00)
Herpes zoster	1	1 (4.55)	1	1 (4.55)
Klebsiella bacteraemia	1	1 (4.55)	0	0 (0.00)
Meningitis bacterial	1	1 (4.55)	1	1 (4.55)
Metapneumovirus infection	1	1 (4.55)	1	1 (4.55)
Molluscum contagiosum	1	1 (4.55)	0	0 (0.00)
Otitis media	1	1 (4.55)	0	0 (0.00)
Otitis media acute	1	1 (4.55)	0	0 (0.00)
Pharyngitis streptococcal	1	1 (4.55)	1	1 (4.55)
Skin infection	1	1 (4.55)	0	0 (0.00)
Staphylococcal infection	1	1 (4.55)	0	0 (0.00)
Viral upper respiratory tract infection	1	1 (4.55)	1	1 (4.55)
Injury, poisoning and procedural complications				

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
- Total	8	7 (31.82)	1	1 (4.55)
Transfusion reaction	2	2 (9.09)	0	0 (0.00)
Abdominal injury	1	1 (4.55)	0	0 (0.00)
Contusion	1	1 (4.55)	0	0 (0.00)
Infusion related reaction	1	1 (4.55)	1	1 (4.55)
Post-traumatic neck syndrome	1	1 (4.55)	0	0 (0.00)
Scratch	1	1 (4.55)	0	0 (0.00)
Skin abrasion	1	1 (4.55)	0	0 (0.00)
Investigations				
- Total	137	17 (77.27)	59	15 (68.18)
White blood cell count decreased	23	9 (40.91)	14	7 (31.82)
Platelet count decreased	19	7 (31.82)	6	3 (13.64)
Aspartate aminotransferase increased	10	8 (36.36)	6	6 (27.27)
Blood bilirubin increased	9	6 (27.27)	6	5 (22.73)
Lymphocyte count decreased	9	5 (22.73)	5	5 (22.73)
Neutrophil count decreased	8	5 (22.73)	8	5 (22.73)
Alanine aminotransferase increased	5	5 (22.73)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Activated partial thromboplastin time prolonged	4	3 (13.64)	0	0 (0.00)
Blood fibrinogen decreased	4	4 (18.18)	0	0 (0.00)
Electrocardiogram QT prolonged	4	3 (13.64)	2	2 (9.09)
Serum ferritin increased	4	4 (18.18)	1	1 (4.55)
Blood immunoglobulin A decreased	3	3 (13.64)	0	0 (0.00)
Blood immunoglobulin G decreased	3	3 (13.64)	0	0 (0.00)
Blood immunoglobulin M decreased	3	3 (13.64)	1	1 (4.55)
International normalised ratio increased	3	3 (13.64)	0	0 (0.00)
Oxygen saturation decreased	3	3 (13.64)	1	1 (4.55)
Blood creatinine increased	2	2 (9.09)	1	1 (4.55)
Blood lactate dehydrogenase increased	2	2 (9.09)	1	1 (4.55)
Blood uric acid increased	2	2 (9.09)	0	0 (0.00)
C-reactive protein increased	2	2 (9.09)	1	1 (4.55)
Fibrin D dimer increased	2	2 (9.09)	1	1 (4.55)
Amylase increased	1	1 (4.55)	0	0 (0.00)
Bacterial test positive	1	1 (4.55)	1	1 (4.55)
Blood phosphorus increased	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Blood urea increased	1	1 (4.55)	1	1 (4.55)
Coagulation test abnormal	1	1 (4.55)	0	0 (0.00)
Electrocardiogram T wave abnormal	1	1 (4.55)	0	0 (0.00)
Heart sounds abnormal	1	1 (4.55)	0	0 (0.00)
Lipase increased	1	1 (4.55)	0	0 (0.00)
SARS-CoV-2 test positive	1	1 (4.55)	0	0 (0.00)
Staphylococcus test positive	1	1 (4.55)	0	0 (0.00)
Troponin increased	1	1 (4.55)	1	1 (4.55)
Urine output decreased	1	1 (4.55)	1	1 (4.55)
Weight increased	1	1 (4.55)	1	1 (4.55)
Metabolism and nutrition disorders				
- Total	65	14 (63.64)	28	11 (50.00)
Hypocalcaemia	10	7 (31.82)	2	2 (9.09)
Decreased appetite	8	8 (36.36)	5	5 (22.73)
Hyperglycaemia	6	5 (22.73)	3	3 (13.64)
Hypervolaemia	5	5 (22.73)	5	5 (22.73)
Hypoalbuminaemia	5	4 (18.18)	1	1 (4.55)
Hypokalaemia	5	5 (22.73)	1	1 (4.55)
Hyperuricaemia	4	3 (13.64)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Hypophosphataemia	4	3 (13.64)	1	1 (4.55)
Metabolic acidosis	3	3 (13.64)	2	2 (9.09)
Hypercalcaemia	2	2 (9.09)	1	1 (4.55)
Hyperphosphataemia	2	2 (9.09)	0	0 (0.00)
Hypertriglyceridaemia	2	2 (9.09)	2	2 (9.09)
Tumour lysis syndrome	2	2 (9.09)	2	2 (9.09)
Acidosis	1	1 (4.55)	1	1 (4.55)
Calcium deficiency	1	1 (4.55)	0	0 (0.00)
Dehydration	1	1 (4.55)	0	0 (0.00)
Hyperkalaemia	1	1 (4.55)	1	1 (4.55)
Hypoglycaemia	1	1 (4.55)	0	0 (0.00)
Hypomagnesaemia	1	1 (4.55)	0	0 (0.00)
Obesity	1	1 (4.55)	1	1 (4.55)
Musculoskeletal and connective tissue disorders				
- Total	17	10 (45.45)	2	1 (4.55)
Back pain	4	1 (4.55)	0	0 (0.00)
Arthralgia	3	2 (9.09)	1	1 (4.55)
Pain in extremity	3	3 (13.64)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Bone pain	2	2 (9.09)	0	0 (0.00)
Haemarthrosis	1	1 (4.55)	1	1 (4.55)
Muscle spasms	1	1 (4.55)	0	0 (0.00)
Muscular weakness	1	1 (4.55)	0	0 (0.00)
Myalgia	1	1 (4.55)	0	0 (0.00)
Neck pain	1	1 (4.55)	0	0 (0.00)
Nervous system disorders				
- Total	26	13 (59.09)	6	4 (18.18)
Headache	6	4 (18.18)	0	0 (0.00)
Cognitive disorder	4	2 (9.09)	1	1 (4.55)
Encephalopathy	3	3 (13.64)	1	1 (4.55)
Migraine	2	1 (4.55)	0	0 (0.00)
Seizure	2	1 (4.55)	0	0 (0.00)
Cerebral haemorrhage	1	1 (4.55)	1	1 (4.55)
Dizziness	1	1 (4.55)	0	0 (0.00)
Dysarthria	1	1 (4.55)	1	1 (4.55)
Dysgeusia	1	1 (4.55)	0	0 (0.00)
Extrapyramidal disorder	1	1 (4.55)	0	0 (0.00)
Lethargy	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Neurological decompensation	1	1 (4.55)	1	1 (4.55)
Paraesthesia	1	1 (4.55)	0	0 (0.00)
Somnolence	1	1 (4.55)	1	1 (4.55)
Psychiatric disorders				
- Total	15	11 (50.00)	4	4 (18.18)
Delirium	4	4 (18.18)	3	3 (13.64)
Anxiety	3	3 (13.64)	1	1 (4.55)
Agitation	2	2 (9.09)	0	0 (0.00)
Confusional state	2	2 (9.09)	0	0 (0.00)
Irritability	2	2 (9.09)	0	0 (0.00)
Insomnia	1	1 (4.55)	0	0 (0.00)
Mental status changes	1	1 (4.55)	0	0 (0.00)
Renal and urinary disorders				
- Total	11	8 (36.36)	7	4 (18.18)
Acute kidney injury	5	4 (18.18)	4	3 (13.64)
Renal failure	3	1 (4.55)	3	1 (4.55)
Dysuria	1	1 (4.55)	0	0 (0.00)
Renal tubular dysfunction	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Urinary retention	1	1 (4.55)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	52	17 (77.27)	26	11 (50.00)
Hypoxia	9	7 (31.82)	8	6 (27.27)
Cough	7	6 (27.27)	0	0 (0.00)
Pulmonary oedema	6	6 (27.27)	3	3 (13.64)
Pleural effusion	5	4 (18.18)	2	2 (9.09)
Respiratory distress	4	3 (13.64)	3	2 (9.09)
Respiratory failure	4	4 (18.18)	4	4 (18.18)
Tachypnoea	4	3 (13.64)	2	1 (4.55)
Rhinitis allergic	2	2 (9.09)	0	0 (0.00)
Rhinorrhoea	2	1 (4.55)	0	0 (0.00)
Acute respiratory distress syndrome	1	1 (4.55)	1	1 (4.55)
Atelectasis	1	1 (4.55)	1	1 (4.55)
Bradypnoea	1	1 (4.55)	1	1 (4.55)
Bronchospasm	1	1 (4.55)	0	0 (0.00)
Dyspnoea	1	1 (4.55)	1	1 (4.55)
Epistaxis	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Nasal congestion	1	1 (4.55)	0	0 (0.00)
Oropharyngeal pain	1	1 (4.55)	0	0 (0.00)
Sleep apnoea syndrome	1	1 (4.55)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	27	14 (63.64)	1	1 (4.55)
Pruritus	4	3 (13.64)	0	0 (0.00)
Blister	2	2 (9.09)	0	0 (0.00)
Dermatitis atopic	2	1 (4.55)	0	0 (0.00)
Dry skin	2	2 (9.09)	0	0 (0.00)
Erythema	2	2 (9.09)	0	0 (0.00)
Rash vesicular	2	1 (4.55)	0	0 (0.00)
Skin discolouration	2	2 (9.09)	0	0 (0.00)
Dermatitis	1	1 (4.55)	0	0 (0.00)
Dermatitis allergic	1	1 (4.55)	0	0 (0.00)
Hyperhidrosis	1	1 (4.55)	0	0 (0.00)
Ingrowing nail	1	1 (4.55)	0	0 (0.00)
Miliaria	1	1 (4.55)	0	0 (0.00)
Rash	1	1 (4.55)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 1

Primary system organ class Preferred term	All grades Total events	All patients N=22 n (%)[1]	Grade >= 3 Total events	All patients N=22 n (%)[2]
Rash maculo-papular	1	1 (4.55)	0	0 (0.00)
Rash papular	1	1 (4.55)	0	0 (0.00)
Rash pruritic	1	1 (4.55)	0	0 (0.00)
Scab	1	1 (4.55)	0	0 (0.00)
Vancomycin infusion reaction	1	1 (4.55)	1	1 (4.55)
Surgical and medical procedures				
- Total	1	1 (4.55)	1	1 (4.55)
Thrombolysis	1	1 (4.55)	1	1 (4.55)
Vascular disorders				
- Total	18	10 (45.45)	10	8 (36.36)
Hypotension	9	9 (40.91)	7	7 (31.82)
Hypertension	6	6 (27.27)	2	2 (9.09)
Capillary leak syndrome	1	1 (4.55)	0	0 (0.00)
Peripheral ischaemia	1	1 (4.55)	0	0 (0.00)
Venoocclusive disease	1	1 (4.55)	1	1 (4.55)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Total number of AE per patient	486	17 (100.00)	170	15 (88.24)
Blood and lymphatic system disorders				
- Total	36	11 (64.71)	24	10 (58.82)
Anaemia	13	4 (23.53)	6	1 (5.88)
Febrile neutropenia	11	8 (47.06)	11	8 (47.06)
Neutropenia	4	2 (11.76)	3	1 (5.88)
Splenomegaly	2	2 (11.76)	0	0 (0.00)
Thrombocytopenia	2	1 (5.88)	2	1 (5.88)
Disseminated intravascular coagulation	1	1 (5.88)	1	1 (5.88)
Hypofibrinogenaemia	1	1 (5.88)	0	0 (0.00)
Leukocytosis	1	1 (5.88)	0	0 (0.00)
Lymphopenia	1	1 (5.88)	1	1 (5.88)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Cardiac disorders				
- Total	11	8 (47.06)	3	2 (11.76)
Tachycardia	5	4 (23.53)	0	0 (0.00)
Cardiac arrest	2	2 (11.76)	2	2 (11.76)
Bradycardia	1	1 (5.88)	0	0 (0.00)
Cardiac dysfunction	1	1 (5.88)	0	0 (0.00)
Cardiac failure	1	1 (5.88)	1	1 (5.88)
Sinus tachycardia	1	1 (5.88)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (5.88)	0	0 (0.00)
Ear pruritus	1	1 (5.88)	0	0 (0.00)
Endocrine disorders				
- Total	3	2 (11.76)	0	0 (0.00)
Hypothyroidism	2	2 (11.76)	0	0 (0.00)
Delayed puberty	1	1 (5.88)	0	0 (0.00)
Eye disorders				
- Total	5	4 (23.53)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Conjunctival haemorrhage	1	1 (5.88)	0	0 (0.00)
Dry eye	1	1 (5.88)	0	0 (0.00)
Mydriasis	1	1 (5.88)	0	0 (0.00)
Periorbital oedema	1	1 (5.88)	0	0 (0.00)
Visual impairment	1	1 (5.88)	0	0 (0.00)
Gastrointestinal disorders				
- Total	30	12 (70.59)	2	2 (11.76)
Diarrhoea	9	7 (41.18)	0	0 (0.00)
Vomiting	6	5 (29.41)	0	0 (0.00)
Constipation	4	3 (17.65)	0	0 (0.00)
Nausea	4	4 (23.53)	0	0 (0.00)
Pancreatitis	2	2 (11.76)	1	1 (5.88)
Dysphagia	1	1 (5.88)	1	1 (5.88)
Gastrointestinal inflammation	1	1 (5.88)	0	0 (0.00)
Gingival erythema	1	1 (5.88)	0	0 (0.00)
Lip oedema	1	1 (5.88)	0	0 (0.00)
Stomatitis	1	1 (5.88)	0	0 (0.00)
General disorders and administration site conditions				

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	24	14 (82.35)	3	3 (17.65)
Pyrexia	9	9 (52.94)	3	3 (17.65)
Fatigue	6	6 (35.29)	0	0 (0.00)
Oedema peripheral	3	2 (11.76)	0	0 (0.00)
Generalised oedema	2	2 (11.76)	0	0 (0.00)
Catheter site haemorrhage	1	1 (5.88)	0	0 (0.00)
Face oedema	1	1 (5.88)	0	0 (0.00)
Localised oedema	1	1 (5.88)	0	0 (0.00)
Malaise	1	1 (5.88)	0	0 (0.00)
Hepatobiliary disorders				
- Total	6	3 (17.65)	1	1 (5.88)
Hyperbilirubinaemia	2	1 (5.88)	0	0 (0.00)
Hypertransaminasaemia	2	1 (5.88)	0	0 (0.00)
Hepatic function abnormal	1	1 (5.88)	0	0 (0.00)
Hepatomegaly	1	1 (5.88)	1	1 (5.88)
Immune system disorders				
- Total	38	14 (82.35)	16	9 (52.94)
Cytokine release syndrome	26	12 (70.59)	14	8 (47.06)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Hypogammaglobulinaemia	6	6 (35.29)	1	1 (5.88)
Seasonal allergy	3	3 (17.65)	0	0 (0.00)
Haemophagocytic lymphohistiocytosis	1	1 (5.88)	0	0 (0.00)
Immunodeficiency	1	1 (5.88)	1	1 (5.88)
Selective IgG subclass deficiency	1	1 (5.88)	0	0 (0.00)
Infections and infestations				
- Total	49	12 (70.59)	18	7 (41.18)
Sinusitis	3	2 (11.76)	0	0 (0.00)
Upper respiratory tract infection	3	3 (17.65)	1	1 (5.88)
Device related sepsis	2	1 (5.88)	2	1 (5.88)
Gastroenteritis viral	2	1 (5.88)	0	0 (0.00)
Nail infection	2	2 (11.76)	0	0 (0.00)
Oral herpes	2	1 (5.88)	1	1 (5.88)
Otitis media	2	2 (11.76)	0	0 (0.00)
Respiratory syncytial virus infection	2	2 (11.76)	1	1 (5.88)
Respiratory tract infection	2	2 (11.76)	0	0 (0.00)
Staphylococcal bacteraemia	2	2 (11.76)	2	2 (11.76)
Staphylococcal infection	2	2 (11.76)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Adenovirus infection	1	1 (5.88)	1	1 (5.88)
BK virus infection	1	1 (5.88)	1	1 (5.88)
Bacteraemia	1	1 (5.88)	0	0 (0.00)
Bronchiolitis	1	1 (5.88)	1	1 (5.88)
Bronchitis	1	1 (5.88)	0	0 (0.00)
Bronchopulmonary aspergillosis	1	1 (5.88)	1	1 (5.88)
COVID-19	1	1 (5.88)	0	0 (0.00)
Conjunctivitis	1	1 (5.88)	0	0 (0.00)
Cytomegalovirus infection reactivation	1	1 (5.88)	1	1 (5.88)
Ear infection	1	1 (5.88)	0	0 (0.00)
Folliculitis	1	1 (5.88)	0	0 (0.00)
Fungal skin infection	1	1 (5.88)	0	0 (0.00)
Gastroenteritis clostridial	1	1 (5.88)	0	0 (0.00)
Herpes simplex	1	1 (5.88)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (5.88)	1	1 (5.88)
Metapneumovirus infection	1	1 (5.88)	1	1 (5.88)
Nasopharyngitis	1	1 (5.88)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (5.88)	1	1 (5.88)
Pneumonia respiratory syncytial viral	1	1 (5.88)	1	1 (5.88)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Rhinovirus infection	1	1 (5.88)	0	0 (0.00)
Sinusitis fungal	1	1 (5.88)	1	1 (5.88)
Syphilis	1	1 (5.88)	0	0 (0.00)
Urinary tract infection viral	1	1 (5.88)	0	0 (0.00)
Varicella zoster virus infection	1	1 (5.88)	0	0 (0.00)
Viral infection	1	1 (5.88)	1	1 (5.88)
Injury, poisoning and procedural complications				
- Total	7	4 (23.53)	0	0 (0.00)
Contusion	2	1 (5.88)	0	0 (0.00)
Procedural pain	2	2 (11.76)	0	0 (0.00)
Infusion related reaction	1	1 (5.88)	0	0 (0.00)
Skin abrasion	1	1 (5.88)	0	0 (0.00)
Wound	1	1 (5.88)	0	0 (0.00)
Investigations				
- Total	91	12 (70.59)	55	10 (58.82)
Platelet count decreased	23	5 (29.41)	18	4 (23.53)
White blood cell count decreased	11	5 (29.41)	10	5 (29.41)
Neutrophil count decreased	7	4 (23.53)	5	4 (23.53)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Alanine aminotransferase increased	6	4 (23.53)	2	2 (11.76)
Aspartate aminotransferase increased	5	5 (29.41)	1	1 (5.88)
International normalised ratio increased	5	2 (11.76)	0	0 (0.00)
Activated partial thromboplastin time prolonged	4	3 (17.65)	1	1 (5.88)
Blood creatinine increased	4	2 (11.76)	4	2 (11.76)
Weight increased	4	1 (5.88)	1	1 (5.88)
Blood bilirubin increased	3	3 (17.65)	3	3 (17.65)
Lymphocyte count decreased	3	3 (17.65)	3	3 (17.65)
Blood fibrinogen decreased	2	2 (11.76)	2	2 (11.76)
Gamma-glutamyltransferase increased	2	2 (11.76)	2	2 (11.76)
Urine output decreased	2	1 (5.88)	2	1 (5.88)
Blood bicarbonate decreased	1	1 (5.88)	0	0 (0.00)
Blood immunoglobulin A decreased	1	1 (5.88)	0	0 (0.00)
Blood immunoglobulin M decreased	1	1 (5.88)	0	0 (0.00)
Blood thyroid stimulating hormone increased	1	1 (5.88)	0	0 (0.00)
Blood uric acid increased	1	1 (5.88)	1	1 (5.88)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Cardiac murmur	1	1 (5.88)	0	0 (0.00)
Ejection fraction decreased	1	1 (5.88)	0	0 (0.00)
Electrocardiogram QT prolonged	1	1 (5.88)	0	0 (0.00)
Fibrin D dimer increased	1	1 (5.88)	0	0 (0.00)
Haptoglobin decreased	1	1 (5.88)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	58	12 (70.59)	23	8 (47.06)
Hypokalaemia	15	5 (29.41)	10	5 (29.41)
Hypophosphataemia	9	5 (29.41)	4	4 (23.53)
Decreased appetite	7	7 (41.18)	2	2 (11.76)
Hypocalcaemia	4	4 (23.53)	1	1 (5.88)
Hypoalbuminaemia	3	3 (17.65)	0	0 (0.00)
Hypercalcaemia	2	1 (5.88)	1	1 (5.88)
Hyperkalaemia	2	2 (11.76)	1	1 (5.88)
Hyperphosphataemia	2	2 (11.76)	1	1 (5.88)
Iron overload	2	1 (5.88)	0	0 (0.00)
Hyperchloraemia	1	1 (5.88)	0	0 (0.00)
Hypercholesterolaemia	1	1 (5.88)	0	0 (0.00)
Hyperlipidaemia	1	1 (5.88)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Hypertriglyceridaemia	1	1 (5.88)	0	0 (0.00)
Hyperuricaemia	1	1 (5.88)	0	0 (0.00)
Hypervolaemia	1	1 (5.88)	0	0 (0.00)
Hypomagnesaemia	1	1 (5.88)	0	0 (0.00)
Hyponatraemia	1	1 (5.88)	0	0 (0.00)
Malnutrition	1	1 (5.88)	1	1 (5.88)
Metabolic acidosis	1	1 (5.88)	1	1 (5.88)
Metabolic syndrome	1	1 (5.88)	0	0 (0.00)
Tumour lysis syndrome	1	1 (5.88)	1	1 (5.88)
Musculoskeletal and connective tissue disorders				
- Total	19	10 (58.82)	3	3 (17.65)
Arthralgia	4	4 (23.53)	0	0 (0.00)
Pain in extremity	4	4 (23.53)	0	0 (0.00)
Back pain	2	2 (11.76)	2	2 (11.76)
Myalgia	2	2 (11.76)	0	0 (0.00)
Growth retardation	1	1 (5.88)	0	0 (0.00)
Joint effusion	1	1 (5.88)	0	0 (0.00)
Muscle rigidity	1	1 (5.88)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Muscular weakness	1	1 (5.88)	1	1 (5.88)
Musculoskeletal chest pain	1	1 (5.88)	0	0 (0.00)
Osteopenia	1	1 (5.88)	0	0 (0.00)
Synovitis	1	1 (5.88)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	1	1 (5.88)	0	0 (0.00)
Cancer pain	1	1 (5.88)	0	0 (0.00)
Nervous system disorders				
- Total	15	7 (41.18)	2	1 (5.88)
Headache	9	5 (29.41)	0	0 (0.00)
Cognitive disorder	1	1 (5.88)	0	0 (0.00)
Encephalopathy	1	1 (5.88)	1	1 (5.88)
Generalised tonic-clonic seizure	1	1 (5.88)	0	0 (0.00)
Neuralgia	1	1 (5.88)	0	0 (0.00)
Somnolence	1	1 (5.88)	1	1 (5.88)
Tremor	1	1 (5.88)	0	0 (0.00)
Psychiatric disorders				

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	16	8 (47.06)	1	1 (5.88)
Anxiety	4	4 (23.53)	0	0 (0.00)
Agitation	3	2 (11.76)	0	0 (0.00)
Confusional state	3	3 (17.65)	0	0 (0.00)
Delirium	3	3 (17.65)	0	0 (0.00)
Automatism	1	1 (5.88)	0	0 (0.00)
Insomnia	1	1 (5.88)	0	0 (0.00)
Mental status changes	1	1 (5.88)	1	1 (5.88)
Renal and urinary disorders				
- Total	10	2 (11.76)	2	2 (11.76)
Acute kidney injury	4	2 (11.76)	1	1 (5.88)
Anuria	1	1 (5.88)	0	0 (0.00)
Azotaemia	1	1 (5.88)	0	0 (0.00)
Dysuria	1	1 (5.88)	0	0 (0.00)
Haematuria	1	1 (5.88)	1	1 (5.88)
Kidney enlargement	1	1 (5.88)	0	0 (0.00)
Renal mass	1	1 (5.88)	0	0 (0.00)
Reproductive system and breast disorders				

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	5	2 (11.76)	1	1 (5.88)
Dysmenorrhoea	2	1 (5.88)	0	0 (0.00)
Endometriosis	2	1 (5.88)	1	1 (5.88)
Perineal rash	1	1 (5.88)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	33	9 (52.94)	7	4 (23.53)
Hypoxia	5	3 (17.65)	4	3 (17.65)
Cough	4	4 (23.53)	0	0 (0.00)
Rhinorrhoea	3	3 (17.65)	0	0 (0.00)
Tachypnoea	3	2 (11.76)	1	1 (5.88)
Nasal congestion	2	2 (11.76)	0	0 (0.00)
Oropharyngeal pain	2	2 (11.76)	0	0 (0.00)
Pleural effusion	2	2 (11.76)	1	1 (5.88)
Wheezing	2	2 (11.76)	0	0 (0.00)
Dyspnoea	1	1 (5.88)	0	0 (0.00)
Epistaxis	1	1 (5.88)	0	0 (0.00)
Haemoptysis	1	1 (5.88)	0	0 (0.00)
Nasal discomfort	1	1 (5.88)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
Nasal dryness	1	1 (5.88)	0	0 (0.00)
Pharyngeal haemorrhage	1	1 (5.88)	0	0 (0.00)
Pulmonary oedema	1	1 (5.88)	0	0 (0.00)
Respiratory distress	1	1 (5.88)	0	0 (0.00)
Respiratory failure	1	1 (5.88)	1	1 (5.88)
Upper respiratory tract inflammation	1	1 (5.88)	0	0 (0.00)
Skin and subcutaneous tissue disorders				
- Total	13	3 (17.65)	0	0 (0.00)
Blister	4	1 (5.88)	0	0 (0.00)
Rash	2	1 (5.88)	0	0 (0.00)
Dermatitis diaper	1	1 (5.88)	0	0 (0.00)
Dry skin	1	1 (5.88)	0	0 (0.00)
Eczema	1	1 (5.88)	0	0 (0.00)
Petechiae	1	1 (5.88)	0	0 (0.00)
Photosensitivity reaction	1	1 (5.88)	0	0 (0.00)
Pruritus	1	1 (5.88)	0	0 (0.00)
Rash erythematous	1	1 (5.88)	0	0 (0.00)
Vascular disorders				

Timing: At anytime, Number of previous relapses: 2

Primary system organ class Preferred term	All grades Total events	All patients N=17 n (%)[1]	Grade >= 3 Total events	All patients N=17 n (%)[2]
- Total	15	11 (64.71)	9	8 (47.06)
Hypotension	8	6 (35.29)	5	4 (23.53)
Hypertension	4	4 (23.53)	2	2 (11.76)
Capillary leak syndrome	1	1 (5.88)	1	1 (5.88)
Thrombosis	1	1 (5.88)	0	0 (0.00)
Venoocclusive disease	1	1 (5.88)	1	1 (5.88)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 250r
Number of adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term and Number of previous relapses
Safety Set

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Total number of AE per patient	1118	35 (100.00)	332	34 (97.14)
Blood and lymphatic system disorders				
- Total	75	24 (68.57)	43	19 (54.29)
Anaemia	32	13 (37.14)	15	6 (17.14)
Febrile neutropenia	11	10 (28.57)	11	10 (28.57)
Neutropenia	7	6 (17.14)	6	5 (14.29)
Thrombocytopenia	5	4 (11.43)	4	4 (11.43)
Disseminated intravascular coagulation	4	4 (11.43)	1	1 (2.86)
B-cell aplasia	3	1 (2.86)	0	0 (0.00)
Eosinophilia	3	1 (2.86)	0	0 (0.00)
Leukopenia	3	2 (5.71)	1	1 (2.86)
Coagulopathy	2	2 (5.71)	1	1 (2.86)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Pancytopenia	2	2 (5.71)	2	2 (5.71)
Agranulocytosis	1	1 (2.86)	1	1 (2.86)
Lymphopenia	1	1 (2.86)	1	1 (2.86)
Splenomegaly	1	1 (2.86)	0	0 (0.00)
Cardiac disorders				
- Total	14	8 (22.86)	2	2 (5.71)
Tachycardia	3	3 (8.57)	0	0 (0.00)
Left ventricular dysfunction	2	2 (5.71)	1	1 (2.86)
Sinus tachycardia	2	1 (2.86)	0	0 (0.00)
Cardiac arrest	1	1 (2.86)	1	1 (2.86)
Cardiac dysfunction	1	1 (2.86)	0	0 (0.00)
Cardiac failure congestive	1	1 (2.86)	0	0 (0.00)
Mitral valve incompetence	1	1 (2.86)	0	0 (0.00)
Pericardial effusion	1	1 (2.86)	0	0 (0.00)
Right ventricular dysfunction	1	1 (2.86)	0	0 (0.00)
Tricuspid valve incompetence	1	1 (2.86)	0	0 (0.00)
Congenital, familial and genetic disorders				
- Total	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Cerebral cavernous malformation	1	1 (2.86)	0	0 (0.00)
Ear and labyrinth disorders				
- Total	1	1 (2.86)	0	0 (0.00)
Deafness unilateral	1	1 (2.86)	0	0 (0.00)
Endocrine disorders				
- Total	1	1 (2.86)	0	0 (0.00)
Adrenal insufficiency	1	1 (2.86)	0	0 (0.00)
Eye disorders				
- Total	15	8 (22.86)	1	1 (2.86)
Eyelid oedema	3	2 (5.71)	0	0 (0.00)
Cataract	2	2 (5.71)	0	0 (0.00)
Eye pain	2	2 (5.71)	1	1 (2.86)
Retinal haemorrhage	2	1 (2.86)	0	0 (0.00)
Eye oedema	1	1 (2.86)	0	0 (0.00)
Hypermetropia	1	1 (2.86)	0	0 (0.00)
Ocular hyperaemia	1	1 (2.86)	0	0 (0.00)
Periorbital swelling	1	1 (2.86)	0	0 (0.00)
Visual field defect	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Visual impairment	1	1 (2.86)	0	0 (0.00)
Gastrointestinal disorders				
- Total	91	29 (82.86)	8	7 (20.00)
Vomiting	20	11 (31.43)	0	0 (0.00)
Diarrhoea	14	13 (37.14)	2	2 (5.71)
Nausea	13	9 (25.71)	1	1 (2.86)
Abdominal pain	9	7 (20.00)	1	1 (2.86)
Constipation	5	5 (14.29)	0	0 (0.00)
Abdominal pain upper	3	3 (8.57)	0	0 (0.00)
Mouth haemorrhage	3	3 (8.57)	1	1 (2.86)
Abdominal distension	2	2 (5.71)	0	0 (0.00)
Ascites	2	2 (5.71)	0	0 (0.00)
Pancreatitis	2	2 (5.71)	0	0 (0.00)
Stomatitis	2	2 (5.71)	1	1 (2.86)
Trichoglossia	2	2 (5.71)	0	0 (0.00)
Abdominal rigidity	1	1 (2.86)	0	0 (0.00)
Dyspepsia	1	1 (2.86)	0	0 (0.00)
Enteritis	1	1 (2.86)	0	0 (0.00)
Enterocolitis	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Gastrointestinal sounds abnormal	1	1 (2.86)	0	0 (0.00)
Gastrooesophageal reflux disease	1	1 (2.86)	0	0 (0.00)
Gingival bleeding	1	1 (2.86)	0	0 (0.00)
Gingivitis ulcerative	1	1 (2.86)	1	1 (2.86)
Lip dry	1	1 (2.86)	0	0 (0.00)
Mouth swelling	1	1 (2.86)	0	0 (0.00)
Odynophagia	1	1 (2.86)	0	0 (0.00)
Peritoneal haematoma	1	1 (2.86)	0	0 (0.00)
Proctalgia	1	1 (2.86)	1	1 (2.86)
Upper gastrointestinal haemorrhage	1	1 (2.86)	0	0 (0.00)
General disorders and administration site conditions				
- Total	82	22 (62.86)	10	4 (11.43)
Pyrexia	37	15 (42.86)	5	4 (11.43)
Chills	8	5 (14.29)	0	0 (0.00)
Fatigue	7	6 (17.14)	0	0 (0.00)
Face oedema	4	3 (8.57)	0	0 (0.00)
Pain	4	4 (11.43)	2	2 (5.71)
Asthenia	3	3 (8.57)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Catheter site pain	3	1 (2.86)	2	1 (2.86)
Catheter site erythema	2	1 (2.86)	0	0 (0.00)
Influenza like illness	2	2 (5.71)	0	0 (0.00)
Non-cardiac chest pain	2	2 (5.71)	0	0 (0.00)
Chest discomfort	1	1 (2.86)	1	1 (2.86)
Crying	1	1 (2.86)	0	0 (0.00)
Facial pain	1	1 (2.86)	0	0 (0.00)
Generalised oedema	1	1 (2.86)	0	0 (0.00)
Localised oedema	1	1 (2.86)	0	0 (0.00)
Malaise	1	1 (2.86)	0	0 (0.00)
Sluggishness	1	1 (2.86)	0	0 (0.00)
Swelling face	1	1 (2.86)	0	0 (0.00)
Vascular device occlusion	1	1 (2.86)	0	0 (0.00)
Xerosis	1	1 (2.86)	0	0 (0.00)
Hepatobiliary disorders				
- Total	12	8 (22.86)	3	2 (5.71)
Hepatic function abnormal	6	2 (5.71)	3	2 (5.71)
Hyperbilirubinaemia	2	2 (5.71)	0	0 (0.00)
Cholelithiasis	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Hepatic cytolysis	1	1 (2.86)	0	0 (0.00)
Hepatomegaly	1	1 (2.86)	0	0 (0.00)
Liver disorder	1	1 (2.86)	0	0 (0.00)
Immune system disorders				
- Total	85	32 (91.43)	29	23 (65.71)
Cytokine release syndrome	56	29 (82.86)	21	18 (51.43)
Hypogammaglobulinaemia	20	15 (42.86)	4	4 (11.43)
Drug hypersensitivity	2	2 (5.71)	1	1 (2.86)
Immunodeficiency	2	2 (5.71)	2	2 (5.71)
Allergy to immunoglobulin therapy	1	1 (2.86)	0	0 (0.00)
Chronic graft versus host disease	1	1 (2.86)	0	0 (0.00)
Graft versus host disease	1	1 (2.86)	1	1 (2.86)
Haemophagocytic lymphohistiocytosis	1	1 (2.86)	0	0 (0.00)
Hypersensitivity	1	1 (2.86)	0	0 (0.00)
Infections and infestations				
- Total	144	30 (85.71)	58	23 (65.71)
Sinusitis	10	4 (11.43)	2	2 (5.71)
Upper respiratory tract infection	9	6 (17.14)	2	2 (5.71)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Bronchopulmonary aspergillosis	5	1 (2.86)	3	1 (2.86)
Conjunctivitis	5	4 (11.43)	0	0 (0.00)
Nasopharyngitis	5	4 (11.43)	0	0 (0.00)
Rhinovirus infection	5	4 (11.43)	1	1 (2.86)
Candida infection	4	3 (8.57)	2	1 (2.86)
Gastroenteritis	4	4 (11.43)	2	2 (5.71)
Oral candidiasis	4	3 (8.57)	0	0 (0.00)
Urinary tract infection	4	3 (8.57)	2	1 (2.86)
Fungal infection	3	2 (5.71)	0	0 (0.00)
Klebsiella infection	3	1 (2.86)	3	1 (2.86)
Oral herpes	3	3 (8.57)	0	0 (0.00)
Otitis media	3	2 (5.71)	1	1 (2.86)
Parainfluenzae virus infection	3	2 (5.71)	2	2 (5.71)
Pneumonia	3	3 (8.57)	1	1 (2.86)
Rhinitis	3	3 (8.57)	0	0 (0.00)
Sepsis	3	3 (8.57)	3	3 (8.57)
Bacteraemia	2	1 (2.86)	2	1 (2.86)
COVID-19	2	1 (2.86)	1	1 (2.86)
Gingivitis	2	2 (5.71)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Herpes zoster	2	2 (5.71)	1	1 (2.86)
Nail infection	2	2 (5.71)	0	0 (0.00)
Oral infection	2	2 (5.71)	0	0 (0.00)
Otitis externa	2	2 (5.71)	1	1 (2.86)
Paronychia	2	2 (5.71)	0	0 (0.00)
Septic shock	2	2 (5.71)	2	2 (5.71)
Skin infection	2	2 (5.71)	0	0 (0.00)
Staphylococcal infection	2	2 (5.71)	2	2 (5.71)
Acute sinusitis	1	1 (2.86)	0	0 (0.00)
Adenovirus infection	1	1 (2.86)	1	1 (2.86)
Anal abscess	1	1 (2.86)	1	1 (2.86)
BK virus infection	1	1 (2.86)	0	0 (0.00)
Clostridium difficile infection	1	1 (2.86)	1	1 (2.86)
Device related infection	1	1 (2.86)	1	1 (2.86)
Ear infection	1	1 (2.86)	1	1 (2.86)
Ear, nose and throat infection	1	1 (2.86)	0	0 (0.00)
Encephalitis	1	1 (2.86)	1	1 (2.86)
Encephalitis viral	1	1 (2.86)	1	1 (2.86)
Enterobacter infection	1	1 (2.86)	1	1 (2.86)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Gastroenteritis norovirus	1	1 (2.86)	0	0 (0.00)
Granulicatella infection	1	1 (2.86)	1	1 (2.86)
Herpes simplex	1	1 (2.86)	1	1 (2.86)
Herpes virus infection	1	1 (2.86)	0	0 (0.00)
Human herpesvirus 6 infection	1	1 (2.86)	1	1 (2.86)
Influenza	1	1 (2.86)	0	0 (0.00)
Mastoiditis	1	1 (2.86)	1	1 (2.86)
Meningitis pneumococcal	1	1 (2.86)	1	1 (2.86)
Metapneumovirus infection	1	1 (2.86)	1	1 (2.86)
Myringitis	1	1 (2.86)	0	0 (0.00)
Neutropenic infection	1	1 (2.86)	1	1 (2.86)
Ophthalmic herpes zoster	1	1 (2.86)	0	0 (0.00)
Pneumocystis jirovecii pneumonia	1	1 (2.86)	1	1 (2.86)
Pneumonia fungal	1	1 (2.86)	1	1 (2.86)
Pneumonia viral	1	1 (2.86)	1	1 (2.86)
Respiratory syncytial virus infection	1	1 (2.86)	1	1 (2.86)
Respiratory tract infection	1	1 (2.86)	0	0 (0.00)
Respiratory tract infection viral	1	1 (2.86)	0	0 (0.00)
Salmonellosis	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Soft tissue infection	1	1 (2.86)	1	1 (2.86)
Staphylococcal abscess	1	1 (2.86)	1	1 (2.86)
Staphylococcal sepsis	1	1 (2.86)	1	1 (2.86)
Staphylococcal skin infection	1	1 (2.86)	0	0 (0.00)
Stomatococcal infection	1	1 (2.86)	0	0 (0.00)
Streptococcal sepsis	1	1 (2.86)	0	0 (0.00)
Systemic candida	1	1 (2.86)	1	1 (2.86)
Tinea pedis	1	1 (2.86)	0	0 (0.00)
Urinary tract infection pseudomonal	1	1 (2.86)	0	0 (0.00)
Varicella zoster virus infection	1	1 (2.86)	1	1 (2.86)
Viral haemorrhagic cystitis	1	1 (2.86)	1	1 (2.86)
Viral infection	1	1 (2.86)	0	0 (0.00)
Viral skin infection	1	1 (2.86)	0	0 (0.00)
Injury, poisoning and procedural complications				
- Total	11	7 (20.00)	1	1 (2.86)
Infusion related reaction	5	2 (5.71)	0	0 (0.00)
Fall	2	2 (5.71)	0	0 (0.00)
Ligament sprain	2	2 (5.71)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Limb injury	1	1 (2.86)	0	0 (0.00)
Transplant failure	1	1 (2.86)	1	1 (2.86)
Investigations				
- Total	198	28 (80.00)	95	20 (57.14)
Platelet count decreased	37	11 (31.43)	21	7 (20.00)
Neutrophil count decreased	33	12 (34.29)	24	9 (25.71)
Lymphocyte count decreased	23	8 (22.86)	17	6 (17.14)
White blood cell count decreased	23	9 (25.71)	13	5 (14.29)
Alanine aminotransferase increased	15	8 (22.86)	4	4 (11.43)
Aspartate aminotransferase increased	13	5 (14.29)	5	3 (8.57)
Immunoglobulins decreased	10	2 (5.71)	0	0 (0.00)
Blood bilirubin increased	8	3 (8.57)	0	0 (0.00)
Serum ferritin increased	4	4 (11.43)	1	1 (2.86)
Blood creatine phosphokinase increased	3	1 (2.86)	1	1 (2.86)
Blood immunoglobulin A decreased	3	3 (8.57)	1	1 (2.86)
Blood lactate dehydrogenase increased	3	3 (8.57)	0	0 (0.00)
C-reactive protein increased	3	3 (8.57)	2	2 (5.71)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
International normalised ratio increased	3	3 (8.57)	0	0 (0.00)
Blood glucose increased	2	1 (2.86)	2	1 (2.86)
Blood immunoglobulin M decreased	2	2 (5.71)	1	1 (2.86)
Haemoglobin decreased	2	1 (2.86)	1	1 (2.86)
Weight decreased	2	2 (5.71)	1	1 (2.86)
Blood fibrinogen decreased	1	1 (2.86)	0	0 (0.00)
Blood testosterone decreased	1	1 (2.86)	0	0 (0.00)
Blood uric acid increased	1	1 (2.86)	1	1 (2.86)
Bone density decreased	1	1 (2.86)	0	0 (0.00)
Breath sounds abnormal	1	1 (2.86)	0	0 (0.00)
Enterovirus test positive	1	1 (2.86)	0	0 (0.00)
Hepatitis B virus test positive	1	1 (2.86)	0	0 (0.00)
Prothrombin time prolonged	1	1 (2.86)	0	0 (0.00)
Weight increased	1	1 (2.86)	0	0 (0.00)
Metabolism and nutrition disorders				
- Total	82	21 (60.00)	26	11 (31.43)
Hypokalaemia	16	9 (25.71)	6	4 (11.43)
Decreased appetite	15	13 (37.14)	7	5 (14.29)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Hypophosphataemia	13	7 (20.00)	4	2 (5.71)
Hypoalbuminaemia	9	3 (8.57)	0	0 (0.00)
Hypocalcaemia	4	3 (8.57)	1	1 (2.86)
Hypomagnesaemia	4	3 (8.57)	0	0 (0.00)
Hyperglycaemia	3	3 (8.57)	2	2 (5.71)
Hyperuricaemia	3	3 (8.57)	0	0 (0.00)
Hypermagnesaemia	2	1 (2.86)	0	0 (0.00)
Hypernatraemia	2	2 (5.71)	1	1 (2.86)
Tumour lysis syndrome	2	2 (5.71)	2	2 (5.71)
Haemochromatosis	1	1 (2.86)	1	1 (2.86)
Hyperchloraemia	1	1 (2.86)	0	0 (0.00)
Hyperphosphataemia	1	1 (2.86)	0	0 (0.00)
Hypervolaemia	1	1 (2.86)	0	0 (0.00)
Hyponatraemia	1	1 (2.86)	0	0 (0.00)
Hypophagia	1	1 (2.86)	0	0 (0.00)
Iron overload	1	1 (2.86)	0	0 (0.00)
Malnutrition	1	1 (2.86)	1	1 (2.86)
Polydipsia	1	1 (2.86)	1	1 (2.86)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Musculoskeletal and connective tissue disorders				
- Total	44	22 (62.86)	3	3 (8.57)
Pain in extremity	11	10 (28.57)	1	1 (2.86)
Back pain	8	7 (20.00)	1	1 (2.86)
Arthralgia	7	6 (17.14)	0	0 (0.00)
Myalgia	7	6 (17.14)	0	0 (0.00)
Bone pain	4	2 (5.71)	0	0 (0.00)
Pain in jaw	2	2 (5.71)	1	1 (2.86)
Growth retardation	1	1 (2.86)	0	0 (0.00)
Musculoskeletal chest pain	1	1 (2.86)	0	0 (0.00)
Musculoskeletal pain	1	1 (2.86)	0	0 (0.00)
Neck pain	1	1 (2.86)	0	0 (0.00)
Osteonecrosis	1	1 (2.86)	0	0 (0.00)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
- Total	5	4 (11.43)	2	2 (5.71)
Bone giant cell tumour benign	2	1 (2.86)	1	1 (2.86)
Skin papilloma	2	2 (5.71)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Myelodysplastic syndrome	1	1 (2.86)	1	1 (2.86)
Nervous system disorders				
- Total	60	23 (65.71)	14	8 (22.86)
Headache	21	15 (42.86)	3	3 (8.57)
Seizure	5	3 (8.57)	3	3 (8.57)
Tremor	5	4 (11.43)	0	0 (0.00)
Dizziness	4	3 (8.57)	0	0 (0.00)
Encephalopathy	3	3 (8.57)	1	1 (2.86)
Hydrocephalus	3	1 (2.86)	3	1 (2.86)
Dysgeusia	2	2 (5.71)	0	0 (0.00)
Hyperaesthesia	2	1 (2.86)	0	0 (0.00)
Lethargy	2	2 (5.71)	0	0 (0.00)
Nervous system disorder	2	1 (2.86)	1	1 (2.86)
Somnolence	2	2 (5.71)	0	0 (0.00)
Amnesia	1	1 (2.86)	0	0 (0.00)
Aphasia	1	1 (2.86)	0	0 (0.00)
Autonomic neuropathy	1	1 (2.86)	1	1 (2.86)
Cerebral haemorrhage	1	1 (2.86)	1	1 (2.86)
Depressed level of consciousness	1	1 (2.86)	1	1 (2.86)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Disturbance in attention	1	1 (2.86)	0	0 (0.00)
Dysarthria	1	1 (2.86)	0	0 (0.00)
Hypoaesthesia	1	1 (2.86)	0	0 (0.00)
Memory impairment	1	1 (2.86)	0	0 (0.00)
Psychiatric disorders				
- Total	31	17 (48.57)	2	2 (5.71)
Anxiety	7	7 (20.00)	1	1 (2.86)
Hallucination	3	3 (8.57)	0	0 (0.00)
Mental status changes	3	3 (8.57)	1	1 (2.86)
Sleep disorder	3	2 (5.71)	0	0 (0.00)
Agitation	2	2 (5.71)	0	0 (0.00)
Insomnia	2	2 (5.71)	0	0 (0.00)
Affect lability	1	1 (2.86)	0	0 (0.00)
Confusional state	1	1 (2.86)	0	0 (0.00)
Delirium	1	1 (2.86)	0	0 (0.00)
Hallucination, visual	1	1 (2.86)	0	0 (0.00)
Irritability	1	1 (2.86)	0	0 (0.00)
Mood altered	1	1 (2.86)	0	0 (0.00)
Nightmare	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Restlessness	1	1 (2.86)	0	0 (0.00)
Social avoidant behaviour	1	1 (2.86)	0	0 (0.00)
Tearfulness	1	1 (2.86)	0	0 (0.00)
Tic	1	1 (2.86)	0	0 (0.00)
Renal and urinary disorders				
- Total	20	13 (37.14)	4	4 (11.43)
Acute kidney injury	4	4 (11.43)	2	2 (5.71)
Dysuria	2	2 (5.71)	0	0 (0.00)
Haematuria	2	2 (5.71)	0	0 (0.00)
Pollakiuria	2	2 (5.71)	0	0 (0.00)
Urinary incontinence	2	1 (2.86)	0	0 (0.00)
Anuria	1	1 (2.86)	1	1 (2.86)
Cystitis haemorrhagic	1	1 (2.86)	0	0 (0.00)
Incontinence	1	1 (2.86)	0	0 (0.00)
Micturition urgency	1	1 (2.86)	0	0 (0.00)
Proteinuria	1	1 (2.86)	0	0 (0.00)
Renal failure	1	1 (2.86)	0	0 (0.00)
Renal tubular disorder	1	1 (2.86)	1	1 (2.86)
Urinary tract disorder	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Reproductive system and breast disorders				
- Total	4	3 (8.57)	0	0 (0.00)
Vaginal haemorrhage	2	1 (2.86)	0	0 (0.00)
Female genital tract fistula	1	1 (2.86)	0	0 (0.00)
Heavy menstrual bleeding	1	1 (2.86)	0	0 (0.00)
Respiratory, thoracic and mediastinal disorders				
- Total	83	26 (74.29)	21	12 (34.29)
Cough	17	12 (34.29)	0	0 (0.00)
Hypoxia	12	9 (25.71)	9	6 (17.14)
Epistaxis	6	5 (14.29)	1	1 (2.86)
Dyspnoea	5	4 (11.43)	2	2 (5.71)
Oropharyngeal pain	5	4 (11.43)	0	0 (0.00)
Pulmonary oedema	5	5 (14.29)	4	4 (11.43)
Nasal congestion	4	4 (11.43)	0	0 (0.00)
Pleural effusion	3	3 (8.57)	0	0 (0.00)
Rhinorrhoea	3	2 (5.71)	0	0 (0.00)
Lung infiltration	2	1 (2.86)	1	1 (2.86)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Pharyngeal erythema	2	2 (5.71)	0	0 (0.00)
Tachypnoea	2	2 (5.71)	1	1 (2.86)
Acute respiratory distress syndrome	1	1 (2.86)	1	1 (2.86)
Atelectasis	1	1 (2.86)	0	0 (0.00)
Bronchial oedema	1	1 (2.86)	0	0 (0.00)
Dyspnoea exertional	1	1 (2.86)	0	0 (0.00)
Laryngeal oedema	1	1 (2.86)	1	1 (2.86)
Lung disorder	1	1 (2.86)	0	0 (0.00)
Oropharyngeal plaque	1	1 (2.86)	0	0 (0.00)
Painful respiration	1	1 (2.86)	0	0 (0.00)
Paranasal sinus discomfort	1	1 (2.86)	0	0 (0.00)
Paranasal sinus inflammation	1	1 (2.86)	0	0 (0.00)
Pharyngeal exudate	1	1 (2.86)	0	0 (0.00)
Pharyngeal oedema	1	1 (2.86)	0	0 (0.00)
Productive cough	1	1 (2.86)	0	0 (0.00)
Pulmonary mass	1	1 (2.86)	0	0 (0.00)
Respiratory disorder	1	1 (2.86)	0	0 (0.00)
Respiratory failure	1	1 (2.86)	1	1 (2.86)
Sleep apnoea syndrome	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Skin and subcutaneous tissue disorders				
- Total	43	19 (54.29)	6	5 (14.29)
Rash	8	4 (11.43)	0	0 (0.00)
Dry skin	4	3 (8.57)	0	0 (0.00)
Pruritus	3	2 (5.71)	0	0 (0.00)
Rash maculo-papular	3	2 (5.71)	1	1 (2.86)
Rash papular	3	2 (5.71)	0	0 (0.00)
Dermatitis atopic	2	2 (5.71)	1	1 (2.86)
Eczema	2	2 (5.71)	1	1 (2.86)
Erythema	2	2 (5.71)	0	0 (0.00)
Rash macular	2	1 (2.86)	2	1 (2.86)
Decubitus ulcer	1	1 (2.86)	1	1 (2.86)
Erythema nodosum	1	1 (2.86)	0	0 (0.00)
Hangnail	1	1 (2.86)	0	0 (0.00)
Hyperhidrosis	1	1 (2.86)	0	0 (0.00)
Ingrowing nail	1	1 (2.86)	0	0 (0.00)
Night sweats	1	1 (2.86)	0	0 (0.00)
Palmar-plantar erythrodysaesthesia syndrome	1	1 (2.86)	0	0 (0.00)

Timing: At anytime, Number of previous relapses: >=3

Primary system organ class Preferred term	All grades Total events	All patients N=35 n (%)[1]	Grade >= 3 Total events	All patients N=35 n (%)[2]
Papule	1	1 (2.86)	0	0 (0.00)
Pruritus allergic	1	1 (2.86)	0	0 (0.00)
Purpura	1	1 (2.86)	0	0 (0.00)
Skin lesion	1	1 (2.86)	0	0 (0.00)
Skin swelling	1	1 (2.86)	0	0 (0.00)
Skin ulcer	1	1 (2.86)	0	0 (0.00)
Urticaria	1	1 (2.86)	0	0 (0.00)
Social circumstances				
- Total	1	1 (2.86)	0	0 (0.00)
Patient uncooperative	1	1 (2.86)	0	0 (0.00)
Vascular disorders				
- Total	15	11 (31.43)	4	3 (8.57)
Hypotension	8	7 (20.00)	4	3 (8.57)
Hypertension	5	5 (14.29)	0	0 (0.00)
Flushing	1	1 (2.86)	0	0 (0.00)
Hot flush	1	1 (2.86)	0	0 (0.00)

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse

events. Percentages are calculated out of number of patients at each timepoint in safety set 1 number of patients with any AE (irrespective of grade) 2 number of patients with Grade 3 or more AE

Table 251a
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Age
Safety Set

Subgroup: Age: <10 years

	All patients N=33
Cytokine Release Syndrome (CRS) - n (%)	
No	9 (27.3)
Yes	24 (72.7)
Maximum CRS grade - n(%)	
Grade 1	3 (9.1)
Grade 2	10 (30.3)
Grade 3	3 (9.1)
Grade 4	8 (24.2)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	24
Mean (SD)	4.1 (2.48)
Median	3.0
Min - Max	1 - 10

	All patients N=33
Time to grade 3/4 CRS (days)	
n	11
Mean (SD)	6.2 (2.93)
Median	6.0
Min - Max	2 - 12
Concurrent infections - n(%)	5 (15.2)
Blood	2 (6.1)
GI	1 (3.0)
Lung	1 (3.0)
Other	1 (3.0)
High fevers during CRS - n (%)	22 (66.7)
Time to high fever onset (days)	
n	22
Mean (SD)	4.4 (2.56)
Median	4.0
Min - Max	1 - 10
Duration (days)	
n	22
Mean (SD)	6.6 (4.77)
Median	5.5
Min - Max	1 - 21

	All patients N=33
Admitted to ICU - n (%)	12 (36.4)
Time to ICU Admission (days)	
n	12
Mean (SD)	6.4 (3.23)
Median	6.0
Min - Max	2 - 12
Duration of ICU stay (days)	
n	12
Mean (SD)	10.0 (6.48)
Median	7.5
Min - Max	5 - 27
Hypotension that required intervention - n (%)	15 (45.5)
High dose vasopressors used - n (%)	7 (21.2)
Oxygen supplementation given - n (%)	11 (33.3)
Patient intubated - n (%)	5 (15.2)
Duration (days)	
n	5
Mean (SD)	9.4 (5.73)
Median	9.0
Min - Max	5 - 19
Patient dialyzed - n (%)	2 (6.1)

	All patients N=33
Duration (days)	
n	2
Mean (SD)	9.5 (7.78)
Median	9.5
Min - Max	4 - 15
Total Parenteral Nutrition (TPN) used - n (%)	12 (36.4)
Duration (days)	
n	12
Mean (SD)	13.4 (8.02)
Median	11.0
Min - Max	2 - 27
Pulmonary abnormalities - n (%)	6 (18.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	6 (18.2)
Bleeding observed - n (%)	4 (12.1)
Blood product support given for bleeding - n (%)	3 (9.1)
Systemic anti-cytokine therapy given - n (%)	10 (30.3)
Tocilizumab	10 (30.3)
1 dose	6 (18.2)
2 doses	2 (6.1)
3 doses	2 (6.1)
4 doses	0

	All patients N=33
>4 doses	0
Siltuximab	3 (9.1)
Corticosteroids	5 (15.2)
Other	2 (6.1)

Only the first CRS episode is summarized for each patient.

Table 251a
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Age
Safety Set

Subgroup: Age: >=10 years to <18 years

	All patients N=33
Cytokine Release Syndrome (CRS) - n (%)	
No	8 (24.2)
Yes	25 (75.8)
Maximum CRS grade - n(%)	
Grade 1	1 (3.0)
Grade 2	5 (15.2)
Grade 3	10 (30.3)
Grade 4	9 (27.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	25
Mean (SD)	3.2 (2.40)
Median	2.0
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=33
n	19
Mean (SD)	5.8 (2.87)
Median	6.0
Min - Max	2 - 11
Concurrent infections - n(%)	2 (6.1)
Blood	2 (6.1)
Other	1 (3.0)
High fevers during CRS - n (%)	24 (72.7)
Time to high fever onset (days)	
n	24
Mean (SD)	3.5 (2.52)
Median	2.0
Min - Max	1 - 9
Duration (days)	
n	24
Mean (SD)	6.5 (5.01)
Median	5.0
Min - Max	1 - 25
Admitted to ICU - n (%)	19 (57.6)
Time to ICU Admission (days)	
n	19

	All patients N=33
Mean (SD)	6.6 (5.00)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	19
Mean (SD)	11.9 (15.86)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	20 (60.6)
High dose vasopressors used - n (%)	9 (27.3)
Oxygen supplementation given - n (%)	17 (51.5)
Patient intubated - n (%)	4 (12.1)
Duration (days)	
n	4
Mean (SD)	9.3 (4.99)
Median	9.5
Min - Max	4 - 14
Patient dialyzed - n (%)	4 (12.1)
Duration (days)	
n	4
Mean (SD)	26.0 (24.18)

	All patients N=33
Median	17.5
Min - Max	8 - 61
Total Parenteral Nutrition (TPN) used - n (%)	11 (33.3)
Duration (days)	
n	11
Mean (SD)	30.5 (32.19)
Median	19.0
Min - Max	5 - 111
Pulmonary abnormalities - n (%)	7 (21.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (15.2)
Bleeding observed - n (%)	3 (9.1)
Blood product support given for bleeding - n (%)	2 (6.1)
Systemic anti-cytokine therapy given - n (%)	15 (45.5)
Tocilizumab	15 (45.5)
1 dose	9 (27.3)
2 doses	6 (18.2)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	1 (3.0)
Corticosteroids	8 (24.2)

	All patients N=33
Other	0

Only the first CRS episode is summarized for each patient.

Table 251a
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Age
Safety Set

Subgroup: Age: >=18

	All patients N=14
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (14.3)
Yes	12 (85.7)
Maximum CRS grade - n(%)	
Grade 1	1 (7.1)
Grade 2	3 (21.4)
Grade 3	4 (28.6)
Grade 4	4 (28.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	12
Mean (SD)	4.8 (5.80)
Median	3.0
Min - Max	1 - 22

	All patients N=14
Time to grade 3/4 CRS (days)	
n	8
Mean (SD)	10.0 (9.53)
Median	7.0
Min - Max	4 - 33
Concurrent infections - n(%)	5 (35.7)
Blood	3 (21.4)
Cns	1 (7.1)
GI	1 (7.1)
Lung	1 (7.1)
Skin	1 (7.1)
High fevers during CRS - n (%)	12 (85.7)
Time to high fever onset (days)	
n	12
Mean (SD)	5.1 (5.78)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	12
Mean (SD)	10.8 (9.43)
Median	6.5

	All patients N=14
Min - Max	4 - 36
Admitted to ICU - n (%)	7 (50.0)
Time to ICU Admission (days)	
n	7
Mean (SD)	8.7 (6.47)
Median	7.0
Min - Max	2 - 22
Duration of ICU stay (days)	
n	7
Mean (SD)	10.9 (8.09)
Median	9.0
Min - Max	3 - 24
Hypotension that required intervention - n (%)	7 (50.0)
High dose vasopressors used - n (%)	3 (21.4)
Oxygen supplementation given - n (%)	7 (50.0)
Patient intubated - n (%)	3 (21.4)
Duration (days)	
n	3
Mean (SD)	6.3 (1.53)
Median	6.0
Min - Max	5 - 8

	All patients N=14
Patient dialyzed - n (%)	2 (14.3)
Duration (days)	
n	2
Mean (SD)	6.0 (1.41)
Median	6.0
Min - Max	5 - 7
Total Parenteral Nutrition (TPN) used - n (%)	6 (42.9)
Duration (days)	
n	6
Mean (SD)	9.7 (1.51)
Median	10.0
Min - Max	7 - 11
Pulmonary abnormalities - n (%)	4 (28.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (14.3)
Bleeding observed - n (%)	1 (7.1)
Blood product support given for bleeding - n (%)	1 (7.1)
Systemic anti-cytokine therapy given - n (%)	6 (42.9)
Tocilizumab	6 (42.9)
1 dose	3 (21.4)
2 doses	2 (14.3)
3 doses	1 (7.1)

	All patients N=14
4 doses	0
>4 doses	0
Siltuximab	1 (7.1)
Corticosteroids	4 (28.6)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251b
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Gender
Safety Set

Subgroup: Gender: Male

	All patients N=46
Cytokine Release Syndrome (CRS) - n (%)	
No	15 (32.6)
Yes	31 (67.4)
Maximum CRS grade - n(%)	
Grade 1	3 (6.5)
Grade 2	9 (19.6)
Grade 3	8 (17.4)
Grade 4	11 (23.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	31
Mean (SD)	4.1 (2.69)
Median	3.0
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	

	All patients N=46
n	19
Mean (SD)	6.3 (3.20)
Median	6.0
Min - Max	2 - 12
Concurrent infections - n(%)	6 (13.0)
Blood	3 (6.5)
GI	1 (2.2)
Lung	1 (2.2)
Other	2 (4.3)
High fevers during CRS - n (%)	29 (63.0)
Time to high fever onset (days)	
n	29
Mean (SD)	4.3 (2.78)
Median	4.0
Min - Max	1 - 10
Duration (days)	
n	29
Mean (SD)	8.4 (7.68)
Median	6.0
Min - Max	1 - 36
Admitted to ICU - n (%)	18 (39.1)

	All patients N=46
Time to ICU Admission (days)	
n	18
Mean (SD)	7.4 (5.26)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	18
Mean (SD)	11.2 (8.54)
Median	7.5
Min - Max	3 - 34
Hypotension that required intervention - n (%)	23 (50.0)
High dose vasopressors used - n (%)	10 (21.7)
Oxygen supplementation given - n (%)	18 (39.1)
Patient intubated - n (%)	7 (15.2)
Duration (days)	
n	7
Mean (SD)	7.7 (3.25)
Median	6.0
Min - Max	5 - 14
Patient dialyzed - n (%)	5 (10.9)
Duration (days)	

	All patients N=46
n	5
Mean (SD)	10.8 (7.40)
Median	8.0
Min - Max	4 - 23
Total Parenteral Nutrition (TPN) used - n (%)	16 (34.8)
Duration (days)	
n	16
Mean (SD)	20.8 (25.69)
Median	12.5
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	10 (21.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	9 (19.6)
Bleeding observed - n (%)	3 (6.5)
Blood product support given for bleeding - n (%)	2 (4.3)
Systemic anti-cytokine therapy given - n (%)	18 (39.1)
Tocilizumab	18 (39.1)
1 dose	12 (26.1)
2 doses	5 (10.9)
3 doses	1 (2.2)
4 doses	0
>4 doses	0

	All patients N=46
Siltuximab	2 (4.3)
Corticosteroids	9 (19.6)
Other	1 (2.2)

Only the first CRS episode is summarized for each patient.

Table 251b
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Gender
Safety Set

Subgroup: Gender: Female

	All patients N=34
Cytokine Release Syndrome (CRS) - n (%)	
No	4 (11.8)
Yes	30 (88.2)
Maximum CRS grade - n(%)	
Grade 1	2 (5.9)
Grade 2	9 (26.5)
Grade 3	9 (26.5)
Grade 4	10 (29.4)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	30
Mean (SD)	3.7 (3.95)
Median	2.5
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=34
n	19
Mean (SD)	7.3 (6.58)
Median	7.0
Min - Max	2 - 33
Concurrent infections - n(%)	6 (17.6)
Blood	4 (11.8)
Cns	1 (2.9)
GI	1 (2.9)
Lung	1 (2.9)
Skin	1 (2.9)
High fevers during CRS - n (%)	29 (85.3)
Time to high fever onset (days)	
n	29
Mean (SD)	4.0 (4.03)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	29
Mean (SD)	6.6 (4.25)
Median	5.0
Min - Max	3 - 21

	All patients N=34
Admitted to ICU - n (%)	20 (58.8)
Time to ICU Admission (days)	
n	20
Mean (SD)	6.5 (4.39)
Median	7.0
Min - Max	2 - 22
Duration of ICU stay (days)	
n	20
Mean (SD)	11.1 (14.81)
Median	6.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	19 (55.9)
High dose vasopressors used - n (%)	9 (26.5)
Oxygen supplementation given - n (%)	17 (50.0)
Patient intubated - n (%)	5 (14.7)
Duration (days)	
n	5
Mean (SD)	9.8 (6.22)
Median	8.0
Min - Max	4 - 19
Patient dialyzed - n (%)	3 (8.8)

	All patients N=34
Duration (days)	
n	3
Mean (SD)	27.0 (29.87)
Median	15.0
Min - Max	5 - 61
Total Parenteral Nutrition (TPN) used - n (%)	13 (38.2)
Duration (days)	
n	13
Mean (SD)	17.1 (16.94)
Median	11.0
Min - Max	4 - 66
Pulmonary abnormalities - n (%)	7 (20.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (11.8)
Bleeding observed - n (%)	5 (14.7)
Blood product support given for bleeding - n (%)	4 (11.8)
Systemic anti-cytokine therapy given - n (%)	13 (38.2)
Tocilizumab	13 (38.2)
1 dose	6 (17.6)
2 doses	5 (14.7)
3 doses	2 (5.9)
4 doses	0

	All patients N=34
>4 doses	0
Siltuximab	3 (8.8)
Corticosteroids	8 (23.5)
Other	1 (2.9)

Only the first CRS episode is summarized for each patient.

Table 251c
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Race
Safety Set

Subgroup: Race: White

	All patients N=59
Cytokine Release Syndrome (CRS) - n (%)	
No	16 (27.1)
Yes	43 (72.9)
Maximum CRS grade - n(%)	
Grade 1	3 (5.1)
Grade 2	14 (23.7)
Grade 3	14 (23.7)
Grade 4	12 (20.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	43
Mean (SD)	4.2 (3.75)
Median	2.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=59
n	26
Mean (SD)	7.1 (5.86)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	8 (13.6)
Blood	5 (8.5)
GI	1 (1.7)
Lung	1 (1.7)
Other	2 (3.4)
Skin	1 (1.7)
High fevers during CRS - n (%)	41 (69.5)
Time to high fever onset (days)	
n	41
Mean (SD)	4.5 (3.80)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	41
Mean (SD)	6.0 (4.10)
Median	5.0
Min - Max	1 - 19

	All patients N=59
Admitted to ICU - n (%)	27 (45.8)
Time to ICU Admission (days)	
n	27
Mean (SD)	7.1 (5.35)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	27
Mean (SD)	7.9 (6.62)
Median	6.0
Min - Max	1 - 27
Hypotension that required intervention - n (%)	29 (49.2)
High dose vasopressors used - n (%)	12 (20.3)
Oxygen supplementation given - n (%)	24 (40.7)
Patient intubated - n (%)	5 (8.5)
Duration (days)	
n	5
Mean (SD)	8.8 (5.93)
Median	6.0
Min - Max	5 - 19
Patient dialyzed - n (%)	3 (5.1)

	All patients N=59
Duration (days)	
n	3
Mean (SD)	8.7 (5.69)
Median	7.0
Min - Max	4 - 15
Total Parenteral Nutrition (TPN) used - n (%)	17 (28.8)
Duration (days)	
n	17
Mean (SD)	18.4 (25.33)
Median	10.0
Min - Max	4 - 111
Pulmonary abnormalities - n (%)	13 (22.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	8 (13.6)
Bleeding observed - n (%)	6 (10.2)
Blood product support given for bleeding - n (%)	4 (6.8)
Systemic anti-cytokine therapy given - n (%)	21 (35.6)
Tocilizumab	21 (35.6)
1 dose	16 (27.1)
2 doses	4 (6.8)
3 doses	1 (1.7)
4 doses	0

	All patients N=59
>4 doses	0
Siltuximab	3 (5.1)
Corticosteroids	8 (13.6)
Other	1 (1.7)

Only the first CRS episode is summarized for each patient.

Table 251c
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Race
Safety Set

Subgroup: Race: Asian

	All patients N=10
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (20.0)
Yes	8 (80.0)
Maximum CRS grade - n(%)	
Grade 1	1 (10.0)
Grade 2	2 (20.0)
Grade 3	2 (20.0)
Grade 4	3 (30.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	8
Mean (SD)	4.1 (2.64)
Median	3.5
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=10
n	5
Mean (SD)	8.4 (3.29)
Median	10.0
Min - Max	4 - 12
Concurrent infections - n(%)	1 (10.0)
Lung	1 (10.0)
High fevers during CRS - n (%)	7 (70.0)
Time to high fever onset (days)	
n	7
Mean (SD)	4.1 (2.97)
Median	4.0
Min - Max	1 - 9
Duration (days)	
n	7
Mean (SD)	13.1 (10.43)
Median	10.0
Min - Max	6 - 36
Admitted to ICU - n (%)	4 (40.0)
Time to ICU Admission (days)	
n	4
Mean (SD)	9.3 (2.50)

	All patients N=10
Median	9.5
Min - Max	6 - 12
Duration of ICU stay (days)	
n	4
Mean (SD)	28.0 (28.61)
Median	21.0
Min - Max	4 - 66
Hypotension that required intervention - n (%)	6 (60.0)
High dose vasopressors used - n (%)	1 (10.0)
Oxygen supplementation given - n (%)	4 (40.0)
Patient intubated - n (%)	3 (30.0)
Duration (days)	
n	3
Mean (SD)	10.7 (4.93)
Median	13.0
Min - Max	5 - 14
Patient dialyzed - n (%)	2 (20.0)
Duration (days)	
n	2
Mean (SD)	36.5 (34.65)
Median	36.5

	All patients N=10
Min - Max	12 - 61
Total Parenteral Nutrition (TPN) used - n (%)	4 (40.0)
Duration (days)	
n	4
Mean (SD)	26.8 (28.51)
Median	19.5
Min - Max	2 - 66
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (30.0)
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	4 (40.0)
Tocilizumab	4 (40.0)
1 dose	1 (10.0)
2 doses	3 (30.0)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	3 (30.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251c
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Race
Safety Set

Subgroup: Race: Other

	All patients N=11
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (9.1)
Yes	10 (90.9)
Maximum CRS grade - n(%)	
Grade 1	1 (9.1)
Grade 2	2 (18.2)
Grade 3	1 (9.1)
Grade 4	6 (54.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	10
Mean (SD)	2.5 (1.08)
Median	2.5
Min - Max	1 - 4

	All patients N=11
Time to grade 3/4 CRS (days)	
n	7
Mean (SD)	4.7 (2.14)
Median	5.0
Min - Max	2 - 7
Concurrent infections - n(%)	3 (27.3)
Blood	2 (18.2)
Cns	1 (9.1)
GI	1 (9.1)
High fevers during CRS - n (%)	10 (90.9)
Time to high fever onset (days)	
n	10
Mean (SD)	2.8 (1.48)
Median	2.5
Min - Max	1 - 5
Duration (days)	
n	10
Mean (SD)	9.4 (7.68)
Median	7.0
Min - Max	1 - 25
Admitted to ICU - n (%)	7 (63.6)

	All patients N=11
Time to ICU Admission (days)	
n	7
Mean (SD)	4.9 (2.19)
Median	6.0
Min - Max	2 - 7
Duration of ICU stay (days)	
n	7
Mean (SD)	13.7 (7.65)
Median	12.0
Min - Max	6 - 29
Hypotension that required intervention - n (%)	7 (63.6)
High dose vasopressors used - n (%)	6 (54.5)
Oxygen supplementation given - n (%)	7 (63.6)
Patient intubated - n (%)	4 (36.4)
Duration (days)	
n	4
Mean (SD)	6.8 (2.22)
Median	7.0
Min - Max	4 - 9
Patient dialyzed - n (%)	3 (27.3)
Duration (days)	

	All patients N=11
n	3
Mean (SD)	12.0 (9.64)
Median	8.0
Min - Max	5 - 23
Total Parenteral Nutrition (TPN) used - n (%)	8 (72.7)
Duration (days)	
n	8
Mean (SD)	16.9 (8.08)
Median	15.0
Min - Max	7 - 30
Pulmonary abnormalities - n (%)	4 (36.4)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (18.2)
Bleeding observed - n (%)	2 (18.2)
Blood product support given for bleeding - n (%)	2 (18.2)
Systemic anti-cytokine therapy given - n (%)	6 (54.5)
Tocilizumab	6 (54.5)
1 dose	1 (9.1)
2 doses	3 (27.3)
3 doses	2 (18.2)
4 doses	0
>4 doses	0

	All patients N=11
Siltuximab	2 (18.2)
Corticosteroids	6 (54.5)
Other	1 (9.1)

Only the first CRS episode is summarized for each patient.

Table 251d
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Ethnicity
Safety Set

Subgroup: Ethnicity: Hispanic or Latino

	All patients N=15
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (13.3)
Yes	13 (86.7)
Maximum CRS grade - n(%)	
Grade 2	4 (26.7)
Grade 3	1 (6.7)
Grade 4	8 (53.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	13
Mean (SD)	3.0 (2.24)
Median	2.0
Min - Max	1 - 8
Time to grade 3/4 CRS (days)	

	All patients N=15
n	9
Mean (SD)	5.3 (2.55)
Median	5.0
Min - Max	2 - 9
Concurrent infections - n(%)	4 (26.7)
Blood	3 (20.0)
Cns	1 (6.7)
GI	1 (6.7)
High fevers during CRS - n (%)	13 (86.7)
Time to high fever onset (days)	
n	13
Mean (SD)	3.2 (2.27)
Median	2.0
Min - Max	1 - 8
Duration (days)	
n	13
Mean (SD)	8.1 (6.38)
Median	5.0
Min - Max	3 - 25
Admitted to ICU - n (%)	9 (60.0)
Time to ICU Admission (days)	

	All patients N=15
n	9
Mean (SD)	5.2 (2.59)
Median	6.0
Min - Max	2 - 9
Duration of ICU stay (days)	
n	9
Mean (SD)	12.8 (7.31)
Median	11.0
Min - Max	3 - 29
Hypotension that required intervention - n (%)	10 (66.7)
High dose vasopressors used - n (%)	7 (46.7)
Oxygen supplementation given - n (%)	8 (53.3)
Patient intubated - n (%)	5 (33.3)
Duration (days)	
n	5
Mean (SD)	6.6 (1.95)
Median	6.0
Min - Max	4 - 9
Patient dialyzed - n (%)	5 (33.3)
Duration (days)	
n	5

	All patients N=15
Mean (SD)	9.4 (7.77)
Median	7.0
Min - Max	4 - 23
Total Parenteral Nutrition (TPN) used - n (%)	8 (53.3)
Duration (days)	
n	8
Mean (SD)	13.8 (7.52)
Median	10.5
Min - Max	7 - 30
Pulmonary abnormalities - n (%)	4 (26.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (26.7)
Bleeding observed - n (%)	3 (20.0)
Blood product support given for bleeding - n (%)	3 (20.0)
Systemic anti-cytokine therapy given - n (%)	8 (53.3)
Tocilizumab	8 (53.3)
1 dose	2 (13.3)
2 doses	5 (33.3)
3 doses	1 (6.7)
4 doses	0
>4 doses	0
Siltuximab	3 (20.0)

	All patients N=15
Corticosteroids	7 (46.7)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251d
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Ethnicity
Safety Set

Subgroup: Ethnicity: Other

	All patients N=65
Cytokine Release Syndrome (CRS) - n (%)	
No	17 (26.2)
Yes	48 (73.8)
Maximum CRS grade - n(%)	
Grade 1	5 (7.7)
Grade 2	14 (21.5)
Grade 3	16 (24.6)
Grade 4	13 (20.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	48
Mean (SD)	4.1 (3.57)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=65
n	29
Mean (SD)	7.3 (5.66)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	8 (12.3)
Blood	4 (6.2)
GI	1 (1.5)
Lung	2 (3.1)
Other	2 (3.1)
Skin	1 (1.5)
High fevers during CRS - n (%)	45 (69.2)
Time to high fever onset (days)	
n	45
Mean (SD)	4.5 (3.67)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	45
Mean (SD)	7.3 (6.23)
Median	6.0
Min - Max	1 - 36

	All patients N=65
Admitted to ICU - n (%)	29 (44.6)
Time to ICU Admission (days)	
n	29
Mean (SD)	7.4 (5.20)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	29
Mean (SD)	10.6 (13.29)
Median	6.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	32 (49.2)
High dose vasopressors used - n (%)	12 (18.5)
Oxygen supplementation given - n (%)	27 (41.5)
Patient intubated - n (%)	7 (10.8)
Duration (days)	
n	7
Mean (SD)	10.0 (5.51)
Median	9.0
Min - Max	5 - 19
Patient dialyzed - n (%)	3 (4.6)

	All patients N=65
Duration (days)	
n	3
Mean (SD)	29.3 (27.47)
Median	15.0
Min - Max	12 - 61
Total Parenteral Nutrition (TPN) used - n (%)	21 (32.3)
Duration (days)	
n	21
Mean (SD)	21.2 (25.23)
Median	12.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	13 (20.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	9 (13.8)
Bleeding observed - n (%)	5 (7.7)
Blood product support given for bleeding - n (%)	3 (4.6)
Systemic anti-cytokine therapy given - n (%)	23 (35.4)
Tocilizumab	23 (35.4)
1 dose	16 (24.6)
2 doses	5 (7.7)
3 doses	2 (3.1)
4 doses	0

	All patients N=65
>4 doses	0
Siltuximab	2 (3.1)
Corticosteroids	10 (15.4)
Other	2 (3.1)

Only the first CRS episode is summarized for each patient.

Table 251e
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Response status at study entry
Safety Set

Subgroup: Response status at study entry: Primary refractory

	All patients N=6
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (16.7)
Yes	5 (83.3)
Maximum CRS grade - n(%)	
Grade 1	1 (16.7)
Grade 2	2 (33.3)
Grade 4	2 (33.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	5
Mean (SD)	4.0 (2.74)
Median	2.0
Min - Max	2 - 7
Time to grade 3/4 CRS (days)	
n	2

	All patients N=6
Mean (SD)	3.5 (0.71)
Median	3.5
Min - Max	3 - 4
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	4 (66.7)
Time to high fever onset (days)	
n	4
Mean (SD)	3.5 (2.38)
Median	2.5
Min - Max	2 - 7
Duration (days)	
n	4
Mean (SD)	5.0 (1.41)
Median	4.5
Min - Max	4 - 7
Admitted to ICU - n (%)	2 (33.3)
Time to ICU Admission (days)	
n	2
Mean (SD)	2.5 (0.71)
Median	2.5
Min - Max	2 - 3

	All patients N=6
Duration of ICU stay (days)	
n	2
Mean (SD)	19.0 (11.31)
Median	19.0
Min - Max	11 - 27
Hypotension that required intervention - n (%)	2 (33.3)
High dose vasopressors used - n (%)	2 (33.3)
Oxygen supplementation given - n (%)	2 (33.3)
Patient intubated - n (%)	1 (16.7)
Duration (days)	
n	1
Mean (SD)	19.0
Median	19.0
Min - Max	19 - 19
Patient dialyzed - n (%)	1 (16.7)
Duration (days)	
n	1
Mean (SD)	15.0
Median	15.0
Min - Max	15 - 15
Total Parenteral Nutrition (TPN) used - n (%)	2 (33.3)

	All patients N=6
Duration (days)	
n	2
Mean (SD)	10.5 (7.78)
Median	10.5
Min - Max	5 - 16
Pulmonary abnormalities - n (%)	1 (16.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (33.3)
Bleeding observed - n (%)	1 (16.7)
Blood product support given for bleeding - n (%)	1 (16.7)
Systemic anti-cytokine therapy given - n (%)	2 (33.3)
Tocilizumab	2 (33.3)
1 dose	0
2 doses	1 (16.7)
3 doses	1 (16.7)
4 doses	0
>4 doses	0
Siltuximab	2 (33.3)
Corticosteroids	2 (33.3)
Other	1 (16.7)

Only the first CRS episode is summarized for each patient.

Table 251e
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Response status at study entry
Safety Set

Subgroup: Response status at study entry: Relapsed disease

	All patients N=74
Cytokine Release Syndrome (CRS) - n (%)	
No	18 (24.3)
Yes	56 (75.7)
Maximum CRS grade - n(%)	
Grade 1	4 (5.4)
Grade 2	16 (21.6)
Grade 3	17 (23.0)
Grade 4	19 (25.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	56
Mean (SD)	3.9 (3.42)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=74
n	36
Mean (SD)	7.0 (5.21)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (16.2)
Blood	7 (9.5)
Cns	1 (1.4)
GI	2 (2.7)
Lung	2 (2.7)
Other	2 (2.7)
Skin	1 (1.4)
High fevers during CRS - n (%)	54 (73.0)
Time to high fever onset (days)	
n	54
Mean (SD)	4.2 (3.51)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	54
Mean (SD)	7.6 (6.40)
Median	6.0

	All patients N=74
Min - Max	1 - 36
Admitted to ICU - n (%)	36 (48.6)
Time to ICU Admission (days)	
n	36
Mean (SD)	7.2 (4.79)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	36
Mean (SD)	10.7 (12.13)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	40 (54.1)
High dose vasopressors used - n (%)	17 (23.0)
Oxygen supplementation given - n (%)	33 (44.6)
Patient intubated - n (%)	11 (14.9)
Duration (days)	
n	11
Mean (SD)	7.6 (3.35)
Median	6.0
Min - Max	4 - 14

	All patients N=74
Patient dialyzed - n (%)	7 (9.5)
Duration (days)	
n	7
Mean (SD)	17.1 (20.38)
Median	8.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	27 (36.5)
Duration (days)	
n	27
Mean (SD)	19.8 (22.55)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	16 (21.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	11 (14.9)
Bleeding observed - n (%)	7 (9.5)
Blood product support given for bleeding - n (%)	5 (6.8)
Systemic anti-cytokine therapy given - n (%)	29 (39.2)
Tocilizumab	29 (39.2)
1 dose	18 (24.3)
2 doses	9 (12.2)
3 doses	2 (2.7)

	All patients N=74
4 doses	0
>4 doses	0
Siltuximab	3 (4.1)
Corticosteroids	15 (20.3)
Other	1 (1.4)

Only the first CRS episode is summarized for each patient.

Table 251f
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Philadelphia chromosome/BCR-ABL
Safety Set

Subgroup: Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2
Cytokine Release Syndrome (CRS) - n (%)	
Yes	2 (100)
Maximum CRS grade - n(%)	
Grade 3	1 (50.0)
Grade 4	1 (50.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	2
Mean (SD)	1.0 (0.00)
Median	1.0
Min - Max	1 - 1
Time to grade 3/4 CRS (days)	
n	2
Mean (SD)	3.5 (2.12)

	All patients N=2
Median	3.5
Min - Max	2 - 5
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	2 (100.0)
Time to high fever onset (days)	
n	2
Mean (SD)	1.0 (0.00)
Median	1.0
Min - Max	1 - 1
Duration (days)	
n	2
Mean (SD)	5.0 (1.41)
Median	5.0
Min - Max	4 - 6
Admitted to ICU - n (%)	2 (100.0)
Time to ICU Admission (days)	
n	2
Mean (SD)	4.0 (2.83)
Median	4.0
Min - Max	2 - 6
Duration of ICU stay (days)	

	All patients N=2
n	2
Mean (SD)	9.0 (4.24)
Median	9.0
Min - Max	6 - 12
Hypotension that required intervention - n (%)	2 (100.0)
High dose vasopressors used - n (%)	2 (100.0)
Oxygen supplementation given - n (%)	2 (100.0)
Patient intubated - n (%)	1 (50.0)
Duration (days)	
n	1
Mean (SD)	6.0
Median	6.0
Min - Max	6 - 6
Patient dialyzed - n (%)	1 (50.0)
Duration (days)	
n	1
Mean (SD)	8.0
Median	8.0
Min - Max	8 - 8
Total Parenteral Nutrition (TPN) used - n (%)	2 (100.0)
Duration (days)	

	All patients N=2
n	2
Mean (SD)	10.0 (5.66)
Median	10.0
Min - Max	6 - 14
Pulmonary abnormalities - n (%)	2 (100.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	2 (100.0)
Tocilizumab	2 (100.0)
1 dose	1 (50.0)
2 doses	1 (50.0)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	2 (100.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251f
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Philadelphia chromosome/BCR-ABL
Safety Set

Subgroup: Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78
Cytokine Release Syndrome (CRS) - n (%)	
No	19 (24.4)
Yes	59 (75.6)
Maximum CRS grade - n(%)	
Grade 1	5 (6.4)
Grade 2	18 (23.1)
Grade 3	16 (20.5)
Grade 4	20 (25.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	59
Mean (SD)	4.0 (3.36)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=78
n	36
Mean (SD)	7.0 (5.20)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (15.4)
Blood	7 (9.0)
Cns	1 (1.3)
GI	2 (2.6)
Lung	2 (2.6)
Other	2 (2.6)
Skin	1 (1.3)
High fevers during CRS - n (%)	56 (71.8)
Time to high fever onset (days)	
n	56
Mean (SD)	4.3 (3.44)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	56
Mean (SD)	7.6 (6.31)
Median	6.0

	All patients N=78
Min - Max	1 - 36
Admitted to ICU - n (%)	36 (46.2)
Time to ICU Admission (days)	
n	36
Mean (SD)	7.1 (4.84)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	36
Mean (SD)	11.2 (12.40)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	40 (51.3)
High dose vasopressors used - n (%)	17 (21.8)
Oxygen supplementation given - n (%)	33 (42.3)
Patient intubated - n (%)	11 (14.1)
Duration (days)	
n	11
Mean (SD)	8.8 (4.73)
Median	8.0
Min - Max	4 - 19

	All patients N=78
Patient dialyzed - n (%)	7 (9.0)
Duration (days)	
n	7
Mean (SD)	18.1 (20.02)
Median	12.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	27 (34.6)
Duration (days)	
n	27
Mean (SD)	19.8 (22.56)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	15 (19.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	13 (16.7)
Bleeding observed - n (%)	8 (10.3)
Blood product support given for bleeding - n (%)	6 (7.7)
Systemic anti-cytokine therapy given - n (%)	29 (37.2)
Tocilizumab	29 (37.2)
1 dose	17 (21.8)
2 doses	9 (11.5)
3 doses	3 (3.8)

	All patients N=78
4 doses	0
>4 doses	0
Siltuximab	5 (6.4)
Corticosteroids	15 (19.2)
Other	2 (2.6)

Only the first CRS episode is summarized for each patient.

Table 251g
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by MLL rearrangement
Safety Set

Subgroup: Mixed-lineage leukemia rearrangement: Yes

	All patients N=1
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (100)
Maximum CRS grade - n(%)	
Fatal - n(%)	0
Time to onset of CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=1
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	0
Time to high fever onset (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration of ICU stay (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	0
Duration (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 251g
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by MLL rearrangement
Safety Set

Subgroup: Mixed-lineage leukemia rearrangement: No

	All patients N=79
Cytokine Release Syndrome (CRS) - n (%)	
No	18 (22.8)
Yes	61 (77.2)
Maximum CRS grade - n(%)	
Grade 1	5 (6.3)
Grade 2	18 (22.8)
Grade 3	17 (21.5)
Grade 4	21 (26.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	61
Mean (SD)	3.9 (3.35)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=79
n	38
Mean (SD)	6.8 (5.13)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (15.2)
Blood	7 (8.9)
Cns	1 (1.3)
GI	2 (2.5)
Lung	2 (2.5)
Other	2 (2.5)
Skin	1 (1.3)
High fevers during CRS - n (%)	58 (73.4)
Time to high fever onset (days)	
n	58
Mean (SD)	4.2 (3.43)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	58
Mean (SD)	7.5 (6.22)
Median	6.0

	All patients N=79
Min - Max	1 - 36
Admitted to ICU - n (%)	38 (48.1)
Time to ICU Admission (days)	
n	38
Mean (SD)	6.9 (4.78)
Median	6.5
Min - Max	2 - 24
Duration of ICU stay (days)	
n	38
Mean (SD)	11.1 (12.09)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	42 (53.2)
High dose vasopressors used - n (%)	19 (24.1)
Oxygen supplementation given - n (%)	35 (44.3)
Patient intubated - n (%)	12 (15.2)
Duration (days)	
n	12
Mean (SD)	8.6 (4.58)
Median	7.0
Min - Max	4 - 19

	All patients N=79
Patient dialyzed - n (%)	8 (10.1)
Duration (days)	
n	8
Mean (SD)	16.9 (18.88)
Median	10.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	29 (36.7)
Duration (days)	
n	29
Mean (SD)	19.1 (21.91)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	17 (21.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	13 (16.5)
Bleeding observed - n (%)	8 (10.1)
Blood product support given for bleeding - n (%)	6 (7.6)
Systemic anti-cytokine therapy given - n (%)	31 (39.2)
Tocilizumab	31 (39.2)
1 dose	18 (22.8)
2 doses	10 (12.7)
3 doses	3 (3.8)

	All patients N=79
4 doses	0
>4 doses	0
Siltuximab	5 (6.3)
Corticosteroids	17 (21.5)
Other	2 (2.5)

Only the first CRS episode is summarized for each patient.

Table 251h
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Hypodiploidy
Safety Set

Subgroup: Hypodiploidy: Yes

	All patients N=1
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (100)
Maximum CRS grade - n(%)	
Fatal - n(%)	0
Time to onset of CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=1
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	0
Time to high fever onset (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration of ICU stay (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	0
Duration (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 251h
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Hypodiploidy
Safety Set

Subgroup: Hypodiploidy: No

	All patients N=79
Cytokine Release Syndrome (CRS) - n (%)	
No	18 (22.8)
Yes	61 (77.2)
Maximum CRS grade - n(%)	
Grade 1	5 (6.3)
Grade 2	18 (22.8)
Grade 3	17 (21.5)
Grade 4	21 (26.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	61
Mean (SD)	3.9 (3.35)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=79
n	38
Mean (SD)	6.8 (5.13)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (15.2)
Blood	7 (8.9)
Cns	1 (1.3)
GI	2 (2.5)
Lung	2 (2.5)
Other	2 (2.5)
Skin	1 (1.3)
High fevers during CRS - n (%)	58 (73.4)
Time to high fever onset (days)	
n	58
Mean (SD)	4.2 (3.43)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	58
Mean (SD)	7.5 (6.22)
Median	6.0

	All patients N=79
Min - Max	1 - 36
Admitted to ICU - n (%)	38 (48.1)
Time to ICU Admission (days)	
n	38
Mean (SD)	6.9 (4.78)
Median	6.5
Min - Max	2 - 24
Duration of ICU stay (days)	
n	38
Mean (SD)	11.1 (12.09)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	42 (53.2)
High dose vasopressors used - n (%)	19 (24.1)
Oxygen supplementation given - n (%)	35 (44.3)
Patient intubated - n (%)	12 (15.2)
Duration (days)	
n	12
Mean (SD)	8.6 (4.58)
Median	7.0
Min - Max	4 - 19

	All patients N=79
Patient dialyzed - n (%)	8 (10.1)
Duration (days)	
n	8
Mean (SD)	16.9 (18.88)
Median	10.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	29 (36.7)
Duration (days)	
n	29
Mean (SD)	19.1 (21.91)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	17 (21.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	13 (16.5)
Bleeding observed - n (%)	8 (10.1)
Blood product support given for bleeding - n (%)	6 (7.6)
Systemic anti-cytokine therapy given - n (%)	31 (39.2)
Tocilizumab	31 (39.2)
1 dose	18 (22.8)
2 doses	10 (12.7)
3 doses	3 (3.8)

	All patients N=79
4 doses	0
>4 doses	0
Siltuximab	5 (6.3)
Corticosteroids	17 (21.5)
Other	2 (2.5)

Only the first CRS episode is summarized for each patient.

Table 251i
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by BCR-ABL1-like
Safety Set

Subgroup: BCR-ABL1-like: Yes

	All patients N=1
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (100)
Maximum CRS grade - n(%)	
Fatal - n(%)	0
Time to onset of CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Time to grade 3/4 CRS (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-

	All patients N=1
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	0
Time to high fever onset (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Admitted to ICU - n (%)	0
Time to ICU Admission (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Duration of ICU stay (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Hypotension that required intervention - n (%)	0
High dose vasopressors used - n (%)	0
Oxygen supplementation given - n (%)	0
Patient intubated - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	0
Duration (days)	
n	-
Mean (SD)	-

	All patients N=1
Median	-
Min - Max	-
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	0
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	0
Tocilizumab	0
1 dose	0
2 doses	0
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	0
Other	0

Only the first CRS episode is summarized for each patient.

Table 251i
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by BCR-ABL1-like
Safety Set

Subgroup: BCR-ABL1-like: No

	All patients N=79
Cytokine Release Syndrome (CRS) - n (%)	
No	18 (22.8)
Yes	61 (77.2)
Maximum CRS grade - n(%)	
Grade 1	5 (6.3)
Grade 2	18 (22.8)
Grade 3	17 (21.5)
Grade 4	21 (26.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	61
Mean (SD)	3.9 (3.35)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=79
n	38
Mean (SD)	6.8 (5.13)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (15.2)
Blood	7 (8.9)
Cns	1 (1.3)
GI	2 (2.5)
Lung	2 (2.5)
Other	2 (2.5)
Skin	1 (1.3)
High fevers during CRS - n (%)	58 (73.4)
Time to high fever onset (days)	
n	58
Mean (SD)	4.2 (3.43)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	58
Mean (SD)	7.5 (6.22)
Median	6.0

	All patients N=79
Min - Max	1 - 36
Admitted to ICU - n (%)	38 (48.1)
Time to ICU Admission (days)	
n	38
Mean (SD)	6.9 (4.78)
Median	6.5
Min - Max	2 - 24
Duration of ICU stay (days)	
n	38
Mean (SD)	11.1 (12.09)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	42 (53.2)
High dose vasopressors used - n (%)	19 (24.1)
Oxygen supplementation given - n (%)	35 (44.3)
Patient intubated - n (%)	12 (15.2)
Duration (days)	
n	12
Mean (SD)	8.6 (4.58)
Median	7.0
Min - Max	4 - 19

	All patients N=79
Patient dialyzed - n (%)	8 (10.1)
Duration (days)	
n	8
Mean (SD)	16.9 (18.88)
Median	10.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	29 (36.7)
Duration (days)	
n	29
Mean (SD)	19.1 (21.91)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	17 (21.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	13 (16.5)
Bleeding observed - n (%)	8 (10.1)
Blood product support given for bleeding - n (%)	6 (7.6)
Systemic anti-cytokine therapy given - n (%)	31 (39.2)
Tocilizumab	31 (39.2)
1 dose	18 (22.8)
2 doses	10 (12.7)
3 doses	3 (3.8)

	All patients N=79
4 doses	0
>4 doses	0
Siltuximab	5 (6.3)
Corticosteroids	17 (21.5)
Other	2 (2.5)

Only the first CRS episode is summarized for each patient.

Table 251j
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Complex Karyotypes
Safety Set

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

	All patients N=27
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (25.9)
Yes	20 (74.1)
Maximum CRS grade - n(%)	
Grade 2	3 (11.1)
Grade 3	8 (29.6)
Grade 4	9 (33.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	20
Mean (SD)	3.5 (2.40)
Median	2.0
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	
n	17

	All patients N=27
Mean (SD)	6.6 (2.85)
Median	6.0
Min - Max	2 - 12
Concurrent infections - n(%)	3 (11.1)
Blood	2 (7.4)
Lung	1 (3.7)
Other	1 (3.7)
High fevers during CRS - n (%)	20 (74.1)
Time to high fever onset (days)	
n	20
Mean (SD)	3.6 (2.52)
Median	2.0
Min - Max	1 - 10
Duration (days)	
n	20
Mean (SD)	7.8 (7.10)
Median	6.0
Min - Max	2 - 36
Admitted to ICU - n (%)	16 (59.3)
Time to ICU Admission (days)	
n	16

	All patients N=27
Mean (SD)	6.7 (3.07)
Median	6.5
Min - Max	2 - 12
Duration of ICU stay (days)	
n	16
Mean (SD)	13.3 (16.89)
Median	7.0
Min - Max	2 - 66
Hypotension that required intervention - n (%)	18 (66.7)
High dose vasopressors used - n (%)	7 (25.9)
Oxygen supplementation given - n (%)	16 (59.3)
Patient intubated - n (%)	6 (22.2)
Duration (days)	
n	6
Mean (SD)	10.8 (5.53)
Median	11.0
Min - Max	5 - 19
Patient dialyzed - n (%)	3 (11.1)
Duration (days)	
n	3
Mean (SD)	29.3 (27.47)

	All patients N=27
Median	15.0
Min - Max	12 - 61
Total Parenteral Nutrition (TPN) used - n (%)	8 (29.6)
Duration (days)	
n	8
Mean (SD)	25.1 (20.00)
Median	21.5
Min - Max	2 - 66
Pulmonary abnormalities - n (%)	6 (22.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	6 (22.2)
Bleeding observed - n (%)	3 (11.1)
Blood product support given for bleeding - n (%)	2 (7.4)
Systemic anti-cytokine therapy given - n (%)	13 (48.1)
Tocilizumab	13 (48.1)
1 dose	8 (29.6)
2 doses	3 (11.1)
3 doses	2 (7.4)
4 doses	0
>4 doses	0
Siltuximab	2 (7.4)
Corticosteroids	6 (22.2)

	All patients N=27
Other	2 (7.4)

Only the first CRS episode is summarized for each patient.

Table 251j
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Complex Karyotypes
Safety Set

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

	All patients N=53
Cytokine Release Syndrome (CRS) - n (%)	
No	12 (22.6)
Yes	41 (77.4)
Maximum CRS grade - n(%)	
Grade 1	5 (9.4)
Grade 2	15 (28.3)
Grade 3	9 (17.0)
Grade 4	12 (22.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	41
Mean (SD)	4.1 (3.74)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=53
n	21
Mean (SD)	7.0 (6.49)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	9 (17.0)
Blood	5 (9.4)
Cns	1 (1.9)
GI	2 (3.8)
Lung	1 (1.9)
Other	1 (1.9)
Skin	1 (1.9)
High fevers during CRS - n (%)	38 (71.7)
Time to high fever onset (days)	
n	38
Mean (SD)	4.5 (3.83)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	38
Mean (SD)	7.3 (5.80)
Median	5.0

	All patients N=53
Min - Max	1 - 25
Admitted to ICU - n (%)	22 (41.5)
Time to ICU Admission (days)	
n	22
Mean (SD)	7.1 (5.78)
Median	6.5
Min - Max	2 - 24
Duration of ICU stay (days)	
n	22
Mean (SD)	9.5 (6.91)
Median	7.5
Min - Max	1 - 29
Hypotension that required intervention - n (%)	24 (45.3)
High dose vasopressors used - n (%)	12 (22.6)
Oxygen supplementation given - n (%)	19 (35.8)
Patient intubated - n (%)	6 (11.3)
Duration (days)	
n	6
Mean (SD)	6.3 (1.86)
Median	6.0
Min - Max	4 - 9

	All patients N=53
Patient dialyzed - n (%)	5 (9.4)
Duration (days)	
n	5
Mean (SD)	9.4 (7.77)
Median	7.0
Min - Max	4 - 23
Total Parenteral Nutrition (TPN) used - n (%)	21 (39.6)
Duration (days)	
n	21
Mean (SD)	16.9 (22.63)
Median	10.0
Min - Max	4 - 111
Pulmonary abnormalities - n (%)	11 (20.8)
Disseminated intravascular coagulation (DIC) observed - n (%)	7 (13.2)
Bleeding observed - n (%)	5 (9.4)
Blood product support given for bleeding - n (%)	4 (7.5)
Systemic anti-cytokine therapy given - n (%)	18 (34.0)
Tocilizumab	18 (34.0)
1 dose	10 (18.9)
2 doses	7 (13.2)
3 doses	1 (1.9)

	All patients N=53
4 doses	0
>4 doses	0
Siltuximab	3 (5.7)
Corticosteroids	11 (20.8)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251k
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Region
Safety Set

Subgroup: Region: Europe

	All patients N=28
Cytokine Release Syndrome (CRS) - n (%)	
No	9 (32.1)
Yes	19 (67.9)
Maximum CRS grade - n(%)	
Grade 2	6 (21.4)
Grade 3	5 (17.9)
Grade 4	8 (28.6)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	19
Mean (SD)	3.4 (2.19)
Median	3.0
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	

	All patients N=28
n	13
Mean (SD)	6.0 (1.96)
Median	6.0
Min - Max	2 - 10
Concurrent infections - n(%)	2 (7.1)
Cns	1 (3.6)
GI	1 (3.6)
Lung	1 (3.6)
High fevers during CRS - n (%)	18 (64.3)
Time to high fever onset (days)	
n	18
Mean (SD)	3.8 (2.20)
Median	3.0
Min - Max	1 - 10
Duration (days)	
n	18
Mean (SD)	4.3 (2.40)
Median	4.0
Min - Max	1 - 10
Admitted to ICU - n (%)	13 (46.4)
Time to ICU Admission (days)	

	All patients N=28
n	13
Mean (SD)	6.2 (2.17)
Median	7.0
Min - Max	2 - 11
Duration of ICU stay (days)	
n	13
Mean (SD)	6.2 (3.91)
Median	6.0
Min - Max	2 - 17
Hypotension that required intervention - n (%)	15 (53.6)
High dose vasopressors used - n (%)	9 (32.1)
Oxygen supplementation given - n (%)	11 (39.3)
Patient intubated - n (%)	2 (7.1)
Duration (days)	
n	2
Mean (SD)	7.0 (2.83)
Median	7.0
Min - Max	5 - 9
Patient dialyzed - n (%)	0
Duration (days)	
n	-

	All patients N=28
Mean (SD)	-
Median	-
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	6 (21.4)
Duration (days)	
n	6
Mean (SD)	10.5 (8.26)
Median	7.5
Min - Max	5 - 27
Pulmonary abnormalities - n (%)	7 (25.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (14.3)
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	9 (32.1)
Tocilizumab	9 (32.1)
1 dose	7 (25.0)
2 doses	1 (3.6)
3 doses	1 (3.6)
4 doses	0
>4 doses	0
Siltuximab	1 (3.6)

	All patients N=28
Corticosteroids	5 (17.9)
Other	1 (3.6)

Only the first CRS episode is summarized for each patient.

Table 251k
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Region
Safety Set

Subgroup: Region: US

	All patients N=45
Cytokine Release Syndrome (CRS) - n (%)	
No	9 (20.0)
Yes	36 (80.0)
Maximum CRS grade - n(%)	
Grade 1	4 (8.9)
Grade 2	12 (26.7)
Grade 3	10 (22.2)
Grade 4	10 (22.2)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	36
Mean (SD)	4.1 (3.94)
Median	2.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=45
n	20
Mean (SD)	7.0 (6.74)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	9 (20.0)
Blood	7 (15.6)
GI	1 (2.2)
Other	2 (4.4)
Skin	1 (2.2)
High fevers during CRS - n (%)	34 (75.6)
Time to high fever onset (days)	
n	34
Mean (SD)	4.4 (4.05)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	34
Mean (SD)	8.2 (5.63)
Median	6.0
Min - Max	2 - 25
Admitted to ICU - n (%)	21 (46.7)

	All patients N=45
Time to ICU Admission (days)	
n	21
Mean (SD)	6.9 (6.09)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	21
Mean (SD)	11.0 (8.08)
Median	9.0
Min - Max	1 - 29
Hypotension that required intervention - n (%)	22 (48.9)
High dose vasopressors used - n (%)	9 (20.0)
Oxygen supplementation given - n (%)	20 (44.4)
Patient intubated - n (%)	7 (15.6)
Duration (days)	
n	7
Mean (SD)	8.1 (5.08)
Median	6.0
Min - Max	4 - 19
Patient dialyzed - n (%)	6 (13.3)
Duration (days)	

	All patients N=45
n	6
Mean (SD)	10.3 (7.31)
Median	7.5
Min - Max	4 - 23
Total Parenteral Nutrition (TPN) used - n (%)	19 (42.2)
Duration (days)	
n	19
Mean (SD)	20.3 (23.52)
Median	14.0
Min - Max	4 - 111
Pulmonary abnormalities - n (%)	10 (22.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	6 (13.3)
Bleeding observed - n (%)	8 (17.8)
Blood product support given for bleeding - n (%)	6 (13.3)
Systemic anti-cytokine therapy given - n (%)	18 (40.0)
Tocilizumab	18 (40.0)
1 dose	10 (22.2)
2 doses	6 (13.3)
3 doses	2 (4.4)
4 doses	0
>4 doses	0

	All patients N=45
Siltuximab	4 (8.9)
Corticosteroids	9 (20.0)
Other	1 (2.2)

Only the first CRS episode is summarized for each patient.

Table 251k
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Region
Safety Set

Subgroup: Region: Rest of World

	All patients N=7
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (14.3)
Yes	6 (85.7)
Maximum CRS grade - n(%)	
Grade 1	1 (14.3)
Grade 3	2 (28.6)
Grade 4	3 (42.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	6
Mean (SD)	4.0 (2.68)
Median	3.5
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=7
n	5
Mean (SD)	8.4 (3.29)
Median	10.0
Min - Max	4 - 12
Concurrent infections - n(%)	1 (14.3)
Lung	1 (14.3)
High fevers during CRS - n (%)	6 (85.7)
Time to high fever onset (days)	
n	6
Mean (SD)	4.0 (2.97)
Median	4.0
Min - Max	1 - 9
Duration (days)	
n	6
Mean (SD)	12.8 (11.70)
Median	9.5
Min - Max	4 - 36
Admitted to ICU - n (%)	4 (57.1)
Time to ICU Admission (days)	
n	4
Mean (SD)	9.3 (2.50)

	All patients N=7
Median	9.5
Min - Max	6 - 12
Duration of ICU stay (days)	
n	4
Mean (SD)	28.0 (28.61)
Median	21.0
Min - Max	4 - 66
Hypotension that required intervention - n (%)	5 (71.4)
High dose vasopressors used - n (%)	1 (14.3)
Oxygen supplementation given - n (%)	4 (57.1)
Patient intubated - n (%)	3 (42.9)
Duration (days)	
n	3
Mean (SD)	10.7 (4.93)
Median	13.0
Min - Max	5 - 14
Patient dialyzed - n (%)	2 (28.6)
Duration (days)	
n	2
Mean (SD)	36.5 (34.65)
Median	36.5

	All patients N=7
Min - Max	12 - 61
Total Parenteral Nutrition (TPN) used - n (%)	4 (57.1)
Duration (days)	
n	4
Mean (SD)	26.8 (28.51)
Median	19.5
Min - Max	2 - 66
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (42.9)
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	4 (57.1)
Tocilizumab	4 (57.1)
1 dose	1 (14.3)
2 doses	3 (42.9)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	3 (42.9)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251l
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Prior SCT therapy
Safety Set

Subgroup: Prior SCT therapy: Yes

	All patients N=48
Cytokine Release Syndrome (CRS) - n (%)	
No	11 (22.9)
Yes	37 (77.1)
Maximum CRS grade - n(%)	
Grade 1	3 (6.3)
Grade 2	11 (22.9)
Grade 3	12 (25.0)
Grade 4	11 (22.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	37
Mean (SD)	3.8 (3.72)
Median	3.0
Min - Max	1 - 22

	All patients N=48
Time to grade 3/4 CRS (days)	
n	23
Mean (SD)	7.3 (6.11)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	8 (16.7)
Blood	3 (6.3)
Cns	1 (2.1)
GI	2 (4.2)
Lung	2 (4.2)
Other	1 (2.1)
Skin	1 (2.1)
High fevers during CRS - n (%)	35 (72.9)
Time to high fever onset (days)	
n	35
Mean (SD)	4.2 (3.80)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	35
Mean (SD)	7.5 (6.70)

	All patients N=48
Median	6.0
Min - Max	1 - 36
Admitted to ICU - n (%)	23 (47.9)
Time to ICU Admission (days)	
n	23
Mean (SD)	7.2 (4.16)
Median	7.0
Min - Max	2 - 22
Duration of ICU stay (days)	
n	23
Mean (SD)	7.6 (6.95)
Median	6.0
Min - Max	1 - 34
Hypotension that required intervention - n (%)	26 (54.2)
High dose vasopressors used - n (%)	11 (22.9)
Oxygen supplementation given - n (%)	22 (45.8)
Patient intubated - n (%)	5 (10.4)
Duration (days)	
n	5
Mean (SD)	7.8 (3.83)
Median	6.0

	All patients N=48
Min - Max	5 - 14
Patient dialyzed - n (%)	2 (4.2)
Duration (days)	
n	2
Mean (SD)	10.0 (2.83)
Median	10.0
Min - Max	8 - 12
Total Parenteral Nutrition (TPN) used - n (%)	15 (31.3)
Duration (days)	
n	15
Mean (SD)	13.4 (8.62)
Median	10.0
Min - Max	2 - 29
Pulmonary abnormalities - n (%)	10 (20.8)
Disseminated intravascular coagulation (DIC) observed - n (%)	5 (10.4)
Bleeding observed - n (%)	2 (4.2)
Blood product support given for bleeding - n (%)	1 (2.1)
Systemic anti-cytokine therapy given - n (%)	17 (35.4)
Tocilizumab	17 (35.4)
1 dose	13 (27.1)
2 doses	3 (6.3)

	All patients N=48
3 doses	1 (2.1)
4 doses	0
>4 doses	0
Siltuximab	1 (2.1)
Corticosteroids	7 (14.6)
Other	1 (2.1)

Only the first CRS episode is summarized for each patient.

Table 251l
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Prior SCT therapy
Safety Set

Subgroup: Prior SCT therapy: No

	All patients N=32
Cytokine Release Syndrome (CRS) - n (%)	
No	8 (25.0)
Yes	24 (75.0)
Maximum CRS grade - n(%)	
Grade 1	2 (6.3)
Grade 2	7 (21.9)
Grade 3	5 (15.6)
Grade 4	10 (31.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	24
Mean (SD)	4.0 (2.74)
Median	3.0
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=32
n	15
Mean (SD)	6.0 (3.12)
Median	6.0
Min - Max	2 - 11
Concurrent infections - n(%)	4 (12.5)
Blood	4 (12.5)
Other	1 (3.1)
High fevers during CRS - n (%)	23 (71.9)
Time to high fever onset (days)	
n	23
Mean (SD)	4.2 (2.87)
Median	3.0
Min - Max	1 - 9
Duration (days)	
n	23
Mean (SD)	7.5 (5.55)
Median	6.0
Min - Max	1 - 25
Admitted to ICU - n (%)	15 (46.9)
Time to ICU Admission (days)	
n	15

	All patients N=32
Mean (SD)	6.5 (5.73)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	15
Mean (SD)	16.5 (16.07)
Median	11.0
Min - Max	2 - 66
Hypotension that required intervention - n (%)	16 (50.0)
High dose vasopressors used - n (%)	8 (25.0)
Oxygen supplementation given - n (%)	13 (40.6)
Patient intubated - n (%)	7 (21.9)
Duration (days)	
n	7
Mean (SD)	9.1 (5.27)
Median	8.0
Min - Max	4 - 19
Patient dialyzed - n (%)	6 (18.8)
Duration (days)	
n	6
Mean (SD)	19.2 (21.73)

	All patients N=32
Median	11.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	14 (43.8)
Duration (days)	
n	14
Mean (SD)	25.3 (29.59)
Median	12.5
Min - Max	5 - 111
Pulmonary abnormalities - n (%)	7 (21.9)
Disseminated intravascular coagulation (DIC) observed - n (%)	8 (25.0)
Bleeding observed - n (%)	6 (18.8)
Blood product support given for bleeding - n (%)	5 (15.6)
Systemic anti-cytokine therapy given - n (%)	14 (43.8)
Tocilizumab	14 (43.8)
1 dose	5 (15.6)
2 doses	7 (21.9)
3 doses	2 (6.3)
4 doses	0
>4 doses	0
Siltuximab	4 (12.5)
Corticosteroids	10 (31.3)

	All patients N=32
Other	1 (3.1)

Only the first CRS episode is summarized for each patient.

Table 251m
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Eligibility for SCT
Safety Set

Subgroup: Eligibility for SCT: Yes

	All patients N=13
Cytokine Release Syndrome (CRS) - n (%)	
No	2 (15.4)
Yes	11 (84.6)
Maximum CRS grade - n(%)	
Grade 2	5 (38.5)
Grade 3	5 (38.5)
Grade 4	1 (7.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	11
Mean (SD)	3.5 (2.42)
Median	3.0
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	
n	6

	All patients N=13
Mean (SD)	7.5 (2.35)
Median	7.5
Min - Max	4 - 10
Concurrent infections - n(%)	2 (15.4)
GI	1 (7.7)
Lung	1 (7.7)
High fevers during CRS - n (%)	11 (84.6)
Time to high fever onset (days)	
n	11
Mean (SD)	3.5 (2.66)
Median	3.0
Min - Max	1 - 9
Duration (days)	
n	11
Mean (SD)	9.0 (9.42)
Median	6.0
Min - Max	2 - 36
Admitted to ICU - n (%)	6 (46.2)
Time to ICU Admission (days)	
n	6
Mean (SD)	8.3 (1.63)

	All patients N=13
Median	8.5
Min - Max	6 - 10
Duration of ICU stay (days)	
n	6
Mean (SD)	9.0 (12.33)
Median	4.5
Min - Max	2 - 34
Hypotension that required intervention - n (%)	6 (46.2)
High dose vasopressors used - n (%)	1 (7.7)
Oxygen supplementation given - n (%)	5 (38.5)
Patient intubated - n (%)	1 (7.7)
Duration (days)	
n	1
Mean (SD)	14.0
Median	14.0
Min - Max	14 - 14
Patient dialyzed - n (%)	1 (7.7)
Duration (days)	
n	1
Mean (SD)	12.0
Median	12.0

	All patients N=13
Min - Max	12 - 12
Total Parenteral Nutrition (TPN) used - n (%)	5 (38.5)
Duration (days)	
n	5
Mean (SD)	16.2 (10.78)
Median	12.0
Min - Max	4 - 29
Pulmonary abnormalities - n (%)	0
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (15.4)
Bleeding observed - n (%)	1 (7.7)
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	5 (38.5)
Tocilizumab	5 (38.5)
1 dose	3 (23.1)
2 doses	2 (15.4)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	2 (15.4)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251m
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Eligibility for SCT
Safety Set

Subgroup: Eligibility for SCT: No

	All patients N=67
Cytokine Release Syndrome (CRS) - n (%)	
No	17 (25.4)
Yes	50 (74.6)
Maximum CRS grade - n(%)	
Grade 1	5 (7.5)
Grade 2	13 (19.4)
Grade 3	12 (17.9)
Grade 4	20 (29.9)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	50
Mean (SD)	4.0 (3.53)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=67
n	32
Mean (SD)	6.7 (5.52)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	10 (14.9)
Blood	7 (10.4)
Cns	1 (1.5)
GI	1 (1.5)
Lung	1 (1.5)
Other	2 (3.0)
Skin	1 (1.5)
High fevers during CRS - n (%)	47 (70.1)
Time to high fever onset (days)	
n	47
Mean (SD)	4.3 (3.60)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	47
Mean (SD)	7.1 (5.28)
Median	5.0

	All patients N=67
Min - Max	1 - 25
Admitted to ICU - n (%)	32 (47.8)
Time to ICU Admission (days)	
n	32
Mean (SD)	6.7 (5.13)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	32
Mean (SD)	11.5 (12.20)
Median	8.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	36 (53.7)
High dose vasopressors used - n (%)	18 (26.9)
Oxygen supplementation given - n (%)	30 (44.8)
Patient intubated - n (%)	11 (16.4)
Duration (days)	
n	11
Mean (SD)	8.1 (4.46)
Median	6.0
Min - Max	4 - 19

	All patients N=67
Patient dialyzed - n (%)	7 (10.4)
Duration (days)	
n	7
Mean (SD)	17.6 (20.28)
Median	8.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	24 (35.8)
Duration (days)	
n	24
Mean (SD)	19.8 (23.71)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	17 (25.4)
Disseminated intravascular coagulation (DIC) observed - n (%)	11 (16.4)
Bleeding observed - n (%)	7 (10.4)
Blood product support given for bleeding - n (%)	6 (9.0)
Systemic anti-cytokine therapy given - n (%)	26 (38.8)
Tocilizumab	26 (38.8)
1 dose	15 (22.4)
2 doses	8 (11.9)
3 doses	3 (4.5)

	All patients N=67
4 doses	0
>4 doses	0
Siltuximab	5 (7.5)
Corticosteroids	15 (22.4)
Other	2 (3.0)

Only the first CRS episode is summarized for each patient.

Table 251n
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Baseline bone marrow tumor burden
Safety Set

Subgroup: Baseline bone marrow tumor burden: Low

	All patients N=26
Cytokine Release Syndrome (CRS) - n (%)	
No	8 (30.8)
Yes	18 (69.2)
Maximum CRS grade - n(%)	
Grade 1	3 (11.5)
Grade 2	8 (30.8)
Grade 3	3 (11.5)
Grade 4	4 (15.4)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	18
Mean (SD)	4.3 (2.67)
Median	3.5
Min - Max	1 - 9

	All patients N=26
Time to grade 3/4 CRS (days)	
n	7
Mean (SD)	5.0 (2.94)
Median	5.0
Min - Max	2 - 10
Concurrent infections - n(%)	2 (7.7)
Blood	2 (7.7)
Other	1 (3.8)
High fevers during CRS - n (%)	16 (61.5)
Time to high fever onset (days)	
n	16
Mean (SD)	4.6 (2.90)
Median	5.0
Min - Max	1 - 9
Duration (days)	
n	16
Mean (SD)	4.3 (1.48)
Median	4.0
Min - Max	1 - 7
Admitted to ICU - n (%)	7 (26.9)
Time to ICU Admission (days)	

	All patients N=26
n	7
Mean (SD)	5.1 (3.18)
Median	6.0
Min - Max	2 - 10
Duration of ICU stay (days)	
n	7
Mean (SD)	10.4 (7.72)
Median	8.0
Min - Max	4 - 27
Hypotension that required intervention - n (%)	9 (34.6)
High dose vasopressors used - n (%)	5 (19.2)
Oxygen supplementation given - n (%)	7 (26.9)
Patient intubated - n (%)	3 (11.5)
Duration (days)	
n	3
Mean (SD)	9.7 (8.14)
Median	6.0
Min - Max	4 - 19
Patient dialyzed - n (%)	2 (7.7)
Duration (days)	
n	2

	All patients N=26
Mean (SD)	11.5 (4.95)
Median	11.5
Min - Max	8 - 15
Total Parenteral Nutrition (TPN) used - n (%)	9 (34.6)
Duration (days)	
n	9
Mean (SD)	10.3 (5.59)
Median	10.0
Min - Max	4 - 19
Pulmonary abnormalities - n (%)	5 (19.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (15.4)
Bleeding observed - n (%)	2 (7.7)
Blood product support given for bleeding - n (%)	2 (7.7)
Systemic anti-cytokine therapy given - n (%)	6 (23.1)
Tocilizumab	6 (23.1)
1 dose	3 (11.5)
2 doses	2 (7.7)
3 doses	1 (3.8)
4 doses	0
>4 doses	0
Siltuximab	1 (3.8)

	All patients N=26
Corticosteroids	5 (19.2)
Other	1 (3.8)

Only the first CRS episode is summarized for each patient.

Table 251n
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Baseline bone marrow tumor burden
Safety Set

Subgroup: Baseline bone marrow tumor burden: High

	All patients N=54
Cytokine Release Syndrome (CRS) - n (%)	
No	11 (20.4)
Yes	43 (79.6)
Maximum CRS grade - n(%)	
Grade 1	2 (3.7)
Grade 2	10 (18.5)
Grade 3	14 (25.9)
Grade 4	17 (31.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	43
Mean (SD)	3.7 (3.61)
Median	2.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=54
n	31
Mean (SD)	7.2 (5.46)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	10 (18.5)
Blood	5 (9.3)
Cns	1 (1.9)
GI	2 (3.7)
Lung	2 (3.7)
Other	1 (1.9)
Skin	1 (1.9)
High fevers during CRS - n (%)	42 (77.8)
Time to high fever onset (days)	
n	42
Mean (SD)	4.0 (3.64)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	42
Mean (SD)	8.7 (6.88)
Median	6.0

	All patients N=54
Min - Max	1 - 36
Admitted to ICU - n (%)	31 (57.4)
Time to ICU Admission (days)	
n	31
Mean (SD)	7.3 (5.02)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	31
Mean (SD)	11.3 (12.97)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	33 (61.1)
High dose vasopressors used - n (%)	14 (25.9)
Oxygen supplementation given - n (%)	28 (51.9)
Patient intubated - n (%)	9 (16.7)
Duration (days)	
n	9
Mean (SD)	8.2 (3.42)
Median	8.0
Min - Max	5 - 14

	All patients N=54
Patient dialyzed - n (%)	6 (11.1)
Duration (days)	
n	6
Mean (SD)	18.7 (21.88)
Median	9.5
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	20 (37.0)
Duration (days)	
n	20
Mean (SD)	23.1 (25.32)
Median	11.5
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	12 (22.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	9 (16.7)
Bleeding observed - n (%)	6 (11.1)
Blood product support given for bleeding - n (%)	4 (7.4)
Systemic anti-cytokine therapy given - n (%)	25 (46.3)
Tocilizumab	25 (46.3)
1 dose	15 (27.8)
2 doses	8 (14.8)
3 doses	2 (3.7)

	All patients N=54
4 doses	0
>4 doses	0
Siltuximab	4 (7.4)
Corticosteroids	12 (22.2)
Other	1 (1.9)

Only the first CRS episode is summarized for each patient.

Table 251o
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Baseline extramedullary disease presence
Safety Set

Subgroup: Baseline extramedullary disease presence: Yes

	All patients N=11
Cytokine Release Syndrome (CRS) - n (%)	
No	5 (45.5)
Yes	6 (54.5)
Maximum CRS grade - n(%)	
Grade 1	1 (9.1)
Grade 2	3 (27.3)
Grade 3	1 (9.1)
Grade 4	1 (9.1)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	6
Mean (SD)	2.2 (0.75)
Median	2.0
Min - Max	1 - 3

	All patients N=11
Time to grade 3/4 CRS (days)	
n	2
Mean (SD)	4.0 (2.83)
Median	4.0
Min - Max	2 - 6
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	6 (54.5)
Time to high fever onset (days)	
n	6
Mean (SD)	2.5 (1.38)
Median	2.0
Min - Max	1 - 5
Duration (days)	
n	6
Mean (SD)	6.5 (2.35)
Median	6.5
Min - Max	4 - 10
Admitted to ICU - n (%)	3 (27.3)
Time to ICU Admission (days)	
n	3
Mean (SD)	5.0 (2.65)

	All patients N=11
Median	6.0
Min - Max	2 - 7
Duration of ICU stay (days)	
n	3
Mean (SD)	8.3 (7.77)
Median	6.0
Min - Max	2 - 17
Hypotension that required intervention - n (%)	3 (27.3)
High dose vasopressors used - n (%)	2 (18.2)
Oxygen supplementation given - n (%)	2 (18.2)
Patient intubated - n (%)	1 (9.1)
Duration (days)	
n	1
Mean (SD)	9.0
Median	9.0
Min - Max	9 - 9
Patient dialyzed - n (%)	0
Duration (days)	
n	-
Mean (SD)	-
Median	-

	All patients N=11
Min - Max	-
Total Parenteral Nutrition (TPN) used - n (%)	2 (18.2)
Duration (days)	
n	2
Mean (SD)	16.5 (14.85)
Median	16.5
Min - Max	6 - 27
Pulmonary abnormalities - n (%)	2 (18.2)
Disseminated intravascular coagulation (DIC) observed - n (%)	1 (9.1)
Bleeding observed - n (%)	0
Blood product support given for bleeding - n (%)	0
Systemic anti-cytokine therapy given - n (%)	2 (18.2)
Tocilizumab	2 (18.2)
1 dose	1 (9.1)
2 doses	0
3 doses	1 (9.1)
4 doses	0
>4 doses	0
Siltuximab	1 (9.1)
Corticosteroids	2 (18.2)
Other	1 (9.1)

Only the first CRS episode is summarized for each patient.

Table 251o
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Baseline extramedullary disease presence
Safety Set

Subgroup: Baseline extramedullary disease presence: No

	All patients N=69
Cytokine Release Syndrome (CRS) - n (%)	
No	14 (20.3)
Yes	55 (79.7)
Maximum CRS grade - n(%)	
Grade 1	4 (5.8)
Grade 2	15 (21.7)
Grade 3	16 (23.2)
Grade 4	20 (29.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	55
Mean (SD)	4.1 (3.47)
Median	3.0
Min - Max	1 - 22

	All patients N=69
Time to grade 3/4 CRS (days)	
n	36
Mean (SD)	7.0 (5.21)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	12 (17.4)
Blood	7 (10.1)
Cns	1 (1.4)
GI	2 (2.9)
Lung	2 (2.9)
Other	2 (2.9)
Skin	1 (1.4)
High fevers during CRS - n (%)	52 (75.4)
Time to high fever onset (days)	
n	52
Mean (SD)	4.4 (3.55)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	52
Mean (SD)	7.6 (6.52)

	All patients N=69
Median	5.5
Min - Max	1 - 36
Admitted to ICU - n (%)	35 (50.7)
Time to ICU Admission (days)	
n	35
Mean (SD)	7.1 (4.91)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	35
Mean (SD)	11.3 (12.44)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	39 (56.5)
High dose vasopressors used - n (%)	17 (24.6)
Oxygen supplementation given - n (%)	33 (47.8)
Patient intubated - n (%)	11 (15.9)
Duration (days)	
n	11
Mean (SD)	8.5 (4.80)
Median	6.0

	All patients N=69
Min - Max	4 - 19
Patient dialyzed - n (%)	8 (11.6)
Duration (days)	
n	8
Mean (SD)	16.9 (18.88)
Median	10.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	27 (39.1)
Duration (days)	
n	27
Mean (SD)	19.3 (22.54)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	15 (21.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	12 (17.4)
Bleeding observed - n (%)	8 (11.6)
Blood product support given for bleeding - n (%)	6 (8.7)
Systemic anti-cytokine therapy given - n (%)	29 (42.0)
Tocilizumab	29 (42.0)
1 dose	17 (24.6)
2 doses	10 (14.5)

	All patients N=69
3 doses	2 (2.9)
4 doses	0
>4 doses	0
Siltuximab	4 (5.8)
Corticosteroids	15 (21.7)
Other	1 (1.4)

Only the first CRS episode is summarized for each patient.

Table 251p
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Down syndrome
Safety Set

Subgroup: Down syndrome: Yes

	All patients N=6
Cytokine Release Syndrome (CRS) - n (%)	
Yes	6 (100)
Maximum CRS grade - n(%)	
Grade 1	2 (33.3)
Grade 2	1 (16.7)
Grade 4	3 (50.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	6
Mean (SD)	4.8 (2.64)
Median	4.0
Min - Max	2 - 9
Time to grade 3/4 CRS (days)	
n	3
Mean (SD)	6.3 (4.04)

	All patients N=6
Median	7.0
Min - Max	2 - 10
Concurrent infections - n(%)	1 (16.7)
Blood	1 (16.7)
High fevers during CRS - n (%)	5 (83.3)
Time to high fever onset (days)	
n	5
Mean (SD)	4.2 (3.11)
Median	4.0
Min - Max	1 - 9
Duration (days)	
n	5
Mean (SD)	7.0 (3.46)
Median	6.0
Min - Max	4 - 12
Admitted to ICU - n (%)	3 (50.0)
Time to ICU Admission (days)	
n	3
Mean (SD)	5.7 (3.51)
Median	6.0
Min - Max	2 - 9

	All patients N=6
Duration of ICU stay (days)	
n	3
Mean (SD)	20.0 (12.49)
Median	16.0
Min - Max	10 - 34
Hypotension that required intervention - n (%)	4 (66.7)
High dose vasopressors used - n (%)	3 (50.0)
Oxygen supplementation given - n (%)	3 (50.0)
Patient intubated - n (%)	2 (33.3)
Duration (days)	
n	2
Mean (SD)	11.5 (3.54)
Median	11.5
Min - Max	9 - 14
Patient dialyzed - n (%)	2 (33.3)
Duration (days)	
n	2
Mean (SD)	8.0 (5.66)
Median	8.0
Min - Max	4 - 12
Total Parenteral Nutrition (TPN) used - n (%)	3 (50.0)

	All patients N=6
Duration (days)	
n	3
Mean (SD)	25.0 (14.42)
Median	29.0
Min - Max	9 - 37
Pulmonary abnormalities - n (%)	1 (16.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (33.3)
Bleeding observed - n (%)	2 (33.3)
Blood product support given for bleeding - n (%)	2 (33.3)
Systemic anti-cytokine therapy given - n (%)	3 (50.0)
Tocilizumab	3 (50.0)
1 dose	1 (16.7)
2 doses	2 (33.3)
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	1 (16.7)
Corticosteroids	2 (33.3)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251p
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Down syndrome
Safety Set

Subgroup: Down syndrome: No

	All patients N=74
Cytokine Release Syndrome (CRS) - n (%)	
No	19 (25.7)
Yes	55 (74.3)
Maximum CRS grade - n(%)	
Grade 1	3 (4.1)
Grade 2	17 (23.0)
Grade 3	17 (23.0)
Grade 4	18 (24.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	55
Mean (SD)	3.8 (3.42)
Median	2.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=74
n	35
Mean (SD)	6.9 (5.26)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	11 (14.9)
Blood	6 (8.1)
Cns	1 (1.4)
GI	2 (2.7)
Lung	2 (2.7)
Other	2 (2.7)
Skin	1 (1.4)
High fevers during CRS - n (%)	53 (71.6)
Time to high fever onset (days)	
n	53
Mean (SD)	4.2 (3.49)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	53
Mean (SD)	7.5 (6.44)
Median	6.0

	All patients N=74
Min - Max	1 - 36
Admitted to ICU - n (%)	35 (47.3)
Time to ICU Admission (days)	
n	35
Mean (SD)	7.0 (4.90)
Median	7.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	35
Mean (SD)	10.3 (11.93)
Median	7.0
Min - Max	1 - 66
Hypotension that required intervention - n (%)	38 (51.4)
High dose vasopressors used - n (%)	16 (21.6)
Oxygen supplementation given - n (%)	32 (43.2)
Patient intubated - n (%)	10 (13.5)
Duration (days)	
n	10
Mean (SD)	8.0 (4.69)
Median	6.0
Min - Max	4 - 19

	All patients N=74
Patient dialyzed - n (%)	6 (8.1)
Duration (days)	
n	6
Mean (SD)	19.8 (21.23)
Median	11.5
Min - Max	5 - 61
Total Parenteral Nutrition (TPN) used - n (%)	26 (35.1)
Duration (days)	
n	26
Mean (SD)	18.5 (22.73)
Median	11.0
Min - Max	2 - 111
Pulmonary abnormalities - n (%)	16 (21.6)
Disseminated intravascular coagulation (DIC) observed - n (%)	11 (14.9)
Bleeding observed - n (%)	6 (8.1)
Blood product support given for bleeding - n (%)	4 (5.4)
Systemic anti-cytokine therapy given - n (%)	28 (37.8)
Tocilizumab	28 (37.8)
1 dose	17 (23.0)
2 doses	8 (10.8)
3 doses	3 (4.1)

	All patients N=74
4 doses	0
>4 doses	0
Siltuximab	4 (5.4)
Corticosteroids	15 (20.3)
Other	2 (2.7)

Only the first CRS episode is summarized for each patient.

Table 251q
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Time since enrollment to CTL019 infusion
Safety Set

Subgroup: Time since enrollment to CTL019 infusion: > Median

	All patients N=40
Cytokine Release Syndrome (CRS) - n (%)	
No	9 (22.5)
Yes	31 (77.5)
Maximum CRS grade - n(%)	
Grade 1	3 (7.5)
Grade 2	8 (20.0)
Grade 3	10 (25.0)
Grade 4	10 (25.0)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	31
Mean (SD)	3.7 (3.83)
Median	3.0
Min - Max	1 - 22
Time to grade 3/4 CRS (days)	

	All patients N=40
n	20
Mean (SD)	7.5 (6.53)
Median	6.0
Min - Max	2 - 33
Concurrent infections - n(%)	6 (15.0)
Blood	2 (5.0)
Cns	1 (2.5)
GI	1 (2.5)
Lung	2 (5.0)
Other	1 (2.5)
Skin	1 (2.5)
High fevers during CRS - n (%)	29 (72.5)
Time to high fever onset (days)	
n	29
Mean (SD)	4.1 (3.92)
Median	3.0
Min - Max	1 - 22
Duration (days)	
n	29
Mean (SD)	7.6 (7.30)
Median	5.0

	All patients N=40
Min - Max	1 - 36
Admitted to ICU - n (%)	19 (47.5)
Time to ICU Admission (days)	
n	19
Mean (SD)	7.1 (4.43)
Median	7.0
Min - Max	2 - 22
Duration of ICU stay (days)	
n	19
Mean (SD)	10.6 (15.18)
Median	6.0
Min - Max	2 - 66
Hypotension that required intervention - n (%)	21 (52.5)
High dose vasopressors used - n (%)	9 (22.5)
Oxygen supplementation given - n (%)	17 (42.5)
Patient intubated - n (%)	4 (10.0)
Duration (days)	
n	4
Mean (SD)	9.3 (4.92)
Median	9.0
Min - Max	5 - 14

	All patients N=40
Patient dialyzed - n (%)	2 (5.0)
Duration (days)	
n	2
Mean (SD)	36.5 (34.65)
Median	36.5
Min - Max	12 - 61
Total Parenteral Nutrition (TPN) used - n (%)	12 (30.0)
Duration (days)	
n	12
Mean (SD)	15.8 (17.52)
Median	9.5
Min - Max	2 - 66
Pulmonary abnormalities - n (%)	7 (17.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	7 (17.5)
Bleeding observed - n (%)	2 (5.0)
Blood product support given for bleeding - n (%)	1 (2.5)
Systemic anti-cytokine therapy given - n (%)	15 (37.5)
Tocilizumab	15 (37.5)
1 dose	11 (27.5)
2 doses	4 (10.0)
3 doses	0

	All patients N=40
4 doses	0
>4 doses	0
Siltuximab	1 (2.5)
Corticosteroids	8 (20.0)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251q
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Time since enrollment to CTL019 infusion
Safety Set

Subgroup: Time since enrollment to CTL019 infusion: <=Median

	All patients N=40
Cytokine Release Syndrome (CRS) - n (%)	
No	10 (25.0)
Yes	30 (75.0)
Maximum CRS grade - n(%)	
Grade 1	2 (5.0)
Grade 2	10 (25.0)
Grade 3	7 (17.5)
Grade 4	11 (27.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	30
Mean (SD)	4.1 (2.82)
Median	3.0
Min - Max	1 - 10
Time to grade 3/4 CRS (days)	

	All patients N=40
n	18
Mean (SD)	6.1 (2.95)
Median	6.5
Min - Max	2 - 11
Concurrent infections - n(%)	6 (15.0)
Blood	5 (12.5)
GI	1 (2.5)
Other	1 (2.5)
High fevers during CRS - n (%)	29 (72.5)
Time to high fever onset (days)	
n	29
Mean (SD)	4.2 (2.94)
Median	3.0
Min - Max	1 - 10
Duration (days)	
n	29
Mean (SD)	7.3 (5.04)
Median	6.0
Min - Max	2 - 25
Admitted to ICU - n (%)	19 (47.5)
Time to ICU Admission (days)	

	All patients N=40
n	19
Mean (SD)	6.8 (5.22)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	19
Mean (SD)	11.6 (8.34)
Median	9.0
Min - Max	1 - 29
Hypotension that required intervention - n (%)	21 (52.5)
High dose vasopressors used - n (%)	10 (25.0)
Oxygen supplementation given - n (%)	18 (45.0)
Patient intubated - n (%)	8 (20.0)
Duration (days)	
n	8
Mean (SD)	8.3 (4.71)
Median	7.0
Min - Max	4 - 19
Patient dialyzed - n (%)	6 (15.0)
Duration (days)	
n	6

	All patients N=40
Mean (SD)	10.3 (7.31)
Median	7.5
Min - Max	4 - 23
Total Parenteral Nutrition (TPN) used - n (%)	17 (42.5)
Duration (days)	
n	17
Mean (SD)	21.5 (24.79)
Median	14.0
Min - Max	4 - 111
Pulmonary abnormalities - n (%)	10 (25.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	6 (15.0)
Bleeding observed - n (%)	6 (15.0)
Blood product support given for bleeding - n (%)	5 (12.5)
Systemic anti-cytokine therapy given - n (%)	16 (40.0)
Tocilizumab	16 (40.0)
1 dose	7 (17.5)
2 doses	6 (15.0)
3 doses	3 (7.5)
4 doses	0
>4 doses	0
Siltuximab	4 (10.0)

	All patients N=40
Corticosteroids	9 (22.5)
Other	2 (5.0)

Only the first CRS episode is summarized for each patient.

Table 251r
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 0

	All patients N=6
Cytokine Release Syndrome (CRS) - n (%)	
No	1 (16.7)
Yes	5 (83.3)
Maximum CRS grade - n(%)	
Grade 1	1 (16.7)
Grade 2	2 (33.3)
Grade 4	2 (33.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	5
Mean (SD)	4.0 (2.74)
Median	2.0
Min - Max	2 - 7
Time to grade 3/4 CRS (days)	
n	2

	All patients N=6
Mean (SD)	3.5 (0.71)
Median	3.5
Min - Max	3 - 4
Concurrent infections - n(%)	0
High fevers during CRS - n (%)	4 (66.7)
Time to high fever onset (days)	
n	4
Mean (SD)	3.5 (2.38)
Median	2.5
Min - Max	2 - 7
Duration (days)	
n	4
Mean (SD)	5.0 (1.41)
Median	4.5
Min - Max	4 - 7
Admitted to ICU - n (%)	2 (33.3)
Time to ICU Admission (days)	
n	2
Mean (SD)	2.5 (0.71)
Median	2.5
Min - Max	2 - 3

	All patients N=6
Duration of ICU stay (days)	
n	2
Mean (SD)	19.0 (11.31)
Median	19.0
Min - Max	11 - 27
Hypotension that required intervention - n (%)	2 (33.3)
High dose vasopressors used - n (%)	2 (33.3)
Oxygen supplementation given - n (%)	2 (33.3)
Patient intubated - n (%)	1 (16.7)
Duration (days)	
n	1
Mean (SD)	19.0
Median	19.0
Min - Max	19 - 19
Patient dialyzed - n (%)	1 (16.7)
Duration (days)	
n	1
Mean (SD)	15.0
Median	15.0
Min - Max	15 - 15
Total Parenteral Nutrition (TPN) used - n (%)	2 (33.3)

	All patients N=6
Duration (days)	
n	2
Mean (SD)	10.5 (7.78)
Median	10.5
Min - Max	5 - 16
Pulmonary abnormalities - n (%)	1 (16.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	2 (33.3)
Bleeding observed - n (%)	1 (16.7)
Blood product support given for bleeding - n (%)	1 (16.7)
Systemic anti-cytokine therapy given - n (%)	2 (33.3)
Tocilizumab	2 (33.3)
1 dose	0
2 doses	1 (16.7)
3 doses	1 (16.7)
4 doses	0
>4 doses	0
Siltuximab	2 (33.3)
Corticosteroids	2 (33.3)
Other	1 (16.7)

Only the first CRS episode is summarized for each patient.

Table 251r
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 1

	All patients N=22
Cytokine Release Syndrome (CRS) - n (%)	
No	7 (31.8)
Yes	15 (68.2)
Maximum CRS grade - n(%)	
Grade 1	1 (4.5)
Grade 2	4 (18.2)
Grade 3	4 (18.2)
Grade 4	6 (27.3)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	15
Mean (SD)	4.0 (2.80)
Median	3.0
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=22
n	10
Mean (SD)	6.4 (2.95)
Median	6.0
Min - Max	2 - 11
Concurrent infections - n(%)	4 (18.2)
Blood	3 (13.6)
GI	1 (4.5)
Other	1 (4.5)
High fevers during CRS - n (%)	15 (68.2)
Time to high fever onset (days)	
n	15
Mean (SD)	4.3 (3.04)
Median	4.0
Min - Max	1 - 9
Duration (days)	
n	15
Mean (SD)	7.5 (4.87)
Median	6.0
Min - Max	1 - 18
Admitted to ICU - n (%)	11 (50.0)
Time to ICU Admission (days)	

	All patients N=22
n	11
Mean (SD)	7.5 (6.28)
Median	6.0
Min - Max	2 - 24
Duration of ICU stay (days)	
n	11
Mean (SD)	15.6 (17.74)
Median	9.0
Min - Max	4 - 66
Hypotension that required intervention - n (%)	11 (50.0)
High dose vasopressors used - n (%)	4 (18.2)
Oxygen supplementation given - n (%)	9 (40.9)
Patient intubated - n (%)	6 (27.3)
Duration (days)	
n	6
Mean (SD)	7.5 (3.27)
Median	7.0
Min - Max	4 - 13
Patient dialyzed - n (%)	4 (18.2)
Duration (days)	
n	4

	All patients N=22
Mean (SD)	19.3 (27.86)
Median	6.0
Min - Max	4 - 61
Total Parenteral Nutrition (TPN) used - n (%)	10 (45.5)
Duration (days)	
n	10
Mean (SD)	28.2 (34.00)
Median	12.5
Min - Max	5 - 111
Pulmonary abnormalities - n (%)	5 (22.7)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (18.2)
Bleeding observed - n (%)	3 (13.6)
Blood product support given for bleeding - n (%)	3 (13.6)
Systemic anti-cytokine therapy given - n (%)	10 (45.5)
Tocilizumab	10 (45.5)
1 dose	5 (22.7)
2 doses	4 (18.2)
3 doses	1 (4.5)
4 doses	0
>4 doses	0
Siltuximab	2 (9.1)

	All patients N=22
Corticosteroids	6 (27.3)
Other	0

Only the first CRS episode is summarized for each patient.

Table 251r
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: 2

	All patients N=17
Cytokine Release Syndrome (CRS) - n (%)	
No	5 (29.4)
Yes	12 (70.6)
Maximum CRS grade - n(%)	
Grade 2	4 (23.5)
Grade 3	4 (23.5)
Grade 4	4 (23.5)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	12
Mean (SD)	3.1 (2.61)
Median	2.0
Min - Max	1 - 9
Time to grade 3/4 CRS (days)	

	All patients N=17
n	8
Mean (SD)	6.0 (2.88)
Median	6.5
Min - Max	2 - 10
Concurrent infections - n(%)	2 (11.8)
Blood	2 (11.8)
High fevers during CRS - n (%)	12 (70.6)
Time to high fever onset (days)	
n	12
Mean (SD)	3.6 (2.75)
Median	2.0
Min - Max	1 - 9
Duration (days)	
n	12
Mean (SD)	8.8 (5.58)
Median	6.5
Min - Max	5 - 25
Admitted to ICU - n (%)	8 (47.1)
Time to ICU Admission (days)	
n	8
Mean (SD)	6.1 (2.85)

	All patients N=17
Median	6.5
Min - Max	2 - 10
Duration of ICU stay (days)	
n	8
Mean (SD)	11.1 (9.30)
Median	9.0
Min - Max	2 - 29
Hypotension that required intervention - n (%)	10 (58.8)
High dose vasopressors used - n (%)	4 (23.5)
Oxygen supplementation given - n (%)	7 (41.2)
Patient intubated - n (%)	2 (11.8)
Duration (days)	
n	2
Mean (SD)	7.5 (2.12)
Median	7.5
Min - Max	6 - 9
Patient dialyzed - n (%)	2 (11.8)
Duration (days)	
n	2
Mean (SD)	15.5 (10.61)
Median	15.5

	All patients N=17
Min - Max	8 - 23
Total Parenteral Nutrition (TPN) used - n (%)	7 (41.2)
Duration (days)	
n	7
Mean (SD)	20.0 (11.09)
Median	14.0
Min - Max	10 - 37
Pulmonary abnormalities - n (%)	4 (23.5)
Disseminated intravascular coagulation (DIC) observed - n (%)	3 (17.6)
Bleeding observed - n (%)	2 (11.8)
Blood product support given for bleeding - n (%)	1 (5.9)
Systemic anti-cytokine therapy given - n (%)	6 (35.3)
Tocilizumab	6 (35.3)
1 dose	2 (11.8)
2 doses	3 (17.6)
3 doses	1 (5.9)
4 doses	0
>4 doses	0
Siltuximab	1 (5.9)
Corticosteroids	4 (23.5)
Other	1 (5.9)

Only the first CRS episode is summarized for each patient.

Table 251r
Cytokine release syndrome post CTL019 infusion, regardles of study drug relationship by Number of previous relapses
Safety Set

Subgroup: Number of previous relapses: >=3

	All patients N=35
Cytokine Release Syndrome (CRS) - n (%)	
No	6 (17.1)
Yes	29 (82.9)
Maximum CRS grade - n(%)	
Grade 1	3 (8.6)
Grade 2	8 (22.9)
Grade 3	9 (25.7)
Grade 4	9 (25.7)
Fatal - n(%)	0
Time to onset of CRS (days)	
n	29
Mean (SD)	4.1 (4.00)
Median	3.0
Min - Max	1 - 22

	All patients N=35
Time to grade 3/4 CRS (days)	
n	18
Mean (SD)	7.8 (6.82)
Median	6.5
Min - Max	2 - 33
Concurrent infections - n(%)	6 (17.1)
Blood	2 (5.7)
Cns	1 (2.9)
GI	1 (2.9)
Lung	2 (5.7)
Other	1 (2.9)
Skin	1 (2.9)
High fevers during CRS - n (%)	27 (77.1)
Time to high fever onset (days)	
n	27
Mean (SD)	4.4 (4.09)
Median	4.0
Min - Max	1 - 22
Duration (days)	
n	27
Mean (SD)	7.2 (7.54)

	All patients N=35
Median	4.0
Min - Max	1 - 36
Admitted to ICU - n (%)	17 (48.6)
Time to ICU Admission (days)	
n	17
Mean (SD)	7.5 (4.61)
Median	7.0
Min - Max	2 - 22
Duration of ICU stay (days)	
n	17
Mean (SD)	7.2 (7.60)
Median	6.0
Min - Max	1 - 34
Hypotension that required intervention - n (%)	19 (54.3)
High dose vasopressors used - n (%)	9 (25.7)
Oxygen supplementation given - n (%)	17 (48.6)
Patient intubated - n (%)	3 (8.6)
Duration (days)	
n	3
Mean (SD)	8.0 (5.20)
Median	5.0

	All patients N=35
Min - Max	5 - 14
Patient dialyzed - n (%)	1 (2.9)
Duration (days)	
n	1
Mean (SD)	12.0
Median	12.0
Min - Max	12 - 12
Total Parenteral Nutrition (TPN) used - n (%)	10 (28.6)
Duration (days)	
n	10
Mean (SD)	11.2 (8.39)
Median	8.5
Min - Max	2 - 29
Pulmonary abnormalities - n (%)	7 (20.0)
Disseminated intravascular coagulation (DIC) observed - n (%)	4 (11.4)
Bleeding observed - n (%)	2 (5.7)
Blood product support given for bleeding - n (%)	1 (2.9)
Systemic anti-cytokine therapy given - n (%)	13 (37.1)
Tocilizumab	13 (37.1)
1 dose	11 (31.4)
2 doses	2 (5.7)

	All patients N=35
3 doses	0
4 doses	0
>4 doses	0
Siltuximab	0
Corticosteroids	5 (14.3)
Other	0

Only the first CRS episode is summarized for each patient.

Table 255a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (51.2)	0	0	15 (36.6)	6 (14.6)
Hematological disorders including cytopenias					
-Total	14 (34.1)	0	0	12 (29.3)	2 (4.9)
Febrile neutropenia	10 (24.4)	0	0	10 (24.4)	0
Neutrophil count decreased	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	0	1 (2.4)	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	11 (26.8)	0	0	8 (19.5)	3 (7.3)

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	1 (2.4)	0
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Escherichia bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	0	0	1 (2.4)	0
Haemophilus bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumonia	1 (2.4)	0	0	1 (2.4)	0
Pneumonia fungal	1 (2.4)	0	0	0	1 (2.4)
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sialoadenitis	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (4.9)	0	0	2 (4.9)	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Mental status changes	1 (2.4)	0	0	1 (2.4)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	19 (47.5)	0	1 (2.5)	10 (25.0)	8 (20.0)
Hematological disorders including cytopenias					
-Total	5 (12.5)	0	0	3 (7.5)	2 (5.0)
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Anaemia	1 (2.5)	0	0	0	1 (2.5)
Neutropenia	1 (2.5)	0	0	1 (2.5)	0
Platelet count decreased	1 (2.5)	0	0	0	1 (2.5)
Thrombocytopenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	16 (40.0)	0	0	10 (25.0)	6 (15.0)

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Aspergillus infection	0	0	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	1 (2.5)	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255a
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (58.8)	0	1 (5.9)	6 (35.3)	3 (17.6)
Hematological disorders including cytopenias					
-Total	5 (29.4)	0	0	3 (17.6)	2 (11.8)
Febrile neutropenia	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Neutrophil count decreased	0	0	0	0	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					

Age: >=18

Primary system organ class Preferred term	All patients N=17				
	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (52.9)	0	1 (5.9)	5 (29.4)	3 (17.6)
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Gastroenteritis	1 (5.9)	0	1 (5.9)	0	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal skin infection	0	0	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Sepsis	0	0	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255b
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (49.1)	0	1 (1.8)	17 (30.9)	9 (16.4)
Hematological disorders including cytopenias					
-Total	11 (20.0)	0	0	8 (14.5)	3 (5.5)
Febrile neutropenia	6 (10.9)	0	0	6 (10.9)	0
Anaemia	2 (3.6)	0	1 (1.8)	0	1 (1.8)
Neutropenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Neutrophil count decreased	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	19 (34.5)	0	0	14 (25.5)	5 (9.1)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	2 (3.6)	0	0	2 (3.6)	0
Staphylococcal sepsis	2 (3.6)	0	0	0	2 (3.6)
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Paronychia	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Sinusitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Encephalopathy	1 (1.8)	0	0	1 (1.8)	0
Mental status changes	1 (1.8)	0	0	1 (1.8)	0
Seizure	1 (1.8)	0	1 (1.8)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.8)	0	0	0	1 (1.8)
Tumour lysis syndrome	1 (1.8)	0	0	0	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255b
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (53.5)	0	1 (2.3)	14 (32.6)	8 (18.6)
Hematological disorders including cytopenias					
-Total	13 (30.2)	0	0	10 (23.3)	3 (7.0)
Febrile neutropenia	10 (23.3)	0	0	9 (20.9)	1 (2.3)
Neutrophil count decreased	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Pancytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Platelet count decreased	1 (2.3)	0	0	0	1 (2.3)
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	17 (39.5)	0	1 (2.3)	9 (20.9)	7 (16.3)

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	2 (4.7)	0	0	0	2 (4.7)
Staphylococcal bacteraemia	2 (4.7)	0	0	2 (4.7)	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Pneumonia	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Fungal sepsis	1 (2.3)	0	0	0	1 (2.3)
Fungal skin infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis adenovirus	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	0	1 (2.3)	0
Haemophilus bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Pneumonia fungal	1 (2.3)	0	0	0	1 (2.3)

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	1 (2.3)	0	0	1 (2.3)	0
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.3)	0	0	1 (2.3)	0
Mental status changes	1 (2.3)	0	0	1 (2.3)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (57.1)	0	1 (1.4)	25 (35.7)	14 (20.0)
Hematological disorders including cytopenias					
-Total	19 (27.1)	0	0	15 (21.4)	4 (5.7)
Febrile neutropenia	12 (17.1)	0	0	12 (17.1)	0
Anaemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Neutropenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Neutrophil count decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Platelet count decreased	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	1 (1.4)	0
Infections					
-Total	30 (42.9)	0	0	20 (28.6)	10 (14.3)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Localised infection	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal skin infection	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	0	0	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Mental status changes	2 (2.9)	0	0	2 (2.9)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (26.7)	0	0	3 (20.0)	1 (6.7)
Hematological disorders including cytopenias					
-Total	1 (6.7)	0	0	1 (6.7)	0
Febrile neutropenia	1 (6.7)	0	0	1 (6.7)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (20.0)	0	0	2 (13.3)	1 (6.7)

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Device related infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255c
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one event	6 (46.2)	0	1 (7.7)	3 (23.1)	2 (15.4)
Hematological disorders including cytopenias					
-Total	4 (30.8)	0	0	2 (15.4)	2 (15.4)
Febrile neutropenia	3 (23.1)	0	0	2 (15.4)	1 (7.7)
Neutrophil count decreased	1 (7.7)	0	0	0	1 (7.7)
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (23.1)	0	1 (7.7)	1 (7.7)	1 (7.7)
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Device related infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Mental status changes	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255d
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	10 (55.6)	0	1 (5.6)	5 (27.8)	4 (22.2)
Hematological disorders including cytopenias					
-Total	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Anaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	1 (5.6)	0
Febrile neutropenia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	9 (50.0)	0	1 (5.6)	6 (33.3)	2 (11.1)

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Abscess limb	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.6)	0	0	1 (5.6)	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255d
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	40 (50.0)	0	1 (1.3)	26 (32.5)	13 (16.3)
Hematological disorders including cytopenias					
-Total	21 (26.3)	0	0	17 (21.3)	4 (5.0)
Febrile neutropenia	16 (20.0)	0	0	15 (18.8)	1 (1.3)
Neutrophil count decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Neutropenia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	27 (33.8)	0	0	17 (21.3)	10 (12.5)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal infection	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Fungal sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis adenovirus	1 (1.3)	0	0	1 (1.3)	0
Haemophilus bacteraemia	1 (1.3)	0	0	0	1 (1.3)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	0	0	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0	1 (1.3)	0
Paronychia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	0	1 (1.3)
Sepsis	1 (1.3)	0	0	0	1 (1.3)
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Sialoadenitis	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal skin infection	1 (1.3)	0	0	1 (1.3)	0
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.3)	0	0	0	1 (1.3)
Tumour lysis syndrome	1 (1.3)	0	0	0	1 (1.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255e
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hematological disorders including cytopenias					
-Total	1 (12.5)	0	0	1 (12.5)	0
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255e
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	46 (51.1)	0	2 (2.2)	29 (32.2)	15 (16.7)
Hematological disorders including cytopenias					
-Total	23 (25.6)	0	0	17 (18.9)	6 (6.7)
Febrile neutropenia	15 (16.7)	0	0	14 (15.6)	1 (1.1)
Neutrophil count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Anaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Neutropenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	1 (1.1)	0	0	1 (1.1)	0
Infections					
-Total	32 (35.6)	0	1 (1.1)	21 (23.3)	10 (11.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Staphylococcal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	0	0	1 (1.1)
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Mental status changes	2 (2.2)	0	0	2 (2.2)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.1)	0	0	0	1 (1.1)
Tumour lysis syndrome	1 (1.1)	0	0	0	1 (1.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255f
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (50.0)	0	0	1 (50.0)	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Anaemia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255f
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	49 (51.0)	0	2 (2.1)	30 (31.3)	17 (17.7)
Hematological disorders including cytopenias					
-Total	24 (25.0)	0	0	18 (18.8)	6 (6.3)
Febrile neutropenia	16 (16.7)	0	0	15 (15.6)	1 (1.0)
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Thrombocytopenia	1 (1.0)	0	0	1 (1.0)	0
Infections					
-Total	35 (36.5)	0	1 (1.0)	22 (22.9)	12 (12.5)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Parainfluenzae virus infection	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	0	0	1 (1.0)
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.0)	0	0	1 (1.0)	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Abscess limb	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (4.2)	0	1 (1.0)	3 (3.1)	0
Mental status changes	2 (2.1)	0	0	2 (2.1)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.0)	0	0	0	1 (1.0)
Tumour lysis syndrome	1 (1.0)	0	0	0	1 (1.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255g
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	50 (51.5)	0	2 (2.1)	31 (32.0)	17 (17.5)
Hematological disorders including cytopenias					
-Total	24 (24.7)	0	0	18 (18.6)	6 (6.2)
Febrile neutropenia	16 (16.5)	0	0	15 (15.5)	1 (1.0)
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Thrombocytopenia	1 (1.0)	0	0	1 (1.0)	0
Infections					
-Total	36 (37.1)	0	1 (1.0)	23 (23.7)	12 (12.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Parainfluenzae virus infection	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	0	0	1 (1.0)
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection	1 (1.0)	0	0	1 (1.0)	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Serious neurological adverse reactions					
-Total	4 (4.1)	0	1 (1.0)	3 (3.1)	0
Mental status changes	2 (2.1)	0	0	2 (2.1)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.0)	0	0	0	1 (1.0)
Tumour lysis syndrome	1 (1.0)	0	0	0	1 (1.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255h
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	3 (100)	0	0	1 (33.3)	2 (66.7)
Hematological disorders including cytopenias					
-Total	1 (33.3)	0	0	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Anaemia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255h
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	47 (49.5)	0	2 (2.1)	30 (31.6)	15 (15.8)
Hematological disorders including cytopenias					
-Total	23 (24.2)	0	0	17 (17.9)	6 (6.3)
Febrile neutropenia	16 (16.8)	0	0	15 (15.8)	1 (1.1)
Neutrophil count decreased	2 (2.1)	0	0	0	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.1)	0	1 (1.1)
Neutropenia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	1 (1.1)	0	0	1 (1.1)	0
Infections					
-Total	33 (34.7)	0	1 (1.1)	22 (23.2)	10 (10.5)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Pneumonia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	0	0	1 (1.1)
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis adenovirus	0	0	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Mental status changes	2 (2.1)	0	0	2 (2.1)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.1)	0	0	0	1 (1.1)
Tumour lysis syndrome	1 (1.1)	0	0	0	1 (1.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255i
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	2 (100)	0	0	2 (100)	0
Hematological disorders including cytopenias					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	2 (100)	0	0	2 (100)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (50.0)	0	0	1 (50.0)	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255i
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	48 (50.0)	0	2 (2.1)	29 (30.2)	17 (17.7)
Hematological disorders including cytopenias					
-Total	22 (22.9)	0	0	16 (16.7)	6 (6.3)
Febrile neutropenia	14 (14.6)	0	0	13 (13.5)	1 (1.0)
Neutrophil count decreased	3 (3.1)	0	0	1 (1.0)	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Neutropenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Platelet count decreased	1 (1.0)	0	0	0	1 (1.0)
Thrombocytopenia	1 (1.0)	0	0	1 (1.0)	0
Infections					
-Total	35 (36.5)	0	1 (1.0)	22 (22.9)	12 (12.5)

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Localised infection	1 (1.0)	0	0	1 (1.0)	0
Parainfluenzae virus infection	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	0	0	1 (1.0)
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Fungal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (4.2)	0	1 (1.0)	3 (3.1)	0
Mental status changes	2 (2.1)	0	0	2 (2.1)	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.0)	0	0	0	1 (1.0)
Tumour lysis syndrome	1 (1.0)	0	0	0	1 (1.0)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255j
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (36.7)	0	0	5 (16.7)	6 (20.0)
Hematological disorders including cytopenias					
-Total	5 (16.7)	0	0	3 (10.0)	2 (6.7)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Neutrophil count decreased	2 (6.7)	0	0	0	2 (6.7)
Platelet count decreased	1 (3.3)	0	0	0	1 (3.3)
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	8 (26.7)	0	0	4 (13.3)	4 (13.3)

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

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Staphylococcal sepsis	2 (6.7)	0	0	0	2 (6.7)
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Paronychia	1 (3.3)	0	0	1 (3.3)	0
Pneumonia	1 (3.3)	0	0	1 (3.3)	0
Respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0

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

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0

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

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255j
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	39 (57.4)	0	2 (2.9)	26 (38.2)	11 (16.2)
Hematological disorders including cytopenias					
-Total	19 (27.9)	0	0	15 (22.1)	4 (5.9)
Febrile neutropenia	13 (19.1)	0	0	12 (17.6)	1 (1.5)
Anaemia	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Neutropenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Pancytopenia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Neutrophil count decreased	1 (1.5)	0	0	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	0	1 (1.5)	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	28 (41.2)	0	1 (1.5)	19 (27.9)	8 (11.8)

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

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Pneumonia	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Fungal sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis adenovirus	1 (1.5)	0	0	1 (1.5)	0

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

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Haemophilus bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Klebsiella bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	0	1 (1.5)
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal skin infection	1 (1.5)	0	0	1 (1.5)	0
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

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

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Mental status changes	1 (1.5)	0	0	1 (1.5)	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.5)	0	0	0	1 (1.5)
Tumour lysis syndrome	1 (1.5)	0	0	0	1 (1.5)

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- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
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Table 255k
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (65.6)	0	1 (3.1)	14 (43.8)	6 (18.8)
Hematological disorders including cytopenias					
-Total	10 (31.3)	0	0	8 (25.0)	2 (6.3)
Febrile neutropenia	7 (21.9)	0	0	6 (18.8)	1 (3.1)
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Neutrophil count decreased	1 (3.1)	0	0	1 (3.1)	0
Pancytopenia	1 (3.1)	0	0	1 (3.1)	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	15 (46.9)	0	1 (3.1)	10 (31.3)	4 (12.5)

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (6.3)	0	0	2 (6.3)	0
Herpes zoster	2 (6.3)	0	0	2 (6.3)	0
Pneumonia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Respiratory tract infection	2 (6.3)	0	0	2 (6.3)	0
Staphylococcal sepsis	2 (6.3)	0	0	0	2 (6.3)
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Device related sepsis	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis adenovirus	1 (3.1)	0	0	1 (3.1)	0
Haemophilus bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Paronychia	1 (3.1)	0	0	1 (3.1)	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.1)	0	0	1 (3.1)	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (3.1)	0	0	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)

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All patients column.
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Table 255k
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	27 (47.4)	0	1 (1.8)	15 (26.3)	11 (19.3)
Hematological disorders including cytopenias					
-Total	13 (22.8)	0	0	9 (15.8)	4 (7.0)
Febrile neutropenia	8 (14.0)	0	0	8 (14.0)	0
Neutrophil count decreased	2 (3.5)	0	0	0	2 (3.5)
Anaemia	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Neutropenia	1 (1.8)	0	0	1 (1.8)	0
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Platelet count decreased	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
Infections					
-Total	20 (35.1)	0	0	12 (21.1)	8 (14.0)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	2 (3.5)	0	0	0	2 (3.5)
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Staphylococcal infection	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Fungal sepsis	1 (1.8)	0	0	0	1 (1.8)
Fungal skin infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia fungal	1 (1.8)	0	0	0	1 (1.8)
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	1 (1.8)	0	0	1 (1.8)	0
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Device related infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Mental status changes	2 (3.5)	0	0	2 (3.5)	0
Seizure	1 (1.8)	0	1 (1.8)	0	0
Encephalopathy	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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All patients column.
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Table 255k
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one event	2 (22.2)	0	0	2 (22.2)	0
Hematological disorders including cytopenias					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Device related infection	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Sialoadenitis	0	0	0	0	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255l
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	32 (55.2)	0	2 (3.4)	19 (32.8)	11 (19.0)
Hematological disorders including cytopenias					
-Total	17 (29.3)	0	0	12 (20.7)	5 (8.6)
Febrile neutropenia	11 (19.0)	0	0	10 (17.2)	1 (1.7)
Neutrophil count decreased	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Pancytopenia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Anaemia	1 (1.7)	0	1 (1.7)	0	0
Neutropenia	1 (1.7)	0	0	0	1 (1.7)
Platelet count decreased	1 (1.7)	0	0	0	1 (1.7)
Thrombocytopenia	1 (1.7)	0	0	1 (1.7)	0
Infections					
-Total	21 (36.2)	0	1 (1.7)	13 (22.4)	7 (12.1)

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (3.4)	0	0	2 (3.4)	0
Herpes zoster	2 (3.4)	0	0	2 (3.4)	0
Pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Septic shock	2 (3.4)	0	0	0	2 (3.4)
Staphylococcal sepsis	2 (3.4)	0	0	0	2 (3.4)
Abscess limb	1 (1.7)	0	0	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0
Fungal sepsis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis adenovirus	1 (1.7)	0	0	1 (1.7)	0
Haemophilus bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Sinusitis	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal skin infection	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Aspergillus infection	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Localised infection	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0
Seizure	1 (1.7)	0	1 (1.7)	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.7)	0	0	0	1 (1.7)
Tumour lysis syndrome	1 (1.7)	0	0	0	1 (1.7)

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255l
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	18 (45.0)	0	0	12 (30.0)	6 (15.0)
Hematological disorders including cytopenias					
-Total	7 (17.5)	0	0	6 (15.0)	1 (2.5)
Febrile neutropenia	5 (12.5)	0	0	5 (12.5)	0
Anaemia	1 (2.5)	0	0	0	1 (2.5)
Neutropenia	1 (2.5)	0	0	1 (2.5)	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	15 (37.5)	0	0	10 (25.0)	5 (12.5)

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	0	1 (2.5)
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	0	0	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	0	0	0	0	0
Pneumonia	0	0	0	0	0
Septic shock	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (5.0)	0	0	2 (5.0)	0
Mental status changes	2 (5.0)	0	0	2 (5.0)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255m
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	7 (41.2)	0	0	6 (35.3)	1 (5.9)
Hematological disorders including cytopenias					
-Total	6 (35.3)	0	0	6 (35.3)	0
Febrile neutropenia	6 (35.3)	0	0	6 (35.3)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	4 (23.5)	0	0	3 (17.6)	1 (5.9)

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.9)	0	0	1 (5.9)	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255m
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	43 (53.1)	0	2 (2.5)	25 (30.9)	16 (19.8)
Hematological disorders including cytopenias					
-Total	18 (22.2)	0	0	12 (14.8)	6 (7.4)
Febrile neutropenia	10 (12.3)	0	0	9 (11.1)	1 (1.2)
Neutrophil count decreased	3 (3.7)	0	0	1 (1.2)	2 (2.5)
Anaemia	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Neutropenia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Pancytopenia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Platelet count decreased	1 (1.2)	0	0	0	1 (1.2)
Thrombocytopenia	1 (1.2)	0	0	1 (1.2)	0
Infections					
-Total	32 (39.5)	0	1 (1.2)	20 (24.7)	11 (13.6)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Pneumonia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Staphylococcal bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Staphylococcal infection	1 (1.2)	0	0	0	1 (1.2)
Abscess limb	1 (1.2)	0	0	1 (1.2)	0
Bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Bacterial sepsis	1 (1.2)	0	0	0	1 (1.2)
Bronchiolitis	1 (1.2)	0	0	1 (1.2)	0
Bronchopulmonary aspergillosis	1 (1.2)	0	0	1 (1.2)	0
Device related sepsis	1 (1.2)	0	0	1 (1.2)	0
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Escherichia bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Fungal sepsis	1 (1.2)	0	0	0	1 (1.2)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis adenovirus	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis viral	1 (1.2)	0	0	1 (1.2)	0
Haemophilus bacteraemia	1 (1.2)	0	0	0	1 (1.2)
Klebsiella bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Localised infection	1 (1.2)	0	0	1 (1.2)	0
Parainfluenzae virus infection	1 (1.2)	0	0	1 (1.2)	0
Paronychia	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Pneumonia fungal	1 (1.2)	0	0	0	1 (1.2)
Sepsis	1 (1.2)	0	0	0	1 (1.2)
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Sialoadenitis	1 (1.2)	0	0	1 (1.2)	0
Sinusitis	1 (1.2)	0	0	1 (1.2)	0
Staphylococcal skin infection	1 (1.2)	0	0	1 (1.2)	0
Urinary tract infection	1 (1.2)	0	0	1 (1.2)	0
Aspergillus infection	0	0	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Mental status changes	1 (1.2)	0	0	1 (1.2)	0
Encephalopathy	1 (1.2)	0	0	1 (1.2)	0
Seizure	1 (1.2)	0	1 (1.2)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.2)	0	0	0	1 (1.2)
Tumour lysis syndrome	1 (1.2)	0	0	0	1 (1.2)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255n
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (32.1)	0	1 (3.6)	8 (28.6)	0
Hematological disorders including cytopenias					
-Total	5 (17.9)	0	0	5 (17.9)	0
Febrile neutropenia	4 (14.3)	0	0	4 (14.3)	0
Anaemia	1 (3.6)	0	1 (3.6)	0	0
Thrombocytopenia	1 (3.6)	0	0	1 (3.6)	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					
-Total	5 (17.9)	0	0	5 (17.9)	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (3.6)	0	0	1 (3.6)	0
Localised infection	1 (3.6)	0	0	1 (3.6)	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	1 (3.6)	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255n
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (58.6)	0	1 (1.4)	23 (32.9)	17 (24.3)
Hematological disorders including cytopenias					
-Total	19 (27.1)	0	0	13 (18.6)	6 (8.6)
Febrile neutropenia	12 (17.1)	0	0	11 (15.7)	1 (1.4)
Neutrophil count decreased	3 (4.3)	0	0	1 (1.4)	2 (2.9)
Neutropenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Anaemia	1 (1.4)	0	0	0	1 (1.4)
Platelet count decreased	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	31 (44.3)	0	1 (1.4)	18 (25.7)	12 (17.1)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Klebsiella bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	0	1 (1.4)
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Abscess limb	0	0	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (4.3)	0	0	3 (4.3)	0
Mental status changes	2 (2.9)	0	0	2 (2.9)	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255o
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	9 (81.8)	0	1 (9.1)	7 (63.6)	1 (9.1)
Hematological disorders including cytopenias					
-Total	3 (27.3)	0	0	3 (27.3)	0
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	5 (45.5)	0	0	4 (36.4)	1 (9.1)

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (9.1)	0	0	1 (9.1)	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	1 (9.1)	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255o
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	41 (47.1)	0	1 (1.1)	24 (27.6)	16 (18.4)
Hematological disorders including cytopenias					
-Total	21 (24.1)	0	0	15 (17.2)	6 (6.9)
Febrile neutropenia	13 (14.9)	0	0	12 (13.8)	1 (1.1)
Neutrophil count decreased	3 (3.4)	0	0	1 (1.1)	2 (2.3)
Anaemia	2 (2.3)	0	1 (1.1)	0	1 (1.1)
Neutropenia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	1 (1.1)	0	0	1 (1.1)	0
Infections					
-Total	31 (35.6)	0	1 (1.1)	19 (21.8)	11 (12.6)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.3)	0	0	2 (2.3)	0
Septic shock	2 (2.3)	0	0	0	2 (2.3)
Staphylococcal bacteraemia	2 (2.3)	0	0	2 (2.3)	0
Staphylococcal infection	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Device related infection	1 (1.1)	0	0	1 (1.1)	0
Herpes zoster	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	0	0	1 (1.1)
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Abscess limb	0	0	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (3.4)	0	0	3 (3.4)	0
Mental status changes	2 (2.3)	0	0	2 (2.3)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (1.1)	0	0	0	1 (1.1)
Tumour lysis syndrome	1 (1.1)	0	0	0	1 (1.1)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
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Table 255p
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	1 (14.3)	0	0	1 (14.3)	0
Hematological disorders including cytopenias					
-Total	0	0	0	0	0
Anaemia	0	0	0	0	0
Febrile neutropenia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255p
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	49 (53.8)	0	2 (2.2)	30 (33.0)	17 (18.7)
Hematological disorders including cytopenias					
-Total	24 (26.4)	0	0	18 (19.8)	6 (6.6)
Febrile neutropenia	16 (17.6)	0	0	15 (16.5)	1 (1.1)
Neutrophil count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Anaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Neutropenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Platelet count decreased	1 (1.1)	0	0	0	1 (1.1)
Thrombocytopenia	1 (1.1)	0	0	1 (1.1)	0
Infections					
-Total	35 (38.5)	0	1 (1.1)	22 (24.2)	12 (13.2)

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Staphylococcal bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal infection	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	0	0	1 (1.1)
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Escherichia bacteraemia	0	0	0	0	0
Serious neurological adverse reactions					
-Total	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Mental status changes	2 (2.2)	0	0	2 (2.2)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Tumour Lysis Syndrome					
-Total	1 (1.1)	0	0	0	1 (1.1)
Tumour lysis syndrome	1 (1.1)	0	0	0	1 (1.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	21 (52.5)	0	1 (2.5)	16 (40.0)	4 (10.0)
Hematological disorders including cytopenias					
-Total	10 (25.0)	0	0	8 (20.0)	2 (5.0)
Febrile neutropenia	8 (20.0)	0	0	8 (20.0)	0
Neutropenia	1 (2.5)	0	0	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	0	0	1 (2.5)
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	15 (37.5)	0	1 (2.5)	11 (27.5)	3 (7.5)

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis adenovirus	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Haemophilus bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Localised infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal skin infection	1 (2.5)	0	0	1 (2.5)	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	15 (37.5)	0	1 (2.5)	10 (25.0)	4 (10.0)
Hematological disorders including cytopenias					
-Total	10 (25.0)	0	0	8 (20.0)	2 (5.0)
Febrile neutropenia	6 (15.0)	0	0	6 (15.0)	0
Anaemia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Neutropenia	1 (2.5)	0	0	1 (2.5)	0
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Platelet count decreased	1 (2.5)	0	0	0	1 (2.5)
Thrombocytopenia	1 (2.5)	0	0	1 (2.5)	0
Pancytopenia	0	0	0	0	0
Infections					
-Total	9 (22.5)	0	0	7 (17.5)	2 (5.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Herpes zoster	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Disseminated trichosporonosis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (2.5)	0	1 (2.5)	0	0
Seizure	1 (2.5)	0	1 (2.5)	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255q
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	14 (77.8)	0	0	5 (27.8)	9 (50.0)
Hematological disorders including cytopenias					
-Total	4 (22.2)	0	0	2 (11.1)	2 (11.1)
Febrile neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Pancytopenia	1 (5.6)	0	0	1 (5.6)	0
Neutropenia	0	0	0	0	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (66.7)	0	0	5 (27.8)	7 (38.9)
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Herpes zoster	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	3 (16.7)	0	0	3 (16.7)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (5.6)	0	0	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	0	0	1 (5.6)

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hematological disorders including cytopenias					
-Total	1 (12.5)	0	0	1 (12.5)	0
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Anaemia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related infection	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	0	0	0	0	0
Encephalopathy	0	0	0	0	0
Mental status changes	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

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- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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All patients column.
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Table 255r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	12 (40.0)	0	0	9 (30.0)	3 (10.0)
Hematological disorders including cytopenias					
-Total	5 (16.7)	0	0	5 (16.7)	0
Febrile neutropenia	2 (6.7)	0	0	2 (6.7)	0
Neutropenia	1 (3.3)	0	0	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	0	0	1 (3.3)	0
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0
Anaemia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					
-Total	10 (33.3)	0	0	7 (23.3)	3 (10.0)

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis adenovirus	1 (3.3)	0	0	1 (3.3)	0
Haemophilus bacteraemia	1 (3.3)	0	0	0	1 (3.3)
Klebsiella bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Pneumonia fungal	1 (3.3)	0	0	0	1 (3.3)
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Disseminated trichosporonosis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia	0	0	0	0	0
Respiratory tract infection	0	0	0	0	0
Septic shock	0	0	0	0	0
Sinusitis	0	0	0	0	0
Staphylococcal sepsis	0	0	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (3.3)	0	0	1 (3.3)	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	11 (61.1)	0	0	9 (50.0)	2 (11.1)
Hematological disorders including cytopenias					
-Total	7 (38.9)	0	0	6 (33.3)	1 (5.6)
Febrile neutropenia	5 (27.8)	0	0	5 (27.8)	0
Anaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	1 (5.6)	0
Neutropenia	0	0	0	0	0
Neutrophil count decreased	0	0	0	0	0
Pancytopenia	0	0	0	0	0
Platelet count decreased	0	0	0	0	0
Infections					

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (38.9)	0	0	6 (33.3)	1 (5.6)
Staphylococcal bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal infection	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Abscess limb	0	0	0	0	0
Bacteraemia	0	0	0	0	0
Bacterial sepsis	0	0	0	0	0
Bronchiolitis	0	0	0	0	0
Device related infection	0	0	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related sepsis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal sepsis	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Herpes zoster	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Parainfluenzae virus infection	0	0	0	0	0
Paronychia	0	0	0	0	0
Pneumonia	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0
Septic shock	0	0	0	0	0
Sialoadenitis	0	0	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal sepsis	0	0	0	0	0
Staphylococcal skin infection	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Vascular device infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	1 (5.6)	0	0	1 (5.6)	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	0	0	0	0	0
Seizure	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	0	0	0	0	0
Tumour lysis syndrome	0	0	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 255r
Serious adverse events of special interest (AESI) before study treatment based on identified risk, by group term, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one event	23 (54.8)	0	2 (4.8)	11 (26.2)	10 (23.8)
Hematological disorders including cytopenias					
-Total	11 (26.2)	0	0	6 (14.3)	5 (11.9)
Febrile neutropenia	8 (19.0)	0	0	7 (16.7)	1 (2.4)
Neutrophil count decreased	2 (4.8)	0	0	0	2 (4.8)
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Pancytopenia	1 (2.4)	0	0	0	1 (2.4)
Platelet count decreased	1 (2.4)	0	0	0	1 (2.4)
Anaemia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
Infections					

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	15 (35.7)	0	1 (2.4)	8 (19.0)	6 (14.3)
Herpes zoster	2 (4.8)	0	0	2 (4.8)	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Septic shock	2 (4.8)	0	0	0	2 (4.8)
Staphylococcal sepsis	2 (4.8)	0	0	0	2 (4.8)
Abscess limb	1 (2.4)	0	0	1 (2.4)	0
Bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Bacterial sepsis	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Fungal sepsis	1 (2.4)	0	0	0	1 (2.4)
Gastroenteritis	1 (2.4)	0	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Paronychia	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal skin infection	1 (2.4)	0	0	1 (2.4)	0
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0
Serratia sepsis	0	0	0	0	0
Staphylococcal bacteraemia	0	0	0	0	0
Staphylococcal infection	0	0	0	0	0
Aspergillus infection	0	0	0	0	0
Bronchopulmonary aspergillosis	0	0	0	0	0
Device related sepsis	0	0	0	0	0
Escherichia bacteraemia	0	0	0	0	0
Fungal skin infection	0	0	0	0	0
Gastroenteritis adenovirus	0	0	0	0	0
Haemophilus bacteraemia	0	0	0	0	0
Klebsiella bacteraemia	0	0	0	0	0
Localised infection	0	0	0	0	0
Pharyngitis	0	0	0	0	0
Pneumonia fungal	0	0	0	0	0
Sepsis	0	0	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sialoadenitis	0	0	0	0	0
Sinusitis	0	0	0	0	0
Systemic mycosis	0	0	0	0	0
Urinary tract infection	0	0	0	0	0
Serious neurological adverse reactions					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	1 (2.4)	0	0
Mental status changes	0	0	0	0	0
Tumour Lysis Syndrome					
-Total	1 (2.4)	0	0	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (97.0)	3 (9.1)	29 (87.9)
Blood and lymphatic system disorders			
-Total	9 (27.3)	3 (9.1)	6 (18.2)
Anaemia	9 (27.3)	3 (9.1)	6 (18.2)
Cardiac disorders			
-Total	8 (24.2)	4 (12.1)	4 (12.1)
Tachycardia	8 (24.2)	4 (12.1)	4 (12.1)
Endocrine disorders			
-Total	1 (3.0)	0	1 (3.0)
Adrenal insufficiency	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	22 (66.7)	11 (33.3)	11 (33.3)
Vomiting	12 (36.4)	7 (21.2)	5 (15.2)
Nausea	10 (30.3)	5 (15.2)	5 (15.2)
Diarrhoea	7 (21.2)	3 (9.1)	4 (12.1)
Constipation	6 (18.2)	4 (12.1)	2 (6.1)
Abdominal pain	5 (15.2)	1 (3.0)	4 (12.1)
General disorders and administration site conditions			
-Total	13 (39.4)	7 (21.2)	6 (18.2)
Fatigue	8 (24.2)	6 (18.2)	2 (6.1)
Pyrexia	7 (21.2)	3 (9.1)	4 (12.1)
Chills	3 (9.1)	2 (6.1)	1 (3.0)
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Hepatic function abnormal	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	24 (72.7)	5 (15.2)	19 (57.6)
Cytokine release syndrome	22 (66.7)	5 (15.2)	17 (51.5)
Hypogammaglobulinaemia	8 (24.2)	1 (3.0)	7 (21.2)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	4 (12.1)	1 (3.0)	3 (9.1)
Conjunctivitis	4 (12.1)	1 (3.0)	3 (9.1)
Investigations			
-Total	19 (57.6)	5 (15.2)	14 (42.4)
Alanine aminotransferase increased	9 (27.3)	2 (6.1)	7 (21.2)
Platelet count decreased	7 (21.2)	3 (9.1)	4 (12.1)
Aspartate aminotransferase increased	5 (15.2)	1 (3.0)	4 (12.1)
Blood immunoglobulin m decreased	5 (15.2)	4 (12.1)	1 (3.0)
Blood immunoglobulin a decreased	4 (12.1)	3 (9.1)	1 (3.0)
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	2 (6.1)	2 (6.1)
Neutrophil count decreased	3 (9.1)	0	3 (9.1)
Blood bilirubin increased	2 (6.1)	1 (3.0)	1 (3.0)
Metabolism and nutrition disorders			
-Total	13 (39.4)	4 (12.1)	9 (27.3)
Hypophosphataemia	7 (21.2)	3 (9.1)	4 (12.1)

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	6 (18.2)	1 (3.0)	5 (15.2)
Hypokalaemia	6 (18.2)	2 (6.1)	4 (12.1)
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)
Decreased appetite	3 (9.1)	2 (6.1)	1 (3.0)
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)
Hypomagnesaemia	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	11 (33.3)	5 (15.2)	6 (18.2)
Pain in extremity	8 (24.2)	4 (12.1)	4 (12.1)
Arthralgia	3 (9.1)	0	3 (9.1)
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)
Nervous system disorders			
-Total	8 (24.2)	7 (21.2)	1 (3.0)
Headache	6 (18.2)	5 (15.2)	1 (3.0)
Tremor	2 (6.1)	2 (6.1)	0
Psychiatric disorders			
-Total	6 (18.2)	4 (12.1)	2 (6.1)
Confusional state	4 (12.1)	4 (12.1)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	3 (9.1)	1 (3.0)	2 (6.1)
Agitation	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	1 (3.0)	1 (3.0)	0
Acute kidney injury	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (24.2)	6 (18.2)	2 (6.1)
Cough	6 (18.2)	5 (15.2)	1 (3.0)
Nasal congestion	1 (3.0)	0	1 (3.0)
Oropharyngeal pain	1 (3.0)	1 (3.0)	0
Skin and subcutaneous tissue disorders			
-Total	4 (12.1)	2 (6.1)	2 (6.1)
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)
Dry skin	1 (3.0)	1 (3.0)	0
Rash	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	9 (27.3)	4 (12.1)	5 (15.2)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	5 (15.2)	1 (3.0)	4 (12.1)
Hypertension	4 (12.1)	3 (9.1)	1 (3.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (97.0)	3 (9.1)	29 (87.9)
Blood and lymphatic system disorders			
-Total	6 (18.2)	2 (6.1)	4 (12.1)
Anaemia	5 (15.2)	2 (6.1)	3 (9.1)
Coagulopathy	1 (3.0)	0	1 (3.0)
Cardiac disorders			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Tachycardia	5 (15.2)	2 (6.1)	3 (9.1)
Sinus tachycardia	1 (3.0)	1 (3.0)	0
Endocrine disorders			
-Total	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	11 (33.3)	6 (18.2)	5 (15.2)
Diarrhoea	5 (15.2)	4 (12.1)	1 (3.0)
Abdominal pain	3 (9.1)	0	3 (9.1)
Nausea	3 (9.1)	3 (9.1)	0
Vomiting	3 (9.1)	2 (6.1)	1 (3.0)
Constipation	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	10 (30.3)	8 (24.2)	2 (6.1)
Pyrexia	7 (21.2)	5 (15.2)	2 (6.1)
Oedema peripheral	3 (9.1)	2 (6.1)	1 (3.0)
Fatigue	2 (6.1)	2 (6.1)	0
Chills	1 (3.0)	1 (3.0)	0
Hepatobiliary disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Hepatic function abnormal	2 (6.1)	1 (3.0)	1 (3.0)
Immune system disorders			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	25 (75.8)	5 (15.2)	20 (60.6)
Cytokine release syndrome	24 (72.7)	6 (18.2)	18 (54.5)
Hypogammaglobulinaemia	5 (15.2)	0	5 (15.2)
Seasonal allergy	1 (3.0)	0	1 (3.0)
Infections and infestations			
-Total	1 (3.0)	0	1 (3.0)
Rhinovirus infection	1 (3.0)	0	1 (3.0)
Investigations			
-Total	10 (30.3)	1 (3.0)	9 (27.3)
Aspartate aminotransferase increased	6 (18.2)	0	6 (18.2)
Alanine aminotransferase increased	5 (15.2)	2 (6.1)	3 (9.1)
Platelet count decreased	5 (15.2)	2 (6.1)	3 (9.1)
White blood cell count decreased	4 (12.1)	1 (3.0)	3 (9.1)
Blood bilirubin increased	3 (9.1)	1 (3.0)	2 (6.1)
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)
Neutrophil count decreased	3 (9.1)	0	3 (9.1)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	15 (45.5)	6 (18.2)	9 (27.3)
Decreased appetite	7 (21.2)	4 (12.1)	3 (9.1)
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)
Hypocalcaemia	5 (15.2)	1 (3.0)	4 (12.1)
Hyperuricaemia	4 (12.1)	4 (12.1)	0
Hypomagnesaemia	3 (9.1)	3 (9.1)	0
Hypokalaemia	2 (6.1)	0	2 (6.1)
Hypophosphataemia	2 (6.1)	1 (3.0)	1 (3.0)
Hyperglycaemia	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	7 (21.2)	6 (18.2)	1 (3.0)
Myalgia	4 (12.1)	3 (9.1)	1 (3.0)
Arthralgia	3 (9.1)	3 (9.1)	0
Pain in extremity	2 (6.1)	1 (3.0)	1 (3.0)
Nervous system disorders			
-Total	12 (36.4)	5 (15.2)	7 (21.2)
Headache	12 (36.4)	5 (15.2)	7 (21.2)
Tremor	2 (6.1)	1 (3.0)	1 (3.0)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Confusional state	3 (9.1)	3 (9.1)	0
Agitation	2 (6.1)	0	2 (6.1)
Anxiety	1 (3.0)	0	1 (3.0)
Renal and urinary disorders			
-Total	2 (6.1)	0	2 (6.1)
Acute kidney injury	2 (6.1)	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.2)	6 (18.2)	0
Cough	4 (12.1)	4 (12.1)	0
Oropharyngeal pain	2 (6.1)	2 (6.1)	0
Nasal congestion	1 (3.0)	1 (3.0)	0
Skin and subcutaneous tissue disorders			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Rash	4 (12.1)	2 (6.1)	2 (6.1)
Hyperhidrosis	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Hypertension	3 (9.1)	1 (3.0)	2 (6.1)
Hypotension	3 (9.1)	1 (3.0)	2 (6.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (92.9)	2 (14.3)	11 (78.6)
Blood and lymphatic system disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Anaemia	2 (14.3)	0	2 (14.3)
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)
Cardiac disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)
Endocrine disorders			

Timing: within 8 weeks post infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (14.3)	0	2 (14.3)
Adrenal insufficiency	2 (14.3)	0	2 (14.3)
Gastrointestinal disorders			
-Total	12 (85.7)	7 (50.0)	5 (35.7)
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)
Constipation	4 (28.6)	2 (14.3)	2 (14.3)
Nausea	3 (21.4)	2 (14.3)	1 (7.1)
Abdominal pain	2 (14.3)	2 (14.3)	0
Diarrhoea	2 (14.3)	1 (7.1)	1 (7.1)
Stomatitis	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	7 (50.0)	5 (35.7)	2 (14.3)
Pyrexia	5 (35.7)	3 (21.4)	2 (14.3)
Chills	2 (14.3)	1 (7.1)	1 (7.1)
Oedema peripheral	2 (14.3)	2 (14.3)	0
Fatigue	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	2 (14.3)	0	2 (14.3)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatic function abnormal	2 (14.3)	0	2 (14.3)
Immune system disorders			
-Total	11 (78.6)	2 (14.3)	9 (64.3)
Cytokine release syndrome	11 (78.6)	2 (14.3)	9 (64.3)
Hypogammaglobulinaemia	3 (21.4)	1 (7.1)	2 (14.3)
Infections and infestations			
-Total	2 (14.3)	0	2 (14.3)
Conjunctivitis	1 (7.1)	0	1 (7.1)
Rhinovirus infection	1 (7.1)	0	1 (7.1)
Investigations			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	2 (14.3)
Aspartate aminotransferase increased	2 (14.3)	2 (14.3)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (50.0)	3 (21.4)	4 (28.6)
Hypokalaemia	4 (28.6)	1 (7.1)	3 (21.4)
Decreased appetite	3 (21.4)	3 (21.4)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)
Hyperuricaemia	1 (7.1)	1 (7.1)	0
Hypoalbuminaemia	1 (7.1)	0	1 (7.1)
Hypocalcaemia	1 (7.1)	0	1 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)
Neck pain	1 (7.1)	0	1 (7.1)
Pain in extremity	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Headache	3 (21.4)	2 (14.3)	1 (7.1)
Tremor	2 (14.3)	2 (14.3)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Agitation	2 (14.3)	1 (7.1)	1 (7.1)
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	3 (21.4)	0
Oropharyngeal pain	2 (14.3)	2 (14.3)	0
Nasal congestion	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Hyperhidrosis	2 (14.3)	0	2 (14.3)
Pruritus	2 (14.3)	1 (7.1)	1 (7.1)
Vascular disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypertension	3 (21.4)	1 (7.1)	2 (14.3)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (76.7)	8 (26.7)	15 (50.0)
Blood and lymphatic system disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Anaemia	2 (6.7)	1 (3.3)	1 (3.3)
Cardiac disorders			
-Total	1 (3.3)	1 (3.3)	0
Tachycardia	1 (3.3)	1 (3.3)	0
Gastrointestinal disorders			
-Total	8 (26.7)	7 (23.3)	1 (3.3)
Vomiting	6 (20.0)	6 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	5 (16.7)	5 (16.7)	0
Nausea	3 (10.0)	3 (10.0)	0
Abdominal pain	1 (3.3)	1 (3.3)	0
Constipation	1 (3.3)	0	1 (3.3)
General disorders and administration site conditions			
-Total	10 (33.3)	7 (23.3)	3 (10.0)
Pyrexia	6 (20.0)	3 (10.0)	3 (10.0)
Fatigue	4 (13.3)	4 (13.3)	0
Immune system disorders			
-Total	3 (10.0)	0	3 (10.0)
Hypogammaglobulinaemia	3 (10.0)	0	3 (10.0)
Infections and infestations			
-Total	8 (26.7)	4 (13.3)	4 (13.3)
Upper respiratory tract infection	4 (13.3)	3 (10.0)	1 (3.3)
Nasopharyngitis	3 (10.0)	2 (6.7)	1 (3.3)
Rhinovirus infection	2 (6.7)	0	2 (6.7)
Conjunctivitis	1 (3.3)	0	1 (3.3)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (33.3)	5 (16.7)	5 (16.7)
White blood cell count decreased	7 (23.3)	4 (13.3)	3 (10.0)
Neutrophil count decreased	4 (13.3)	1 (3.3)	3 (10.0)
Platelet count decreased	4 (13.3)	3 (10.0)	1 (3.3)
Alanine aminotransferase increased	1 (3.3)	1 (3.3)	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Decreased appetite	3 (10.0)	2 (6.7)	1 (3.3)
Hypokalaemia	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Pain in extremity	2 (6.7)	1 (3.3)	1 (3.3)
Arthralgia	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	1 (3.3)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Psychiatric disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Anxiety	2 (6.7)	1 (3.3)	1 (3.3)
Agitation	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (23.3)	7 (23.3)	0
Cough	6 (20.0)	6 (20.0)	0
Nasal congestion	3 (10.0)	3 (10.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Dry skin	1 (3.3)	0	1 (3.3)
Rash	1 (3.3)	1 (3.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (74.2)	4 (12.9)	19 (61.3)
Blood and lymphatic system disorders			
-Total	1 (3.2)	1 (3.2)	0
Anaemia	1 (3.2)	1 (3.2)	0
Cardiac disorders			
-Total	1 (3.2)	1 (3.2)	0
Tachycardia	1 (3.2)	1 (3.2)	0
Gastrointestinal disorders			
-Total	5 (16.1)	2 (6.5)	3 (9.7)
Constipation	2 (6.5)	1 (3.2)	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	2 (6.5)	1 (3.2)	1 (3.2)
Nausea	1 (3.2)	0	1 (3.2)
General disorders and administration site conditions			
-Total	7 (22.6)	6 (19.4)	1 (3.2)
Pyrexia	4 (12.9)	3 (9.7)	1 (3.2)
Fatigue	2 (6.5)	2 (6.5)	0
Chills	1 (3.2)	1 (3.2)	0
Oedema peripheral	1 (3.2)	1 (3.2)	0
Immune system disorders			
-Total	5 (16.1)	0	5 (16.1)
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)
Infections and infestations			
-Total	8 (25.8)	1 (3.2)	7 (22.6)
Sinusitis	3 (9.7)	0	3 (9.7)
Nasopharyngitis	2 (6.5)	1 (3.2)	1 (3.2)
Upper respiratory tract infection	2 (6.5)	0	2 (6.5)
Rhinovirus infection	1 (3.2)	0	1 (3.2)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (16.1)	3 (9.7)	2 (6.5)
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0
Blood bilirubin increased	1 (3.2)	0	1 (3.2)
Metabolism and nutrition disorders			
-Total	6 (19.4)	2 (6.5)	4 (12.9)
Hyperuricaemia	3 (9.7)	3 (9.7)	0
Decreased appetite	2 (6.5)	0	2 (6.5)
Hypokalaemia	1 (3.2)	0	1 (3.2)
Hypophosphataemia	1 (3.2)	0	1 (3.2)
Musculoskeletal and connective tissue disorders			
-Total	3 (9.7)	2 (6.5)	1 (3.2)
Pain in extremity	2 (6.5)	1 (3.2)	1 (3.2)
Arthralgia	1 (3.2)	1 (3.2)	0
Myalgia	1 (3.2)	0	1 (3.2)
Nervous system disorders			
-Total	6 (19.4)	4 (12.9)	2 (6.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	6 (19.4)	4 (12.9)	2 (6.5)
Psychiatric disorders			
-Total	1 (3.2)	0	1 (3.2)
Anxiety	1 (3.2)	0	1 (3.2)
Renal and urinary disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Acute kidney injury	2 (6.5)	1 (3.2)	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (19.4)	2 (6.5)	4 (12.9)
Cough	5 (16.1)	2 (6.5)	3 (9.7)
Nasal congestion	3 (9.7)	2 (6.5)	1 (3.2)
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)
Skin and subcutaneous tissue disorders			
-Total	6 (19.4)	5 (16.1)	1 (3.2)
Dry skin	4 (12.9)	3 (9.7)	1 (3.2)
Rash	3 (9.7)	2 (6.5)	1 (3.2)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Hypertension	1 (3.2)	0	1 (3.2)
Hypotension	1 (3.2)	1 (3.2)	0

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Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (78.6)	1 (7.1)	10 (71.4)
Blood and lymphatic system disorders			
-Total	2 (14.3)	2 (14.3)	0
Anaemia	2 (14.3)	2 (14.3)	0
Gastrointestinal disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Abdominal pain	1 (7.1)	0	1 (7.1)
Nausea	1 (7.1)	0	1 (7.1)
Stomatitis	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Pyrexia	3 (21.4)	1 (7.1)	2 (14.3)
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0
Pain	1 (7.1)	0	1 (7.1)
Immune system disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)
Infections and infestations			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)
Acute sinusitis	1 (7.1)	0	1 (7.1)
Rhinovirus infection	1 (7.1)	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)
Investigations			
-Total	1 (7.1)	0	1 (7.1)
Blood bilirubin increased	1 (7.1)	0	1 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (7.1)	0	1 (7.1)
Neck pain	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Headache	3 (21.4)	1 (7.1)	2 (14.3)
Psychiatric disorders			
-Total	3 (21.4)	0	3 (21.4)
Anxiety	3 (21.4)	0	3 (21.4)
Skin and subcutaneous tissue disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Dry skin	1 (7.1)	1 (7.1)	0
Pruritus	1 (7.1)	0	1 (7.1)

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Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (40.0)	3 (15.0)	5 (25.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Anaemia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	2 (10.0)	2 (10.0)	0
Constipation	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)
Investigations			
-Total	2 (10.0)	2 (10.0)	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	0	2 (10.0)
Pain in extremity	2 (10.0)	0	2 (10.0)
Nervous system disorders			
-Total	1 (5.0)	0	1 (5.0)
Headache	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Cough	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (10.0)	2 (10.0)	0
Dry skin	1 (5.0)	1 (5.0)	0
Rash	1 (5.0)	1 (5.0)	0

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Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (50.0)	1 (4.5)	10 (45.5)
Gastrointestinal disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)
Nausea	1 (4.5)	1 (4.5)	0
Vomiting	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Pyrexia	2 (9.1)	1 (4.5)	1 (4.5)
Fatigue	1 (4.5)	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (4.5)	0	1 (4.5)
Immune system disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Seasonal allergy	3 (13.6)	2 (9.1)	1 (4.5)
Hypogammaglobulinaemia	2 (9.1)	0	2 (9.1)
Infections and infestations			
-Total	6 (27.3)	1 (4.5)	5 (22.7)
Sinusitis	4 (18.2)	0	4 (18.2)
Conjunctivitis	2 (9.1)	1 (4.5)	1 (4.5)
Rhinovirus infection	2 (9.1)	0	2 (9.1)
Upper respiratory tract infection	2 (9.1)	0	2 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (4.5)	0	1 (4.5)
Arthralgia	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	1 (4.5)	0	1 (4.5)
Headache	1 (4.5)	0	1 (4.5)
Psychiatric disorders			

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.5)	0	1 (4.5)
Anxiety	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Cough	2 (9.1)	1 (4.5)	1 (4.5)
Oropharyngeal pain	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			
-Total	1 (4.5)	0	1 (4.5)
Rash	1 (4.5)	0	1 (4.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (37.5)	0	3 (37.5)
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Diarrhoea	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	2 (25.0)	2 (25.0)	0
Non-cardiac chest pain	1 (12.5)	1 (12.5)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (37.5)	0	3 (37.5)
Sinusitis	2 (25.0)	0	2 (25.0)
Acute sinusitis	1 (12.5)	0	1 (12.5)
Rhinovirus infection	1 (12.5)	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Neutrophil count decreased	2 (25.0)	1 (12.5)	1 (12.5)
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Anxiety	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Cough	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (12.5)	0	1 (12.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	32 (97.0)	2 (6.1)	30 (90.9)
Blood and lymphatic system disorders			
-Total	10 (30.3)	3 (9.1)	7 (21.2)
Anaemia	10 (30.3)	3 (9.1)	7 (21.2)
Cardiac disorders			
-Total	8 (24.2)	4 (12.1)	4 (12.1)
Tachycardia	8 (24.2)	4 (12.1)	4 (12.1)
Endocrine disorders			
-Total	1 (3.0)	0	1 (3.0)
Adrenal insufficiency	1 (3.0)	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	26 (78.8)	14 (42.4)	12 (36.4)
Vomiting	16 (48.5)	11 (33.3)	5 (15.2)
Diarrhoea	12 (36.4)	8 (24.2)	4 (12.1)
Nausea	12 (36.4)	7 (21.2)	5 (15.2)
Constipation	7 (21.2)	4 (12.1)	3 (9.1)
Abdominal pain	6 (18.2)	2 (6.1)	4 (12.1)
General disorders and administration site conditions			
-Total	18 (54.5)	10 (30.3)	8 (24.2)
Pyrexia	12 (36.4)	6 (18.2)	6 (18.2)
Fatigue	11 (33.3)	9 (27.3)	2 (6.1)
Chills	3 (9.1)	2 (6.1)	1 (3.0)
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Hepatic function abnormal	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	26 (78.8)	5 (15.2)	21 (63.6)
Cytokine release syndrome	22 (66.7)	5 (15.2)	17 (51.5)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	11 (33.3)	1 (3.0)	10 (30.3)
Infections and infestations			
-Total	14 (42.4)	6 (18.2)	8 (24.2)
Upper respiratory tract infection	6 (18.2)	4 (12.1)	2 (6.1)
Conjunctivitis	5 (15.2)	1 (3.0)	4 (12.1)
Nasopharyngitis	3 (9.1)	2 (6.1)	1 (3.0)
Rhinovirus infection	2 (6.1)	0	2 (6.1)
Investigations			
-Total	20 (60.6)	5 (15.2)	15 (45.5)
Alanine aminotransferase increased	9 (27.3)	2 (6.1)	7 (21.2)
Platelet count decreased	9 (27.3)	5 (15.2)	4 (12.1)
White blood cell count decreased	8 (24.2)	3 (9.1)	5 (15.2)
Aspartate aminotransferase increased	5 (15.2)	1 (3.0)	4 (12.1)
Blood immunoglobulin a decreased	5 (15.2)	4 (12.1)	1 (3.0)
Blood immunoglobulin m decreased	5 (15.2)	4 (12.1)	1 (3.0)
Neutrophil count decreased	5 (15.2)	1 (3.0)	4 (12.1)
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	2 (6.1)	1 (3.0)	1 (3.0)
Metabolism and nutrition disorders			
-Total	15 (45.5)	6 (18.2)	9 (27.3)
Hypophosphataemia	7 (21.2)	3 (9.1)	4 (12.1)
Decreased appetite	6 (18.2)	4 (12.1)	2 (6.1)
Hypocalcaemia	6 (18.2)	1 (3.0)	5 (15.2)
Hypokalaemia	6 (18.2)	2 (6.1)	4 (12.1)
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)
Hypomagnesaemia	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	14 (42.4)	7 (21.2)	7 (21.2)
Pain in extremity	11 (33.3)	5 (15.2)	6 (18.2)
Arthralgia	4 (12.1)	1 (3.0)	3 (9.1)
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)
Nervous system disorders			
-Total	9 (27.3)	7 (21.2)	2 (6.1)
Headache	7 (21.2)	5 (15.2)	2 (6.1)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tremor	2 (6.1)	2 (6.1)	0
Psychiatric disorders			
-Total	7 (21.2)	4 (12.1)	3 (9.1)
Anxiety	5 (15.2)	2 (6.1)	3 (9.1)
Confusional state	4 (12.1)	4 (12.1)	0
Agitation	2 (6.1)	2 (6.1)	0
Renal and urinary disorders			
-Total	1 (3.0)	1 (3.0)	0
Acute kidney injury	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	14 (42.4)	12 (36.4)	2 (6.1)
Cough	11 (33.3)	10 (30.3)	1 (3.0)
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)
Oropharyngeal pain	1 (3.0)	1 (3.0)	0
Skin and subcutaneous tissue disorders			
-Total	8 (24.2)	5 (15.2)	3 (9.1)
Dry skin	3 (9.1)	2 (6.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)
Rash	3 (9.1)	2 (6.1)	1 (3.0)
Vascular disorders			
-Total	9 (27.3)	4 (12.1)	5 (15.2)
Hypotension	5 (15.2)	1 (3.0)	4 (12.1)
Hypertension	4 (12.1)	3 (9.1)	1 (3.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (100)	1 (3.0)	32 (97.0)
Blood and lymphatic system disorders			
-Total	7 (21.2)	3 (9.1)	4 (12.1)
Anaemia	6 (18.2)	3 (9.1)	3 (9.1)
Coagulopathy	1 (3.0)	0	1 (3.0)
Cardiac disorders			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Tachycardia	6 (18.2)	3 (9.1)	3 (9.1)
Sinus tachycardia	1 (3.0)	1 (3.0)	0
Endocrine disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (3.0)	0	1 (3.0)
Adrenal insufficiency	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	16 (48.5)	7 (21.2)	9 (27.3)
Diarrhoea	9 (27.3)	6 (18.2)	3 (9.1)
Nausea	4 (12.1)	3 (9.1)	1 (3.0)
Vomiting	4 (12.1)	3 (9.1)	1 (3.0)
Abdominal pain	3 (9.1)	0	3 (9.1)
Constipation	3 (9.1)	1 (3.0)	2 (6.1)
General disorders and administration site conditions			
-Total	17 (51.5)	11 (33.3)	6 (18.2)
Pyrexia	11 (33.3)	7 (21.2)	4 (12.1)
Fatigue	5 (15.2)	4 (12.1)	1 (3.0)
Oedema peripheral	4 (12.1)	3 (9.1)	1 (3.0)
Chills	2 (6.1)	2 (6.1)	0
Pain	1 (3.0)	0	1 (3.0)
Hepatobiliary disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatic function abnormal	2 (6.1)	1 (3.0)	1 (3.0)
Immune system disorders			
-Total	27 (81.8)	5 (15.2)	22 (66.7)
Cytokine release syndrome	24 (72.7)	6 (18.2)	18 (54.5)
Hypogammaglobulinaemia	10 (30.3)	0	10 (30.3)
Seasonal allergy	4 (12.1)	2 (6.1)	2 (6.1)
Infections and infestations			
-Total	11 (33.3)	1 (3.0)	10 (30.3)
Rhinovirus infection	4 (12.1)	0	4 (12.1)
Sinusitis	4 (12.1)	0	4 (12.1)
Upper respiratory tract infection	4 (12.1)	0	4 (12.1)
Conjunctivitis	2 (6.1)	1 (3.0)	1 (3.0)
Nasopharyngitis	2 (6.1)	1 (3.0)	1 (3.0)
Investigations			
-Total	10 (30.3)	1 (3.0)	9 (27.3)
Aspartate aminotransferase increased	6 (18.2)	0	6 (18.2)
Alanine aminotransferase increased	5 (15.2)	2 (6.1)	3 (9.1)
Platelet count decreased	5 (15.2)	2 (6.1)	3 (9.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	4 (12.1)	1 (3.0)	3 (9.1)
Neutrophil count decreased	4 (12.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	4 (12.1)	1 (3.0)	3 (9.1)
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)
Metabolism and nutrition disorders			
-Total	19 (57.6)	6 (18.2)	13 (39.4)
Decreased appetite	9 (27.3)	4 (12.1)	5 (15.2)
Hyperuricaemia	6 (18.2)	6 (18.2)	0
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)
Hypocalcaemia	5 (15.2)	1 (3.0)	4 (12.1)
Hypokalaemia	3 (9.1)	0	3 (9.1)
Hypomagnesaemia	3 (9.1)	3 (9.1)	0
Hypophosphataemia	3 (9.1)	1 (3.0)	2 (6.1)
Hyperglycaemia	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	10 (30.3)	7 (21.2)	3 (9.1)
Myalgia	5 (15.2)	3 (9.1)	2 (6.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	4 (12.1)	3 (9.1)	1 (3.0)
Pain in extremity	4 (12.1)	2 (6.1)	2 (6.1)
Nervous system disorders			
-Total	15 (45.5)	6 (18.2)	9 (27.3)
Headache	15 (45.5)	6 (18.2)	9 (27.3)
Tremor	2 (6.1)	1 (3.0)	1 (3.0)
Psychiatric disorders			
-Total	7 (21.2)	2 (6.1)	5 (15.2)
Anxiety	3 (9.1)	0	3 (9.1)
Confusional state	3 (9.1)	3 (9.1)	0
Agitation	2 (6.1)	0	2 (6.1)
Renal and urinary disorders			
-Total	4 (12.1)	1 (3.0)	3 (9.1)
Acute kidney injury	4 (12.1)	1 (3.0)	3 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (42.4)	9 (27.3)	5 (15.2)
Cough	11 (33.3)	7 (21.2)	4 (12.1)
Oropharyngeal pain	5 (15.2)	4 (12.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)
Skin and subcutaneous tissue disorders			
-Total	9 (27.3)	5 (15.2)	4 (12.1)
Rash	5 (15.2)	2 (6.1)	3 (9.1)
Dry skin	4 (12.1)	3 (9.1)	1 (3.0)
Hyperhidrosis	1 (3.0)	1 (3.0)	0
Pruritus	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	7 (21.2)	3 (9.1)	4 (12.1)
Hypertension	4 (12.1)	1 (3.0)	3 (9.1)
Hypotension	4 (12.1)	2 (6.1)	2 (6.1)

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Table 257a
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (100)	1 (7.1)	13 (92.9)
Blood and lymphatic system disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Anaemia	3 (21.4)	1 (7.1)	2 (14.3)
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)
Cardiac disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)
Endocrine disorders			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (14.3)	0	2 (14.3)
Adrenal insufficiency	2 (14.3)	0	2 (14.3)
Gastrointestinal disorders			
-Total	12 (85.7)	7 (50.0)	5 (35.7)
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)
Constipation	4 (28.6)	2 (14.3)	2 (14.3)
Nausea	4 (28.6)	2 (14.3)	2 (14.3)
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)
Abdominal pain	2 (14.3)	1 (7.1)	1 (7.1)
Stomatitis	2 (14.3)	1 (7.1)	1 (7.1)
General disorders and administration site conditions			
-Total	10 (71.4)	5 (35.7)	5 (35.7)
Pyrexia	6 (42.9)	2 (14.3)	4 (28.6)
Chills	2 (14.3)	1 (7.1)	1 (7.1)
Non-cardiac chest pain	2 (14.3)	2 (14.3)	0
Oedema peripheral	2 (14.3)	2 (14.3)	0
Pain	2 (14.3)	1 (7.1)	1 (7.1)
Fatigue	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (14.3)	0	2 (14.3)
Hepatic function abnormal	2 (14.3)	0	2 (14.3)
Immune system disorders			
-Total	11 (78.6)	1 (7.1)	10 (71.4)
Cytokine release syndrome	11 (78.6)	2 (14.3)	9 (64.3)
Hypogammaglobulinaemia	5 (35.7)	1 (7.1)	4 (28.6)
Infections and infestations			
-Total	7 (50.0)	1 (7.1)	6 (42.9)
Acute sinusitis	2 (14.3)	0	2 (14.3)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)
Rhinovirus infection	2 (14.3)	0	2 (14.3)
Sinusitis	2 (14.3)	0	2 (14.3)
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)
Conjunctivitis	1 (7.1)	0	1 (7.1)
Investigations			
-Total	5 (35.7)	0	5 (35.7)
Alanine aminotransferase increased	2 (14.3)	0	2 (14.3)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	2 (14.3)	2 (14.3)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Blood bilirubin increased	1 (7.1)	0	1 (7.1)
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	7 (50.0)	3 (21.4)	4 (28.6)
Hypokalaemia	4 (28.6)	1 (7.1)	3 (21.4)
Decreased appetite	3 (21.4)	3 (21.4)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)
Hyperuricaemia	1 (7.1)	1 (7.1)	0
Hypoalbuminaemia	1 (7.1)	0	1 (7.1)
Hypocalcaemia	1 (7.1)	0	1 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	5 (35.7)	2 (14.3)	3 (21.4)

Timing: Any time post CTL019 infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)
Neck pain	2 (14.3)	1 (7.1)	1 (7.1)
Pain in extremity	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	5 (35.7)	3 (21.4)	2 (14.3)
Headache	4 (28.6)	2 (14.3)	2 (14.3)
Tremor	2 (14.3)	2 (14.3)	0
Psychiatric disorders			
-Total	6 (42.9)	2 (14.3)	4 (28.6)
Anxiety	4 (28.6)	1 (7.1)	3 (21.4)
Agitation	2 (14.3)	1 (7.1)	1 (7.1)
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	3 (21.4)	0
Oropharyngeal pain	2 (14.3)	2 (14.3)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (7.1)	1 (7.1)	0
Nasal congestion	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Pruritus	3 (21.4)	1 (7.1)	2 (14.3)
Hyperhidrosis	2 (14.3)	0	2 (14.3)
Dry skin	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Hypertension	4 (28.6)	1 (7.1)	3 (21.4)
Hypotension	1 (7.1)	0	1 (7.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

		All patients N=46	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	43 (93.5)	6 (13.0)	37 (80.4)
Blood and lymphatic system disorders			
-Total	10 (21.7)	1 (2.2)	9 (19.6)
Anaemia	5 (10.9)	1 (2.2)	4 (8.7)
Disseminated intravascular coagulation	5 (10.9)	0	5 (10.9)
Cardiac disorders			
-Total	7 (15.2)	3 (6.5)	4 (8.7)
Tachycardia	7 (15.2)	3 (6.5)	4 (8.7)
Gastrointestinal disorders			
-Total	23 (50.0)	12 (26.1)	11 (23.9)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	12 (26.1)	9 (19.6)	3 (6.5)
Nausea	11 (23.9)	7 (15.2)	4 (8.7)
Diarrhoea	6 (13.0)	4 (8.7)	2 (4.3)
Abdominal pain	5 (10.9)	0	5 (10.9)
Constipation	5 (10.9)	2 (4.3)	3 (6.5)
General disorders and administration site conditions			
-Total	15 (32.6)	10 (21.7)	5 (10.9)
Pyrexia	8 (17.4)	6 (13.0)	2 (4.3)
Fatigue	7 (15.2)	5 (10.9)	2 (4.3)
Chills	3 (6.5)	2 (4.3)	1 (2.2)
Face oedema	3 (6.5)	3 (6.5)	0
Oedema peripheral	2 (4.3)	2 (4.3)	0
Generalised oedema	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	30 (65.2)	5 (10.9)	25 (54.3)
Cytokine release syndrome	28 (60.9)	6 (13.0)	22 (47.8)
Hypogammaglobulinaemia	9 (19.6)	1 (2.2)	8 (17.4)
Infections and infestations			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (6.5)	1 (2.2)	2 (4.3)
Conjunctivitis	3 (6.5)	1 (2.2)	2 (4.3)
Investigations			
-Total	21 (45.7)	5 (10.9)	16 (34.8)
Alanine aminotransferase increased	12 (26.1)	4 (8.7)	8 (17.4)
Aspartate aminotransferase increased	7 (15.2)	1 (2.2)	6 (13.0)
Platelet count decreased	7 (15.2)	3 (6.5)	4 (8.7)
Serum ferritin increased	5 (10.9)	1 (2.2)	4 (8.7)
White blood cell count decreased	4 (8.7)	2 (4.3)	2 (4.3)
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)
Blood immunoglobulin m decreased	1 (2.2)	1 (2.2)	0
Lymphocyte count decreased	1 (2.2)	0	1 (2.2)
Neutrophil count decreased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	16 (34.8)	6 (13.0)	10 (21.7)
Decreased appetite	6 (13.0)	3 (6.5)	3 (6.5)
Hypocalcaemia	6 (13.0)	2 (4.3)	4 (8.7)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	5 (10.9)	1 (2.2)	4 (8.7)
Hypophosphataemia	5 (10.9)	4 (8.7)	1 (2.2)
Hyperuricaemia	4 (8.7)	3 (6.5)	1 (2.2)
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)
Musculoskeletal and connective tissue disorders			
-Total	13 (28.3)	5 (10.9)	8 (17.4)
Arthralgia	7 (15.2)	3 (6.5)	4 (8.7)
Pain in extremity	7 (15.2)	3 (6.5)	4 (8.7)
Back pain	2 (4.3)	0	2 (4.3)
Myalgia	2 (4.3)	2 (4.3)	0
Nervous system disorders			
-Total	9 (19.6)	7 (15.2)	2 (4.3)
Headache	9 (19.6)	7 (15.2)	2 (4.3)
Psychiatric disorders			
-Total	3 (6.5)	0	3 (6.5)
Anxiety	3 (6.5)	0	3 (6.5)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (23.9)	10 (21.7)	1 (2.2)
Cough	4 (8.7)	4 (8.7)	0
Oropharyngeal pain	3 (6.5)	3 (6.5)	0
Pleural effusion	3 (6.5)	3 (6.5)	0
Nasal congestion	2 (4.3)	1 (2.2)	1 (2.2)
Epistaxis	1 (2.2)	1 (2.2)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.5)	1 (2.2)	2 (4.3)
Rash	3 (6.5)	1 (2.2)	2 (4.3)
Vascular disorders			
-Total	9 (19.6)	3 (6.5)	6 (13.0)
Hypertension	5 (10.9)	3 (6.5)	2 (4.3)
Hypotension	5 (10.9)	0	5 (10.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (100)	3 (8.8)	31 (91.2)
Blood and lymphatic system disorders			
-Total	11 (32.4)	4 (11.8)	7 (20.6)
Anaemia	11 (32.4)	4 (11.8)	7 (20.6)
Cardiac disorders			
-Total	8 (23.5)	4 (11.8)	4 (11.8)
Tachycardia	8 (23.5)	4 (11.8)	4 (11.8)
Gastrointestinal disorders			
-Total	22 (64.7)	12 (35.3)	10 (29.4)
Diarrhoea	8 (23.5)	4 (11.8)	4 (11.8)
Vomiting	8 (23.5)	3 (8.8)	5 (14.7)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	6 (17.6)	4 (11.8)	2 (5.9)
Abdominal pain	5 (14.7)	3 (8.8)	2 (5.9)
Nausea	5 (14.7)	3 (8.8)	2 (5.9)
General disorders and administration site conditions			
-Total	16 (47.1)	9 (26.5)	7 (20.6)
Pyrexia	11 (32.4)	5 (14.7)	6 (17.6)
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)
Fatigue	4 (11.8)	4 (11.8)	0
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)
Chills	3 (8.8)	2 (5.9)	1 (2.9)
Oedema peripheral	3 (8.8)	2 (5.9)	1 (2.9)
Immune system disorders			
-Total	30 (88.2)	7 (20.6)	23 (67.6)
Cytokine release syndrome	29 (85.3)	7 (20.6)	22 (64.7)
Hypogammaglobulinaemia	7 (20.6)	1 (2.9)	6 (17.6)
Infections and infestations			
-Total	4 (11.8)	0	4 (11.8)
Conjunctivitis	2 (5.9)	0	2 (5.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	2 (5.9)	0	2 (5.9)
Investigations			
-Total	17 (50.0)	3 (8.8)	14 (41.2)
Aspartate aminotransferase increased	6 (17.6)	2 (5.9)	4 (11.8)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)
Platelet count decreased	6 (17.6)	3 (8.8)	3 (8.8)
Neutrophil count decreased	5 (14.7)	0	5 (14.7)
Alanine aminotransferase increased	4 (11.8)	0	4 (11.8)
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)
White blood cell count decreased	4 (11.8)	1 (2.9)	3 (8.8)
Lymphocyte count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Serum ferritin increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	18 (52.9)	6 (17.6)	12 (35.3)
Decreased appetite	7 (20.6)	6 (17.6)	1 (2.9)
Hypokalaemia	7 (20.6)	2 (5.9)	5 (14.7)
Hypoalbuminaemia	6 (17.6)	0	6 (17.6)

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	6 (17.6)	0	6 (17.6)
Hyperglycaemia	4 (11.8)	0	4 (11.8)
Hypophosphataemia	4 (11.8)	0	4 (11.8)
Hyperuricaemia	3 (8.8)	3 (8.8)	0
Musculoskeletal and connective tissue disorders			
-Total	13 (38.2)	8 (23.5)	5 (14.7)
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)
Pain in extremity	4 (11.8)	3 (8.8)	1 (2.9)
Back pain	3 (8.8)	2 (5.9)	1 (2.9)
Arthralgia	2 (5.9)	1 (2.9)	1 (2.9)
Nervous system disorders			
-Total	15 (44.1)	8 (23.5)	7 (20.6)
Headache	12 (35.3)	5 (14.7)	7 (20.6)
Tremor	6 (17.6)	5 (14.7)	1 (2.9)
Psychiatric disorders			
-Total	1 (2.9)	1 (2.9)	0
Anxiety	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	11 (32.4)	9 (26.5)	2 (5.9)
Cough	6 (17.6)	5 (14.7)	1 (2.9)
Epistaxis	2 (5.9)	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	2 (5.9)	0
Rhinorrhoea	2 (5.9)	2 (5.9)	0
Nasal congestion	1 (2.9)	1 (2.9)	0
Pleural effusion	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			
-Total	3 (8.8)	2 (5.9)	1 (2.9)
Rash	2 (5.9)	1 (2.9)	1 (2.9)
Dry skin	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	8 (23.5)	4 (11.8)	4 (11.8)
Hypertension	5 (14.7)	2 (5.9)	3 (8.8)
Hypotension	4 (11.8)	2 (5.9)	2 (5.9)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (72.1)	7 (16.3)	24 (55.8)
Blood and lymphatic system disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Anaemia	2 (4.7)	1 (2.3)	1 (2.3)
Cardiac disorders			
-Total	2 (4.7)	2 (4.7)	0
Tachycardia	2 (4.7)	2 (4.7)	0
Gastrointestinal disorders			
-Total	9 (20.9)	6 (14.0)	3 (7.0)
Diarrhoea	5 (11.6)	4 (9.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	3 (7.0)	3 (7.0)	0
Constipation	2 (4.7)	1 (2.3)	1 (2.3)
Nausea	2 (4.7)	1 (2.3)	1 (2.3)
Abdominal pain	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	11 (25.6)	7 (16.3)	4 (9.3)
Pyrexia	8 (18.6)	4 (9.3)	4 (9.3)
Fatigue	3 (7.0)	3 (7.0)	0
Immune system disorders			
-Total	5 (11.6)	0	5 (11.6)
Hypogammaglobulinaemia	5 (11.6)	0	5 (11.6)
Infections and infestations			
-Total	12 (27.9)	5 (11.6)	7 (16.3)
Nasopharyngitis	5 (11.6)	3 (7.0)	2 (4.7)
Upper respiratory tract infection	5 (11.6)	3 (7.0)	2 (4.7)
Rhinovirus infection	2 (4.7)	0	2 (4.7)
Conjunctivitis	1 (2.3)	0	1 (2.3)
Sinusitis	1 (2.3)	0	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	6 (14.0)	3 (7.0)	3 (7.0)
White blood cell count decreased	5 (11.6)	2 (4.7)	3 (7.0)
Alanine aminotransferase increased	2 (4.7)	2 (4.7)	0
Platelet count decreased	2 (4.7)	1 (2.3)	1 (2.3)
Lymphocyte count decreased	1 (2.3)	0	1 (2.3)
Neutrophil count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	6 (14.0)	2 (4.7)	4 (9.3)
Decreased appetite	4 (9.3)	1 (2.3)	3 (7.0)
Hyperuricaemia	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	1 (2.3)
Musculoskeletal and connective tissue disorders			
-Total	7 (16.3)	4 (9.3)	3 (7.0)
Arthralgia	3 (7.0)	2 (4.7)	1 (2.3)
Pain in extremity	3 (7.0)	1 (2.3)	2 (4.7)
Back pain	2 (4.7)	2 (4.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	1 (2.3)	0	1 (2.3)
Nervous system disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)
Headache	3 (7.0)	2 (4.7)	1 (2.3)
Psychiatric disorders			
-Total	4 (9.3)	1 (2.3)	3 (7.0)
Anxiety	4 (9.3)	1 (2.3)	3 (7.0)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (20.9)	6 (14.0)	3 (7.0)
Cough	5 (11.6)	4 (9.3)	1 (2.3)
Nasal congestion	3 (7.0)	3 (7.0)	0
Pleural effusion	2 (4.7)	1 (2.3)	1 (2.3)
Epistaxis	1 (2.3)	0	1 (2.3)
Oropharyngeal pain	1 (2.3)	0	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	4 (9.3)	3 (7.0)	1 (2.3)
Rash	3 (7.0)	2 (4.7)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	2 (4.7)	1 (2.3)	1 (2.3)
Vascular disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Hypertension	1 (2.3)	0	1 (2.3)
Hypotension	1 (2.3)	1 (2.3)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (81.3)	6 (18.8)	20 (62.5)
Blood and lymphatic system disorders			
-Total	3 (9.4)	3 (9.4)	0
Anaemia	3 (9.4)	3 (9.4)	0
Gastrointestinal disorders			
-Total	5 (15.6)	3 (9.4)	2 (6.3)
Nausea	3 (9.4)	2 (6.3)	1 (3.1)
Vomiting	3 (9.4)	3 (9.4)	0
Diarrhoea	2 (6.3)	2 (6.3)	0
Abdominal pain	1 (3.1)	0	1 (3.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	1 (3.1)	0	1 (3.1)
General disorders and administration site conditions			
-Total	9 (28.1)	7 (21.9)	2 (6.3)
Pyrexia	5 (15.6)	3 (9.4)	2 (6.3)
Fatigue	3 (9.4)	3 (9.4)	0
Chills	1 (3.1)	1 (3.1)	0
Oedema peripheral	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	5 (15.6)	0	5 (15.6)
Hypogammaglobulinaemia	5 (15.6)	0	5 (15.6)
Infections and infestations			
-Total	8 (25.0)	1 (3.1)	7 (21.9)
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)
Rhinovirus infection	2 (6.3)	0	2 (6.3)
Sinusitis	2 (6.3)	0	2 (6.3)
Upper respiratory tract infection	2 (6.3)	0	2 (6.3)
Investigations			
-Total	8 (25.0)	4 (12.5)	4 (12.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	5 (15.6)	2 (6.3)	3 (9.4)
White blood cell count decreased	4 (12.5)	3 (9.4)	1 (3.1)
Lymphocyte count decreased	2 (6.3)	1 (3.1)	1 (3.1)
Platelet count decreased	2 (6.3)	2 (6.3)	0
Metabolism and nutrition disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Hyperuricaemia	2 (6.3)	2 (6.3)	0
Decreased appetite	1 (3.1)	1 (3.1)	0
Hypokalaemia	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Back pain	2 (6.3)	0	2 (6.3)
Pain in extremity	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	7 (21.9)	4 (12.5)	3 (9.4)
Headache	7 (21.9)	4 (12.5)	3 (9.4)
Psychiatric disorders			
-Total	2 (6.3)	0	2 (6.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	2 (6.3)	0	2 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (25.0)	5 (15.6)	3 (9.4)
Cough	6 (18.8)	4 (12.5)	2 (6.3)
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)
Rhinorrhoea	3 (9.4)	3 (9.4)	0
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Oropharyngeal pain	1 (3.1)	1 (3.1)	0
Skin and subcutaneous tissue disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Dry skin	4 (12.5)	3 (9.4)	1 (3.1)
Rash	1 (3.1)	1 (3.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (34.5)	2 (6.9)	8 (27.6)
Blood and lymphatic system disorders			
-Total	1 (3.4)	0	1 (3.4)
Anaemia	1 (3.4)	0	1 (3.4)
Gastrointestinal disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Diarrhoea	2 (6.9)	1 (3.4)	1 (3.4)
Nausea	1 (3.4)	1 (3.4)	0
Vomiting	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (10.3)	0	3 (10.3)
Pyrexia	2 (6.9)	0	2 (6.9)
Fatigue	1 (3.4)	0	1 (3.4)
Infections and infestations			
-Total	7 (24.1)	3 (10.3)	4 (13.8)
Conjunctivitis	4 (13.8)	2 (6.9)	2 (6.9)
Sinusitis	2 (6.9)	0	2 (6.9)
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)
Rhinovirus infection	1 (3.4)	0	1 (3.4)
Investigations			
-Total	1 (3.4)	1 (3.4)	0
Neutrophil count decreased	1 (3.4)	1 (3.4)	0
Platelet count decreased	1 (3.4)	1 (3.4)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.9)	0	2 (6.9)
Arthralgia	1 (3.4)	0	1 (3.4)
Pain in extremity	1 (3.4)	0	1 (3.4)
Nervous system disorders			

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (3.4)	0	1 (3.4)
Headache	1 (3.4)	0	1 (3.4)
Psychiatric disorders			
-Total	1 (3.4)	0	1 (3.4)
Anxiety	1 (3.4)	0	1 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (13.8)	2 (6.9)	2 (6.9)
Cough	4 (13.8)	3 (10.3)	1 (3.4)
Rhinorrhoea	2 (6.9)	1 (3.4)	1 (3.4)
Oropharyngeal pain	1 (3.4)	1 (3.4)	0
Pleural effusion	1 (3.4)	0	1 (3.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (57.1)	3 (14.3)	9 (42.9)
Gastrointestinal disorders			
-Total	3 (14.3)	3 (14.3)	0
Diarrhoea	2 (9.5)	2 (9.5)	0
Constipation	1 (4.8)	1 (4.8)	0
General disorders and administration site conditions			
-Total	2 (9.5)	2 (9.5)	0
Pyrexia	2 (9.5)	2 (9.5)	0
Immune system disorders			
-Total	3 (14.3)	0	3 (14.3)

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	3 (14.3)	0	3 (14.3)
Infections and infestations			
-Total	6 (28.6)	1 (4.8)	5 (23.8)
Sinusitis	4 (19.0)	0	4 (19.0)
Upper respiratory tract infection	3 (14.3)	1 (4.8)	2 (9.5)
Rhinovirus infection	2 (9.5)	0	2 (9.5)
Investigations			
-Total	3 (14.3)	2 (9.5)	1 (4.8)
Neutrophil count decreased	2 (9.5)	1 (4.8)	1 (4.8)
Platelet count decreased	1 (4.8)	1 (4.8)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.8)	0	1 (4.8)
Pain in extremity	1 (4.8)	0	1 (4.8)
Nervous system disorders			
-Total	1 (4.8)	0	1 (4.8)
Headache	1 (4.8)	0	1 (4.8)
Psychiatric disorders			
-Total	1 (4.8)	1 (4.8)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	1 (4.8)	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Epistaxis	1 (4.8)	1 (4.8)	0
Rhinorrhoea	1 (4.8)	0	1 (4.8)
Skin and subcutaneous tissue disorders			
-Total	3 (14.3)	2 (9.5)	1 (4.8)
Rash	2 (9.5)	1 (4.8)	1 (4.8)
Dry skin	1 (4.8)	1 (4.8)	0
Vascular disorders			
-Total	1 (4.8)	0	1 (4.8)
Hypertension	1 (4.8)	0	1 (4.8)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

		All patients N=46	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	45 (97.8)	3 (6.5)	42 (91.3)
Blood and lymphatic system disorders			
-Total	12 (26.1)	2 (4.3)	10 (21.7)
Anaemia	7 (15.2)	2 (4.3)	5 (10.9)
Disseminated intravascular coagulation	5 (10.9)	0	5 (10.9)
Cardiac disorders			
-Total	8 (17.4)	4 (8.7)	4 (8.7)
Tachycardia	8 (17.4)	4 (8.7)	4 (8.7)
Gastrointestinal disorders			
-Total	31 (67.4)	16 (34.8)	15 (32.6)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	15 (32.6)	12 (26.1)	3 (6.5)
Nausea	13 (28.3)	8 (17.4)	5 (10.9)
Diarrhoea	12 (26.1)	8 (17.4)	4 (8.7)
Constipation	7 (15.2)	3 (6.5)	4 (8.7)
Abdominal pain	6 (13.0)	1 (2.2)	5 (10.9)
General disorders and administration site conditions			
-Total	23 (50.0)	11 (23.9)	12 (26.1)
Pyrexia	15 (32.6)	7 (15.2)	8 (17.4)
Fatigue	11 (23.9)	8 (17.4)	3 (6.5)
Chills	3 (6.5)	2 (4.3)	1 (2.2)
Face oedema	3 (6.5)	3 (6.5)	0
Oedema peripheral	2 (4.3)	2 (4.3)	0
Generalised oedema	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	32 (69.6)	5 (10.9)	27 (58.7)
Cytokine release syndrome	28 (60.9)	6 (13.0)	22 (47.8)
Hypogammaglobulinaemia	14 (30.4)	1 (2.2)	13 (28.3)
Infections and infestations			

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (39.1)	7 (15.2)	11 (23.9)
Upper respiratory tract infection	7 (15.2)	4 (8.7)	3 (6.5)
Conjunctivitis	6 (13.0)	2 (4.3)	4 (8.7)
Nasopharyngitis	5 (10.9)	3 (6.5)	2 (4.3)
Rhinovirus infection	3 (6.5)	0	3 (6.5)
Sinusitis	2 (4.3)	0	2 (4.3)
Investigations			
-Total	21 (45.7)	4 (8.7)	17 (37.0)
Alanine aminotransferase increased	12 (26.1)	4 (8.7)	8 (17.4)
Aspartate aminotransferase increased	7 (15.2)	1 (2.2)	6 (13.0)
Platelet count decreased	7 (15.2)	3 (6.5)	4 (8.7)
White blood cell count decreased	6 (13.0)	1 (2.2)	5 (10.9)
Serum ferritin increased	5 (10.9)	1 (2.2)	4 (8.7)
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)
Neutrophil count decreased	3 (6.5)	1 (2.2)	2 (4.3)
Lymphocyte count decreased	2 (4.3)	0	2 (4.3)
Blood immunoglobulin m decreased	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	20 (43.5)	7 (15.2)	13 (28.3)
Decreased appetite	10 (21.7)	4 (8.7)	6 (13.0)
Hypocalcaemia	6 (13.0)	2 (4.3)	4 (8.7)
Hypophosphataemia	6 (13.0)	4 (8.7)	2 (4.3)
Hyperuricaemia	5 (10.9)	4 (8.7)	1 (2.2)
Hypokalaemia	5 (10.9)	1 (2.2)	4 (8.7)
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)
Musculoskeletal and connective tissue disorders			
-Total	18 (39.1)	8 (17.4)	10 (21.7)
Pain in extremity	10 (21.7)	4 (8.7)	6 (13.0)
Arthralgia	9 (19.6)	4 (8.7)	5 (10.9)
Back pain	3 (6.5)	1 (2.2)	2 (4.3)
Myalgia	3 (6.5)	2 (4.3)	1 (2.2)
Nervous system disorders			
-Total	11 (23.9)	7 (15.2)	4 (8.7)
Headache	11 (23.9)	7 (15.2)	4 (8.7)
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (17.4)	1 (2.2)	7 (15.2)
Anxiety	8 (17.4)	1 (2.2)	7 (15.2)
Respiratory, thoracic and mediastinal disorders			
-Total	21 (45.7)	15 (32.6)	6 (13.0)
Cough	13 (28.3)	11 (23.9)	2 (4.3)
Nasal congestion	5 (10.9)	4 (8.7)	1 (2.2)
Oropharyngeal pain	5 (10.9)	4 (8.7)	1 (2.2)
Pleural effusion	5 (10.9)	3 (6.5)	2 (4.3)
Epistaxis	2 (4.3)	1 (2.2)	1 (2.2)
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)
Skin and subcutaneous tissue disorders			
-Total	5 (10.9)	3 (6.5)	2 (4.3)
Rash	4 (8.7)	2 (4.3)	2 (4.3)
Dry skin	2 (4.3)	1 (2.2)	1 (2.2)
Vascular disorders			
-Total	11 (23.9)	4 (8.7)	7 (15.2)
Hypertension	6 (13.0)	3 (6.5)	3 (6.5)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	6 (13.0)	1 (2.2)	5 (10.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257b
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	33 (97.1)
Blood and lymphatic system disorders			
-Total	12 (35.3)	5 (14.7)	7 (20.6)
Anaemia	12 (35.3)	5 (14.7)	7 (20.6)
Cardiac disorders			
-Total	8 (23.5)	4 (11.8)	4 (11.8)
Tachycardia	8 (23.5)	4 (11.8)	4 (11.8)
Gastrointestinal disorders			
-Total	23 (67.6)	12 (35.3)	11 (32.4)
Diarrhoea	12 (35.3)	8 (23.5)	4 (11.8)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	10 (29.4)	5 (14.7)	5 (14.7)
Constipation	7 (20.6)	4 (11.8)	3 (8.8)
Nausea	7 (20.6)	4 (11.8)	3 (8.8)
Abdominal pain	5 (14.7)	2 (5.9)	3 (8.8)
General disorders and administration site conditions			
-Total	20 (58.8)	13 (38.2)	7 (20.6)
Pyrexia	14 (41.2)	8 (23.5)	6 (17.6)
Fatigue	6 (17.6)	6 (17.6)	0
Chills	4 (11.8)	3 (8.8)	1 (2.9)
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)
Oedema peripheral	4 (11.8)	3 (8.8)	1 (2.9)
Immune system disorders			
-Total	31 (91.2)	6 (17.6)	25 (73.5)
Cytokine release syndrome	29 (85.3)	7 (20.6)	22 (64.7)
Hypogammaglobulinaemia	12 (35.3)	1 (2.9)	11 (32.4)
Infections and infestations			
-Total	13 (38.2)	2 (5.9)	11 (32.4)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	5 (14.7)	0	5 (14.7)
Upper respiratory tract infection	5 (14.7)	1 (2.9)	4 (11.8)
Sinusitis	4 (11.8)	0	4 (11.8)
Conjunctivitis	2 (5.9)	0	2 (5.9)
Nasopharyngitis	2 (5.9)	1 (2.9)	1 (2.9)
Investigations			
-Total	18 (52.9)	3 (8.8)	15 (44.1)
Neutrophil count decreased	8 (23.5)	2 (5.9)	6 (17.6)
Platelet count decreased	8 (23.5)	5 (14.7)	3 (8.8)
Aspartate aminotransferase increased	6 (17.6)	2 (5.9)	4 (11.8)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)
White blood cell count decreased	6 (17.6)	3 (8.8)	3 (8.8)
Alanine aminotransferase increased	4 (11.8)	0	4 (11.8)
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)
Lymphocyte count decreased	4 (11.8)	2 (5.9)	2 (5.9)
Serum ferritin increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	20 (58.8)	7 (20.6)	13 (38.2)
Decreased appetite	8 (23.5)	7 (20.6)	1 (2.9)
Hypokalaemia	8 (23.5)	2 (5.9)	6 (17.6)
Hypoalbuminaemia	6 (17.6)	0	6 (17.6)
Hypocalcaemia	6 (17.6)	0	6 (17.6)
Hyperglycaemia	4 (11.8)	0	4 (11.8)
Hyperuricaemia	4 (11.8)	4 (11.8)	0
Hypophosphataemia	4 (11.8)	0	4 (11.8)
Musculoskeletal and connective tissue disorders			
-Total	16 (47.1)	8 (23.5)	8 (23.5)
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)
Pain in extremity	6 (17.6)	4 (11.8)	2 (5.9)
Back pain	4 (11.8)	1 (2.9)	3 (8.8)
Arthralgia	2 (5.9)	1 (2.9)	1 (2.9)
Nervous system disorders			
-Total	18 (52.9)	9 (26.5)	9 (26.5)
Headache	15 (44.1)	6 (17.6)	9 (26.5)
Tremor	6 (17.6)	5 (14.7)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Anxiety	4 (11.8)	2 (5.9)	2 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (47.1)	12 (35.3)	4 (11.8)
Cough	10 (29.4)	7 (20.6)	3 (8.8)
Epistaxis	5 (14.7)	3 (8.8)	2 (5.9)
Nasal congestion	4 (11.8)	3 (8.8)	1 (2.9)
Rhinorrhoea	4 (11.8)	3 (8.8)	1 (2.9)
Oropharyngeal pain	3 (8.8)	3 (8.8)	0
Pleural effusion	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			
-Total	10 (29.4)	7 (20.6)	3 (8.8)
Dry skin	6 (17.6)	5 (14.7)	1 (2.9)
Rash	4 (11.8)	2 (5.9)	2 (5.9)
Vascular disorders			
-Total	9 (26.5)	4 (11.8)	5 (14.7)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	6 (17.6)	2 (5.9)	4 (11.8)
Hypotension	4 (11.8)	2 (5.9)	2 (5.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	58 (98.3)	7 (11.9)	51 (86.4)
Blood and lymphatic system disorders			
-Total	16 (27.1)	4 (6.8)	12 (20.3)
Anaemia	12 (20.3)	4 (6.8)	8 (13.6)
Disseminated intravascular coagulation	3 (5.1)	0	3 (5.1)
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)
Cardiac disorders			
-Total	13 (22.0)	6 (10.2)	7 (11.9)
Tachycardia	13 (22.0)	6 (10.2)	7 (11.9)
Endocrine disorders			

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (3.4)	0	2 (3.4)
Adrenal insufficiency	2 (3.4)	0	2 (3.4)
Gastrointestinal disorders			
-Total	35 (59.3)	18 (30.5)	17 (28.8)
Vomiting	18 (30.5)	11 (18.6)	7 (11.9)
Nausea	13 (22.0)	7 (11.9)	6 (10.2)
Diarrhoea	11 (18.6)	7 (11.9)	4 (6.8)
Abdominal pain	9 (15.3)	2 (3.4)	7 (11.9)
Constipation	6 (10.2)	3 (5.1)	3 (5.1)
Stomatitis	1 (1.7)	0	1 (1.7)
Trichoglossia	1 (1.7)	0	1 (1.7)
General disorders and administration site conditions			
-Total	25 (42.4)	16 (27.1)	9 (15.3)
Pyrexia	17 (28.8)	11 (18.6)	6 (10.2)
Fatigue	9 (15.3)	7 (11.9)	2 (3.4)
Face oedema	7 (11.9)	5 (8.5)	2 (3.4)
Chills	5 (8.5)	3 (5.1)	2 (3.4)
Hepatobiliary disorders			

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (1.7)	0	1 (1.7)
Hepatic function abnormal	1 (1.7)	0	1 (1.7)
Immune system disorders			
-Total	42 (71.2)	8 (13.6)	34 (57.6)
Cytokine release syndrome	40 (67.8)	8 (13.6)	32 (54.2)
Hypogammaglobulinaemia	11 (18.6)	1 (1.7)	10 (16.9)
Seasonal allergy	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	6 (10.2)	1 (1.7)	5 (8.5)
Conjunctivitis	4 (6.8)	1 (1.7)	3 (5.1)
Oral herpes	1 (1.7)	0	1 (1.7)
Rhinovirus infection	1 (1.7)	0	1 (1.7)
Investigations			
-Total	27 (45.8)	8 (13.6)	19 (32.2)
Alanine aminotransferase increased	12 (20.3)	4 (6.8)	8 (13.6)
Platelet count decreased	10 (16.9)	5 (8.5)	5 (8.5)
Aspartate aminotransferase increased	9 (15.3)	1 (1.7)	8 (13.6)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)
White blood cell count decreased	7 (11.9)	3 (5.1)	4 (6.8)
Neutrophil count decreased	6 (10.2)	0	6 (10.2)
Blood bilirubin increased	4 (6.8)	2 (3.4)	2 (3.4)
Lymphocyte count decreased	4 (6.8)	2 (3.4)	2 (3.4)
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)
Serum ferritin increased	2 (3.4)	0	2 (3.4)
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	26 (44.1)	11 (18.6)	15 (25.4)
Decreased appetite	12 (20.3)	9 (15.3)	3 (5.1)
Hypocalcaemia	9 (15.3)	2 (3.4)	7 (11.9)
Hypokalaemia	9 (15.3)	2 (3.4)	7 (11.9)
Hypophosphataemia	7 (11.9)	4 (6.8)	3 (5.1)
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)
Hyperuricaemia	4 (6.8)	3 (5.1)	1 (1.7)
Hypomagnesaemia	3 (5.1)	3 (5.1)	0
Hyperglycaemia	2 (3.4)	0	2 (3.4)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	21 (35.6)	11 (18.6)	10 (16.9)
Pain in extremity	10 (16.9)	6 (10.2)	4 (6.8)
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)
Myalgia	7 (11.9)	4 (6.8)	3 (5.1)
Back pain	3 (5.1)	1 (1.7)	2 (3.4)
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	18 (30.5)	11 (18.6)	7 (11.9)
Headache	18 (30.5)	11 (18.6)	7 (11.9)
Psychiatric disorders			
-Total	9 (15.3)	5 (8.5)	4 (6.8)
Confusional state	5 (8.5)	5 (8.5)	0
Delirium	4 (6.8)	2 (3.4)	2 (3.4)
Anxiety	3 (5.1)	1 (1.7)	2 (3.4)
Renal and urinary disorders			
-Total	4 (6.8)	1 (1.7)	3 (5.1)
Acute kidney injury	4 (6.8)	1 (1.7)	3 (5.1)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Haematuria	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (28.8)	14 (23.7)	3 (5.1)
Cough	8 (13.6)	7 (11.9)	1 (1.7)
Oropharyngeal pain	4 (6.8)	4 (6.8)	0
Epistaxis	3 (5.1)	2 (3.4)	1 (1.7)
Pleural effusion	3 (5.1)	3 (5.1)	0
Nasal congestion	2 (3.4)	1 (1.7)	1 (1.7)
Rhinorrhoea	2 (3.4)	2 (3.4)	0
Skin and subcutaneous tissue disorders			
-Total	11 (18.6)	4 (6.8)	7 (11.9)
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)
Rash	5 (8.5)	2 (3.4)	3 (5.1)
Dry skin	1 (1.7)	1 (1.7)	0
Rash maculo-papular	1 (1.7)	0	1 (1.7)
Skin ulcer	1 (1.7)	1 (1.7)	0
Vascular disorders			

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	14 (23.7)	6 (10.2)	8 (13.6)
Hypertension	8 (13.6)	4 (6.8)	4 (6.8)
Hypotension	8 (13.6)	2 (3.4)	6 (10.2)

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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (100)	1 (10.0)	9 (90.0)
Blood and lymphatic system disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	2 (20.0)	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)
Splenomegaly	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0
Tachycardia	1 (10.0)	0	1 (10.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	6 (60.0)	3 (30.0)	3 (30.0)
Constipation	2 (20.0)	2 (20.0)	0
Nausea	2 (20.0)	2 (20.0)	0
Pancreatitis	2 (20.0)	0	2 (20.0)
Diarrhoea	1 (10.0)	0	1 (10.0)
Enterocolitis	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Fatigue	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	0	1 (10.0)
Hepatobiliary disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hepatic function abnormal	4 (40.0)	1 (10.0)	3 (30.0)
Immune system disorders			
-Total	8 (80.0)	2 (20.0)	6 (60.0)
Cytokine release syndrome	7 (70.0)	3 (30.0)	4 (40.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Bk virus infection	1 (10.0)	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)
Urinary tract infection viral	1 (10.0)	1 (10.0)	0
Investigations			
-Total	6 (60.0)	1 (10.0)	5 (50.0)
Serum ferritin increased	3 (30.0)	0	3 (30.0)
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)
Blood fibrinogen decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)
Blood creatine phosphokinase increased	1 (10.0)	0	1 (10.0)
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Hypercalcaemia	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	1 (10.0)	1 (10.0)	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	0	2 (20.0)
Arthralgia	1 (10.0)	0	1 (10.0)
Pain in extremity	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	2 (20.0)	0	2 (20.0)
Headache	1 (10.0)	0	1 (10.0)
Seizure	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	1 (10.0)	1 (10.0)	0
Haematuria	1 (10.0)	1 (10.0)	0
Proteinuria	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (50.0)	4 (40.0)	1 (10.0)
Cough	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Haemoptysis	1 (10.0)	0	1 (10.0)
Nasal congestion	1 (10.0)	1 (10.0)	0
Nasal dryness	1 (10.0)	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0
Pleural effusion	1 (10.0)	1 (10.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Erythema nodosum	1 (10.0)	1 (10.0)	0
Pruritus	1 (10.0)	1 (10.0)	0
Skin ulcer	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypertension	1 (10.0)	0	1 (10.0)

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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (90.9)	0	10 (90.9)
Blood and lymphatic system disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Anaemia	4 (36.4)	1 (9.1)	3 (27.3)
Cardiac disorders			
-Total	1 (9.1)	1 (9.1)	0
Tachycardia	1 (9.1)	1 (9.1)	0
Endocrine disorders			
-Total	2 (18.2)	0	2 (18.2)
Adrenal insufficiency	2 (18.2)	0	2 (18.2)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	6 (54.5)	2 (18.2)	4 (36.4)
Constipation	3 (27.3)	1 (9.1)	2 (18.2)
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)
Vomiting	2 (18.2)	1 (9.1)	1 (9.1)
Abdominal pain	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Chills	1 (9.1)	1 (9.1)	0
Fatigue	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	0	1 (9.1)
Immune system disorders			
-Total	10 (90.9)	2 (18.2)	8 (72.7)
Cytokine release syndrome	10 (90.9)	2 (18.2)	8 (72.7)
Hypogammaglobulinaemia	2 (18.2)	1 (9.1)	1 (9.1)
Infections and infestations			

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (18.2)	0	2 (18.2)
Conjunctivitis	1 (9.1)	0	1 (9.1)
Rhinovirus infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Alanine aminotransferase increased	3 (27.3)	0	3 (27.3)
Platelet count decreased	3 (27.3)	1 (9.1)	2 (18.2)
Aspartate aminotransferase increased	2 (18.2)	1 (9.1)	1 (9.1)
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Serum ferritin increased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Hypoalbuminaemia	3 (27.3)	0	3 (27.3)
Hypocalcaemia	3 (27.3)	0	3 (27.3)
Hypokalaemia	3 (27.3)	1 (9.1)	2 (18.2)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)
Hyperglycaemia	2 (18.2)	0	2 (18.2)
Hyperuricaemia	2 (18.2)	2 (18.2)	0
Hypophosphataemia	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	0	1 (9.1)
Hypercalcaemia	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Back pain	2 (18.2)	1 (9.1)	1 (9.1)
Myalgia	2 (18.2)	2 (18.2)	0
Nervous system disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Cognitive disorder	3 (27.3)	0	3 (27.3)
Headache	2 (18.2)	1 (9.1)	1 (9.1)
Psychiatric disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Confusional state	2 (18.2)	2 (18.2)	0
Anxiety	1 (9.1)	0	1 (9.1)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Cough	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	0	1 (9.1)
Rash maculo-papular	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypertension	1 (9.1)	1 (9.1)	0
Hypotension	1 (9.1)	0	1 (9.1)

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Table 257c
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	44 (80.0)	10 (18.2)	34 (61.8)
Blood and lymphatic system disorders			
-Total	5 (9.1)	4 (7.3)	1 (1.8)
Anaemia	5 (9.1)	4 (7.3)	1 (1.8)
Cardiac disorders			
-Total	2 (3.6)	2 (3.6)	0
Tachycardia	2 (3.6)	2 (3.6)	0
Gastrointestinal disorders			
-Total	9 (16.4)	6 (10.9)	3 (5.5)
Diarrhoea	4 (7.3)	3 (5.5)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	3 (5.5)	2 (3.6)	1 (1.8)
Vomiting	3 (5.5)	3 (5.5)	0
Abdominal pain	1 (1.8)	1 (1.8)	0
Constipation	1 (1.8)	0	1 (1.8)
Pancreatitis	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	15 (27.3)	11 (20.0)	4 (7.3)
Pyrexia	9 (16.4)	5 (9.1)	4 (7.3)
Fatigue	6 (10.9)	6 (10.9)	0
Chills	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	6 (10.9)	0	6 (10.9)
Hypogammaglobulinaemia	6 (10.9)	0	6 (10.9)
Infections and infestations			
-Total	18 (32.7)	4 (7.3)	14 (25.5)
Upper respiratory tract infection	6 (10.9)	2 (3.6)	4 (7.3)
Nasopharyngitis	4 (7.3)	2 (3.6)	2 (3.6)
Rhinovirus infection	3 (5.5)	0	3 (5.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	3 (5.5)	0	3 (5.5)
Otitis externa	1 (1.8)	0	1 (1.8)
Otitis media	1 (1.8)	0	1 (1.8)
Investigations			
-Total	14 (25.5)	5 (9.1)	9 (16.4)
White blood cell count decreased	8 (14.5)	4 (7.3)	4 (7.3)
Neutrophil count decreased	5 (9.1)	1 (1.8)	4 (7.3)
Lymphocyte count decreased	3 (5.5)	1 (1.8)	2 (3.6)
Platelet count decreased	3 (5.5)	2 (3.6)	1 (1.8)
Alanine aminotransferase increased	2 (3.6)	2 (3.6)	0
Blood bilirubin increased	2 (3.6)	0	2 (3.6)
Metabolism and nutrition disorders			
-Total	9 (16.4)	3 (5.5)	6 (10.9)
Decreased appetite	4 (7.3)	1 (1.8)	3 (5.5)
Hyperuricaemia	3 (5.5)	3 (5.5)	0
Hypokalaemia	2 (3.6)	0	2 (3.6)
Hypophosphataemia	1 (1.8)	0	1 (1.8)
Iron overload	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	8 (14.5)	4 (7.3)	4 (7.3)
Pain in extremity	4 (7.3)	2 (3.6)	2 (3.6)
Back pain	3 (5.5)	2 (3.6)	1 (1.8)
Arthralgia	2 (3.6)	1 (1.8)	1 (1.8)
Myalgia	1 (1.8)	0	1 (1.8)
Nervous system disorders			
-Total	9 (16.4)	6 (10.9)	3 (5.5)
Headache	9 (16.4)	6 (10.9)	3 (5.5)
Psychiatric disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Anxiety	2 (3.6)	1 (1.8)	1 (1.8)
Renal and urinary disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Acute kidney injury	2 (3.6)	1 (1.8)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (25.5)	10 (18.2)	4 (7.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	11 (20.0)	8 (14.5)	3 (5.5)
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)
Epistaxis	2 (3.6)	1 (1.8)	1 (1.8)
Oropharyngeal pain	2 (3.6)	1 (1.8)	1 (1.8)
Rhinorrhoea	2 (3.6)	2 (3.6)	0
Pleural effusion	1 (1.8)	1 (1.8)	0
Skin and subcutaneous tissue disorders			
-Total	8 (14.5)	6 (10.9)	2 (3.6)
Dry skin	5 (9.1)	3 (5.5)	2 (3.6)
Rash	4 (7.3)	3 (5.5)	1 (1.8)
Vascular disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Hypertension	1 (1.8)	0	1 (1.8)
Hypotension	1 (1.8)	1 (1.8)	0

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (55.6)	0	5 (55.6)
Gastrointestinal disorders			
-Total	4 (44.4)	3 (33.3)	1 (11.1)
Constipation	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	1 (11.1)	0
Enteritis	1 (11.1)	0	1 (11.1)
Nausea	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
Trichoglossia	1 (11.1)	1 (11.1)	0
Vomiting	1 (11.1)	1 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (11.1)	1 (11.1)	0
Pyrexia	1 (11.1)	1 (11.1)	0
Immune system disorders			
-Total	2 (22.2)	0	2 (22.2)
Hypogammaglobulinaemia	2 (22.2)	0	2 (22.2)
Infections and infestations			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Nasopharyngitis	1 (11.1)	1 (11.1)	0
Oral herpes	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	1 (11.1)	0
Decreased appetite	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (11.1)	1 (11.1)	0
Arthralgia	1 (11.1)	1 (11.1)	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	1 (11.1)	0	1 (11.1)
Anxiety	1 (11.1)	0	1 (11.1)
Delirium	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			
-Total	1 (11.1)	0	1 (11.1)
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Pleural effusion	1 (11.1)	0	1 (11.1)
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	2 (22.2)	2 (22.2)	0
Dry skin	1 (11.1)	1 (11.1)	0
Skin swelling	1 (11.1)	1 (11.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (90.9)	2 (18.2)	8 (72.7)
Gastrointestinal disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Diarrhoea	2 (18.2)	2 (18.2)	0
Vomiting	2 (18.2)	2 (18.2)	0
Abdominal pain	1 (9.1)	0	1 (9.1)
Constipation	1 (9.1)	0	1 (9.1)
Nausea	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	3 (27.3)	1 (9.1)	2 (18.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	3 (27.3)	1 (9.1)	2 (18.2)
Immune system disorders			
-Total	2 (18.2)	0	2 (18.2)
Hypogammaglobulinaemia	2 (18.2)	0	2 (18.2)
Infections and infestations			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)
Otitis media	1 (9.1)	0	1 (9.1)
Rhinovirus infection	1 (9.1)	0	1 (9.1)
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	2 (18.2)	2 (18.2)	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	0	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	3 (27.3)	0	3 (27.3)
Anxiety	3 (27.3)	0	3 (27.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Epistaxis	1 (9.1)	0	1 (9.1)
Rhinorrhoea	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	0	1 (9.1)
Pruritus	1 (9.1)	0	1 (9.1)

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All patients column.
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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (38.5)	4 (10.3)	11 (28.2)
Blood and lymphatic system disorders			
-Total	1 (2.6)	0	1 (2.6)
Anaemia	1 (2.6)	0	1 (2.6)
Gastrointestinal disorders			
-Total	1 (2.6)	1 (2.6)	0
Diarrhoea	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Pyrexia	3 (7.7)	2 (5.1)	1 (2.6)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	4 (10.3)	0	4 (10.3)
Hypogammaglobulinaemia	3 (7.7)	0	3 (7.7)
Seasonal allergy	1 (2.6)	0	1 (2.6)
Infections and infestations			
-Total	9 (23.1)	3 (7.7)	6 (15.4)
Sinusitis	5 (12.8)	0	5 (12.8)
Conjunctivitis	3 (7.7)	1 (2.6)	2 (5.1)
Rhinovirus infection	3 (7.7)	0	3 (7.7)
Upper respiratory tract infection	3 (7.7)	2 (5.1)	1 (2.6)
Oral herpes	2 (5.1)	1 (2.6)	1 (2.6)
Otitis media	1 (2.6)	0	1 (2.6)
Investigations			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Neutrophil count decreased	2 (5.1)	1 (2.6)	1 (2.6)
Platelet count decreased	2 (5.1)	2 (5.1)	0
Blood bilirubin increased	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (5.1)	0	2 (5.1)
Pain in extremity	2 (5.1)	0	2 (5.1)
Nervous system disorders			
-Total	3 (7.7)	0	3 (7.7)
Headache	2 (5.1)	0	2 (5.1)
Seizure	1 (2.6)	0	1 (2.6)
Psychiatric disorders			
-Total	2 (5.1)	1 (2.6)	1 (2.6)
Anxiety	2 (5.1)	1 (2.6)	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (10.3)	3 (7.7)	1 (2.6)
Cough	2 (5.1)	2 (5.1)	0
Rhinorrhoea	2 (5.1)	1 (2.6)	1 (2.6)
Epistaxis	1 (2.6)	1 (2.6)	0
Oropharyngeal pain	1 (2.6)	1 (2.6)	0
Skin and subcutaneous tissue disorders			
-Total	2 (5.1)	1 (2.6)	1 (2.6)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	1 (2.6)	1 (2.6)	0
Rash	1 (2.6)	0	1 (2.6)

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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (50.0)	0	3 (50.0)
Eye disorders			
-Total	1 (16.7)	0	1 (16.7)
Mydriasis	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Diarrhoea	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	2 (33.3)	0	2 (33.3)
Fungal skin infection	1 (16.7)	0	1 (16.7)

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (16.7)	0	1 (16.7)
Sinusitis	1 (16.7)	0	1 (16.7)
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)
Varicella zoster virus infection	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypercholesterolaemia	1 (16.7)	0	1 (16.7)
Hypertriglyceridaemia	1 (16.7)	0	1 (16.7)
Iron overload	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Joint effusion	1 (16.7)	0	1 (16.7)
Synovitis	1 (16.7)	0	1 (16.7)
Reproductive system and breast disorders			
-Total	1 (16.7)	0	1 (16.7)
Endometriosis	1 (16.7)	0	1 (16.7)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (16.7)	0	1 (16.7)
Hypertension	1 (16.7)	0	1 (16.7)

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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	1 (20.0)	4 (80.0)
Gastrointestinal disorders			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Diarrhoea	2 (40.0)	1 (20.0)	1 (20.0)
Constipation	1 (20.0)	1 (20.0)	0
Nausea	1 (20.0)	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	2 (40.0)	0	2 (40.0)
Fatigue	1 (20.0)	0	1 (20.0)

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	2 (40.0)	2 (40.0)	0
Seasonal allergy	2 (40.0)	2 (40.0)	0
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Conjunctivitis	1 (20.0)	1 (20.0)	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Arthralgia	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (40.0)	0	2 (40.0)
Cough	2 (40.0)	1 (20.0)	1 (20.0)

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pleural effusion	1 (20.0)	0	1 (20.0)
Rhinorrhoea	1 (20.0)	0	1 (20.0)
Skin and subcutaneous tissue disorders			
-Total	1 (20.0)	1 (20.0)	0
Rash	1 (20.0)	1 (20.0)	0
Rash maculo-papular	1 (20.0)	1 (20.0)	0

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Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	59 (100)	4 (6.8)	55 (93.2)
Blood and lymphatic system disorders			
-Total	19 (32.2)	6 (10.2)	13 (22.0)
Anaemia	15 (25.4)	6 (10.2)	9 (15.3)
Disseminated intravascular coagulation	3 (5.1)	0	3 (5.1)
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)
Cardiac disorders			
-Total	14 (23.7)	7 (11.9)	7 (11.9)
Tachycardia	14 (23.7)	7 (11.9)	7 (11.9)
Endocrine disorders			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (3.4)	0	2 (3.4)
Adrenal insufficiency	2 (3.4)	0	2 (3.4)
Gastrointestinal disorders			
-Total	40 (67.8)	20 (33.9)	20 (33.9)
Vomiting	19 (32.2)	12 (20.3)	7 (11.9)
Diarrhoea	16 (27.1)	11 (18.6)	5 (8.5)
Nausea	14 (23.7)	7 (11.9)	7 (11.9)
Abdominal pain	10 (16.9)	3 (5.1)	7 (11.9)
Constipation	7 (11.9)	3 (5.1)	4 (6.8)
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	1 (1.7)
Trichoglossia	1 (1.7)	0	1 (1.7)
General disorders and administration site conditions			
-Total	32 (54.2)	19 (32.2)	13 (22.0)
Pyrexia	23 (39.0)	13 (22.0)	10 (16.9)
Fatigue	14 (23.7)	12 (20.3)	2 (3.4)
Face oedema	7 (11.9)	5 (8.5)	2 (3.4)
Chills	6 (10.2)	4 (6.8)	2 (3.4)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	1 (1.7)	0	1 (1.7)
Hepatic function abnormal	1 (1.7)	0	1 (1.7)
Immune system disorders			
-Total	46 (78.0)	7 (11.9)	39 (66.1)
Cytokine release syndrome	40 (67.8)	8 (13.6)	32 (54.2)
Hypogammaglobulinaemia	17 (28.8)	1 (1.7)	16 (27.1)
Seasonal allergy	2 (3.4)	0	2 (3.4)
Infections and infestations			
-Total	26 (44.1)	7 (11.9)	19 (32.2)
Upper respiratory tract infection	9 (15.3)	4 (6.8)	5 (8.5)
Conjunctivitis	7 (11.9)	2 (3.4)	5 (8.5)
Rhinovirus infection	7 (11.9)	0	7 (11.9)
Sinusitis	5 (8.5)	0	5 (8.5)
Nasopharyngitis	4 (6.8)	2 (3.4)	2 (3.4)
Oral herpes	3 (5.1)	1 (1.7)	2 (3.4)
Otitis media	2 (3.4)	0	2 (3.4)
Otitis externa	1 (1.7)	0	1 (1.7)
Investigations			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	28 (47.5)	6 (10.2)	22 (37.3)
Alanine aminotransferase increased	12 (20.3)	4 (6.8)	8 (13.6)
Platelet count decreased	12 (20.3)	7 (11.9)	5 (8.5)
White blood cell count decreased	11 (18.6)	4 (6.8)	7 (11.9)
Neutrophil count decreased	10 (16.9)	2 (3.4)	8 (13.6)
Aspartate aminotransferase increased	9 (15.3)	1 (1.7)	8 (13.6)
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)
Blood bilirubin increased	6 (10.2)	2 (3.4)	4 (6.8)
Lymphocyte count decreased	6 (10.2)	2 (3.4)	4 (6.8)
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)
Serum ferritin increased	2 (3.4)	0	2 (3.4)
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	31 (52.5)	12 (20.3)	19 (32.2)
Decreased appetite	16 (27.1)	10 (16.9)	6 (10.2)
Hypokalaemia	10 (16.9)	2 (3.4)	8 (13.6)
Hypocalcaemia	9 (15.3)	2 (3.4)	7 (11.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	8 (13.6)	4 (6.8)	4 (6.8)
Hyperuricaemia	6 (10.2)	5 (8.5)	1 (1.7)
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)
Hypomagnesaemia	3 (5.1)	3 (5.1)	0
Hyperglycaemia	2 (3.4)	0	2 (3.4)
Iron overload	1 (1.7)	0	1 (1.7)
Musculoskeletal and connective tissue disorders			
-Total	27 (45.8)	14 (23.7)	13 (22.0)
Pain in extremity	15 (25.4)	8 (13.6)	7 (11.9)
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)
Myalgia	8 (13.6)	4 (6.8)	4 (6.8)
Back pain	5 (8.5)	2 (3.4)	3 (5.1)
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	23 (39.0)	12 (20.3)	11 (18.6)
Headache	23 (39.0)	12 (20.3)	11 (18.6)
Seizure	1 (1.7)	0	1 (1.7)
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	12 (20.3)	6 (10.2)	6 (10.2)
Anxiety	7 (11.9)	3 (5.1)	4 (6.8)
Confusional state	5 (8.5)	5 (8.5)	0
Delirium	4 (6.8)	2 (3.4)	2 (3.4)
Renal and urinary disorders			
-Total	6 (10.2)	2 (3.4)	4 (6.8)
Acute kidney injury	6 (10.2)	2 (3.4)	4 (6.8)
Haematuria	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	28 (47.5)	22 (37.3)	6 (10.2)
Cough	19 (32.2)	15 (25.4)	4 (6.8)
Nasal congestion	8 (13.6)	6 (10.2)	2 (3.4)
Oropharyngeal pain	7 (11.9)	6 (10.2)	1 (1.7)
Epistaxis	6 (10.2)	4 (6.8)	2 (3.4)
Rhinorrhoea	4 (6.8)	3 (5.1)	1 (1.7)
Pleural effusion	3 (5.1)	3 (5.1)	0
Skin and subcutaneous tissue disorders			

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	17 (28.8)	8 (13.6)	9 (15.3)
Dry skin	7 (11.9)	5 (8.5)	2 (3.4)
Rash	7 (11.9)	3 (5.1)	4 (6.8)
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)
Rash maculo-papular	1 (1.7)	0	1 (1.7)
Skin ulcer	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	16 (27.1)	7 (11.9)	9 (15.3)
Hypertension	9 (15.3)	4 (6.8)	5 (8.5)
Hypotension	9 (15.3)	3 (5.1)	6 (10.2)

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Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (100)	0	10 (100)
Blood and lymphatic system disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	2 (20.0)	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)
Splenomegaly	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0
Tachycardia	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eye disorders			
-Total	1 (10.0)	0	1 (10.0)
Mydriasis	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	7 (70.0)	3 (30.0)	4 (40.0)
Constipation	3 (30.0)	3 (30.0)	0
Diarrhoea	3 (30.0)	2 (20.0)	1 (10.0)
Nausea	3 (30.0)	3 (30.0)	0
Pancreatitis	2 (20.0)	0	2 (20.0)
Enteritis	1 (10.0)	0	1 (10.0)
Enterocolitis	1 (10.0)	0	1 (10.0)
Stomatitis	1 (10.0)	1 (10.0)	0
Trichoglossia	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Pyrexia	2 (20.0)	1 (10.0)	1 (10.0)
Fatigue	1 (10.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hepatic function abnormal	4 (40.0)	1 (10.0)	3 (30.0)
Immune system disorders			
-Total	8 (80.0)	2 (20.0)	6 (60.0)
Cytokine release syndrome	7 (70.0)	3 (30.0)	4 (40.0)
Hypogammaglobulinaemia	5 (50.0)	0	5 (50.0)
Infections and infestations			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Bk virus infection	1 (10.0)	1 (10.0)	0
Fungal skin infection	1 (10.0)	0	1 (10.0)
Nasopharyngitis	1 (10.0)	1 (10.0)	0
Oral herpes	1 (10.0)	0	1 (10.0)
Otitis externa	1 (10.0)	0	1 (10.0)
Otitis media	1 (10.0)	0	1 (10.0)
Sinusitis	1 (10.0)	0	1 (10.0)
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)
Urinary tract infection viral	1 (10.0)	1 (10.0)	0
Varicella zoster virus infection	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	6 (60.0)	1 (10.0)	5 (50.0)
Serum ferritin increased	3 (30.0)	0	3 (30.0)
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)
Blood fibrinogen decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)
Blood creatine phosphokinase increased	1 (10.0)	0	1 (10.0)
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	5 (50.0)	3 (30.0)	2 (20.0)
Decreased appetite	1 (10.0)	1 (10.0)	0
Hypercalcaemia	1 (10.0)	1 (10.0)	0
Hypercholesterolaemia	1 (10.0)	0	1 (10.0)
Hypertriglyceridaemia	1 (10.0)	0	1 (10.0)
Hyperuricaemia	1 (10.0)	1 (10.0)	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Iron overload	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Arthralgia	2 (20.0)	1 (10.0)	1 (10.0)
Joint effusion	1 (10.0)	0	1 (10.0)
Musculoskeletal chest pain	1 (10.0)	1 (10.0)	0
Pain in extremity	1 (10.0)	0	1 (10.0)
Synovitis	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	2 (20.0)	0	2 (20.0)
Headache	1 (10.0)	0	1 (10.0)
Seizure	1 (10.0)	0	1 (10.0)
Psychiatric disorders			
-Total	1 (10.0)	0	1 (10.0)
Anxiety	1 (10.0)	0	1 (10.0)
Delirium	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cystitis haemorrhagic	1 (10.0)	0	1 (10.0)
Haematuria	1 (10.0)	1 (10.0)	0
Proteinuria	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders			
-Total	1 (10.0)	0	1 (10.0)
Endometriosis	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (60.0)	3 (30.0)	3 (30.0)
Pleural effusion	2 (20.0)	1 (10.0)	1 (10.0)
Cough	1 (10.0)	1 (10.0)	0
Haemoptysis	1 (10.0)	0	1 (10.0)
Nasal congestion	1 (10.0)	1 (10.0)	0
Nasal dryness	1 (10.0)	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0
Upper respiratory tract inflammation	1 (10.0)	0	1 (10.0)
Skin and subcutaneous tissue disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Dry skin	1 (10.0)	1 (10.0)	0
Erythema nodosum	1 (10.0)	1 (10.0)	0
Pruritus	1 (10.0)	1 (10.0)	0
Skin swelling	1 (10.0)	1 (10.0)	0
Skin ulcer	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	2 (20.0)	0	2 (20.0)
Hypertension	2 (20.0)	0	2 (20.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257c
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (100)	0	11 (100)
Blood and lymphatic system disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Anaemia	4 (36.4)	1 (9.1)	3 (27.3)
Cardiac disorders			
-Total	1 (9.1)	1 (9.1)	0
Tachycardia	1 (9.1)	1 (9.1)	0
Endocrine disorders			
-Total	2 (18.2)	0	2 (18.2)
Adrenal insufficiency	2 (18.2)	0	2 (18.2)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	9 (81.8)	3 (27.3)	6 (54.5)
Diarrhoea	5 (45.5)	3 (27.3)	2 (18.2)
Vomiting	5 (45.5)	4 (36.4)	1 (9.1)
Constipation	4 (36.4)	1 (9.1)	3 (27.3)
Nausea	3 (27.3)	2 (18.2)	1 (9.1)
Abdominal pain	1 (9.1)	0	1 (9.1)
Pancreatitis	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	6 (54.5)	2 (18.2)	4 (36.4)
Pyrexia	4 (36.4)	1 (9.1)	3 (27.3)
Fatigue	2 (18.2)	1 (9.1)	1 (9.1)
Chills	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	10 (90.9)	2 (18.2)	8 (72.7)
Cytokine release syndrome	10 (90.9)	2 (18.2)	8 (72.7)
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)
Seasonal allergy	2 (18.2)	2 (18.2)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)
Upper respiratory tract infection	2 (18.2)	1 (9.1)	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)
Otitis media	1 (9.1)	0	1 (9.1)
Rhinovirus infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Alanine aminotransferase increased	3 (27.3)	0	3 (27.3)
Platelet count decreased	3 (27.3)	1 (9.1)	2 (18.2)
Aspartate aminotransferase increased	2 (18.2)	1 (9.1)	1 (9.1)
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Neutrophil count decreased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	1 (9.1)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Hypoalbuminaemia	3 (27.3)	0	3 (27.3)
Hypocalcaemia	3 (27.3)	0	3 (27.3)
Hypokalaemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)
Hyperglycaemia	2 (18.2)	0	2 (18.2)
Hyperuricaemia	2 (18.2)	2 (18.2)	0
Hypophosphataemia	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	0	1 (9.1)
Hypercalcaemia	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Back pain	2 (18.2)	0	2 (18.2)
Myalgia	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cognitive disorder	3 (27.3)	0	3 (27.3)
Headache	2 (18.2)	1 (9.1)	1 (9.1)
Psychiatric disorders			
-Total	6 (54.5)	2 (18.2)	4 (36.4)
Anxiety	4 (36.4)	0	4 (36.4)
Confusional state	2 (18.2)	2 (18.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Cough	3 (27.3)	2 (18.2)	1 (9.1)
Rhinorrhoea	2 (18.2)	1 (9.1)	1 (9.1)
Epistaxis	1 (9.1)	0	1 (9.1)
Pleural effusion	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Rash maculo-papular	2 (18.2)	1 (9.1)	1 (9.1)
Pruritus	1 (9.1)	0	1 (9.1)
Rash	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Vascular disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypertension	1 (9.1)	1 (9.1)	0
Hypotension	1 (9.1)	0	1 (9.1)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (100)	0	15 (100)
Blood and lymphatic system disorders			
-Total	3 (20.0)	0	3 (20.0)
Anaemia	3 (20.0)	0	3 (20.0)
Cardiac disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Tachycardia	3 (20.0)	0	3 (20.0)
Sinus tachycardia	2 (13.3)	2 (13.3)	0
Endocrine disorders			
-Total	3 (20.0)	0	3 (20.0)
Adrenal insufficiency	3 (20.0)	0	3 (20.0)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	8 (53.3)	3 (20.0)	5 (33.3)
Constipation	4 (26.7)	1 (6.7)	3 (20.0)
Diarrhoea	2 (13.3)	1 (6.7)	1 (6.7)
Abdominal pain	1 (6.7)	1 (6.7)	0
Nausea	1 (6.7)	0	1 (6.7)
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	4 (26.7)	2 (13.3)	2 (13.3)
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)
Chills	2 (13.3)	2 (13.3)	0
Generalised oedema	2 (13.3)	0	2 (13.3)
Pyrexia	2 (13.3)	1 (6.7)	1 (6.7)
Fatigue	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	14 (93.3)	1 (6.7)	13 (86.7)
Cytokine release syndrome	13 (86.7)	1 (6.7)	12 (80.0)
Hypogammaglobulinaemia	3 (20.0)	1 (6.7)	2 (13.3)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Seasonal allergy	1 (6.7)	0	1 (6.7)
Infections and infestations			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Conjunctivitis	1 (6.7)	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)
Investigations			
-Total	6 (40.0)	0	6 (40.0)
Alanine aminotransferase increased	4 (26.7)	0	4 (26.7)
Aspartate aminotransferase increased	3 (20.0)	1 (6.7)	2 (13.3)
Platelet count decreased	3 (20.0)	1 (6.7)	2 (13.3)
International normalised ratio increased	2 (13.3)	0	2 (13.3)
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
White blood cell count decreased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	9 (60.0)	0	9 (60.0)
Hypocalcaemia	5 (33.3)	0	5 (33.3)
Hypoalbuminaemia	4 (26.7)	0	4 (26.7)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	4 (26.7)	1 (6.7)	3 (20.0)
Hyperglycaemia	3 (20.0)	0	3 (20.0)
Hyperuricaemia	3 (20.0)	3 (20.0)	0
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)
Decreased appetite	2 (13.3)	0	2 (13.3)
Hypophosphataemia	2 (13.3)	1 (6.7)	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Myalgia	2 (13.3)	2 (13.3)	0
Arthralgia	1 (6.7)	0	1 (6.7)
Nervous system disorders			
-Total	6 (40.0)	2 (13.3)	4 (26.7)
Headache	4 (26.7)	2 (13.3)	2 (13.3)
Cognitive disorder	3 (20.0)	0	3 (20.0)
Psychiatric disorders			
-Total	2 (13.3)	0	2 (13.3)
Anxiety	1 (6.7)	0	1 (6.7)
Mental status changes	1 (6.7)	0	1 (6.7)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	1 (6.7)	0	1 (6.7)
Acute kidney injury	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (6.7)	0	1 (6.7)
Nasal congestion	1 (6.7)	0	1 (6.7)
Skin and subcutaneous tissue disorders			
-Total	1 (6.7)	0	1 (6.7)
Pruritus	1 (6.7)	0	1 (6.7)
Vascular disorders			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Hypertension	2 (13.3)	2 (13.3)	0
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

		All patients N=65	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	62 (95.4)	9 (13.8)	53 (81.5)
Blood and lymphatic system disorders			
-Total	13 (20.0)	5 (7.7)	8 (12.3)
Anaemia	13 (20.0)	5 (7.7)	8 (12.3)
Cardiac disorders			
-Total	13 (20.0)	7 (10.8)	6 (9.2)
Tachycardia	12 (18.5)	7 (10.8)	5 (7.7)
Sinus tachycardia	1 (1.5)	0	1 (1.5)
Endocrine disorders			
-Total	1 (1.5)	0	1 (1.5)
Adrenal insufficiency	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	37 (56.9)	21 (32.3)	16 (24.6)
Vomiting	19 (29.2)	11 (16.9)	8 (12.3)
Nausea	15 (23.1)	10 (15.4)	5 (7.7)
Diarrhoea	12 (18.5)	7 (10.8)	5 (7.7)
Abdominal pain	9 (13.8)	2 (3.1)	7 (10.8)
Constipation	7 (10.8)	5 (7.7)	2 (3.1)
General disorders and administration site conditions			
-Total	26 (40.0)	17 (26.2)	9 (13.8)
Pyrexia	17 (26.2)	10 (15.4)	7 (10.8)
Fatigue	10 (15.4)	8 (12.3)	2 (3.1)
Chills	4 (6.2)	2 (3.1)	2 (3.1)
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)
Oedema peripheral	2 (3.1)	2 (3.1)	0
Immune system disorders			
-Total	46 (70.8)	11 (16.9)	35 (53.8)
Cytokine release syndrome	44 (67.7)	12 (18.5)	32 (49.2)
Hypogammaglobulinaemia	13 (20.0)	1 (1.5)	12 (18.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	5 (7.7)	0	5 (7.7)
Conjunctivitis	4 (6.2)	0	4 (6.2)
Rhinovirus infection	1 (1.5)	0	1 (1.5)
Investigations			
-Total	26 (40.0)	6 (9.2)	20 (30.8)
Alanine aminotransferase increased	12 (18.5)	4 (6.2)	8 (12.3)
Aspartate aminotransferase increased	10 (15.4)	2 (3.1)	8 (12.3)
Platelet count decreased	10 (15.4)	5 (7.7)	5 (7.7)
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)
White blood cell count decreased	7 (10.8)	3 (4.6)	4 (6.2)
Neutrophil count decreased	5 (7.7)	0	5 (7.7)
Metabolism and nutrition disorders			
-Total	26 (40.0)	13 (20.0)	13 (20.0)
Decreased appetite	11 (16.9)	9 (13.8)	2 (3.1)
Hypokalaemia	8 (12.3)	2 (3.1)	6 (9.2)
Hypocalcaemia	7 (10.8)	2 (3.1)	5 (7.7)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	7 (10.8)	3 (4.6)	4 (6.2)
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)
Hyperuricaemia	4 (6.2)	3 (4.6)	1 (1.5)
Hypomagnesaemia	3 (4.6)	3 (4.6)	0
Hyperglycaemia	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	20 (30.8)	11 (16.9)	9 (13.8)
Pain in extremity	11 (16.9)	6 (9.2)	5 (7.7)
Arthralgia	8 (12.3)	4 (6.2)	4 (6.2)
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)
Nervous system disorders			
-Total	17 (26.2)	10 (15.4)	7 (10.8)
Headache	17 (26.2)	10 (15.4)	7 (10.8)
Psychiatric disorders			
-Total	10 (15.4)	8 (12.3)	2 (3.1)
Confusional state	7 (10.8)	7 (10.8)	0
Anxiety	3 (4.6)	1 (1.5)	2 (3.1)
Mental status changes	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	3 (4.6)	1 (1.5)	2 (3.1)
Acute kidney injury	3 (4.6)	1 (1.5)	2 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (29.2)	17 (26.2)	2 (3.1)
Cough	10 (15.4)	9 (13.8)	1 (1.5)
Oropharyngeal pain	5 (7.7)	5 (7.7)	0
Epistaxis	3 (4.6)	2 (3.1)	1 (1.5)
Nasal congestion	2 (3.1)	2 (3.1)	0
Skin and subcutaneous tissue disorders			
-Total	10 (15.4)	5 (7.7)	5 (7.7)
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)
Rash	5 (7.7)	2 (3.1)	3 (4.6)
Dry skin	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	13 (20.0)	4 (6.2)	9 (13.8)
Hypertension	8 (12.3)	3 (4.6)	5 (7.7)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	7 (10.8)	1 (1.5)	6 (9.2)

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Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (85.7)	1 (7.1)	11 (78.6)
Blood and lymphatic system disorders			
-Total	1 (7.1)	0	1 (7.1)
Anaemia	1 (7.1)	0	1 (7.1)
Cardiac disorders			
-Total	1 (7.1)	1 (7.1)	0
Tachycardia	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	1 (7.1)	0	1 (7.1)
Nausea	1 (7.1)	0	1 (7.1)
Vomiting	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	5 (35.7)	3 (21.4)	2 (14.3)
Pyrexia	3 (21.4)	1 (7.1)	2 (14.3)
Fatigue	2 (14.3)	2 (14.3)	0
Immune system disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)
Infections and infestations			
-Total	3 (21.4)	0	3 (21.4)
Upper respiratory tract infection	2 (14.3)	0	2 (14.3)
Rhinovirus infection	1 (7.1)	0	1 (7.1)
Investigations			
-Total	2 (14.3)	0	2 (14.3)
White blood cell count decreased	2 (14.3)	0	2 (14.3)
Neutrophil count decreased	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	4 (28.6)	1 (7.1)	3 (21.4)
Decreased appetite	2 (14.3)	0	2 (14.3)
Hyperuricaemia	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	0	2 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)
Arthralgia	1 (7.1)	0	1 (7.1)
Myalgia	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Headache	2 (14.3)	1 (7.1)	1 (7.1)
Psychiatric disorders			
-Total	4 (28.6)	0	4 (28.6)
Anxiety	3 (21.4)	0	3 (21.4)
Mental status changes	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Nasal congestion	2 (14.3)	2 (14.3)	0
Rhinitis allergic	2 (14.3)	1 (7.1)	1 (7.1)
Cough	1 (7.1)	1 (7.1)	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Dry skin	2 (14.3)	2 (14.3)	0
Pruritus	1 (7.1)	0	1 (7.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	42 (68.9)	12 (19.7)	30 (49.2)
Blood and lymphatic system disorders			
-Total	4 (6.6)	4 (6.6)	0
Anaemia	4 (6.6)	4 (6.6)	0
Cardiac disorders			
-Total	1 (1.6)	1 (1.6)	0
Tachycardia	1 (1.6)	1 (1.6)	0
Gastrointestinal disorders			
-Total	10 (16.4)	7 (11.5)	3 (4.9)
Vomiting	5 (8.2)	5 (8.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	4 (6.6)	4 (6.6)	0
Nausea	4 (6.6)	3 (4.9)	1 (1.6)
Constipation	3 (4.9)	1 (1.6)	2 (3.3)
Abdominal pain	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	15 (24.6)	11 (18.0)	4 (6.6)
Pyrexia	10 (16.4)	6 (9.8)	4 (6.6)
Fatigue	4 (6.6)	4 (6.6)	0
Chills	1 (1.6)	1 (1.6)	0
Oedema peripheral	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	8 (13.1)	0	8 (13.1)
Hypogammaglobulinaemia	8 (13.1)	0	8 (13.1)
Infections and infestations			
-Total	14 (23.0)	6 (9.8)	8 (13.1)
Nasopharyngitis	7 (11.5)	4 (6.6)	3 (4.9)
Upper respiratory tract infection	5 (8.2)	3 (4.9)	2 (3.3)
Rhinovirus infection	3 (4.9)	0	3 (4.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (1.6)	0	1 (1.6)
Investigations			
-Total	11 (18.0)	7 (11.5)	4 (6.6)
White blood cell count decreased	7 (11.5)	5 (8.2)	2 (3.3)
Neutrophil count decreased	5 (8.2)	2 (3.3)	3 (4.9)
Platelet count decreased	3 (4.9)	3 (4.9)	0
Alanine aminotransferase increased	2 (3.3)	2 (3.3)	0
Metabolism and nutrition disorders			
-Total	5 (8.2)	3 (4.9)	2 (3.3)
Decreased appetite	3 (4.9)	2 (3.3)	1 (1.6)
Hyperuricaemia	1 (1.6)	1 (1.6)	0
Hypophosphataemia	1 (1.6)	0	1 (1.6)
Musculoskeletal and connective tissue disorders			
-Total	4 (6.6)	3 (4.9)	1 (1.6)
Arthralgia	2 (3.3)	2 (3.3)	0
Pain in extremity	2 (3.3)	1 (1.6)	1 (1.6)
Nervous system disorders			
-Total	8 (13.1)	5 (8.2)	3 (4.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	8 (13.1)	5 (8.2)	3 (4.9)
Psychiatric disorders			
-Total	3 (4.9)	1 (1.6)	2 (3.3)
Anxiety	3 (4.9)	1 (1.6)	2 (3.3)
Renal and urinary disorders			
-Total	1 (1.6)	1 (1.6)	0
Acute kidney injury	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (19.7)	7 (11.5)	5 (8.2)
Cough	10 (16.4)	7 (11.5)	3 (4.9)
Nasal congestion	4 (6.6)	3 (4.9)	1 (1.6)
Epistaxis	3 (4.9)	1 (1.6)	2 (3.3)
Oropharyngeal pain	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	7 (11.5)	5 (8.2)	2 (3.3)
Dry skin	4 (6.6)	2 (3.3)	2 (3.3)
Rash	4 (6.6)	3 (4.9)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	2 (3.3)	1 (1.6)	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)
Hypotension	1 (1.6)	1 (1.6)	0

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Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (42.9)	0	3 (42.9)
Gastrointestinal disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Constipation	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)
Nausea	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	0	1 (14.3)
Fatigue	1 (14.3)	0	1 (14.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	2 (28.6)	2 (28.6)	0
Seasonal allergy	2 (28.6)	2 (28.6)	0
Infections and infestations			
-Total	1 (14.3)	0	1 (14.3)
Upper respiratory tract infection	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Arthralgia	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Cough	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Rash	1 (14.3)	1 (14.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (44.2)	6 (14.0)	13 (30.2)
Blood and lymphatic system disorders			
-Total	1 (2.3)	0	1 (2.3)
Anaemia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	3 (7.0)	3 (7.0)	0
Diarrhoea	3 (7.0)	3 (7.0)	0
General disorders and administration site conditions			
-Total	4 (9.3)	2 (4.7)	2 (4.7)
Pyrexia	4 (9.3)	2 (4.7)	2 (4.7)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	4 (9.3)	0	4 (9.3)
Hypogammaglobulinaemia	3 (7.0)	0	3 (7.0)
Seasonal allergy	1 (2.3)	0	1 (2.3)
Infections and infestations			
-Total	10 (23.3)	4 (9.3)	6 (14.0)
Conjunctivitis	4 (9.3)	2 (4.7)	2 (4.7)
Upper respiratory tract infection	4 (9.3)	2 (4.7)	2 (4.7)
Rhinovirus infection	3 (7.0)	0	3 (7.0)
Investigations			
-Total	4 (9.3)	3 (7.0)	1 (2.3)
Neutrophil count decreased	3 (7.0)	2 (4.7)	1 (2.3)
Platelet count decreased	2 (4.7)	2 (4.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (4.7)	0	2 (4.7)
Pain in extremity	2 (4.7)	0	2 (4.7)
Nervous system disorders			
-Total	2 (4.7)	0	2 (4.7)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	2 (4.7)	0	2 (4.7)
Psychiatric disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Anxiety	2 (4.7)	1 (2.3)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (9.3)	4 (9.3)	0
Cough	3 (7.0)	3 (7.0)	0
Epistaxis	1 (2.3)	1 (2.3)	0
Oropharyngeal pain	1 (2.3)	1 (2.3)	0
Skin and subcutaneous tissue disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Dry skin	1 (2.3)	1 (2.3)	0
Rash	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	0	1 (2.3)
Hypertension	1 (2.3)	0	1 (2.3)

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Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (100)	0	15 (100)
Blood and lymphatic system disorders			
-Total	3 (20.0)	0	3 (20.0)
Anaemia	3 (20.0)	0	3 (20.0)
Cardiac disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Tachycardia	3 (20.0)	0	3 (20.0)
Sinus tachycardia	2 (13.3)	2 (13.3)	0
Endocrine disorders			
-Total	3 (20.0)	0	3 (20.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	3 (20.0)	0	3 (20.0)
Gastrointestinal disorders			
-Total	11 (73.3)	4 (26.7)	7 (46.7)
Diarrhoea	6 (40.0)	3 (20.0)	3 (20.0)
Constipation	4 (26.7)	1 (6.7)	3 (20.0)
Nausea	3 (20.0)	1 (6.7)	2 (13.3)
Vomiting	3 (20.0)	3 (20.0)	0
Abdominal pain	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
-Total	8 (53.3)	3 (20.0)	5 (33.3)
Fatigue	4 (26.7)	3 (20.0)	1 (6.7)
Pyrexia	4 (26.7)	1 (6.7)	3 (20.0)
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)
Chills	2 (13.3)	2 (13.3)	0
Generalised oedema	2 (13.3)	0	2 (13.3)
Immune system disorders			
-Total	14 (93.3)	1 (6.7)	13 (86.7)
Cytokine release syndrome	13 (86.7)	1 (6.7)	12 (80.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	5 (33.3)	1 (6.7)	4 (26.7)
Seasonal allergy	3 (20.0)	2 (13.3)	1 (6.7)
Infections and infestations			
-Total	5 (33.3)	1 (6.7)	4 (26.7)
Upper respiratory tract infection	3 (20.0)	0	3 (20.0)
Conjunctivitis	1 (6.7)	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)
Investigations			
-Total	6 (40.0)	0	6 (40.0)
Alanine aminotransferase increased	4 (26.7)	0	4 (26.7)
Aspartate aminotransferase increased	3 (20.0)	1 (6.7)	2 (13.3)
Platelet count decreased	3 (20.0)	1 (6.7)	2 (13.3)
International normalised ratio increased	2 (13.3)	0	2 (13.3)
White blood cell count decreased	2 (13.3)	0	2 (13.3)
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	11 (73.3)	0	11 (73.3)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	5 (33.3)	0	5 (33.3)
Hypokalaemia	5 (33.3)	1 (6.7)	4 (26.7)
Decreased appetite	4 (26.7)	0	4 (26.7)
Hyperuricaemia	4 (26.7)	4 (26.7)	0
Hypoalbuminaemia	4 (26.7)	0	4 (26.7)
Hyperglycaemia	3 (20.0)	0	3 (20.0)
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)
Hypophosphataemia	2 (13.3)	1 (6.7)	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	6 (40.0)	3 (20.0)	3 (20.0)
Myalgia	3 (20.0)	2 (13.3)	1 (6.7)
Arthralgia	2 (13.3)	0	2 (13.3)
Pain in extremity	2 (13.3)	1 (6.7)	1 (6.7)
Nervous system disorders			
-Total	6 (40.0)	2 (13.3)	4 (26.7)
Headache	4 (26.7)	2 (13.3)	2 (13.3)
Cognitive disorder	3 (20.0)	0	3 (20.0)
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (40.0)	0	6 (40.0)
Anxiety	4 (26.7)	0	4 (26.7)
Mental status changes	2 (13.3)	0	2 (13.3)
Renal and urinary disorders			
-Total	2 (13.3)	0	2 (13.3)
Acute kidney injury	2 (13.3)	0	2 (13.3)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (33.3)	2 (13.3)	3 (20.0)
Nasal congestion	3 (20.0)	2 (13.3)	1 (6.7)
Cough	2 (13.3)	1 (6.7)	1 (6.7)
Rhinitis allergic	2 (13.3)	1 (6.7)	1 (6.7)
Oropharyngeal pain	1 (6.7)	1 (6.7)	0
Skin and subcutaneous tissue disorders			
-Total	5 (33.3)	3 (20.0)	2 (13.3)
Dry skin	2 (13.3)	2 (13.3)	0
Pruritus	2 (13.3)	0	2 (13.3)
Rash	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Hypertension	2 (13.3)	2 (13.3)	0
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257d
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

		All patients N=65	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	64 (98.5)	5 (7.7)	59 (90.8)
Blood and lymphatic system disorders			
-Total	16 (24.6)	7 (10.8)	9 (13.8)
Anaemia	16 (24.6)	7 (10.8)	9 (13.8)
Cardiac disorders			
-Total	14 (21.5)	8 (12.3)	6 (9.2)
Tachycardia	13 (20.0)	8 (12.3)	5 (7.7)
Sinus tachycardia	1 (1.5)	0	1 (1.5)
Endocrine disorders			
-Total	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	43 (66.2)	24 (36.9)	19 (29.2)
Vomiting	22 (33.8)	14 (21.5)	8 (12.3)
Diarrhoea	18 (27.7)	13 (20.0)	5 (7.7)
Nausea	17 (26.2)	11 (16.9)	6 (9.2)
Abdominal pain	10 (15.4)	3 (4.6)	7 (10.8)
Constipation	10 (15.4)	6 (9.2)	4 (6.2)
General disorders and administration site conditions			
-Total	34 (52.3)	21 (32.3)	13 (20.0)
Pyrexia	25 (38.5)	14 (21.5)	11 (16.9)
Fatigue	13 (20.0)	11 (16.9)	2 (3.1)
Chills	5 (7.7)	3 (4.6)	2 (3.1)
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)
Oedema peripheral	3 (4.6)	3 (4.6)	0
Immune system disorders			
-Total	50 (76.9)	10 (15.4)	40 (61.5)
Cytokine release syndrome	44 (67.7)	12 (18.5)	32 (49.2)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	21 (32.3)	1 (1.5)	20 (30.8)
Seasonal allergy	1 (1.5)	0	1 (1.5)
Infections and infestations			
-Total	24 (36.9)	8 (12.3)	16 (24.6)
Upper respiratory tract infection	9 (13.8)	5 (7.7)	4 (6.2)
Conjunctivitis	7 (10.8)	1 (1.5)	6 (9.2)
Nasopharyngitis	7 (10.8)	4 (6.2)	3 (4.6)
Rhinovirus infection	7 (10.8)	0	7 (10.8)
Investigations			
-Total	29 (44.6)	7 (10.8)	22 (33.8)
Alanine aminotransferase increased	12 (18.5)	4 (6.2)	8 (12.3)
Platelet count decreased	12 (18.5)	7 (10.8)	5 (7.7)
Aspartate aminotransferase increased	10 (15.4)	2 (3.1)	8 (12.3)
Neutrophil count decreased	10 (15.4)	3 (4.6)	7 (10.8)
White blood cell count decreased	10 (15.4)	4 (6.2)	6 (9.2)
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	30 (46.2)	15 (23.1)	15 (23.1)
Decreased appetite	14 (21.5)	11 (16.9)	3 (4.6)
Hypokalaemia	8 (12.3)	2 (3.1)	6 (9.2)
Hypophosphataemia	8 (12.3)	3 (4.6)	5 (7.7)
Hypocalcaemia	7 (10.8)	2 (3.1)	5 (7.7)
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)
Hyperuricaemia	5 (7.7)	4 (6.2)	1 (1.5)
Hypomagnesaemia	3 (4.6)	3 (4.6)	0
Hyperglycaemia	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	23 (35.4)	13 (20.0)	10 (15.4)
Pain in extremity	14 (21.5)	7 (10.8)	7 (10.8)
Arthralgia	9 (13.8)	5 (7.7)	4 (6.2)
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)
Nervous system disorders			
-Total	22 (33.8)	11 (16.9)	11 (16.9)
Headache	22 (33.8)	11 (16.9)	11 (16.9)
Psychiatric disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	14 (21.5)	9 (13.8)	5 (7.7)
Anxiety	8 (12.3)	3 (4.6)	5 (7.7)
Confusional state	7 (10.8)	7 (10.8)	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	4 (6.2)	2 (3.1)	2 (3.1)
Acute kidney injury	4 (6.2)	2 (3.1)	2 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (44.6)	23 (35.4)	6 (9.2)
Cough	21 (32.3)	17 (26.2)	4 (6.2)
Epistaxis	7 (10.8)	4 (6.2)	3 (4.6)
Oropharyngeal pain	7 (10.8)	6 (9.2)	1 (1.5)
Nasal congestion	6 (9.2)	5 (7.7)	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	15 (23.1)	8 (12.3)	7 (10.8)
Rash	7 (10.8)	3 (4.6)	4 (6.2)
Dry skin	6 (9.2)	4 (6.2)	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)
Vascular disorders			
-Total	16 (24.6)	5 (7.7)	11 (16.9)
Hypertension	10 (15.4)	3 (4.6)	7 (10.8)
Hypotension	8 (12.3)	2 (3.1)	6 (9.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)
Cardiac disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Tachycardia	3 (50.0)	1 (16.7)	2 (33.3)
Sinus tachycardia	1 (16.7)	1 (16.7)	0
Eye disorders			
-Total	1 (16.7)	1 (16.7)	0
Eyelid oedema	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal distension	1 (16.7)	0	1 (16.7)
Ascites	1 (16.7)	1 (16.7)	0
Constipation	1 (16.7)	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)
Nausea	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Pyrexia	3 (50.0)	1 (16.7)	2 (33.3)
Catheter site pain	1 (16.7)	1 (16.7)	0
Chills	1 (16.7)	1 (16.7)	0
Face oedema	1 (16.7)	0	1 (16.7)
Fatigue	1 (16.7)	1 (16.7)	0
Generalised oedema	1 (16.7)	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)
Hepatobiliary disorders			
-Total	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cholelithiasis	1 (16.7)	1 (16.7)	0
Gallbladder enlargement	1 (16.7)	1 (16.7)	0
Immune system disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	2 (33.3)	0	2 (33.3)
Infusion related reaction	1 (16.7)	0	1 (16.7)
Skin injury	1 (16.7)	0	1 (16.7)
Skin wound	1 (16.7)	1 (16.7)	0
Wound	1 (16.7)	0	1 (16.7)
Investigations			

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (50.0)	0	3 (50.0)
Neutrophil count decreased	2 (33.3)	0	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)
International normalised ratio increased	1 (16.7)	1 (16.7)	0
Lipase increased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)
Hyperuricaemia	2 (33.3)	2 (33.3)	0
Hypocalcaemia	2 (33.3)	0	2 (33.3)
Acidosis	1 (16.7)	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)
Hyperglycaemia	1 (16.7)	0	1 (16.7)
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)
Hypokalaemia	1 (16.7)	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0
Hyponatraemia	1 (16.7)	1 (16.7)	0
Hypophosphataemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0
Myositis	1 (16.7)	0	1 (16.7)
Nervous system disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Headache	3 (50.0)	2 (33.3)	1 (16.7)
Monoparesis	1 (16.7)	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)
Tremor	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Confusional state	1 (16.7)	1 (16.7)	0
Sleep disorder	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	0	2 (33.3)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Atelectasis	1 (16.7)	0	1 (16.7)
Nasal congestion	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Rash	2 (33.3)	1 (16.7)	1 (16.7)
Decubitus ulcer	1 (16.7)	0	1 (16.7)
Erythema	1 (16.7)	1 (16.7)	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Skin ulcer	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	2 (33.3)	0
Hypertension	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	71 (95.9)	8 (10.8)	63 (85.1)
Blood and lymphatic system disorders			
-Total	14 (18.9)	4 (5.4)	10 (13.5)
Anaemia	14 (18.9)	4 (5.4)	10 (13.5)
Cardiac disorders			
-Total	14 (18.9)	7 (9.5)	7 (9.5)
Tachycardia	12 (16.2)	6 (8.1)	6 (8.1)
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)
Eye disorders			
-Total	1 (1.4)	0	1 (1.4)
Eyelid oedema	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	43 (58.1)	22 (29.7)	21 (28.4)
Vomiting	20 (27.0)	12 (16.2)	8 (10.8)
Nausea	15 (20.3)	9 (12.2)	6 (8.1)
Diarrhoea	14 (18.9)	8 (10.8)	6 (8.1)
Abdominal pain	10 (13.5)	3 (4.1)	7 (9.5)
Constipation	10 (13.5)	5 (6.8)	5 (6.8)
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)
Ascites	2 (2.7)	1 (1.4)	1 (1.4)
Mouth haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	27 (36.5)	17 (23.0)	10 (13.5)
Pyrexia	16 (21.6)	10 (13.5)	6 (8.1)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)
Face oedema	6 (8.1)	5 (6.8)	1 (1.4)
Chills	5 (6.8)	3 (4.1)	2 (2.7)
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)
Oedema peripheral	4 (5.4)	4 (5.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (1.4)	0	1 (1.4)
Hepatobiliary disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Cholelithiasis	1 (1.4)	0	1 (1.4)
Gallbladder enlargement	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	55 (74.3)	11 (14.9)	44 (59.5)
Cytokine release syndrome	52 (70.3)	11 (14.9)	41 (55.4)
Hypogammaglobulinaemia	15 (20.3)	2 (2.7)	13 (17.6)
Infections and infestations			
-Total	7 (9.5)	1 (1.4)	6 (8.1)
Conjunctivitis	4 (5.4)	1 (1.4)	3 (4.1)
Rhinovirus infection	2 (2.7)	0	2 (2.7)
Otitis externa	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	2 (2.7)	0	2 (2.7)
Infusion related reaction	1 (1.4)	0	1 (1.4)
Wound	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	32 (43.2)	9 (12.2)	23 (31.1)
Alanine aminotransferase increased	15 (20.3)	4 (5.4)	11 (14.9)
Aspartate aminotransferase increased	12 (16.2)	3 (4.1)	9 (12.2)
Platelet count decreased	12 (16.2)	5 (6.8)	7 (9.5)
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)
White blood cell count decreased	6 (8.1)	3 (4.1)	3 (4.1)
Blood bilirubin increased	4 (5.4)	2 (2.7)	2 (2.7)
Blood immunoglobulin m decreased	4 (5.4)	4 (5.4)	0
Neutrophil count decreased	4 (5.4)	0	4 (5.4)
Electrocardiogram qt prolonged	3 (4.1)	2 (2.7)	1 (1.4)
Weight increased	2 (2.7)	2 (2.7)	0
Blood immunoglobulin g decreased	1 (1.4)	1 (1.4)	0
Lipase increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	30 (40.5)	11 (14.9)	19 (25.7)
Decreased appetite	11 (14.9)	8 (10.8)	3 (4.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	11 (14.9)	3 (4.1)	8 (10.8)
Hypocalcaemia	10 (13.5)	2 (2.7)	8 (10.8)
Hypoalbuminaemia	9 (12.2)	0	9 (12.2)
Hypophosphataemia	8 (10.8)	4 (5.4)	4 (5.4)
Hyperuricaemia	5 (6.8)	4 (5.4)	1 (1.4)
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)
Hyperglycaemia	3 (4.1)	0	3 (4.1)
Hyponatraemia	2 (2.7)	2 (2.7)	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	22 (29.7)	12 (16.2)	10 (13.5)
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)
Arthralgia	9 (12.2)	4 (5.4)	5 (6.8)
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)
Nervous system disorders			
-Total	21 (28.4)	12 (16.2)	9 (12.2)
Headache	18 (24.3)	10 (13.5)	8 (10.8)
Tremor	5 (6.8)	4 (5.4)	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)
Psychiatric disorders			
-Total	10 (13.5)	6 (8.1)	4 (5.4)
Confusional state	6 (8.1)	6 (8.1)	0
Anxiety	4 (5.4)	1 (1.4)	3 (4.1)
Sleep disorder	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	4 (5.4)	1 (1.4)	3 (4.1)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Urinary retention	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (21.6)	13 (17.6)	3 (4.1)
Cough	10 (13.5)	9 (12.2)	1 (1.4)
Oropharyngeal pain	5 (6.8)	5 (6.8)	0
Nasal congestion	2 (2.7)	1 (1.4)	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	13 (17.6)	5 (6.8)	8 (10.8)
Pruritus	5 (6.8)	2 (2.7)	3 (4.1)
Erythema	3 (4.1)	3 (4.1)	0
Rash	3 (4.1)	1 (1.4)	2 (2.7)
Hyperhidrosis	2 (2.7)	0	2 (2.7)
Dry skin	1 (1.4)	1 (1.4)	0
Skin ulcer	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	15 (20.3)	5 (6.8)	10 (13.5)
Hypertension	9 (12.2)	4 (5.4)	5 (6.8)
Hypotension	8 (10.8)	1 (1.4)	7 (9.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Lymphocytosis	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	1 (20.0)	0
Fatigue	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	2 (40.0)	0	2 (40.0)
Gastroenteritis	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0
Otitis externa	1 (20.0)	0	1 (20.0)
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Injury, poisoning and procedural complications			
-Total	1 (20.0)	0	1 (20.0)
Fibula fracture	1 (20.0)	0	1 (20.0)
Investigations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	1 (20.0)	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	1 (20.0)	1 (20.0)	0
Headache	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Persistent depressive disorder	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Cough	1 (20.0)	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (40.0)	2 (40.0)	0
Dry skin	2 (40.0)	2 (40.0)	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	53 (75.7)	14 (20.0)	39 (55.7)
Blood and lymphatic system disorders			
-Total	5 (7.1)	4 (5.7)	1 (1.4)
Anaemia	5 (7.1)	4 (5.7)	1 (1.4)
Cardiac disorders			
-Total	2 (2.9)	2 (2.9)	0
Tachycardia	2 (2.9)	2 (2.9)	0
Gastrointestinal disorders			
-Total	15 (21.4)	10 (14.3)	5 (7.1)
Diarrhoea	7 (10.0)	6 (8.6)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	6 (8.6)	6 (8.6)	0
Nausea	5 (7.1)	3 (4.3)	2 (2.9)
Constipation	3 (4.3)	1 (1.4)	2 (2.9)
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)
Mouth haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	19 (27.1)	13 (18.6)	6 (8.6)
Pyrexia	13 (18.6)	7 (10.0)	6 (8.6)
Fatigue	5 (7.1)	5 (7.1)	0
Chills	1 (1.4)	1 (1.4)	0
Oedema peripheral	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	10 (14.3)	0	10 (14.3)
Hypogammaglobulinaemia	10 (14.3)	0	10 (14.3)
Infections and infestations			
-Total	14 (20.0)	3 (4.3)	11 (15.7)
Upper respiratory tract infection	6 (8.6)	3 (4.3)	3 (4.3)
Rhinovirus infection	4 (5.7)	0	4 (5.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	3 (4.3)	0	3 (4.3)
Gastroenteritis	2 (2.9)	2 (2.9)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Infusion related reaction	3 (4.3)	2 (2.9)	1 (1.4)
Investigations			
-Total	15 (21.4)	6 (8.6)	9 (12.9)
White blood cell count decreased	8 (11.4)	5 (7.1)	3 (4.3)
Neutrophil count decreased	4 (5.7)	1 (1.4)	3 (4.3)
Platelet count decreased	4 (5.7)	3 (4.3)	1 (1.4)
Alanine aminotransferase increased	2 (2.9)	2 (2.9)	0
Blood bilirubin increased	2 (2.9)	0	2 (2.9)
Blood creatinine increased	1 (1.4)	0	1 (1.4)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)
Weight increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	8 (11.4)	3 (4.3)	5 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	5 (7.1)	2 (2.9)	3 (4.3)
Hyperuricaemia	2 (2.9)	2 (2.9)	0
Hypokalaemia	2 (2.9)	0	2 (2.9)
Hypophosphataemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (10.0)	4 (5.7)	3 (4.3)
Pain in extremity	4 (5.7)	2 (2.9)	2 (2.9)
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)
Myalgia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	9 (12.9)	5 (7.1)	4 (5.7)
Headache	9 (12.9)	5 (7.1)	4 (5.7)
Psychiatric disorders			
-Total	7 (10.0)	1 (1.4)	6 (8.6)
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)
Sleep disorder	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (17.1)	8 (11.4)	4 (5.7)
Cough	10 (14.3)	7 (10.0)	3 (4.3)
Nasal congestion	5 (7.1)	4 (5.7)	1 (1.4)
Oropharyngeal pain	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	9 (12.9)	5 (7.1)	4 (5.7)
Dry skin	4 (5.7)	2 (2.9)	2 (2.9)
Rash	4 (5.7)	3 (4.3)	1 (1.4)
Erythema	1 (1.4)	0	1 (1.4)
Pruritus	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	1 (1.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Rhinovirus infection	1 (33.3)	0	1 (33.3)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (33.3)	0	1 (33.3)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (46.8)	5 (10.6)	17 (36.2)
Blood and lymphatic system disorders			
-Total	1 (2.1)	0	1 (2.1)
Anaemia	1 (2.1)	0	1 (2.1)
Eye disorders			
-Total	1 (2.1)	1 (2.1)	0
Eyelid oedema	1 (2.1)	1 (2.1)	0
Gastrointestinal disorders			
-Total	5 (10.6)	4 (8.5)	1 (2.1)
Diarrhoea	4 (8.5)	3 (6.4)	1 (2.1)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	1 (2.1)	1 (2.1)	0
Nausea	1 (2.1)	1 (2.1)	0
Vomiting	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			
-Total	4 (8.5)	2 (4.3)	2 (4.3)
Pyrexia	3 (6.4)	2 (4.3)	1 (2.1)
Fatigue	1 (2.1)	0	1 (2.1)
Immune system disorders			
-Total	6 (12.8)	2 (4.3)	4 (8.5)
Hypogammaglobulinaemia	3 (6.4)	0	3 (6.4)
Seasonal allergy	3 (6.4)	2 (4.3)	1 (2.1)
Infections and infestations			
-Total	13 (27.7)	5 (10.6)	8 (17.0)
Sinusitis	5 (10.6)	0	5 (10.6)
Upper respiratory tract infection	5 (10.6)	2 (4.3)	3 (6.4)
Conjunctivitis	4 (8.5)	2 (4.3)	2 (4.3)
Rhinovirus infection	2 (4.3)	0	2 (4.3)
Gastroenteritis	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	5 (10.6)	3 (6.4)	2 (4.3)
Neutrophil count decreased	3 (6.4)	2 (4.3)	1 (2.1)
Platelet count decreased	2 (4.3)	2 (4.3)	0
Blood bilirubin increased	1 (2.1)	1 (2.1)	0
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (6.4)	0	3 (6.4)
Pain in extremity	2 (4.3)	0	2 (4.3)
Arthralgia	1 (2.1)	0	1 (2.1)
Nervous system disorders			
-Total	2 (4.3)	0	2 (4.3)
Headache	2 (4.3)	0	2 (4.3)
Psychiatric disorders			
-Total	2 (4.3)	1 (2.1)	1 (2.1)
Anxiety	2 (4.3)	1 (2.1)	1 (2.1)
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (8.5)	3 (6.4)	1 (2.1)
Cough	4 (8.5)	3 (6.4)	1 (2.1)
Oropharyngeal pain	1 (2.1)	1 (2.1)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.4)	2 (4.3)	1 (2.1)
Rash	2 (4.3)	1 (2.1)	1 (2.1)
Dry skin	1 (2.1)	1 (2.1)	0
Vascular disorders			
-Total	1 (2.1)	0	1 (2.1)
Hypertension	1 (2.1)	0	1 (2.1)

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Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	0	6 (100)
Blood and lymphatic system disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)
Lymphocytosis	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Tachycardia	3 (50.0)	1 (16.7)	2 (33.3)
Sinus tachycardia	1 (16.7)	1 (16.7)	0
Eye disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Eyelid oedema	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	0	2 (33.3)
Abdominal distension	1 (16.7)	0	1 (16.7)
Ascites	1 (16.7)	1 (16.7)	0
Constipation	1 (16.7)	1 (16.7)	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)
Mouth haemorrhage	1 (16.7)	0	1 (16.7)
Nausea	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Pyrexia	3 (50.0)	0	3 (50.0)
Fatigue	2 (33.3)	2 (33.3)	0
Catheter site pain	1 (16.7)	1 (16.7)	0
Chills	1 (16.7)	1 (16.7)	0
Face oedema	1 (16.7)	0	1 (16.7)
Generalised oedema	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	1 (16.7)	0	1 (16.7)
Hepatobiliary disorders			
-Total	1 (16.7)	1 (16.7)	0
Cholelithiasis	1 (16.7)	1 (16.7)	0
Gallbladder enlargement	1 (16.7)	1 (16.7)	0
Immune system disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	3 (50.0)	0	3 (50.0)
Conjunctivitis	1 (16.7)	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0
Localised infection	1 (16.7)	1 (16.7)	0
Otitis externa	1 (16.7)	0	1 (16.7)
Rhinovirus infection	1 (16.7)	0	1 (16.7)
Sinusitis	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	3 (50.0)	0	3 (50.0)
Fibula fracture	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)
Skin injury	1 (16.7)	0	1 (16.7)
Skin wound	1 (16.7)	1 (16.7)	0
Wound	1 (16.7)	0	1 (16.7)
Investigations			
-Total	3 (50.0)	0	3 (50.0)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)
International normalised ratio increased	1 (16.7)	1 (16.7)	0
Lipase increased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)
Hyperuricaemia	2 (33.3)	2 (33.3)	0
Hypocalcaemia	2 (33.3)	0	2 (33.3)
Acidosis	1 (16.7)	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)
Hyperglycaemia	1 (16.7)	0	1 (16.7)
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	1 (16.7)	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0
Hyponatraemia	1 (16.7)	1 (16.7)	0
Hypophosphataemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0
Myositis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Headache	3 (50.0)	2 (33.3)	1 (16.7)
Monoparesis	1 (16.7)	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)
Tremor	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Confusional state	1 (16.7)	1 (16.7)	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sleep disorder	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	0	2 (33.3)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0
Atelectasis	1 (16.7)	0	1 (16.7)
Cough	1 (16.7)	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	4 (66.7)	3 (50.0)	1 (16.7)
Dry skin	2 (33.3)	2 (33.3)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)
Decubitus ulcer	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Erythema	1 (16.7)	1 (16.7)	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Skin hypopigmentation	1 (16.7)	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	2 (33.3)	0
Hypertension	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257e
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	73 (98.6)	5 (6.8)	68 (91.9)
Blood and lymphatic system disorders			
-Total	17 (23.0)	6 (8.1)	11 (14.9)
Anaemia	17 (23.0)	6 (8.1)	11 (14.9)
Cardiac disorders			
-Total	15 (20.3)	8 (10.8)	7 (9.5)
Tachycardia	13 (17.6)	7 (9.5)	6 (8.1)
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)
Eye disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eyelid oedema	2 (2.7)	1 (1.4)	1 (1.4)
Gastrointestinal disorders			
-Total	53 (71.6)	27 (36.5)	26 (35.1)
Vomiting	25 (33.8)	17 (23.0)	8 (10.8)
Diarrhoea	24 (32.4)	16 (21.6)	8 (10.8)
Nausea	19 (25.7)	11 (14.9)	8 (10.8)
Constipation	13 (17.6)	6 (8.1)	7 (9.5)
Abdominal pain	11 (14.9)	3 (4.1)	8 (10.8)
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)
Ascites	2 (2.7)	1 (1.4)	1 (1.4)
Mouth haemorrhage	2 (2.7)	2 (2.7)	0
General disorders and administration site conditions			
-Total	39 (52.7)	23 (31.1)	16 (21.6)
Pyrexia	26 (35.1)	15 (20.3)	11 (14.9)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)
Chills	6 (8.1)	4 (5.4)	2 (2.7)
Face oedema	6 (8.1)	5 (6.8)	1 (1.4)
Oedema peripheral	5 (6.8)	5 (6.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)
Catheter site pain	1 (1.4)	0	1 (1.4)
Hepatobiliary disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Cholelithiasis	1 (1.4)	0	1 (1.4)
Gallbladder enlargement	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	59 (79.7)	10 (13.5)	49 (66.2)
Cytokine release syndrome	52 (70.3)	11 (14.9)	41 (55.4)
Hypogammaglobulinaemia	25 (33.8)	2 (2.7)	23 (31.1)
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)
Infections and infestations			
-Total	26 (35.1)	8 (10.8)	18 (24.3)
Upper respiratory tract infection	11 (14.9)	5 (6.8)	6 (8.1)
Conjunctivitis	7 (9.5)	2 (2.7)	5 (6.8)
Rhinovirus infection	7 (9.5)	0	7 (9.5)
Sinusitis	5 (6.8)	0	5 (6.8)
Gastroenteritis	3 (4.1)	3 (4.1)	0
Otitis externa	1 (1.4)	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (5.4)	2 (2.7)	2 (2.7)
Infusion related reaction	3 (4.1)	2 (2.7)	1 (1.4)
Wound	1 (1.4)	0	1 (1.4)
Investigations			
-Total	35 (47.3)	7 (9.5)	28 (37.8)
Alanine aminotransferase increased	15 (20.3)	4 (5.4)	11 (14.9)
Platelet count decreased	14 (18.9)	7 (9.5)	7 (9.5)
Aspartate aminotransferase increased	12 (16.2)	3 (4.1)	9 (12.2)
White blood cell count decreased	10 (13.5)	4 (5.4)	6 (8.1)
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)
Neutrophil count decreased	8 (10.8)	2 (2.7)	6 (8.1)
Blood bilirubin increased	6 (8.1)	2 (2.7)	4 (5.4)
Blood immunoglobulin m decreased	4 (5.4)	4 (5.4)	0
Blood immunoglobulin g decreased	3 (4.1)	1 (1.4)	2 (2.7)
Electrocardiogram qt prolonged	3 (4.1)	2 (2.7)	1 (1.4)
Weight increased	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood creatinine increased	1 (1.4)	0	1 (1.4)
Lipase increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	36 (48.6)	13 (17.6)	23 (31.1)
Decreased appetite	16 (21.6)	10 (13.5)	6 (8.1)
Hypokalaemia	12 (16.2)	3 (4.1)	9 (12.2)
Hypocalcaemia	10 (13.5)	2 (2.7)	8 (10.8)
Hypoalbuminaemia	9 (12.2)	0	9 (12.2)
Hypophosphataemia	9 (12.2)	4 (5.4)	5 (6.8)
Hyperuricaemia	7 (9.5)	6 (8.1)	1 (1.4)
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)
Hyperglycaemia	3 (4.1)	0	3 (4.1)
Hyponatraemia	2 (2.7)	2 (2.7)	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	28 (37.8)	15 (20.3)	13 (17.6)
Pain in extremity	16 (21.6)	8 (10.8)	8 (10.8)
Arthralgia	11 (14.9)	5 (6.8)	6 (8.1)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)
Nervous system disorders			
-Total	26 (35.1)	13 (17.6)	13 (17.6)
Headache	23 (31.1)	11 (14.9)	12 (16.2)
Tremor	5 (6.8)	4 (5.4)	1 (1.4)
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)
Psychiatric disorders			
-Total	18 (24.3)	7 (9.5)	11 (14.9)
Anxiety	12 (16.2)	3 (4.1)	9 (12.2)
Confusional state	6 (8.1)	6 (8.1)	0
Sleep disorder	2 (2.7)	0	2 (2.7)
Renal and urinary disorders			
-Total	6 (8.1)	2 (2.7)	4 (5.4)
Acute kidney injury	5 (6.8)	2 (2.7)	3 (4.1)
Urinary retention	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	29 (39.2)	21 (28.4)	8 (10.8)
Cough	22 (29.7)	17 (23.0)	5 (6.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	7 (9.5)	5 (6.8)	2 (2.7)
Oropharyngeal pain	7 (9.5)	6 (8.1)	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	21 (28.4)	9 (12.2)	12 (16.2)
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)
Pruritus	6 (8.1)	2 (2.7)	4 (5.4)
Rash	6 (8.1)	3 (4.1)	3 (4.1)
Erythema	4 (5.4)	3 (4.1)	1 (1.4)
Hyperhidrosis	2 (2.7)	0	2 (2.7)
Skin ulcer	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	18 (24.3)	6 (8.1)	12 (16.2)
Hypertension	11 (14.9)	4 (5.4)	7 (9.5)
Hypotension	9 (12.2)	2 (2.7)	7 (9.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Immune system disorders			
-Total	2 (100)	0	2 (100)
Cytokine release syndrome	2 (100)	0	2 (100)
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Cognitive disorder	1 (50.0)	0	1 (50.0)
Psychiatric disorders			
-Total	1 (50.0)	0	1 (50.0)
Anxiety	1 (50.0)	0	1 (50.0)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Wheezing	1 (50.0)	0	1 (50.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	75 (96.2)	9 (11.5)	66 (84.6)
Blood and lymphatic system disorders			
-Total	16 (20.5)	5 (6.4)	11 (14.1)
Anaemia	16 (20.5)	5 (6.4)	11 (14.1)
Cardiac disorders			
-Total	15 (19.2)	7 (9.0)	8 (10.3)
Tachycardia	15 (19.2)	7 (9.0)	8 (10.3)
Endocrine disorders			
-Total	1 (1.3)	0	1 (1.3)
Hypothyroidism	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	45 (57.7)	24 (30.8)	21 (26.9)
Vomiting	20 (25.6)	12 (15.4)	8 (10.3)
Nausea	16 (20.5)	10 (12.8)	6 (7.7)
Diarrhoea	14 (17.9)	8 (10.3)	6 (7.7)
Constipation	11 (14.1)	6 (7.7)	5 (6.4)
Abdominal pain	10 (12.8)	3 (3.8)	7 (9.0)
General disorders and administration site conditions			
-Total	26 (33.3)	17 (21.8)	9 (11.5)
Pyrexia	19 (24.4)	11 (14.1)	8 (10.3)
Fatigue	11 (14.1)	9 (11.5)	2 (2.6)
Immune system disorders			
-Total	58 (74.4)	12 (15.4)	46 (59.0)
Cytokine release syndrome	55 (70.5)	13 (16.7)	42 (53.8)
Hypogammaglobulinaemia	16 (20.5)	2 (2.6)	14 (17.9)
Seasonal allergy	1 (1.3)	0	1 (1.3)
Infections and infestations			
-Total	8 (10.3)	1 (1.3)	7 (9.0)
Conjunctivitis	5 (6.4)	1 (1.3)	4 (5.1)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	2 (2.6)	0	2 (2.6)
Paronychia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	32 (41.0)	6 (7.7)	26 (33.3)
Alanine aminotransferase increased	16 (20.5)	4 (5.1)	12 (15.4)
Aspartate aminotransferase increased	13 (16.7)	3 (3.8)	10 (12.8)
Platelet count decreased	13 (16.7)	6 (7.7)	7 (9.0)
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)
White blood cell count decreased	8 (10.3)	3 (3.8)	5 (6.4)
Neutrophil count decreased	6 (7.7)	0	6 (7.7)
Metabolism and nutrition disorders			
-Total	33 (42.3)	12 (15.4)	21 (26.9)
Decreased appetite	13 (16.7)	9 (11.5)	4 (5.1)
Hypocalcaemia	12 (15.4)	2 (2.6)	10 (12.8)
Hypokalaemia	12 (15.4)	3 (3.8)	9 (11.5)
Hypoalbuminaemia	10 (12.8)	0	10 (12.8)
Hypophosphataemia	9 (11.5)	4 (5.1)	5 (6.4)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	7 (9.0)	6 (7.7)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	23 (29.5)	13 (16.7)	10 (12.8)
Pain in extremity	11 (14.1)	6 (7.7)	5 (6.4)
Arthralgia	9 (11.5)	4 (5.1)	5 (6.4)
Myalgia	9 (11.5)	6 (7.7)	3 (3.8)
Nervous system disorders			
-Total	22 (28.2)	12 (15.4)	10 (12.8)
Headache	21 (26.9)	12 (15.4)	9 (11.5)
Cognitive disorder	2 (2.6)	0	2 (2.6)
Psychiatric disorders			
-Total	5 (6.4)	1 (1.3)	4 (5.1)
Anxiety	3 (3.8)	1 (1.3)	2 (2.6)
Sleep disorder	2 (2.6)	0	2 (2.6)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (21.8)	15 (19.2)	2 (2.6)
Cough	10 (12.8)	9 (11.5)	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oropharyngeal pain	5 (6.4)	5 (6.4)	0
Nasal congestion	3 (3.8)	2 (2.6)	1 (1.3)
Rhinorrhoea	2 (2.6)	2 (2.6)	0
Skin and subcutaneous tissue disorders			
-Total	6 (7.7)	3 (3.8)	3 (3.8)
Rash	5 (6.4)	2 (2.6)	3 (3.8)
Dry skin	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	17 (21.8)	7 (9.0)	10 (12.8)
Hypertension	10 (12.8)	5 (6.4)	5 (6.4)
Hypotension	9 (11.5)	2 (2.6)	7 (9.0)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0
Hepatobiliary disorders			
-Total	1 (50.0)	1 (50.0)	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypophosphataemia	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Growth retardation	1 (50.0)	0	1 (50.0)
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Memory impairment	1 (50.0)	0	1 (50.0)
Psychiatric disorders			
-Total	1 (50.0)	0	1 (50.0)
Sleep disorder	1 (50.0)	0	1 (50.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Lung disorder	1 (50.0)	1 (50.0)	0
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

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Table 257f
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	52 (71.2)	16 (21.9)	36 (49.3)
Blood and lymphatic system disorders			
-Total	5 (6.8)	4 (5.5)	1 (1.4)
Anaemia	5 (6.8)	4 (5.5)	1 (1.4)
Cardiac disorders			
-Total	2 (2.7)	2 (2.7)	0
Tachycardia	2 (2.7)	2 (2.7)	0
Endocrine disorders			
-Total	1 (1.4)	0	1 (1.4)
Hypothyroidism	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	14 (19.2)	9 (12.3)	5 (6.8)
Diarrhoea	7 (9.6)	6 (8.2)	1 (1.4)
Vomiting	6 (8.2)	6 (8.2)	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)
Constipation	3 (4.1)	1 (1.4)	2 (2.7)
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	19 (26.0)	13 (17.8)	6 (8.2)
Pyrexia	13 (17.8)	7 (9.6)	6 (8.2)
Fatigue	6 (8.2)	6 (8.2)	0
Immune system disorders			
-Total	9 (12.3)	0	9 (12.3)
Hypogammaglobulinaemia	9 (12.3)	0	9 (12.3)
Infections and infestations			
-Total	11 (15.1)	2 (2.7)	9 (12.3)
Upper respiratory tract infection	7 (9.6)	3 (4.1)	4 (5.5)
Rhinovirus infection	4 (5.5)	0	4 (5.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (1.4)	0	1 (1.4)
Investigations			
-Total	13 (17.8)	7 (9.6)	6 (8.2)
White blood cell count decreased	9 (12.3)	5 (6.8)	4 (5.5)
Neutrophil count decreased	6 (8.2)	2 (2.7)	4 (5.5)
Platelet count decreased	4 (5.5)	3 (4.1)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	2 (2.7)	0
Metabolism and nutrition disorders			
-Total	8 (11.0)	4 (5.5)	4 (5.5)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)
Hyperuricaemia	3 (4.1)	3 (4.1)	0
Hypokalaemia	2 (2.7)	0	2 (2.7)
Musculoskeletal and connective tissue disorders			
-Total	7 (9.6)	4 (5.5)	3 (4.1)
Pain in extremity	4 (5.5)	2 (2.7)	2 (2.7)
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)
Myalgia	1 (1.4)	0	1 (1.4)
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (13.7)	6 (8.2)	4 (5.5)
Headache	10 (13.7)	6 (8.2)	4 (5.5)
Psychiatric disorders			
-Total	6 (8.2)	1 (1.4)	5 (6.8)
Anxiety	6 (8.2)	1 (1.4)	5 (6.8)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (19.2)	10 (13.7)	4 (5.5)
Cough	11 (15.1)	8 (11.0)	3 (4.1)
Nasal congestion	6 (8.2)	5 (6.8)	1 (1.4)
Rhinorrhoea	3 (4.1)	3 (4.1)	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	9 (12.3)	7 (9.6)	2 (2.7)
Dry skin	6 (8.2)	4 (5.5)	2 (2.7)
Rash	4 (5.5)	3 (4.1)	1 (1.4)
Vascular disorders			
-Total	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Endocrine disorders			
-Total	1 (50.0)	0	1 (50.0)
Delayed puberty	1 (50.0)	0	1 (50.0)
Hypothyroidism	1 (50.0)	0	1 (50.0)
Eye disorders			
-Total	1 (50.0)	1 (50.0)	0
Dry eye	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (50.0)	0	1 (50.0)
Nausea	1 (50.0)	1 (50.0)	0
Vomiting	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Fatigue	1 (50.0)	0	1 (50.0)
Immune system disorders			
-Total	1 (50.0)	1 (50.0)	0
Seasonal allergy	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Osteopenia	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Dysarthria	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (50.0)	0	1 (50.0)
Rhinorrhoea	1 (50.0)	0	1 (50.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (43.8)	5 (10.4)	16 (33.3)
Blood and lymphatic system disorders			
-Total	1 (2.1)	0	1 (2.1)
Anaemia	1 (2.1)	0	1 (2.1)
Gastrointestinal disorders			
-Total	4 (8.3)	4 (8.3)	0
Diarrhoea	3 (6.3)	3 (6.3)	0
Constipation	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			
-Total	4 (8.3)	2 (4.2)	2 (4.2)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	4 (8.3)	2 (4.2)	2 (4.2)
Immune system disorders			
-Total	5 (10.4)	1 (2.1)	4 (8.3)
Hypogammaglobulinaemia	3 (6.3)	0	3 (6.3)
Seasonal allergy	2 (4.2)	1 (2.1)	1 (2.1)
Infections and infestations			
-Total	11 (22.9)	4 (8.3)	7 (14.6)
Upper respiratory tract infection	5 (10.4)	2 (4.2)	3 (6.3)
Conjunctivitis	4 (8.3)	2 (4.2)	2 (4.2)
Rhinovirus infection	3 (6.3)	0	3 (6.3)
Investigations			
-Total	4 (8.3)	3 (6.3)	1 (2.1)
Neutrophil count decreased	3 (6.3)	2 (4.2)	1 (2.1)
Platelet count decreased	2 (4.2)	2 (4.2)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (8.3)	0	4 (8.3)
Pain in extremity	2 (4.2)	0	2 (4.2)
Arthralgia	1 (2.1)	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Growth retardation	1 (2.1)	0	1 (2.1)
Nervous system disorders			
-Total	2 (4.2)	0	2 (4.2)
Headache	2 (4.2)	0	2 (4.2)
Psychiatric disorders			
-Total	2 (4.2)	1 (2.1)	1 (2.1)
Anxiety	2 (4.2)	1 (2.1)	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (8.3)	3 (6.3)	1 (2.1)
Cough	3 (6.3)	3 (6.3)	0
Rhinorrhoea	2 (4.2)	1 (2.1)	1 (2.1)
Oropharyngeal pain	1 (2.1)	1 (2.1)	0
Wheezing	1 (2.1)	0	1 (2.1)
Skin and subcutaneous tissue disorders			
-Total	3 (6.3)	2 (4.2)	1 (2.1)
Rash	2 (4.2)	1 (2.1)	1 (2.1)
Dry skin	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	1 (2.1)	0	1 (2.1)
Hypertension	1 (2.1)	0	1 (2.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)
Endocrine disorders			
-Total	1 (50.0)	0	1 (50.0)
Delayed puberty	1 (50.0)	0	1 (50.0)
Hypothyroidism	1 (50.0)	0	1 (50.0)
Eye disorders			
-Total	1 (50.0)	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry eye	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Diarrhoea	1 (50.0)	0	1 (50.0)
Nausea	1 (50.0)	1 (50.0)	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0
Vomiting	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Fatigue	1 (50.0)	0	1 (50.0)
Hepatobiliary disorders			
-Total	1 (50.0)	1 (50.0)	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	0	2 (100)
Cytokine release syndrome	2 (100)	0	2 (100)
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Seasonal allergy	1 (50.0)	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypophosphataemia	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Growth retardation	1 (50.0)	0	1 (50.0)
Osteopenia	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	2 (100)	0	2 (100)
Cognitive disorder	1 (50.0)	0	1 (50.0)
Dysarthria	1 (50.0)	0	1 (50.0)
Memory impairment	1 (50.0)	0	1 (50.0)
Psychiatric disorders			
-Total	2 (100)	0	2 (100)
Anxiety	1 (50.0)	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sleep disorder	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Cough	1 (50.0)	0	1 (50.0)
Lung disorder	1 (50.0)	1 (50.0)	0
Rhinorrhoea	1 (50.0)	0	1 (50.0)
Wheezing	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257f
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	77 (98.7)	5 (6.4)	72 (92.3)
Blood and lymphatic system disorders			
-Total	19 (24.4)	7 (9.0)	12 (15.4)
Anaemia	19 (24.4)	7 (9.0)	12 (15.4)
Cardiac disorders			
-Total	16 (20.5)	8 (10.3)	8 (10.3)
Tachycardia	16 (20.5)	8 (10.3)	8 (10.3)
Endocrine disorders			
-Total	2 (2.6)	0	2 (2.6)
Hypothyroidism	2 (2.6)	0	2 (2.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	53 (67.9)	28 (35.9)	25 (32.1)
Vomiting	24 (30.8)	16 (20.5)	8 (10.3)
Diarrhoea	23 (29.5)	16 (20.5)	7 (9.0)
Nausea	19 (24.4)	11 (14.1)	8 (10.3)
Constipation	14 (17.9)	7 (9.0)	7 (9.0)
Abdominal pain	11 (14.1)	3 (3.8)	8 (10.3)
General disorders and administration site conditions			
-Total	37 (47.4)	22 (28.2)	15 (19.2)
Pyrexia	29 (37.2)	15 (19.2)	14 (17.9)
Fatigue	16 (20.5)	14 (17.9)	2 (2.6)
Immune system disorders			
-Total	62 (79.5)	11 (14.1)	51 (65.4)
Cytokine release syndrome	55 (70.5)	13 (16.7)	42 (53.8)
Hypogammaglobulinaemia	25 (32.1)	2 (2.6)	23 (29.5)
Seasonal allergy	3 (3.8)	1 (1.3)	2 (2.6)
Infections and infestations			
-Total	25 (32.1)	6 (7.7)	19 (24.4)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	12 (15.4)	5 (6.4)	7 (9.0)
Conjunctivitis	8 (10.3)	2 (2.6)	6 (7.7)
Rhinovirus infection	8 (10.3)	0	8 (10.3)
Paronychia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	35 (44.9)	7 (9.0)	28 (35.9)
Alanine aminotransferase increased	16 (20.5)	4 (5.1)	12 (15.4)
Platelet count decreased	15 (19.2)	8 (10.3)	7 (9.0)
Aspartate aminotransferase increased	13 (16.7)	3 (3.8)	10 (12.8)
White blood cell count decreased	12 (15.4)	4 (5.1)	8 (10.3)
Neutrophil count decreased	11 (14.1)	3 (3.8)	8 (10.3)
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)
Metabolism and nutrition disorders			
-Total	38 (48.7)	14 (17.9)	24 (30.8)
Decreased appetite	18 (23.1)	11 (14.1)	7 (9.0)
Hypokalaemia	13 (16.7)	3 (3.8)	10 (12.8)
Hypocalcaemia	12 (15.4)	2 (2.6)	10 (12.8)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	10 (12.8)	0	10 (12.8)
Hyperuricaemia	9 (11.5)	8 (10.3)	1 (1.3)
Hypophosphataemia	9 (11.5)	4 (5.1)	5 (6.4)
Musculoskeletal and connective tissue disorders			
-Total	30 (38.5)	16 (20.5)	14 (17.9)
Pain in extremity	16 (20.5)	8 (10.3)	8 (10.3)
Arthralgia	11 (14.1)	5 (6.4)	6 (7.7)
Myalgia	10 (12.8)	6 (7.7)	4 (5.1)
Growth retardation	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	27 (34.6)	13 (16.7)	14 (17.9)
Headache	26 (33.3)	13 (16.7)	13 (16.7)
Cognitive disorder	2 (2.6)	0	2 (2.6)
Psychiatric disorders			
-Total	13 (16.7)	3 (3.8)	10 (12.8)
Anxiety	11 (14.1)	3 (3.8)	8 (10.3)
Sleep disorder	2 (2.6)	0	2 (2.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	31 (39.7)	25 (32.1)	6 (7.7)
Cough	22 (28.2)	18 (23.1)	4 (5.1)
Nasal congestion	9 (11.5)	7 (9.0)	2 (2.6)
Oropharyngeal pain	8 (10.3)	7 (9.0)	1 (1.3)
Rhinorrhoea	5 (6.4)	4 (5.1)	1 (1.3)
Wheezing	1 (1.3)	0	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	15 (19.2)	10 (12.8)	5 (6.4)
Dry skin	8 (10.3)	6 (7.7)	2 (2.6)
Rash	8 (10.3)	4 (5.1)	4 (5.1)
Vascular disorders			
-Total	19 (24.4)	7 (9.0)	12 (15.4)
Hypertension	12 (15.4)	5 (6.4)	7 (9.0)
Hypotension	9 (11.5)	2 (2.6)	7 (9.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Abdominal pain	1 (100)	1 (100)	0
Anal haemorrhage	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Blood fibrinogen decreased	1 (100)	1 (100)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	1 (100)	1 (100)	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0
Blood uric acid increased	1 (100)	1 (100)	0
Metabolism and nutrition disorders			
-Total	1 (100)	1 (100)	0
Decreased appetite	1 (100)	1 (100)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (100)	1 (100)	0
Pain in extremity	1 (100)	1 (100)	0
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Irritability	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Rhinorrhoea	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (100)	1 (100)	0
Dry skin	1 (100)	1 (100)	0
Rash papular	1 (100)	1 (100)	0
Rash pruritic	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	76 (96.2)	8 (10.1)	68 (86.1)
Blood and lymphatic system disorders			
-Total	15 (19.0)	4 (5.1)	11 (13.9)
Anaemia	15 (19.0)	4 (5.1)	11 (13.9)
Cardiac disorders			
-Total	15 (19.0)	7 (8.9)	8 (10.1)
Tachycardia	15 (19.0)	7 (8.9)	8 (10.1)
Gastrointestinal disorders			
-Total	44 (55.7)	23 (29.1)	21 (26.6)
Vomiting	20 (25.3)	12 (15.2)	8 (10.1)
Nausea	16 (20.3)	10 (12.7)	6 (7.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	14 (17.7)	8 (10.1)	6 (7.6)
Constipation	11 (13.9)	6 (7.6)	5 (6.3)
Abdominal pain	9 (11.4)	2 (2.5)	7 (8.9)
General disorders and administration site conditions			
-Total	26 (32.9)	17 (21.5)	9 (11.4)
Pyrexia	19 (24.1)	11 (13.9)	8 (10.1)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)
Immune system disorders			
-Total	60 (75.9)	12 (15.2)	48 (60.8)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	16 (20.3)	2 (2.5)	14 (17.7)
Infections and infestations			
-Total	7 (8.9)	1 (1.3)	6 (7.6)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)
Rhinovirus infection	2 (2.5)	0	2 (2.5)
Investigations			
-Total	34 (43.0)	6 (7.6)	28 (35.4)
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
Platelet count decreased	13 (16.5)	6 (7.6)	7 (8.9)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
White blood cell count decreased	8 (10.1)	3 (3.8)	5 (6.3)
Neutrophil count decreased	6 (7.6)	0	6 (7.6)
Blood fibrinogen decreased	4 (5.1)	1 (1.3)	3 (3.8)
Blood immunoglobulin a decreased	4 (5.1)	3 (3.8)	1 (1.3)
Blood immunoglobulin m decreased	4 (5.1)	3 (3.8)	1 (1.3)
Blood uric acid increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	32 (40.5)	11 (13.9)	21 (26.6)
Decreased appetite	12 (15.2)	8 (10.1)	4 (5.1)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)
Hypokalaemia	12 (15.2)	3 (3.8)	9 (11.4)
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)
Hypophosphataemia	9 (11.4)	4 (5.1)	5 (6.3)
Hyperuricaemia	7 (8.9)	6 (7.6)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	22 (27.8)	12 (15.2)	10 (12.7)
Pain in extremity	10 (12.7)	5 (6.3)	5 (6.3)
Arthralgia	9 (11.4)	4 (5.1)	5 (6.3)
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)
Nervous system disorders			
-Total	21 (26.6)	12 (15.2)	9 (11.4)
Headache	21 (26.6)	12 (15.2)	9 (11.4)
Psychiatric disorders			
-Total	6 (7.6)	3 (3.8)	3 (3.8)
Anxiety	4 (5.1)	1 (1.3)	3 (3.8)
Irritability	2 (2.5)	2 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (20.3)	14 (17.7)	2 (2.5)
Cough	9 (11.4)	8 (10.1)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinorrhoea	1 (1.3)	1 (1.3)	0
Skin and subcutaneous tissue disorders			
-Total	7 (8.9)	3 (3.8)	4 (5.1)
Rash	5 (6.3)	2 (2.5)	3 (3.8)
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)
Vascular disorders			
-Total	17 (21.5)	7 (8.9)	10 (12.7)
Hypertension	10 (12.7)	5 (6.3)	5 (6.3)
Hypotension	9 (11.4)	2 (2.5)	7 (8.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Diarrhoea	1 (100)	1 (100)	0
Nausea	1 (100)	1 (100)	0
Proctalgia	1 (100)	1 (100)	0
Vomiting	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypogammaglobulinaemia	1 (100)	0	1 (100)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Rhinorrhoea	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	53 (71.6)	16 (21.6)	37 (50.0)
Blood and lymphatic system disorders			
-Total	5 (6.8)	4 (5.4)	1 (1.4)
Anaemia	5 (6.8)	4 (5.4)	1 (1.4)
Cardiac disorders			
-Total	2 (2.7)	2 (2.7)	0
Tachycardia	2 (2.7)	2 (2.7)	0
Gastrointestinal disorders			
-Total	13 (17.6)	8 (10.8)	5 (6.8)
Diarrhoea	6 (8.1)	5 (6.8)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	5 (6.8)	5 (6.8)	0
Nausea	4 (5.4)	2 (2.7)	2 (2.7)
Constipation	3 (4.1)	1 (1.4)	2 (2.7)
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	19 (25.7)	13 (17.6)	6 (8.1)
Pyrexia	13 (17.6)	7 (9.5)	6 (8.1)
Fatigue	6 (8.1)	6 (8.1)	0
Immune system disorders			
-Total	9 (12.2)	0	9 (12.2)
Hypogammaglobulinaemia	9 (12.2)	0	9 (12.2)
Infections and infestations			
-Total	11 (14.9)	2 (2.7)	9 (12.2)
Upper respiratory tract infection	7 (9.5)	3 (4.1)	4 (5.4)
Rhinovirus infection	4 (5.4)	0	4 (5.4)
Conjunctivitis	1 (1.4)	0	1 (1.4)
Investigations			
-Total	13 (17.6)	7 (9.5)	6 (8.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	8 (10.8)	4 (5.4)	4 (5.4)
Neutrophil count decreased	6 (8.1)	2 (2.7)	4 (5.4)
Platelet count decreased	3 (4.1)	2 (2.7)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	2 (2.7)	0
Blood immunoglobulin a decreased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	9 (12.2)	4 (5.4)	5 (6.8)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)
Hyperuricaemia	3 (4.1)	3 (4.1)	0
Hypokalaemia	2 (2.7)	0	2 (2.7)
Hypophosphataemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (9.5)	4 (5.4)	3 (4.1)
Pain in extremity	4 (5.4)	2 (2.7)	2 (2.7)
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)
Myalgia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	10 (13.5)	6 (8.1)	4 (5.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	10 (13.5)	6 (8.1)	4 (5.4)
Psychiatric disorders			
-Total	6 (8.1)	1 (1.4)	5 (6.8)
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (17.6)	9 (12.2)	4 (5.4)
Cough	10 (13.5)	7 (9.5)	3 (4.1)
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)
Rhinorrhoea	2 (2.7)	2 (2.7)	0
Skin and subcutaneous tissue disorders			
-Total	9 (12.2)	7 (9.5)	2 (2.7)
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)
Rash	4 (5.4)	3 (4.1)	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	1 (1.4)	1 (1.4)	0

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Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (44.0)	6 (12.0)	16 (32.0)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)
Gastrointestinal disorders			
-Total	5 (10.0)	4 (8.0)	1 (2.0)
Diarrhoea	4 (8.0)	3 (6.0)	1 (2.0)
Constipation	1 (2.0)	1 (2.0)	0
Nausea	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (10.0)	2 (4.0)	3 (6.0)
Pyrexia	4 (8.0)	2 (4.0)	2 (4.0)
Fatigue	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	3 (6.0)	0	3 (6.0)
Hypogammaglobulinaemia	3 (6.0)	0	3 (6.0)
Infections and infestations			
-Total	11 (22.0)	4 (8.0)	7 (14.0)
Upper respiratory tract infection	5 (10.0)	2 (4.0)	3 (6.0)
Conjunctivitis	4 (8.0)	2 (4.0)	2 (4.0)
Rhinovirus infection	3 (6.0)	0	3 (6.0)
Investigations			
-Total	4 (8.0)	3 (6.0)	1 (2.0)
Neutrophil count decreased	3 (6.0)	2 (4.0)	1 (2.0)
Platelet count decreased	2 (4.0)	2 (4.0)	0
Musculoskeletal and connective tissue disorders			

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (6.0)	0	3 (6.0)
Pain in extremity	2 (4.0)	0	2 (4.0)
Arthralgia	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	2 (4.0)	0	2 (4.0)
Headache	2 (4.0)	0	2 (4.0)
Psychiatric disorders			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Anxiety	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (10.0)	3 (6.0)	2 (4.0)
Cough	4 (8.0)	3 (6.0)	1 (2.0)
Rhinorrhoea	3 (6.0)	1 (2.0)	2 (4.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Rash	2 (4.0)	1 (2.0)	1 (2.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	1 (2.0)	0	1 (2.0)
Hypertension	1 (2.0)	0	1 (2.0)

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Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Abdominal pain	1 (100)	1 (100)	0
Anal haemorrhage	1 (100)	1 (100)	0
Diarrhoea	1 (100)	1 (100)	0
Nausea	1 (100)	1 (100)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Proctalgia	1 (100)	1 (100)	0
Vomiting	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypogammaglobulinaemia	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	1 (100)	0
Blood fibrinogen decreased	1 (100)	1 (100)	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0
Blood uric acid increased	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Metabolism and nutrition disorders			
-Total	1 (100)	1 (100)	0
Decreased appetite	1 (100)	1 (100)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (100)	1 (100)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	1 (100)	1 (100)	0
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Irritability	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Rhinorrhoea	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			
-Total	1 (100)	1 (100)	0
Dry skin	1 (100)	1 (100)	0
Rash papular	1 (100)	1 (100)	0
Rash pruritic	1 (100)	1 (100)	0

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Table 257g
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	78 (98.7)	5 (6.3)	73 (92.4)
Blood and lymphatic system disorders			
-Total	18 (22.8)	6 (7.6)	12 (15.2)
Anaemia	18 (22.8)	6 (7.6)	12 (15.2)
Cardiac disorders			
-Total	16 (20.3)	8 (10.1)	8 (10.1)
Tachycardia	16 (20.3)	8 (10.1)	8 (10.1)
Gastrointestinal disorders			
-Total	53 (67.1)	27 (34.2)	26 (32.9)
Vomiting	24 (30.4)	16 (20.3)	8 (10.1)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	23 (29.1)	15 (19.0)	8 (10.1)
Nausea	19 (24.1)	11 (13.9)	8 (10.1)
Constipation	14 (17.7)	7 (8.9)	7 (8.9)
Abdominal pain	10 (12.7)	2 (2.5)	8 (10.1)
General disorders and administration site conditions			
-Total	38 (48.1)	22 (27.8)	16 (20.3)
Pyrexia	29 (36.7)	15 (19.0)	14 (17.7)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)
Immune system disorders			
-Total	62 (78.5)	11 (13.9)	51 (64.6)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	25 (31.6)	2 (2.5)	23 (29.1)
Infections and infestations			
-Total	25 (31.6)	6 (7.6)	19 (24.1)
Upper respiratory tract infection	12 (15.2)	5 (6.3)	7 (8.9)
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)
Rhinovirus infection	8 (10.1)	0	8 (10.1)
Investigations			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	36 (45.6)	6 (7.6)	30 (38.0)
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)
Platelet count decreased	14 (17.7)	7 (8.9)	7 (8.9)
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
Neutrophil count decreased	11 (13.9)	3 (3.8)	8 (10.1)
White blood cell count decreased	11 (13.9)	3 (3.8)	8 (10.1)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
Blood immunoglobulin a decreased	5 (6.3)	4 (5.1)	1 (1.3)
Blood fibrinogen decreased	4 (5.1)	1 (1.3)	3 (3.8)
Blood immunoglobulin m decreased	4 (5.1)	3 (3.8)	1 (1.3)
Blood uric acid increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	38 (48.1)	13 (16.5)	25 (31.6)
Decreased appetite	17 (21.5)	10 (12.7)	7 (8.9)
Hypokalaemia	13 (16.5)	3 (3.8)	10 (12.7)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	10 (12.7)	4 (5.1)	6 (7.6)
Hyperuricaemia	9 (11.4)	8 (10.1)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	28 (35.4)	15 (19.0)	13 (16.5)
Pain in extremity	15 (19.0)	7 (8.9)	8 (10.1)
Arthralgia	11 (13.9)	5 (6.3)	6 (7.6)
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)
Nervous system disorders			
-Total	26 (32.9)	13 (16.5)	13 (16.5)
Headache	26 (32.9)	13 (16.5)	13 (16.5)
Psychiatric disorders			
-Total	14 (17.7)	5 (6.3)	9 (11.4)
Anxiety	12 (15.2)	3 (3.8)	9 (11.4)
Irritability	2 (2.5)	2 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	31 (39.2)	24 (30.4)	7 (8.9)
Cough	22 (27.8)	17 (21.5)	5 (6.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)
Rhinorrhoea	5 (6.3)	3 (3.8)	2 (2.5)
Skin and subcutaneous tissue disorders			
-Total	15 (19.0)	9 (11.4)	6 (7.6)
Rash	8 (10.1)	4 (5.1)	4 (5.1)
Dry skin	7 (8.9)	5 (6.3)	2 (2.5)
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)
Vascular disorders			
-Total	20 (25.3)	8 (10.1)	12 (15.2)
Hypertension	12 (15.2)	5 (6.3)	7 (8.9)
Hypotension	10 (12.7)	3 (3.8)	7 (8.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Constipation	1 (100)	0	1 (100)
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypogammaglobulinaemia	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Lymphocyte count decreased	1 (100)	0	1 (100)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (100)	1 (100)	0
Dermatitis atopic	1 (100)	1 (100)	0
Rash vesicular	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	76 (96.2)	9 (11.4)	67 (84.8)
Blood and lymphatic system disorders			
-Total	16 (20.3)	5 (6.3)	11 (13.9)
Anaemia	16 (20.3)	5 (6.3)	11 (13.9)
Cardiac disorders			
-Total	15 (19.0)	7 (8.9)	8 (10.1)
Tachycardia	15 (19.0)	7 (8.9)	8 (10.1)
Gastrointestinal disorders			
-Total	44 (55.7)	24 (30.4)	20 (25.3)
Vomiting	20 (25.3)	12 (15.2)	8 (10.1)
Nausea	16 (20.3)	10 (12.7)	6 (7.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	14 (17.7)	8 (10.1)	6 (7.6)
Abdominal pain	10 (12.7)	3 (3.8)	7 (8.9)
Constipation	10 (12.7)	6 (7.6)	4 (5.1)
General disorders and administration site conditions			
-Total	26 (32.9)	17 (21.5)	9 (11.4)
Pyrexia	19 (24.1)	11 (13.9)	8 (10.1)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)
Immune system disorders			
-Total	59 (74.7)	12 (15.2)	47 (59.5)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	15 (19.0)	2 (2.5)	13 (16.5)
Infections and infestations			
-Total	7 (8.9)	1 (1.3)	6 (7.6)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)
Rhinovirus infection	2 (2.5)	0	2 (2.5)
Investigations			
-Total	33 (41.8)	7 (8.9)	26 (32.9)
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
Platelet count decreased	13 (16.5)	6 (7.6)	7 (8.9)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
White blood cell count decreased	8 (10.1)	3 (3.8)	5 (6.3)
Neutrophil count decreased	6 (7.6)	0	6 (7.6)
Lymphocyte count decreased	3 (3.8)	2 (2.5)	1 (1.3)
Metabolism and nutrition disorders			
-Total	33 (41.8)	12 (15.2)	21 (26.6)
Decreased appetite	13 (16.5)	9 (11.4)	4 (5.1)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)
Hypokalaemia	12 (15.2)	3 (3.8)	9 (11.4)
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)
Hypophosphataemia	9 (11.4)	4 (5.1)	5 (6.3)
Hyperuricaemia	7 (8.9)	6 (7.6)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	23 (29.1)	13 (16.5)	10 (12.7)
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	9 (11.4)	4 (5.1)	5 (6.3)
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)
Nervous system disorders			
-Total	21 (26.6)	12 (15.2)	9 (11.4)
Headache	21 (26.6)	12 (15.2)	9 (11.4)
Psychiatric disorders			
-Total	4 (5.1)	1 (1.3)	3 (3.8)
Anxiety	4 (5.1)	1 (1.3)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (21.5)	15 (19.0)	2 (2.5)
Cough	10 (12.7)	9 (11.4)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	7 (8.9)	4 (5.1)	3 (3.8)
Rash	5 (6.3)	2 (2.5)	3 (3.8)
Dermatitis atopic	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	17 (21.5)	7 (8.9)	10 (12.7)
Hypertension	10 (12.7)	5 (6.3)	5 (6.3)
Hypotension	9 (11.4)	2 (2.5)	7 (8.9)

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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Cystitis	1 (100)	0	1 (100)
Nasopharyngitis	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			
-Total	1 (100)	1 (100)	0
Dermatitis atopic	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	54 (73.0)	13 (17.6)	41 (55.4)
Blood and lymphatic system disorders			
-Total	6 (8.1)	5 (6.8)	1 (1.4)
Anaemia	5 (6.8)	4 (5.4)	1 (1.4)
Lymphadenopathy	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.7)	2 (2.7)	0
Tachycardia	2 (2.7)	2 (2.7)	0
Gastrointestinal disorders			
-Total	14 (18.9)	9 (12.2)	5 (6.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)
Vomiting	6 (8.1)	6 (8.1)	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)
Constipation	3 (4.1)	1 (1.4)	2 (2.7)
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	19 (25.7)	13 (17.6)	6 (8.1)
Pyrexia	13 (17.6)	7 (9.5)	6 (8.1)
Fatigue	6 (8.1)	6 (8.1)	0
Immune system disorders			
-Total	10 (13.5)	0	10 (13.5)
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)
Infections and infestations			
-Total	17 (23.0)	6 (8.1)	11 (14.9)
Upper respiratory tract infection	7 (9.5)	3 (4.1)	4 (5.4)
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)
Rhinovirus infection	4 (5.4)	0	4 (5.4)
Gastroenteritis	3 (4.1)	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (1.4)	0	1 (1.4)
Investigations			
-Total	13 (17.6)	6 (8.1)	7 (9.5)
White blood cell count decreased	8 (10.8)	4 (5.4)	4 (5.4)
Neutrophil count decreased	6 (8.1)	2 (2.7)	4 (5.4)
Lymphocyte count decreased	3 (4.1)	1 (1.4)	2 (2.7)
Platelet count decreased	3 (4.1)	2 (2.7)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	2 (2.7)	0
Metabolism and nutrition disorders			
-Total	9 (12.2)	4 (5.4)	5 (6.8)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)
Hyperuricaemia	3 (4.1)	3 (4.1)	0
Hypokalaemia	2 (2.7)	0	2 (2.7)
Hypophosphataemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (9.5)	4 (5.4)	3 (4.1)
Pain in extremity	4 (5.4)	2 (2.7)	2 (2.7)
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	10 (13.5)	6 (8.1)	4 (5.4)
Headache	10 (13.5)	6 (8.1)	4 (5.4)
Psychiatric disorders			
-Total	6 (8.1)	1 (1.4)	5 (6.8)
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (16.2)	8 (10.8)	4 (5.4)
Cough	10 (13.5)	7 (9.5)	3 (4.1)
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	9 (12.2)	7 (9.5)	2 (2.7)
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)
Rash	4 (5.4)	3 (4.1)	1 (1.4)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	1 (1.4)	0

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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	0	1 (100)
Lymphadenopathy	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Bronchitis	1 (100)	0	1 (100)
Gastroenteritis	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	1 (100)	1 (100)	0

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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (42.9)	5 (10.2)	16 (32.7)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)
Gastrointestinal disorders			
-Total	5 (10.2)	4 (8.2)	1 (2.0)
Diarrhoea	4 (8.2)	3 (6.1)	1 (2.0)
Constipation	1 (2.0)	1 (2.0)	0
Nausea	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (10.2)	2 (4.1)	3 (6.1)
Pyrexia	4 (8.2)	2 (4.1)	2 (4.1)
Fatigue	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	3 (6.1)	0	3 (6.1)
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)
Infections and infestations			
-Total	11 (22.4)	4 (8.2)	7 (14.3)
Upper respiratory tract infection	5 (10.2)	2 (4.1)	3 (6.1)
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)
Rhinovirus infection	3 (6.1)	0	3 (6.1)
Bronchitis	1 (2.0)	0	1 (2.0)
Investigations			
-Total	3 (6.1)	2 (4.1)	1 (2.0)
Neutrophil count decreased	3 (6.1)	2 (4.1)	1 (2.0)
Platelet count decreased	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (6.1)	0	3 (6.1)
Pain in extremity	2 (4.1)	0	2 (4.1)
Arthralgia	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	2 (4.1)	0	2 (4.1)
Headache	2 (4.1)	0	2 (4.1)
Psychiatric disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (8.2)	3 (6.1)	1 (2.0)
Cough	4 (8.2)	3 (6.1)	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.1)	2 (4.1)	1 (2.0)
Rash	2 (4.1)	1 (2.0)	1 (2.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	1 (2.0)	0	1 (2.0)
Hypertension	1 (2.0)	0	1 (2.0)

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Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	0	1 (100)
Lymphadenopathy	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Constipation	1 (100)	0	1 (100)
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypogammaglobulinaemia	1 (100)	0	1 (100)

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (100)	0	1 (100)
Bronchitis	1 (100)	0	1 (100)
Cystitis	1 (100)	0	1 (100)
Gastroenteritis	1 (100)	1 (100)	0
Nasopharyngitis	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	0	1 (100)
Lymphocyte count decreased	1 (100)	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			
-Total	1 (100)	1 (100)	0
Dermatitis atopic	1 (100)	1 (100)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash vesicular	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257h
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	78 (98.7)	5 (6.3)	73 (92.4)
Blood and lymphatic system disorders			
-Total	19 (24.1)	7 (8.9)	12 (15.2)
Anaemia	19 (24.1)	7 (8.9)	12 (15.2)
Lymphadenopathy	1 (1.3)	1 (1.3)	0
Cardiac disorders			
-Total	16 (20.3)	8 (10.1)	8 (10.1)
Tachycardia	16 (20.3)	8 (10.1)	8 (10.1)
Gastrointestinal disorders			
-Total	53 (67.1)	28 (35.4)	25 (31.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	25 (31.6)	17 (21.5)	8 (10.1)
Diarrhoea	24 (30.4)	16 (20.3)	8 (10.1)
Nausea	20 (25.3)	12 (15.2)	8 (10.1)
Constipation	13 (16.5)	7 (8.9)	6 (7.6)
Abdominal pain	11 (13.9)	3 (3.8)	8 (10.1)
General disorders and administration site conditions			
-Total	38 (48.1)	22 (27.8)	16 (20.3)
Pyrexia	29 (36.7)	15 (19.0)	14 (17.7)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)
Immune system disorders			
-Total	62 (78.5)	11 (13.9)	51 (64.6)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	25 (31.6)	2 (2.5)	23 (29.1)
Infections and infestations			
-Total	28 (35.4)	8 (10.1)	20 (25.3)
Upper respiratory tract infection	12 (15.2)	5 (6.3)	7 (8.9)
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)
Rhinovirus infection	8 (10.1)	0	8 (10.1)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	6 (7.6)	3 (3.8)	3 (3.8)
Gastroenteritis	3 (3.8)	3 (3.8)	0
Bronchitis	1 (1.3)	0	1 (1.3)
Investigations			
-Total	35 (44.3)	7 (8.9)	28 (35.4)
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)
Platelet count decreased	14 (17.7)	7 (8.9)	7 (8.9)
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
Neutrophil count decreased	11 (13.9)	3 (3.8)	8 (10.1)
White blood cell count decreased	11 (13.9)	3 (3.8)	8 (10.1)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
Lymphocyte count decreased	5 (6.3)	2 (2.5)	3 (3.8)
Metabolism and nutrition disorders			
-Total	39 (49.4)	14 (17.7)	25 (31.6)
Decreased appetite	18 (22.8)	11 (13.9)	7 (8.9)
Hypokalaemia	13 (16.5)	3 (3.8)	10 (12.7)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)
Hypophosphataemia	10 (12.7)	4 (5.1)	6 (7.6)
Hyperuricaemia	9 (11.4)	8 (10.1)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	29 (36.7)	16 (20.3)	13 (16.5)
Pain in extremity	16 (20.3)	8 (10.1)	8 (10.1)
Arthralgia	11 (13.9)	5 (6.3)	6 (7.6)
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)
Nervous system disorders			
-Total	26 (32.9)	13 (16.5)	13 (16.5)
Headache	26 (32.9)	13 (16.5)	13 (16.5)
Psychiatric disorders			
-Total	12 (15.2)	3 (3.8)	9 (11.4)
Anxiety	12 (15.2)	3 (3.8)	9 (11.4)
Respiratory, thoracic and mediastinal disorders			
-Total	30 (38.0)	23 (29.1)	7 (8.9)
Cough	22 (27.8)	17 (21.5)	5 (6.3)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	16 (20.3)	11 (13.9)	5 (6.3)
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)
Rash	8 (10.1)	4 (5.1)	4 (5.1)
Dermatitis atopic	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	20 (25.3)	8 (10.1)	12 (15.2)
Hypertension	12 (15.2)	5 (6.3)	7 (8.9)
Hypotension	10 (12.7)	3 (3.8)	7 (8.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Staphylococcal infection	1 (100)	0	1 (100)

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All patients column.
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Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	76 (96.2)	8 (10.1)	68 (86.1)
Blood and lymphatic system disorders			
-Total	16 (20.3)	5 (6.3)	11 (13.9)
Anaemia	16 (20.3)	5 (6.3)	11 (13.9)
Cardiac disorders			
-Total	15 (19.0)	7 (8.9)	8 (10.1)
Tachycardia	15 (19.0)	7 (8.9)	8 (10.1)
Gastrointestinal disorders			
-Total	45 (57.0)	24 (30.4)	21 (26.6)
Vomiting	20 (25.3)	12 (15.2)	8 (10.1)
Nausea	16 (20.3)	10 (12.7)	6 (7.6)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	14 (17.7)	8 (10.1)	6 (7.6)
Constipation	11 (13.9)	6 (7.6)	5 (6.3)
Abdominal pain	10 (12.7)	3 (3.8)	7 (8.9)
General disorders and administration site conditions			
-Total	25 (31.6)	16 (20.3)	9 (11.4)
Pyrexia	18 (22.8)	10 (12.7)	8 (10.1)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)
Immune system disorders			
-Total	60 (75.9)	12 (15.2)	48 (60.8)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	16 (20.3)	2 (2.5)	14 (17.7)
Infections and infestations			
-Total	9 (11.4)	1 (1.3)	8 (10.1)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)
Rhinovirus infection	2 (2.5)	0	2 (2.5)
Staphylococcal infection	2 (2.5)	0	2 (2.5)
Investigations			
-Total	32 (40.5)	6 (7.6)	26 (32.9)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
Platelet count decreased	13 (16.5)	6 (7.6)	7 (8.9)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
White blood cell count decreased	8 (10.1)	3 (3.8)	5 (6.3)
Neutrophil count decreased	6 (7.6)	0	6 (7.6)
Metabolism and nutrition disorders			
-Total	33 (41.8)	12 (15.2)	21 (26.6)
Decreased appetite	13 (16.5)	9 (11.4)	4 (5.1)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)
Hypokalaemia	12 (15.2)	3 (3.8)	9 (11.4)
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)
Hypophosphataemia	9 (11.4)	4 (5.1)	5 (6.3)
Hyperuricaemia	7 (8.9)	6 (7.6)	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	23 (29.1)	13 (16.5)	10 (12.7)
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	9 (11.4)	4 (5.1)	5 (6.3)
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)
Nervous system disorders			
-Total	21 (26.6)	12 (15.2)	9 (11.4)
Headache	21 (26.6)	12 (15.2)	9 (11.4)
Psychiatric disorders			
-Total	4 (5.1)	1 (1.3)	3 (3.8)
Anxiety	4 (5.1)	1 (1.3)	3 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (21.5)	15 (19.0)	2 (2.5)
Cough	10 (12.7)	9 (11.4)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	6 (7.6)	3 (3.8)	3 (3.8)
Rash	5 (6.3)	2 (2.5)	3 (3.8)
Dry skin	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	17 (21.5)	7 (8.9)	10 (12.7)
Hypertension	10 (12.7)	5 (6.3)	5 (6.3)
Hypotension	9 (11.4)	2 (2.5)	7 (8.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Skin and subcutaneous tissue disorders			
-Total	1 (100)	0	1 (100)
Photosensitivity reaction	1 (100)	0	1 (100)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	54 (73.0)	16 (21.6)	38 (51.4)
Blood and lymphatic system disorders			
-Total	5 (6.8)	4 (5.4)	1 (1.4)
Anaemia	5 (6.8)	4 (5.4)	1 (1.4)
Cardiac disorders			
-Total	2 (2.7)	2 (2.7)	0
Tachycardia	2 (2.7)	2 (2.7)	0
Gastrointestinal disorders			
-Total	14 (18.9)	9 (12.2)	5 (6.8)
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	6 (8.1)	6 (8.1)	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)
Constipation	3 (4.1)	1 (1.4)	2 (2.7)
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	19 (25.7)	13 (17.6)	6 (8.1)
Pyrexia	13 (17.6)	7 (9.5)	6 (8.1)
Fatigue	6 (8.1)	6 (8.1)	0
Immune system disorders			
-Total	10 (13.5)	0	10 (13.5)
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)
Infections and infestations			
-Total	11 (14.9)	2 (2.7)	9 (12.2)
Upper respiratory tract infection	7 (9.5)	3 (4.1)	4 (5.4)
Rhinovirus infection	4 (5.4)	0	4 (5.4)
Conjunctivitis	1 (1.4)	0	1 (1.4)
Investigations			
-Total	13 (17.6)	7 (9.5)	6 (8.1)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	9 (12.2)	5 (6.8)	4 (5.4)
Neutrophil count decreased	6 (8.1)	2 (2.7)	4 (5.4)
Platelet count decreased	4 (5.4)	3 (4.1)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	2 (2.7)	0
Metabolism and nutrition disorders			
-Total	9 (12.2)	4 (5.4)	5 (6.8)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)
Hyperuricaemia	3 (4.1)	3 (4.1)	0
Hypokalaemia	2 (2.7)	0	2 (2.7)
Hypophosphataemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (9.5)	4 (5.4)	3 (4.1)
Pain in extremity	4 (5.4)	2 (2.7)	2 (2.7)
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)
Myalgia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	10 (13.5)	6 (8.1)	4 (5.4)
Headache	10 (13.5)	6 (8.1)	4 (5.4)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	6 (8.1)	1 (1.4)	5 (6.8)
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (17.6)	9 (12.2)	4 (5.4)
Cough	11 (14.9)	8 (10.8)	3 (4.1)
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	9 (12.2)	7 (9.5)	2 (2.7)
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)
Rash	4 (5.4)	3 (4.1)	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	1 (1.4)	0

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Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (44.9)	6 (12.2)	16 (32.7)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)
Gastrointestinal disorders			
-Total	5 (10.2)	4 (8.2)	1 (2.0)
Diarrhoea	4 (8.2)	3 (6.1)	1 (2.0)
Constipation	1 (2.0)	1 (2.0)	0
Nausea	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (10.2)	2 (4.1)	3 (6.1)
Pyrexia	4 (8.2)	2 (4.1)	2 (4.1)
Fatigue	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	3 (6.1)	0	3 (6.1)
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)
Infections and infestations			
-Total	11 (22.4)	4 (8.2)	7 (14.3)
Upper respiratory tract infection	5 (10.2)	2 (4.1)	3 (6.1)
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)
Rhinovirus infection	3 (6.1)	0	3 (6.1)
Investigations			
-Total	4 (8.2)	3 (6.1)	1 (2.0)
Neutrophil count decreased	3 (6.1)	2 (4.1)	1 (2.0)
Platelet count decreased	2 (4.1)	2 (4.1)	0
Musculoskeletal and connective tissue disorders			

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (6.1)	0	3 (6.1)
Pain in extremity	2 (4.1)	0	2 (4.1)
Arthralgia	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	2 (4.1)	0	2 (4.1)
Headache	2 (4.1)	0	2 (4.1)
Psychiatric disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (8.2)	3 (6.1)	1 (2.0)
Cough	4 (8.2)	3 (6.1)	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (6.1)	2 (4.1)	1 (2.0)
Rash	2 (4.1)	1 (2.0)	1 (2.0)
Dry skin	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	1 (2.0)	0	1 (2.0)
Hypertension	1 (2.0)	0	1 (2.0)

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Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Staphylococcal infection	1 (100)	0	1 (100)
Skin and subcutaneous tissue disorders			
-Total	1 (100)	0	1 (100)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Photosensitivity reaction	1 (100)	0	1 (100)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257i
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	78 (98.7)	4 (5.1)	74 (93.7)
Blood and lymphatic system disorders			
-Total	19 (24.1)	7 (8.9)	12 (15.2)
Anaemia	19 (24.1)	7 (8.9)	12 (15.2)
Cardiac disorders			
-Total	16 (20.3)	8 (10.1)	8 (10.1)
Tachycardia	16 (20.3)	8 (10.1)	8 (10.1)
Gastrointestinal disorders			
-Total	54 (68.4)	28 (35.4)	26 (32.9)
Vomiting	25 (31.6)	17 (21.5)	8 (10.1)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	24 (30.4)	16 (20.3)	8 (10.1)
Nausea	20 (25.3)	12 (15.2)	8 (10.1)
Constipation	14 (17.7)	7 (8.9)	7 (8.9)
Abdominal pain	11 (13.9)	3 (3.8)	8 (10.1)
General disorders and administration site conditions			
-Total	37 (46.8)	21 (26.6)	16 (20.3)
Pyrexia	28 (35.4)	14 (17.7)	14 (17.7)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)
Immune system disorders			
-Total	63 (79.7)	11 (13.9)	52 (65.8)
Cytokine release syndrome	57 (72.2)	13 (16.5)	44 (55.7)
Hypogammaglobulinaemia	26 (32.9)	2 (2.5)	24 (30.4)
Infections and infestations			
-Total	26 (32.9)	6 (7.6)	20 (25.3)
Upper respiratory tract infection	12 (15.2)	5 (6.3)	7 (8.9)
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)
Rhinovirus infection	8 (10.1)	0	8 (10.1)
Staphylococcal infection	2 (2.5)	0	2 (2.5)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	35 (44.3)	7 (8.9)	28 (35.4)
Alanine aminotransferase increased	16 (20.3)	4 (5.1)	12 (15.2)
Platelet count decreased	15 (19.0)	8 (10.1)	7 (8.9)
Aspartate aminotransferase increased	13 (16.5)	3 (3.8)	10 (12.7)
White blood cell count decreased	12 (15.2)	4 (5.1)	8 (10.1)
Neutrophil count decreased	11 (13.9)	3 (3.8)	8 (10.1)
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)
Metabolism and nutrition disorders			
-Total	39 (49.4)	14 (17.7)	25 (31.6)
Decreased appetite	18 (22.8)	11 (13.9)	7 (8.9)
Hypokalaemia	13 (16.5)	3 (3.8)	10 (12.7)
Hypocalcaemia	12 (15.2)	2 (2.5)	10 (12.7)
Hypoalbuminaemia	10 (12.7)	0	10 (12.7)
Hypophosphataemia	10 (12.7)	4 (5.1)	6 (7.6)
Hyperuricaemia	9 (11.4)	8 (10.1)	1 (1.3)
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	29 (36.7)	16 (20.3)	13 (16.5)
Pain in extremity	16 (20.3)	8 (10.1)	8 (10.1)
Arthralgia	11 (13.9)	5 (6.3)	6 (7.6)
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)
Nervous system disorders			
-Total	26 (32.9)	13 (16.5)	13 (16.5)
Headache	26 (32.9)	13 (16.5)	13 (16.5)
Psychiatric disorders			
-Total	12 (15.2)	3 (3.8)	9 (11.4)
Anxiety	12 (15.2)	3 (3.8)	9 (11.4)
Respiratory, thoracic and mediastinal disorders			
-Total	31 (39.2)	24 (30.4)	7 (8.9)
Cough	23 (29.1)	18 (22.8)	5 (6.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	15 (19.0)	10 (12.7)	5 (6.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)
Rash	8 (10.1)	4 (5.1)	4 (5.1)
Vascular disorders			
-Total	20 (25.3)	8 (10.1)	12 (15.2)
Hypertension	12 (15.2)	5 (6.3)	7 (8.9)
Hypotension	10 (12.7)	3 (3.8)	7 (8.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	25 (92.6)	3 (11.1)	22 (81.5)
Blood and lymphatic system disorders			
-Total	7 (25.9)	2 (7.4)	5 (18.5)
Anaemia	4 (14.8)	2 (7.4)	2 (7.4)
Disseminated intravascular coagulation	3 (11.1)	0	3 (11.1)
Cardiac disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Tachycardia	2 (7.4)	1 (3.7)	1 (3.7)
Eye disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eyelid oedema	2 (7.4)	1 (3.7)	1 (3.7)
Gastrointestinal disorders			
-Total	18 (66.7)	12 (44.4)	6 (22.2)
Vomiting	7 (25.9)	6 (22.2)	1 (3.7)
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)
Diarrhoea	5 (18.5)	3 (11.1)	2 (7.4)
Nausea	4 (14.8)	3 (11.1)	1 (3.7)
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)
Constipation	2 (7.4)	2 (7.4)	0
General disorders and administration site conditions			
-Total	9 (33.3)	7 (25.9)	2 (7.4)
Pyrexia	5 (18.5)	4 (14.8)	1 (3.7)
Fatigue	4 (14.8)	3 (11.1)	1 (3.7)
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)
Oedema peripheral	2 (7.4)	2 (7.4)	0
Hepatobiliary disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Hepatic function abnormal	3 (11.1)	1 (3.7)	2 (7.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	17 (63.0)	4 (14.8)	13 (48.1)
Cytokine release syndrome	17 (63.0)	4 (14.8)	13 (48.1)
Hypogammaglobulinaemia	4 (14.8)	1 (3.7)	3 (11.1)
Infections and infestations			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Conjunctivitis	2 (7.4)	0	2 (7.4)
Nail infection	1 (3.7)	1 (3.7)	0
Investigations			
-Total	13 (48.1)	2 (7.4)	11 (40.7)
Alanine aminotransferase increased	5 (18.5)	1 (3.7)	4 (14.8)
Aspartate aminotransferase increased	5 (18.5)	0	5 (18.5)
Blood fibrinogen decreased	4 (14.8)	1 (3.7)	3 (11.1)
Serum ferritin increased	4 (14.8)	0	4 (14.8)
Lymphocyte count decreased	3 (11.1)	2 (7.4)	1 (3.7)
Neutrophil count decreased	3 (11.1)	0	3 (11.1)
Platelet count decreased	3 (11.1)	1 (3.7)	2 (7.4)
Blood bilirubin increased	2 (7.4)	1 (3.7)	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)
White blood cell count decreased	1 (3.7)	0	1 (3.7)
Metabolism and nutrition disorders			
-Total	12 (44.4)	6 (22.2)	6 (22.2)
Hypokalaemia	5 (18.5)	1 (3.7)	4 (14.8)
Decreased appetite	4 (14.8)	4 (14.8)	0
Hypophosphataemia	4 (14.8)	2 (7.4)	2 (7.4)
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)
Hypocalcaemia	3 (11.1)	1 (3.7)	2 (7.4)
Hyperuricaemia	1 (3.7)	0	1 (3.7)
Musculoskeletal and connective tissue disorders			
-Total	10 (37.0)	5 (18.5)	5 (18.5)
Pain in extremity	5 (18.5)	2 (7.4)	3 (11.1)
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)
Back pain	1 (3.7)	0	1 (3.7)
Nervous system disorders			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (29.6)	4 (14.8)	4 (14.8)
Headache	7 (25.9)	3 (11.1)	4 (14.8)
Tremor	3 (11.1)	2 (7.4)	1 (3.7)
Psychiatric disorders			
-Total	5 (18.5)	3 (11.1)	2 (7.4)
Delirium	3 (11.1)	2 (7.4)	1 (3.7)
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)
Anxiety	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (29.6)	7 (25.9)	1 (3.7)
Cough	3 (11.1)	3 (11.1)	0
Pleural effusion	3 (11.1)	3 (11.1)	0
Pulmonary oedema	3 (11.1)	2 (7.4)	1 (3.7)
Oropharyngeal pain	2 (7.4)	2 (7.4)	0
Epistaxis	1 (3.7)	0	1 (3.7)
Skin and subcutaneous tissue disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	2 (7.4)	0	2 (7.4)
Dry skin	1 (3.7)	1 (3.7)	0
Vascular disorders			
-Total	6 (22.2)	2 (7.4)	4 (14.8)
Hypertension	4 (14.8)	2 (7.4)	2 (7.4)
Hypotension	2 (7.4)	0	2 (7.4)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	52 (98.1)	5 (9.4)	47 (88.7)
Blood and lymphatic system disorders			
-Total	14 (26.4)	3 (5.7)	11 (20.8)
Anaemia	12 (22.6)	3 (5.7)	9 (17.0)
Disseminated intravascular coagulation	2 (3.8)	0	2 (3.8)
Cardiac disorders			
-Total	13 (24.5)	6 (11.3)	7 (13.2)
Tachycardia	13 (24.5)	6 (11.3)	7 (13.2)
Gastrointestinal disorders			
-Total	28 (52.8)	12 (22.6)	16 (30.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	13 (24.5)	6 (11.3)	7 (13.2)
Nausea	12 (22.6)	7 (13.2)	5 (9.4)
Constipation	9 (17.0)	4 (7.5)	5 (9.4)
Diarrhoea	9 (17.0)	5 (9.4)	4 (7.5)
Abdominal pain	5 (9.4)	2 (3.8)	3 (5.7)
General disorders and administration site conditions			
-Total	22 (41.5)	13 (24.5)	9 (17.0)
Pyrexia	14 (26.4)	7 (13.2)	7 (13.2)
Fatigue	7 (13.2)	6 (11.3)	1 (1.9)
Chills	6 (11.3)	4 (7.5)	2 (3.8)
Face oedema	4 (7.5)	3 (5.7)	1 (1.9)
Oedema peripheral	3 (5.7)	2 (3.8)	1 (1.9)
Hepatobiliary disorders			
-Total	2 (3.8)	0	2 (3.8)
Hepatic function abnormal	2 (3.8)	0	2 (3.8)
Immune system disorders			
-Total	43 (81.1)	8 (15.1)	35 (66.0)
Cytokine release syndrome	40 (75.5)	9 (17.0)	31 (58.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	12 (22.6)	1 (1.9)	11 (20.8)
Infections and infestations			
-Total	6 (11.3)	2 (3.8)	4 (7.5)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)
Rhinovirus infection	2 (3.8)	0	2 (3.8)
Nail infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	25 (47.2)	6 (11.3)	19 (35.8)
Alanine aminotransferase increased	11 (20.8)	3 (5.7)	8 (15.1)
Platelet count decreased	10 (18.9)	5 (9.4)	5 (9.4)
Aspartate aminotransferase increased	8 (15.1)	3 (5.7)	5 (9.4)
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)
White blood cell count decreased	7 (13.2)	3 (5.7)	4 (7.5)
Blood bilirubin increased	3 (5.7)	1 (1.9)	2 (3.8)
Neutrophil count decreased	3 (5.7)	0	3 (5.7)
Serum ferritin increased	2 (3.8)	1 (1.9)	1 (1.9)
Blood fibrinogen decreased	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Lymphocyte count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	21 (39.6)	6 (11.3)	15 (28.3)
Decreased appetite	9 (17.0)	5 (9.4)	4 (7.5)
Hypocalcaemia	9 (17.0)	1 (1.9)	8 (15.1)
Hypoalbuminaemia	7 (13.2)	0	7 (13.2)
Hypokalaemia	7 (13.2)	2 (3.8)	5 (9.4)
Hyperuricaemia	6 (11.3)	6 (11.3)	0
Hypophosphataemia	5 (9.4)	2 (3.8)	3 (5.7)
Musculoskeletal and connective tissue disorders			
-Total	16 (30.2)	8 (15.1)	8 (15.1)
Myalgia	7 (13.2)	5 (9.4)	2 (3.8)
Pain in extremity	6 (11.3)	4 (7.5)	2 (3.8)
Arthralgia	5 (9.4)	2 (3.8)	3 (5.7)
Back pain	4 (7.5)	2 (3.8)	2 (3.8)
Nervous system disorders			
-Total	16 (30.2)	11 (20.8)	5 (9.4)
Headache	14 (26.4)	9 (17.0)	5 (9.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tremor	3 (5.7)	3 (5.7)	0
Psychiatric disorders			
-Total	5 (9.4)	2 (3.8)	3 (5.7)
Anxiety	3 (5.7)	1 (1.9)	2 (3.8)
Delirium	1 (1.9)	0	1 (1.9)
Insomnia	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (32.1)	13 (24.5)	4 (7.5)
Cough	7 (13.2)	6 (11.3)	1 (1.9)
Nasal congestion	3 (5.7)	2 (3.8)	1 (1.9)
Oropharyngeal pain	3 (5.7)	3 (5.7)	0
Epistaxis	2 (3.8)	2 (3.8)	0
Pulmonary oedema	2 (3.8)	0	2 (3.8)
Pleural effusion	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Rash	3 (5.7)	2 (3.8)	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	11 (20.8)	5 (9.4)	6 (11.3)
Hypotension	7 (13.2)	2 (3.8)	5 (9.4)
Hypertension	6 (11.3)	3 (5.7)	3 (5.7)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (76.0)	3 (12.0)	16 (64.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	1 (4.0)	0
Anaemia	1 (4.0)	1 (4.0)	0
Cardiac disorders			
-Total	1 (4.0)	1 (4.0)	0
Tachycardia	1 (4.0)	1 (4.0)	0
Gastrointestinal disorders			
-Total	5 (20.0)	3 (12.0)	2 (8.0)
Constipation	2 (8.0)	1 (4.0)	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	2 (8.0)	2 (8.0)	0
Nausea	2 (8.0)	1 (4.0)	1 (4.0)
Vomiting	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	6 (24.0)	4 (16.0)	2 (8.0)
Pyrexia	4 (16.0)	2 (8.0)	2 (8.0)
Fatigue	1 (4.0)	1 (4.0)	0
Oedema peripheral	1 (4.0)	1 (4.0)	0
Immune system disorders			
-Total	3 (12.0)	0	3 (12.0)
Hypogammaglobulinaemia	3 (12.0)	0	3 (12.0)
Infections and infestations			
-Total	8 (32.0)	2 (8.0)	6 (24.0)
Nasopharyngitis	3 (12.0)	2 (8.0)	1 (4.0)
Sinusitis	3 (12.0)	0	3 (12.0)
Rhinovirus infection	2 (8.0)	0	2 (8.0)
Nail infection	1 (4.0)	1 (4.0)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (16.0)	2 (8.0)	2 (8.0)
Alanine aminotransferase increased	1 (4.0)	1 (4.0)	0
Blood bilirubin increased	1 (4.0)	0	1 (4.0)
Lymphocyte count decreased	1 (4.0)	0	1 (4.0)
Platelet count decreased	1 (4.0)	1 (4.0)	0
White blood cell count decreased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	3 (12.0)	1 (4.0)	2 (8.0)
Hyperuricaemia	2 (8.0)	2 (8.0)	0
Decreased appetite	1 (4.0)	0	1 (4.0)
Hypokalaemia	1 (4.0)	0	1 (4.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (4.0)	1 (4.0)	0
Pain in extremity	1 (4.0)	1 (4.0)	0
Nervous system disorders			
-Total	3 (12.0)	3 (12.0)	0
Headache	3 (12.0)	3 (12.0)	0
Psychiatric disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.0)	0	1 (4.0)
Anxiety	1 (4.0)	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (28.0)	4 (16.0)	3 (12.0)
Cough	4 (16.0)	3 (12.0)	1 (4.0)
Nasal congestion	2 (8.0)	1 (4.0)	1 (4.0)
Pleural effusion	2 (8.0)	1 (4.0)	1 (4.0)
Epistaxis	1 (4.0)	0	1 (4.0)
Oropharyngeal pain	1 (4.0)	0	1 (4.0)
Skin and subcutaneous tissue disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Dry skin	2 (8.0)	1 (4.0)	1 (4.0)
Rash	2 (8.0)	1 (4.0)	1 (4.0)
Vascular disorders			
-Total	1 (4.0)	0	1 (4.0)
Hypertension	1 (4.0)	0	1 (4.0)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (78.0)	10 (20.0)	29 (58.0)
Blood and lymphatic system disorders			
-Total	4 (8.0)	3 (6.0)	1 (2.0)
Anaemia	4 (8.0)	3 (6.0)	1 (2.0)
Cardiac disorders			
-Total	1 (2.0)	1 (2.0)	0
Tachycardia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	9 (18.0)	6 (12.0)	3 (6.0)
Diarrhoea	5 (10.0)	4 (8.0)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	5 (10.0)	5 (10.0)	0
Nausea	3 (6.0)	2 (4.0)	1 (2.0)
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)
Abdominal pain upper	1 (2.0)	1 (2.0)	0
Constipation	1 (2.0)	0	1 (2.0)
General disorders and administration site conditions			
-Total	14 (28.0)	10 (20.0)	4 (8.0)
Pyrexia	9 (18.0)	5 (10.0)	4 (8.0)
Fatigue	5 (10.0)	5 (10.0)	0
Chills	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	7 (14.0)	0	7 (14.0)
Hypogammaglobulinaemia	7 (14.0)	0	7 (14.0)
Infections and infestations			
-Total	12 (24.0)	4 (8.0)	8 (16.0)
Upper respiratory tract infection	7 (14.0)	3 (6.0)	4 (8.0)
Nasopharyngitis	4 (8.0)	2 (4.0)	2 (4.0)
Rhinovirus infection	2 (4.0)	0	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (2.0)	0	1 (2.0)
Investigations			
-Total	12 (24.0)	5 (10.0)	7 (14.0)
White blood cell count decreased	8 (16.0)	4 (8.0)	4 (8.0)
Neutrophil count decreased	6 (12.0)	2 (4.0)	4 (8.0)
Platelet count decreased	3 (6.0)	2 (4.0)	1 (2.0)
Lymphocyte count decreased	2 (4.0)	1 (2.0)	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
Blood bilirubin increased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	6 (12.0)	3 (6.0)	3 (6.0)
Decreased appetite	4 (8.0)	2 (4.0)	2 (4.0)
Hyperuricaemia	1 (2.0)	1 (2.0)	0
Hypokalaemia	1 (2.0)	0	1 (2.0)
Hypophosphataemia	1 (2.0)	0	1 (2.0)
Musculoskeletal and connective tissue disorders			
-Total	9 (18.0)	4 (8.0)	5 (10.0)
Back pain	4 (8.0)	2 (4.0)	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)
Pain in extremity	3 (6.0)	1 (2.0)	2 (4.0)
Myalgia	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	7 (14.0)	3 (6.0)	4 (8.0)
Headache	7 (14.0)	3 (6.0)	4 (8.0)
Psychiatric disorders			
-Total	5 (10.0)	1 (2.0)	4 (8.0)
Anxiety	5 (10.0)	1 (2.0)	4 (8.0)
Delirium	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (18.0)	6 (12.0)	3 (6.0)
Cough	7 (14.0)	5 (10.0)	2 (4.0)
Nasal congestion	4 (8.0)	4 (8.0)	0
Epistaxis	2 (4.0)	1 (2.0)	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0
Skin and subcutaneous tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (12.0)	5 (10.0)	1 (2.0)
Dry skin	4 (8.0)	3 (6.0)	1 (2.0)
Rash	2 (4.0)	2 (4.0)	0
Vascular disorders			
-Total	1 (2.0)	1 (2.0)	0
Hypotension	1 (2.0)	1 (2.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (43.8)	1 (6.3)	6 (37.5)
Blood and lymphatic system disorders			
-Total	1 (6.3)	0	1 (6.3)
Anaemia	1 (6.3)	0	1 (6.3)
Eye disorders			
-Total	1 (6.3)	1 (6.3)	0
Eyelid oedema	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	1 (6.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Immune system disorders			
-Total	1 (6.3)	0	1 (6.3)
Hypogammaglobulinaemia	1 (6.3)	0	1 (6.3)
Infections and infestations			
-Total	6 (37.5)	1 (6.3)	5 (31.3)
Conjunctivitis	3 (18.8)	1 (6.3)	2 (12.5)
Sinusitis	3 (18.8)	0	3 (18.8)
Upper respiratory tract infection	2 (12.5)	0	2 (12.5)
Nail infection	1 (6.3)	0	1 (6.3)
Rhinovirus infection	1 (6.3)	0	1 (6.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (6.3)	0	1 (6.3)
Pain in extremity	1 (6.3)	0	1 (6.3)
Nervous system disorders			

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (12.5)	0	2 (12.5)
Headache	2 (12.5)	0	2 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	2 (12.5)	0
Cough	1 (6.3)	1 (6.3)	0
Epistaxis	1 (6.3)	1 (6.3)	0
Oropharyngeal pain	1 (6.3)	1 (6.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (6.3)	0	1 (6.3)
Rash	1 (6.3)	0	1 (6.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (44.1)	4 (11.8)	11 (32.4)
Gastrointestinal disorders			
-Total	4 (11.8)	3 (8.8)	1 (2.9)
Diarrhoea	3 (8.8)	2 (5.9)	1 (2.9)
Constipation	1 (2.9)	1 (2.9)	0
Nausea	1 (2.9)	1 (2.9)	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Pyrexia	3 (8.8)	1 (2.9)	2 (5.9)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	2 (5.9)	0	2 (5.9)
Hypogammaglobulinaemia	2 (5.9)	0	2 (5.9)
Infections and infestations			
-Total	7 (20.6)	3 (8.8)	4 (11.8)
Sinusitis	3 (8.8)	0	3 (8.8)
Upper respiratory tract infection	3 (8.8)	2 (5.9)	1 (2.9)
Rhinovirus infection	2 (5.9)	0	2 (5.9)
Conjunctivitis	1 (2.9)	1 (2.9)	0
Investigations			
-Total	4 (11.8)	3 (8.8)	1 (2.9)
Neutrophil count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Platelet count decreased	2 (5.9)	2 (5.9)	0
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.9)	0	2 (5.9)
Arthralgia	1 (2.9)	0	1 (2.9)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	1 (2.9)	0	1 (2.9)
Psychiatric disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Anxiety	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Cough	3 (8.8)	2 (5.9)	1 (2.9)
Pleural effusion	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	2 (5.9)	2 (5.9)	0
Dry skin	1 (2.9)	1 (2.9)	0
Rash	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypertension	1 (2.9)	0	1 (2.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (96.3)	1 (3.7)	25 (92.6)
Blood and lymphatic system disorders			
-Total	9 (33.3)	3 (11.1)	6 (22.2)
Anaemia	6 (22.2)	3 (11.1)	3 (11.1)
Disseminated intravascular coagulation	3 (11.1)	0	3 (11.1)
Cardiac disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Tachycardia	3 (11.1)	2 (7.4)	1 (3.7)
Eye disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eyelid oedema	3 (11.1)	2 (7.4)	1 (3.7)
Gastrointestinal disorders			
-Total	21 (77.8)	13 (48.1)	8 (29.6)
Diarrhoea	8 (29.6)	6 (22.2)	2 (7.4)
Vomiting	8 (29.6)	7 (25.9)	1 (3.7)
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)
Nausea	5 (18.5)	3 (11.1)	2 (7.4)
Constipation	4 (14.8)	3 (11.1)	1 (3.7)
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)
General disorders and administration site conditions			
-Total	13 (48.1)	9 (33.3)	4 (14.8)
Pyrexia	9 (33.3)	6 (22.2)	3 (11.1)
Fatigue	5 (18.5)	4 (14.8)	1 (3.7)
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)
Oedema peripheral	3 (11.1)	3 (11.1)	0
Hepatobiliary disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Hepatic function abnormal	3 (11.1)	1 (3.7)	2 (7.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	19 (70.4)	4 (14.8)	15 (55.6)
Cytokine release syndrome	17 (63.0)	4 (14.8)	13 (48.1)
Hypogammaglobulinaemia	8 (29.6)	1 (3.7)	7 (25.9)
Infections and infestations			
-Total	11 (40.7)	2 (7.4)	9 (33.3)
Conjunctivitis	5 (18.5)	1 (3.7)	4 (14.8)
Nail infection	3 (11.1)	2 (7.4)	1 (3.7)
Nasopharyngitis	3 (11.1)	2 (7.4)	1 (3.7)
Rhinovirus infection	3 (11.1)	0	3 (11.1)
Sinusitis	3 (11.1)	0	3 (11.1)
Upper respiratory tract infection	2 (7.4)	0	2 (7.4)
Investigations			
-Total	13 (48.1)	2 (7.4)	11 (40.7)
Alanine aminotransferase increased	5 (18.5)	1 (3.7)	4 (14.8)
Aspartate aminotransferase increased	5 (18.5)	0	5 (18.5)
Blood fibrinogen decreased	4 (14.8)	1 (3.7)	3 (11.1)
Platelet count decreased	4 (14.8)	2 (7.4)	2 (7.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Serum ferritin increased	4 (14.8)	0	4 (14.8)
Blood bilirubin increased	3 (11.1)	1 (3.7)	2 (7.4)
Lymphocyte count decreased	3 (11.1)	1 (3.7)	2 (7.4)
Neutrophil count decreased	3 (11.1)	0	3 (11.1)
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)
White blood cell count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Metabolism and nutrition disorders			
-Total	14 (51.9)	6 (22.2)	8 (29.6)
Hypokalaemia	6 (22.2)	1 (3.7)	5 (18.5)
Decreased appetite	5 (18.5)	4 (14.8)	1 (3.7)
Hypophosphataemia	4 (14.8)	2 (7.4)	2 (7.4)
Hyperuricaemia	3 (11.1)	2 (7.4)	1 (3.7)
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)
Hypocalcaemia	3 (11.1)	1 (3.7)	2 (7.4)
Musculoskeletal and connective tissue disorders			
-Total	11 (40.7)	6 (22.2)	5 (18.5)
Pain in extremity	7 (25.9)	3 (11.1)	4 (14.8)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)
Back pain	1 (3.7)	0	1 (3.7)
Nervous system disorders			
-Total	9 (33.3)	4 (14.8)	5 (18.5)
Headache	8 (29.6)	3 (11.1)	5 (18.5)
Tremor	3 (11.1)	2 (7.4)	1 (3.7)
Psychiatric disorders			
-Total	6 (22.2)	3 (11.1)	3 (11.1)
Delirium	3 (11.1)	2 (7.4)	1 (3.7)
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)
Anxiety	2 (7.4)	0	2 (7.4)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (51.9)	11 (40.7)	3 (11.1)
Cough	7 (25.9)	6 (22.2)	1 (3.7)
Oropharyngeal pain	4 (14.8)	3 (11.1)	1 (3.7)
Pleural effusion	4 (14.8)	3 (11.1)	1 (3.7)
Epistaxis	3 (11.1)	1 (3.7)	2 (7.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pulmonary oedema	3 (11.1)	2 (7.4)	1 (3.7)
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)
Skin and subcutaneous tissue disorders			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Dry skin	3 (11.1)	2 (7.4)	1 (3.7)
Rash	3 (11.1)	0	3 (11.1)
Vascular disorders			
-Total	7 (25.9)	2 (7.4)	5 (18.5)
Hypertension	5 (18.5)	2 (7.4)	3 (11.1)
Hypotension	2 (7.4)	0	2 (7.4)

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Table 257j
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	53 (100)	2 (3.8)	51 (96.2)
Blood and lymphatic system disorders			
-Total	15 (28.3)	4 (7.5)	11 (20.8)
Anaemia	13 (24.5)	4 (7.5)	9 (17.0)
Disseminated intravascular coagulation	2 (3.8)	0	2 (3.8)
Cardiac disorders			
-Total	13 (24.5)	6 (11.3)	7 (13.2)
Tachycardia	13 (24.5)	6 (11.3)	7 (13.2)
Gastrointestinal disorders			
-Total	34 (64.2)	15 (28.3)	19 (35.8)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	17 (32.1)	10 (18.9)	7 (13.2)
Diarrhoea	16 (30.2)	10 (18.9)	6 (11.3)
Nausea	15 (28.3)	9 (17.0)	6 (11.3)
Constipation	10 (18.9)	4 (7.5)	6 (11.3)
Abdominal pain	6 (11.3)	2 (3.8)	4 (7.5)
Abdominal pain upper	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	30 (56.6)	16 (30.2)	14 (26.4)
Pyrexia	20 (37.7)	9 (17.0)	11 (20.8)
Fatigue	12 (22.6)	10 (18.9)	2 (3.8)
Chills	7 (13.2)	5 (9.4)	2 (3.8)
Face oedema	4 (7.5)	3 (5.7)	1 (1.9)
Oedema peripheral	3 (5.7)	2 (3.8)	1 (1.9)
Hepatobiliary disorders			
-Total	2 (3.8)	0	2 (3.8)
Hepatic function abnormal	2 (3.8)	0	2 (3.8)
Immune system disorders			
-Total	44 (83.0)	7 (13.2)	37 (69.8)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	40 (75.5)	9 (17.0)	31 (58.5)
Hypogammaglobulinaemia	18 (34.0)	1 (1.9)	17 (32.1)
Infections and infestations			
-Total	20 (37.7)	7 (13.2)	13 (24.5)
Upper respiratory tract infection	10 (18.9)	5 (9.4)	5 (9.4)
Rhinovirus infection	5 (9.4)	0	5 (9.4)
Nasopharyngitis	4 (7.5)	2 (3.8)	2 (3.8)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)
Sinusitis	3 (5.7)	0	3 (5.7)
Nail infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	26 (49.1)	4 (7.5)	22 (41.5)
Alanine aminotransferase increased	11 (20.8)	3 (5.7)	8 (15.1)
Platelet count decreased	11 (20.8)	6 (11.3)	5 (9.4)
White blood cell count decreased	10 (18.9)	3 (5.7)	7 (13.2)
Aspartate aminotransferase increased	8 (15.1)	3 (5.7)	5 (9.4)
Neutrophil count decreased	8 (15.1)	3 (5.7)	5 (9.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)
Blood bilirubin increased	4 (7.5)	1 (1.9)	3 (5.7)
Lymphocyte count decreased	3 (5.7)	1 (1.9)	2 (3.8)
Serum ferritin increased	2 (3.8)	1 (1.9)	1 (1.9)
Blood fibrinogen decreased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	25 (47.2)	8 (15.1)	17 (32.1)
Decreased appetite	13 (24.5)	7 (13.2)	6 (11.3)
Hypocalcaemia	9 (17.0)	1 (1.9)	8 (15.1)
Hypoalbuminaemia	7 (13.2)	0	7 (13.2)
Hypokalaemia	7 (13.2)	2 (3.8)	5 (9.4)
Hyperuricaemia	6 (11.3)	6 (11.3)	0
Hypophosphataemia	6 (11.3)	2 (3.8)	4 (7.5)
Musculoskeletal and connective tissue disorders			
-Total	23 (43.4)	10 (18.9)	13 (24.5)
Pain in extremity	9 (17.0)	5 (9.4)	4 (7.5)
Myalgia	8 (15.1)	5 (9.4)	3 (5.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	7 (13.2)	3 (5.7)	4 (7.5)
Back pain	6 (11.3)	2 (3.8)	4 (7.5)
Nervous system disorders			
-Total	20 (37.7)	12 (22.6)	8 (15.1)
Headache	18 (34.0)	10 (18.9)	8 (15.1)
Tremor	3 (5.7)	3 (5.7)	0
Psychiatric disorders			
-Total	11 (20.8)	3 (5.7)	8 (15.1)
Anxiety	10 (18.9)	3 (5.7)	7 (13.2)
Delirium	2 (3.8)	0	2 (3.8)
Insomnia	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	25 (47.2)	16 (30.2)	9 (17.0)
Cough	16 (30.2)	12 (22.6)	4 (7.5)
Nasal congestion	7 (13.2)	6 (11.3)	1 (1.9)
Epistaxis	4 (7.5)	3 (5.7)	1 (1.9)
Oropharyngeal pain	4 (7.5)	4 (7.5)	0
Pleural effusion	2 (3.8)	1 (1.9)	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pulmonary oedema	2 (3.8)	0	2 (3.8)
Skin and subcutaneous tissue disorders			
-Total	10 (18.9)	8 (15.1)	2 (3.8)
Dry skin	5 (9.4)	4 (7.5)	1 (1.9)
Rash	5 (9.4)	4 (7.5)	1 (1.9)
Vascular disorders			
-Total	13 (24.5)	6 (11.3)	7 (13.2)
Hypotension	8 (15.1)	3 (5.7)	5 (9.4)
Hypertension	7 (13.2)	3 (5.7)	4 (7.5)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (92.9)	4 (14.3)	22 (78.6)
Blood and lymphatic system disorders			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Disseminated intravascular coagulation	2 (7.1)	0	2 (7.1)
Anaemia	1 (3.6)	1 (3.6)	0
Gastrointestinal disorders			
-Total	15 (53.6)	5 (17.9)	10 (35.7)
Vomiting	7 (25.0)	5 (17.9)	2 (7.1)
Abdominal pain	5 (17.9)	0	5 (17.9)
Diarrhoea	5 (17.9)	1 (3.6)	4 (14.3)

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	3 (10.7)	1 (3.6)	2 (7.1)
Nausea	3 (10.7)	1 (3.6)	2 (7.1)
Abdominal pain upper	2 (7.1)	1 (3.6)	1 (3.6)
General disorders and administration site conditions			
-Total	10 (35.7)	7 (25.0)	3 (10.7)
Pyrexia	5 (17.9)	3 (10.7)	2 (7.1)
Asthenia	2 (7.1)	2 (7.1)	0
Face oedema	2 (7.1)	1 (3.6)	1 (3.6)
Fatigue	1 (3.6)	1 (3.6)	0
Influenza like illness	1 (3.6)	0	1 (3.6)
Oedema peripheral	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	19 (67.9)	4 (14.3)	15 (53.6)
Cytokine release syndrome	18 (64.3)	4 (14.3)	14 (50.0)
Hypogammaglobulinaemia	6 (21.4)	1 (3.6)	5 (17.9)
Infections and infestations			
-Total	5 (17.9)	2 (7.1)	3 (10.7)
Conjunctivitis	3 (10.7)	0	3 (10.7)

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nail infection	2 (7.1)	2 (7.1)	0
Investigations			
-Total	6 (21.4)	1 (3.6)	5 (17.9)
Platelet count decreased	3 (10.7)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	2 (7.1)	0	2 (7.1)
White blood cell count decreased	2 (7.1)	1 (3.6)	1 (3.6)
Aspartate aminotransferase increased	1 (3.6)	1 (3.6)	0
Neutrophil count decreased	1 (3.6)	0	1 (3.6)
Serum ferritin increased	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	7 (25.0)	3 (10.7)	4 (14.3)
Decreased appetite	3 (10.7)	2 (7.1)	1 (3.6)
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)
Hypokalaemia	2 (7.1)	1 (3.6)	1 (3.6)
Hyperuricaemia	1 (3.6)	0	1 (3.6)
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (32.1)	4 (14.3)	5 (17.9)
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)
Pain in extremity	4 (14.3)	2 (7.1)	2 (7.1)
Back pain	3 (10.7)	1 (3.6)	2 (7.1)
Myalgia	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	9 (32.1)	7 (25.0)	2 (7.1)
Headache	9 (32.1)	7 (25.0)	2 (7.1)
Psychiatric disorders			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Confusional state	2 (7.1)	2 (7.1)	0
Anxiety	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (21.4)	3 (10.7)	3 (10.7)
Cough	4 (14.3)	3 (10.7)	1 (3.6)
Hypoxia	3 (10.7)	0	3 (10.7)
Oropharyngeal pain	2 (7.1)	2 (7.1)	0

Timing: within 8 weeks post infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	4 (14.3)	0	4 (14.3)
Pruritus	2 (7.1)	0	2 (7.1)
Rash	2 (7.1)	0	2 (7.1)
Vascular disorders			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Hypotension	2 (7.1)	0	2 (7.1)
Hypertension	1 (3.6)	1 (3.6)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	44 (97.8)	2 (4.4)	42 (93.3)
Blood and lymphatic system disorders			
-Total	15 (33.3)	4 (8.9)	11 (24.4)
Anaemia	14 (31.1)	4 (8.9)	10 (22.2)
Disseminated intravascular coagulation	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	15 (33.3)	7 (15.6)	8 (17.8)
Tachycardia	15 (33.3)	7 (15.6)	8 (17.8)
Gastrointestinal disorders			
-Total	27 (60.0)	15 (33.3)	12 (26.7)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	13 (28.9)	7 (15.6)	6 (13.3)
Nausea	11 (24.4)	7 (15.6)	4 (8.9)
Diarrhoea	8 (17.8)	7 (15.6)	1 (2.2)
Constipation	7 (15.6)	4 (8.9)	3 (6.7)
Abdominal pain	4 (8.9)	2 (4.4)	2 (4.4)
Abdominal pain upper	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	0	1 (2.2)
Stomatitis	1 (2.2)	0	1 (2.2)
Trichoglossia	1 (2.2)	0	1 (2.2)
General disorders and administration site conditions			
-Total	22 (48.9)	14 (31.1)	8 (17.8)
Pyrexia	13 (28.9)	7 (15.6)	6 (13.3)
Fatigue	10 (22.2)	8 (17.8)	2 (4.4)
Chills	6 (13.3)	4 (8.9)	2 (4.4)
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)
Oedema peripheral	4 (8.9)	3 (6.7)	1 (2.2)
Hepatobiliary disorders			
-Total	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatic function abnormal	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	35 (77.8)	5 (11.1)	30 (66.7)
Cytokine release syndrome	34 (75.6)	6 (13.3)	28 (62.2)
Hypogammaglobulinaemia	8 (17.8)	1 (2.2)	7 (15.6)
Infections and infestations			
-Total	4 (8.9)	1 (2.2)	3 (6.7)
Conjunctivitis	2 (4.4)	1 (2.2)	1 (2.2)
Rhinovirus infection	2 (4.4)	0	2 (4.4)
Investigations			
-Total	27 (60.0)	5 (11.1)	22 (48.9)
Alanine aminotransferase increased	14 (31.1)	4 (8.9)	10 (22.2)
Aspartate aminotransferase increased	12 (26.7)	2 (4.4)	10 (22.2)
Platelet count decreased	10 (22.2)	4 (8.9)	6 (13.3)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)
White blood cell count decreased	6 (13.3)	2 (4.4)	4 (8.9)
Activated partial thromboplastin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	5 (11.1)	2 (4.4)	3 (6.7)
Blood immunoglobulin a decreased	5 (11.1)	4 (8.9)	1 (2.2)
Blood immunoglobulin m decreased	5 (11.1)	4 (8.9)	1 (2.2)
Neutrophil count decreased	5 (11.1)	0	5 (11.1)
Blood fibrinogen decreased	3 (6.7)	2 (4.4)	1 (2.2)
Serum ferritin increased	2 (4.4)	0	2 (4.4)
Metabolism and nutrition disorders			
-Total	27 (60.0)	10 (22.2)	17 (37.8)
Hypocalcaemia	12 (26.7)	2 (4.4)	10 (22.2)
Decreased appetite	10 (22.2)	7 (15.6)	3 (6.7)
Hypokalaemia	10 (22.2)	2 (4.4)	8 (17.8)
Hypophosphataemia	9 (20.0)	4 (8.9)	5 (11.1)
Hypoalbuminaemia	8 (17.8)	0	8 (17.8)
Hyperuricaemia	6 (13.3)	6 (13.3)	0
Hypomagnesaemia	3 (6.7)	3 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	16 (35.6)	9 (20.0)	7 (15.6)
Myalgia	8 (17.8)	5 (11.1)	3 (6.7)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	6 (13.3)	4 (8.9)	2 (4.4)
Arthralgia	5 (11.1)	2 (4.4)	3 (6.7)
Back pain	2 (4.4)	1 (2.2)	1 (2.2)
Nervous system disorders			
-Total	11 (24.4)	4 (8.9)	7 (15.6)
Headache	11 (24.4)	4 (8.9)	7 (15.6)
Psychiatric disorders			
-Total	12 (26.7)	6 (13.3)	6 (13.3)
Agitation	5 (11.1)	2 (4.4)	3 (6.7)
Confusional state	5 (11.1)	5 (11.1)	0
Delirium	4 (8.9)	2 (4.4)	2 (4.4)
Anxiety	3 (6.7)	1 (2.2)	2 (4.4)
Renal and urinary disorders			
-Total	4 (8.9)	1 (2.2)	3 (6.7)
Acute kidney injury	4 (8.9)	1 (2.2)	3 (6.7)
Haematuria	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (37.8)	13 (28.9)	4 (8.9)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	6 (13.3)	6 (13.3)	0
Tachypnoea	5 (11.1)	4 (8.9)	1 (2.2)
Nasal congestion	3 (6.7)	2 (4.4)	1 (2.2)
Pleural effusion	3 (6.7)	3 (6.7)	0
Epistaxis	2 (4.4)	1 (2.2)	1 (2.2)
Hypoxia	2 (4.4)	0	2 (4.4)
Oropharyngeal pain	2 (4.4)	2 (4.4)	0
Rhinorrhoea	2 (4.4)	2 (4.4)	0
Skin and subcutaneous tissue disorders			
-Total	6 (13.3)	4 (8.9)	2 (4.4)
Pruritus	3 (6.7)	1 (2.2)	2 (4.4)
Rash	3 (6.7)	2 (4.4)	1 (2.2)
Dry skin	1 (2.2)	1 (2.2)	0
Skin ulcer	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	13 (28.9)	6 (13.3)	7 (15.6)
Hypertension	8 (17.8)	4 (8.9)	4 (8.9)
Hypotension	7 (15.6)	2 (4.4)	5 (11.1)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	0	4 (57.1)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)
Anaemia	1 (14.3)	0	1 (14.3)
B-cell aplasia	1 (14.3)	0	1 (14.3)
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Cardiac dysfunction	2 (28.6)	2 (28.6)	0

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)
Nausea	2 (28.6)	2 (28.6)	0
Pancreatitis	2 (28.6)	0	2 (28.6)
Abdominal pain	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)
Enterocolitis	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Face oedema	1 (14.3)	1 (14.3)	0
Influenza like illness	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hepatic function abnormal	4 (57.1)	1 (14.3)	3 (42.9)
Immune system disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cytokine release syndrome	5 (71.4)	3 (42.9)	2 (28.6)
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)
Infections and infestations			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Bk virus infection	1 (14.3)	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)
Urinary tract infection viral	1 (14.3)	1 (14.3)	0
Investigations			
-Total	3 (42.9)	0	3 (42.9)
Serum ferritin increased	3 (42.9)	0	3 (42.9)
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)
Blood creatine phosphokinase increased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Headache	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Haematuria	1 (14.3)	1 (14.3)	0
Proteinuria	1 (14.3)	1 (14.3)	0
Reproductive system and breast disorders			
-Total	1 (14.3)	1 (14.3)	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	3 (42.9)	0
Epistaxis	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0
Pleural effusion	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Erythema nodosum	1 (14.3)	1 (14.3)	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0
Pruritus	1 (14.3)	1 (14.3)	0
Skin ulcer	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (82.1)	6 (21.4)	17 (60.7)
Blood and lymphatic system disorders			
-Total	2 (7.1)	2 (7.1)	0
Anaemia	2 (7.1)	2 (7.1)	0
Gastrointestinal disorders			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Constipation	2 (7.1)	0	2 (7.1)
Vomiting	2 (7.1)	2 (7.1)	0
Abdominal pain upper	1 (3.6)	1 (3.6)	0
Diarrhoea	1 (3.6)	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (3.6)	1 (3.6)	0
Pancreatitis	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	4 (14.3)	1 (3.6)	3 (10.7)
Pyrexia	4 (14.3)	1 (3.6)	3 (10.7)
Asthenia	1 (3.6)	1 (3.6)	0
Infections and infestations			
-Total	12 (42.9)	4 (14.3)	8 (28.6)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)
Rhinitis	2 (7.1)	1 (3.6)	1 (3.6)
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0
Conjunctivitis	1 (3.6)	0	1 (3.6)
Nail infection	1 (3.6)	1 (3.6)	0
Otitis media	1 (3.6)	0	1 (3.6)
Rhinovirus infection	1 (3.6)	0	1 (3.6)
Sinusitis	1 (3.6)	0	1 (3.6)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (14.3)	3 (10.7)	1 (3.6)
White blood cell count decreased	3 (10.7)	3 (10.7)	0
Platelet count decreased	2 (7.1)	2 (7.1)	0
Neutrophil count decreased	1 (3.6)	0	1 (3.6)
Metabolism and nutrition disorders			
-Total	1 (3.6)	0	1 (3.6)
Hypophosphataemia	1 (3.6)	0	1 (3.6)
Musculoskeletal and connective tissue disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Back pain	2 (7.1)	1 (3.6)	1 (3.6)
Arthralgia	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Headache	2 (7.1)	1 (3.6)	1 (3.6)
Psychiatric disorders			
-Total	2 (7.1)	0	2 (7.1)
Anxiety	2 (7.1)	0	2 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	4 (14.3)	3 (10.7)	1 (3.6)
Cough	4 (14.3)	3 (10.7)	1 (3.6)
Skin and subcutaneous tissue disorders			
-Total	1 (3.6)	0	1 (3.6)
Dry skin	1 (3.6)	0	1 (3.6)
Rash	1 (3.6)	0	1 (3.6)
Vascular disorders			
-Total	1 (3.6)	1 (3.6)	0
Hypotension	1 (3.6)	1 (3.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	33 (82.5)	6 (15.0)	27 (67.5)
Blood and lymphatic system disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Anaemia	2 (5.0)	1 (2.5)	1 (2.5)
Cardiac disorders			
-Total	2 (5.0)	2 (5.0)	0
Tachycardia	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Diarrhoea	6 (15.0)	5 (12.5)	1 (2.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	4 (10.0)	2 (5.0)	2 (5.0)
Vomiting	4 (10.0)	4 (10.0)	0
Abdominal pain	2 (5.0)	1 (2.5)	1 (2.5)
General disorders and administration site conditions			
-Total	16 (40.0)	12 (30.0)	4 (10.0)
Pyrexia	8 (20.0)	5 (12.5)	3 (7.5)
Fatigue	6 (15.0)	6 (15.0)	0
Chills	1 (2.5)	1 (2.5)	0
Oedema peripheral	1 (2.5)	1 (2.5)	0
Pain	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	8 (20.0)	0	8 (20.0)
Hypogammaglobulinaemia	8 (20.0)	0	8 (20.0)
Infections and infestations			
-Total	11 (27.5)	1 (2.5)	10 (25.0)
Upper respiratory tract infection	4 (10.0)	1 (2.5)	3 (7.5)
Rhinovirus infection	3 (7.5)	0	3 (7.5)
Sinusitis	2 (5.0)	0	2 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis externa	1 (2.5)	0	1 (2.5)
Otitis media	1 (2.5)	0	1 (2.5)
Investigations			
-Total	12 (30.0)	5 (12.5)	7 (17.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	4 (10.0)
Neutrophil count decreased	5 (12.5)	2 (5.0)	3 (7.5)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	2 (5.0)	0	2 (5.0)
Platelet count decreased	2 (5.0)	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	8 (20.0)	4 (10.0)	4 (10.0)
Decreased appetite	5 (12.5)	2 (5.0)	3 (7.5)
Hyperuricaemia	3 (7.5)	3 (7.5)	0
Hypokalaemia	2 (5.0)	0	2 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	8 (20.0)	4 (10.0)	4 (10.0)
Pain in extremity	4 (10.0)	2 (5.0)	2 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	2 (5.0)	1 (2.5)	1 (2.5)
Back pain	2 (5.0)	1 (2.5)	1 (2.5)
Myalgia	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	7 (17.5)	4 (10.0)	3 (7.5)
Headache	7 (17.5)	4 (10.0)	3 (7.5)
Psychiatric disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)
Agitation	1 (2.5)	1 (2.5)	0
Delirium	1 (2.5)	0	1 (2.5)
Renal and urinary disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Acute kidney injury	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (30.0)	8 (20.0)	4 (10.0)
Cough	7 (17.5)	5 (12.5)	2 (5.0)
Nasal congestion	6 (15.0)	5 (12.5)	1 (2.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)
Rhinorrhoea	3 (7.5)	3 (7.5)	0
Oropharyngeal pain	2 (5.0)	1 (2.5)	1 (2.5)
Pleural effusion	1 (2.5)	1 (2.5)	0
Skin and subcutaneous tissue disorders			
-Total	8 (20.0)	6 (15.0)	2 (5.0)
Dry skin	4 (10.0)	3 (7.5)	1 (2.5)
Rash	3 (7.5)	3 (7.5)	0
Pruritus	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypertension	1 (2.5)	0	1 (2.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (57.1)	0	4 (57.1)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Anaemia	1 (14.3)	1 (14.3)	0
B-cell aplasia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Constipation	1 (14.3)	1 (14.3)	0
Enteritis	1 (14.3)	0	1 (14.3)
Stomatitis	1 (14.3)	1 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Trichoglossia	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Nasopharyngitis	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Pleural effusion	1 (14.3)	0	1 (14.3)
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	2 (28.6)	2 (28.6)	0
Dry skin	1 (14.3)	1 (14.3)	0
Skin swelling	1 (14.3)	1 (14.3)	0

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Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (36.4)	4 (18.2)	4 (18.2)
Blood and lymphatic system disorders			
-Total	1 (4.5)	0	1 (4.5)
Anaemia	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	2 (9.1)	2 (9.1)	0
Diarrhoea	2 (9.1)	2 (9.1)	0
General disorders and administration site conditions			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Pyrexia	2 (9.1)	1 (4.5)	1 (4.5)

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Conjunctivitis	3 (13.6)	2 (9.1)	1 (4.5)
Rhinitis	1 (4.5)	1 (4.5)	0
Sinusitis	1 (4.5)	0	1 (4.5)
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0
Investigations			
-Total	1 (4.5)	1 (4.5)	0
Platelet count decreased	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (9.1)	0	2 (9.1)
Pain in extremity	2 (9.1)	0	2 (9.1)
Nervous system disorders			
-Total	1 (4.5)	0	1 (4.5)
Headache	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	2 (9.1)	2 (9.1)	0
Epistaxis	1 (4.5)	1 (4.5)	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0
Pleural effusion	1 (4.5)	0	1 (4.5)
Skin and subcutaneous tissue disorders			
-Total	1 (4.5)	1 (4.5)	0
Dry skin	1 (4.5)	1 (4.5)	0

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Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (56.5)	2 (8.7)	11 (47.8)
Gastrointestinal disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Diarrhoea	2 (8.7)	1 (4.3)	1 (4.3)
Constipation	1 (4.3)	1 (4.3)	0
Nausea	1 (4.3)	1 (4.3)	0
Vomiting	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			
-Total	3 (13.0)	0	3 (13.0)
Fatigue	1 (4.3)	0	1 (4.3)

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (4.3)	0	1 (4.3)
Pyrexia	1 (4.3)	0	1 (4.3)
Immune system disorders			
-Total	3 (13.0)	0	3 (13.0)
Hypogammaglobulinaemia	3 (13.0)	0	3 (13.0)
Infections and infestations			
-Total	7 (30.4)	1 (4.3)	6 (26.1)
Sinusitis	4 (17.4)	0	4 (17.4)
Upper respiratory tract infection	3 (13.0)	1 (4.3)	2 (8.7)
Rhinovirus infection	2 (8.7)	0	2 (8.7)
Conjunctivitis	1 (4.3)	0	1 (4.3)
Nail infection	1 (4.3)	0	1 (4.3)
Otitis media	1 (4.3)	0	1 (4.3)
Urinary tract infection	1 (4.3)	0	1 (4.3)
Investigations			
-Total	2 (8.7)	2 (8.7)	0
Neutrophil count decreased	2 (8.7)	2 (8.7)	0
Blood bilirubin increased	1 (4.3)	1 (4.3)	0
Platelet count decreased	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (4.3)	0	1 (4.3)
Arthralgia	1 (4.3)	0	1 (4.3)
Nervous system disorders			
-Total	2 (8.7)	0	2 (8.7)
Headache	1 (4.3)	0	1 (4.3)
Seizure	1 (4.3)	0	1 (4.3)
Psychiatric disorders			
-Total	1 (4.3)	0	1 (4.3)
Anxiety	1 (4.3)	0	1 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.0)	1 (4.3)	2 (8.7)
Rhinorrhoea	3 (13.0)	1 (4.3)	2 (8.7)
Cough	2 (8.7)	1 (4.3)	1 (4.3)
Skin and subcutaneous tissue disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Rash	2 (8.7)	1 (4.3)	1 (4.3)

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	1 (4.3)	0	1 (4.3)
Hypertension	1 (4.3)	0	1 (4.3)

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Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (40.0)	0	2 (40.0)
General disorders and administration site conditions			
-Total	1 (20.0)	1 (20.0)	0
Pain	1 (20.0)	1 (20.0)	0
Pyrexia	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	2 (40.0)	0	2 (40.0)
Otitis media	1 (20.0)	0	1 (20.0)
Rhinovirus infection	1 (20.0)	0	1 (20.0)
Sinusitis	1 (20.0)	0	1 (20.0)

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Urinary tract infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
Psychiatric disorders			
-Total	1 (20.0)	1 (20.0)	0
Anxiety	1 (20.0)	1 (20.0)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (100)	3 (10.7)	25 (89.3)
Blood and lymphatic system disorders			
-Total	6 (21.4)	3 (10.7)	3 (10.7)
Anaemia	4 (14.3)	3 (10.7)	1 (3.6)
Disseminated intravascular coagulation	2 (7.1)	0	2 (7.1)
Gastrointestinal disorders			
-Total	19 (67.9)	7 (25.0)	12 (42.9)
Vomiting	8 (28.6)	6 (21.4)	2 (7.1)
Diarrhoea	7 (25.0)	3 (10.7)	4 (14.3)
Abdominal pain	5 (17.9)	0	5 (17.9)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	5 (17.9)	1 (3.6)	4 (14.3)
Abdominal pain upper	3 (10.7)	2 (7.1)	1 (3.6)
Nausea	3 (10.7)	1 (3.6)	2 (7.1)
Pancreatitis	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	13 (46.4)	7 (25.0)	6 (21.4)
Pyrexia	9 (32.1)	4 (14.3)	5 (17.9)
Asthenia	3 (10.7)	3 (10.7)	0
Face oedema	2 (7.1)	1 (3.6)	1 (3.6)
Fatigue	1 (3.6)	1 (3.6)	0
Influenza like illness	1 (3.6)	0	1 (3.6)
Oedema peripheral	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	19 (67.9)	4 (14.3)	15 (53.6)
Cytokine release syndrome	18 (64.3)	4 (14.3)	14 (50.0)
Hypogammaglobulinaemia	6 (21.4)	1 (3.6)	5 (17.9)
Infections and infestations			
-Total	16 (57.1)	6 (21.4)	10 (35.7)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)
Conjunctivitis	5 (17.9)	1 (3.6)	4 (14.3)
Nail infection	3 (10.7)	3 (10.7)	0
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)
Rhinitis	3 (10.7)	2 (7.1)	1 (3.6)
Upper respiratory tract infection	3 (10.7)	3 (10.7)	0
Otitis media	1 (3.6)	0	1 (3.6)
Rhinovirus infection	1 (3.6)	0	1 (3.6)
Sinusitis	1 (3.6)	0	1 (3.6)
Investigations			
-Total	7 (25.0)	2 (7.1)	5 (17.9)
Platelet count decreased	4 (14.3)	3 (10.7)	1 (3.6)
White blood cell count decreased	3 (10.7)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	2 (7.1)	0	2 (7.1)
Aspartate aminotransferase increased	1 (3.6)	1 (3.6)	0
Neutrophil count decreased	1 (3.6)	0	1 (3.6)
Serum ferritin increased	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (28.6)	3 (10.7)	5 (17.9)
Decreased appetite	3 (10.7)	2 (7.1)	1 (3.6)
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)
Hypokalaemia	2 (7.1)	1 (3.6)	1 (3.6)
Hyperuricaemia	1 (3.6)	0	1 (3.6)
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)
Hypophosphataemia	1 (3.6)	0	1 (3.6)
Musculoskeletal and connective tissue disorders			
-Total	11 (39.3)	4 (14.3)	7 (25.0)
Pain in extremity	6 (21.4)	2 (7.1)	4 (14.3)
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)
Back pain	4 (14.3)	1 (3.6)	3 (10.7)
Myalgia	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	10 (35.7)	6 (21.4)	4 (14.3)
Headache	10 (35.7)	6 (21.4)	4 (14.3)
Psychiatric disorders			
-Total	5 (17.9)	2 (7.1)	3 (10.7)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	3 (10.7)	0	3 (10.7)
Confusional state	2 (7.1)	2 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (46.4)	8 (28.6)	5 (17.9)
Cough	10 (35.7)	8 (28.6)	2 (7.1)
Hypoxia	3 (10.7)	0	3 (10.7)
Oropharyngeal pain	3 (10.7)	3 (10.7)	0
Epistaxis	1 (3.6)	1 (3.6)	0
Pleural effusion	1 (3.6)	0	1 (3.6)
Skin and subcutaneous tissue disorders			
-Total	5 (17.9)	1 (3.6)	4 (14.3)
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)
Pruritus	2 (7.1)	0	2 (7.1)
Rash	2 (7.1)	0	2 (7.1)
Vascular disorders			
-Total	4 (14.3)	2 (7.1)	2 (7.1)
Hypotension	3 (10.7)	1 (3.6)	2 (7.1)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (3.6)	1 (3.6)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	44 (97.8)	0	44 (97.8)
Blood and lymphatic system disorders			
-Total	15 (33.3)	4 (8.9)	11 (24.4)
Anaemia	14 (31.1)	4 (8.9)	10 (22.2)
Disseminated intravascular coagulation	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	16 (35.6)	8 (17.8)	8 (17.8)
Tachycardia	16 (35.6)	8 (17.8)	8 (17.8)
Gastrointestinal disorders			
-Total	32 (71.1)	17 (37.8)	15 (33.3)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	17 (37.8)	11 (24.4)	6 (13.3)
Diarrhoea	16 (35.6)	13 (28.9)	3 (6.7)
Nausea	15 (33.3)	9 (20.0)	6 (13.3)
Constipation	7 (15.6)	4 (8.9)	3 (6.7)
Abdominal pain	5 (11.1)	2 (4.4)	3 (6.7)
Abdominal pain upper	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	0	1 (2.2)
Stomatitis	1 (2.2)	0	1 (2.2)
Trichoglossia	1 (2.2)	0	1 (2.2)
General disorders and administration site conditions			
-Total	33 (73.3)	19 (42.2)	14 (31.1)
Pyrexia	19 (42.2)	10 (22.2)	9 (20.0)
Fatigue	16 (35.6)	13 (28.9)	3 (6.7)
Chills	7 (15.6)	5 (11.1)	2 (4.4)
Oedema peripheral	5 (11.1)	4 (8.9)	1 (2.2)
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)
Pain	2 (4.4)	0	2 (4.4)
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (2.2)	0	1 (2.2)
Hepatic function abnormal	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	38 (84.4)	5 (11.1)	33 (73.3)
Cytokine release syndrome	34 (75.6)	6 (13.3)	28 (62.2)
Hypogammaglobulinaemia	16 (35.6)	1 (2.2)	15 (33.3)
Infections and infestations			
-Total	16 (35.6)	2 (4.4)	14 (31.1)
Upper respiratory tract infection	7 (15.6)	2 (4.4)	5 (11.1)
Rhinovirus infection	6 (13.3)	0	6 (13.3)
Sinusitis	4 (8.9)	0	4 (8.9)
Conjunctivitis	3 (6.7)	1 (2.2)	2 (4.4)
Otitis media	2 (4.4)	0	2 (4.4)
Nail infection	1 (2.2)	0	1 (2.2)
Otitis externa	1 (2.2)	0	1 (2.2)
Urinary tract infection	1 (2.2)	0	1 (2.2)
Investigations			
-Total	27 (60.0)	3 (6.7)	24 (53.3)
Alanine aminotransferase increased	14 (31.1)	4 (8.9)	10 (22.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	12 (26.7)	2 (4.4)	10 (22.2)
Platelet count decreased	11 (24.4)	5 (11.1)	6 (13.3)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)
Neutrophil count decreased	9 (20.0)	3 (6.7)	6 (13.3)
White blood cell count decreased	9 (20.0)	2 (4.4)	7 (15.6)
Blood bilirubin increased	7 (15.6)	2 (4.4)	5 (11.1)
Blood immunoglobulin a decreased	6 (13.3)	5 (11.1)	1 (2.2)
Activated partial thromboplastin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)
Blood immunoglobulin m decreased	5 (11.1)	4 (8.9)	1 (2.2)
Blood fibrinogen decreased	3 (6.7)	2 (4.4)	1 (2.2)
Serum ferritin increased	2 (4.4)	0	2 (4.4)
Metabolism and nutrition disorders			
-Total	32 (71.1)	12 (26.7)	20 (44.4)
Decreased appetite	15 (33.3)	9 (20.0)	6 (13.3)
Hypocalcaemia	12 (26.7)	2 (4.4)	10 (22.2)
Hypokalaemia	11 (24.4)	2 (4.4)	9 (20.0)
Hypophosphataemia	9 (20.0)	4 (8.9)	5 (11.1)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	8 (17.8)	8 (17.8)	0
Hypoalbuminaemia	8 (17.8)	0	8 (17.8)
Hypomagnesaemia	3 (6.7)	3 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	22 (48.9)	12 (26.7)	10 (22.2)
Myalgia	9 (20.0)	5 (11.1)	4 (8.9)
Pain in extremity	9 (20.0)	6 (13.3)	3 (6.7)
Arthralgia	7 (15.6)	3 (6.7)	4 (8.9)
Back pain	3 (6.7)	1 (2.2)	2 (4.4)
Nervous system disorders			
-Total	15 (33.3)	6 (13.3)	9 (20.0)
Headache	15 (33.3)	6 (13.3)	9 (20.0)
Seizure	1 (2.2)	0	1 (2.2)
Psychiatric disorders			
-Total	16 (35.6)	6 (13.3)	10 (22.2)
Anxiety	8 (17.8)	2 (4.4)	6 (13.3)
Agitation	6 (13.3)	3 (6.7)	3 (6.7)
Confusional state	5 (11.1)	5 (11.1)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Delirium	5 (11.1)	2 (4.4)	3 (6.7)
Renal and urinary disorders			
-Total	6 (13.3)	2 (4.4)	4 (8.9)
Acute kidney injury	6 (13.3)	2 (4.4)	4 (8.9)
Haematuria	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	23 (51.1)	15 (33.3)	8 (17.8)
Cough	13 (28.9)	10 (22.2)	3 (6.7)
Nasal congestion	9 (20.0)	7 (15.6)	2 (4.4)
Rhinorrhoea	6 (13.3)	4 (8.9)	2 (4.4)
Epistaxis	5 (11.1)	2 (4.4)	3 (6.7)
Tachypnoea	5 (11.1)	4 (8.9)	1 (2.2)
Oropharyngeal pain	4 (8.9)	3 (6.7)	1 (2.2)
Pleural effusion	3 (6.7)	3 (6.7)	0
Hypoxia	2 (4.4)	0	2 (4.4)
Skin and subcutaneous tissue disorders			
-Total	14 (31.1)	9 (20.0)	5 (11.1)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	6 (13.3)	4 (8.9)	2 (4.4)
Dry skin	5 (11.1)	4 (8.9)	1 (2.2)
Pruritus	4 (8.9)	1 (2.2)	3 (6.7)
Skin ulcer	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	15 (33.3)	6 (13.3)	9 (20.0)
Hypertension	10 (22.2)	4 (8.9)	6 (13.3)
Hypotension	7 (15.6)	2 (4.4)	5 (11.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257k
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	4 (57.1)	0	4 (57.1)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)
Anaemia	1 (14.3)	0	1 (14.3)
B-cell aplasia	1 (14.3)	0	1 (14.3)
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	2 (28.6)	2 (28.6)	0
Cardiac dysfunction	2 (28.6)	2 (28.6)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Constipation	2 (28.6)	2 (28.6)	0
Nausea	2 (28.6)	2 (28.6)	0
Pancreatitis	2 (28.6)	0	2 (28.6)
Abdominal pain	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)
Enteritis	1 (14.3)	0	1 (14.3)
Enterocolitis	1 (14.3)	0	1 (14.3)
Stomatitis	1 (14.3)	1 (14.3)	0
Trichoglossia	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Face oedema	1 (14.3)	1 (14.3)	0
Influenza like illness	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hepatic function abnormal	4 (57.1)	1 (14.3)	3 (42.9)
Immune system disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cytokine release syndrome	5 (71.4)	3 (42.9)	2 (28.6)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)
Infections and infestations			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)
Bk virus infection	1 (14.3)	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)
Otitis media	1 (14.3)	0	1 (14.3)
Rhinovirus infection	1 (14.3)	0	1 (14.3)
Sinusitis	1 (14.3)	0	1 (14.3)
Urinary tract infection	1 (14.3)	0	1 (14.3)
Urinary tract infection viral	1 (14.3)	1 (14.3)	0
Investigations			
-Total	4 (57.1)	0	4 (57.1)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Serum ferritin increased	3 (42.9)	0	3 (42.9)
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)
Blood creatine phosphokinase increased	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Pain in extremity	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Headache	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	0	1 (14.3)
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Anxiety	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)
Haematuria	1 (14.3)	1 (14.3)	0
Proteinuria	1 (14.3)	1 (14.3)	0
Reproductive system and breast disorders			
-Total	1 (14.3)	1 (14.3)	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Pleural effusion	2 (28.6)	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Dry skin	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Erythema nodosum	1 (14.3)	1 (14.3)	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0
Pruritus	1 (14.3)	1 (14.3)	0
Skin swelling	1 (14.3)	1 (14.3)	0
Skin ulcer	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	47 (97.9)	5 (10.4)	42 (87.5)
Blood and lymphatic system disorders			
-Total	8 (16.7)	2 (4.2)	6 (12.5)
Anaemia	8 (16.7)	2 (4.2)	6 (12.5)
Cardiac disorders			
-Total	6 (12.5)	4 (8.3)	2 (4.2)
Tachycardia	6 (12.5)	4 (8.3)	2 (4.2)
Gastrointestinal disorders			
-Total	28 (58.3)	15 (31.3)	13 (27.1)
Vomiting	14 (29.2)	7 (14.6)	7 (14.6)
Diarrhoea	11 (22.9)	6 (12.5)	5 (10.4)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	11 (22.9)	8 (16.7)	3 (6.3)
Abdominal pain	8 (16.7)	2 (4.2)	6 (12.5)
Constipation	5 (10.4)	3 (6.3)	2 (4.2)
General disorders and administration site conditions			
-Total	17 (35.4)	11 (22.9)	6 (12.5)
Pyrexia	10 (20.8)	5 (10.4)	5 (10.4)
Fatigue	6 (12.5)	6 (12.5)	0
Chills	4 (8.3)	2 (4.2)	2 (4.2)
Oedema peripheral	2 (4.2)	2 (4.2)	0
Immune system disorders			
-Total	37 (77.1)	7 (14.6)	30 (62.5)
Cytokine release syndrome	34 (70.8)	7 (14.6)	27 (56.3)
Hypogammaglobulinaemia	9 (18.8)	0	9 (18.8)
Infections and infestations			
-Total	4 (8.3)	1 (2.1)	3 (6.3)
Conjunctivitis	3 (6.3)	1 (2.1)	2 (4.2)
Rhinovirus infection	1 (2.1)	0	1 (2.1)
Investigations			

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	20 (41.7)	7 (14.6)	13 (27.1)
Alanine aminotransferase increased	12 (25.0)	3 (6.3)	9 (18.8)
Aspartate aminotransferase increased	8 (16.7)	3 (6.3)	5 (10.4)
Platelet count decreased	7 (14.6)	3 (6.3)	4 (8.3)
Blood immunoglobulin a decreased	4 (8.3)	4 (8.3)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0
Neutrophil count decreased	3 (6.3)	0	3 (6.3)
White blood cell count decreased	3 (6.3)	3 (6.3)	0
Metabolism and nutrition disorders			
-Total	16 (33.3)	8 (16.7)	8 (16.7)
Decreased appetite	7 (14.6)	6 (12.5)	1 (2.1)
Hypokalaemia	6 (12.5)	2 (4.2)	4 (8.3)
Hypophosphataemia	6 (12.5)	4 (8.3)	2 (4.2)
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)
Hypocalcaemia	4 (8.3)	2 (4.2)	2 (4.2)
Hyperuricaemia	1 (2.1)	0	1 (2.1)
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	19 (39.6)	8 (16.7)	11 (22.9)
Pain in extremity	9 (18.8)	5 (10.4)	4 (8.3)
Arthralgia	8 (16.7)	4 (8.3)	4 (8.3)
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)
Back pain	4 (8.3)	1 (2.1)	3 (6.3)
Nervous system disorders			
-Total	10 (20.8)	8 (16.7)	2 (4.2)
Headache	10 (20.8)	8 (16.7)	2 (4.2)
Psychiatric disorders			
-Total	4 (8.3)	1 (2.1)	3 (6.3)
Anxiety	4 (8.3)	1 (2.1)	3 (6.3)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (27.1)	11 (22.9)	2 (4.2)
Cough	7 (14.6)	6 (12.5)	1 (2.1)
Oropharyngeal pain	3 (6.3)	3 (6.3)	0
Epistaxis	2 (4.2)	2 (4.2)	0
Nasal congestion	2 (4.2)	1 (2.1)	1 (2.1)
Rhinorrhoea	2 (4.2)	2 (4.2)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	7 (14.6)	3 (6.3)	4 (8.3)
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)
Rash	3 (6.3)	1 (2.1)	2 (4.2)
Dry skin	1 (2.1)	1 (2.1)	0
Vascular disorders			
-Total	9 (18.8)	4 (8.3)	5 (10.4)
Hypertension	5 (10.4)	3 (6.3)	2 (4.2)
Hypotension	5 (10.4)	1 (2.1)	4 (8.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (93.8)	4 (12.5)	26 (81.3)
Blood and lymphatic system disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Anaemia	8 (25.0)	3 (9.4)	5 (15.6)
Cardiac disorders			
-Total	9 (28.1)	3 (9.4)	6 (18.8)
Tachycardia	9 (28.1)	3 (9.4)	6 (18.8)
Gastrointestinal disorders			
-Total	17 (53.1)	9 (28.1)	8 (25.0)
Constipation	6 (18.8)	3 (9.4)	3 (9.4)
Vomiting	6 (18.8)	5 (15.6)	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	5 (15.6)	2 (6.3)	3 (9.4)
Diarrhoea	3 (9.4)	2 (6.3)	1 (3.1)
Abdominal pain	2 (6.3)	1 (3.1)	1 (3.1)
General disorders and administration site conditions			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Pyrexia	9 (28.1)	6 (18.8)	3 (9.4)
Fatigue	5 (15.6)	3 (9.4)	2 (6.3)
Oedema peripheral	3 (9.4)	2 (6.3)	1 (3.1)
Chills	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	23 (71.9)	5 (15.6)	18 (56.3)
Cytokine release syndrome	23 (71.9)	6 (18.8)	17 (53.1)
Hypogammaglobulinaemia	7 (21.9)	2 (6.3)	5 (15.6)
Infections and infestations			
-Total	3 (9.4)	0	3 (9.4)
Conjunctivitis	2 (6.3)	0	2 (6.3)
Rhinovirus infection	1 (3.1)	0	1 (3.1)
Investigations			

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	14 (43.8)	1 (3.1)	13 (40.6)
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)
Platelet count decreased	6 (18.8)	3 (9.4)	3 (9.4)
Aspartate aminotransferase increased	5 (15.6)	0	5 (15.6)
White blood cell count decreased	5 (15.6)	0	5 (15.6)
Alanine aminotransferase increased	4 (12.5)	1 (3.1)	3 (9.4)
Electrocardiogram qt prolonged	4 (12.5)	2 (6.3)	2 (6.3)
Neutrophil count decreased	3 (9.4)	0	3 (9.4)
Blood immunoglobulin g decreased	2 (6.3)	1 (3.1)	1 (3.1)
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			
-Total	18 (56.3)	5 (15.6)	13 (40.6)
Hypocalcaemia	8 (25.0)	0	8 (25.0)
Decreased appetite	6 (18.8)	3 (9.4)	3 (9.4)
Hyperuricaemia	6 (18.8)	6 (18.8)	0
Hypokalaemia	6 (18.8)	1 (3.1)	5 (15.6)
Hypoalbuminaemia	5 (15.6)	0	5 (15.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	4 (12.5)	4 (12.5)	0
Hypophosphataemia	3 (9.4)	0	3 (9.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (21.9)	5 (15.6)	2 (6.3)
Myalgia	4 (12.5)	3 (9.4)	1 (3.1)
Pain in extremity	2 (6.3)	1 (3.1)	1 (3.1)
Arthralgia	1 (3.1)	0	1 (3.1)
Back pain	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	11 (34.4)	4 (12.5)	7 (21.9)
Headache	11 (34.4)	4 (12.5)	7 (21.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Cough	3 (9.4)	3 (9.4)	0
Oropharyngeal pain	2 (6.3)	2 (6.3)	0
Epistaxis	1 (3.1)	0	1 (3.1)
Nasal congestion	1 (3.1)	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Pruritus	3 (9.4)	1 (3.1)	2 (6.3)
Rash	2 (6.3)	1 (3.1)	1 (3.1)
Vascular disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Hypertension	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	4 (12.5)	1 (3.1)	3 (9.4)

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Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (81.3)	10 (20.8)	29 (60.4)
Blood and lymphatic system disorders			
-Total	5 (10.4)	4 (8.3)	1 (2.1)
Anaemia	5 (10.4)	4 (8.3)	1 (2.1)
Cardiac disorders			
-Total	2 (4.2)	2 (4.2)	0
Tachycardia	2 (4.2)	2 (4.2)	0
Gastrointestinal disorders			
-Total	9 (18.8)	6 (12.5)	3 (6.3)
Nausea	4 (8.3)	3 (6.3)	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	4 (8.3)	4 (8.3)	0
Constipation	3 (6.3)	1 (2.1)	2 (4.2)
Diarrhoea	3 (6.3)	3 (6.3)	0
Abdominal pain	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			
-Total	12 (25.0)	9 (18.8)	3 (6.3)
Pyrexia	8 (16.7)	5 (10.4)	3 (6.3)
Fatigue	4 (8.3)	4 (8.3)	0
Chills	1 (2.1)	1 (2.1)	0
Immune system disorders			
-Total	9 (18.8)	0	9 (18.8)
Hypogammaglobulinaemia	9 (18.8)	0	9 (18.8)
Infections and infestations			
-Total	11 (22.9)	4 (8.3)	7 (14.6)
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)
Rhinovirus infection	3 (6.3)	0	3 (6.3)
Upper respiratory tract infection	3 (6.3)	1 (2.1)	2 (4.2)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (20.8)	6 (12.5)	4 (8.3)
White blood cell count decreased	6 (12.5)	4 (8.3)	2 (4.2)
Neutrophil count decreased	4 (8.3)	1 (2.1)	3 (6.3)
Platelet count decreased	3 (6.3)	2 (4.2)	1 (2.1)
Alanine aminotransferase increased	2 (4.2)	2 (4.2)	0
Blood immunoglobulin a decreased	1 (2.1)	1 (2.1)	0
Metabolism and nutrition disorders			
-Total	6 (12.5)	3 (6.3)	3 (6.3)
Decreased appetite	3 (6.3)	2 (4.2)	1 (2.1)
Hyperuricaemia	2 (4.2)	2 (4.2)	0
Hypokalaemia	2 (4.2)	0	2 (4.2)
Hypophosphataemia	1 (2.1)	0	1 (2.1)
Musculoskeletal and connective tissue disorders			
-Total	6 (12.5)	4 (8.3)	2 (4.2)
Back pain	3 (6.3)	2 (4.2)	1 (2.1)
Arthralgia	2 (4.2)	2 (4.2)	0
Pain in extremity	2 (4.2)	1 (2.1)	1 (2.1)
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (12.5)	3 (6.3)	3 (6.3)
Headache	6 (12.5)	3 (6.3)	3 (6.3)
Psychiatric disorders			
-Total	3 (6.3)	1 (2.1)	2 (4.2)
Anxiety	3 (6.3)	1 (2.1)	2 (4.2)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (25.0)	9 (18.8)	3 (6.3)
Cough	9 (18.8)	7 (14.6)	2 (4.2)
Nasal congestion	4 (8.3)	4 (8.3)	0
Rhinorrhoea	3 (6.3)	3 (6.3)	0
Epistaxis	2 (4.2)	1 (2.1)	1 (2.1)
Skin and subcutaneous tissue disorders			
-Total	5 (10.4)	3 (6.3)	2 (4.2)
Dry skin	3 (6.3)	1 (2.1)	2 (4.2)
Rash	3 (6.3)	2 (4.2)	1 (2.1)
Vascular disorders			
-Total	2 (4.2)	1 (2.1)	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (2.1)	0	1 (2.1)
Hypotension	1 (2.1)	1 (2.1)	0

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Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (55.6)	4 (14.8)	11 (40.7)
Gastrointestinal disorders			
-Total	5 (18.5)	3 (11.1)	2 (7.4)
Diarrhoea	4 (14.8)	3 (11.1)	1 (3.7)
Vomiting	2 (7.4)	2 (7.4)	0
Abdominal pain	1 (3.7)	0	1 (3.7)
Nausea	1 (3.7)	0	1 (3.7)
General disorders and administration site conditions			
-Total	8 (29.6)	5 (18.5)	3 (11.1)
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	2 (7.4)	2 (7.4)	0
Oedema peripheral	1 (3.7)	1 (3.7)	0
Immune system disorders			
-Total	1 (3.7)	0	1 (3.7)
Hypogammaglobulinaemia	1 (3.7)	0	1 (3.7)
Infections and infestations			
-Total	6 (22.2)	2 (7.4)	4 (14.8)
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)
Nasopharyngitis	2 (7.4)	1 (3.7)	1 (3.7)
Conjunctivitis	1 (3.7)	0	1 (3.7)
Rhinovirus infection	1 (3.7)	0	1 (3.7)
Investigations			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
White blood cell count decreased	3 (11.1)	1 (3.7)	2 (7.4)
Neutrophil count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)
Platelet count decreased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	2 (7.4)	0	2 (7.4)
Hyperuricaemia	1 (3.7)	1 (3.7)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (14.8)	1 (3.7)	3 (11.1)
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)
Arthralgia	1 (3.7)	0	1 (3.7)
Back pain	1 (3.7)	0	1 (3.7)
Myalgia	1 (3.7)	0	1 (3.7)
Nervous system disorders			
-Total	4 (14.8)	3 (11.1)	1 (3.7)
Headache	4 (14.8)	3 (11.1)	1 (3.7)
Psychiatric disorders			
-Total	3 (11.1)	0	3 (11.1)
Anxiety	3 (11.1)	0	3 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Cough	2 (7.4)	1 (3.7)	1 (3.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)
Oropharyngeal pain	2 (7.4)	1 (3.7)	1 (3.7)
Epistaxis	1 (3.7)	0	1 (3.7)
Skin and subcutaneous tissue disorders			
-Total	5 (18.5)	4 (14.8)	1 (3.7)
Dry skin	3 (11.1)	3 (11.1)	0
Pruritus	1 (3.7)	0	1 (3.7)
Rash	1 (3.7)	1 (3.7)	0

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Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (48.5)	6 (18.2)	10 (30.3)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Anaemia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Diarrhoea	3 (9.1)	2 (6.1)	1 (3.0)
Nausea	1 (3.0)	1 (3.0)	0
Vomiting	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Pyrexia	2 (6.1)	2 (6.1)	0
Fatigue	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	2 (6.1)	0	2 (6.1)
Hypogammaglobulinaemia	2 (6.1)	0	2 (6.1)
Infections and infestations			
-Total	7 (21.2)	3 (9.1)	4 (12.1)
Conjunctivitis	3 (9.1)	1 (3.0)	2 (6.1)
Upper respiratory tract infection	3 (9.1)	2 (6.1)	1 (3.0)
Rhinovirus infection	1 (3.0)	0	1 (3.0)
Investigations			
-Total	4 (12.1)	3 (9.1)	1 (3.0)
Neutrophil count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Platelet count decreased	2 (6.1)	2 (6.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.1)	0	2 (6.1)
Pain in extremity	2 (6.1)	0	2 (6.1)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	1 (3.0)	0	1 (3.0)
Headache	1 (3.0)	0	1 (3.0)
Psychiatric disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Anxiety	2 (6.1)	1 (3.0)	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (12.1)	3 (9.1)	1 (3.0)
Cough	3 (9.1)	2 (6.1)	1 (3.0)
Rhinorrhoea	2 (6.1)	1 (3.0)	1 (3.0)
Epistaxis	1 (3.0)	1 (3.0)	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (3.0)	1 (3.0)	0
Dry skin	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (3.0)	0	1 (3.0)

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Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (41.2)	0	7 (41.2)
Gastrointestinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Constipation	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	2 (11.8)	0	2 (11.8)
Pyrexia	2 (11.8)	0	2 (11.8)
Immune system disorders			
-Total	1 (5.9)	0	1 (5.9)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	4 (23.5)	1 (5.9)	3 (17.6)
Rhinovirus infection	2 (11.8)	0	2 (11.8)
Upper respiratory tract infection	2 (11.8)	0	2 (11.8)
Conjunctivitis	1 (5.9)	1 (5.9)	0
Investigations			
-Total	1 (5.9)	0	1 (5.9)
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)
Musculoskeletal and connective tissue disorders			
-Total	1 (5.9)	0	1 (5.9)
Arthralgia	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Headache	1 (5.9)	0	1 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (5.9)	1 (5.9)	0
Rhinorrhoea	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Rash	2 (11.8)	1 (5.9)	1 (5.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	48 (100)	2 (4.2)	46 (95.8)
Blood and lymphatic system disorders			
-Total	11 (22.9)	4 (8.3)	7 (14.6)
Anaemia	11 (22.9)	4 (8.3)	7 (14.6)
Cardiac disorders			
-Total	7 (14.6)	5 (10.4)	2 (4.2)
Tachycardia	7 (14.6)	5 (10.4)	2 (4.2)
Gastrointestinal disorders			
-Total	34 (70.8)	17 (35.4)	17 (35.4)
Diarrhoea	17 (35.4)	11 (22.9)	6 (12.5)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	17 (35.4)	10 (20.8)	7 (14.6)
Nausea	14 (29.2)	10 (20.8)	4 (8.3)
Abdominal pain	9 (18.8)	3 (6.3)	6 (12.5)
Constipation	8 (16.7)	4 (8.3)	4 (8.3)
General disorders and administration site conditions			
-Total	23 (47.9)	15 (31.3)	8 (16.7)
Pyrexia	15 (31.3)	9 (18.8)	6 (12.5)
Fatigue	10 (20.8)	9 (18.8)	1 (2.1)
Chills	5 (10.4)	3 (6.3)	2 (4.2)
Oedema peripheral	2 (4.2)	2 (4.2)	0
Immune system disorders			
-Total	40 (83.3)	6 (12.5)	34 (70.8)
Cytokine release syndrome	34 (70.8)	7 (14.6)	27 (56.3)
Hypogammaglobulinaemia	17 (35.4)	0	17 (35.4)
Infections and infestations			
-Total	19 (39.6)	7 (14.6)	12 (25.0)
Conjunctivitis	6 (12.5)	2 (4.2)	4 (8.3)
Upper respiratory tract infection	6 (12.5)	3 (6.3)	3 (6.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)
Rhinovirus infection	5 (10.4)	0	5 (10.4)
Investigations			
-Total	22 (45.8)	7 (14.6)	15 (31.3)
Alanine aminotransferase increased	12 (25.0)	3 (6.3)	9 (18.8)
Platelet count decreased	9 (18.8)	5 (10.4)	4 (8.3)
Aspartate aminotransferase increased	8 (16.7)	3 (6.3)	5 (10.4)
Neutrophil count decreased	7 (14.6)	2 (4.2)	5 (10.4)
White blood cell count decreased	6 (12.5)	4 (8.3)	2 (4.2)
Blood immunoglobulin a decreased	5 (10.4)	5 (10.4)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0
Metabolism and nutrition disorders			
-Total	20 (41.7)	10 (20.8)	10 (20.8)
Decreased appetite	10 (20.8)	8 (16.7)	2 (4.2)
Hypokalaemia	7 (14.6)	2 (4.2)	5 (10.4)
Hypophosphataemia	7 (14.6)	4 (8.3)	3 (6.3)
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	4 (8.3)	2 (4.2)	2 (4.2)
Hyperuricaemia	3 (6.3)	2 (4.2)	1 (2.1)
Musculoskeletal and connective tissue disorders			
-Total	24 (50.0)	11 (22.9)	13 (27.1)
Pain in extremity	12 (25.0)	6 (12.5)	6 (12.5)
Arthralgia	9 (18.8)	5 (10.4)	4 (8.3)
Back pain	6 (12.5)	2 (4.2)	4 (8.3)
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)
Nervous system disorders			
-Total	14 (29.2)	8 (16.7)	6 (12.5)
Headache	14 (29.2)	8 (16.7)	6 (12.5)
Psychiatric disorders			
-Total	9 (18.8)	3 (6.3)	6 (12.5)
Anxiety	9 (18.8)	3 (6.3)	6 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	24 (50.0)	18 (37.5)	6 (12.5)
Cough	17 (35.4)	13 (27.1)	4 (8.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasal congestion	6 (12.5)	5 (10.4)	1 (2.1)
Epistaxis	5 (10.4)	4 (8.3)	1 (2.1)
Rhinorrhoea	5 (10.4)	4 (8.3)	1 (2.1)
Oropharyngeal pain	4 (8.3)	4 (8.3)	0
Skin and subcutaneous tissue disorders			
-Total	11 (22.9)	6 (12.5)	5 (10.4)
Dry skin	5 (10.4)	3 (6.3)	2 (4.2)
Rash	4 (8.3)	2 (4.2)	2 (4.2)
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)
Vascular disorders			
-Total	12 (25.0)	5 (10.4)	7 (14.6)
Hypertension	7 (14.6)	3 (6.3)	4 (8.3)
Hypotension	6 (12.5)	2 (4.2)	4 (8.3)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257l
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (96.9)	3 (9.4)	28 (87.5)
Blood and lymphatic system disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Anaemia	8 (25.0)	3 (9.4)	5 (15.6)
Cardiac disorders			
-Total	9 (28.1)	3 (9.4)	6 (18.8)
Tachycardia	9 (28.1)	3 (9.4)	6 (18.8)
Gastrointestinal disorders			
-Total	20 (62.5)	11 (34.4)	9 (28.1)
Vomiting	8 (25.0)	7 (21.9)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	7 (21.9)	5 (15.6)	2 (6.3)
Constipation	6 (18.8)	3 (9.4)	3 (9.4)
Nausea	6 (18.8)	2 (6.3)	4 (12.5)
Abdominal pain	2 (6.3)	0	2 (6.3)
General disorders and administration site conditions			
-Total	19 (59.4)	10 (31.3)	9 (28.1)
Pyrexia	14 (43.8)	6 (18.8)	8 (25.0)
Fatigue	7 (21.9)	5 (15.6)	2 (6.3)
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)
Chills	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	23 (71.9)	5 (15.6)	18 (56.3)
Cytokine release syndrome	23 (71.9)	6 (18.8)	17 (53.1)
Hypogammaglobulinaemia	9 (28.1)	2 (6.3)	7 (21.9)
Infections and infestations			
-Total	10 (31.3)	2 (6.3)	8 (25.0)
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)
Rhinovirus infection	3 (9.4)	0	3 (9.4)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	2 (6.3)	0	2 (6.3)
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)
Investigations			
-Total	15 (46.9)	1 (3.1)	14 (43.8)
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)
Platelet count decreased	6 (18.8)	3 (9.4)	3 (9.4)
White blood cell count decreased	6 (18.8)	0	6 (18.8)
Aspartate aminotransferase increased	5 (15.6)	0	5 (15.6)
Alanine aminotransferase increased	4 (12.5)	1 (3.1)	3 (9.4)
Blood immunoglobulin g decreased	4 (12.5)	1 (3.1)	3 (9.4)
Electrocardiogram qt prolonged	4 (12.5)	2 (6.3)	2 (6.3)
Neutrophil count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			
-Total	20 (62.5)	5 (15.6)	15 (46.9)
Decreased appetite	8 (25.0)	3 (9.4)	5 (15.6)
Hypocalcaemia	8 (25.0)	0	8 (25.0)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	6 (18.8)	6 (18.8)	0
Hypokalaemia	6 (18.8)	1 (3.1)	5 (15.6)
Hypoalbuminaemia	5 (15.6)	0	5 (15.6)
Hyperphosphataemia	4 (12.5)	4 (12.5)	0
Hypophosphataemia	3 (9.4)	0	3 (9.4)
Musculoskeletal and connective tissue disorders			
-Total	10 (31.3)	5 (15.6)	5 (15.6)
Myalgia	5 (15.6)	3 (9.4)	2 (6.3)
Pain in extremity	4 (12.5)	2 (6.3)	2 (6.3)
Arthralgia	2 (6.3)	0	2 (6.3)
Back pain	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	12 (37.5)	5 (15.6)	7 (21.9)
Headache	12 (37.5)	5 (15.6)	7 (21.9)
Psychiatric disorders			
-Total	3 (9.4)	0	3 (9.4)
Anxiety	3 (9.4)	0	3 (9.4)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	10 (31.3)	8 (25.0)	2 (6.3)
Cough	6 (18.8)	5 (15.6)	1 (3.1)
Oropharyngeal pain	4 (12.5)	3 (9.4)	1 (3.1)
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)
Epistaxis	2 (6.3)	0	2 (6.3)
Rhinorrhoea	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	9 (28.1)	5 (15.6)	4 (12.5)
Pruritus	4 (12.5)	1 (3.1)	3 (9.4)
Rash	4 (12.5)	2 (6.3)	2 (6.3)
Dry skin	3 (9.4)	3 (9.4)	0
Vascular disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Hypertension	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	4 (12.5)	1 (3.1)	3 (9.4)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (100)	2 (15.4)	11 (84.6)
Blood and lymphatic system disorders			
-Total	8 (61.5)	3 (23.1)	5 (38.5)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)
Cardiac disorders			
-Total	6 (46.2)	6 (46.2)	0
Tachycardia	6 (46.2)	6 (46.2)	0
Eye disorders			
-Total	1 (7.7)	1 (7.7)	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (69.2)	5 (38.5)	4 (30.8)
Nausea	6 (46.2)	5 (38.5)	1 (7.7)
Vomiting	5 (38.5)	2 (15.4)	3 (23.1)
Diarrhoea	4 (30.8)	4 (30.8)	0
Abdominal pain	2 (15.4)	1 (7.7)	1 (7.7)
Constipation	2 (15.4)	2 (15.4)	0
General disorders and administration site conditions			
-Total	5 (38.5)	4 (30.8)	1 (7.7)
Fatigue	5 (38.5)	4 (30.8)	1 (7.7)
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)
Hepatobiliary disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hepatic function abnormal	2 (15.4)	1 (7.7)	1 (7.7)
Immune system disorders			
-Total	11 (84.6)	1 (7.7)	10 (76.9)
Cytokine release syndrome	10 (76.9)	1 (7.7)	9 (69.2)
Hypogammaglobulinaemia	2 (15.4)	0	2 (15.4)
Investigations			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (76.9)	2 (15.4)	8 (61.5)
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)
Platelet count decreased	5 (38.5)	3 (23.1)	2 (15.4)
Blood immunoglobulin a decreased	4 (30.8)	4 (30.8)	0
Blood immunoglobulin m decreased	4 (30.8)	4 (30.8)	0
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)
Alanine aminotransferase increased	3 (23.1)	0	3 (23.1)
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)
Neutrophil count decreased	3 (23.1)	0	3 (23.1)
White blood cell count decreased	3 (23.1)	1 (7.7)	2 (15.4)
Aspartate aminotransferase increased	2 (15.4)	0	2 (15.4)
Blood bilirubin increased	2 (15.4)	2 (15.4)	0
Lymphocyte count decreased	2 (15.4)	1 (7.7)	1 (7.7)
Serum ferritin increased	2 (15.4)	0	2 (15.4)
Metabolism and nutrition disorders			
-Total	6 (46.2)	4 (30.8)	2 (15.4)
Decreased appetite	5 (38.5)	4 (30.8)	1 (7.7)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (15.4)	2 (15.4)	0
Hyperuricaemia	1 (7.7)	1 (7.7)	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)
Hypokalaemia	1 (7.7)	0	1 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	8 (61.5)	6 (46.2)	2 (15.4)
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)
Arthralgia	2 (15.4)	2 (15.4)	0
Nervous system disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Headache	3 (23.1)	2 (15.4)	1 (7.7)
Psychiatric disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)
Confusional state	2 (15.4)	2 (15.4)	0
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (61.5)	8 (61.5)	0
Oropharyngeal pain	3 (23.1)	3 (23.1)	0
Cough	2 (15.4)	2 (15.4)	0
Rhinorrhoea	2 (15.4)	2 (15.4)	0
Tachypnoea	2 (15.4)	2 (15.4)	0
Pleural effusion	1 (7.7)	1 (7.7)	0
Skin and subcutaneous tissue disorders			
-Total	4 (30.8)	4 (30.8)	0
Pruritus	2 (15.4)	2 (15.4)	0
Rash papular	2 (15.4)	2 (15.4)	0
Dry skin	1 (7.7)	1 (7.7)	0
Vascular disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)
Hypertension	1 (7.7)	1 (7.7)	0

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Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

		All patients N=67	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	64 (95.5)	6 (9.0)	58 (86.6)
Blood and lymphatic system disorders			
-Total	8 (11.9)	2 (3.0)	6 (9.0)
Anaemia	8 (11.9)	2 (3.0)	6 (9.0)
Cardiac disorders			
-Total	9 (13.4)	1 (1.5)	8 (11.9)
Tachycardia	9 (13.4)	1 (1.5)	8 (11.9)
Eye disorders			
-Total	1 (1.5)	1 (1.5)	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	36 (53.7)	19 (28.4)	17 (25.4)
Vomiting	15 (22.4)	10 (14.9)	5 (7.5)
Diarrhoea	10 (14.9)	4 (6.0)	6 (9.0)
Nausea	10 (14.9)	5 (7.5)	5 (7.5)
Constipation	9 (13.4)	4 (6.0)	5 (7.5)
Abdominal pain	8 (11.9)	2 (3.0)	6 (9.0)
General disorders and administration site conditions			
-Total	23 (34.3)	14 (20.9)	9 (13.4)
Pyrexia	16 (23.9)	9 (13.4)	7 (10.4)
Face oedema	7 (10.4)	5 (7.5)	2 (3.0)
Fatigue	6 (9.0)	5 (7.5)	1 (1.5)
Hepatobiliary disorders			
-Total	3 (4.5)	0	3 (4.5)
Hepatic function abnormal	3 (4.5)	0	3 (4.5)
Immune system disorders			
-Total	49 (73.1)	11 (16.4)	38 (56.7)
Cytokine release syndrome	47 (70.1)	12 (17.9)	35 (52.2)
Hypogammaglobulinaemia	14 (20.9)	2 (3.0)	12 (17.9)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	7 (10.4)	1 (1.5)	6 (9.0)
Conjunctivitis	5 (7.5)	1 (1.5)	4 (6.0)
Rhinovirus infection	2 (3.0)	0	2 (3.0)
Investigations			
-Total	28 (41.8)	5 (7.5)	23 (34.3)
Alanine aminotransferase increased	13 (19.4)	4 (6.0)	9 (13.4)
Aspartate aminotransferase increased	11 (16.4)	3 (4.5)	8 (11.9)
Platelet count decreased	8 (11.9)	3 (4.5)	5 (7.5)
White blood cell count decreased	5 (7.5)	2 (3.0)	3 (4.5)
Serum ferritin increased	4 (6.0)	1 (1.5)	3 (4.5)
Blood bilirubin increased	3 (4.5)	0	3 (4.5)
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)
Neutrophil count decreased	3 (4.5)	0	3 (4.5)
Activated partial thromboplastin time prolonged	2 (3.0)	1 (1.5)	1 (1.5)
Blood fibrinogen decreased	2 (3.0)	0	2 (3.0)
Lymphocyte count decreased	2 (3.0)	1 (1.5)	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)
Blood immunoglobulin m decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	28 (41.8)	9 (13.4)	19 (28.4)
Hypocalcaemia	12 (17.9)	2 (3.0)	10 (14.9)
Hypokalaemia	11 (16.4)	3 (4.5)	8 (11.9)
Hypoalbuminaemia	9 (13.4)	0	9 (13.4)
Hypophosphataemia	9 (13.4)	4 (6.0)	5 (7.5)
Decreased appetite	8 (11.9)	5 (7.5)	3 (4.5)
Hyperuricaemia	6 (9.0)	5 (7.5)	1 (1.5)
Hyperphosphataemia	2 (3.0)	2 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	18 (26.9)	7 (10.4)	11 (16.4)
Arthralgia	7 (10.4)	2 (3.0)	5 (7.5)
Pain in extremity	6 (9.0)	2 (3.0)	4 (6.0)
Back pain	5 (7.5)	2 (3.0)	3 (4.5)
Myalgia	5 (7.5)	4 (6.0)	1 (1.5)
Nervous system disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (26.9)	10 (14.9)	8 (11.9)
Headache	18 (26.9)	10 (14.9)	8 (11.9)
Psychiatric disorders			
-Total	7 (10.4)	5 (7.5)	2 (3.0)
Confusional state	5 (7.5)	5 (7.5)	0
Anxiety	2 (3.0)	0	2 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (20.9)	11 (16.4)	3 (4.5)
Cough	8 (11.9)	7 (10.4)	1 (1.5)
Nasal congestion	3 (4.5)	2 (3.0)	1 (1.5)
Pleural effusion	3 (4.5)	3 (4.5)	0
Tachypnoea	3 (4.5)	2 (3.0)	1 (1.5)
Oropharyngeal pain	2 (3.0)	2 (3.0)	0
Skin and subcutaneous tissue disorders			
-Total	9 (13.4)	2 (3.0)	7 (10.4)
Rash	5 (7.5)	2 (3.0)	3 (4.5)
Pruritus	4 (6.0)	0	4 (6.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash papular	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	14 (20.9)	5 (7.5)	9 (13.4)
Hypertension	9 (13.4)	4 (6.0)	5 (7.5)
Hypotension	7 (10.4)	1 (1.5)	6 (9.0)

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (84.6)	5 (38.5)	6 (46.2)
Blood and lymphatic system disorders			
-Total	1 (7.7)	1 (7.7)	0
Anaemia	1 (7.7)	1 (7.7)	0
Eye disorders			
-Total	1 (7.7)	1 (7.7)	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	3 (23.1)	3 (23.1)	0
Vomiting	2 (15.4)	2 (15.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	1 (7.7)	1 (7.7)	0
Constipation	1 (7.7)	1 (7.7)	0
Diarrhoea	1 (7.7)	1 (7.7)	0
Nausea	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			
-Total	2 (15.4)	2 (15.4)	0
Fatigue	2 (15.4)	2 (15.4)	0
Immune system disorders			
-Total	3 (23.1)	0	3 (23.1)
Hypogammaglobulinaemia	3 (23.1)	0	3 (23.1)
Investigations			
-Total	7 (53.8)	4 (30.8)	3 (23.1)
Lymphocyte count decreased	2 (15.4)	1 (7.7)	1 (7.7)
Neutrophil count decreased	2 (15.4)	1 (7.7)	1 (7.7)
White blood cell count decreased	2 (15.4)	2 (15.4)	0
Alanine aminotransferase increased	1 (7.7)	1 (7.7)	0
Blood bilirubin increased	1 (7.7)	0	1 (7.7)
Blood immunoglobulin a decreased	1 (7.7)	1 (7.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	2 (15.4)	2 (15.4)	0
Decreased appetite	1 (7.7)	1 (7.7)	0
Hyperuricaemia	1 (7.7)	1 (7.7)	0
Nervous system disorders			
-Total	2 (15.4)	2 (15.4)	0
Headache	2 (15.4)	2 (15.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (38.5)	4 (30.8)	1 (7.7)
Cough	3 (23.1)	3 (23.1)	0
Rhinorrhoea	3 (23.1)	3 (23.1)	0
Nasal congestion	2 (15.4)	2 (15.4)	0
Pleural effusion	1 (7.7)	0	1 (7.7)
Skin and subcutaneous tissue disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Dry skin	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	46 (74.2)	11 (17.7)	35 (56.5)
Blood and lymphatic system disorders			
-Total	4 (6.5)	3 (4.8)	1 (1.6)
Anaemia	4 (6.5)	3 (4.8)	1 (1.6)
Cardiac disorders			
-Total	2 (3.2)	2 (3.2)	0
Tachycardia	2 (3.2)	2 (3.2)	0
Gastrointestinal disorders			
-Total	11 (17.7)	6 (9.7)	5 (8.1)
Diarrhoea	6 (9.7)	5 (8.1)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	4 (6.5)	2 (3.2)	2 (3.2)
Vomiting	4 (6.5)	4 (6.5)	0
Constipation	2 (3.2)	0	2 (3.2)
Abdominal pain	1 (1.6)	0	1 (1.6)
General disorders and administration site conditions			
-Total	17 (27.4)	11 (17.7)	6 (9.7)
Pyrexia	13 (21.0)	7 (11.3)	6 (9.7)
Fatigue	4 (6.5)	4 (6.5)	0
Immune system disorders			
-Total	7 (11.3)	0	7 (11.3)
Hypogammaglobulinaemia	7 (11.3)	0	7 (11.3)
Infections and infestations			
-Total	11 (17.7)	2 (3.2)	9 (14.5)
Upper respiratory tract infection	7 (11.3)	3 (4.8)	4 (6.5)
Rhinovirus infection	4 (6.5)	0	4 (6.5)
Conjunctivitis	1 (1.6)	0	1 (1.6)
Investigations			
-Total	10 (16.1)	4 (6.5)	6 (9.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	7 (11.3)	3 (4.8)	4 (6.5)
Neutrophil count decreased	4 (6.5)	1 (1.6)	3 (4.8)
Platelet count decreased	3 (4.8)	2 (3.2)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	0	1 (1.6)
Lymphocyte count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	7 (11.3)	2 (3.2)	5 (8.1)
Decreased appetite	4 (6.5)	1 (1.6)	3 (4.8)
Hyperuricaemia	2 (3.2)	2 (3.2)	0
Hypokalaemia	2 (3.2)	0	2 (3.2)
Hypophosphataemia	1 (1.6)	0	1 (1.6)
Musculoskeletal and connective tissue disorders			
-Total	10 (16.1)	5 (8.1)	5 (8.1)
Back pain	4 (6.5)	2 (3.2)	2 (3.2)
Pain in extremity	4 (6.5)	2 (3.2)	2 (3.2)
Arthralgia	3 (4.8)	2 (3.2)	1 (1.6)
Myalgia	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	8 (12.9)	4 (6.5)	4 (6.5)
Headache	8 (12.9)	4 (6.5)	4 (6.5)
Psychiatric disorders			
-Total	6 (9.7)	1 (1.6)	5 (8.1)
Anxiety	6 (9.7)	1 (1.6)	5 (8.1)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (17.7)	7 (11.3)	4 (6.5)
Cough	8 (12.9)	5 (8.1)	3 (4.8)
Nasal congestion	4 (6.5)	3 (4.8)	1 (1.6)
Oropharyngeal pain	2 (3.2)	1 (1.6)	1 (1.6)
Pleural effusion	1 (1.6)	1 (1.6)	0
Skin and subcutaneous tissue disorders			
-Total	8 (12.9)	6 (9.7)	2 (3.2)
Dry skin	4 (6.5)	3 (4.8)	1 (1.6)
Rash	4 (6.5)	3 (4.8)	1 (1.6)
Pruritus	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	2 (3.2)	1 (1.6)	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)
Hypotension	1 (1.6)	1 (1.6)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	2 (25.0)	4 (50.0)
Immune system disorders			
-Total	2 (25.0)	0	2 (25.0)
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)
Infections and infestations			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	1 (12.5)	1 (12.5)
Conjunctivitis	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	2 (25.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	2 (25.0)	2 (25.0)	0
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Cough	1 (12.5)	1 (12.5)	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (38.1)	4 (9.5)	12 (28.6)
Blood and lymphatic system disorders			
-Total	1 (2.4)	0	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders			
-Total	5 (11.9)	4 (9.5)	1 (2.4)
Diarrhoea	4 (9.5)	3 (7.1)	1 (2.4)
Constipation	1 (2.4)	1 (2.4)	0
Nausea	1 (2.4)	1 (2.4)	0
Vomiting	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (11.9)	2 (4.8)	3 (7.1)
Pyrexia	4 (9.5)	2 (4.8)	2 (4.8)
Fatigue	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	1 (2.4)	0	1 (2.4)
Hypogammaglobulinaemia	1 (2.4)	0	1 (2.4)
Infections and infestations			
-Total	8 (19.0)	3 (7.1)	5 (11.9)
Conjunctivitis	3 (7.1)	2 (4.8)	1 (2.4)
Rhinovirus infection	3 (7.1)	0	3 (7.1)
Upper respiratory tract infection	3 (7.1)	1 (2.4)	2 (4.8)
Investigations			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Neutrophil count decreased	1 (2.4)	0	1 (2.4)
Platelet count decreased	1 (2.4)	1 (2.4)	0
Musculoskeletal and connective tissue disorders			

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (7.1)	0	3 (7.1)
Pain in extremity	2 (4.8)	0	2 (4.8)
Arthralgia	1 (2.4)	0	1 (2.4)
Nervous system disorders			
-Total	2 (4.8)	0	2 (4.8)
Headache	2 (4.8)	0	2 (4.8)
Psychiatric disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Anxiety	2 (4.8)	1 (2.4)	1 (2.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (9.5)	1 (2.4)	3 (7.1)
Cough	3 (7.1)	2 (4.8)	1 (2.4)
Rhinorrhoea	2 (4.8)	0	2 (4.8)
Oropharyngeal pain	1 (2.4)	1 (2.4)	0
Pleural effusion	1 (2.4)	0	1 (2.4)
Skin and subcutaneous tissue disorders			
-Total	3 (7.1)	2 (4.8)	1 (2.4)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rash	2 (4.8)	1 (2.4)	1 (2.4)
Dry skin	1 (2.4)	1 (2.4)	0
Vascular disorders			
-Total	1 (2.4)	0	1 (2.4)
Hypertension	1 (2.4)	0	1 (2.4)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (100)	0	13 (100)
Blood and lymphatic system disorders			
-Total	8 (61.5)	3 (23.1)	5 (38.5)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)
Cardiac disorders			
-Total	6 (46.2)	6 (46.2)	0
Tachycardia	6 (46.2)	6 (46.2)	0
Eye disorders			
-Total	2 (15.4)	2 (15.4)	0
Ocular hyperaemia	2 (15.4)	2 (15.4)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	10 (76.9)	6 (46.2)	4 (30.8)
Nausea	7 (53.8)	6 (46.2)	1 (7.7)
Vomiting	6 (46.2)	3 (23.1)	3 (23.1)
Diarrhoea	5 (38.5)	5 (38.5)	0
Abdominal pain	3 (23.1)	2 (15.4)	1 (7.7)
Constipation	3 (23.1)	3 (23.1)	0
General disorders and administration site conditions			
-Total	6 (46.2)	5 (38.5)	1 (7.7)
Fatigue	6 (46.2)	5 (38.5)	1 (7.7)
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)
Hepatobiliary disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hepatic function abnormal	2 (15.4)	1 (7.7)	1 (7.7)
Immune system disorders			
-Total	12 (92.3)	1 (7.7)	11 (84.6)
Cytokine release syndrome	10 (76.9)	1 (7.7)	9 (69.2)
Hypogammaglobulinaemia	6 (46.2)	0	6 (46.2)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	3 (23.1)	1 (7.7)	2 (15.4)
Upper respiratory tract infection	2 (15.4)	1 (7.7)	1 (7.7)
Conjunctivitis	1 (7.7)	0	1 (7.7)
Investigations			
-Total	10 (76.9)	1 (7.7)	9 (69.2)
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)
Platelet count decreased	6 (46.2)	4 (30.8)	2 (15.4)
Blood immunoglobulin a decreased	5 (38.5)	5 (38.5)	0
Neutrophil count decreased	5 (38.5)	2 (15.4)	3 (23.1)
Blood immunoglobulin m decreased	4 (30.8)	4 (30.8)	0
White blood cell count decreased	4 (30.8)	2 (15.4)	2 (15.4)
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)
Alanine aminotransferase increased	3 (23.1)	0	3 (23.1)
Blood bilirubin increased	3 (23.1)	2 (15.4)	1 (7.7)
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)
Lymphocyte count decreased	3 (23.1)	1 (7.7)	2 (15.4)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	2 (15.4)	0	2 (15.4)
Serum ferritin increased	2 (15.4)	0	2 (15.4)
Metabolism and nutrition disorders			
-Total	7 (53.8)	5 (38.5)	2 (15.4)
Decreased appetite	6 (46.2)	5 (38.5)	1 (7.7)
Hyperphosphataemia	2 (15.4)	2 (15.4)	0
Hyperuricaemia	2 (15.4)	2 (15.4)	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)
Hypokalaemia	1 (7.7)	0	1 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	8 (61.5)	6 (46.2)	2 (15.4)
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)
Arthralgia	2 (15.4)	2 (15.4)	0
Nervous system disorders			
-Total	4 (30.8)	3 (23.1)	1 (7.7)
Headache	4 (30.8)	3 (23.1)	1 (7.7)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)
Confusional state	2 (15.4)	2 (15.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (76.9)	9 (69.2)	1 (7.7)
Cough	4 (30.8)	4 (30.8)	0
Rhinorrhoea	4 (30.8)	4 (30.8)	0
Oropharyngeal pain	3 (23.1)	3 (23.1)	0
Nasal congestion	2 (15.4)	2 (15.4)	0
Pleural effusion	2 (15.4)	1 (7.7)	1 (7.7)
Tachypnoea	2 (15.4)	2 (15.4)	0
Skin and subcutaneous tissue disorders			
-Total	4 (30.8)	3 (23.1)	1 (7.7)
Dry skin	3 (23.1)	2 (15.4)	1 (7.7)
Pruritus	2 (15.4)	2 (15.4)	0
Rash papular	2 (15.4)	2 (15.4)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vascular disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)
Hypertension	1 (7.7)	1 (7.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257m
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

		All patients N=67	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	66 (98.5)	3 (4.5)	63 (94.0)
Blood and lymphatic system disorders			
-Total	11 (16.4)	4 (6.0)	7 (10.4)
Anaemia	11 (16.4)	4 (6.0)	7 (10.4)
Cardiac disorders			
-Total	10 (14.9)	2 (3.0)	8 (11.9)
Tachycardia	10 (14.9)	2 (3.0)	8 (11.9)
Eye disorders			
-Total	1 (1.5)	1 (1.5)	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	44 (65.7)	22 (32.8)	22 (32.8)
Diarrhoea	19 (28.4)	11 (16.4)	8 (11.9)
Vomiting	19 (28.4)	14 (20.9)	5 (7.5)
Nausea	13 (19.4)	6 (9.0)	7 (10.4)
Constipation	11 (16.4)	4 (6.0)	7 (10.4)
Abdominal pain	8 (11.9)	1 (1.5)	7 (10.4)
General disorders and administration site conditions			
-Total	34 (50.7)	18 (26.9)	16 (23.9)
Pyrexia	26 (38.8)	13 (19.4)	13 (19.4)
Fatigue	11 (16.4)	9 (13.4)	2 (3.0)
Face oedema	7 (10.4)	5 (7.5)	2 (3.0)
Hepatobiliary disorders			
-Total	3 (4.5)	0	3 (4.5)
Hepatic function abnormal	3 (4.5)	0	3 (4.5)
Immune system disorders			
-Total	51 (76.1)	10 (14.9)	41 (61.2)
Cytokine release syndrome	47 (70.1)	12 (17.9)	35 (52.2)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	20 (29.9)	2 (3.0)	18 (26.9)
Infections and infestations			
-Total	22 (32.8)	5 (7.5)	17 (25.4)
Upper respiratory tract infection	10 (14.9)	4 (6.0)	6 (9.0)
Rhinovirus infection	8 (11.9)	0	8 (11.9)
Conjunctivitis	7 (10.4)	2 (3.0)	5 (7.5)
Investigations			
-Total	29 (43.3)	4 (6.0)	25 (37.3)
Alanine aminotransferase increased	13 (19.4)	4 (6.0)	9 (13.4)
Aspartate aminotransferase increased	11 (16.4)	3 (4.5)	8 (11.9)
Platelet count decreased	9 (13.4)	4 (6.0)	5 (7.5)
White blood cell count decreased	8 (11.9)	2 (3.0)	6 (9.0)
Neutrophil count decreased	6 (9.0)	1 (1.5)	5 (7.5)
Blood bilirubin increased	4 (6.0)	0	4 (6.0)
Serum ferritin increased	4 (6.0)	1 (1.5)	3 (4.5)
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)
Lymphocyte count decreased	3 (4.5)	1 (1.5)	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Activated partial thromboplastin time prolonged	2 (3.0)	1 (1.5)	1 (1.5)
Blood fibrinogen decreased	2 (3.0)	0	2 (3.0)
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)
Blood immunoglobulin m decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	33 (49.3)	10 (14.9)	23 (34.3)
Decreased appetite	12 (17.9)	6 (9.0)	6 (9.0)
Hypocalcaemia	12 (17.9)	2 (3.0)	10 (14.9)
Hypokalaemia	12 (17.9)	3 (4.5)	9 (13.4)
Hypophosphataemia	10 (14.9)	4 (6.0)	6 (9.0)
Hypoalbuminaemia	9 (13.4)	0	9 (13.4)
Hyperuricaemia	7 (10.4)	6 (9.0)	1 (1.5)
Hyperphosphataemia	2 (3.0)	2 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	26 (38.8)	10 (14.9)	16 (23.9)
Pain in extremity	11 (16.4)	4 (6.0)	7 (10.4)
Arthralgia	9 (13.4)	3 (4.5)	6 (9.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	7 (10.4)	2 (3.0)	5 (7.5)
Myalgia	6 (9.0)	4 (6.0)	2 (3.0)
Nervous system disorders			
-Total	22 (32.8)	10 (14.9)	12 (17.9)
Headache	22 (32.8)	10 (14.9)	12 (17.9)
Psychiatric disorders			
-Total	14 (20.9)	6 (9.0)	8 (11.9)
Anxiety	10 (14.9)	2 (3.0)	8 (11.9)
Confusional state	5 (7.5)	5 (7.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	26 (38.8)	17 (25.4)	9 (13.4)
Cough	19 (28.4)	14 (20.9)	5 (7.5)
Nasal congestion	7 (10.4)	5 (7.5)	2 (3.0)
Oropharyngeal pain	5 (7.5)	4 (6.0)	1 (1.5)
Pleural effusion	4 (6.0)	3 (4.5)	1 (1.5)
Tachypnoea	3 (4.5)	2 (3.0)	1 (1.5)
Rhinorrhoea	2 (3.0)	0	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	17 (25.4)	8 (11.9)	9 (13.4)
Rash	8 (11.9)	4 (6.0)	4 (6.0)
Dry skin	5 (7.5)	4 (6.0)	1 (1.5)
Pruritus	5 (7.5)	0	5 (7.5)
Rash papular	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	17 (25.4)	6 (9.0)	11 (16.4)
Hypertension	11 (16.4)	4 (6.0)	7 (10.4)
Hypotension	8 (11.9)	2 (3.0)	6 (9.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	24 (92.3)	3 (11.5)	21 (80.8)
Blood and lymphatic system disorders			
-Total	7 (26.9)	3 (11.5)	4 (15.4)
Anaemia	7 (26.9)	3 (11.5)	4 (15.4)
Cardiac disorders			
-Total	5 (19.2)	3 (11.5)	2 (7.7)
Tachycardia	5 (19.2)	3 (11.5)	2 (7.7)
Eye disorders			
-Total	2 (7.7)	2 (7.7)	0
Ocular hyperaemia	2 (7.7)	2 (7.7)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (42.3)	7 (26.9)	4 (15.4)
Constipation	5 (19.2)	5 (19.2)	0
Diarrhoea	4 (15.4)	2 (7.7)	2 (7.7)
Nausea	4 (15.4)	2 (7.7)	2 (7.7)
Vomiting	4 (15.4)	2 (7.7)	2 (7.7)
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)
General disorders and administration site conditions			
-Total	10 (38.5)	5 (19.2)	5 (19.2)
Pyrexia	8 (30.8)	4 (15.4)	4 (15.4)
Face oedema	3 (11.5)	1 (3.8)	2 (7.7)
Fatigue	3 (11.5)	2 (7.7)	1 (3.8)
Immune system disorders			
-Total	20 (76.9)	4 (15.4)	16 (61.5)
Cytokine release syndrome	18 (69.2)	5 (19.2)	13 (50.0)
Hypogammaglobulinaemia	7 (26.9)	1 (3.8)	6 (23.1)
Infections and infestations			
-Total	4 (15.4)	1 (3.8)	3 (11.5)
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	11 (42.3)	1 (3.8)	10 (38.5)
Alanine aminotransferase increased	5 (19.2)	2 (7.7)	3 (11.5)
Platelet count decreased	5 (19.2)	2 (7.7)	3 (11.5)
White blood cell count decreased	4 (15.4)	1 (3.8)	3 (11.5)
Aspartate aminotransferase increased	3 (11.5)	1 (3.8)	2 (7.7)
International normalised ratio increased	3 (11.5)	3 (11.5)	0
Blood immunoglobulin g decreased	2 (7.7)	1 (3.8)	1 (3.8)
Neutrophil count decreased	2 (7.7)	0	2 (7.7)
Blood bilirubin increased	1 (3.8)	0	1 (3.8)
Metabolism and nutrition disorders			
-Total	9 (34.6)	3 (11.5)	6 (23.1)
Hypocalcaemia	5 (19.2)	0	5 (19.2)
Decreased appetite	3 (11.5)	2 (7.7)	1 (3.8)
Hyperuricaemia	3 (11.5)	3 (11.5)	0
Hypokalaemia	3 (11.5)	1 (3.8)	2 (7.7)
Hypophosphataemia	3 (11.5)	1 (3.8)	2 (7.7)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	4 (15.4)	2 (7.7)	2 (7.7)
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)
Pain in extremity	2 (7.7)	2 (7.7)	0
Arthralgia	1 (3.8)	0	1 (3.8)
Nervous system disorders			
-Total	4 (15.4)	3 (11.5)	1 (3.8)
Headache	4 (15.4)	3 (11.5)	1 (3.8)
Psychiatric disorders			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Anxiety	2 (7.7)	1 (3.8)	1 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (23.1)	4 (15.4)	2 (7.7)
Cough	3 (11.5)	2 (7.7)	1 (3.8)
Nasal congestion	2 (7.7)	1 (3.8)	1 (3.8)
Epistaxis	1 (3.8)	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	4 (15.4)	3 (11.5)	1 (3.8)
Rash	3 (11.5)	2 (7.7)	1 (3.8)
Erythema	2 (7.7)	2 (7.7)	0
Pruritus	1 (3.8)	0	1 (3.8)
Vascular disorders			
-Total	4 (15.4)	2 (7.7)	2 (7.7)
Hypotension	3 (11.5)	1 (3.8)	2 (7.7)
Hypertension	1 (3.8)	1 (3.8)	0

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Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	53 (98.1)	6 (11.1)	47 (87.0)
Blood and lymphatic system disorders			
-Total	9 (16.7)	2 (3.7)	7 (13.0)
Anaemia	9 (16.7)	2 (3.7)	7 (13.0)
Cardiac disorders			
-Total	10 (18.5)	4 (7.4)	6 (11.1)
Tachycardia	10 (18.5)	4 (7.4)	6 (11.1)
Gastrointestinal disorders			
-Total	34 (63.0)	17 (31.5)	17 (31.5)
Vomiting	16 (29.6)	10 (18.5)	6 (11.1)
Nausea	12 (22.2)	8 (14.8)	4 (7.4)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	10 (18.5)	6 (11.1)	4 (7.4)
Abdominal pain	7 (13.0)	2 (3.7)	5 (9.3)
Constipation	6 (11.1)	1 (1.9)	5 (9.3)
General disorders and administration site conditions			
-Total	21 (38.9)	15 (27.8)	6 (11.1)
Pyrexia	11 (20.4)	7 (13.0)	4 (7.4)
Fatigue	8 (14.8)	7 (13.0)	1 (1.9)
Chills	6 (11.1)	4 (7.4)	2 (3.7)
Oedema peripheral	5 (9.3)	4 (7.4)	1 (1.9)
Face oedema	4 (7.4)	4 (7.4)	0
Immune system disorders			
-Total	40 (74.1)	8 (14.8)	32 (59.3)
Cytokine release syndrome	39 (72.2)	8 (14.8)	31 (57.4)
Hypogammaglobulinaemia	9 (16.7)	1 (1.9)	8 (14.8)
Infections and infestations			
-Total	3 (5.6)	0	3 (5.6)
Rhinovirus infection	2 (3.7)	0	2 (3.7)
Conjunctivitis	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	21 (38.9)	5 (9.3)	16 (29.6)
Alanine aminotransferase increased	11 (20.4)	2 (3.7)	9 (16.7)
Aspartate aminotransferase increased	10 (18.5)	2 (3.7)	8 (14.8)
Platelet count decreased	8 (14.8)	4 (7.4)	4 (7.4)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)
Blood bilirubin increased	4 (7.4)	2 (3.7)	2 (3.7)
Neutrophil count decreased	4 (7.4)	0	4 (7.4)
White blood cell count decreased	4 (7.4)	2 (3.7)	2 (3.7)
Metabolism and nutrition disorders			
-Total	24 (44.4)	9 (16.7)	15 (27.8)
Decreased appetite	10 (18.5)	7 (13.0)	3 (5.6)
Hypokalaemia	9 (16.7)	2 (3.7)	7 (13.0)
Hypoalbuminaemia	8 (14.8)	0	8 (14.8)
Hypocalcaemia	7 (13.0)	2 (3.7)	5 (9.3)
Hypophosphataemia	6 (11.1)	3 (5.6)	3 (5.6)
Hyperuricaemia	4 (7.4)	3 (5.6)	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	19 (35.2)	11 (20.4)	8 (14.8)
Pain in extremity	9 (16.7)	4 (7.4)	5 (9.3)
Arthralgia	8 (14.8)	4 (7.4)	4 (7.4)
Myalgia	7 (13.0)	5 (9.3)	2 (3.7)
Nervous system disorders			
-Total	17 (31.5)	9 (16.7)	8 (14.8)
Headache	17 (31.5)	9 (16.7)	8 (14.8)
Psychiatric disorders			
-Total	7 (13.0)	2 (3.7)	5 (9.3)
Agitation	5 (9.3)	2 (3.7)	3 (5.6)
Anxiety	2 (3.7)	0	2 (3.7)
Renal and urinary disorders			
-Total	4 (7.4)	1 (1.9)	3 (5.6)
Acute kidney injury	4 (7.4)	1 (1.9)	3 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (25.9)	13 (24.1)	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	7 (13.0)	7 (13.0)	0
Oropharyngeal pain	5 (9.3)	5 (9.3)	0
Epistaxis	2 (3.7)	1 (1.9)	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders			
-Total	9 (16.7)	4 (7.4)	5 (9.3)
Pruritus	5 (9.3)	2 (3.7)	3 (5.6)
Erythema	2 (3.7)	2 (3.7)	0
Rash	2 (3.7)	0	2 (3.7)
Dry skin	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	13 (24.1)	5 (9.3)	8 (14.8)
Hypertension	9 (16.7)	4 (7.4)	5 (9.3)
Hypotension	6 (11.1)	1 (1.9)	5 (9.3)

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Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (68.0)	3 (12.0)	14 (56.0)
Blood and lymphatic system disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Anaemia	3 (12.0)	2 (8.0)	1 (4.0)
Cardiac disorders			
-Total	1 (4.0)	1 (4.0)	0
Tachycardia	1 (4.0)	1 (4.0)	0
Eye disorders			
-Total	1 (4.0)	1 (4.0)	0
Ocular hyperaemia	1 (4.0)	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	5 (20.0)	5 (20.0)	0
Diarrhoea	4 (16.0)	4 (16.0)	0
Vomiting	3 (12.0)	3 (12.0)	0
Nausea	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	6 (24.0)	5 (20.0)	1 (4.0)
Pyrexia	4 (16.0)	3 (12.0)	1 (4.0)
Fatigue	2 (8.0)	2 (8.0)	0
Immune system disorders			
-Total	5 (20.0)	0	5 (20.0)
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)
Infections and infestations			
-Total	4 (16.0)	1 (4.0)	3 (12.0)
Upper respiratory tract infection	3 (12.0)	2 (8.0)	1 (4.0)
Conjunctivitis	1 (4.0)	0	1 (4.0)
Nasopharyngitis	1 (4.0)	0	1 (4.0)
Rhinovirus infection	1 (4.0)	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	5 (20.0)	2 (8.0)	3 (12.0)
White blood cell count decreased	4 (16.0)	2 (8.0)	2 (8.0)
Neutrophil count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Platelet count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Metabolism and nutrition disorders			
-Total	4 (16.0)	1 (4.0)	3 (12.0)
Decreased appetite	3 (12.0)	1 (4.0)	2 (8.0)
Hypokalaemia	1 (4.0)	0	1 (4.0)
Hypophosphataemia	1 (4.0)	0	1 (4.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (4.0)	1 (4.0)	0
Pain in extremity	1 (4.0)	1 (4.0)	0
Nervous system disorders			
-Total	5 (20.0)	3 (12.0)	2 (8.0)
Headache	5 (20.0)	3 (12.0)	2 (8.0)
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (16.0)	2 (8.0)	2 (8.0)
Cough	2 (8.0)	1 (4.0)	1 (4.0)
Epistaxis	2 (8.0)	1 (4.0)	1 (4.0)
Nasal congestion	2 (8.0)	2 (8.0)	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)
Skin and subcutaneous tissue disorders			
-Total	3 (12.0)	1 (4.0)	2 (8.0)
Dry skin	1 (4.0)	0	1 (4.0)
Erythema	1 (4.0)	0	1 (4.0)
Rash	1 (4.0)	1 (4.0)	0
Vascular disorders			
-Total	1 (4.0)	1 (4.0)	0
Hypotension	1 (4.0)	1 (4.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (78.0)	10 (20.0)	29 (58.0)
Blood and lymphatic system disorders			
-Total	2 (4.0)	2 (4.0)	0
Anaemia	2 (4.0)	2 (4.0)	0
Cardiac disorders			
-Total	1 (2.0)	1 (2.0)	0
Tachycardia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	9 (18.0)	4 (8.0)	5 (10.0)
Nausea	4 (8.0)	2 (4.0)	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	3 (6.0)	1 (2.0)	2 (4.0)
Diarrhoea	3 (6.0)	2 (4.0)	1 (2.0)
Vomiting	3 (6.0)	3 (6.0)	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)
General disorders and administration site conditions			
-Total	14 (28.0)	9 (18.0)	5 (10.0)
Pyrexia	9 (18.0)	4 (8.0)	5 (10.0)
Fatigue	4 (8.0)	4 (8.0)	0
Chills	1 (2.0)	1 (2.0)	0
Oedema peripheral	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	5 (10.0)	0	5 (10.0)
Hypogammaglobulinaemia	5 (10.0)	0	5 (10.0)
Infections and infestations			
-Total	16 (32.0)	5 (10.0)	11 (22.0)
Nasopharyngitis	6 (12.0)	4 (8.0)	2 (4.0)
Upper respiratory tract infection	4 (8.0)	1 (2.0)	3 (6.0)
Rhinovirus infection	3 (6.0)	0	3 (6.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	3 (6.0)	0	3 (6.0)
Investigations			
-Total	11 (22.0)	5 (10.0)	6 (12.0)
White blood cell count decreased	5 (10.0)	3 (6.0)	2 (4.0)
Neutrophil count decreased	4 (8.0)	1 (2.0)	3 (6.0)
Alanine aminotransferase increased	2 (4.0)	2 (4.0)	0
Blood bilirubin increased	2 (4.0)	0	2 (4.0)
Platelet count decreased	2 (4.0)	2 (4.0)	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	5 (10.0)	3 (6.0)	2 (4.0)
Hyperuricaemia	3 (6.0)	3 (6.0)	0
Decreased appetite	2 (4.0)	1 (2.0)	1 (2.0)
Hypokalaemia	1 (2.0)	0	1 (2.0)
Musculoskeletal and connective tissue disorders			
-Total	6 (12.0)	3 (6.0)	3 (6.0)
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)
Pain in extremity	3 (6.0)	1 (2.0)	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	5 (10.0)	3 (6.0)	2 (4.0)
Headache	5 (10.0)	3 (6.0)	2 (4.0)
Psychiatric disorders			
-Total	6 (12.0)	1 (2.0)	5 (10.0)
Anxiety	6 (12.0)	1 (2.0)	5 (10.0)
Agitation	1 (2.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Acute kidney injury	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (20.0)	7 (14.0)	3 (6.0)
Cough	9 (18.0)	7 (14.0)	2 (4.0)
Nasal congestion	4 (8.0)	3 (6.0)	1 (2.0)
Epistaxis	1 (2.0)	0	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	8 (16.0)	6 (12.0)	2 (4.0)
Dry skin	5 (10.0)	4 (8.0)	1 (2.0)
Rash	3 (6.0)	2 (4.0)	1 (2.0)
Pruritus	1 (2.0)	0	1 (2.0)
Vascular disorders			
-Total	1 (2.0)	0	1 (2.0)
Hypertension	1 (2.0)	0	1 (2.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (55.0)	1 (5.0)	10 (50.0)
Gastrointestinal disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Diarrhoea	3 (15.0)	2 (10.0)	1 (5.0)
Constipation	1 (5.0)	1 (5.0)	0
Nausea	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Pyrexia	3 (15.0)	1 (5.0)	2 (10.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	6 (30.0)	2 (10.0)	4 (20.0)
Sinusitis	3 (15.0)	0	3 (15.0)
Rhinovirus infection	2 (10.0)	0	2 (10.0)
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)
Conjunctivitis	1 (5.0)	1 (5.0)	0
Investigations			
-Total	2 (10.0)	0	2 (10.0)
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)
Neutrophil count decreased	1 (5.0)	0	1 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	0	1 (5.0)
Pain in extremity	1 (5.0)	0	1 (5.0)
Psychiatric disorders			

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)
Skin and subcutaneous tissue disorders			
-Total	2 (10.0)	2 (10.0)	0
Dry skin	1 (5.0)	1 (5.0)	0
Rash	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypertension	1 (5.0)	0	1 (5.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (40.0)	4 (13.3)	8 (26.7)
Blood and lymphatic system disorders			
-Total	1 (3.3)	0	1 (3.3)
Anaemia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	1 (3.3)	1 (3.3)	0
Diarrhoea	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	1 (3.3)	1 (3.3)	0
Pyrexia	1 (3.3)	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	2 (6.7)	0	2 (6.7)
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)
Infections and infestations			
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)
Sinusitis	3 (10.0)	0	3 (10.0)
Upper respiratory tract infection	3 (10.0)	1 (3.3)	2 (6.7)
Rhinovirus infection	1 (3.3)	0	1 (3.3)
Investigations			
-Total	3 (10.0)	3 (10.0)	0
Neutrophil count decreased	2 (6.7)	2 (6.7)	0
Platelet count decreased	2 (6.7)	2 (6.7)	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.7)	0	2 (6.7)
Arthralgia	1 (3.3)	0	1 (3.3)
Pain in extremity	1 (3.3)	0	1 (3.3)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	2 (6.7)	0	2 (6.7)
Headache	2 (6.7)	0	2 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	3 (10.0)	0
Cough	2 (6.7)	2 (6.7)	0
Epistaxis	1 (3.3)	1 (3.3)	0
Oropharyngeal pain	1 (3.3)	1 (3.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (3.3)	0	1 (3.3)
Rash	1 (3.3)	0	1 (3.3)

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Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	25 (96.2)	0	25 (96.2)
Blood and lymphatic system disorders			
-Total	7 (26.9)	3 (11.5)	4 (15.4)
Anaemia	7 (26.9)	3 (11.5)	4 (15.4)
Cardiac disorders			
-Total	5 (19.2)	3 (11.5)	2 (7.7)
Tachycardia	5 (19.2)	3 (11.5)	2 (7.7)
Eye disorders			
-Total	3 (11.5)	3 (11.5)	0
Ocular hyperaemia	3 (11.5)	3 (11.5)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	15 (57.7)	10 (38.5)	5 (19.2)
Diarrhoea	10 (38.5)	7 (26.9)	3 (11.5)
Vomiting	7 (26.9)	5 (19.2)	2 (7.7)
Constipation	5 (19.2)	5 (19.2)	0
Nausea	5 (19.2)	3 (11.5)	2 (7.7)
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)
General disorders and administration site conditions			
-Total	15 (57.7)	7 (26.9)	8 (30.8)
Pyrexia	11 (42.3)	5 (19.2)	6 (23.1)
Fatigue	5 (19.2)	3 (11.5)	2 (7.7)
Face oedema	3 (11.5)	1 (3.8)	2 (7.7)
Immune system disorders			
-Total	21 (80.8)	3 (11.5)	18 (69.2)
Cytokine release syndrome	18 (69.2)	5 (19.2)	13 (50.0)
Hypogammaglobulinaemia	12 (46.2)	1 (3.8)	11 (42.3)
Infections and infestations			
-Total	11 (42.3)	3 (11.5)	8 (30.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	5 (19.2)	3 (11.5)	2 (7.7)
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)
Rhinovirus infection	3 (11.5)	0	3 (11.5)
Sinusitis	3 (11.5)	0	3 (11.5)
Nasopharyngitis	1 (3.8)	0	1 (3.8)
Investigations			
-Total	13 (50.0)	1 (3.8)	12 (46.2)
White blood cell count decreased	6 (23.1)	1 (3.8)	5 (19.2)
Alanine aminotransferase increased	5 (19.2)	2 (7.7)	3 (11.5)
Platelet count decreased	5 (19.2)	2 (7.7)	3 (11.5)
Neutrophil count decreased	4 (15.4)	1 (3.8)	3 (11.5)
Aspartate aminotransferase increased	3 (11.5)	1 (3.8)	2 (7.7)
Blood immunoglobulin g decreased	3 (11.5)	1 (3.8)	2 (7.7)
International normalised ratio increased	3 (11.5)	3 (11.5)	0
Blood bilirubin increased	1 (3.8)	0	1 (3.8)
Metabolism and nutrition disorders			
-Total	12 (46.2)	4 (15.4)	8 (30.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	6 (23.1)	3 (11.5)	3 (11.5)
Hypocalcaemia	5 (19.2)	0	5 (19.2)
Hypophosphataemia	4 (15.4)	1 (3.8)	3 (11.5)
Hyperuricaemia	3 (11.5)	3 (11.5)	0
Hypokalaemia	3 (11.5)	1 (3.8)	2 (7.7)
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	6 (23.1)	3 (11.5)	3 (11.5)
Pain in extremity	4 (15.4)	3 (11.5)	1 (3.8)
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)
Arthralgia	1 (3.8)	0	1 (3.8)
Nervous system disorders			
-Total	8 (30.8)	5 (19.2)	3 (11.5)
Headache	8 (30.8)	5 (19.2)	3 (11.5)
Psychiatric disorders			
-Total	4 (15.4)	2 (7.7)	2 (7.7)
Anxiety	4 (15.4)	2 (7.7)	2 (7.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	11 (42.3)	6 (23.1)	5 (19.2)
Cough	6 (23.1)	3 (11.5)	3 (11.5)
Nasal congestion	4 (15.4)	3 (11.5)	1 (3.8)
Epistaxis	3 (11.5)	2 (7.7)	1 (3.8)
Oropharyngeal pain	1 (3.8)	0	1 (3.8)
Skin and subcutaneous tissue disorders			
-Total	8 (30.8)	5 (19.2)	3 (11.5)
Rash	4 (15.4)	3 (11.5)	1 (3.8)
Erythema	3 (11.5)	2 (7.7)	1 (3.8)
Dry skin	2 (7.7)	1 (3.8)	1 (3.8)
Pruritus	1 (3.8)	0	1 (3.8)
Vascular disorders			
-Total	6 (23.1)	3 (11.5)	3 (11.5)
Hypotension	4 (15.4)	2 (7.7)	2 (7.7)
Hypertension	2 (7.7)	1 (3.8)	1 (3.8)

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Table 257n
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	54 (100)	5 (9.3)	49 (90.7)
Blood and lymphatic system disorders			
-Total	12 (22.2)	4 (7.4)	8 (14.8)
Anaemia	12 (22.2)	4 (7.4)	8 (14.8)
Cardiac disorders			
-Total	11 (20.4)	5 (9.3)	6 (11.1)
Tachycardia	11 (20.4)	5 (9.3)	6 (11.1)
Gastrointestinal disorders			
-Total	39 (72.2)	18 (33.3)	21 (38.9)
Vomiting	18 (33.3)	12 (22.2)	6 (11.1)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	15 (27.8)	9 (16.7)	6 (11.1)
Diarrhoea	14 (25.9)	9 (16.7)	5 (9.3)
Constipation	9 (16.7)	2 (3.7)	7 (13.0)
Abdominal pain	8 (14.8)	2 (3.7)	6 (11.1)
General disorders and administration site conditions			
-Total	28 (51.9)	18 (33.3)	10 (18.5)
Pyrexia	18 (33.3)	10 (18.5)	8 (14.8)
Fatigue	12 (22.2)	11 (20.4)	1 (1.9)
Chills	7 (13.0)	5 (9.3)	2 (3.7)
Oedema peripheral	6 (11.1)	5 (9.3)	1 (1.9)
Face oedema	4 (7.4)	4 (7.4)	0
Immune system disorders			
-Total	42 (77.8)	8 (14.8)	34 (63.0)
Cytokine release syndrome	39 (72.2)	8 (14.8)	31 (57.4)
Hypogammaglobulinaemia	14 (25.9)	1 (1.9)	13 (24.1)
Infections and infestations			
-Total	20 (37.0)	6 (11.1)	14 (25.9)
Upper respiratory tract infection	7 (13.0)	2 (3.7)	5 (9.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	6 (11.1)	4 (7.4)	2 (3.7)
Rhinovirus infection	5 (9.3)	0	5 (9.3)
Conjunctivitis	4 (7.4)	1 (1.9)	3 (5.6)
Sinusitis	3 (5.6)	0	3 (5.6)
Investigations			
-Total	23 (42.6)	5 (9.3)	18 (33.3)
Alanine aminotransferase increased	11 (20.4)	2 (3.7)	9 (16.7)
Aspartate aminotransferase increased	10 (18.5)	2 (3.7)	8 (14.8)
Platelet count decreased	10 (18.5)	6 (11.1)	4 (7.4)
Neutrophil count decreased	7 (13.0)	2 (3.7)	5 (9.3)
Blood bilirubin increased	6 (11.1)	2 (3.7)	4 (7.4)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)
White blood cell count decreased	6 (11.1)	3 (5.6)	3 (5.6)
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	27 (50.0)	10 (18.5)	17 (31.5)
Decreased appetite	12 (22.2)	8 (14.8)	4 (7.4)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	10 (18.5)	2 (3.7)	8 (14.8)
Hypoalbuminaemia	8 (14.8)	0	8 (14.8)
Hypocalcaemia	7 (13.0)	2 (3.7)	5 (9.3)
Hyperuricaemia	6 (11.1)	5 (9.3)	1 (1.9)
Hypophosphataemia	6 (11.1)	3 (5.6)	3 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	23 (42.6)	13 (24.1)	10 (18.5)
Pain in extremity	12 (22.2)	5 (9.3)	7 (13.0)
Arthralgia	10 (18.5)	5 (9.3)	5 (9.3)
Myalgia	8 (14.8)	5 (9.3)	3 (5.6)
Nervous system disorders			
-Total	18 (33.3)	8 (14.8)	10 (18.5)
Headache	18 (33.3)	8 (14.8)	10 (18.5)
Psychiatric disorders			
-Total	13 (24.1)	3 (5.6)	10 (18.5)
Anxiety	8 (14.8)	1 (1.9)	7 (13.0)
Agitation	6 (11.1)	3 (5.6)	3 (5.6)
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (11.1)	2 (3.7)	4 (7.4)
Acute kidney injury	6 (11.1)	2 (3.7)	4 (7.4)
Respiratory, thoracic and mediastinal disorders			
-Total	22 (40.7)	19 (35.2)	3 (5.6)
Cough	17 (31.5)	15 (27.8)	2 (3.7)
Oropharyngeal pain	7 (13.0)	7 (13.0)	0
Nasal congestion	5 (9.3)	4 (7.4)	1 (1.9)
Epistaxis	4 (7.4)	2 (3.7)	2 (3.7)
Skin and subcutaneous tissue disorders			
-Total	15 (27.8)	8 (14.8)	7 (13.0)
Dry skin	6 (11.1)	5 (9.3)	1 (1.9)
Pruritus	6 (11.1)	2 (3.7)	4 (7.4)
Rash	4 (7.4)	1 (1.9)	3 (5.6)
Erythema	2 (3.7)	2 (3.7)	0
Vascular disorders			
-Total	14 (25.9)	5 (9.3)	9 (16.7)
Hypertension	10 (18.5)	4 (7.4)	6 (11.1)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	6 (11.1)	1 (1.9)	5 (9.3)

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (90.9)	3 (27.3)	7 (63.6)
Blood and lymphatic system disorders			
-Total	1 (9.1)	0	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Abdominal pain	1 (9.1)	1 (9.1)	0
Constipation	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)
Immune system disorders			
-Total	6 (54.5)	2 (18.2)	4 (36.4)
Cytokine release syndrome	6 (54.5)	2 (18.2)	4 (36.4)
Hypogammaglobulinaemia	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	1 (9.1)	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)
Investigations			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	1 (9.1)	0
Decreased appetite	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (9.1)	0	1 (9.1)
Arthralgia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	2 (18.2)	1 (9.1)	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Rash	1 (9.1)	1 (9.1)	0

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	67 (97.1)	6 (8.7)	61 (88.4)
Blood and lymphatic system disorders			
-Total	15 (21.7)	5 (7.2)	10 (14.5)
Anaemia	15 (21.7)	5 (7.2)	10 (14.5)
Cardiac disorders			
-Total	15 (21.7)	7 (10.1)	8 (11.6)
Tachycardia	15 (21.7)	7 (10.1)	8 (11.6)
Gastrointestinal disorders			
-Total	42 (60.9)	21 (30.4)	21 (30.4)
Vomiting	19 (27.5)	11 (15.9)	8 (11.6)
Nausea	16 (23.2)	10 (14.5)	6 (8.7)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	14 (20.3)	8 (11.6)	6 (8.7)
Constipation	10 (14.5)	5 (7.2)	5 (7.2)
Abdominal pain	9 (13.0)	2 (2.9)	7 (10.1)
General disorders and administration site conditions			
-Total	23 (33.3)	14 (20.3)	9 (13.0)
Pyrexia	15 (21.7)	8 (11.6)	7 (10.1)
Fatigue	11 (15.9)	9 (13.0)	2 (2.9)
Chills	6 (8.7)	4 (5.8)	2 (2.9)
Immune system disorders			
-Total	54 (78.3)	10 (14.5)	44 (63.8)
Cytokine release syndrome	51 (73.9)	11 (15.9)	40 (58.0)
Hypogammaglobulinaemia	15 (21.7)	1 (1.4)	14 (20.3)
Infections and infestations			
-Total	6 (8.7)	1 (1.4)	5 (7.2)
Conjunctivitis	4 (5.8)	1 (1.4)	3 (4.3)
Rhinovirus infection	2 (2.9)	0	2 (2.9)
Investigations			
-Total	29 (42.0)	5 (7.2)	24 (34.8)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	13 (18.8)	3 (4.3)	10 (14.5)
Platelet count decreased	13 (18.8)	6 (8.7)	7 (10.1)
Aspartate aminotransferase increased	12 (17.4)	2 (2.9)	10 (14.5)
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)
White blood cell count decreased	8 (11.6)	3 (4.3)	5 (7.2)
Neutrophil count decreased	6 (8.7)	0	6 (8.7)
Blood bilirubin increased	5 (7.2)	2 (2.9)	3 (4.3)
Metabolism and nutrition disorders			
-Total	32 (46.4)	11 (15.9)	21 (30.4)
Decreased appetite	12 (17.4)	8 (11.6)	4 (5.8)
Hypocalcaemia	12 (17.4)	2 (2.9)	10 (14.5)
Hypokalaemia	12 (17.4)	3 (4.3)	9 (13.0)
Hypoalbuminaemia	10 (14.5)	0	10 (14.5)
Hypophosphataemia	9 (13.0)	4 (5.8)	5 (7.2)
Hyperuricaemia	7 (10.1)	6 (8.7)	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	25 (36.2)	13 (18.8)	12 (17.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	11 (15.9)	6 (8.7)	5 (7.2)
Myalgia	9 (13.0)	6 (8.7)	3 (4.3)
Arthralgia	8 (11.6)	4 (5.8)	4 (5.8)
Back pain	5 (7.2)	2 (2.9)	3 (4.3)
Nervous system disorders			
-Total	19 (27.5)	11 (15.9)	8 (11.6)
Headache	19 (27.5)	11 (15.9)	8 (11.6)
Psychiatric disorders			
-Total	4 (5.8)	1 (1.4)	3 (4.3)
Anxiety	4 (5.8)	1 (1.4)	3 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (24.6)	15 (21.7)	2 (2.9)
Cough	10 (14.5)	9 (13.0)	1 (1.4)
Oropharyngeal pain	5 (7.2)	5 (7.2)	0
Nasal congestion	3 (4.3)	2 (2.9)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	10 (14.5)	4 (5.8)	6 (8.7)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	6 (8.7)	2 (2.9)	4 (5.8)
Rash	4 (5.8)	1 (1.4)	3 (4.3)
Dry skin	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	17 (24.6)	7 (10.1)	10 (14.5)
Hypertension	10 (14.5)	5 (7.2)	5 (7.2)
Hypotension	9 (13.0)	2 (2.9)	7 (10.1)

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Anaemia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Constipation	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	2 (18.2)	2 (18.2)	0
Pyrexia	2 (18.2)	2 (18.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypogammaglobulinaemia	3 (27.3)	0	3 (27.3)
Infections and infestations			
-Total	1 (9.1)	0	1 (9.1)
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Back pain	2 (18.2)	1 (9.1)	1 (9.1)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	2 (18.2)	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Rash	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypotension	1 (9.1)	1 (9.1)	0

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	49 (76.6)	12 (18.8)	37 (57.8)
Blood and lymphatic system disorders			
-Total	4 (6.3)	3 (4.7)	1 (1.6)
Anaemia	4 (6.3)	3 (4.7)	1 (1.6)
Cardiac disorders			
-Total	2 (3.1)	2 (3.1)	0
Tachycardia	2 (3.1)	2 (3.1)	0
Gastrointestinal disorders			
-Total	12 (18.8)	9 (14.1)	3 (4.7)
Diarrhoea	7 (10.9)	6 (9.4)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	6 (9.4)	6 (9.4)	0
Nausea	5 (7.8)	3 (4.7)	2 (3.1)
Abdominal pain	2 (3.1)	1 (1.6)	1 (1.6)
Constipation	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	18 (28.1)	11 (17.2)	7 (10.9)
Pyrexia	11 (17.2)	5 (7.8)	6 (9.4)
Fatigue	6 (9.4)	6 (9.4)	0
Chills	1 (1.6)	1 (1.6)	0
Pain	1 (1.6)	0	1 (1.6)
Immune system disorders			
-Total	7 (10.9)	0	7 (10.9)
Hypogammaglobulinaemia	7 (10.9)	0	7 (10.9)
Infections and infestations			
-Total	19 (29.7)	6 (9.4)	13 (20.3)
Nasopharyngitis	7 (10.9)	4 (6.3)	3 (4.7)
Upper respiratory tract infection	6 (9.4)	3 (4.7)	3 (4.7)
Rhinovirus infection	4 (6.3)	0	4 (6.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	3 (4.7)	0	3 (4.7)
Conjunctivitis	1 (1.6)	0	1 (1.6)
Investigations			
-Total	15 (23.4)	7 (10.9)	8 (12.5)
White blood cell count decreased	9 (14.1)	5 (7.8)	4 (6.3)
Neutrophil count decreased	6 (9.4)	2 (3.1)	4 (6.3)
Platelet count decreased	4 (6.3)	3 (4.7)	1 (1.6)
Alanine aminotransferase increased	2 (3.1)	2 (3.1)	0
Blood bilirubin increased	2 (3.1)	0	2 (3.1)
Metabolism and nutrition disorders			
-Total	8 (12.5)	4 (6.3)	4 (6.3)
Decreased appetite	5 (7.8)	2 (3.1)	3 (4.7)
Hyperuricaemia	3 (4.7)	3 (4.7)	0
Hypokalaemia	2 (3.1)	0	2 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	8 (12.5)	4 (6.3)	4 (6.3)
Pain in extremity	4 (6.3)	2 (3.1)	2 (3.1)
Arthralgia	3 (4.7)	2 (3.1)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	2 (3.1)	1 (1.6)	1 (1.6)
Myalgia	1 (1.6)	0	1 (1.6)
Nervous system disorders			
-Total	8 (12.5)	5 (7.8)	3 (4.7)
Headache	8 (12.5)	5 (7.8)	3 (4.7)
Psychiatric disorders			
-Total	6 (9.4)	1 (1.6)	5 (7.8)
Anxiety	6 (9.4)	1 (1.6)	5 (7.8)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (18.8)	9 (14.1)	3 (4.7)
Cough	10 (15.6)	8 (12.5)	2 (3.1)
Nasal congestion	6 (9.4)	5 (7.8)	1 (1.6)
Oropharyngeal pain	2 (3.1)	1 (1.6)	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	9 (14.1)	6 (9.4)	3 (4.7)
Dry skin	6 (9.4)	4 (6.3)	2 (3.1)
Rash	3 (4.7)	2 (3.1)	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	1 (1.6)	0	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (33.3)	0	3 (33.3)
Gastrointestinal disorders			
-Total	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Pain	2 (22.2)	1 (11.1)	1 (11.1)
Pyrexia	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	2 (22.2)	0	2 (22.2)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	2 (22.2)	0	2 (22.2)
Rhinovirus infection	1 (11.1)	0	1 (11.1)
Investigations			
-Total	1 (11.1)	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Anxiety	2 (22.2)	1 (11.1)	1 (11.1)
Vascular disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypertension	1 (11.1)	0	1 (11.1)

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Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (46.3)	5 (12.2)	14 (34.1)
Blood and lymphatic system disorders			
-Total	1 (2.4)	0	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders			
-Total	4 (9.8)	3 (7.3)	1 (2.4)
Diarrhoea	3 (7.3)	2 (4.9)	1 (2.4)
Constipation	1 (2.4)	1 (2.4)	0
Nausea	1 (2.4)	1 (2.4)	0
Vomiting	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	4 (9.8)	1 (2.4)	3 (7.3)
Pyrexia	3 (7.3)	1 (2.4)	2 (4.9)
Fatigue	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	3 (7.3)	0	3 (7.3)
Hypogammaglobulinaemia	3 (7.3)	0	3 (7.3)
Infections and infestations			
-Total	11 (26.8)	4 (9.8)	7 (17.1)
Upper respiratory tract infection	5 (12.2)	2 (4.9)	3 (7.3)
Conjunctivitis	4 (9.8)	2 (4.9)	2 (4.9)
Sinusitis	4 (9.8)	0	4 (9.8)
Rhinovirus infection	2 (4.9)	0	2 (4.9)
Investigations			
-Total	3 (7.3)	3 (7.3)	0
Neutrophil count decreased	2 (4.9)	2 (4.9)	0
Platelet count decreased	2 (4.9)	2 (4.9)	0
Blood bilirubin increased	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (7.3)	0	3 (7.3)
Pain in extremity	2 (4.9)	0	2 (4.9)
Arthralgia	1 (2.4)	0	1 (2.4)
Nervous system disorders			
-Total	2 (4.9)	0	2 (4.9)
Headache	2 (4.9)	0	2 (4.9)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (9.8)	3 (7.3)	1 (2.4)
Cough	4 (9.8)	3 (7.3)	1 (2.4)
Oropharyngeal pain	1 (2.4)	1 (2.4)	0
Skin and subcutaneous tissue disorders			
-Total	3 (7.3)	2 (4.9)	1 (2.4)
Rash	2 (4.9)	1 (2.4)	1 (2.4)
Dry skin	1 (2.4)	1 (2.4)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (100)	2 (18.2)	9 (81.8)
Blood and lymphatic system disorders			
-Total	1 (9.1)	0	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Constipation	3 (27.3)	1 (9.1)	2 (18.2)
Abdominal pain	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)
Pain	2 (18.2)	1 (9.1)	1 (9.1)
Immune system disorders			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Cytokine release syndrome	6 (54.5)	2 (18.2)	4 (36.4)
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)
Infections and infestations			
-Total	3 (27.3)	0	3 (27.3)
Sinusitis	2 (18.2)	0	2 (18.2)
Conjunctivitis	1 (9.1)	0	1 (9.1)
Rhinovirus infection	1 (9.1)	0	1 (9.1)
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	2 (18.2)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Decreased appetite	1 (9.1)	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Back pain	2 (18.2)	1 (9.1)	1 (9.1)
Arthralgia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Headache	3 (27.3)	1 (9.1)	2 (18.2)
Psychiatric disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Anxiety	2 (18.2)	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Rash	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypertension	1 (9.1)	0	1 (9.1)
Hypotension	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257o
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	68 (98.6)	3 (4.3)	65 (94.2)
Blood and lymphatic system disorders			
-Total	18 (26.1)	7 (10.1)	11 (15.9)
Anaemia	18 (26.1)	7 (10.1)	11 (15.9)
Cardiac disorders			
-Total	16 (23.2)	8 (11.6)	8 (11.6)
Tachycardia	16 (23.2)	8 (11.6)	8 (11.6)
Gastrointestinal disorders			
-Total	49 (71.0)	25 (36.2)	24 (34.8)
Vomiting	24 (34.8)	16 (23.2)	8 (11.6)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	23 (33.3)	15 (21.7)	8 (11.6)
Nausea	20 (29.0)	12 (17.4)	8 (11.6)
Constipation	11 (15.9)	6 (8.7)	5 (7.2)
Abdominal pain	10 (14.5)	2 (2.9)	8 (11.6)
General disorders and administration site conditions			
-Total	35 (50.7)	18 (26.1)	17 (24.6)
Pyrexia	25 (36.2)	12 (17.4)	13 (18.8)
Fatigue	17 (24.6)	14 (20.3)	3 (4.3)
Chills	7 (10.1)	5 (7.2)	2 (2.9)
Pain	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	56 (81.2)	10 (14.5)	46 (66.7)
Cytokine release syndrome	51 (73.9)	11 (15.9)	40 (58.0)
Hypogammaglobulinaemia	22 (31.9)	1 (1.4)	21 (30.4)
Infections and infestations			
-Total	28 (40.6)	9 (13.0)	19 (27.5)
Upper respiratory tract infection	11 (15.9)	5 (7.2)	6 (8.7)
Conjunctivitis	7 (10.1)	2 (2.9)	5 (7.2)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	7 (10.1)	4 (5.8)	3 (4.3)
Rhinovirus infection	7 (10.1)	0	7 (10.1)
Sinusitis	4 (5.8)	0	4 (5.8)
Investigations			
-Total	31 (44.9)	5 (7.2)	26 (37.7)
Platelet count decreased	15 (21.7)	8 (11.6)	7 (10.1)
Alanine aminotransferase increased	13 (18.8)	3 (4.3)	10 (14.5)
Aspartate aminotransferase increased	12 (17.4)	2 (2.9)	10 (14.5)
White blood cell count decreased	12 (17.4)	4 (5.8)	8 (11.6)
Neutrophil count decreased	10 (14.5)	3 (4.3)	7 (10.1)
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)
Blood bilirubin increased	7 (10.1)	2 (2.9)	5 (7.2)
Metabolism and nutrition disorders			
-Total	37 (53.6)	13 (18.8)	24 (34.8)
Decreased appetite	17 (24.6)	10 (14.5)	7 (10.1)
Hypokalaemia	13 (18.8)	3 (4.3)	10 (14.5)
Hypocalcaemia	12 (17.4)	2 (2.9)	10 (14.5)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	10 (14.5)	0	10 (14.5)
Hyperuricaemia	9 (13.0)	8 (11.6)	1 (1.4)
Hypophosphataemia	9 (13.0)	4 (5.8)	5 (7.2)
Musculoskeletal and connective tissue disorders			
-Total	31 (44.9)	15 (21.7)	16 (23.2)
Pain in extremity	16 (23.2)	8 (11.6)	8 (11.6)
Arthralgia	10 (14.5)	5 (7.2)	5 (7.2)
Myalgia	10 (14.5)	6 (8.7)	4 (5.8)
Back pain	5 (7.2)	1 (1.4)	4 (5.8)
Nervous system disorders			
-Total	23 (33.3)	12 (17.4)	11 (15.9)
Headache	23 (33.3)	12 (17.4)	11 (15.9)
Psychiatric disorders			
-Total	10 (14.5)	2 (2.9)	8 (11.6)
Anxiety	10 (14.5)	2 (2.9)	8 (11.6)
Respiratory, thoracic and mediastinal disorders			
-Total	30 (43.5)	24 (34.8)	6 (8.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	22 (31.9)	18 (26.1)	4 (5.8)
Nasal congestion	9 (13.0)	7 (10.1)	2 (2.9)
Oropharyngeal pain	8 (11.6)	7 (10.1)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	19 (27.5)	10 (14.5)	9 (13.0)
Dry skin	8 (11.6)	6 (8.7)	2 (2.9)
Pruritus	7 (10.1)	2 (2.9)	5 (7.2)
Rash	7 (10.1)	3 (4.3)	4 (5.8)
Vascular disorders			
-Total	18 (26.1)	7 (10.1)	11 (15.9)
Hypertension	11 (15.9)	5 (7.2)	6 (8.7)
Hypotension	9 (13.0)	2 (2.9)	7 (10.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	0	6 (100)
Blood and lymphatic system disorders			
-Total	4 (66.7)	0	4 (66.7)
Anaemia	2 (33.3)	0	2 (33.3)
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)
Splenomegaly	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	2 (33.3)	0	2 (33.3)
Bradycardia	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Ear and labyrinth disorders			
-Total	1 (16.7)	1 (16.7)	0
Ear pruritus	1 (16.7)	1 (16.7)	0
Eye disorders			
-Total	2 (33.3)	2 (33.3)	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0
Periorbital oedema	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Diarrhoea	2 (33.3)	2 (33.3)	0
Anal fissure	1 (16.7)	0	1 (16.7)
Constipation	1 (16.7)	1 (16.7)	0
Enterocolitis	1 (16.7)	0	1 (16.7)
Gingival erythema	1 (16.7)	1 (16.7)	0
Nausea	1 (16.7)	0	1 (16.7)
Vomiting	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Face oedema	2 (33.3)	2 (33.3)	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)
Chills	1 (16.7)	1 (16.7)	0
Fatigue	1 (16.7)	1 (16.7)	0
Localised oedema	1 (16.7)	1 (16.7)	0
Pyrexia	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hepatic function abnormal	1 (16.7)	1 (16.7)	0
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	6 (100)	2 (33.3)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Infections and infestations			

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (33.3)	0	2 (33.3)
Otitis externa	1 (16.7)	0	1 (16.7)
Staphylococcal infection	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	2 (33.3)	0	2 (33.3)
Contusion	1 (16.7)	1 (16.7)	0
Skin abrasion	1 (16.7)	1 (16.7)	0
Transfusion reaction	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	0	1 (16.7)
Investigations			
-Total	6 (100)	1 (16.7)	5 (83.3)
Alanine aminotransferase increased	2 (33.3)	1 (16.7)	1 (16.7)
Platelet count decreased	2 (33.3)	0	2 (33.3)
Serum ferritin increased	2 (33.3)	0	2 (33.3)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0
Cardiac murmur	1 (16.7)	1 (16.7)	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	1 (16.7)	0
White blood cell count decreased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)
Hypokalaemia	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)
Hyperphosphataemia	2 (33.3)	2 (33.3)	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)
Hyperchloraemia	1 (16.7)	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypervolaemia	1 (16.7)	0	1 (16.7)
Hyponatraemia	1 (16.7)	1 (16.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	2 (33.3)	0
Muscle rigidity	1 (16.7)	1 (16.7)	0
Myalgia	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	1 (16.7)	0	1 (16.7)
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)
Headache	1 (16.7)	0	1 (16.7)
Tremor	1 (16.7)	0	1 (16.7)
Psychiatric disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Agitation	1 (16.7)	0	1 (16.7)
Automatism	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0
Delirium	1 (16.7)	0	1 (16.7)
Insomnia	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Irritability	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	1 (16.7)	0	1 (16.7)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Anuria	1 (16.7)	1 (16.7)	0
Azotaemia	1 (16.7)	0	1 (16.7)
Reproductive system and breast disorders			
-Total	1 (16.7)	0	1 (16.7)
Perineal rash	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (83.3)	3 (50.0)	2 (33.3)
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)
Pleural effusion	2 (33.3)	2 (33.3)	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)
Cough	1 (16.7)	1 (16.7)	0
Hypoxia	1 (16.7)	0	1 (16.7)
Nasal discomfort	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)
Respiratory distress	1 (16.7)	0	1 (16.7)
Tachypnoea	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Blister	2 (33.3)	1 (16.7)	1 (16.7)
Dermatitis diaper	1 (16.7)	0	1 (16.7)
Erythema	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	0	1 (16.7)
Scab	1 (16.7)	1 (16.7)	0
Skin discolouration	1 (16.7)	1 (16.7)	0
Skin ulcer	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)
Thrombosis	1 (16.7)	0	1 (16.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	71 (95.9)	7 (9.5)	64 (86.5)
Blood and lymphatic system disorders			
-Total	19 (25.7)	6 (8.1)	13 (17.6)
Anaemia	14 (18.9)	5 (6.8)	9 (12.2)
Disseminated intravascular coagulation	3 (4.1)	0	3 (4.1)
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)
Cardiac disorders			
-Total	15 (20.3)	8 (10.8)	7 (9.5)
Tachycardia	14 (18.9)	7 (9.5)	7 (9.5)
Bradycardia	2 (2.7)	2 (2.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	1 (1.4)	0	1 (1.4)
Hypothyroidism	1 (1.4)	0	1 (1.4)
Eye disorders			
-Total	1 (1.4)	1 (1.4)	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	41 (55.4)	21 (28.4)	20 (27.0)
Vomiting	19 (25.7)	11 (14.9)	8 (10.8)
Nausea	15 (20.3)	10 (13.5)	5 (6.8)
Diarrhoea	12 (16.2)	6 (8.1)	6 (8.1)
Abdominal pain	10 (13.5)	3 (4.1)	7 (9.5)
Constipation	10 (13.5)	5 (6.8)	5 (6.8)
General disorders and administration site conditions			
-Total	27 (36.5)	16 (21.6)	11 (14.9)
Pyrexia	18 (24.3)	10 (13.5)	8 (10.8)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)
Chills	5 (6.8)	3 (4.1)	2 (2.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Face oedema	5 (6.8)	3 (4.1)	2 (2.7)
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)
Localised oedema	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	8 (10.8)	2 (2.7)	6 (8.1)
Hepatic function abnormal	4 (5.4)	0	4 (5.4)
Hyperbilirubinaemia	3 (4.1)	1 (1.4)	2 (2.7)
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	55 (74.3)	10 (13.5)	45 (60.8)
Cytokine release syndrome	52 (70.3)	11 (14.9)	41 (55.4)
Hypogammaglobulinaemia	15 (20.3)	2 (2.7)	13 (17.6)
Haemophagocytic lymphohistiocytosis	1 (1.4)	1 (1.4)	0
Seasonal allergy	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	11 (14.9)	3 (4.1)	8 (10.8)
Conjunctivitis	5 (6.8)	1 (1.4)	4 (5.4)
Nail infection	2 (2.7)	2 (2.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	2 (2.7)	0	2 (2.7)
Staphylococcal infection	2 (2.7)	0	2 (2.7)
Injury, poisoning and procedural complications			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Transfusion reaction	1 (1.4)	1 (1.4)	0
Wound	1 (1.4)	0	1 (1.4)
Investigations			
-Total	34 (45.9)	6 (8.1)	28 (37.8)
Alanine aminotransferase increased	14 (18.9)	3 (4.1)	11 (14.9)
Aspartate aminotransferase increased	13 (17.6)	3 (4.1)	10 (13.5)
Platelet count decreased	11 (14.9)	6 (8.1)	5 (6.8)
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)
White blood cell count decreased	7 (9.5)	2 (2.7)	5 (6.8)
Neutrophil count decreased	6 (8.1)	0	6 (8.1)
Activated partial thromboplastin time prolonged	4 (5.4)	3 (4.1)	1 (1.4)
Blood fibrinogen decreased	4 (5.4)	2 (2.7)	2 (2.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	4 (5.4)	4 (5.4)	0
Lymphocyte count decreased	4 (5.4)	2 (2.7)	2 (2.7)
Serum ferritin increased	4 (5.4)	1 (1.4)	3 (4.1)
Blood lactate dehydrogenase increased	3 (4.1)	2 (2.7)	1 (1.4)
Weight increased	2 (2.7)	1 (1.4)	1 (1.4)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	1 (1.4)	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	29 (39.2)	12 (16.2)	17 (23.0)
Decreased appetite	13 (17.6)	9 (12.2)	4 (5.4)
Hypokalaemia	9 (12.2)	1 (1.4)	8 (10.8)
Hypoalbuminaemia	8 (10.8)	0	8 (10.8)
Hypocalcaemia	8 (10.8)	1 (1.4)	7 (9.5)
Hyperuricaemia	7 (9.5)	6 (8.1)	1 (1.4)
Hypophosphataemia	6 (8.1)	3 (4.1)	3 (4.1)
Hyperphosphataemia	2 (2.7)	2 (2.7)	0
Hyponatraemia	2 (2.7)	2 (2.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypermagnesaemia	1 (1.4)	1 (1.4)	0
Hypervolaemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	23 (31.1)	11 (14.9)	12 (16.2)
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)
Arthralgia	9 (12.2)	4 (5.4)	5 (6.8)
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)
Bone pain	2 (2.7)	0	2 (2.7)
Nervous system disorders			
-Total	23 (31.1)	15 (20.3)	8 (10.8)
Headache	20 (27.0)	12 (16.2)	8 (10.8)
Tremor	5 (6.8)	5 (6.8)	0
Psychiatric disorders			
-Total	17 (23.0)	11 (14.9)	6 (8.1)
Confusional state	6 (8.1)	6 (8.1)	0
Agitation	4 (5.4)	2 (2.7)	2 (2.7)
Anxiety	4 (5.4)	1 (1.4)	3 (4.1)
Delirium	3 (4.1)	2 (2.7)	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)
Irritability	2 (2.7)	2 (2.7)	0
Renal and urinary disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
-Total	24 (32.4)	16 (21.6)	8 (10.8)
Cough	9 (12.2)	8 (10.8)	1 (1.4)
Oropharyngeal pain	5 (6.8)	5 (6.8)	0
Hypoxia	4 (5.4)	0	4 (5.4)
Tachypnoea	4 (5.4)	3 (4.1)	1 (1.4)
Nasal congestion	3 (4.1)	2 (2.7)	1 (1.4)
Pulmonary oedema	3 (4.1)	2 (2.7)	1 (1.4)
Pleural effusion	2 (2.7)	2 (2.7)	0
Rhinorrhoea	2 (2.7)	2 (2.7)	0
Epistaxis	1 (1.4)	1 (1.4)	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Wheezing	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	12 (16.2)	7 (9.5)	5 (6.8)
Rash	5 (6.8)	2 (2.7)	3 (4.1)
Erythema	3 (4.1)	3 (4.1)	0
Rash maculo-papular	2 (2.7)	0	2 (2.7)
Blister	1 (1.4)	1 (1.4)	0
Dry skin	1 (1.4)	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0
Skin ulcer	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	14 (18.9)	5 (6.8)	9 (12.2)
Hypotension	9 (12.2)	2 (2.7)	7 (9.5)
Hypertension	7 (9.5)	3 (4.1)	4 (5.4)

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Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Endocrine disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypothyroidism	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	2 (40.0)	2 (40.0)	0
Constipation	1 (20.0)	1 (20.0)	0
Diarrhoea	1 (20.0)	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (60.0)	3 (60.0)	0
Pyrexia	2 (40.0)	2 (40.0)	0
Fatigue	1 (20.0)	1 (20.0)	0
Hepatobiliary disorders			
-Total	1 (20.0)	1 (20.0)	0
Hypertransaminasaemia	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Cellulitis	1 (20.0)	0	1 (20.0)
Ear infection	1 (20.0)	0	1 (20.0)
Nasopharyngitis	1 (20.0)	1 (20.0)	0
Sinusitis	1 (20.0)	0	1 (20.0)
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Investigations			
-Total	3 (60.0)	0	3 (60.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (20.0)	1 (20.0)	0
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0
Blood thyroid stimulating hormone increased	1 (20.0)	1 (20.0)	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
Weight increased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	0	1 (20.0)
Metabolic syndrome	1 (20.0)	0	1 (20.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (40.0)	2 (40.0)	0
Bone pain	1 (20.0)	1 (20.0)	0
Pain in extremity	1 (20.0)	1 (20.0)	0
Reproductive system and breast disorders			
-Total	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dysmenorrhoea	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Cough	2 (40.0)	1 (20.0)	1 (20.0)
Nasal congestion	2 (40.0)	1 (20.0)	1 (20.0)
Rhinitis allergic	1 (20.0)	0	1 (20.0)
Skin and subcutaneous tissue disorders			
-Total	3 (60.0)	3 (60.0)	0
Eczema	1 (20.0)	1 (20.0)	0
Miliaria	1 (20.0)	1 (20.0)	0
Rash	1 (20.0)	1 (20.0)	0
Skin swelling	1 (20.0)	1 (20.0)	0

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Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

		All patients N=70	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	54 (77.1)	12 (17.1)	42 (60.0)
Blood and lymphatic system disorders			
-Total	5 (7.1)	4 (5.7)	1 (1.4)
Anaemia	5 (7.1)	4 (5.7)	1 (1.4)
Cardiac disorders			
-Total	2 (2.9)	2 (2.9)	0
Tachycardia	2 (2.9)	2 (2.9)	0
Eye disorders			
-Total	1 (1.4)	1 (1.4)	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	12 (17.1)	7 (10.0)	5 (7.1)
Diarrhoea	6 (8.6)	5 (7.1)	1 (1.4)
Nausea	5 (7.1)	3 (4.3)	2 (2.9)
Vomiting	5 (7.1)	5 (7.1)	0
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)
Constipation	2 (2.9)	0	2 (2.9)
General disorders and administration site conditions			
-Total	16 (22.9)	10 (14.3)	6 (8.6)
Pyrexia	11 (15.7)	5 (7.1)	6 (8.6)
Fatigue	5 (7.1)	5 (7.1)	0
Chills	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	9 (12.9)	0	9 (12.9)
Hypogammaglobulinaemia	9 (12.9)	0	9 (12.9)
Infections and infestations			
-Total	19 (27.1)	4 (5.7)	15 (21.4)
Nasopharyngitis	6 (8.6)	3 (4.3)	3 (4.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	6 (8.6)	2 (2.9)	4 (5.7)
Rhinovirus infection	4 (5.7)	0	4 (5.7)
Otitis media	2 (2.9)	0	2 (2.9)
Sinusitis	2 (2.9)	0	2 (2.9)
Conjunctivitis	1 (1.4)	0	1 (1.4)
Ear infection	1 (1.4)	0	1 (1.4)
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Nail infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	2 (2.9)	2 (2.9)	0
Contusion	1 (1.4)	1 (1.4)	0
Skin abrasion	1 (1.4)	1 (1.4)	0
Investigations			
-Total	15 (21.4)	8 (11.4)	7 (10.0)
White blood cell count decreased	7 (10.0)	5 (7.1)	2 (2.9)
Neutrophil count decreased	5 (7.1)	2 (2.9)	3 (4.3)
Platelet count decreased	4 (5.7)	3 (4.3)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Lymphocyte count decreased	2 (2.9)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	1 (1.4)	1 (1.4)	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	9 (12.9)	4 (5.7)	5 (7.1)
Decreased appetite	5 (7.1)	2 (2.9)	3 (4.3)
Hyperuricaemia	3 (4.3)	3 (4.3)	0
Hypokalaemia	2 (2.9)	0	2 (2.9)
Hyperchloraemia	1 (1.4)	1 (1.4)	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	7 (10.0)	3 (4.3)	4 (5.7)
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)
Pain in extremity	3 (4.3)	1 (1.4)	2 (2.9)
Bone pain	1 (1.4)	0	1 (1.4)
Myalgia	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	10 (14.3)	6 (8.6)	4 (5.7)
Headache	10 (14.3)	6 (8.6)	4 (5.7)
Psychiatric disorders			
-Total	6 (8.6)	1 (1.4)	5 (7.1)
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)
Agitation	1 (1.4)	1 (1.4)	0
Delirium	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Acute kidney injury	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	15 (21.4)	10 (14.3)	5 (7.1)
Cough	9 (12.9)	7 (10.0)	2 (2.9)
Nasal congestion	4 (5.7)	4 (5.7)	0
Epistaxis	3 (4.3)	1 (1.4)	2 (2.9)
Rhinorrhoea	3 (4.3)	3 (4.3)	0
Oropharyngeal pain	2 (2.9)	1 (1.4)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)
Dyspnoea	1 (1.4)	0	1 (1.4)
Rhinitis allergic	1 (1.4)	1 (1.4)	0
Skin and subcutaneous tissue disorders			
-Total	9 (12.9)	6 (8.6)	3 (4.3)
Dry skin	6 (8.6)	4 (5.7)	2 (2.9)
Rash	3 (4.3)	2 (2.9)	1 (1.4)
Erythema	1 (1.4)	0	1 (1.4)
Skin discolouration	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)
Hypotension	1 (1.4)	1 (1.4)	0

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Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	1 (25.0)	0	1 (25.0)
Seasonal allergy	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	3 (75.0)	0	3 (75.0)
Upper respiratory tract infection	3 (75.0)	0	3 (75.0)

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	2 (50.0)	0	2 (50.0)
Bronchitis	1 (25.0)	0	1 (25.0)
Folliculitis	1 (25.0)	0	1 (25.0)
Gastroenteritis viral	1 (25.0)	0	1 (25.0)
Nail infection	1 (25.0)	0	1 (25.0)
Rhinovirus infection	1 (25.0)	0	1 (25.0)
Sinusitis	1 (25.0)	0	1 (25.0)
Skin infection	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	1 (25.0)	0
Abdominal injury	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	0	1 (25.0)
Hyperlipidaemia	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Headache	1 (25.0)	0	1 (25.0)

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	0	2 (50.0)
Dyspnoea	1 (25.0)	0	1 (25.0)
Rhinorrhoea	1 (25.0)	0	1 (25.0)
Sleep apnoea syndrome	1 (25.0)	0	1 (25.0)
Wheezing	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Rash	2 (50.0)	1 (25.0)	1 (25.0)
Rash erythematous	1 (25.0)	1 (25.0)	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0

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Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (43.5)	3 (6.5)	17 (37.0)
Blood and lymphatic system disorders			
-Total	1 (2.2)	0	1 (2.2)
Anaemia	1 (2.2)	0	1 (2.2)
Endocrine disorders			
-Total	1 (2.2)	0	1 (2.2)
Hypothyroidism	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	4 (8.7)	3 (6.5)	1 (2.2)
Diarrhoea	4 (8.7)	3 (6.5)	1 (2.2)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (2.2)	1 (2.2)	0
Vomiting	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	5 (10.9)	2 (4.3)	3 (6.5)
Pyrexia	4 (8.7)	2 (4.3)	2 (4.3)
Fatigue	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	5 (10.9)	2 (4.3)	3 (6.5)
Hypogammaglobulinaemia	3 (6.5)	0	3 (6.5)
Seasonal allergy	2 (4.3)	2 (4.3)	0
Infections and infestations			
-Total	11 (23.9)	3 (6.5)	8 (17.4)
Sinusitis	5 (10.9)	0	5 (10.9)
Conjunctivitis	4 (8.7)	2 (4.3)	2 (4.3)
Rhinovirus infection	2 (4.3)	0	2 (4.3)
Skin infection	2 (4.3)	0	2 (4.3)
Upper respiratory tract infection	2 (4.3)	2 (4.3)	0
Bronchitis	1 (2.2)	0	1 (2.2)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	5 (10.9)	3 (6.5)	2 (4.3)
Neutrophil count decreased	3 (6.5)	2 (4.3)	1 (2.2)
Platelet count decreased	2 (4.3)	2 (4.3)	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)
Musculoskeletal and connective tissue disorders			
-Total	3 (6.5)	0	3 (6.5)
Pain in extremity	2 (4.3)	0	2 (4.3)
Arthralgia	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	1 (2.2)	0	1 (2.2)
Headache	1 (2.2)	0	1 (2.2)
Psychiatric disorders			
-Total	2 (4.3)	1 (2.2)	1 (2.2)
Anxiety	2 (4.3)	1 (2.2)	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.0)	4 (8.7)	2 (4.3)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	4 (8.7)	3 (6.5)	1 (2.2)
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)
Dyspnoea	1 (2.2)	1 (2.2)	0
Epistaxis	1 (2.2)	1 (2.2)	0
Oropharyngeal pain	1 (2.2)	1 (2.2)	0
Pleural effusion	1 (2.2)	0	1 (2.2)
Sleep apnoea syndrome	1 (2.2)	1 (2.2)	0
Skin and subcutaneous tissue disorders			
-Total	1 (2.2)	1 (2.2)	0
Dry skin	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	1 (2.2)	0	1 (2.2)
Hypertension	1 (2.2)	0	1 (2.2)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	0	6 (100)
Blood and lymphatic system disorders			
-Total	4 (66.7)	0	4 (66.7)
Anaemia	2 (33.3)	0	2 (33.3)
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)
Splenomegaly	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	2 (33.3)	0	2 (33.3)
Bradycardia	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Ear and labyrinth disorders			
-Total	1 (16.7)	1 (16.7)	0
Ear pruritus	1 (16.7)	1 (16.7)	0
Endocrine disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypothyroidism	1 (16.7)	0	1 (16.7)
Eye disorders			
-Total	2 (33.3)	2 (33.3)	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0
Periorbital oedema	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Diarrhoea	3 (50.0)	3 (50.0)	0
Constipation	2 (33.3)	2 (33.3)	0
Vomiting	2 (33.3)	2 (33.3)	0
Anal fissure	1 (16.7)	0	1 (16.7)
Enterocolitis	1 (16.7)	0	1 (16.7)
Gingival erythema	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (16.7)	0	1 (16.7)
General disorders and administration site conditions			
-Total	4 (66.7)	3 (50.0)	1 (16.7)
Pyrexia	3 (50.0)	3 (50.0)	0
Face oedema	2 (33.3)	2 (33.3)	0
Fatigue	2 (33.3)	2 (33.3)	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)
Chills	1 (16.7)	1 (16.7)	0
Localised oedema	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hepatic function abnormal	1 (16.7)	1 (16.7)	0
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	6 (100)	2 (33.3)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Hypogammaglobulinaemia	2 (33.3)	0	2 (33.3)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	4 (66.7)	0	4 (66.7)
Upper respiratory tract infection	4 (66.7)	1 (16.7)	3 (50.0)
Otitis media	2 (33.3)	0	2 (33.3)
Bronchitis	1 (16.7)	0	1 (16.7)
Cellulitis	1 (16.7)	0	1 (16.7)
Ear infection	1 (16.7)	0	1 (16.7)
Folliculitis	1 (16.7)	0	1 (16.7)
Gastroenteritis viral	1 (16.7)	0	1 (16.7)
Nail infection	1 (16.7)	0	1 (16.7)
Nasopharyngitis	1 (16.7)	1 (16.7)	0
Otitis externa	1 (16.7)	0	1 (16.7)
Rhinovirus infection	1 (16.7)	0	1 (16.7)
Sinusitis	1 (16.7)	0	1 (16.7)
Skin infection	1 (16.7)	0	1 (16.7)
Staphylococcal infection	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Abdominal injury	1 (16.7)	1 (16.7)	0
Contusion	1 (16.7)	1 (16.7)	0
Skin abrasion	1 (16.7)	1 (16.7)	0
Transfusion reaction	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	0	1 (16.7)
Investigations			
-Total	6 (100)	0	6 (100)
Alanine aminotransferase increased	2 (33.3)	1 (16.7)	1 (16.7)
Platelet count decreased	2 (33.3)	0	2 (33.3)
Serum ferritin increased	2 (33.3)	0	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0
Blood lactate dehydrogenase increased	1 (16.7)	1 (16.7)	0
Blood thyroid stimulating hormone increased	1 (16.7)	1 (16.7)	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0
C-reactive protein increased	1 (16.7)	1 (16.7)	0
Cardiac murmur	1 (16.7)	1 (16.7)	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)
Hypokalaemia	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	2 (33.3)	2 (33.3)	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)
Hyperchloraemia	1 (16.7)	1 (16.7)	0
Hyperlipidaemia	1 (16.7)	0	1 (16.7)
Hypermagnesaemia	1 (16.7)	1 (16.7)	0
Hypervolaemia	1 (16.7)	0	1 (16.7)
Hyponatraemia	1 (16.7)	1 (16.7)	0
Metabolic syndrome	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	3 (50.0)	3 (50.0)	0
Bone pain	1 (16.7)	1 (16.7)	0
Muscle rigidity	1 (16.7)	1 (16.7)	0
Myalgia	1 (16.7)	1 (16.7)	0
Pain in extremity	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	1 (16.7)	0	1 (16.7)
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)
Headache	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tremor	1 (16.7)	0	1 (16.7)
Psychiatric disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Agitation	1 (16.7)	0	1 (16.7)
Automatism	1 (16.7)	1 (16.7)	0
Confusional state	1 (16.7)	1 (16.7)	0
Delirium	1 (16.7)	0	1 (16.7)
Insomnia	1 (16.7)	0	1 (16.7)
Irritability	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	1 (16.7)	0	1 (16.7)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Anuria	1 (16.7)	1 (16.7)	0
Azotaemia	1 (16.7)	0	1 (16.7)
Reproductive system and breast disorders			
-Total	1 (16.7)	0	1 (16.7)
Dysmenorrhoea	1 (16.7)	0	1 (16.7)
Perineal rash	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	6 (100)	3 (50.0)	3 (50.0)
Cough	3 (50.0)	2 (33.3)	1 (16.7)
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)
Nasal congestion	2 (33.3)	1 (16.7)	1 (16.7)
Pleural effusion	2 (33.3)	2 (33.3)	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)
Dyspnoea	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	0	1 (16.7)
Nasal discomfort	1 (16.7)	0	1 (16.7)
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)
Respiratory distress	1 (16.7)	0	1 (16.7)
Rhinitis allergic	1 (16.7)	0	1 (16.7)
Rhinorrhoea	1 (16.7)	0	1 (16.7)
Sleep apnoea syndrome	1 (16.7)	0	1 (16.7)
Tachypnoea	1 (16.7)	1 (16.7)	0
Wheezing	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Blister	2 (33.3)	1 (16.7)	1 (16.7)
Rash	2 (33.3)	1 (16.7)	1 (16.7)
Dermatitis diaper	1 (16.7)	0	1 (16.7)
Eczema	1 (16.7)	1 (16.7)	0
Erythema	1 (16.7)	1 (16.7)	0
Miliaria	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	0	1 (16.7)
Rash erythematous	1 (16.7)	1 (16.7)	0
Rash maculo-papular	1 (16.7)	1 (16.7)	0
Scab	1 (16.7)	1 (16.7)	0
Skin discolouration	1 (16.7)	1 (16.7)	0
Skin swelling	1 (16.7)	1 (16.7)	0
Skin ulcer	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Thrombosis	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257p
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	73 (98.6)	2 (2.7)	71 (95.9)
Blood and lymphatic system disorders			
-Total	22 (29.7)	8 (10.8)	14 (18.9)
Anaemia	17 (23.0)	7 (9.5)	10 (13.5)
Disseminated intravascular coagulation	3 (4.1)	0	3 (4.1)
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)
Cardiac disorders			
-Total	15 (20.3)	8 (10.8)	7 (9.5)
Tachycardia	15 (20.3)	8 (10.8)	7 (9.5)
Bradycardia	2 (2.7)	2 (2.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	2 (2.7)	0	2 (2.7)
Hypothyroidism	2 (2.7)	0	2 (2.7)
Eye disorders			
-Total	2 (2.7)	2 (2.7)	0
Ocular hyperaemia	2 (2.7)	2 (2.7)	0
Gastrointestinal disorders			
-Total	49 (66.2)	24 (32.4)	25 (33.8)
Vomiting	23 (31.1)	15 (20.3)	8 (10.8)
Diarrhoea	21 (28.4)	13 (17.6)	8 (10.8)
Nausea	19 (25.7)	12 (16.2)	7 (9.5)
Constipation	12 (16.2)	5 (6.8)	7 (9.5)
Abdominal pain	11 (14.9)	3 (4.1)	8 (10.8)
General disorders and administration site conditions			
-Total	36 (48.6)	18 (24.3)	18 (24.3)
Pyrexia	26 (35.1)	12 (16.2)	14 (18.9)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)
Chills	6 (8.1)	4 (5.4)	2 (2.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Face oedema	5 (6.8)	3 (4.1)	2 (2.7)
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)
Localised oedema	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	8 (10.8)	2 (2.7)	6 (8.1)
Hepatic function abnormal	4 (5.4)	0	4 (5.4)
Hyperbilirubinaemia	3 (4.1)	1 (1.4)	2 (2.7)
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	58 (78.4)	9 (12.2)	49 (66.2)
Cytokine release syndrome	52 (70.3)	11 (14.9)	41 (55.4)
Hypogammaglobulinaemia	24 (32.4)	2 (2.7)	22 (29.7)
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)
Haemophagocytic lymphohistiocytosis	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	29 (39.2)	5 (6.8)	24 (32.4)
Conjunctivitis	8 (10.8)	2 (2.7)	6 (8.1)
Upper respiratory tract infection	8 (10.8)	4 (5.4)	4 (5.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	7 (9.5)	0	7 (9.5)
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)
Sinusitis	5 (6.8)	0	5 (6.8)
Nail infection	3 (4.1)	3 (4.1)	0
Otitis media	2 (2.7)	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)
Staphylococcal infection	2 (2.7)	0	2 (2.7)
Bronchitis	1 (1.4)	0	1 (1.4)
Ear infection	1 (1.4)	0	1 (1.4)
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Contusion	1 (1.4)	1 (1.4)	0
Skin abrasion	1 (1.4)	1 (1.4)	0
Transfusion reaction	1 (1.4)	1 (1.4)	0
Wound	1 (1.4)	0	1 (1.4)
Investigations			

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	36 (48.6)	6 (8.1)	30 (40.5)
Alanine aminotransferase increased	14 (18.9)	3 (4.1)	11 (14.9)
Aspartate aminotransferase increased	13 (17.6)	3 (4.1)	10 (13.5)
Platelet count decreased	13 (17.6)	8 (10.8)	5 (6.8)
Neutrophil count decreased	10 (13.5)	3 (4.1)	7 (9.5)
White blood cell count decreased	10 (13.5)	4 (5.4)	6 (8.1)
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)
Blood immunoglobulin a decreased	5 (6.8)	5 (6.8)	0
Lymphocyte count decreased	5 (6.8)	2 (2.7)	3 (4.1)
Activated partial thromboplastin time prolonged	4 (5.4)	3 (4.1)	1 (1.4)
Blood fibrinogen decreased	4 (5.4)	2 (2.7)	2 (2.7)
Serum ferritin increased	4 (5.4)	1 (1.4)	3 (4.1)
Blood immunoglobulin g decreased	3 (4.1)	0	3 (4.1)
Blood lactate dehydrogenase increased	3 (4.1)	2 (2.7)	1 (1.4)
Weight increased	2 (2.7)	1 (1.4)	1 (1.4)
Blood uric acid increased	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
C-reactive protein increased	1 (1.4)	1 (1.4)	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	35 (47.3)	14 (18.9)	21 (28.4)
Decreased appetite	18 (24.3)	11 (14.9)	7 (9.5)
Hypokalaemia	10 (13.5)	1 (1.4)	9 (12.2)
Hyperuricaemia	9 (12.2)	8 (10.8)	1 (1.4)
Hypoalbuminaemia	8 (10.8)	0	8 (10.8)
Hypocalcaemia	8 (10.8)	1 (1.4)	7 (9.5)
Hypophosphataemia	7 (9.5)	3 (4.1)	4 (5.4)
Hyperphosphataemia	2 (2.7)	2 (2.7)	0
Hyponatraemia	2 (2.7)	2 (2.7)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0
Hypervolaemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	29 (39.2)	13 (17.6)	16 (21.6)
Pain in extremity	15 (20.3)	7 (9.5)	8 (10.8)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	11 (14.9)	5 (6.8)	6 (8.1)
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)
Bone pain	3 (4.1)	0	3 (4.1)
Nervous system disorders			
-Total	28 (37.8)	16 (21.6)	12 (16.2)
Headache	25 (33.8)	13 (17.6)	12 (16.2)
Tremor	5 (6.8)	5 (6.8)	0
Psychiatric disorders			
-Total	24 (32.4)	12 (16.2)	12 (16.2)
Anxiety	12 (16.2)	3 (4.1)	9 (12.2)
Confusional state	6 (8.1)	6 (8.1)	0
Agitation	5 (6.8)	3 (4.1)	2 (2.7)
Delirium	4 (5.4)	2 (2.7)	2 (2.7)
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)
Irritability	2 (2.7)	2 (2.7)	0
Renal and urinary disorders			
-Total	5 (6.8)	2 (2.7)	3 (4.1)
Acute kidney injury	5 (6.8)	2 (2.7)	3 (4.1)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	37 (50.0)	23 (31.1)	14 (18.9)
Cough	20 (27.0)	16 (21.6)	4 (5.4)
Oropharyngeal pain	8 (10.8)	7 (9.5)	1 (1.4)
Nasal congestion	7 (9.5)	6 (8.1)	1 (1.4)
Epistaxis	5 (6.8)	3 (4.1)	2 (2.7)
Rhinorrhoea	5 (6.8)	4 (5.4)	1 (1.4)
Hypoxia	4 (5.4)	0	4 (5.4)
Pleural effusion	4 (5.4)	2 (2.7)	2 (2.7)
Tachypnoea	4 (5.4)	3 (4.1)	1 (1.4)
Pulmonary oedema	3 (4.1)	2 (2.7)	1 (1.4)
Dyspnoea	2 (2.7)	1 (1.4)	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Rhinitis allergic	1 (1.4)	1 (1.4)	0
Sleep apnoea syndrome	1 (1.4)	1 (1.4)	0
Wheezing	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (24.3)	11 (14.9)	7 (9.5)
Dry skin	8 (10.8)	6 (8.1)	2 (2.7)
Rash	6 (8.1)	3 (4.1)	3 (4.1)
Erythema	4 (5.4)	3 (4.1)	1 (1.4)
Rash maculo-papular	2 (2.7)	0	2 (2.7)
Blister	1 (1.4)	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0
Skin discolouration	1 (1.4)	1 (1.4)	0
Skin ulcer	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	17 (23.0)	6 (8.1)	11 (14.9)
Hypotension	10 (13.5)	3 (4.1)	7 (9.5)
Hypertension	9 (12.2)	3 (4.1)	6 (8.1)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	38 (95.0)	5 (12.5)	33 (82.5)
Blood and lymphatic system disorders			
-Total	9 (22.5)	1 (2.5)	8 (20.0)
Anaemia	5 (12.5)	1 (2.5)	4 (10.0)
Disseminated intravascular coagulation	4 (10.0)	0	4 (10.0)
Cardiac disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)
Gastrointestinal disorders			
-Total	22 (55.0)	10 (25.0)	12 (30.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	10 (25.0)	5 (12.5)	5 (12.5)
Diarrhoea	9 (22.5)	3 (7.5)	6 (15.0)
Abdominal pain	7 (17.5)	1 (2.5)	6 (15.0)
Nausea	6 (15.0)	4 (10.0)	2 (5.0)
Constipation	4 (10.0)	2 (5.0)	2 (5.0)
General disorders and administration site conditions			
-Total	14 (35.0)	7 (17.5)	7 (17.5)
Pyrexia	9 (22.5)	4 (10.0)	5 (12.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)
Face oedema	3 (7.5)	2 (5.0)	1 (2.5)
Fatigue	2 (5.0)	2 (5.0)	0
Oedema peripheral	2 (5.0)	1 (2.5)	1 (2.5)
Hepatobiliary disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Hepatic function abnormal	4 (10.0)	1 (2.5)	3 (7.5)
Immune system disorders			
-Total	31 (77.5)	9 (22.5)	22 (55.0)
Cytokine release syndrome	29 (72.5)	9 (22.5)	20 (50.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	8 (20.0)	1 (2.5)	7 (17.5)
Infections and infestations			
-Total	3 (7.5)	0	3 (7.5)
Conjunctivitis	3 (7.5)	0	3 (7.5)
Investigations			
-Total	15 (37.5)	4 (10.0)	11 (27.5)
Platelet count decreased	7 (17.5)	4 (10.0)	3 (7.5)
Alanine aminotransferase increased	6 (15.0)	2 (5.0)	4 (10.0)
Aspartate aminotransferase increased	5 (12.5)	2 (5.0)	3 (7.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)
White blood cell count decreased	4 (10.0)	2 (5.0)	2 (5.0)
Neutrophil count decreased	3 (7.5)	0	3 (7.5)
Blood bilirubin increased	2 (5.0)	0	2 (5.0)
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	15 (37.5)	5 (12.5)	10 (25.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	6 (15.0)	4 (10.0)	2 (5.0)
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)
Hypokalaemia	4 (10.0)	2 (5.0)	2 (5.0)
Hypocalcaemia	3 (7.5)	1 (2.5)	2 (5.0)
Hypophosphataemia	3 (7.5)	1 (2.5)	2 (5.0)
Hyperuricaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	14 (35.0)	7 (17.5)	7 (17.5)
Arthralgia	6 (15.0)	4 (10.0)	2 (5.0)
Pain in extremity	6 (15.0)	2 (5.0)	4 (10.0)
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)
Back pain	3 (7.5)	1 (2.5)	2 (5.0)
Nervous system disorders			
-Total	9 (22.5)	7 (17.5)	2 (5.0)
Headache	9 (22.5)	7 (17.5)	2 (5.0)
Psychiatric disorders			
-Total	3 (7.5)	3 (7.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Confusional state	2 (5.0)	2 (5.0)	0
Agitation	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	11 (27.5)	2 (5.0)
Cough	5 (12.5)	4 (10.0)	1 (2.5)
Oropharyngeal pain	3 (7.5)	3 (7.5)	0
Epistaxis	2 (5.0)	2 (5.0)	0
Pleural effusion	2 (5.0)	2 (5.0)	0
Nasal congestion	1 (2.5)	1 (2.5)	0
Pulmonary oedema	1 (2.5)	1 (2.5)	0
Tachypnoea	1 (2.5)	0	1 (2.5)
Skin and subcutaneous tissue disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)
Rash	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	7 (17.5)	4 (10.0)	3 (7.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	5 (12.5)	3 (7.5)	2 (5.0)
Hypotension	3 (7.5)	1 (2.5)	2 (5.0)

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Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (97.5)	3 (7.5)	36 (90.0)
Blood and lymphatic system disorders			
-Total	12 (30.0)	4 (10.0)	8 (20.0)
Anaemia	11 (27.5)	4 (10.0)	7 (17.5)
Disseminated intravascular coagulation	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	12 (30.0)	6 (15.0)	6 (15.0)
Tachycardia	12 (30.0)	6 (15.0)	6 (15.0)
Gastrointestinal disorders			
-Total	23 (57.5)	14 (35.0)	9 (22.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	10 (25.0)	6 (15.0)	4 (10.0)
Vomiting	10 (25.0)	7 (17.5)	3 (7.5)
Constipation	7 (17.5)	4 (10.0)	3 (7.5)
Diarrhoea	5 (12.5)	5 (12.5)	0
Abdominal pain	3 (7.5)	2 (5.0)	1 (2.5)
General disorders and administration site conditions			
-Total	17 (42.5)	13 (32.5)	4 (10.0)
Pyrexia	10 (25.0)	7 (17.5)	3 (7.5)
Fatigue	9 (22.5)	7 (17.5)	2 (5.0)
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)
Oedema peripheral	3 (7.5)	3 (7.5)	0
Chills	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			
-Total	1 (2.5)	0	1 (2.5)
Hepatic function abnormal	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	29 (72.5)	3 (7.5)	26 (65.0)
Cytokine release syndrome	28 (70.0)	4 (10.0)	24 (60.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	8 (20.0)	1 (2.5)	7 (17.5)
Infections and infestations			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)
Rhinovirus infection	2 (5.0)	0	2 (5.0)
Investigations			
-Total	22 (55.0)	3 (7.5)	19 (47.5)
Alanine aminotransferase increased	10 (25.0)	2 (5.0)	8 (20.0)
Aspartate aminotransferase increased	8 (20.0)	1 (2.5)	7 (17.5)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)
Platelet count decreased	6 (15.0)	2 (5.0)	4 (10.0)
Activated partial thromboplastin time prolonged	5 (12.5)	3 (7.5)	2 (5.0)
Blood immunoglobulin m decreased	5 (12.5)	4 (10.0)	1 (2.5)
Blood immunoglobulin a decreased	4 (10.0)	3 (7.5)	1 (2.5)
Electrocardiogram qt prolonged	4 (10.0)	2 (5.0)	2 (5.0)
White blood cell count decreased	4 (10.0)	1 (2.5)	3 (7.5)
Blood bilirubin increased	3 (7.5)	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	3 (7.5)	0	3 (7.5)
Serum ferritin increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	21 (52.5)	9 (22.5)	12 (30.0)
Hypocalcaemia	9 (22.5)	1 (2.5)	8 (20.0)
Hypokalaemia	8 (20.0)	1 (2.5)	7 (17.5)
Decreased appetite	7 (17.5)	5 (12.5)	2 (5.0)
Hyperuricaemia	6 (15.0)	5 (12.5)	1 (2.5)
Hypophosphataemia	6 (15.0)	3 (7.5)	3 (7.5)
Hyperphosphataemia	4 (10.0)	4 (10.0)	0
Hypoalbuminaemia	4 (10.0)	0	4 (10.0)
Hypomagnesaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	12 (30.0)	6 (15.0)	6 (15.0)
Pain in extremity	5 (12.5)	4 (10.0)	1 (2.5)
Myalgia	4 (10.0)	2 (5.0)	2 (5.0)
Arthralgia	3 (7.5)	0	3 (7.5)
Back pain	2 (5.0)	1 (2.5)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	12 (30.0)	5 (12.5)	7 (17.5)
Headache	12 (30.0)	5 (12.5)	7 (17.5)
Psychiatric disorders			
-Total	12 (30.0)	6 (15.0)	6 (15.0)
Confusional state	5 (12.5)	5 (12.5)	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (35.0)	10 (25.0)	4 (10.0)
Cough	5 (12.5)	5 (12.5)	0
Pulmonary oedema	4 (10.0)	1 (2.5)	3 (7.5)
Tachypnoea	4 (10.0)	4 (10.0)	0
Nasal congestion	2 (5.0)	1 (2.5)	1 (2.5)
Oropharyngeal pain	2 (5.0)	2 (5.0)	0
Pleural effusion	2 (5.0)	2 (5.0)	0
Rhinorrhoea	2 (5.0)	2 (5.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (2.5)	0	1 (2.5)
Skin and subcutaneous tissue disorders			
-Total	8 (20.0)	4 (10.0)	4 (10.0)
Pruritus	4 (10.0)	1 (2.5)	3 (7.5)
Rash	4 (10.0)	2 (5.0)	2 (5.0)
Dry skin	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	10 (25.0)	3 (7.5)	7 (17.5)
Hypotension	6 (15.0)	1 (2.5)	5 (12.5)
Hypertension	5 (12.5)	2 (5.0)	3 (7.5)

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	30 (75.0)	8 (20.0)	22 (55.0)
Blood and lymphatic system disorders			
-Total	3 (7.5)	3 (7.5)	0
Anaemia	3 (7.5)	3 (7.5)	0
Gastrointestinal disorders			
-Total	5 (12.5)	4 (10.0)	1 (2.5)
Vomiting	3 (7.5)	3 (7.5)	0
Constipation	2 (5.0)	1 (2.5)	1 (2.5)
Diarrhoea	2 (5.0)	2 (5.0)	0
Nausea	2 (5.0)	2 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Pyrexia	7 (17.5)	4 (10.0)	3 (7.5)
Fatigue	2 (5.0)	2 (5.0)	0
Immune system disorders			
-Total	2 (5.0)	0	2 (5.0)
Hypogammaglobulinaemia	2 (5.0)	0	2 (5.0)
Infections and infestations			
-Total	13 (32.5)	6 (15.0)	7 (17.5)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)
Upper respiratory tract infection	5 (12.5)	2 (5.0)	3 (7.5)
Gastroenteritis	3 (7.5)	3 (7.5)	0
Conjunctivitis	1 (2.5)	0	1 (2.5)
Rhinovirus infection	1 (2.5)	0	1 (2.5)
Investigations			
-Total	8 (20.0)	4 (10.0)	4 (10.0)
White blood cell count decreased	5 (12.5)	3 (7.5)	2 (5.0)
Neutrophil count decreased	3 (7.5)	0	3 (7.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Platelet count decreased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Hyperuricaemia	2 (5.0)	2 (5.0)	0
Decreased appetite	1 (2.5)	1 (2.5)	0
Hypophosphataemia	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Arthralgia	2 (5.0)	2 (5.0)	0
Back pain	2 (5.0)	1 (2.5)	1 (2.5)
Pain in extremity	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Headache	3 (7.5)	2 (5.0)	1 (2.5)
Psychiatric disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)
Agitation	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Cough	7 (17.5)	6 (15.0)	1 (2.5)
Nasal congestion	3 (7.5)	3 (7.5)	0
Epistaxis	1 (2.5)	0	1 (2.5)
Oropharyngeal pain	1 (2.5)	1 (2.5)	0
Pleural effusion	1 (2.5)	0	1 (2.5)
Skin and subcutaneous tissue disorders			
-Total	4 (10.0)	4 (10.0)	0
Dry skin	3 (7.5)	3 (7.5)	0
Rash	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	1 (2.5)	1 (2.5)	0
Hypotension	1 (2.5)	1 (2.5)	0

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Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (74.3)	6 (17.1)	20 (57.1)
Blood and lymphatic system disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Anaemia	2 (5.7)	1 (2.9)	1 (2.9)
Cardiac disorders			
-Total	2 (5.7)	2 (5.7)	0
Tachycardia	2 (5.7)	2 (5.7)	0
Gastrointestinal disorders			
-Total	9 (25.7)	5 (14.3)	4 (11.4)
Diarrhoea	5 (14.3)	4 (11.4)	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	3 (8.6)	1 (2.9)	2 (5.7)
Vomiting	3 (8.6)	3 (8.6)	0
Abdominal pain	2 (5.7)	1 (2.9)	1 (2.9)
Constipation	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	11 (31.4)	8 (22.9)	3 (8.6)
Pyrexia	6 (17.1)	3 (8.6)	3 (8.6)
Fatigue	4 (11.4)	4 (11.4)	0
Chills	1 (2.9)	1 (2.9)	0
Oedema peripheral	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	8 (22.9)	0	8 (22.9)
Hypogammaglobulinaemia	8 (22.9)	0	8 (22.9)
Infections and infestations			
-Total	5 (14.3)	1 (2.9)	4 (11.4)
Rhinovirus infection	3 (8.6)	0	3 (8.6)
Upper respiratory tract infection	2 (5.7)	1 (2.9)	1 (2.9)
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (22.9)	4 (11.4)	4 (11.4)
White blood cell count decreased	4 (11.4)	2 (5.7)	2 (5.7)
Neutrophil count decreased	3 (8.6)	2 (5.7)	1 (2.9)
Platelet count decreased	2 (5.7)	1 (2.9)	1 (2.9)
Blood bilirubin increased	1 (2.9)	0	1 (2.9)
Blood immunoglobulin a decreased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	5 (14.3)	1 (2.9)	4 (11.4)
Decreased appetite	4 (11.4)	1 (2.9)	3 (8.6)
Hypokalaemia	2 (5.7)	0	2 (5.7)
Hyperuricaemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (17.1)	3 (8.6)	3 (8.6)
Pain in extremity	3 (8.6)	2 (5.7)	1 (2.9)
Back pain	2 (5.7)	1 (2.9)	1 (2.9)
Arthralgia	1 (2.9)	0	1 (2.9)
Myalgia	1 (2.9)	0	1 (2.9)
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (20.0)	4 (11.4)	3 (8.6)
Headache	7 (20.0)	4 (11.4)	3 (8.6)
Psychiatric disorders			
-Total	2 (5.7)	0	2 (5.7)
Anxiety	2 (5.7)	0	2 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (22.9)	5 (14.3)	3 (8.6)
Cough	4 (11.4)	2 (5.7)	2 (5.7)
Nasal congestion	3 (8.6)	2 (5.7)	1 (2.9)
Rhinorrhoea	3 (8.6)	3 (8.6)	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)
Oropharyngeal pain	1 (2.9)	0	1 (2.9)
Pleural effusion	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			
-Total	6 (17.1)	3 (8.6)	3 (8.6)
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)
Rash	3 (8.6)	2 (5.7)	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pruritus	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypertension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (30.0)	4 (13.3)	5 (16.7)
Gastrointestinal disorders			
-Total	2 (6.7)	2 (6.7)	0
Diarrhoea	2 (6.7)	2 (6.7)	0
General disorders and administration site conditions			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Pyrexia	3 (10.0)	2 (6.7)	1 (3.3)
Infections and infestations			
-Total	7 (23.3)	4 (13.3)	3 (10.0)
Upper respiratory tract infection	3 (10.0)	2 (6.7)	1 (3.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	2 (6.7)	1 (3.3)	1 (3.3)
Gastroenteritis	1 (3.3)	1 (3.3)	0
Rhinovirus infection	1 (3.3)	0	1 (3.3)
Investigations			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Neutrophil count decreased	2 (6.7)	1 (3.3)	1 (3.3)
Platelet count decreased	2 (6.7)	2 (6.7)	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	0	1 (3.3)
Pain in extremity	1 (3.3)	0	1 (3.3)
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Anxiety	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Cough	2 (6.7)	2 (6.7)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (3.3)	1 (3.3)	0
Pleural effusion	1 (3.3)	0	1 (3.3)
Rhinorrhoea	1 (3.3)	1 (3.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Dry skin	1 (3.3)	1 (3.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (65.0)	2 (10.0)	11 (55.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Anaemia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Diarrhoea	2 (10.0)	1 (5.0)	1 (5.0)
Constipation	1 (5.0)	1 (5.0)	0
Nausea	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	2 (10.0)	0	2 (10.0)
Fatigue	1 (5.0)	0	1 (5.0)
Pyrexia	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	3 (15.0)	0	3 (15.0)
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)
Infections and infestations			
-Total	5 (25.0)	1 (5.0)	4 (20.0)
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)
Rhinovirus infection	2 (10.0)	0	2 (10.0)
Upper respiratory tract infection	2 (10.0)	0	2 (10.0)
Investigations			
-Total	1 (5.0)	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	0	2 (10.0)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (5.0)	0	1 (5.0)
Pain in extremity	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	0	2 (10.0)
Headache	2 (10.0)	0	2 (10.0)
Psychiatric disorders			
-Total	1 (5.0)	0	1 (5.0)
Anxiety	1 (5.0)	0	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)
Rhinorrhoea	2 (10.0)	0	2 (10.0)
Oropharyngeal pain	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Rash	2 (10.0)	1 (5.0)	1 (5.0)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (5.0)	0	1 (5.0)
Hypertension	1 (5.0)	0	1 (5.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	40 (100)	3 (7.5)	37 (92.5)
Blood and lymphatic system disorders			
-Total	11 (27.5)	3 (7.5)	8 (20.0)
Anaemia	7 (17.5)	3 (7.5)	4 (10.0)
Disseminated intravascular coagulation	4 (10.0)	0	4 (10.0)
Cardiac disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)
Gastrointestinal disorders			
-Total	26 (65.0)	13 (32.5)	13 (32.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)
Vomiting	12 (30.0)	7 (17.5)	5 (12.5)
Abdominal pain	7 (17.5)	1 (2.5)	6 (15.0)
Nausea	7 (17.5)	5 (12.5)	2 (5.0)
Constipation	6 (15.0)	3 (7.5)	3 (7.5)
General disorders and administration site conditions			
-Total	18 (45.0)	9 (22.5)	9 (22.5)
Pyrexia	14 (35.0)	7 (17.5)	7 (17.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)
Fatigue	4 (10.0)	4 (10.0)	0
Face oedema	3 (7.5)	2 (5.0)	1 (2.5)
Oedema peripheral	2 (5.0)	1 (2.5)	1 (2.5)
Hepatobiliary disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Hepatic function abnormal	4 (10.0)	1 (2.5)	3 (7.5)
Immune system disorders			
-Total	31 (77.5)	8 (20.0)	23 (57.5)
Cytokine release syndrome	29 (72.5)	9 (22.5)	20 (50.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	10 (25.0)	1 (2.5)	9 (22.5)
Infections and infestations			
-Total	16 (40.0)	6 (15.0)	10 (25.0)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	4 (10.0)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)
Conjunctivitis	4 (10.0)	0	4 (10.0)
Gastroenteritis	4 (10.0)	4 (10.0)	0
Rhinovirus infection	2 (5.0)	0	2 (5.0)
Investigations			
-Total	17 (42.5)	3 (7.5)	14 (35.0)
Platelet count decreased	8 (20.0)	5 (12.5)	3 (7.5)
Alanine aminotransferase increased	6 (15.0)	2 (5.0)	4 (10.0)
Neutrophil count decreased	6 (15.0)	1 (2.5)	5 (12.5)
Aspartate aminotransferase increased	5 (12.5)	2 (5.0)	3 (7.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)
White blood cell count decreased	5 (12.5)	2 (5.0)	3 (7.5)
Blood bilirubin increased	3 (7.5)	0	3 (7.5)
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	17 (42.5)	6 (15.0)	11 (27.5)
Decreased appetite	7 (17.5)	5 (12.5)	2 (5.0)
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)
Hypokalaemia	4 (10.0)	2 (5.0)	2 (5.0)
Hypophosphataemia	4 (10.0)	1 (2.5)	3 (7.5)
Hypocalcaemia	3 (7.5)	1 (2.5)	2 (5.0)
Hyperuricaemia	2 (5.0)	2 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	17 (42.5)	8 (20.0)	9 (22.5)
Arthralgia	7 (17.5)	5 (12.5)	2 (5.0)
Pain in extremity	7 (17.5)	2 (5.0)	5 (12.5)
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)
Back pain	4 (10.0)	1 (2.5)	3 (7.5)
Nervous system disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (25.0)	7 (17.5)	3 (7.5)
Headache	10 (25.0)	7 (17.5)	3 (7.5)
Psychiatric disorders			
-Total	7 (17.5)	4 (10.0)	3 (7.5)
Anxiety	5 (12.5)	2 (5.0)	3 (7.5)
Agitation	2 (5.0)	2 (5.0)	0
Confusional state	2 (5.0)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	22 (55.0)	16 (40.0)	6 (15.0)
Cough	14 (35.0)	12 (30.0)	2 (5.0)
Epistaxis	4 (10.0)	3 (7.5)	1 (2.5)
Nasal congestion	4 (10.0)	4 (10.0)	0
Oropharyngeal pain	4 (10.0)	4 (10.0)	0
Pleural effusion	4 (10.0)	2 (5.0)	2 (5.0)
Pulmonary oedema	1 (2.5)	1 (2.5)	0
Rhinorrhoea	1 (2.5)	1 (2.5)	0
Tachypnoea	1 (2.5)	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	7 (17.5)	5 (12.5)	2 (5.0)
Dry skin	4 (10.0)	4 (10.0)	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)
Rash	2 (5.0)	1 (2.5)	1 (2.5)
Vascular disorders			
-Total	8 (20.0)	5 (12.5)	3 (7.5)
Hypertension	5 (12.5)	3 (7.5)	2 (5.0)
Hypotension	4 (10.0)	2 (5.0)	2 (5.0)

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257q
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	39 (97.5)	0	39 (97.5)
Blood and lymphatic system disorders			
-Total	13 (32.5)	4 (10.0)	9 (22.5)
Anaemia	12 (30.0)	4 (10.0)	8 (20.0)
Disseminated intravascular coagulation	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	13 (32.5)	7 (17.5)	6 (15.0)
Tachycardia	13 (32.5)	7 (17.5)	6 (15.0)
Gastrointestinal disorders			
-Total	28 (70.0)	15 (37.5)	13 (32.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	13 (32.5)	7 (17.5)	6 (15.0)
Vomiting	13 (32.5)	10 (25.0)	3 (7.5)
Diarrhoea	12 (30.0)	10 (25.0)	2 (5.0)
Constipation	8 (20.0)	4 (10.0)	4 (10.0)
Abdominal pain	4 (10.0)	2 (5.0)	2 (5.0)
General disorders and administration site conditions			
-Total	25 (62.5)	16 (40.0)	9 (22.5)
Pyrexia	15 (37.5)	8 (20.0)	7 (17.5)
Fatigue	13 (32.5)	10 (25.0)	3 (7.5)
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)
Oedema peripheral	4 (10.0)	4 (10.0)	0
Chills	2 (5.0)	2 (5.0)	0
Hepatobiliary disorders			
-Total	1 (2.5)	0	1 (2.5)
Hepatic function abnormal	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	32 (80.0)	3 (7.5)	29 (72.5)
Cytokine release syndrome	28 (70.0)	4 (10.0)	24 (60.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	16 (40.0)	1 (2.5)	15 (37.5)
Infections and infestations			
-Total	13 (32.5)	3 (7.5)	10 (25.0)
Rhinovirus infection	6 (15.0)	0	6 (15.0)
Conjunctivitis	4 (10.0)	2 (5.0)	2 (5.0)
Upper respiratory tract infection	4 (10.0)	1 (2.5)	3 (7.5)
Investigations			
-Total	22 (55.0)	3 (7.5)	19 (47.5)
Alanine aminotransferase increased	10 (25.0)	2 (5.0)	8 (20.0)
Aspartate aminotransferase increased	8 (20.0)	1 (2.5)	7 (17.5)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)
Platelet count decreased	7 (17.5)	3 (7.5)	4 (10.0)
White blood cell count decreased	7 (17.5)	2 (5.0)	5 (12.5)
Activated partial thromboplastin time prolonged	5 (12.5)	3 (7.5)	2 (5.0)
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)
Blood immunoglobulin m decreased	5 (12.5)	4 (10.0)	1 (2.5)
Neutrophil count decreased	5 (12.5)	2 (5.0)	3 (7.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	4 (10.0)	2 (5.0)	2 (5.0)
Electrocardiogram qt prolonged	4 (10.0)	2 (5.0)	2 (5.0)
Serum ferritin increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	25 (62.5)	10 (25.0)	15 (37.5)
Decreased appetite	11 (27.5)	6 (15.0)	5 (12.5)
Hypocalcaemia	9 (22.5)	1 (2.5)	8 (20.0)
Hypokalaemia	9 (22.5)	1 (2.5)	8 (20.0)
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)
Hypophosphataemia	6 (15.0)	3 (7.5)	3 (7.5)
Hyperphosphataemia	4 (10.0)	4 (10.0)	0
Hypoalbuminaemia	4 (10.0)	0	4 (10.0)
Hypomagnesaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	17 (42.5)	8 (20.0)	9 (22.5)
Pain in extremity	9 (22.5)	6 (15.0)	3 (7.5)
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)
Arthralgia	4 (10.0)	0	4 (10.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	3 (7.5)	1 (2.5)	2 (5.0)
Nervous system disorders			
-Total	16 (40.0)	6 (15.0)	10 (25.0)
Headache	16 (40.0)	6 (15.0)	10 (25.0)
Psychiatric disorders			
-Total	15 (37.5)	6 (15.0)	9 (22.5)
Anxiety	7 (17.5)	1 (2.5)	6 (15.0)
Confusional state	5 (12.5)	5 (12.5)	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (47.5)	12 (30.0)	7 (17.5)
Cough	9 (22.5)	6 (15.0)	3 (7.5)
Nasal congestion	5 (12.5)	3 (7.5)	2 (5.0)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)
Oropharyngeal pain	4 (10.0)	3 (7.5)	1 (2.5)
Pulmonary oedema	4 (10.0)	1 (2.5)	3 (7.5)
Tachypnoea	4 (10.0)	4 (10.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)
Pleural effusion	2 (5.0)	2 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	13 (32.5)	6 (15.0)	7 (17.5)
Rash	6 (15.0)	3 (7.5)	3 (7.5)
Pruritus	5 (12.5)	1 (2.5)	4 (10.0)
Dry skin	4 (10.0)	2 (5.0)	2 (5.0)
Vascular disorders			
-Total	12 (30.0)	3 (7.5)	9 (22.5)
Hypertension	7 (17.5)	2 (5.0)	5 (12.5)
Hypotension	6 (15.0)	1 (2.5)	5 (12.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)
Cardiac disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Tachycardia	3 (50.0)	1 (16.7)	2 (33.3)
Sinus tachycardia	1 (16.7)	1 (16.7)	0
Eye disorders			
-Total	1 (16.7)	1 (16.7)	0
Eyelid oedema	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal distension	1 (16.7)	0	1 (16.7)
Ascites	1 (16.7)	1 (16.7)	0
Constipation	1 (16.7)	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)
Nausea	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Pyrexia	3 (50.0)	1 (16.7)	2 (33.3)
Catheter site pain	1 (16.7)	1 (16.7)	0
Chills	1 (16.7)	1 (16.7)	0
Face oedema	1 (16.7)	0	1 (16.7)
Fatigue	1 (16.7)	1 (16.7)	0
Generalised oedema	1 (16.7)	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)
Hepatobiliary disorders			
-Total	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cholelithiasis	1 (16.7)	1 (16.7)	0
Gallbladder enlargement	1 (16.7)	1 (16.7)	0
Immune system disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	2 (33.3)	0	2 (33.3)
Infusion related reaction	1 (16.7)	0	1 (16.7)
Skin injury	1 (16.7)	0	1 (16.7)
Skin wound	1 (16.7)	1 (16.7)	0
Wound	1 (16.7)	0	1 (16.7)
Investigations			

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (50.0)	0	3 (50.0)
Neutrophil count decreased	2 (33.3)	0	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)
International normalised ratio increased	1 (16.7)	1 (16.7)	0
Lipase increased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)
Hyperuricaemia	2 (33.3)	2 (33.3)	0
Hypocalcaemia	2 (33.3)	0	2 (33.3)
Acidosis	1 (16.7)	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)
Hyperglycaemia	1 (16.7)	0	1 (16.7)
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)
Hypokalaemia	1 (16.7)	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0
Hyponatraemia	1 (16.7)	1 (16.7)	0
Hypophosphataemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0
Myositis	1 (16.7)	0	1 (16.7)
Nervous system disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Headache	3 (50.0)	2 (33.3)	1 (16.7)
Monoparesis	1 (16.7)	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)
Tremor	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Confusional state	1 (16.7)	1 (16.7)	0
Sleep disorder	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	0	2 (33.3)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Atelectasis	1 (16.7)	0	1 (16.7)
Nasal congestion	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Rash	2 (33.3)	1 (16.7)	1 (16.7)
Decubitus ulcer	1 (16.7)	0	1 (16.7)
Erythema	1 (16.7)	1 (16.7)	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Skin ulcer	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	2 (33.3)	0
Hypertension	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (95.5)	2 (9.1)	19 (86.4)
Blood and lymphatic system disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Anaemia	5 (22.7)	2 (9.1)	3 (13.6)
Splenomegaly	1 (4.5)	1 (4.5)	0
Cardiac disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Tachycardia	5 (22.7)	2 (9.1)	3 (13.6)
Endocrine disorders			
-Total	4 (18.2)	0	4 (18.2)
Adrenal insufficiency	3 (13.6)	0	3 (13.6)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypothyroidism	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	14 (63.6)	5 (22.7)	9 (40.9)
Vomiting	6 (27.3)	4 (18.2)	2 (9.1)
Constipation	5 (22.7)	2 (9.1)	3 (13.6)
Nausea	5 (22.7)	2 (9.1)	3 (13.6)
Abdominal pain	3 (13.6)	2 (9.1)	1 (4.5)
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)
General disorders and administration site conditions			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Oedema peripheral	3 (13.6)	3 (13.6)	0
Pyrexia	3 (13.6)	2 (9.1)	1 (4.5)
Face oedema	2 (9.1)	2 (9.1)	0
Fatigue	2 (9.1)	1 (4.5)	1 (4.5)
Chills	1 (4.5)	1 (4.5)	0
Generalised oedema	1 (4.5)	0	1 (4.5)
Hepatobiliary disorders			
-Total	1 (4.5)	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gallbladder enlargement	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	18 (81.8)	4 (18.2)	14 (63.6)
Cytokine release syndrome	15 (68.2)	4 (18.2)	11 (50.0)
Hypogammaglobulinaemia	8 (36.4)	1 (4.5)	7 (31.8)
Infections and infestations			
-Total	4 (18.2)	0	4 (18.2)
Conjunctivitis	2 (9.1)	0	2 (9.1)
Rhinovirus infection	1 (4.5)	0	1 (4.5)
Staphylococcal infection	1 (4.5)	0	1 (4.5)
Investigations			
-Total	14 (63.6)	2 (9.1)	12 (54.5)
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)
Aspartate aminotransferase increased	3 (13.6)	0	3 (13.6)
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Platelet count decreased	3 (13.6)	1 (4.5)	2 (9.1)
Serum ferritin increased	3 (13.6)	1 (4.5)	2 (9.1)
Blood bilirubin increased	2 (9.1)	1 (4.5)	1 (4.5)
Blood immunoglobulin a decreased	2 (9.1)	1 (4.5)	1 (4.5)
Blood immunoglobulin m decreased	2 (9.1)	2 (9.1)	0
Electrocardiogram qt prolonged	2 (9.1)	1 (4.5)	1 (4.5)
White blood cell count decreased	2 (9.1)	0	2 (9.1)
Blood immunoglobulin g decreased	1 (4.5)	1 (4.5)	0
Lipase increased	1 (4.5)	1 (4.5)	0
Lymphocyte count decreased	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	11 (50.0)	3 (13.6)	8 (36.4)
Hypocalcaemia	5 (22.7)	1 (4.5)	4 (18.2)
Hypokalaemia	4 (18.2)	1 (4.5)	3 (13.6)
Hyperuricaemia	3 (13.6)	3 (13.6)	0
Hypoalbuminaemia	3 (13.6)	0	3 (13.6)
Decreased appetite	2 (9.1)	1 (4.5)	1 (4.5)
Hyperglycaemia	2 (9.1)	0	2 (9.1)
Hypophosphataemia	2 (9.1)	1 (4.5)	1 (4.5)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypomagnesaemia	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (27.3)	5 (22.7)	1 (4.5)
Pain in extremity	3 (13.6)	3 (13.6)	0
Arthralgia	1 (4.5)	0	1 (4.5)
Back pain	1 (4.5)	1 (4.5)	0
Myalgia	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Headache	3 (13.6)	2 (9.1)	1 (4.5)
Psychiatric disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Agitation	2 (9.1)	0	2 (9.1)
Confusional state	2 (9.1)	2 (9.1)	0
Anxiety	1 (4.5)	0	1 (4.5)
Delirium	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	1 (4.5)	0	1 (4.5)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Urinary retention	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (31.8)	5 (22.7)	2 (9.1)
Cough	4 (18.2)	4 (18.2)	0
Pulmonary oedema	3 (13.6)	1 (4.5)	2 (9.1)
Tachypnoea	2 (9.1)	2 (9.1)	0
Rhinorrhoea	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			
-Total	5 (22.7)	3 (13.6)	2 (9.1)
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)
Dry skin	1 (4.5)	1 (4.5)	0
Erythema	1 (4.5)	1 (4.5)	0
Hyperhidrosis	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Hypertension	3 (13.6)	1 (4.5)	2 (9.1)
Hypotension	2 (9.1)	0	2 (9.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 257r
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Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (94.1)	1 (5.9)	15 (88.2)
Blood and lymphatic system disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Anaemia	4 (23.5)	0	4 (23.5)
Splenomegaly	2 (11.8)	2 (11.8)	0
Cardiac disorders			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)
Sinus tachycardia	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (41.2)	5 (29.4)	2 (11.8)
Vomiting	3 (17.6)	2 (11.8)	1 (5.9)
Constipation	2 (11.8)	1 (5.9)	1 (5.9)
Diarrhoea	2 (11.8)	2 (11.8)	0
Nausea	2 (11.8)	2 (11.8)	0
General disorders and administration site conditions			
-Total	7 (41.2)	5 (29.4)	2 (11.8)
Fatigue	3 (17.6)	2 (11.8)	1 (5.9)
Pyrexia	3 (17.6)	2 (11.8)	1 (5.9)
Generalised oedema	2 (11.8)	2 (11.8)	0
Face oedema	1 (5.9)	1 (5.9)	0
Oedema peripheral	1 (5.9)	1 (5.9)	0
Immune system disorders			
-Total	11 (64.7)	3 (17.6)	8 (47.1)
Cytokine release syndrome	11 (64.7)	3 (17.6)	8 (47.1)
Hypogammaglobulinaemia	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	3 (17.6)	1 (5.9)	2 (11.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Staphylococcal infection	2 (11.8)	0	2 (11.8)
Conjunctivitis	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)
Wound	1 (5.9)	0	1 (5.9)
Investigations			
-Total	7 (41.2)	1 (5.9)	6 (35.3)
Aspartate aminotransferase increased	4 (23.5)	1 (5.9)	3 (17.6)
Alanine aminotransferase increased	3 (17.6)	0	3 (17.6)
Activated partial thromboplastin time prolonged	2 (11.8)	1 (5.9)	1 (5.9)
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)
Platelet count decreased	2 (11.8)	0	2 (11.8)
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Weight increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)
Hypocalcaemia	3 (17.6)	0	3 (17.6)
Decreased appetite	2 (11.8)	1 (5.9)	1 (5.9)
Hypokalaemia	2 (11.8)	0	2 (11.8)
Hypophosphataemia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperuricaemia	1 (5.9)	1 (5.9)	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0
Hyponatraemia	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)
Myalgia	1 (5.9)	0	1 (5.9)
Pain in extremity	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	5 (29.4)	0	5 (29.4)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	5 (29.4)	0	5 (29.4)
Tremor	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
Confusional state	3 (17.6)	3 (17.6)	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)
Delirium	2 (11.8)	1 (5.9)	1 (5.9)
Anxiety	1 (5.9)	0	1 (5.9)
Renal and urinary disorders			
-Total	1 (5.9)	0	1 (5.9)
Acute kidney injury	1 (5.9)	0	1 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Cough	2 (11.8)	2 (11.8)	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0
Tachypnoea	2 (11.8)	2 (11.8)	0
Epistaxis	1 (5.9)	0	1 (5.9)
Nasal congestion	1 (5.9)	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Wheezing	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			
-Total	1 (5.9)	1 (5.9)	0
Pruritus	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	4 (23.5)	0	4 (23.5)
Hypotension	3 (17.6)	0	3 (17.6)
Hypertension	1 (5.9)	0	1 (5.9)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (97.1)	4 (11.4)	30 (85.7)
Blood and lymphatic system disorders			
-Total	6 (17.1)	2 (5.7)	4 (11.4)
Anaemia	5 (14.3)	2 (5.7)	3 (8.6)
Splenomegaly	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)
Sinus tachycardia	1 (2.9)	0	1 (2.9)
Endocrine disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (2.9)	0	1 (2.9)
Adrenal insufficiency	1 (2.9)	0	1 (2.9)
Eye disorders			
-Total	1 (2.9)	0	1 (2.9)
Eyelid oedema	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	22 (62.9)	12 (34.3)	10 (28.6)
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)
Diarrhoea	10 (28.6)	5 (14.3)	5 (14.3)
Nausea	8 (22.9)	5 (14.3)	3 (8.6)
Abdominal pain	7 (20.0)	1 (2.9)	6 (17.1)
Constipation	3 (8.6)	2 (5.7)	1 (2.9)
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)
Ascites	2 (5.7)	1 (2.9)	1 (2.9)
Mouth haemorrhage	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	14 (40.0)	8 (22.9)	6 (17.1)
Pyrexia	10 (28.6)	6 (17.1)	4 (11.4)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	5 (14.3)	5 (14.3)	0
Chills	4 (11.4)	2 (5.7)	2 (5.7)
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)
Catheter site pain	1 (2.9)	0	1 (2.9)
Generalised oedema	1 (2.9)	0	1 (2.9)
Hepatobiliary disorders			
-Total	1 (2.9)	0	1 (2.9)
Cholelithiasis	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	26 (74.3)	4 (11.4)	22 (62.9)
Cytokine release syndrome	26 (74.3)	4 (11.4)	22 (62.9)
Hypogammaglobulinaemia	6 (17.1)	0	6 (17.1)
Infections and infestations			
-Total	5 (14.3)	2 (5.7)	3 (8.6)
Nail infection	2 (5.7)	2 (5.7)	0
Conjunctivitis	1 (2.9)	0	1 (2.9)
Otitis externa	1 (2.9)	0	1 (2.9)
Rhinovirus infection	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	1 (2.9)
Infusion related reaction	1 (2.9)	0	1 (2.9)
Investigations			
-Total	16 (45.7)	6 (17.1)	10 (28.6)
Alanine aminotransferase increased	7 (20.0)	3 (8.6)	4 (11.4)
Platelet count decreased	7 (20.0)	4 (11.4)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	2 (5.7)	3 (8.6)
Neutrophil count decreased	4 (11.4)	0	4 (11.4)
White blood cell count decreased	4 (11.4)	3 (8.6)	1 (2.9)
International normalised ratio increased	3 (8.6)	3 (8.6)	0
Lymphocyte count decreased	3 (8.6)	2 (5.7)	1 (2.9)
Serum ferritin increased	3 (8.6)	0	3 (8.6)
Blood bilirubin increased	2 (5.7)	1 (2.9)	1 (2.9)
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Weight increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	14 (40.0)	7 (20.0)	7 (20.0)
Decreased appetite	7 (20.0)	6 (17.1)	1 (2.9)
Hypokalaemia	5 (14.3)	2 (5.7)	3 (8.6)
Hypophosphataemia	4 (11.4)	2 (5.7)	2 (5.7)
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)
Hypocalcaemia	2 (5.7)	1 (2.9)	1 (2.9)
Hyperglycaemia	1 (2.9)	0	1 (2.9)
Hypermagnesaemia	1 (2.9)	1 (2.9)	0
Hyperuricaemia	1 (2.9)	0	1 (2.9)
Hyponatraemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	16 (45.7)	6 (17.1)	10 (28.6)
Pain in extremity	7 (20.0)	3 (8.6)	4 (11.4)
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	4 (11.4)	1 (2.9)	3 (8.6)
Nervous system disorders			
-Total	13 (37.1)	10 (28.6)	3 (8.6)
Headache	10 (28.6)	8 (22.9)	2 (5.7)
Tremor	4 (11.4)	4 (11.4)	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)
Psychiatric disorders			
-Total	5 (14.3)	2 (5.7)	3 (8.6)
Anxiety	2 (5.7)	1 (2.9)	1 (2.9)
Agitation	1 (2.9)	1 (2.9)	0
Confusional state	1 (2.9)	1 (2.9)	0
Delirium	1 (2.9)	0	1 (2.9)
Sleep disorder	1 (2.9)	0	1 (2.9)
Renal and urinary disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Acute kidney injury	2 (5.7)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (28.6)	8 (22.9)	2 (5.7)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	4 (11.4)	3 (8.6)	1 (2.9)
Oropharyngeal pain	3 (8.6)	3 (8.6)	0
Epistaxis	2 (5.7)	2 (5.7)	0
Atelectasis	1 (2.9)	0	1 (2.9)
Nasal congestion	1 (2.9)	1 (2.9)	0
Pulmonary oedema	1 (2.9)	1 (2.9)	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0
Tachypnoea	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	7 (20.0)	1 (2.9)	6 (17.1)
Rash	3 (8.6)	1 (2.9)	2 (5.7)
Erythema	2 (5.7)	2 (5.7)	0
Pruritus	2 (5.7)	0	2 (5.7)
Hyperhidrosis	1 (2.9)	0	1 (2.9)
Skin ulcer	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	7 (20.0)	4 (11.4)	3 (8.6)
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypotension	3 (8.6)	1 (2.9)	2 (5.7)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Lymphocytosis	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	1 (20.0)	0
Fatigue	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	2 (40.0)	0	2 (40.0)
Gastroenteritis	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0
Otitis externa	1 (20.0)	0	1 (20.0)
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)
Injury, poisoning and procedural complications			
-Total	1 (20.0)	0	1 (20.0)
Fibula fracture	1 (20.0)	0	1 (20.0)
Investigations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	1 (20.0)	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	1 (20.0)	1 (20.0)	0
Headache	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Persistent depressive disorder	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Cough	1 (20.0)	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0
Skin and subcutaneous tissue disorders			
-Total	2 (40.0)	2 (40.0)	0
Dry skin	2 (40.0)	2 (40.0)	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (55.0)	4 (20.0)	7 (35.0)
Cardiac disorders			
-Total	1 (5.0)	1 (5.0)	0
Tachycardia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			
-Total	7 (35.0)	5 (25.0)	2 (10.0)
Diarrhoea	4 (20.0)	4 (20.0)	0
Vomiting	4 (20.0)	4 (20.0)	0
Nausea	3 (15.0)	1 (5.0)	2 (10.0)
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Pyrexia	3 (15.0)	2 (10.0)	1 (5.0)
Fatigue	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	5 (25.0)	2 (10.0)	3 (15.0)
Nasopharyngitis	2 (10.0)	1 (5.0)	1 (5.0)
Rhinovirus infection	2 (10.0)	0	2 (10.0)
Upper respiratory tract infection	2 (10.0)	2 (10.0)	0
Conjunctivitis	1 (5.0)	0	1 (5.0)
Otitis media	1 (5.0)	0	1 (5.0)
Investigations			
-Total	7 (35.0)	4 (20.0)	3 (15.0)
White blood cell count decreased	4 (20.0)	3 (15.0)	1 (5.0)
Platelet count decreased	3 (15.0)	3 (15.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	1 (5.0)	0	1 (5.0)
Blood creatinine increased	1 (5.0)	0	1 (5.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)
Lymphocyte count decreased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	1 (5.0)	0	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	0	2 (10.0)
Arthralgia	1 (5.0)	0	1 (5.0)
Back pain	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Headache	2 (10.0)	1 (5.0)	1 (5.0)
Psychiatric disorders			
-Total	1 (5.0)	0	1 (5.0)
Anxiety	1 (5.0)	0	1 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Cough	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	0	1 (5.0)
Nasal congestion	1 (5.0)	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Dry skin	1 (5.0)	1 (5.0)	0
Erythema	1 (5.0)	0	1 (5.0)
Pruritus	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	1 (5.0)	0	1 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (5.0)	0	1 (5.0)

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Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (86.7)	3 (20.0)	10 (66.7)
Blood and lymphatic system disorders			
-Total	1 (6.7)	0	1 (6.7)
Anaemia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	1 (6.7)	1 (6.7)	0
Tachycardia	1 (6.7)	1 (6.7)	0
Endocrine disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypothyroidism	1 (6.7)	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	4 (26.7)	2 (13.3)	2 (13.3)
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)
Constipation	1 (6.7)	0	1 (6.7)
Nausea	1 (6.7)	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	6 (40.0)	4 (26.7)	2 (13.3)
Pyrexia	3 (20.0)	1 (6.7)	2 (13.3)
Fatigue	2 (13.3)	2 (13.3)	0
Oedema peripheral	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	3 (20.0)	0	3 (20.0)
Hypogammaglobulinaemia	3 (20.0)	0	3 (20.0)
Infections and infestations			
-Total	5 (33.3)	1 (6.7)	4 (26.7)
Respiratory tract infection	2 (13.3)	1 (6.7)	1 (6.7)
Nail infection	1 (6.7)	1 (6.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	1 (6.7)	1 (6.7)	0
Otitis media	1 (6.7)	0	1 (6.7)
Sinusitis	1 (6.7)	0	1 (6.7)
Upper respiratory tract infection	1 (6.7)	0	1 (6.7)
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Infusion related reaction	1 (6.7)	1 (6.7)	0
Investigations			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Neutrophil count decreased	1 (6.7)	1 (6.7)	0
Platelet count decreased	1 (6.7)	0	1 (6.7)
Weight increased	1 (6.7)	0	1 (6.7)
White blood cell count decreased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Decreased appetite	3 (20.0)	1 (6.7)	2 (13.3)
Hypokalaemia	1 (6.7)	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Pain in extremity	3 (20.0)	2 (13.3)	1 (6.7)
Arthralgia	1 (6.7)	1 (6.7)	0
Myalgia	1 (6.7)	0	1 (6.7)
Nervous system disorders			
-Total	1 (6.7)	1 (6.7)	0
Headache	1 (6.7)	1 (6.7)	0
Psychiatric disorders			
-Total	3 (20.0)	0	3 (20.0)
Anxiety	3 (20.0)	0	3 (20.0)
Delirium	1 (6.7)	0	1 (6.7)
Renal and urinary disorders			
-Total	1 (6.7)	0	1 (6.7)
Acute kidney injury	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All grades n (%)	All patients N=15 Grade 1 n (%)	Grade 2 n (%)
Cough	1 (6.7)	0	1 (6.7)
Nasal congestion	1 (6.7)	0	1 (6.7)
Rhinorrhoea	1 (6.7)	1 (6.7)	0
Skin and subcutaneous tissue disorders			
-Total	2 (13.3)	2 (13.3)	0
Dry skin	1 (6.7)	1 (6.7)	0
Rash	1 (6.7)	1 (6.7)	0

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	31 (88.6)	5 (14.3)	26 (74.3)
Blood and lymphatic system disorders			
-Total	4 (11.4)	4 (11.4)	0
Anaemia	4 (11.4)	4 (11.4)	0
Gastrointestinal disorders			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Constipation	2 (5.7)	1 (2.9)	1 (2.9)
Mouth haemorrhage	1 (2.9)	1 (2.9)	0
Nausea	1 (2.9)	1 (2.9)	0
Vomiting	1 (2.9)	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	9 (25.7)	6 (17.1)	3 (8.6)
Pyrexia	7 (20.0)	4 (11.4)	3 (8.6)
Fatigue	2 (5.7)	2 (5.7)	0
Chills	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	6 (17.1)	0	6 (17.1)
Hypogammaglobulinaemia	6 (17.1)	0	6 (17.1)
Infections and infestations			
-Total	12 (34.3)	3 (8.6)	9 (25.7)
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)
Upper respiratory tract infection	3 (8.6)	1 (2.9)	2 (5.7)
Gastroenteritis	2 (5.7)	2 (5.7)	0
Rhinovirus infection	2 (5.7)	0	2 (5.7)
Sinusitis	2 (5.7)	0	2 (5.7)
Respiratory tract infection	1 (2.9)	0	1 (2.9)
Injury, poisoning and procedural complications			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)
Investigations			
-Total	7 (20.0)	2 (5.7)	5 (14.3)
Neutrophil count decreased	3 (8.6)	0	3 (8.6)
White blood cell count decreased	3 (8.6)	2 (5.7)	1 (2.9)
Alanine aminotransferase increased	2 (5.7)	2 (5.7)	0
Lymphocyte count decreased	2 (5.7)	1 (2.9)	1 (2.9)
Blood bilirubin increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Hyperuricaemia	2 (5.7)	2 (5.7)	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Hypokalaemia	1 (2.9)	0	1 (2.9)
Hypophosphataemia	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Back pain	3 (8.6)	2 (5.7)	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (2.9)	1 (2.9)	0
Pain in extremity	1 (2.9)	0	1 (2.9)
Nervous system disorders			
-Total	6 (17.1)	3 (8.6)	3 (8.6)
Headache	6 (17.1)	3 (8.6)	3 (8.6)
Psychiatric disorders			
-Total	3 (8.6)	1 (2.9)	2 (5.7)
Anxiety	2 (5.7)	1 (2.9)	1 (2.9)
Agitation	1 (2.9)	1 (2.9)	0
Sleep disorder	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (22.9)	5 (14.3)	3 (8.6)
Cough	7 (20.0)	5 (14.3)	2 (5.7)
Nasal congestion	3 (8.6)	3 (8.6)	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)
Rhinorrhoea	1 (2.9)	1 (2.9)	0
Skin and subcutaneous tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Rash	3 (8.6)	2 (5.7)	1 (2.9)
Dry skin	2 (5.7)	0	2 (5.7)
Vascular disorders			
-Total	1 (2.9)	1 (2.9)	0
Hypotension	1 (2.9)	1 (2.9)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Rhinovirus infection	1 (33.3)	0	1 (33.3)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (33.3)	0	1 (33.3)

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-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (30.8)	1 (7.7)	3 (23.1)
Gastrointestinal disorders			
-Total	2 (15.4)	2 (15.4)	0
Constipation	1 (7.7)	1 (7.7)	0
Diarrhoea	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			
-Total	1 (7.7)	0	1 (7.7)
Pyrexia	1 (7.7)	0	1 (7.7)
Infections and infestations			
-Total	3 (23.1)	2 (15.4)	1 (7.7)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (7.7)	1 (7.7)	0
Gastroenteritis	1 (7.7)	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	0	1 (7.7)
Investigations			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)
Platelet count decreased	1 (7.7)	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.7)	1 (7.7)	0
Cough	1 (7.7)	1 (7.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (7.7)	1 (7.7)	0
Rash	1 (7.7)	1 (7.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

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Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (54.5)	1 (9.1)	5 (45.5)
Endocrine disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypothyroidism	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)
Nausea	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (9.1)	0	1 (9.1)
Fatigue	1 (9.1)	0	1 (9.1)
Immune system disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Seasonal allergy	3 (27.3)	2 (18.2)	1 (9.1)
Hypogammaglobulinaemia	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	2 (18.2)	0	2 (18.2)
Sinusitis	2 (18.2)	0	2 (18.2)
Nail infection	1 (9.1)	0	1 (9.1)
Otitis media	1 (9.1)	0	1 (9.1)
Rhinovirus infection	1 (9.1)	0	1 (9.1)
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	1 (9.1)	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Rhinorrhoea	2 (18.2)	0	2 (18.2)
Cough	1 (9.1)	0	1 (9.1)
Wheezing	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	0	1 (9.1)
Rash	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypertension	1 (9.1)	0	1 (9.1)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (52.2)	3 (13.0)	9 (39.1)
Blood and lymphatic system disorders			
-Total	1 (4.3)	0	1 (4.3)
Anaemia	1 (4.3)	0	1 (4.3)
Eye disorders			
-Total	1 (4.3)	1 (4.3)	0
Eyelid oedema	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders			
-Total	1 (4.3)	1 (4.3)	0
Diarrhoea	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	2 (8.7)	2 (8.7)	0
Pyrexia	2 (8.7)	2 (8.7)	0
Immune system disorders			
-Total	2 (8.7)	0	2 (8.7)
Hypogammaglobulinaemia	2 (8.7)	0	2 (8.7)
Infections and infestations			
-Total	8 (34.8)	3 (13.0)	5 (21.7)
Conjunctivitis	3 (13.0)	1 (4.3)	2 (8.7)
Sinusitis	3 (13.0)	0	3 (13.0)
Upper respiratory tract infection	3 (13.0)	2 (8.7)	1 (4.3)
Otitis media	1 (4.3)	0	1 (4.3)
Rhinovirus infection	1 (4.3)	0	1 (4.3)
Investigations			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Neutrophil count decreased	2 (8.7)	1 (4.3)	1 (4.3)
Blood bilirubin increased	1 (4.3)	1 (4.3)	0
Platelet count decreased	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (8.7)	0	2 (8.7)
Pain in extremity	2 (8.7)	0	2 (8.7)
Nervous system disorders			
-Total	1 (4.3)	0	1 (4.3)
Headache	1 (4.3)	0	1 (4.3)
Psychiatric disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Anxiety	2 (8.7)	1 (4.3)	1 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.0)	3 (13.0)	0
Cough	2 (8.7)	2 (8.7)	0
Epistaxis	1 (4.3)	1 (4.3)	0
Oropharyngeal pain	1 (4.3)	1 (4.3)	0
Rhinorrhoea	1 (4.3)	1 (4.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dry skin	1 (4.3)	1 (4.3)	0

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Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (100)	0	6 (100)
Blood and lymphatic system disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)
Lymphocytosis	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Tachycardia	3 (50.0)	1 (16.7)	2 (33.3)
Sinus tachycardia	1 (16.7)	1 (16.7)	0
Eye disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Eyelid oedema	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	0	2 (33.3)
Abdominal distension	1 (16.7)	0	1 (16.7)
Ascites	1 (16.7)	1 (16.7)	0
Constipation	1 (16.7)	1 (16.7)	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)
Mouth haemorrhage	1 (16.7)	0	1 (16.7)
Nausea	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Pyrexia	3 (50.0)	0	3 (50.0)
Fatigue	2 (33.3)	2 (33.3)	0
Catheter site pain	1 (16.7)	1 (16.7)	0
Chills	1 (16.7)	1 (16.7)	0
Face oedema	1 (16.7)	0	1 (16.7)
Generalised oedema	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	1 (16.7)	0	1 (16.7)
Hepatobiliary disorders			
-Total	1 (16.7)	1 (16.7)	0
Cholelithiasis	1 (16.7)	1 (16.7)	0
Gallbladder enlargement	1 (16.7)	1 (16.7)	0
Immune system disorders			
-Total	5 (83.3)	1 (16.7)	4 (66.7)
Cytokine release syndrome	5 (83.3)	2 (33.3)	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	3 (50.0)	0	3 (50.0)
Conjunctivitis	1 (16.7)	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0
Localised infection	1 (16.7)	1 (16.7)	0
Otitis externa	1 (16.7)	0	1 (16.7)
Rhinovirus infection	1 (16.7)	0	1 (16.7)
Sinusitis	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	3 (50.0)	0	3 (50.0)
Fibula fracture	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)
Skin injury	1 (16.7)	0	1 (16.7)
Skin wound	1 (16.7)	1 (16.7)	0
Wound	1 (16.7)	0	1 (16.7)
Investigations			
-Total	3 (50.0)	0	3 (50.0)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)
International normalised ratio increased	1 (16.7)	1 (16.7)	0
Lipase increased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	5 (83.3)	2 (33.3)	3 (50.0)
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)
Hyperuricaemia	2 (33.3)	2 (33.3)	0
Hypocalcaemia	2 (33.3)	0	2 (33.3)
Acidosis	1 (16.7)	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)
Hyperglycaemia	1 (16.7)	0	1 (16.7)
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	1 (16.7)	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0
Hyponatraemia	1 (16.7)	1 (16.7)	0
Hypophosphataemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0
Myositis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Headache	3 (50.0)	2 (33.3)	1 (16.7)
Monoparesis	1 (16.7)	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)
Tremor	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Confusional state	1 (16.7)	1 (16.7)	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sleep disorder	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	0	2 (33.3)
Acute kidney injury	1 (16.7)	0	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0
Atelectasis	1 (16.7)	0	1 (16.7)
Cough	1 (16.7)	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	4 (66.7)	3 (50.0)	1 (16.7)
Dry skin	2 (33.3)	2 (33.3)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)
Decubitus ulcer	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Erythema	1 (16.7)	1 (16.7)	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Skin hypopigmentation	1 (16.7)	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	2 (33.3)	0
Hypertension	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	21 (95.5)	1 (4.5)	20 (90.9)
Blood and lymphatic system disorders			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Anaemia	5 (22.7)	2 (9.1)	3 (13.6)
Splenomegaly	1 (4.5)	1 (4.5)	0
Cardiac disorders			
-Total	6 (27.3)	3 (13.6)	3 (13.6)
Tachycardia	6 (27.3)	3 (13.6)	3 (13.6)
Endocrine disorders			
-Total	4 (18.2)	0	4 (18.2)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	3 (13.6)	0	3 (13.6)
Hypothyroidism	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	16 (72.7)	6 (27.3)	10 (45.5)
Vomiting	9 (40.9)	7 (31.8)	2 (9.1)
Nausea	7 (31.8)	2 (9.1)	5 (22.7)
Diarrhoea	6 (27.3)	5 (22.7)	1 (4.5)
Constipation	5 (22.7)	2 (9.1)	3 (13.6)
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)
General disorders and administration site conditions			
-Total	10 (45.5)	6 (27.3)	4 (18.2)
Pyrexia	6 (27.3)	3 (13.6)	3 (13.6)
Fatigue	3 (13.6)	2 (9.1)	1 (4.5)
Oedema peripheral	3 (13.6)	3 (13.6)	0
Face oedema	2 (9.1)	2 (9.1)	0
Chills	1 (4.5)	1 (4.5)	0
Generalised oedema	1 (4.5)	0	1 (4.5)
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (4.5)	1 (4.5)	0
Gallbladder enlargement	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	19 (86.4)	4 (18.2)	15 (68.2)
Cytokine release syndrome	15 (68.2)	4 (18.2)	11 (50.0)
Hypogammaglobulinaemia	9 (40.9)	1 (4.5)	8 (36.4)
Infections and infestations			
-Total	8 (36.4)	2 (9.1)	6 (27.3)
Upper respiratory tract infection	3 (13.6)	2 (9.1)	1 (4.5)
Conjunctivitis	2 (9.1)	0	2 (9.1)
Nasopharyngitis	2 (9.1)	1 (4.5)	1 (4.5)
Rhinovirus infection	2 (9.1)	0	2 (9.1)
Gastroenteritis	1 (4.5)	1 (4.5)	0
Otitis media	1 (4.5)	0	1 (4.5)
Staphylococcal infection	1 (4.5)	0	1 (4.5)
Investigations			
-Total	15 (68.2)	2 (9.1)	13 (59.1)
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)
Platelet count decreased	5 (22.7)	3 (13.6)	2 (9.1)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	5 (22.7)	2 (9.1)	3 (13.6)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)
Aspartate aminotransferase increased	3 (13.6)	0	3 (13.6)
Blood bilirubin increased	3 (13.6)	1 (4.5)	2 (9.1)
Blood immunoglobulin a decreased	3 (13.6)	2 (9.1)	1 (4.5)
Blood immunoglobulin g decreased	3 (13.6)	1 (4.5)	2 (9.1)
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)
Serum ferritin increased	3 (13.6)	1 (4.5)	2 (9.1)
Blood immunoglobulin m decreased	2 (9.1)	2 (9.1)	0
Electrocardiogram qt prolonged	2 (9.1)	1 (4.5)	1 (4.5)
Lymphocyte count decreased	2 (9.1)	0	2 (9.1)
Blood creatinine increased	1 (4.5)	0	1 (4.5)
Lipase increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	12 (54.5)	3 (13.6)	9 (40.9)
Hypocalcaemia	5 (22.7)	1 (4.5)	4 (18.2)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	4 (18.2)	1 (4.5)	3 (13.6)
Decreased appetite	3 (13.6)	1 (4.5)	2 (9.1)
Hyperuricaemia	3 (13.6)	3 (13.6)	0
Hypoalbuminaemia	3 (13.6)	0	3 (13.6)
Hyperglycaemia	2 (9.1)	0	2 (9.1)
Hypophosphataemia	2 (9.1)	1 (4.5)	1 (4.5)
Hypomagnesaemia	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Pain in extremity	3 (13.6)	3 (13.6)	0
Arthralgia	1 (4.5)	0	1 (4.5)
Back pain	1 (4.5)	0	1 (4.5)
Myalgia	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	4 (18.2)	3 (13.6)	1 (4.5)
Headache	4 (18.2)	3 (13.6)	1 (4.5)
Psychiatric disorders			
-Total	6 (27.3)	2 (9.1)	4 (18.2)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Agitation	2 (9.1)	0	2 (9.1)
Anxiety	2 (9.1)	0	2 (9.1)
Confusional state	2 (9.1)	2 (9.1)	0
Delirium	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Acute kidney injury	1 (4.5)	1 (4.5)	0
Urinary retention	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (50.0)	8 (36.4)	3 (13.6)
Cough	6 (27.3)	6 (27.3)	0
Pulmonary oedema	3 (13.6)	1 (4.5)	2 (9.1)
Tachypnoea	2 (9.1)	2 (9.1)	0
Epistaxis	1 (4.5)	0	1 (4.5)
Nasal congestion	1 (4.5)	1 (4.5)	0
Oropharyngeal pain	1 (4.5)	0	1 (4.5)
Rhinorrhoea	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	9 (40.9)	5 (22.7)	4 (18.2)
Pruritus	3 (13.6)	1 (4.5)	2 (9.1)
Dry skin	2 (9.1)	2 (9.1)	0
Erythema	2 (9.1)	1 (4.5)	1 (4.5)
Hyperhidrosis	1 (4.5)	0	1 (4.5)
Rash	1 (4.5)	1 (4.5)	0
Vascular disorders			
-Total	5 (22.7)	1 (4.5)	4 (18.2)
Hypertension	4 (18.2)	1 (4.5)	3 (13.6)
Hypotension	2 (9.1)	0	2 (9.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (100)	1 (5.9)	16 (94.1)
Blood and lymphatic system disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Anaemia	4 (23.5)	0	4 (23.5)
Splenomegaly	2 (11.8)	2 (11.8)	0
Cardiac disorders			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)
Sinus tachycardia	1 (5.9)	1 (5.9)	0
Endocrine disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (11.8)	0	2 (11.8)
Hypothyroidism	2 (11.8)	0	2 (11.8)
Gastrointestinal disorders			
-Total	12 (70.6)	7 (41.2)	5 (29.4)
Diarrhoea	7 (41.2)	5 (29.4)	2 (11.8)
Vomiting	5 (29.4)	4 (23.5)	1 (5.9)
Nausea	4 (23.5)	4 (23.5)	0
Constipation	3 (17.6)	1 (5.9)	2 (11.8)
General disorders and administration site conditions			
-Total	12 (70.6)	7 (41.2)	5 (29.4)
Fatigue	6 (35.3)	4 (23.5)	2 (11.8)
Pyrexia	6 (35.3)	3 (17.6)	3 (17.6)
Generalised oedema	2 (11.8)	2 (11.8)	0
Oedema peripheral	2 (11.8)	2 (11.8)	0
Face oedema	1 (5.9)	1 (5.9)	0
Immune system disorders			
-Total	12 (70.6)	3 (17.6)	9 (52.9)
Cytokine release syndrome	11 (64.7)	3 (17.6)	8 (47.1)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	5 (29.4)	1 (5.9)	4 (23.5)
Seasonal allergy	3 (17.6)	2 (11.8)	1 (5.9)
Infections and infestations			
-Total	7 (41.2)	1 (5.9)	6 (35.3)
Nail infection	2 (11.8)	1 (5.9)	1 (5.9)
Otitis media	2 (11.8)	0	2 (11.8)
Respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)
Sinusitis	2 (11.8)	0	2 (11.8)
Staphylococcal infection	2 (11.8)	0	2 (11.8)
Upper respiratory tract infection	2 (11.8)	0	2 (11.8)
Conjunctivitis	1 (5.9)	1 (5.9)	0
Nasopharyngitis	1 (5.9)	1 (5.9)	0
Rhinovirus infection	1 (5.9)	0	1 (5.9)
Injury, poisoning and procedural complications			
-Total	4 (23.5)	2 (11.8)	2 (11.8)
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)
Infusion related reaction	1 (5.9)	1 (5.9)	0
Wound	1 (5.9)	0	1 (5.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	7 (41.2)	0	7 (41.2)
Aspartate aminotransferase increased	4 (23.5)	1 (5.9)	3 (17.6)
Alanine aminotransferase increased	3 (17.6)	0	3 (17.6)
Activated partial thromboplastin time prolonged	2 (11.8)	1 (5.9)	1 (5.9)
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)
Platelet count decreased	2 (11.8)	0	2 (11.8)
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	1 (5.9)	0
Weight increased	1 (5.9)	0	1 (5.9)
White blood cell count decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	7 (41.2)	2 (11.8)	5 (29.4)
Decreased appetite	5 (29.4)	2 (11.8)	3 (17.6)
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	3 (17.6)	0	3 (17.6)
Hypokalaemia	2 (11.8)	0	2 (11.8)
Hypophosphataemia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperuricaemia	1 (5.9)	1 (5.9)	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0
Hyponatraemia	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	8 (47.1)	4 (23.5)	4 (23.5)
Arthralgia	4 (23.5)	2 (11.8)	2 (11.8)
Pain in extremity	4 (23.5)	2 (11.8)	2 (11.8)
Myalgia	2 (11.8)	0	2 (11.8)
Nervous system disorders			
-Total	5 (29.4)	0	5 (29.4)
Headache	5 (29.4)	0	5 (29.4)
Tremor	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	8 (47.1)	3 (17.6)	5 (29.4)
Anxiety	4 (23.5)	0	4 (23.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Confusional state	3 (17.6)	3 (17.6)	0
Delirium	3 (17.6)	1 (5.9)	2 (11.8)
Agitation	2 (11.8)	1 (5.9)	1 (5.9)
Renal and urinary disorders			
-Total	2 (11.8)	0	2 (11.8)
Acute kidney injury	2 (11.8)	0	2 (11.8)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Cough	4 (23.5)	2 (11.8)	2 (11.8)
Rhinorrhoea	3 (17.6)	1 (5.9)	2 (11.8)
Nasal congestion	2 (11.8)	0	2 (11.8)
Oropharyngeal pain	2 (11.8)	2 (11.8)	0
Tachypnoea	2 (11.8)	2 (11.8)	0
Wheezing	2 (11.8)	0	2 (11.8)
Epistaxis	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Dry skin	1 (5.9)	1 (5.9)	0
Pruritus	1 (5.9)	1 (5.9)	0
Rash	1 (5.9)	0	1 (5.9)
Vascular disorders			
-Total	5 (29.4)	0	5 (29.4)
Hypotension	3 (17.6)	0	3 (17.6)
Hypertension	2 (11.8)	0	2 (11.8)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 257r
Non-severe adverse events (AE CTCAE Grade 1/2) post CTL019 infusion that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) ,regardless of study drug relationship, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	35 (100)	2 (5.7)	33 (94.3)
Blood and lymphatic system disorders			
-Total	9 (25.7)	4 (11.4)	5 (14.3)
Anaemia	8 (22.9)	4 (11.4)	4 (11.4)
Splenomegaly	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)
Sinus tachycardia	1 (2.9)	0	1 (2.9)
Endocrine disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (2.9)	0	1 (2.9)
Adrenal insufficiency	1 (2.9)	0	1 (2.9)
Eye disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Eyelid oedema	2 (5.7)	1 (2.9)	1 (2.9)
Gastrointestinal disorders			
-Total	25 (71.4)	14 (40.0)	11 (31.4)
Diarrhoea	11 (31.4)	6 (17.1)	5 (14.3)
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)
Nausea	8 (22.9)	5 (14.3)	3 (8.6)
Abdominal pain	7 (20.0)	1 (2.9)	6 (17.1)
Constipation	5 (14.3)	3 (8.6)	2 (5.7)
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)
Ascites	2 (5.7)	1 (2.9)	1 (2.9)
Mouth haemorrhage	2 (5.7)	2 (5.7)	0
General disorders and administration site conditions			
-Total	17 (48.6)	10 (28.6)	7 (20.0)
Pyrexia	14 (40.0)	9 (25.7)	5 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Fatigue	6 (17.1)	6 (17.1)	0
Chills	5 (14.3)	3 (8.6)	2 (5.7)
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)
Catheter site pain	1 (2.9)	0	1 (2.9)
Generalised oedema	1 (2.9)	0	1 (2.9)
Hepatobiliary disorders			
-Total	1 (2.9)	0	1 (2.9)
Cholelithiasis	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	28 (80.0)	3 (8.6)	25 (71.4)
Cytokine release syndrome	26 (74.3)	4 (11.4)	22 (62.9)
Hypogammaglobulinaemia	11 (31.4)	0	11 (31.4)
Infections and infestations			
-Total	17 (48.6)	5 (14.3)	12 (34.3)
Upper respiratory tract infection	6 (17.1)	3 (8.6)	3 (8.6)
Conjunctivitis	4 (11.4)	1 (2.9)	3 (8.6)
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)
Rhinovirus infection	4 (11.4)	0	4 (11.4)
Sinusitis	3 (8.6)	0	3 (8.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis	2 (5.7)	2 (5.7)	0
Nail infection	2 (5.7)	2 (5.7)	0
Otitis externa	1 (2.9)	0	1 (2.9)
Otitis media	1 (2.9)	0	1 (2.9)
Respiratory tract infection	1 (2.9)	0	1 (2.9)
Injury, poisoning and procedural complications			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)
Investigations			
-Total	17 (48.6)	4 (11.4)	13 (37.1)
Alanine aminotransferase increased	7 (20.0)	3 (8.6)	4 (11.4)
Neutrophil count decreased	7 (20.0)	1 (2.9)	6 (17.1)
Platelet count decreased	7 (20.0)	4 (11.4)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	2 (5.7)	3 (8.6)
Lymphocyte count decreased	4 (11.4)	2 (5.7)	2 (5.7)
White blood cell count decreased	4 (11.4)	2 (5.7)	2 (5.7)
Blood bilirubin increased	3 (8.6)	1 (2.9)	2 (5.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	3 (8.6)	3 (8.6)	0
Serum ferritin increased	3 (8.6)	0	3 (8.6)
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0
Weight increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	17 (48.6)	8 (22.9)	9 (25.7)
Decreased appetite	8 (22.9)	7 (20.0)	1 (2.9)
Hypokalaemia	6 (17.1)	2 (5.7)	4 (11.4)
Hypophosphataemia	5 (14.3)	2 (5.7)	3 (8.6)
Hyperuricaemia	3 (8.6)	2 (5.7)	1 (2.9)
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)
Hypocalcaemia	2 (5.7)	1 (2.9)	1 (2.9)
Hyperglycaemia	1 (2.9)	0	1 (2.9)
Hypermagnesaemia	1 (2.9)	1 (2.9)	0
Hyponatraemia	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	19 (54.3)	7 (20.0)	12 (34.3)
Pain in extremity	9 (25.7)	3 (8.6)	6 (17.1)
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)
Back pain	6 (17.1)	2 (5.7)	4 (11.4)
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)
Nervous system disorders			
-Total	17 (48.6)	10 (28.6)	7 (20.0)
Headache	14 (40.0)	8 (22.9)	6 (17.1)
Tremor	4 (11.4)	4 (11.4)	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)
Psychiatric disorders			
-Total	9 (25.7)	3 (8.6)	6 (17.1)
Anxiety	6 (17.1)	3 (8.6)	3 (8.6)
Agitation	2 (5.7)	2 (5.7)	0
Sleep disorder	2 (5.7)	0	2 (5.7)
Confusional state	1 (2.9)	1 (2.9)	0
Delirium	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Renal and urinary disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Acute kidney injury	2 (5.7)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (48.6)	12 (34.3)	5 (14.3)
Cough	12 (34.3)	9 (25.7)	3 (8.6)
Epistaxis	5 (14.3)	4 (11.4)	1 (2.9)
Nasal congestion	4 (11.4)	4 (11.4)	0
Oropharyngeal pain	4 (11.4)	4 (11.4)	0
Rhinorrhoea	2 (5.7)	2 (5.7)	0
Atelectasis	1 (2.9)	0	1 (2.9)
Pulmonary oedema	1 (2.9)	1 (2.9)	0
Tachypnoea	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	10 (28.6)	3 (8.6)	7 (20.0)
Rash	4 (11.4)	2 (5.7)	2 (5.7)
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Erythema	2 (5.7)	2 (5.7)	0
Pruritus	2 (5.7)	0	2 (5.7)
Hyperhidrosis	1 (2.9)	0	1 (2.9)
Skin ulcer	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	8 (22.9)	5 (14.3)	3 (8.6)
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)
Hypotension	4 (11.4)	2 (5.7)	2 (5.7)

-A patient with multiple adverse events within a group term is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (34.1)	2 (4.9)	12 (29.3)
Blood and lymphatic system disorders			
-Total	5 (12.2)	1 (2.4)	4 (9.8)
Anaemia	5 (12.2)	1 (2.4)	4 (9.8)
Gastrointestinal disorders			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Abdominal pain	2 (4.9)	1 (2.4)	1 (2.4)
Nausea	1 (2.4)	0	1 (2.4)
General disorders and administration site conditions			
-Total	4 (9.8)	2 (4.9)	2 (4.9)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pyrexia	3 (7.3)	1 (2.4)	2 (4.9)
Fatigue	2 (4.9)	1 (2.4)	1 (2.4)
Immune system disorders			
-Total	3 (7.3)	0	3 (7.3)
Hypogammaglobulinaemia	3 (7.3)	0	3 (7.3)
Musculoskeletal and connective tissue disorders			
-Total	2 (4.9)	1 (2.4)	1 (2.4)
Arthralgia	2 (4.9)	1 (2.4)	1 (2.4)
Vascular disorders			
-Total	2 (4.9)	0	2 (4.9)
Hypertension	2 (4.9)	0	2 (4.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (42.5)	4 (10.0)	13 (32.5)
Blood and lymphatic system disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Anaemia	2 (5.0)	1 (2.5)	1 (2.5)
Gastrointestinal disorders			
-Total	9 (22.5)	1 (2.5)	8 (20.0)
Constipation	5 (12.5)	3 (7.5)	2 (5.0)
Abdominal pain	4 (10.0)	1 (2.5)	3 (7.5)
Nausea	3 (7.5)	0	3 (7.5)
General disorders and administration site conditions			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (17.5)	1 (2.5)	6 (15.0)
Pyrexia	7 (17.5)	1 (2.5)	6 (15.0)
Fatigue	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0
Arthralgia	2 (5.0)	2 (5.0)	0
Nervous system disorders			
-Total	1 (2.5)	1 (2.5)	0
Paraesthesia	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Hypertension	4 (10.0)	2 (5.0)	2 (5.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259a
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (64.7)	2 (11.8)	9 (52.9)
Blood and lymphatic system disorders			
-Total	1 (5.9)	0	1 (5.9)
Anaemia	1 (5.9)	0	1 (5.9)
Gastrointestinal disorders			
-Total	3 (17.6)	0	3 (17.6)
Constipation	2 (11.8)	0	2 (11.8)
Nausea	2 (11.8)	1 (5.9)	1 (5.9)
General disorders and administration site conditions			
-Total	6 (35.3)	1 (5.9)	5 (29.4)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pyrexia	4 (23.5)	1 (5.9)	3 (17.6)
Fatigue	2 (11.8)	0	2 (11.8)
Immune system disorders			
-Total	2 (11.8)	0	2 (11.8)
Hypogammaglobulinaemia	2 (11.8)	0	2 (11.8)
Musculoskeletal and connective tissue disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)
Nervous system disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Paraesthesia	2 (11.8)	1 (5.9)	1 (5.9)
Vascular disorders			
-Total	1 (5.9)	0	1 (5.9)
Hypertension	1 (5.9)	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259b
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (25.5)	3 (5.5)	11 (20.0)
Blood and lymphatic system disorders			
-Total	7 (12.7)	1 (1.8)	6 (10.9)
Anaemia	7 (12.7)	1 (1.8)	6 (10.9)
General disorders and administration site conditions			
-Total	8 (14.5)	3 (5.5)	5 (9.1)
Pyrexia	8 (14.5)	3 (5.5)	5 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259b
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (16.3)	1 (2.3)	6 (14.0)
Blood and lymphatic system disorders			
-Total	1 (2.3)	1 (2.3)	0
Anaemia	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	6 (14.0)	0	6 (14.0)
Pyrexia	6 (14.0)	0	6 (14.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (27.1)	4 (5.7)	15 (21.4)
Blood and lymphatic system disorders			
-Total	5 (7.1)	1 (1.4)	4 (5.7)
Anaemia	5 (7.1)	1 (1.4)	4 (5.7)
Gastrointestinal disorders			
-Total	7 (10.0)	3 (4.3)	4 (5.7)
Constipation	7 (10.0)	3 (4.3)	4 (5.7)
General disorders and administration site conditions			
-Total	12 (17.1)	3 (4.3)	9 (12.9)
Pyrexia	12 (17.1)	3 (4.3)	9 (12.9)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Investigations			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
C-reactive protein increased	2 (2.9)	1 (1.4)	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (20.0)	0	3 (20.0)
Blood and lymphatic system disorders			
-Total	1 (6.7)	0	1 (6.7)
Anaemia	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
-Total	2 (13.3)	0	2 (13.3)
Pyrexia	2 (13.3)	0	2 (13.3)
Investigations			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 259c
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (15.4)	1 (7.7)	1 (7.7)
Blood and lymphatic system disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Anaemia	2 (15.4)	1 (7.7)	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259d
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (66.7)	3 (16.7)	9 (50.0)
Blood and lymphatic system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Anaemia	2 (11.1)	1 (5.6)	1 (5.6)
Gastrointestinal disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Nausea	2 (11.1)	1 (5.6)	1 (5.6)
General disorders and administration site conditions			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Pyrexia	4 (22.2)	1 (5.6)	3 (16.7)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Immune system disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypogammaglobulinaemia	2 (11.1)	0	2 (11.1)
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	2 (11.1)	2 (11.1)	0
Arthralgia	2 (11.1)	2 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Oropharyngeal pain	2 (11.1)	1 (5.6)	1 (5.6)
Vascular disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Hypertension	3 (16.7)	2 (11.1)	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259d
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	25 (31.3)	4 (5.0)	21 (26.3)
Blood and lymphatic system disorders			
-Total	6 (7.5)	1 (1.3)	5 (6.3)
Anaemia	6 (7.5)	1 (1.3)	5 (6.3)
Gastrointestinal disorders			
-Total	4 (5.0)	0	4 (5.0)
Nausea	4 (5.0)	0	4 (5.0)
General disorders and administration site conditions			
-Total	10 (12.5)	2 (2.5)	8 (10.0)
Pyrexia	10 (12.5)	2 (2.5)	8 (10.0)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Immune system disorders			
-Total	4 (5.0)	0	4 (5.0)
Hypogammaglobulinaemia	4 (5.0)	0	4 (5.0)
Metabolism and nutrition disorders			
-Total	1 (1.3)	1 (1.3)	0
Hypomagnesaemia	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Arthralgia	4 (5.0)	2 (2.5)	2 (2.5)
Vascular disorders			
-Total	4 (5.0)	0	4 (5.0)
Hypertension	4 (5.0)	0	4 (5.0)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259e
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	0	6 (75.0)
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	2 (25.0)	0
Gingival erythema	1 (12.5)	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	4 (50.0)	0	4 (50.0)
Pyrexia	3 (37.5)	0	3 (37.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)
Procedural pain	1 (12.5)	0	1 (12.5)
Radius fracture	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	1 (12.5)	0
Blood creatinine increased	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Hypocalcaemia	2 (25.0)	0	2 (25.0)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	0	1 (12.5)
Neuropathy peripheral	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	2 (25.0)	2 (25.0)	0
Acute kidney injury	2 (25.0)	2 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Ingrowing nail	1 (12.5)	1 (12.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259e
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (31.1)	8 (8.9)	20 (22.2)
Cardiac disorders			
-Total	3 (3.3)	1 (1.1)	2 (2.2)
Tachycardia	3 (3.3)	1 (1.1)	2 (2.2)
Gastrointestinal disorders			
-Total	1 (1.1)	1 (1.1)	0
Haematemesis	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	11 (12.2)	1 (1.1)	10 (11.1)
Pyrexia	11 (12.2)	3 (3.3)	8 (8.9)
Pain	3 (3.3)	0	3 (3.3)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Chills	1 (1.1)	0	1 (1.1)
Immune system disorders			
-Total	5 (5.6)	0	5 (5.6)
Hypogammaglobulinaemia	5 (5.6)	0	5 (5.6)
Injury, poisoning and procedural complications			
-Total	1 (1.1)	1 (1.1)	0
Procedural pain	1 (1.1)	1 (1.1)	0
Investigations			
-Total	4 (4.4)	2 (2.2)	2 (2.2)
Alanine aminotransferase increased	4 (4.4)	2 (2.2)	2 (2.2)
Aspartate aminotransferase increased	2 (2.2)	1 (1.1)	1 (1.1)
Metabolism and nutrition disorders			
-Total	4 (4.4)	2 (2.2)	2 (2.2)
Hypomagnesaemia	2 (2.2)	1 (1.1)	1 (1.1)
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)
Hypocalcaemia	1 (1.1)	1 (1.1)	0
Nervous system disorders			

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=90 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (1.1)	1 (1.1)	0
Neuropathy peripheral	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.1)	0	1 (1.1)
Oropharyngeal pain	1 (1.1)	0	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259f
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Hepatobiliary disorders			
-Total	1 (50.0)	1 (50.0)	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Device related bacteraemia	1 (50.0)	0	1 (50.0)
Fungal infection	1 (50.0)	0	1 (50.0)
Tonsillitis	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Transfusion reaction	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259f
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (15.6)	3 (3.1)	12 (12.5)
General disorders and administration site conditions			
-Total	14 (14.6)	3 (3.1)	11 (11.5)
Pyrexia	14 (14.6)	3 (3.1)	11 (11.5)
Injury, poisoning and procedural complications			
-Total	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259g
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Anal fissure	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259g
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (14.4)	3 (3.1)	11 (11.3)
General disorders and administration site conditions			
-Total	14 (14.4)	3 (3.1)	11 (11.3)
Pyrexia	14 (14.4)	3 (3.1)	11 (11.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259h
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Tachycardia	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	2 (66.7)	0	2 (66.7)
Pyrexia	2 (66.7)	0	2 (66.7)
Pain	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	1 (33.3)	0

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood creatinine increased	1 (33.3)	1 (33.3)	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypocalcaemia	1 (33.3)	0	1 (33.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	0	1 (33.3)
Myositis	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
-Total	1 (33.3)	1 (33.3)	0
Acute kidney injury	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259h
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (20.0)	5 (5.3)	14 (14.7)
Cardiac disorders			
-Total	3 (3.2)	2 (2.1)	1 (1.1)
Tachycardia	3 (3.2)	2 (2.1)	1 (1.1)
General disorders and administration site conditions			
-Total	12 (12.6)	1 (1.1)	11 (11.6)
Pyrexia	12 (12.6)	3 (3.2)	9 (9.5)
Pain	3 (3.2)	0	3 (3.2)
Investigations			
-Total	4 (4.2)	2 (2.1)	2 (2.1)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Alanine aminotransferase increased	4 (4.2)	2 (2.1)	2 (2.1)
Aspartate aminotransferase increased	2 (2.1)	1 (1.1)	1 (1.1)
Metabolism and nutrition disorders			
-Total	3 (3.2)	1 (1.1)	2 (2.1)
Hypocalcaemia	2 (2.1)	1 (1.1)	1 (1.1)
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)
Renal and urinary disorders			
-Total	1 (1.1)	1 (1.1)	0
Acute kidney injury	1 (1.1)	1 (1.1)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259i
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Immune system disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypersensitivity	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259i
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (17.7)	4 (4.2)	13 (13.5)
General disorders and administration site conditions			
-Total	14 (14.6)	3 (3.1)	11 (11.5)
Pyrexia	14 (14.6)	3 (3.1)	11 (11.5)
Investigations			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Alanine aminotransferase increased	4 (4.2)	2 (2.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259j
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set

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

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (43.3)	3 (10.0)	10 (33.3)
Blood and lymphatic system disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Anaemia	3 (10.0)	1 (3.3)	2 (6.7)
Cardiac disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Tachycardia	3 (10.0)	2 (6.7)	1 (3.3)
Gastrointestinal disorders			
-Total	4 (13.3)	1 (3.3)	3 (10.0)
Abdominal pain	4 (13.3)	1 (3.3)	3 (10.0)
General disorders and administration site conditions			

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Pyrexia	6 (20.0)	1 (3.3)	5 (16.7)
Fatigue	3 (10.0)	1 (3.3)	2 (6.7)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259j
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	15 (22.1)	3 (4.4)	12 (17.6)
Blood and lymphatic system disorders			
-Total	5 (7.4)	1 (1.5)	4 (5.9)
Anaemia	5 (7.4)	1 (1.5)	4 (5.9)
Cardiac disorders			
-Total	1 (1.5)	0	1 (1.5)
Tachycardia	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	2 (2.9)	1 (1.5)	1 (1.5)
Abdominal pain	2 (2.9)	1 (1.5)	1 (1.5)
General disorders and administration site conditions			

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (14.7)	2 (2.9)	8 (11.8)
Pyrexia	8 (11.8)	2 (2.9)	6 (8.8)
Fatigue	2 (2.9)	0	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259k
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (37.5)	3 (9.4)	9 (28.1)
Blood and lymphatic system disorders			
-Total	2 (6.3)	0	2 (6.3)
Anaemia	2 (6.3)	0	2 (6.3)
Gastrointestinal disorders			
-Total	1 (3.1)	1 (3.1)	0
Constipation	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Fatigue	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	4 (12.5)	0	4 (12.5)
Hypogammaglobulinaemia	4 (12.5)	0	4 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Arthralgia	2 (6.3)	1 (3.1)	1 (3.1)
Pain in extremity	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Headache	4 (12.5)	2 (6.3)	2 (6.3)
Vascular disorders			
-Total	1 (3.1)	0	1 (3.1)
Hypertension	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259k
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (45.6)	4 (7.0)	22 (38.6)
Blood and lymphatic system disorders			
-Total	6 (10.5)	2 (3.5)	4 (7.0)
Anaemia	6 (10.5)	2 (3.5)	4 (7.0)
Gastrointestinal disorders			
-Total	6 (10.5)	2 (3.5)	4 (7.0)
Constipation	6 (10.5)	2 (3.5)	4 (7.0)
General disorders and administration site conditions			
-Total	13 (22.8)	2 (3.5)	11 (19.3)
Pyrexia	12 (21.1)	2 (3.5)	10 (17.5)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Fatigue	3 (5.3)	0	3 (5.3)
Immune system disorders			
-Total	2 (3.5)	0	2 (3.5)
Hypogammaglobulinaemia	2 (3.5)	0	2 (3.5)
Musculoskeletal and connective tissue disorders			
-Total	5 (8.8)	2 (3.5)	3 (5.3)
Arthralgia	3 (5.3)	2 (3.5)	1 (1.8)
Pain in extremity	2 (3.5)	0	2 (3.5)
Nervous system disorders			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Headache	2 (3.5)	1 (1.8)	1 (1.8)
Vascular disorders			
-Total	6 (10.5)	2 (3.5)	4 (7.0)
Hypertension	6 (10.5)	2 (3.5)	4 (7.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259k
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (66.7)	1 (11.1)	5 (55.6)
Gastrointestinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Gastritis	1 (11.1)	0	1 (11.1)
Haemorrhoids	1 (11.1)	0	1 (11.1)
General disorders and administration site conditions			
-Total	1 (11.1)	0	1 (11.1)
Fatigue	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	1 (11.1)	0	1 (11.1)

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Tumour lysis syndrome	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (22.2)	2 (22.2)	0
Arthralgia	1 (11.1)	1 (11.1)	0
Pain in extremity	1 (11.1)	1 (11.1)	0
Reproductive system and breast disorders			
-Total	1 (11.1)	0	1 (11.1)
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	1 (11.1)	1 (11.1)	0
Erythema nodosum	1 (11.1)	1 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259l
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (22.4)	3 (5.2)	10 (17.2)
Blood and lymphatic system disorders			
-Total	3 (5.2)	0	3 (5.2)
Anaemia	3 (5.2)	0	3 (5.2)
Gastrointestinal disorders			
-Total	3 (5.2)	2 (3.4)	1 (1.7)
Constipation	3 (5.2)	2 (3.4)	1 (1.7)
General disorders and administration site conditions			
-Total	6 (10.3)	1 (1.7)	5 (8.6)
Pyrexia	6 (10.3)	1 (1.7)	5 (8.6)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Nervous system disorders			
-Total	6 (10.3)	3 (5.2)	3 (5.2)
Headache	6 (10.3)	3 (5.2)	3 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259l
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (32.5)	2 (5.0)	11 (27.5)
Blood and lymphatic system disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Anaemia	5 (12.5)	2 (5.0)	3 (7.5)
Gastrointestinal disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Constipation	4 (10.0)	1 (2.5)	3 (7.5)
General disorders and administration site conditions			
-Total	8 (20.0)	2 (5.0)	6 (15.0)
Pyrexia	8 (20.0)	2 (5.0)	6 (15.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259m
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (17.3)	3 (3.7)	11 (13.6)
General disorders and administration site conditions			
-Total	14 (17.3)	3 (3.7)	11 (13.6)
Pyrexia	14 (17.3)	3 (3.7)	11 (13.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 259n
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (10.7)	2 (7.1)	1 (3.6)
General disorders and administration site conditions			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Pyrexia	3 (10.7)	2 (7.1)	1 (3.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259n
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (15.7)	1 (1.4)	10 (14.3)
General disorders and administration site conditions			
-Total	11 (15.7)	1 (1.4)	10 (14.3)
Pyrexia	11 (15.7)	1 (1.4)	10 (14.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259o
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	1 (9.1)	3 (27.3)
General disorders and administration site conditions			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Pyrexia	2 (18.2)	1 (9.1)	1 (9.1)
Infections and infestations			
-Total	2 (18.2)	0	2 (18.2)
Sinusitis	2 (18.2)	0	2 (18.2)
Skin and subcutaneous tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pruritus	2 (18.2)	2 (18.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259o
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (14.9)	2 (2.3)	11 (12.6)
General disorders and administration site conditions			
-Total	12 (13.8)	2 (2.3)	10 (11.5)
Pyrexia	12 (13.8)	2 (2.3)	10 (11.5)
Skin and subcutaneous tissue disorders			
-Total	2 (2.3)	0	2 (2.3)
Pruritus	2 (2.3)	0	2 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259p
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (42.9)	0	3 (42.9)
Blood and lymphatic system disorders			
-Total	1 (14.3)	1 (14.3)	0
Neutropenia	1 (14.3)	1 (14.3)	0
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypothyroidism	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Constipation	1 (14.3)	0	1 (14.3)
Gastritis	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoaesthesia oral	1 (14.3)	0	1 (14.3)
Oral pain	1 (14.3)	0	1 (14.3)
Stomatitis	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Complication associated with device	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	1 (14.3)	0	1 (14.3)
Pneumonia	1 (14.3)	0	1 (14.3)
Investigations			
-Total	2 (28.6)	2 (28.6)	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0
Decreased appetite	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperphosphataemia	1 (14.3)	1 (14.3)	0
Hypocalcaemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Dizziness	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Dry skin	1 (14.3)	1 (14.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259p
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (18.7)	4 (4.4)	13 (14.3)
Endocrine disorders			
-Total	1 (1.1)	0	1 (1.1)
Hypothyroidism	1 (1.1)	0	1 (1.1)
Gastrointestinal disorders			
-Total	6 (6.6)	3 (3.3)	3 (3.3)
Constipation	6 (6.6)	3 (3.3)	3 (3.3)
General disorders and administration site conditions			
-Total	14 (15.4)	3 (3.3)	11 (12.1)
Pyrexia	14 (15.4)	3 (3.3)	11 (12.1)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Metabolism and nutrition disorders			
-Total	3 (3.3)	0	3 (3.3)
Hypocalcaemia	2 (2.2)	0	2 (2.2)
Decreased appetite	1 (1.1)	0	1 (1.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.1)	1 (1.1)	0
Oropharyngeal pain	1 (1.1)	1 (1.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (30.0)	1 (2.5)	11 (27.5)
Blood and lymphatic system disorders			
-Total	3 (7.5)	0	3 (7.5)
Anaemia	3 (7.5)	0	3 (7.5)
Gastrointestinal disorders			
-Total	2 (5.0)	0	2 (5.0)
Constipation	2 (5.0)	1 (2.5)	1 (2.5)
Abdominal pain	1 (2.5)	1 (2.5)	0
Nausea	1 (2.5)	0	1 (2.5)
General disorders and administration site conditions			
-Total	4 (10.0)	1 (2.5)	3 (7.5)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Pyrexia	3 (7.5)	1 (2.5)	2 (5.0)
Fatigue	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	5 (12.5)	0	5 (12.5)
Hypogammaglobulinaemia	5 (12.5)	0	5 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (50.0)	3 (7.5)	17 (42.5)
Blood and lymphatic system disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Anaemia	5 (12.5)	2 (5.0)	3 (7.5)
Cardiac disorders			
-Total	2 (5.0)	2 (5.0)	0
Tachycardia	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	12 (30.0)	3 (7.5)	9 (22.5)
Constipation	5 (12.5)	2 (5.0)	3 (7.5)
Abdominal pain	4 (10.0)	1 (2.5)	3 (7.5)
Nausea	4 (10.0)	1 (2.5)	3 (7.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	11 (27.5)	3 (7.5)	8 (20.0)
Pyrexia	7 (17.5)	2 (5.0)	5 (12.5)
Fatigue	4 (10.0)	1 (2.5)	3 (7.5)
Catheter site pain	2 (5.0)	0	2 (5.0)
Immune system disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	1 (2.5)	1 (2.5)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Hypertension	4 (10.0)	1 (2.5)	3 (7.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259q
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (55.6)	1 (5.6)	9 (50.0)
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Tachycardia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	3 (16.7)	0	3 (16.7)
Diarrhoea	2 (11.1)	0	2 (11.1)
Abdominal pain	1 (5.6)	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Pyrexia	4 (22.2)	0	4 (22.2)
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	2 (11.1)	2 (11.1)	0
Acute kidney injury	2 (11.1)	2 (11.1)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	0	6 (75.0)
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	2 (25.0)	0
Gingival erythema	1 (12.5)	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	4 (50.0)	0	4 (50.0)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	3 (37.5)	0	3 (37.5)
Chills	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	1 (12.5)	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)
Procedural pain	1 (12.5)	0	1 (12.5)
Radius fracture	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood creatinine increased	1 (12.5)	1 (12.5)	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Hypocalcaemia	2 (25.0)	0	2 (25.0)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	0	1 (12.5)
Neuropathy peripheral	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	2 (25.0)	2 (25.0)	0
Acute kidney injury	2 (25.0)	2 (25.0)	0
Respiratory, thoracic and mediastinal disorders			

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Ingrowing nail	1 (12.5)	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (46.7)	4 (13.3)	10 (33.3)
Blood and lymphatic system disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Anaemia	3 (10.0)	1 (3.3)	2 (6.7)
Cardiac disorders			
-Total	1 (3.3)	0	1 (3.3)
Tachycardia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Constipation	3 (10.0)	1 (3.3)	2 (6.7)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Pyrexia	4 (13.3)	3 (10.0)	1 (3.3)
Catheter site pain	3 (10.0)	1 (3.3)	2 (6.7)
Pain	2 (6.7)	0	2 (6.7)
Investigations			
-Total	1 (3.3)	0	1 (3.3)
Alanine aminotransferase increased	1 (3.3)	0	1 (3.3)
Aspartate aminotransferase increased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	2 (6.7)	0	2 (6.7)
Hypoalbuminaemia	1 (3.3)	0	1 (3.3)
Hypomagnesaemia	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	4 (13.3)	2 (6.7)	2 (6.7)
Pain in extremity	3 (10.0)	1 (3.3)	2 (6.7)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.3)	0	1 (3.3)
Oropharyngeal pain	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	1 (3.3)	0	1 (3.3)
Hypertension	1 (3.3)	0	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (72.2)	4 (22.2)	9 (50.0)
Blood and lymphatic system disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Anaemia	4 (22.2)	1 (5.6)	3 (16.7)
Thrombocytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Gastrointestinal disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Abdominal pain	2 (11.1)	0	2 (11.1)
Constipation	1 (5.6)	0	1 (5.6)
Haematemesis	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (16.7)	0	3 (16.7)
Pyrexia	3 (16.7)	0	3 (16.7)
Infections and infestations			
-Total	2 (11.1)	0	2 (11.1)
Oral herpes	2 (11.1)	0	2 (11.1)
Investigations			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Alanine aminotransferase increased	2 (11.1)	2 (11.1)	0
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypocalcaemia	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (11.1)	2 (11.1)	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Arthralgia	2 (11.1)	2 (11.1)	0
Vascular disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypertension	1 (5.6)	0	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 259r
Non-severe adverse events (AE CTCAE Grade 1/2) before study treatment that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (45.2)	3 (7.1)	16 (38.1)
Blood and lymphatic system disorders			
-Total	2 (4.8)	0	2 (4.8)
Anaemia	1 (2.4)	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)
Cardiac disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Tachycardia	2 (4.8)	1 (2.4)	1 (2.4)
Gastrointestinal disorders			
-Total	6 (14.3)	3 (7.1)	3 (7.1)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	4 (9.5)	2 (4.8)	2 (4.8)
Constipation	3 (7.1)	2 (4.8)	1 (2.4)
General disorders and administration site conditions			
-Total	6 (14.3)	1 (2.4)	5 (11.9)
Pyrexia	4 (9.5)	0	4 (9.5)
Catheter site pain	2 (4.8)	1 (2.4)	1 (2.4)
Chills	1 (2.4)	0	1 (2.4)
Pain	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	5 (11.9)	0	5 (11.9)
Hypogammaglobulinaemia	5 (11.9)	0	5 (11.9)
Injury, poisoning and procedural complications			
-Total	1 (2.4)	1 (2.4)	0
Procedural pain	1 (2.4)	1 (2.4)	0
Investigations			
-Total	3 (7.1)	1 (2.4)	2 (4.8)
C-reactive protein increased	2 (4.8)	1 (2.4)	1 (2.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	1 (2.4)	1 (2.4)	0
Hypomagnesaemia	1 (2.4)	1 (2.4)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (9.5)	1 (2.4)	3 (7.1)
Arthralgia	3 (7.1)	1 (2.4)	2 (4.8)
Pain in extremity	1 (2.4)	0	1 (2.4)
Nervous system disorders			
-Total	1 (2.4)	1 (2.4)	0
Neuropathy peripheral	1 (2.4)	1 (2.4)	0
Vascular disorders			
-Total	5 (11.9)	2 (4.8)	3 (7.1)
Hypertension	5 (11.9)	2 (4.8)	3 (7.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (32.4)	6 (17.6)	5 (14.7)
Gastrointestinal disorders			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Nausea	5 (14.7)	3 (8.8)	2 (5.9)
General disorders and administration site conditions			
-Total	6 (17.6)	4 (11.8)	2 (5.9)
Pyrexia	6 (17.6)	4 (11.8)	2 (5.9)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	0	1 (2.9)

Age: <10 years

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	1 (2.9)	0	1 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (19.4)	2 (6.5)	4 (12.9)
Gastrointestinal disorders			
-Total	4 (12.9)	1 (3.2)	3 (9.7)
Nausea	4 (12.9)	1 (3.2)	3 (9.7)
General disorders and administration site conditions			
-Total	1 (3.2)	0	1 (3.2)
Pyrexia	1 (3.2)	0	1 (3.2)
Skin and subcutaneous tissue disorders			
-Total	1 (3.2)	1 (3.2)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	1 (3.2)	1 (3.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261a
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (30.8)	1 (7.7)	3 (23.1)
Gastrointestinal disorders			
-Total	3 (23.1)	1 (7.7)	2 (15.4)
Nausea	3 (23.1)	1 (7.7)	2 (15.4)
General disorders and administration site conditions			
-Total	1 (7.7)	0	1 (7.7)
Pyrexia	1 (7.7)	0	1 (7.7)
Skin and subcutaneous tissue disorders			

Age: >=18

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Pruritus	2 (15.4)	1 (7.7)	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 261b
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (23.9)	6 (13.0)	5 (10.9)
Gastrointestinal disorders			
-Total	4 (8.7)	2 (4.3)	2 (4.3)
Nausea	4 (8.7)	2 (4.3)	2 (4.3)
General disorders and administration site conditions			
-Total	7 (15.2)	4 (8.7)	3 (6.5)
Pyrexia	7 (15.2)	4 (8.7)	3 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261b
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (31.3)	3 (9.4)	7 (21.9)
Gastrointestinal disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Nausea	8 (25.0)	3 (9.4)	5 (15.6)
General disorders and administration site conditions			
-Total	1 (3.1)	0	1 (3.1)
Pyrexia	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	4 (12.5)	2 (6.3)	2 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (35.1)	9 (15.8)	11 (19.3)
Gastrointestinal disorders			
-Total	8 (14.0)	4 (7.0)	4 (7.0)
Nausea	8 (14.0)	4 (7.0)	4 (7.0)
Abdominal pain	2 (3.5)	2 (3.5)	0
General disorders and administration site conditions			
-Total	7 (12.3)	3 (5.3)	4 (7.0)
Pyrexia	7 (12.3)	3 (5.3)	4 (7.0)
Investigations			
-Total	2 (3.5)	2 (3.5)	0

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Blood fibrinogen decreased	1 (1.8)	1 (1.8)	0
International normalised ratio increased	1 (1.8)	1 (1.8)	0
Metabolism and nutrition disorders			
-Total	5 (8.8)	2 (3.5)	3 (5.3)
Decreased appetite	5 (8.8)	2 (3.5)	3 (5.3)
Nervous system disorders			
-Total	1 (1.8)	1 (1.8)	0
Headache	1 (1.8)	1 (1.8)	0
Skin and subcutaneous tissue disorders			
-Total	1 (1.8)	0	1 (1.8)
Pruritus	1 (1.8)	0	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (70.0)	5 (50.0)	2 (20.0)
Gastrointestinal disorders			
-Total	5 (50.0)	4 (40.0)	1 (10.0)
Nausea	2 (20.0)	1 (10.0)	1 (10.0)
Abdominal pain	1 (10.0)	1 (10.0)	0
Constipation	1 (10.0)	1 (10.0)	0
Haematemesis	1 (10.0)	1 (10.0)	0
Immune system disorders			
-Total	1 (10.0)	0	1 (10.0)
Seasonal allergy	1 (10.0)	0	1 (10.0)

Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Infections and infestations			
-Total	1 (10.0)	1 (10.0)	0
Tinea pedis	1 (10.0)	1 (10.0)	0
Investigations			
-Total	1 (10.0)	0	1 (10.0)
Blood fibrinogen decreased	1 (10.0)	0	1 (10.0)
International normalised ratio increased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	2 (20.0)	2 (20.0)	0
Decreased appetite	1 (10.0)	1 (10.0)	0
Vitamin d deficiency	1 (10.0)	1 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (10.0)	0	1 (10.0)
Muscular weakness	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Headache	1 (10.0)	1 (10.0)	0

Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Posterior reversible encephalopathy syndrome	1 (10.0)	0	1 (10.0)
Seizure	1 (10.0)	0	1 (10.0)
Skin and subcutaneous tissue disorders			
-Total	2 (20.0)	2 (20.0)	0
Pruritus	2 (20.0)	2 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261c
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (36.4)	2 (18.2)	2 (18.2)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Constipation	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypomagnesaemia	2 (18.2)	1 (9.1)	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	0	1 (9.1)
Pruritus	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261d
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (42.9)	2 (14.3)	4 (28.6)
Gastrointestinal disorders			
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Vomiting	3 (21.4)	2 (14.3)	1 (7.1)
Nausea	2 (14.3)	0	2 (14.3)
General disorders and administration site conditions			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Chills	2 (14.3)	1 (7.1)	1 (7.1)
Pyrexia	2 (14.3)	1 (7.1)	1 (7.1)
Metabolism and nutrition disorders			

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261d
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (25.0)	8 (12.5)	8 (12.5)
Gastrointestinal disorders			
-Total	11 (17.2)	6 (9.4)	5 (7.8)
Nausea	10 (15.6)	5 (7.8)	5 (7.8)
Vomiting	3 (4.7)	3 (4.7)	0
General disorders and administration site conditions			
-Total	6 (9.4)	3 (4.7)	3 (4.7)
Pyrexia	6 (9.4)	3 (4.7)	3 (4.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261e
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0
Eye disorders			
-Total	1 (16.7)	0	1 (16.7)
Eyelid oedema	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal pain	2 (33.3)	2 (33.3)	0
Nausea	1 (16.7)	1 (16.7)	0

Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Stomatitis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	2 (33.3)	2 (33.3)	0
Decreased appetite	2 (33.3)	2 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	1 (16.7)	0
Pain in extremity	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0

Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	1 (16.7)	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	1 (16.7)	1 (16.7)	0
Dysuria	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Petechiae	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Rash	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261e
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	27 (37.5)	9 (12.5)	18 (25.0)
Blood and lymphatic system disorders			
-Total	1 (1.4)	0	1 (1.4)
Anaemia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	13 (18.1)	4 (5.6)	9 (12.5)
Nausea	11 (15.3)	4 (5.6)	7 (9.7)
Stomatitis	2 (2.8)	0	2 (2.8)
Abdominal pain	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (11.1)	4 (5.6)	4 (5.6)
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)
Investigations			
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	2 (2.8)	1 (1.4)	1 (1.4)
Aspartate aminotransferase increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	4 (5.6)	1 (1.4)	3 (4.2)
Decreased appetite	4 (5.6)	1 (1.4)	3 (4.2)
Nervous system disorders			
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Headache	2 (2.8)	1 (1.4)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	4 (5.6)	3 (4.2)	1 (1.4)
Pruritus	3 (4.2)	2 (2.8)	1 (1.4)
Rash	1 (1.4)	1 (1.4)	0
Vascular disorders			

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=72 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Hypotension	2 (2.8)	1 (1.4)	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261f
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Pleural effusion	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261f
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=77	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (26.0)	9 (11.7)	11 (14.3)
Gastrointestinal disorders			
-Total	12 (15.6)	5 (6.5)	7 (9.1)
Nausea	12 (15.6)	5 (6.5)	7 (9.1)
General disorders and administration site conditions			
-Total	8 (10.4)	4 (5.2)	4 (5.2)
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261g
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Abdominal pain	1 (100)	1 (100)	0
Nausea	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261g
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (26.0)	9 (11.7)	11 (14.3)
Gastrointestinal disorders			
-Total	12 (15.6)	5 (6.5)	7 (9.1)
Nausea	11 (14.3)	4 (5.2)	7 (9.1)
Abdominal pain	2 (2.6)	2 (2.6)	0
General disorders and administration site conditions			
-Total	8 (10.4)	4 (5.2)	4 (5.2)
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261h
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (26.0)	9 (11.7)	11 (14.3)
Gastrointestinal disorders			
-Total	12 (15.6)	5 (6.5)	7 (9.1)
Nausea	12 (15.6)	5 (6.5)	7 (9.1)
General disorders and administration site conditions			
-Total	8 (10.4)	4 (5.2)	4 (5.2)
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261i
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	20 (26.0)	9 (11.7)	11 (14.3)
Gastrointestinal disorders			
-Total	12 (15.6)	5 (6.5)	7 (9.1)
Nausea	12 (15.6)	5 (6.5)	7 (9.1)
General disorders and administration site conditions			
-Total	8 (10.4)	4 (5.2)	4 (5.2)
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261j
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (29.6)	5 (18.5)	3 (11.1)
Gastrointestinal disorders			
-Total	7 (25.9)	5 (18.5)	2 (7.4)
Nausea	5 (18.5)	3 (11.1)	2 (7.4)
Vomiting	3 (11.1)	3 (11.1)	0
General disorders and administration site conditions			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261j
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

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

		All patients N=51	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (27.5)	5 (9.8)	9 (17.6)
Gastrointestinal disorders			
-Total	9 (17.6)	3 (5.9)	6 (11.8)
Nausea	7 (13.7)	2 (3.9)	5 (9.8)
Vomiting	3 (5.9)	2 (3.9)	1 (2.0)
General disorders and administration site conditions			
-Total	6 (11.8)	3 (5.9)	3 (5.9)
Pyrexia	6 (11.8)	3 (5.9)	3 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261k
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (25.9)	2 (7.4)	5 (18.5)
Gastrointestinal disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Nausea	2 (7.4)	0	2 (7.4)
Vomiting	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261k
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	18 (40.9)	8 (18.2)	10 (22.7)
Gastrointestinal disorders			
-Total	12 (27.3)	6 (13.6)	6 (13.6)
Nausea	9 (20.5)	4 (9.1)	5 (11.4)
Vomiting	5 (11.4)	4 (9.1)	1 (2.3)
Constipation	1 (2.3)	0	1 (2.3)
General disorders and administration site conditions			
-Total	3 (6.8)	2 (4.5)	1 (2.3)
Pyrexia	3 (6.8)	2 (4.5)	1 (2.3)
Metabolism and nutrition disorders			

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	6 (13.6)	3 (6.8)	3 (6.8)
Decreased appetite	6 (13.6)	3 (6.8)	3 (6.8)
Nervous system disorders			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Headache	2 (4.5)	1 (2.3)	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	3 (6.8)	1 (2.3)	2 (4.5)
Pruritus	3 (6.8)	1 (2.3)	2 (4.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261k
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	4 (57.1)	4 (57.1)	0
Gastrointestinal disorders			
-Total	2 (28.6)	2 (28.6)	0
Constipation	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Tinea pedis	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0

Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Headache	1 (14.3)	1 (14.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Pruritus	1 (14.3)	1 (14.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261l
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (28.3)	6 (13.0)	7 (15.2)
Gastrointestinal disorders			
-Total	7 (15.2)	3 (6.5)	4 (8.7)
Nausea	7 (15.2)	3 (6.5)	4 (8.7)
General disorders and administration site conditions			
-Total	6 (13.0)	3 (6.5)	3 (6.5)
Pyrexia	6 (13.0)	3 (6.5)	3 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261l
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (21.9)	3 (9.4)	4 (12.5)
Gastrointestinal disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Nausea	5 (15.6)	2 (6.3)	3 (9.4)
General disorders and administration site conditions			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261m
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (46.2)	4 (30.8)	2 (15.4)
Gastrointestinal disorders			
-Total	6 (46.2)	4 (30.8)	2 (15.4)
Nausea	6 (46.2)	4 (30.8)	2 (15.4)
Vomiting	2 (15.4)	2 (15.4)	0
Skin and subcutaneous tissue disorders			
-Total	2 (15.4)	2 (15.4)	0
Rash papular	2 (15.4)	2 (15.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261m
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (24.6)	6 (9.2)	10 (15.4)
Gastrointestinal disorders			
-Total	10 (15.4)	4 (6.2)	6 (9.2)
Nausea	6 (9.2)	1 (1.5)	5 (7.7)
Vomiting	4 (6.2)	3 (4.6)	1 (1.5)
General disorders and administration site conditions			
-Total	8 (12.3)	4 (6.2)	4 (6.2)
Pyrexia	8 (12.3)	4 (6.2)	4 (6.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261n
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (36.0)	5 (20.0)	4 (16.0)
Gastrointestinal disorders			
-Total	5 (20.0)	2 (8.0)	3 (12.0)
Nausea	3 (12.0)	1 (4.0)	2 (8.0)
Vomiting	3 (12.0)	2 (8.0)	1 (4.0)
General disorders and administration site conditions			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Pyrexia	2 (8.0)	1 (4.0)	1 (4.0)
Metabolism and nutrition disorders			
-Total	4 (16.0)	3 (12.0)	1 (4.0)

Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	4 (16.0)	3 (12.0)	1 (4.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261n
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (32.1)	7 (13.2)	10 (18.9)
Gastrointestinal disorders			
-Total	11 (20.8)	6 (11.3)	5 (9.4)
Nausea	9 (17.0)	4 (7.5)	5 (9.4)
Vomiting	3 (5.7)	3 (5.7)	0
General disorders and administration site conditions			
-Total	6 (11.3)	3 (5.7)	3 (5.7)
Pyrexia	6 (11.3)	3 (5.7)	3 (5.7)
Metabolism and nutrition disorders			
-Total	2 (3.8)	0	2 (3.8)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	2 (3.8)	0	2 (3.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261o
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (27.3)	1 (9.1)	2 (18.2)
Gastrointestinal disorders			
-Total	2 (18.2)	0	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
General disorders and administration site conditions			
-Total	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 261o
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

		All patients N=67	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (25.4)	8 (11.9)	9 (13.4)
Gastrointestinal disorders			
-Total	10 (14.9)	5 (7.5)	5 (7.5)
Nausea	10 (14.9)	5 (7.5)	5 (7.5)
General disorders and administration site conditions			
-Total	7 (10.4)	3 (4.5)	4 (6.0)
Pyrexia	7 (10.4)	3 (4.5)	4 (6.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261p
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (83.3)	3 (50.0)	2 (33.3)
Gastrointestinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Constipation	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	1 (16.7)	0	1 (16.7)
Catheter site pain	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	1 (16.7)	0
Paronychia	1 (16.7)	1 (16.7)	0

Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	2 (33.3)	2 (33.3)	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	1 (16.7)	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Erythema	1 (16.7)	1 (16.7)	0
Ingrowing nail	1 (16.7)	0	1 (16.7)
Rash	1 (16.7)	1 (16.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261p
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	23 (31.9)	11 (15.3)	12 (16.7)
Gastrointestinal disorders			
-Total	12 (16.7)	5 (6.9)	7 (9.7)
Nausea	12 (16.7)	5 (6.9)	7 (9.7)
Constipation	1 (1.4)	0	1 (1.4)
General disorders and administration site conditions			
-Total	8 (11.1)	4 (5.6)	4 (5.6)
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)
Infections and infestations			
-Total	1 (1.4)	0	1 (1.4)

Down syndrome: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Paronychia	1 (1.4)	0	1 (1.4)
Investigations			
-Total	2 (2.8)	2 (2.8)	0
Alanine aminotransferase increased	2 (2.8)	2 (2.8)	0
Metabolism and nutrition disorders			
-Total	2 (2.8)	2 (2.8)	0
Hyperphosphataemia	1 (1.4)	1 (1.4)	0
Hypoalbuminaemia	1 (1.4)	1 (1.4)	0
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Rash	1 (1.4)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (18.4)	3 (7.9)	4 (10.5)
Cardiac disorders			
-Total	1 (2.6)	1 (2.6)	0
Tachycardia	1 (2.6)	1 (2.6)	0
Gastrointestinal disorders			
-Total	3 (7.9)	2 (5.3)	1 (2.6)
Nausea	3 (7.9)	2 (5.3)	1 (2.6)
Vomiting	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	4 (10.5)	2 (5.3)	2 (5.3)

Time since enrollment to CTL019 infusion: > Median

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	4 (10.5)	2 (5.3)	2 (5.3)
Metabolism and nutrition disorders			
-Total	1 (2.6)	0	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	19 (48.7)	9 (23.1)	10 (25.6)
Gastrointestinal disorders			
-Total	13 (33.3)	6 (15.4)	7 (17.9)
Nausea	9 (23.1)	3 (7.7)	6 (15.4)
Vomiting	5 (12.8)	4 (10.3)	1 (2.6)
General disorders and administration site conditions			
-Total	4 (10.3)	2 (5.1)	2 (5.1)
Pyrexia	4 (10.3)	2 (5.1)	2 (5.1)
Metabolism and nutrition disorders			
-Total	5 (12.8)	3 (7.7)	2 (5.1)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All grades n (%)	All patients N=39 Grade 1 n (%)	Grade 2 n (%)
Decreased appetite	5 (12.8)	3 (7.7)	2 (5.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261q
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Cardiac disorders			
-Total	1 (100)	1 (100)	0
Tachycardia	1 (100)	1 (100)	0
Renal and urinary disorders			
-Total	1 (100)	1 (100)	0
Acute kidney injury	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0
Eye disorders			
-Total	1 (16.7)	0	1 (16.7)
Eyelid oedema	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal pain	2 (33.3)	2 (33.3)	0

Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	1 (16.7)	1 (16.7)	0
Stomatitis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	2 (33.3)	2 (33.3)	0
Decreased appetite	2 (33.3)	2 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	1 (16.7)	0
Pain in extremity	1 (16.7)	1 (16.7)	0
Nervous system disorders			

Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (16.7)	1 (16.7)	0
Headache	1 (16.7)	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	1 (16.7)	1 (16.7)	0
Dysuria	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Petechiae	1 (16.7)	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)
Rash	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (36.4)	6 (27.3)	2 (9.1)
Gastrointestinal disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Nausea	3 (13.6)	2 (9.1)	1 (4.5)
Abdominal pain	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Pyrexia	3 (13.6)	2 (9.1)	1 (4.5)
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	1 (4.5)	1 (4.5)	0
Skin and subcutaneous tissue disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (33.3)	2 (13.3)	3 (20.0)
Gastrointestinal disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Nausea	4 (26.7)	1 (6.7)	3 (20.0)
General disorders and administration site conditions			
-Total	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)

Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	2 (13.3)	1 (6.7)	1 (6.7)
Skin and subcutaneous tissue disorders			
-Total	1 (6.7)	1 (6.7)	0
Pruritus	1 (6.7)	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 261r
Non-severe adverse events (AE CTCAE Grade 1/2) during lymphodepleting period that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (40.0)	1 (2.9)	13 (37.1)
Blood and lymphatic system disorders			
-Total	1 (2.9)	0	1 (2.9)
Anaemia	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	6 (17.1)	1 (2.9)	5 (14.3)
Nausea	4 (11.4)	1 (2.9)	3 (8.6)
Stomatitis	2 (5.7)	0	2 (5.7)
General disorders and administration site conditions			

Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (11.4)	1 (2.9)	3 (8.6)
Pyrexia	4 (11.4)	1 (2.9)	3 (8.6)
Investigations			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Alanine aminotransferase increased	2 (5.7)	1 (2.9)	1 (2.9)
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	3 (8.6)	0	3 (8.6)
Decreased appetite	3 (8.6)	0	3 (8.6)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Rash	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Hypotension	2 (5.7)	1 (2.9)	1 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	0	6 (75.0)
Cardiac disorders			
-Total	1 (12.5)	0	1 (12.5)
Tachycardia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Abdominal pain	1 (12.5)	0	1 (12.5)
Diarrhoea	1 (12.5)	0	1 (12.5)
Gastritis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)
Oedema peripheral	2 (25.0)	1 (12.5)	1 (12.5)
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypersensitivity	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Procedural pain	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	1 (12.5)	0	1 (12.5)
Hyperuricaemia	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	1 (12.5)	1 (12.5)	0
Acute kidney injury	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)

Age: <10 years

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypoxia	1 (12.5)	0	1 (12.5)
Tachypnoea	1 (12.5)	0	1 (12.5)
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	0	1 (12.5)
Pain of skin	1 (12.5)	1 (12.5)	0
Skin ulcer	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	2 (25.0)	0	2 (25.0)
Hypertension	2 (25.0)	0	2 (25.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Cardiac disorders			
-Total	1 (14.3)	0	1 (14.3)
Tachycardia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Diarrhoea	1 (14.3)	0	1 (14.3)
Haematemesis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	0	3 (42.9)

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	3 (42.9)	0	3 (42.9)
Pain	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	0	1 (14.3)
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)
Investigations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Alanine aminotransferase increased	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	1 (14.3)	0
Blood magnesium decreased	1 (14.3)	0	1 (14.3)
Blood potassium decreased	1 (14.3)	0	1 (14.3)
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	3 (42.9)	0	3 (42.9)
Hypocalcaemia	2 (28.6)	0	2 (28.6)

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Hypokalaemia	1 (14.3)	0	1 (14.3)
Hypomagnesaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Myositis	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Intraventricular haemorrhage	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	2 (28.6)	2 (28.6)	0
Acute kidney injury	2 (28.6)	2 (28.6)	0
Vascular disorders			
-Total	1 (14.3)	1 (14.3)	0
Hypertension	1 (14.3)	1 (14.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	1 (33.3)	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	1 (33.3)	0
Endocrine disorders			
-Total	1 (33.3)	0	1 (33.3)
Adrenal insufficiency	1 (33.3)	0	1 (33.3)
Eye disorders			
-Total	1 (33.3)	1 (33.3)	0
Eyelid oedema	1 (33.3)	1 (33.3)	0

Age: >=18

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Abdominal pain upper	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Catheter site pain	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Clostridium difficile colitis	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Decreased appetite	1 (33.3)	0	1 (33.3)
Hyperglycaemia	1 (33.3)	0	1 (33.3)
Musculoskeletal and connective tissue disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)

Age: >=18

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Arthralgia	1 (33.3)	0	1 (33.3)
Back pain	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Headache	1 (33.3)	1 (33.3)	0
Paraesthesia	1 (33.3)	1 (33.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Rash	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (88.9)	0	8 (88.9)
Cardiac disorders			
-Total	2 (22.2)	0	2 (22.2)
Tachycardia	2 (22.2)	0	2 (22.2)
Gastrointestinal disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Abdominal pain	1 (11.1)	0	1 (11.1)
Diarrhoea	1 (11.1)	0	1 (11.1)
Gastritis	1 (11.1)	0	1 (11.1)
Haematemesis	1 (11.1)	1 (11.1)	0

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	5 (55.6)	1 (11.1)	4 (44.4)
Pyrexia	3 (33.3)	0	3 (33.3)
Oedema peripheral	2 (22.2)	1 (11.1)	1 (11.1)
Catheter site pain	1 (11.1)	1 (11.1)	0
Pain	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			
-Total	1 (11.1)	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0
Investigations			
-Total	1 (11.1)	1 (11.1)	0
Alanine aminotransferase increased	1 (11.1)	1 (11.1)	0
Aspartate aminotransferase increased	1 (11.1)	1 (11.1)	0
Blood creatinine increased	1 (11.1)	1 (11.1)	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0
White blood cell count decreased	1 (11.1)	1 (11.1)	0

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	3 (33.3)	0	3 (33.3)
Hypocalcaemia	2 (22.2)	0	2 (22.2)
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)
Hypokalaemia	1 (11.1)	0	1 (11.1)
Hypomagnesaemia	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (11.1)	0	1 (11.1)
Myositis	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	1 (11.1)	1 (11.1)	0
Intraventricular haemorrhage	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	3 (33.3)	3 (33.3)	0
Acute kidney injury	3 (33.3)	3 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (22.2)	0	2 (22.2)

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypoxia	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	1 (11.1)	0	1 (11.1)
Pain of skin	1 (11.1)	1 (11.1)	0
Skin ulcer	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	2 (22.2)	0	2 (22.2)
Hypertension	2 (22.2)	0	2 (22.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (77.8)	1 (11.1)	6 (66.7)
Cardiac disorders			
-Total	1 (11.1)	1 (11.1)	0
Bradycardia	1 (11.1)	1 (11.1)	0
Endocrine disorders			
-Total	1 (11.1)	0	1 (11.1)
Adrenal insufficiency	1 (11.1)	0	1 (11.1)
Eye disorders			
-Total	1 (11.1)	1 (11.1)	0
Eyelid oedema	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			

Gender: Female

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Abdominal pain upper	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	0	1 (11.1)
Nausea	1 (11.1)	0	1 (11.1)
General disorders and administration site conditions			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Catheter site pain	2 (22.2)	1 (11.1)	1 (11.1)
Pyrexia	1 (11.1)	0	1 (11.1)
Immune system disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypersensitivity	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	2 (22.2)	0	2 (22.2)
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)
Investigations			
-Total	1 (11.1)	0	1 (11.1)

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood magnesium decreased	1 (11.1)	0	1 (11.1)
Blood potassium decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	2 (22.2)	0	2 (22.2)
Decreased appetite	1 (11.1)	0	1 (11.1)
Hyperglycaemia	1 (11.1)	0	1 (11.1)
Hyperuricaemia	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Arthralgia	1 (11.1)	0	1 (11.1)
Back pain	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	1 (11.1)	0
Headache	1 (11.1)	1 (11.1)	0
Paraesthesia	1 (11.1)	1 (11.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (11.1)	1 (11.1)	0

Gender: Female

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	1 (11.1)	1 (11.1)	0
Hypertension	1 (11.1)	1 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (63.6)	1 (9.1)	6 (54.5)
Gastrointestinal disorders			
-Total	1 (9.1)	0	1 (9.1)
Diarrhoea	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	6 (54.5)	2 (18.2)	4 (36.4)
Pyrexia	3 (27.3)	0	3 (27.3)
Catheter site pain	2 (18.2)	2 (18.2)	0
Oedema peripheral	2 (18.2)	1 (9.1)	1 (9.1)
Metabolism and nutrition disorders			

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	2 (18.2)	0	2 (18.2)
Hypocalcaemia	2 (18.2)	0	2 (18.2)
Renal and urinary disorders			
-Total	2 (18.2)	2 (18.2)	0
Acute kidney injury	2 (18.2)	2 (18.2)	0
Vascular disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Hypertension	2 (18.2)	1 (9.1)	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Cardiac disorders			
-Total	1 (20.0)	0	1 (20.0)
Tachycardia	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Gastritis	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	2 (40.0)	0	2 (40.0)
Catheter site pain	1 (20.0)	0	1 (20.0)

Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pyrexia	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)
Epstein-barr virus infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Blood magnesium decreased	1 (20.0)	0	1 (20.0)
Blood potassium decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	0	1 (20.0)
Hyperuricaemia	1 (20.0)	0	1 (20.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (20.0)	0	1 (20.0)
Myositis	1 (20.0)	0	1 (20.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Tachycardia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal pain	1 (50.0)	0	1 (50.0)
Diarrhoea	1 (50.0)	0	1 (50.0)
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Acute kidney injury	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Tachypnoea	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypertension	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Gastrointestinal disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Diarrhoea	1 (33.3)	0	1 (33.3)
Haematemesis	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pyrexia	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypocalcaemia	1 (33.3)	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	1 (33.3)	1 (33.3)	0
Acute kidney injury	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypertension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (53.3)	1 (6.7)	7 (46.7)
Cardiac disorders			
-Total	2 (13.3)	0	2 (13.3)
Tachycardia	2 (13.3)	0	2 (13.3)
Gastrointestinal disorders			
-Total	1 (6.7)	0	1 (6.7)
Diarrhoea	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
-Total	7 (46.7)	2 (13.3)	5 (33.3)
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)

Ethnicity: Other

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pyrexia	3 (20.0)	0	3 (20.0)
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypocalcaemia	1 (6.7)	0	1 (6.7)
Renal and urinary disorders			
-Total	2 (13.3)	2 (13.3)	0
Acute kidney injury	2 (13.3)	2 (13.3)	0
Vascular disorders			
-Total	2 (13.3)	0	2 (13.3)
Hypertension	2 (13.3)	0	2 (13.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Haematemesis	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	0	2 (100)
Pyrexia	2 (100)	0	2 (100)
Pain	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0

Response status at study entry: Primary refractory

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (100)	0	2 (100)
Hypocalcaemia	2 (100)	0	2 (100)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)
Hypomagnesaemia	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	2 (100)	2 (100)	0
Acute kidney injury	2 (100)	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (50.0)	1 (6.3)	7 (43.8)
Cardiac disorders			
-Total	2 (12.5)	0	2 (12.5)
Tachycardia	2 (12.5)	0	2 (12.5)
Gastrointestinal disorders			
-Total	2 (12.5)	0	2 (12.5)
Diarrhoea	2 (12.5)	0	2 (12.5)
General disorders and administration site conditions			
-Total	6 (37.5)	2 (12.5)	4 (25.0)
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	2 (12.5)	0	2 (12.5)
Renal and urinary disorders			
-Total	1 (6.3)	1 (6.3)	0
Acute kidney injury	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (55.6)	1 (5.6)	9 (50.0)
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Tachycardia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Diarrhoea	2 (11.1)	0	2 (11.1)
General disorders and administration site conditions			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Pyrexia	4 (22.2)	0	4 (22.2)
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	3 (16.7)	3 (16.7)	0
Acute kidney injury	3 (16.7)	3 (16.7)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (55.6)	1 (5.6)	9 (50.0)
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Tachycardia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Diarrhoea	2 (11.1)	0	2 (11.1)
General disorders and administration site conditions			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Pyrexia	4 (22.2)	0	4 (22.2)
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)

Mixed-lineage leukemia rearrangement: No			
		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	3 (16.7)	3 (16.7)	0
Acute kidney injury	3 (16.7)	3 (16.7)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Tachycardia	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	2 (100)	0	2 (100)
Pyrexia	2 (100)	0	2 (100)
Pain	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)
Hypocalcaemia	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Myositis	1 (50.0)	0	1 (50.0)
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0
Acute kidney injury	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (50.0)	1 (6.3)	7 (43.8)
Cardiac disorders			
-Total	1 (6.3)	0	1 (6.3)
Tachycardia	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	2 (12.5)	0	2 (12.5)
Diarrhoea	2 (12.5)	0	2 (12.5)
General disorders and administration site conditions			
-Total	6 (37.5)	2 (12.5)	4 (25.0)
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)

Hypodiploidy: No

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)
Pyrexia	2 (12.5)	0	2 (12.5)
Metabolism and nutrition disorders			
-Total	1 (6.3)	0	1 (6.3)
Hypocalcaemia	1 (6.3)	0	1 (6.3)
Renal and urinary disorders			
-Total	2 (12.5)	2 (12.5)	0
Acute kidney injury	2 (12.5)	2 (12.5)	0
Vascular disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypersensitivity	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (58.8)	1 (5.9)	9 (52.9)
Cardiac disorders			
-Total	2 (11.8)	0	2 (11.8)
Tachycardia	2 (11.8)	0	2 (11.8)
Gastrointestinal disorders			
-Total	2 (11.8)	0	2 (11.8)
Diarrhoea	2 (11.8)	0	2 (11.8)
General disorders and administration site conditions			
-Total	8 (47.1)	2 (11.8)	6 (35.3)
Pyrexia	4 (23.5)	0	4 (23.5)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)
Metabolism and nutrition disorders			
-Total	2 (11.8)	0	2 (11.8)
Hypocalcaemia	2 (11.8)	0	2 (11.8)
Renal and urinary disorders			
-Total	3 (17.6)	3 (17.6)	0
Acute kidney injury	3 (17.6)	3 (17.6)	0
Vascular disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)
Tachycardia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal pain	1 (33.3)	0	1 (33.3)
Diarrhoea	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pain	1 (33.3)	0	1 (33.3)

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood creatinine increased	1 (33.3)	1 (33.3)	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypocalcaemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
-Total	2 (66.7)	2 (66.7)	0
Acute kidney injury	2 (66.7)	2 (66.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)

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

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tachypnoea	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypertension	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

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

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (53.3)	1 (6.7)	7 (46.7)
Cardiac disorders			
-Total	1 (6.7)	0	1 (6.7)
Tachycardia	1 (6.7)	0	1 (6.7)
Gastrointestinal disorders			
-Total	1 (6.7)	0	1 (6.7)
Diarrhoea	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
-Total	7 (46.7)	2 (13.3)	5 (33.3)
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)
Pyrexia	3 (20.0)	0	3 (20.0)

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

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypocalcaemia	1 (6.7)	0	1 (6.7)
Renal and urinary disorders			
-Total	1 (6.7)	1 (6.7)	0
Acute kidney injury	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Hypertension	2 (13.3)	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Cardiac disorders			
-Total	1 (25.0)	1 (25.0)	0
Bradycardia	1 (25.0)	1 (25.0)	0
Eye disorders			
-Total	1 (25.0)	1 (25.0)	0
Eyelid oedema	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Abdominal pain upper	1 (25.0)	1 (25.0)	0

Region: Europe

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Catheter site pain	2 (50.0)	2 (50.0)	0
Oedema peripheral	2 (50.0)	1 (25.0)	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	1 (25.0)	0
Procedural pain	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Back pain	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Headache	1 (25.0)	1 (25.0)	0
Paraesthesia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			

Region: Europe

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	0	1 (25.0)
Skin and subcutaneous tissue disorders			
-Total	1 (25.0)	0	1 (25.0)
Pain of skin	1 (25.0)	1 (25.0)	0
Skin ulcer	1 (25.0)	0	1 (25.0)
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypertension	1 (25.0)	0	1 (25.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (58.3)	0	7 (58.3)
Cardiac disorders			
-Total	2 (16.7)	0	2 (16.7)
Tachycardia	2 (16.7)	0	2 (16.7)
Gastrointestinal disorders			
-Total	2 (16.7)	0	2 (16.7)
Diarrhoea	2 (16.7)	0	2 (16.7)
General disorders and administration site conditions			
-Total	5 (41.7)	0	5 (41.7)
Pyrexia	4 (33.3)	0	4 (33.3)

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Catheter site pain	1 (8.3)	0	1 (8.3)
Metabolism and nutrition disorders			
-Total	2 (16.7)	0	2 (16.7)
Hypocalcaemia	2 (16.7)	0	2 (16.7)
Renal and urinary disorders			
-Total	3 (25.0)	3 (25.0)	0
Acute kidney injury	3 (25.0)	3 (25.0)	0
Vascular disorders			
-Total	2 (16.7)	1 (8.3)	1 (8.3)
Hypertension	2 (16.7)	1 (8.3)	1 (8.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Gastritis	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (90.0)	1 (10.0)	8 (80.0)
Cardiac disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Tachycardia	2 (20.0)	0	2 (20.0)
Bradycardia	1 (10.0)	1 (10.0)	0
Endocrine disorders			
-Total	1 (10.0)	0	1 (10.0)
Adrenal insufficiency	1 (10.0)	0	1 (10.0)
Eye disorders			
-Total	1 (10.0)	1 (10.0)	0
Eyelid oedema	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	5 (50.0)	1 (10.0)	4 (40.0)
Diarrhoea	2 (20.0)	0	2 (20.0)
Abdominal pain	1 (10.0)	0	1 (10.0)
Abdominal pain upper	1 (10.0)	1 (10.0)	0
Gastritis	1 (10.0)	0	1 (10.0)
Nausea	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Catheter site pain	2 (20.0)	2 (20.0)	0
Oedema peripheral	2 (20.0)	1 (10.0)	1 (10.0)
Pyrexia	2 (20.0)	0	2 (20.0)
Infections and infestations			
-Total	2 (20.0)	0	2 (20.0)
Clostridium difficile colitis	1 (10.0)	0	1 (10.0)
Epstein-barr virus infection	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (10.0)	1 (10.0)	0
Procedural pain	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	1 (10.0)	0	1 (10.0)
Decreased appetite	1 (10.0)	0	1 (10.0)
Hyperglycaemia	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Arthralgia	1 (10.0)	0	1 (10.0)
Back pain	1 (10.0)	1 (10.0)	0
Myositis	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	1 (10.0)	0
Headache	1 (10.0)	1 (10.0)	0
Paraesthesia	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Tachypnoea	1 (10.0)	0	1 (10.0)
Skin and subcutaneous tissue disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Pain of skin	1 (10.0)	1 (10.0)	0
Rash	1 (10.0)	1 (10.0)	0
Skin ulcer	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Hypertension	3 (30.0)	1 (10.0)	2 (20.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (75.0)	0	6 (75.0)
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	3 (37.5)	0	3 (37.5)
Pyrexia	2 (25.0)	0	2 (25.0)
Catheter site pain	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Immune system disorders			

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (12.5)	0	1 (12.5)
Hypersensitivity	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	1 (12.5)	0
Blood creatinine increased	1 (12.5)	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	0	1 (12.5)
Blood potassium decreased	1 (12.5)	0	1 (12.5)
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	4 (50.0)	0	4 (50.0)
Hypocalcaemia	2 (25.0)	0	2 (25.0)
Hyperuricaemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	1 (12.5)

Prior SCT therapy: No

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	2 (25.0)	0
Acute kidney injury	2 (25.0)	2 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Gastrointestinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Gastritis	1 (25.0)	0	1 (25.0)
Immune system disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypersensitivity	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Epstein-barr virus infection	1 (25.0)	0	1 (25.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (71.4)	1 (7.1)	9 (64.3)
Cardiac disorders			
-Total	2 (14.3)	0	2 (14.3)
Tachycardia	2 (14.3)	0	2 (14.3)
Gastrointestinal disorders			
-Total	2 (14.3)	0	2 (14.3)
Diarrhoea	2 (14.3)	0	2 (14.3)
General disorders and administration site conditions			
-Total	8 (57.1)	2 (14.3)	6 (42.9)
Pyrexia	4 (28.6)	0	4 (28.6)

Eligibility for SCT: No

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Catheter site pain	3 (21.4)	2 (14.3)	1 (7.1)
Oedema peripheral	2 (14.3)	1 (7.1)	1 (7.1)
Metabolism and nutrition disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypocalcaemia	2 (14.3)	0	2 (14.3)
Renal and urinary disorders			
-Total	3 (21.4)	3 (21.4)	0
Acute kidney injury	3 (21.4)	3 (21.4)	0
Vascular disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypertension	3 (21.4)	1 (7.1)	2 (14.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Blood magnesium decreased	1 (50.0)	0	1 (50.0)
Blood potassium decreased	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (62.5)	1 (6.3)	9 (56.3)
Cardiac disorders			
-Total	2 (12.5)	0	2 (12.5)
Tachycardia	2 (12.5)	0	2 (12.5)
Gastrointestinal disorders			
-Total	2 (12.5)	0	2 (12.5)
Diarrhoea	2 (12.5)	0	2 (12.5)
General disorders and administration site conditions			
-Total	8 (50.0)	2 (12.5)	6 (37.5)
Pyrexia	4 (25.0)	0	4 (25.0)
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)
Metabolism and nutrition disorders			
-Total	2 (12.5)	0	2 (12.5)
Hypocalcaemia	2 (12.5)	0	2 (12.5)
Renal and urinary disorders			
-Total	3 (18.8)	3 (18.8)	0
Acute kidney injury	3 (18.8)	3 (18.8)	0
Vascular disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (55.6)	1 (5.6)	9 (50.0)
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Tachycardia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Diarrhoea	2 (11.1)	0	2 (11.1)
General disorders and administration site conditions			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Pyrexia	4 (22.2)	0	4 (22.2)
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	3 (16.7)	3 (16.7)	0
Acute kidney injury	3 (16.7)	3 (16.7)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Gastritis	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (58.8)	1 (5.9)	9 (52.9)
Cardiac disorders			
-Total	2 (11.8)	0	2 (11.8)
Tachycardia	2 (11.8)	0	2 (11.8)
Gastrointestinal disorders			
-Total	2 (11.8)	0	2 (11.8)
Diarrhoea	2 (11.8)	0	2 (11.8)
General disorders and administration site conditions			
-Total	8 (47.1)	2 (11.8)	6 (35.3)
Pyrexia	4 (23.5)	0	4 (23.5)

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)
Metabolism and nutrition disorders			
-Total	2 (11.8)	0	2 (11.8)
Hypocalcaemia	2 (11.8)	0	2 (11.8)
Renal and urinary disorders			
-Total	3 (17.6)	3 (17.6)	0
Acute kidney injury	3 (17.6)	3 (17.6)	0
Vascular disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (55.6)	1 (5.6)	9 (50.0)
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Tachycardia	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	2 (11.1)	0	2 (11.1)
Diarrhoea	2 (11.1)	0	2 (11.1)
General disorders and administration site conditions			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Pyrexia	4 (22.2)	0	4 (22.2)
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	3 (16.7)	3 (16.7)	0
Acute kidney injury	3 (16.7)	3 (16.7)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Haematemesis	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	0	2 (100)
Pyrexia	2 (100)	0	2 (100)
Pain	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (100)	0	2 (100)
Hypocalcaemia	2 (100)	0	2 (100)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)
Hypomagnesaemia	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	2 (100)	2 (100)	0
Acute kidney injury	2 (100)	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (87.5)	1 (12.5)	6 (75.0)
Cardiac disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Bradycardia	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	0	1 (12.5)
Eye disorders			
-Total	1 (12.5)	1 (12.5)	0
Eyelid oedema	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Abdominal pain upper	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)
Pyrexia	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypersensitivity	1 (12.5)	0	1 (12.5)
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Blood magnesium decreased	1 (12.5)	0	1 (12.5)
Blood potassium decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	2 (25.0)	0	2 (25.0)
Hyperuricaemia	1 (12.5)	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Back pain	1 (12.5)	1 (12.5)	0
Myositis	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	2 (25.0)	2 (25.0)	0
Headache	1 (12.5)	1 (12.5)	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0
Paraesthesia	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	0	1 (12.5)
Skin and subcutaneous tissue disorders			
-Total	1 (12.5)	0	1 (12.5)
Pain of skin	1 (12.5)	1 (12.5)	0
Skin ulcer	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 263r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Cardiac disorders			
-Total	1 (14.3)	0	1 (14.3)
Tachycardia	1 (14.3)	0	1 (14.3)
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Adrenal insufficiency	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	4 (57.1)	0	4 (57.1)
Diarrhoea	2 (28.6)	0	2 (28.6)

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	1 (14.3)	0	1 (14.3)
Gastritis	1 (14.3)	0	1 (14.3)
Nausea	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Catheter site pain	1 (14.3)	1 (14.3)	0
Oedema peripheral	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	2 (28.6)	0	2 (28.6)
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	1 (14.3)	0	1 (14.3)
Hyperglycaemia	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	0	1 (14.3)
Arthralgia	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Rash	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)

Number of previous relapses: >=3

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (82.9)	1 (2.4)	33 (80.5)
Blood and lymphatic system disorders			
-Total	13 (31.7)	3 (7.3)	10 (24.4)
Anaemia	13 (31.7)	3 (7.3)	10 (24.4)
Cardiac disorders			
-Total	9 (22.0)	4 (9.8)	5 (12.2)
Tachycardia	9 (22.0)	4 (9.8)	5 (12.2)
Endocrine disorders			
-Total	1 (2.4)	0	1 (2.4)
Adrenal insufficiency	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders			

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	30 (73.2)	14 (34.1)	16 (39.0)
Vomiting	18 (43.9)	13 (31.7)	5 (12.2)
Diarrhoea	14 (34.1)	9 (22.0)	5 (12.2)
Nausea	14 (34.1)	7 (17.1)	7 (17.1)
Abdominal pain	9 (22.0)	4 (9.8)	5 (12.2)
Constipation	7 (17.1)	4 (9.8)	3 (7.3)
Stomatitis	2 (4.9)	0	2 (4.9)
General disorders and administration site conditions			
-Total	24 (58.5)	15 (36.6)	9 (22.0)
Pyrexia	18 (43.9)	11 (26.8)	7 (17.1)
Fatigue	11 (26.8)	9 (22.0)	2 (4.9)
Chills	4 (9.8)	3 (7.3)	1 (2.4)
Asthenia	1 (2.4)	1 (2.4)	0
Hepatobiliary disorders			
-Total	1 (2.4)	0	1 (2.4)
Hepatic function abnormal	1 (2.4)	0	1 (2.4)
Immune system disorders			

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	26 (63.4)	5 (12.2)	21 (51.2)
Cytokine release syndrome	22 (53.7)	5 (12.2)	17 (41.5)
Hypogammaglobulinaemia	12 (29.3)	1 (2.4)	11 (26.8)
Infections and infestations			
-Total	15 (36.6)	6 (14.6)	9 (22.0)
Upper respiratory tract infection	7 (17.1)	4 (9.8)	3 (7.3)
Conjunctivitis	6 (14.6)	2 (4.9)	4 (9.8)
Nasopharyngitis	4 (9.8)	3 (7.3)	1 (2.4)
Rhinovirus infection	2 (4.9)	0	2 (4.9)
Investigations			
-Total	22 (53.7)	6 (14.6)	16 (39.0)
Alanine aminotransferase increased	11 (26.8)	3 (7.3)	8 (19.5)
Platelet count decreased	9 (22.0)	5 (12.2)	4 (9.8)
White blood cell count decreased	9 (22.0)	3 (7.3)	6 (14.6)
Aspartate aminotransferase increased	5 (12.2)	1 (2.4)	4 (9.8)
Blood immunoglobulin a decreased	5 (12.2)	4 (9.8)	1 (2.4)
Blood immunoglobulin m decreased	5 (12.2)	4 (9.8)	1 (2.4)

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	5 (12.2)	1 (2.4)	4 (9.8)
International normalised ratio increased	4 (9.8)	3 (7.3)	1 (2.4)
Blood bilirubin increased	2 (4.9)	1 (2.4)	1 (2.4)
Blood fibrinogen decreased	2 (4.9)	2 (4.9)	0
Metabolism and nutrition disorders			
-Total	17 (41.5)	7 (17.1)	10 (24.4)
Decreased appetite	9 (22.0)	5 (12.2)	4 (9.8)
Hypokalaemia	7 (17.1)	3 (7.3)	4 (9.8)
Hypophosphataemia	7 (17.1)	3 (7.3)	4 (9.8)
Hypocalcaemia	6 (14.6)	1 (2.4)	5 (12.2)
Hypoalbuminaemia	4 (9.8)	0	4 (9.8)
Hyperuricaemia	2 (4.9)	1 (2.4)	1 (2.4)
Hypomagnesaemia	1 (2.4)	1 (2.4)	0
Musculoskeletal and connective tissue disorders			
-Total	17 (41.5)	8 (19.5)	9 (22.0)
Pain in extremity	12 (29.3)	6 (14.6)	6 (14.6)
Arthralgia	4 (9.8)	1 (2.4)	3 (7.3)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Back pain	3 (7.3)	1 (2.4)	2 (4.9)
Myalgia	3 (7.3)	2 (4.9)	1 (2.4)
Nervous system disorders			
-Total	12 (29.3)	10 (24.4)	2 (4.9)
Headache	9 (22.0)	7 (17.1)	2 (4.9)
Lethargy	2 (4.9)	2 (4.9)	0
Tremor	2 (4.9)	2 (4.9)	0
Psychiatric disorders			
-Total	6 (14.6)	3 (7.3)	3 (7.3)
Anxiety	5 (12.2)	2 (4.9)	3 (7.3)
Agitation	2 (4.9)	2 (4.9)	0
Renal and urinary disorders			
-Total	2 (4.9)	2 (4.9)	0
Acute kidney injury	2 (4.9)	2 (4.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (41.5)	12 (29.3)	5 (12.2)
Cough	13 (31.7)	12 (29.3)	1 (2.4)

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Nasal congestion	5 (12.2)	4 (9.8)	1 (2.4)
Epistaxis	4 (9.8)	3 (7.3)	1 (2.4)
Oropharyngeal pain	2 (4.9)	1 (2.4)	1 (2.4)
Pleural effusion	2 (4.9)	1 (2.4)	1 (2.4)
Skin and subcutaneous tissue disorders			
-Total	10 (24.4)	6 (14.6)	4 (9.8)
Rash	5 (12.2)	3 (7.3)	2 (4.9)
Pruritus	4 (9.8)	1 (2.4)	3 (7.3)
Dry skin	3 (7.3)	2 (4.9)	1 (2.4)
Vascular disorders			
-Total	12 (29.3)	5 (12.2)	7 (17.1)
Hypotension	7 (17.1)	3 (7.3)	4 (9.8)
Hypertension	6 (14.6)	3 (7.3)	3 (7.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	35 (87.5)	1 (2.5)	34 (85.0)
Blood and lymphatic system disorders			
-Total	7 (17.5)	3 (7.5)	4 (10.0)
Anaemia	7 (17.5)	3 (7.5)	4 (10.0)
Coagulopathy	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Tachycardia	6 (15.0)	3 (7.5)	3 (7.5)
Sinus tachycardia	1 (2.5)	1 (2.5)	0
Endocrine disorders			
-Total	2 (5.0)	0	2 (5.0)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	2 (5.0)	0	2 (5.0)
Gastrointestinal disorders			
-Total	23 (57.5)	8 (20.0)	15 (37.5)
Nausea	10 (25.0)	4 (10.0)	6 (15.0)
Diarrhoea	9 (22.5)	6 (15.0)	3 (7.5)
Constipation	7 (17.5)	3 (7.5)	4 (10.0)
Abdominal pain	6 (15.0)	1 (2.5)	5 (12.5)
Vomiting	5 (12.5)	3 (7.5)	2 (5.0)
Stomatitis	1 (2.5)	0	1 (2.5)
General disorders and administration site conditions			
-Total	21 (52.5)	10 (25.0)	11 (27.5)
Pyrexia	14 (35.0)	7 (17.5)	7 (17.5)
Fatigue	6 (15.0)	5 (12.5)	1 (2.5)
Oedema peripheral	5 (12.5)	4 (10.0)	1 (2.5)
Chills	3 (7.5)	1 (2.5)	2 (5.0)
Pain	3 (7.5)	0	3 (7.5)
Asthenia	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatobiliary disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hepatic function abnormal	2 (5.0)	1 (2.5)	1 (2.5)
Immune system disorders			
-Total	28 (70.0)	5 (12.5)	23 (57.5)
Cytokine release syndrome	24 (60.0)	6 (15.0)	18 (45.0)
Hypogammaglobulinaemia	11 (27.5)	0	11 (27.5)
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)
Infections and infestations			
-Total	13 (32.5)	1 (2.5)	12 (30.0)
Sinusitis	5 (12.5)	0	5 (12.5)
Paronychia	4 (10.0)	1 (2.5)	3 (7.5)
Rhinovirus infection	4 (10.0)	0	4 (10.0)
Upper respiratory tract infection	4 (10.0)	0	4 (10.0)
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)
Investigations			
-Total	14 (35.0)	2 (5.0)	12 (30.0)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	7 (17.5)	1 (2.5)	6 (15.0)
Alanine aminotransferase increased	6 (15.0)	3 (7.5)	3 (7.5)
Blood fibrinogen decreased	5 (12.5)	1 (2.5)	4 (10.0)
Platelet count decreased	5 (12.5)	2 (5.0)	3 (7.5)
White blood cell count decreased	5 (12.5)	2 (5.0)	3 (7.5)
Blood bilirubin increased	4 (10.0)	1 (2.5)	3 (7.5)
International normalised ratio increased	4 (10.0)	2 (5.0)	2 (5.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	3 (7.5)
Metabolism and nutrition disorders			
-Total	21 (52.5)	5 (12.5)	16 (40.0)
Decreased appetite	11 (27.5)	5 (12.5)	6 (15.0)
Hyperuricaemia	6 (15.0)	6 (15.0)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)
Hypocalcaemia	6 (15.0)	1 (2.5)	5 (12.5)
Hypomagnesaemia	5 (12.5)	5 (12.5)	0
Hypophosphataemia	4 (10.0)	1 (2.5)	3 (7.5)
Hypokalaemia	3 (7.5)	0	3 (7.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperglycaemia	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	15 (37.5)	8 (20.0)	7 (17.5)
Pain in extremity	6 (15.0)	2 (5.0)	4 (10.0)
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)
Arthralgia	4 (10.0)	3 (7.5)	1 (2.5)
Back pain	4 (10.0)	1 (2.5)	3 (7.5)
Nervous system disorders			
-Total	18 (45.0)	6 (15.0)	12 (30.0)
Headache	17 (42.5)	6 (15.0)	11 (27.5)
Seizure	4 (10.0)	0	4 (10.0)
Tremor	2 (5.0)	1 (2.5)	1 (2.5)
Psychiatric disorders			
-Total	6 (15.0)	1 (2.5)	5 (12.5)
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)
Agitation	3 (7.5)	1 (2.5)	2 (5.0)
Renal and urinary disorders			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Acute kidney injury	6 (15.0)	3 (7.5)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (47.5)	13 (32.5)	6 (15.0)
Cough	11 (27.5)	7 (17.5)	4 (10.0)
Oropharyngeal pain	6 (15.0)	5 (12.5)	1 (2.5)
Nasal congestion	5 (12.5)	4 (10.0)	1 (2.5)
Epistaxis	4 (10.0)	2 (5.0)	2 (5.0)
Pleural effusion	4 (10.0)	3 (7.5)	1 (2.5)
Skin and subcutaneous tissue disorders			
-Total	12 (30.0)	6 (15.0)	6 (15.0)
Dry skin	5 (12.5)	4 (10.0)	1 (2.5)
Rash	5 (12.5)	2 (5.0)	3 (7.5)
Ingrowing nail	4 (10.0)	1 (2.5)	3 (7.5)
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)
Hyperhidrosis	1 (2.5)	1 (2.5)	0
Vascular disorders			

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	9 (22.5)	3 (7.5)	6 (15.0)
Hypertension	5 (12.5)	1 (2.5)	4 (10.0)
Hypotension	5 (12.5)	2 (5.0)	3 (7.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265a
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	14 (82.4)	0	14 (82.4)
Blood and lymphatic system disorders			
-Total	4 (23.5)	1 (5.9)	3 (17.6)
Anaemia	3 (17.6)	1 (5.9)	2 (11.8)
Coagulopathy	2 (11.8)	1 (5.9)	1 (5.9)
Cardiac disorders			
-Total	4 (23.5)	2 (11.8)	2 (11.8)
Sinus tachycardia	2 (11.8)	1 (5.9)	1 (5.9)
Tachycardia	2 (11.8)	1 (5.9)	1 (5.9)
Endocrine disorders			

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (17.6)	0	3 (17.6)
Adrenal insufficiency	3 (17.6)	0	3 (17.6)
Gastrointestinal disorders			
-Total	12 (70.6)	6 (35.3)	6 (35.3)
Nausea	6 (35.3)	3 (17.6)	3 (17.6)
Vomiting	6 (35.3)	4 (23.5)	2 (11.8)
Constipation	5 (29.4)	2 (11.8)	3 (17.6)
Diarrhoea	3 (17.6)	2 (11.8)	1 (5.9)
Stomatitis	3 (17.6)	1 (5.9)	2 (11.8)
Abdominal pain	2 (11.8)	1 (5.9)	1 (5.9)
General disorders and administration site conditions			
-Total	11 (64.7)	6 (35.3)	5 (29.4)
Pyrexia	6 (35.3)	2 (11.8)	4 (23.5)
Pain	3 (17.6)	1 (5.9)	2 (11.8)
Asthenia	2 (11.8)	1 (5.9)	1 (5.9)
Chills	2 (11.8)	1 (5.9)	1 (5.9)
Fatigue	2 (11.8)	1 (5.9)	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Non-cardiac chest pain	2 (11.8)	2 (11.8)	0
Oedema peripheral	2 (11.8)	2 (11.8)	0
Hepatobiliary disorders			
-Total	2 (11.8)	0	2 (11.8)
Hepatic function abnormal	2 (11.8)	0	2 (11.8)
Immune system disorders			
-Total	11 (64.7)	1 (5.9)	10 (58.8)
Cytokine release syndrome	11 (64.7)	2 (11.8)	9 (52.9)
Hypogammaglobulinaemia	5 (29.4)	1 (5.9)	4 (23.5)
Seasonal allergy	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	7 (41.2)	1 (5.9)	6 (35.3)
Acute sinusitis	2 (11.8)	0	2 (11.8)
Nasopharyngitis	2 (11.8)	1 (5.9)	1 (5.9)
Rhinovirus infection	2 (11.8)	0	2 (11.8)
Sinusitis	2 (11.8)	0	2 (11.8)
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)
Conjunctivitis	1 (5.9)	0	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Investigations			
-Total	5 (29.4)	0	5 (29.4)
Alanine aminotransferase increased	3 (17.6)	0	3 (17.6)
Aspartate aminotransferase increased	2 (11.8)	2 (11.8)	0
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)
Neutrophil count decreased	2 (11.8)	1 (5.9)	1 (5.9)
Blood bilirubin increased	1 (5.9)	0	1 (5.9)
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0
Platelet count decreased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	7 (41.2)	3 (17.6)	4 (23.5)
Hypokalaemia	4 (23.5)	1 (5.9)	3 (17.6)
Decreased appetite	3 (17.6)	3 (17.6)	0
Hyperglycaemia	3 (17.6)	0	3 (17.6)
Hypomagnesaemia	3 (17.6)	1 (5.9)	2 (11.8)
Hyperuricaemia	1 (5.9)	1 (5.9)	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypocalcaemia	1 (5.9)	0	1 (5.9)
Hypophosphataemia	1 (5.9)	0	1 (5.9)
Musculoskeletal and connective tissue disorders			
-Total	7 (41.2)	3 (17.6)	4 (23.5)
Arthralgia	4 (23.5)	2 (11.8)	2 (11.8)
Myalgia	2 (11.8)	1 (5.9)	1 (5.9)
Neck pain	2 (11.8)	1 (5.9)	1 (5.9)
Pain in extremity	2 (11.8)	1 (5.9)	1 (5.9)
Back pain	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	7 (41.2)	3 (17.6)	4 (23.5)
Headache	5 (29.4)	3 (17.6)	2 (11.8)
Lethargy	2 (11.8)	1 (5.9)	1 (5.9)
Paraesthesia	2 (11.8)	1 (5.9)	1 (5.9)
Tremor	2 (11.8)	2 (11.8)	0
Psychiatric disorders			
-Total	6 (35.3)	2 (11.8)	4 (23.5)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Anxiety	4 (23.5)	1 (5.9)	3 (17.6)
Agitation	2 (11.8)	1 (5.9)	1 (5.9)
Renal and urinary disorders			
-Total	1 (5.9)	0	1 (5.9)
Acute kidney injury	1 (5.9)	0	1 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (29.4)	4 (23.5)	1 (5.9)
Cough	2 (11.8)	2 (11.8)	0
Epistaxis	2 (11.8)	2 (11.8)	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0
Nasal congestion	1 (5.9)	1 (5.9)	0
Pleural effusion	1 (5.9)	0	1 (5.9)
Skin and subcutaneous tissue disorders			
-Total	6 (35.3)	2 (11.8)	4 (23.5)
Pruritus	4 (23.5)	2 (11.8)	2 (11.8)
Hyperhidrosis	2 (11.8)	0	2 (11.8)
Dry skin	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Vascular disorders			
-Total	4 (23.5)	1 (5.9)	3 (17.6)
Hypertension	4 (23.5)	1 (5.9)	3 (17.6)
Hypotension	1 (5.9)	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	49 (89.1)	2 (3.6)	47 (85.5)
Blood and lymphatic system disorders			
-Total	11 (20.0)	2 (3.6)	9 (16.4)
Anaemia	11 (20.0)	2 (3.6)	9 (16.4)
Cardiac disorders			
-Total	9 (16.4)	4 (7.3)	5 (9.1)
Tachycardia	9 (16.4)	4 (7.3)	5 (9.1)
Gastrointestinal disorders			
-Total	39 (70.9)	20 (36.4)	19 (34.5)
Nausea	18 (32.7)	10 (18.2)	8 (14.5)
Vomiting	17 (30.9)	14 (25.5)	3 (5.5)

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	14 (25.5)	9 (16.4)	5 (9.1)
Constipation	10 (18.2)	5 (9.1)	5 (9.1)
Abdominal pain	9 (16.4)	3 (5.5)	6 (10.9)
General disorders and administration site conditions			
-Total	29 (52.7)	15 (27.3)	14 (25.5)
Pyrexia	23 (41.8)	12 (21.8)	11 (20.0)
Fatigue	11 (20.0)	8 (14.5)	3 (5.5)
Chills	4 (7.3)	3 (5.5)	1 (1.8)
Immune system disorders			
-Total	33 (60.0)	5 (9.1)	28 (50.9)
Cytokine release syndrome	28 (50.9)	6 (10.9)	22 (40.0)
Hypogammaglobulinaemia	16 (29.1)	1 (1.8)	15 (27.3)
Infections and infestations			
-Total	19 (34.5)	7 (12.7)	12 (21.8)
Upper respiratory tract infection	8 (14.5)	4 (7.3)	4 (7.3)
Conjunctivitis	7 (12.7)	3 (5.5)	4 (7.3)
Nasopharyngitis	6 (10.9)	4 (7.3)	2 (3.6)

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Rhinovirus infection	3 (5.5)	0	3 (5.5)
Investigations			
-Total	24 (43.6)	5 (9.1)	19 (34.5)
Alanine aminotransferase increased	16 (29.1)	6 (10.9)	10 (18.2)
Aspartate aminotransferase increased	8 (14.5)	2 (3.6)	6 (10.9)
White blood cell count decreased	8 (14.5)	2 (3.6)	6 (10.9)
Platelet count decreased	7 (12.7)	3 (5.5)	4 (7.3)
Serum ferritin increased	6 (10.9)	2 (3.6)	4 (7.3)
International normalised ratio increased	3 (5.5)	2 (3.6)	1 (1.8)
Neutrophil count decreased	3 (5.5)	1 (1.8)	2 (3.6)
Metabolism and nutrition disorders			
-Total	24 (43.6)	9 (16.4)	15 (27.3)
Decreased appetite	14 (25.5)	7 (12.7)	7 (12.7)
Hypocalcaemia	7 (12.7)	2 (3.6)	5 (9.1)
Hypophosphataemia	7 (12.7)	4 (7.3)	3 (5.5)
Hypokalaemia	6 (10.9)	2 (3.6)	4 (7.3)
Hypoalbuminaemia	5 (9.1)	0	5 (9.1)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypomagnesaemia	4 (7.3)	4 (7.3)	0
Musculoskeletal and connective tissue disorders			
-Total	19 (34.5)	8 (14.5)	11 (20.0)
Pain in extremity	12 (21.8)	3 (5.5)	9 (16.4)
Arthralgia	9 (16.4)	4 (7.3)	5 (9.1)
Back pain	3 (5.5)	1 (1.8)	2 (3.6)
Myalgia	3 (5.5)	2 (3.6)	1 (1.8)
Nervous system disorders			
-Total	14 (25.5)	8 (14.5)	6 (10.9)
Headache	14 (25.5)	8 (14.5)	6 (10.9)
Psychiatric disorders			
-Total	9 (16.4)	2 (3.6)	7 (12.7)
Anxiety	9 (16.4)	2 (3.6)	7 (12.7)
Renal and urinary disorders			
-Total	6 (10.9)	5 (9.1)	1 (1.8)
Acute kidney injury	6 (10.9)	5 (9.1)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	24 (43.6)	16 (29.1)	8 (14.5)
Cough	14 (25.5)	12 (21.8)	2 (3.6)
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)
Oropharyngeal pain	6 (10.9)	4 (7.3)	2 (3.6)
Pleural effusion	6 (10.9)	3 (5.5)	3 (5.5)
Epistaxis	4 (7.3)	3 (5.5)	1 (1.8)
Skin and subcutaneous tissue disorders			
-Total	11 (20.0)	5 (9.1)	6 (10.9)
Pruritus	6 (10.9)	2 (3.6)	4 (7.3)
Rash	6 (10.9)	3 (5.5)	3 (5.5)
Dry skin	2 (3.6)	1 (1.8)	1 (1.8)
Vascular disorders			
-Total	15 (27.3)	5 (9.1)	10 (18.2)
Hypertension	8 (14.5)	3 (5.5)	5 (9.1)
Hypotension	8 (14.5)	2 (3.6)	6 (10.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265b
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (79.1)	1 (2.3)	33 (76.7)
Blood and lymphatic system disorders			
-Total	12 (27.9)	5 (11.6)	7 (16.3)
Anaemia	12 (27.9)	5 (11.6)	7 (16.3)
Cardiac disorders			
-Total	8 (18.6)	4 (9.3)	4 (9.3)
Tachycardia	8 (18.6)	4 (9.3)	4 (9.3)
Gastrointestinal disorders			
-Total	26 (60.5)	8 (18.6)	18 (41.9)
Diarrhoea	12 (27.9)	8 (18.6)	4 (9.3)
Nausea	12 (27.9)	4 (9.3)	8 (18.6)

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	12 (27.9)	6 (14.0)	6 (14.0)
Constipation	9 (20.9)	4 (9.3)	5 (11.6)
Abdominal pain	8 (18.6)	3 (7.0)	5 (11.6)
Stomatitis	6 (14.0)	1 (2.3)	5 (11.6)
General disorders and administration site conditions			
-Total	20 (46.5)	11 (25.6)	9 (20.9)
Pyrexia	15 (34.9)	8 (18.6)	7 (16.3)
Fatigue	8 (18.6)	7 (16.3)	1 (2.3)
Chills	5 (11.6)	2 (4.7)	3 (7.0)
Immune system disorders			
-Total	31 (72.1)	6 (14.0)	25 (58.1)
Cytokine release syndrome	29 (67.4)	7 (16.3)	22 (51.2)
Hypogammaglobulinaemia	12 (27.9)	1 (2.3)	11 (25.6)
Infections and infestations			
-Total	11 (25.6)	2 (4.7)	9 (20.9)
Rhinovirus infection	5 (11.6)	0	5 (11.6)
Upper respiratory tract infection	5 (11.6)	1 (2.3)	4 (9.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Conjunctivitis	2 (4.7)	0	2 (4.7)
Nasopharyngitis	2 (4.7)	1 (2.3)	1 (2.3)
Investigations			
-Total	18 (41.9)	3 (7.0)	15 (34.9)
Neutrophil count decreased	8 (18.6)	2 (4.7)	6 (14.0)
Platelet count decreased	8 (18.6)	5 (11.6)	3 (7.0)
International normalised ratio increased	7 (16.3)	4 (9.3)	3 (7.0)
Aspartate aminotransferase increased	6 (14.0)	2 (4.7)	4 (9.3)
White blood cell count decreased	6 (14.0)	3 (7.0)	3 (7.0)
Alanine aminotransferase increased	4 (9.3)	0	4 (9.3)
Serum ferritin increased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	21 (48.8)	6 (14.0)	15 (34.9)
Decreased appetite	9 (20.9)	6 (14.0)	3 (7.0)
Hypokalaemia	8 (18.6)	2 (4.7)	6 (14.0)
Hypoalbuminaemia	6 (14.0)	0	6 (14.0)
Hypocalcaemia	6 (14.0)	0	6 (14.0)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypomagnesaemia	5 (11.6)	3 (7.0)	2 (4.7)
Hypophosphataemia	5 (11.6)	0	5 (11.6)
Musculoskeletal and connective tissue disorders			
-Total	20 (46.5)	11 (25.6)	9 (20.9)
Pain in extremity	8 (18.6)	6 (14.0)	2 (4.7)
Myalgia	7 (16.3)	4 (9.3)	3 (7.0)
Back pain	5 (11.6)	1 (2.3)	4 (9.3)
Arthralgia	3 (7.0)	2 (4.7)	1 (2.3)
Nervous system disorders			
-Total	19 (44.2)	10 (23.3)	9 (20.9)
Headache	17 (39.5)	8 (18.6)	9 (20.9)
Tremor	6 (14.0)	5 (11.6)	1 (2.3)
Psychiatric disorders			
-Total	4 (9.3)	2 (4.7)	2 (4.7)
Anxiety	4 (9.3)	2 (4.7)	2 (4.7)
Renal and urinary disorders			
-Total	3 (7.0)	0	3 (7.0)

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	3 (7.0)	0	3 (7.0)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (39.5)	13 (30.2)	4 (9.3)
Cough	12 (27.9)	9 (20.9)	3 (7.0)
Epistaxis	6 (14.0)	4 (9.3)	2 (4.7)
Nasal congestion	5 (11.6)	4 (9.3)	1 (2.3)
Oropharyngeal pain	4 (9.3)	4 (9.3)	0
Pleural effusion	1 (2.3)	1 (2.3)	0
Skin and subcutaneous tissue disorders			
-Total	13 (30.2)	9 (20.9)	4 (9.3)
Dry skin	7 (16.3)	6 (14.0)	1 (2.3)
Pruritus	5 (11.6)	3 (7.0)	2 (4.7)
Rash	4 (9.3)	2 (4.7)	2 (4.7)
Vascular disorders			
-Total	10 (23.3)	4 (9.3)	6 (14.0)
Hypertension	7 (16.3)	2 (4.7)	5 (11.6)
Hypotension	5 (11.6)	3 (7.0)	2 (4.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	61 (87.1)	2 (2.9)	59 (84.3)
Blood and lymphatic system disorders			
-Total	21 (30.0)	6 (8.6)	15 (21.4)
Anaemia	18 (25.7)	6 (8.6)	12 (17.1)
Disseminated intravascular coagulation	3 (4.3)	0	3 (4.3)
Cardiac disorders			
-Total	14 (20.0)	7 (10.0)	7 (10.0)
Tachycardia	14 (20.0)	7 (10.0)	7 (10.0)
Endocrine disorders			
-Total	3 (4.3)	0	3 (4.3)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Adrenal insufficiency	3 (4.3)	0	3 (4.3)
Gastrointestinal disorders			
-Total	46 (65.7)	21 (30.0)	25 (35.7)
Vomiting	22 (31.4)	15 (21.4)	7 (10.0)
Nausea	21 (30.0)	9 (12.9)	12 (17.1)
Diarrhoea	18 (25.7)	12 (17.1)	6 (8.6)
Abdominal pain	13 (18.6)	5 (7.1)	8 (11.4)
Constipation	12 (17.1)	5 (7.1)	7 (10.0)
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	40 (57.1)	23 (32.9)	17 (24.3)
Pyrexia	30 (42.9)	17 (24.3)	13 (18.6)
Fatigue	16 (22.9)	13 (18.6)	3 (4.3)
Chills	7 (10.0)	4 (5.7)	3 (4.3)
Face oedema	7 (10.0)	5 (7.1)	2 (2.9)
Hepatobiliary disorders			
-Total	1 (1.4)	0	1 (1.4)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatic function abnormal	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	47 (67.1)	7 (10.0)	40 (57.1)
Cytokine release syndrome	40 (57.1)	8 (11.4)	32 (45.7)
Hypogammaglobulinaemia	19 (27.1)	1 (1.4)	18 (25.7)
Seasonal allergy	2 (2.9)	0	2 (2.9)
Infections and infestations			
-Total	25 (35.7)	8 (11.4)	17 (24.3)
Upper respiratory tract infection	10 (14.3)	4 (5.7)	6 (8.6)
Conjunctivitis	8 (11.4)	3 (4.3)	5 (7.1)
Rhinovirus infection	7 (10.0)	0	7 (10.0)
Nasopharyngitis	5 (7.1)	3 (4.3)	2 (2.9)
Investigations			
-Total	31 (44.3)	7 (10.0)	24 (34.3)
Alanine aminotransferase increased	15 (21.4)	5 (7.1)	10 (14.3)
White blood cell count decreased	13 (18.6)	5 (7.1)	8 (11.4)
Platelet count decreased	12 (17.1)	7 (10.0)	5 (7.1)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	10 (14.3)	2 (2.9)	8 (11.4)
Neutrophil count decreased	10 (14.3)	2 (2.9)	8 (11.4)
International normalised ratio increased	7 (10.0)	5 (7.1)	2 (2.9)
Lymphocyte count decreased	7 (10.0)	3 (4.3)	4 (5.7)
Blood fibrinogen decreased	4 (5.7)	3 (4.3)	1 (1.4)
C-reactive protein increased	3 (4.3)	2 (2.9)	1 (1.4)
Serum ferritin increased	2 (2.9)	0	2 (2.9)
Metabolism and nutrition disorders			
-Total	35 (50.0)	12 (17.1)	23 (32.9)
Decreased appetite	20 (28.6)	11 (15.7)	9 (12.9)
Hypokalaemia	11 (15.7)	3 (4.3)	8 (11.4)
Hypocalcaemia	10 (14.3)	2 (2.9)	8 (11.4)
Hypophosphataemia	9 (12.9)	4 (5.7)	5 (7.1)
Hypoalbuminaemia	7 (10.0)	0	7 (10.0)
Hyperuricaemia	6 (8.6)	5 (7.1)	1 (1.4)
Hypomagnesaemia	4 (5.7)	4 (5.7)	0
Hyperglycaemia	2 (2.9)	0	2 (2.9)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	29 (41.4)	15 (21.4)	14 (20.0)
Pain in extremity	18 (25.7)	8 (11.4)	10 (14.3)
Arthralgia	8 (11.4)	4 (5.7)	4 (5.7)
Myalgia	8 (11.4)	4 (5.7)	4 (5.7)
Back pain	5 (7.1)	2 (2.9)	3 (4.3)
Nervous system disorders			
-Total	25 (35.7)	13 (18.6)	12 (17.1)
Headache	25 (35.7)	13 (18.6)	12 (17.1)
Seizure	2 (2.9)	0	2 (2.9)
Psychiatric disorders			
-Total	11 (15.7)	7 (10.0)	4 (5.7)
Anxiety	8 (11.4)	4 (5.7)	4 (5.7)
Confusional state	5 (7.1)	5 (7.1)	0
Renal and urinary disorders			
-Total	8 (11.4)	4 (5.7)	4 (5.7)
Acute kidney injury	8 (11.4)	4 (5.7)	4 (5.7)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	33 (47.1)	24 (34.3)	9 (12.9)
Cough	21 (30.0)	17 (24.3)	4 (5.7)
Epistaxis	9 (12.9)	7 (10.0)	2 (2.9)
Nasal congestion	9 (12.9)	7 (10.0)	2 (2.9)
Oropharyngeal pain	9 (12.9)	7 (10.0)	2 (2.9)
Pleural effusion	4 (5.7)	3 (4.3)	1 (1.4)
Rhinorrhoea	4 (5.7)	3 (4.3)	1 (1.4)
Tachypnoea	4 (5.7)	3 (4.3)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	20 (28.6)	10 (14.3)	10 (14.3)
Rash	9 (12.9)	4 (5.7)	5 (7.1)
Dry skin	8 (11.4)	6 (8.6)	2 (2.9)
Pruritus	7 (10.0)	2 (2.9)	5 (7.1)
Rash maculo-papular	2 (2.9)	1 (1.4)	1 (1.4)
Vascular disorders			
-Total	19 (27.1)	8 (11.4)	11 (15.7)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypotension	12 (17.1)	5 (7.1)	7 (10.0)
Hypertension	10 (14.3)	4 (5.7)	6 (8.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	10 (66.7)	0	10 (66.7)
Blood and lymphatic system disorders			
-Total	3 (20.0)	0	3 (20.0)
Disseminated intravascular coagulation	2 (13.3)	0	2 (13.3)
Anaemia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Cardiac dysfunction	2 (13.3)	2 (13.3)	0
Tachycardia	1 (6.7)	0	1 (6.7)
Gastrointestinal disorders			

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	9 (60.0)	5 (33.3)	4 (26.7)
Nausea	4 (26.7)	3 (20.0)	1 (6.7)
Constipation	3 (20.0)	3 (20.0)	0
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)
Abdominal pain	2 (13.3)	1 (6.7)	1 (6.7)
Pancreatitis	2 (13.3)	0	2 (13.3)
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Pyrexia	3 (20.0)	1 (6.7)	2 (13.3)
Fatigue	1 (6.7)	1 (6.7)	0
Hepatobiliary disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Hepatic function abnormal	4 (26.7)	1 (6.7)	3 (20.0)
Immune system disorders			
-Total	8 (53.3)	2 (13.3)	6 (40.0)
Cytokine release syndrome	7 (46.7)	3 (20.0)	4 (26.7)

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	5 (33.3)	0	5 (33.3)
Seasonal allergy	1 (6.7)	0	1 (6.7)
Infections and infestations			
-Total	1 (6.7)	0	1 (6.7)
Nasopharyngitis	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	0	1 (6.7)
Investigations			
-Total	6 (40.0)	0	6 (40.0)
Serum ferritin increased	4 (26.7)	1 (6.7)	3 (20.0)
Blood fibrinogen decreased	3 (20.0)	0	3 (20.0)
Alanine aminotransferase increased	2 (13.3)	1 (6.7)	1 (6.7)
Aspartate aminotransferase increased	2 (13.3)	1 (6.7)	1 (6.7)
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)
International normalised ratio increased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Decreased appetite	2 (13.3)	2 (13.3)	0

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	1 (6.7)	1 (6.7)	0
Hypoalbuminaemia	1 (6.7)	0	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	6 (40.0)	3 (20.0)	3 (20.0)
Arthralgia	3 (20.0)	2 (13.3)	1 (6.7)
Pain in extremity	2 (13.3)	1 (6.7)	1 (6.7)
Back pain	1 (6.7)	0	1 (6.7)
Nervous system disorders			
-Total	4 (26.7)	2 (13.3)	2 (13.3)
Headache	3 (20.0)	2 (13.3)	1 (6.7)
Seizure	2 (13.3)	0	2 (13.3)
Psychiatric disorders			
-Total	1 (6.7)	0	1 (6.7)
Anxiety	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (33.3)	4 (26.7)	1 (6.7)
Pleural effusion	2 (13.3)	1 (6.7)	1 (6.7)

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Cough	1 (6.7)	1 (6.7)	0
Nasal congestion	1 (6.7)	1 (6.7)	0
Oropharyngeal pain	1 (6.7)	1 (6.7)	0
Skin and subcutaneous tissue disorders			
-Total	3 (20.0)	3 (20.0)	0
Pruritus	3 (20.0)	3 (20.0)	0
Dry skin	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	3 (20.0)	0	3 (20.0)
Hypertension	3 (20.0)	0	3 (20.0)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265c
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	12 (92.3)	0	12 (92.3)
Blood and lymphatic system disorders			
-Total	4 (30.8)	1 (7.7)	3 (23.1)
Anaemia	4 (30.8)	1 (7.7)	3 (23.1)
Cardiac disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Tachycardia	2 (15.4)	1 (7.7)	1 (7.7)
Endocrine disorders			
-Total	3 (23.1)	0	3 (23.1)
Adrenal insufficiency	3 (23.1)	0	3 (23.1)

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	11 (84.6)	3 (23.1)	8 (61.5)
Vomiting	6 (46.2)	4 (30.8)	2 (15.4)
Diarrhoea	5 (38.5)	3 (23.1)	2 (15.4)
Nausea	5 (38.5)	2 (15.4)	3 (23.1)
Constipation	4 (30.8)	1 (7.7)	3 (23.1)
Abdominal pain	2 (15.4)	0	2 (15.4)
Pancreatitis	1 (7.7)	0	1 (7.7)
General disorders and administration site conditions			
-Total	8 (61.5)	3 (23.1)	5 (38.5)
Pyrexia	5 (38.5)	2 (15.4)	3 (23.1)
Chills	2 (15.4)	1 (7.7)	1 (7.7)
Fatigue	2 (15.4)	1 (7.7)	1 (7.7)
Immune system disorders			
-Total	10 (76.9)	2 (15.4)	8 (61.5)
Cytokine release syndrome	10 (76.9)	2 (15.4)	8 (61.5)
Hypogammaglobulinaemia	4 (30.8)	1 (7.7)	3 (23.1)

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Seasonal allergy	2 (15.4)	2 (15.4)	0
Infections and infestations			
-Total	4 (30.8)	1 (7.7)	3 (23.1)
Nasopharyngitis	2 (15.4)	1 (7.7)	1 (7.7)
Upper respiratory tract infection	2 (15.4)	1 (7.7)	1 (7.7)
Conjunctivitis	1 (7.7)	0	1 (7.7)
Rhinovirus infection	1 (7.7)	0	1 (7.7)
Investigations			
-Total	7 (53.8)	1 (7.7)	6 (46.2)
Alanine aminotransferase increased	3 (23.1)	0	3 (23.1)
Platelet count decreased	3 (23.1)	1 (7.7)	2 (15.4)
Aspartate aminotransferase increased	2 (15.4)	1 (7.7)	1 (7.7)
International normalised ratio increased	2 (15.4)	1 (7.7)	1 (7.7)
Neutrophil count decreased	1 (7.7)	1 (7.7)	0
Serum ferritin increased	1 (7.7)	1 (7.7)	0
White blood cell count decreased	1 (7.7)	0	1 (7.7)
Metabolism and nutrition disorders			

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	7 (53.8)	1 (7.7)	6 (46.2)
Hypomagnesaemia	5 (38.5)	3 (23.1)	2 (15.4)
Hypoalbuminaemia	3 (23.1)	0	3 (23.1)
Hypocalcaemia	3 (23.1)	0	3 (23.1)
Hypokalaemia	3 (23.1)	1 (7.7)	2 (15.4)
Hypophosphataemia	3 (23.1)	0	3 (23.1)
Hyperglycaemia	2 (15.4)	0	2 (15.4)
Hyperuricaemia	2 (15.4)	2 (15.4)	0
Decreased appetite	1 (7.7)	0	1 (7.7)
Musculoskeletal and connective tissue disorders			
-Total	4 (30.8)	1 (7.7)	3 (23.1)
Back pain	2 (15.4)	0	2 (15.4)
Myalgia	2 (15.4)	2 (15.4)	0
Arthralgia	1 (7.7)	0	1 (7.7)
Nervous system disorders			
-Total	5 (38.5)	0	5 (38.5)
Cognitive disorder	3 (23.1)	0	3 (23.1)

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Headache	3 (23.1)	1 (7.7)	2 (15.4)
Paraesthesia	2 (15.4)	1 (7.7)	1 (7.7)
Psychiatric disorders			
-Total	6 (46.2)	2 (15.4)	4 (30.8)
Anxiety	4 (30.8)	0	4 (30.8)
Confusional state	2 (15.4)	2 (15.4)	0
Renal and urinary disorders			
-Total	1 (7.7)	1 (7.7)	0
Acute kidney injury	1 (7.7)	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (38.5)	1 (7.7)	4 (30.8)
Cough	4 (30.8)	3 (23.1)	1 (7.7)
Rhinorrhoea	2 (15.4)	1 (7.7)	1 (7.7)
Tachypnoea	2 (15.4)	1 (7.7)	1 (7.7)
Epistaxis	1 (7.7)	0	1 (7.7)
Nasal congestion	1 (7.7)	1 (7.7)	0
Pleural effusion	1 (7.7)	0	1 (7.7)

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	3 (23.1)	1 (7.7)	2 (15.4)
Rash maculo-papular	2 (15.4)	1 (7.7)	1 (7.7)
Pruritus	1 (7.7)	0	1 (7.7)
Rash	1 (7.7)	1 (7.7)	0
Vascular disorders			
-Total	3 (23.1)	1 (7.7)	2 (15.4)
Hypertension	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	1 (7.7)	0	1 (7.7)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	16 (88.9)	0	16 (88.9)
Blood and lymphatic system disorders			
-Total	3 (16.7)	0	3 (16.7)
Anaemia	3 (16.7)	0	3 (16.7)
Cardiac disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Tachycardia	3 (16.7)	0	3 (16.7)
Sinus tachycardia	2 (11.1)	2 (11.1)	0
Endocrine disorders			
-Total	4 (22.2)	0	4 (22.2)
Adrenal insufficiency	4 (22.2)	0	4 (22.2)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	13 (72.2)	5 (27.8)	8 (44.4)
Diarrhoea	6 (33.3)	3 (16.7)	3 (16.7)
Nausea	6 (33.3)	2 (11.1)	4 (22.2)
Vomiting	6 (33.3)	5 (27.8)	1 (5.6)
Constipation	4 (22.2)	1 (5.6)	3 (16.7)
Abdominal pain	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	11 (61.1)	4 (22.2)	7 (38.9)
Pyrexia	6 (33.3)	2 (11.1)	4 (22.2)
Chills	4 (22.2)	2 (11.1)	2 (11.1)
Fatigue	4 (22.2)	3 (16.7)	1 (5.6)
Oedema peripheral	3 (16.7)	2 (11.1)	1 (5.6)
Generalised oedema	2 (11.1)	0	2 (11.1)
Immune system disorders			
-Total	14 (77.8)	1 (5.6)	13 (72.2)
Cytokine release syndrome	13 (72.2)	1 (5.6)	12 (66.7)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	5 (27.8)	1 (5.6)	4 (22.2)
Seasonal allergy	3 (16.7)	2 (11.1)	1 (5.6)
Infections and infestations			
-Total	6 (33.3)	1 (5.6)	5 (27.8)
Upper respiratory tract infection	4 (22.2)	0	4 (22.2)
Conjunctivitis	2 (11.1)	2 (11.1)	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)
Investigations			
-Total	6 (33.3)	0	6 (33.3)
Alanine aminotransferase increased	4 (22.2)	0	4 (22.2)
Aspartate aminotransferase increased	3 (16.7)	1 (5.6)	2 (11.1)
Platelet count decreased	3 (16.7)	1 (5.6)	2 (11.1)
International normalised ratio increased	2 (11.1)	0	2 (11.1)
White blood cell count decreased	2 (11.1)	0	2 (11.1)
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	12 (66.7)	1 (5.6)	11 (61.1)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	5 (27.8)	1 (5.6)	4 (22.2)
Hypocalcaemia	5 (27.8)	0	5 (27.8)
Hypokalaemia	5 (27.8)	1 (5.6)	4 (22.2)
Hypomagnesaemia	5 (27.8)	3 (16.7)	2 (11.1)
Hyperuricaemia	4 (22.2)	4 (22.2)	0
Hypoalbuminaemia	4 (22.2)	0	4 (22.2)
Hyperglycaemia	3 (16.7)	0	3 (16.7)
Hypophosphataemia	3 (16.7)	1 (5.6)	2 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	6 (33.3)	3 (16.7)	3 (16.7)
Myalgia	3 (16.7)	2 (11.1)	1 (5.6)
Pain in extremity	3 (16.7)	1 (5.6)	2 (11.1)
Arthralgia	2 (11.1)	0	2 (11.1)
Nervous system disorders			
-Total	7 (38.9)	1 (5.6)	6 (33.3)
Headache	5 (27.8)	2 (11.1)	3 (16.7)
Cognitive disorder	3 (16.7)	0	3 (16.7)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Paraesthesia	2 (11.1)	1 (5.6)	1 (5.6)
Psychiatric disorders			
-Total	7 (38.9)	1 (5.6)	6 (33.3)
Anxiety	4 (22.2)	0	4 (22.2)
Insomnia	2 (11.1)	1 (5.6)	1 (5.6)
Mental status changes	2 (11.1)	0	2 (11.1)
Renal and urinary disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Acute kidney injury	3 (16.7)	1 (5.6)	2 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (38.9)	3 (16.7)	4 (22.2)
Cough	3 (16.7)	2 (11.1)	1 (5.6)
Nasal congestion	3 (16.7)	2 (11.1)	1 (5.6)
Oropharyngeal pain	3 (16.7)	2 (11.1)	1 (5.6)
Pulmonary oedema	2 (11.1)	1 (5.6)	1 (5.6)
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)
Skin and subcutaneous tissue disorders			

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Dry skin	2 (11.1)	2 (11.1)	0
Pruritus	2 (11.1)	0	2 (11.1)
Rash	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypertension	2 (11.1)	2 (11.1)	0
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

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Table 265d
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	67 (83.8)	4 (5.0)	63 (78.8)
Blood and lymphatic system disorders			
-Total	20 (25.0)	7 (8.8)	13 (16.3)
Anaemia	20 (25.0)	7 (8.8)	13 (16.3)
Cardiac disorders			
-Total	15 (18.8)	8 (10.0)	7 (8.8)
Tachycardia	14 (17.5)	8 (10.0)	6 (7.5)
Sinus tachycardia	1 (1.3)	0	1 (1.3)
Endocrine disorders			
-Total	2 (2.5)	0	2 (2.5)
Adrenal insufficiency	2 (2.5)	0	2 (2.5)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	52 (65.0)	24 (30.0)	28 (35.0)
Nausea	24 (30.0)	12 (15.0)	12 (15.0)
Vomiting	23 (28.8)	15 (18.8)	8 (10.0)
Diarrhoea	20 (25.0)	14 (17.5)	6 (7.5)
Abdominal pain	16 (20.0)	6 (7.5)	10 (12.5)
Constipation	15 (18.8)	8 (10.0)	7 (8.8)
General disorders and administration site conditions			
-Total	41 (51.3)	24 (30.0)	17 (21.3)
Pyrexia	32 (40.0)	18 (22.5)	14 (17.5)
Fatigue	15 (18.8)	12 (15.0)	3 (3.8)
Chills	5 (6.3)	3 (3.8)	2 (2.5)
Oedema peripheral	4 (5.0)	4 (5.0)	0
Generalised oedema	3 (3.8)	2 (2.5)	1 (1.3)
Immune system disorders			
-Total	51 (63.8)	10 (12.5)	41 (51.3)
Cytokine release syndrome	44 (55.0)	12 (15.0)	32 (40.0)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	23 (28.8)	1 (1.3)	22 (27.5)
Seasonal allergy	2 (2.5)	0	2 (2.5)
Infections and infestations			
-Total	19 (23.8)	8 (10.0)	11 (13.8)
Upper respiratory tract infection	9 (11.3)	5 (6.3)	4 (5.0)
Nasopharyngitis	8 (10.0)	5 (6.3)	3 (3.8)
Conjunctivitis	7 (8.8)	1 (1.3)	6 (7.5)
Gastroenteritis	3 (3.8)	3 (3.8)	0
Investigations			
-Total	33 (41.3)	8 (10.0)	25 (31.3)
Alanine aminotransferase increased	16 (20.0)	6 (7.5)	10 (12.5)
Platelet count decreased	12 (15.0)	7 (8.8)	5 (6.3)
White blood cell count decreased	12 (15.0)	5 (6.3)	7 (8.8)
Aspartate aminotransferase increased	11 (13.8)	3 (3.8)	8 (10.0)
Neutrophil count decreased	10 (12.5)	3 (3.8)	7 (8.8)
International normalised ratio increased	8 (10.0)	6 (7.5)	2 (2.5)
Metabolism and nutrition disorders			

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	33 (41.3)	14 (17.5)	19 (23.8)
Decreased appetite	18 (22.5)	12 (15.0)	6 (7.5)
Hypokalaemia	9 (11.3)	3 (3.8)	6 (7.5)
Hypophosphataemia	9 (11.3)	3 (3.8)	6 (7.5)
Hypocalcaemia	8 (10.0)	2 (2.5)	6 (7.5)
Hypoalbuminaemia	7 (8.8)	0	7 (8.8)
Hyperuricaemia	5 (6.3)	4 (5.0)	1 (1.3)
Hypomagnesaemia	4 (5.0)	4 (5.0)	0
Hyperglycaemia	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	27 (33.8)	15 (18.8)	12 (15.0)
Pain in extremity	17 (21.3)	8 (10.0)	9 (11.3)
Arthralgia	10 (12.5)	6 (7.5)	4 (5.0)
Myalgia	7 (8.8)	4 (5.0)	3 (3.8)
Nervous system disorders			
-Total	26 (32.5)	14 (17.5)	12 (15.0)
Headache	26 (32.5)	14 (17.5)	12 (15.0)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Psychiatric disorders			
-Total	12 (15.0)	6 (7.5)	6 (7.5)
Anxiety	9 (11.3)	4 (5.0)	5 (6.3)
Insomnia	4 (5.0)	1 (1.3)	3 (3.8)
Mental status changes	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	6 (7.5)	4 (5.0)	2 (2.5)
Acute kidney injury	6 (7.5)	4 (5.0)	2 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	34 (42.5)	27 (33.8)	7 (8.8)
Cough	23 (28.8)	19 (23.8)	4 (5.0)
Epistaxis	10 (12.5)	7 (8.8)	3 (3.8)
Nasal congestion	8 (10.0)	7 (8.8)	1 (1.3)
Oropharyngeal pain	7 (8.8)	6 (7.5)	1 (1.3)
Pulmonary oedema	4 (5.0)	2 (2.5)	2 (2.5)
Skin and subcutaneous tissue disorders			
-Total	19 (23.8)	11 (13.8)	8 (10.0)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	9 (11.3)	5 (6.3)	4 (5.0)
Rash	9 (11.3)	4 (5.0)	5 (6.3)
Dry skin	7 (8.8)	5 (6.3)	2 (2.5)
Vascular disorders			
-Total	21 (26.3)	6 (7.5)	15 (18.8)
Hypertension	13 (16.3)	3 (3.8)	10 (12.5)
Hypotension	11 (13.8)	4 (5.0)	7 (8.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (100)	0	8 (100)
Blood and lymphatic system disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Anaemia	2 (25.0)	1 (12.5)	1 (12.5)
Lymphocytosis	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Tachycardia	3 (37.5)	1 (12.5)	2 (25.0)
Sinus tachycardia	1 (12.5)	1 (12.5)	0
Eye disorders			
-Total	1 (12.5)	0	1 (12.5)
Eyelid oedema	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Abdominal pain	2 (25.0)	2 (25.0)	0
Nausea	2 (25.0)	2 (25.0)	0
Abdominal distension	1 (12.5)	0	1 (12.5)
Ascites	1 (12.5)	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)
Mouth haemorrhage	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Pyrexia	5 (62.5)	0	5 (62.5)
Fatigue	2 (25.0)	2 (25.0)	0
Catheter site pain	1 (12.5)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Face oedema	1 (12.5)	0	1 (12.5)
Generalised oedema	1 (12.5)	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Hepatobiliary disorders			
-Total	1 (12.5)	1 (12.5)	0
Cholelithiasis	1 (12.5)	1 (12.5)	0
Gallbladder enlargement	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Cytokine release syndrome	5 (62.5)	2 (25.0)	3 (37.5)
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)
Seasonal allergy	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	3 (37.5)	0	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis externa	1 (12.5)	0	1 (12.5)
Rhinovirus infection	1 (12.5)	0	1 (12.5)
Sinusitis	1 (12.5)	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	3 (37.5)	0	3 (37.5)
Fibula fracture	1 (12.5)	0	1 (12.5)
Infusion related reaction	1 (12.5)	0	1 (12.5)
Procedural pain	1 (12.5)	0	1 (12.5)
Radius fracture	1 (12.5)	0	1 (12.5)
Skin injury	1 (12.5)	0	1 (12.5)
Skin wound	1 (12.5)	1 (12.5)	0
Wound	1 (12.5)	0	1 (12.5)
Investigations			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0
Blood bilirubin increased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)
International normalised ratio increased	1 (12.5)	1 (12.5)	0
Lipase increased	1 (12.5)	1 (12.5)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	1 (12.5)	0
Weight increased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)
Hypocalcaemia	3 (37.5)	0	3 (37.5)
Hyperuricaemia	2 (25.0)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)
Acidosis	1 (12.5)	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Hyponatraemia	1 (12.5)	1 (12.5)	0
Hypophosphataemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Myalgia	1 (12.5)	1 (12.5)	0
Myositis	1 (12.5)	0	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	4 (50.0)	0	4 (50.0)
Headache	4 (50.0)	3 (37.5)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)
Monoparesis	1 (12.5)	0	1 (12.5)
Neuropathy peripheral	1 (12.5)	0	1 (12.5)
Tremor	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Confusional state	1 (12.5)	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)
Sleep disorder	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Acute kidney injury	3 (37.5)	2 (25.0)	1 (12.5)
Bladder dilatation	1 (12.5)	0	1 (12.5)
Dysuria	1 (12.5)	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Nasal congestion	2 (25.0)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oropharyngeal pain	2 (25.0)	2 (25.0)	0
Atelectasis	1 (12.5)	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Dry skin	2 (25.0)	2 (25.0)	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)
Decubitus ulcer	1 (12.5)	0	1 (12.5)
Erythema	1 (12.5)	1 (12.5)	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0
Ingrowing nail	1 (12.5)	1 (12.5)	0
Petechiae	1 (12.5)	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)
Skin hypopigmentation	1 (12.5)	1 (12.5)	0
Skin ulcer	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	2 (25.0)	0
Hypotension	2 (25.0)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	1 (12.5)	1 (12.5)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265e
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	76 (84.4)	5 (5.6)	71 (78.9)
Blood and lymphatic system disorders			
-Total	21 (23.3)	6 (6.7)	15 (16.7)
Anaemia	21 (23.3)	6 (6.7)	15 (16.7)
Cardiac disorders			
-Total	16 (17.8)	8 (8.9)	8 (8.9)
Tachycardia	14 (15.6)	7 (7.8)	7 (7.8)
Sinus tachycardia	2 (2.2)	1 (1.1)	1 (1.1)
Eye disorders			
-Total	2 (2.2)	1 (1.1)	1 (1.1)
Eyelid oedema	2 (2.2)	1 (1.1)	1 (1.1)
Gastrointestinal disorders			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	62 (68.9)	25 (27.8)	37 (41.1)
Vomiting	29 (32.2)	20 (22.2)	9 (10.0)
Nausea	28 (31.1)	12 (13.3)	16 (17.8)
Diarrhoea	26 (28.9)	17 (18.9)	9 (10.0)
Constipation	18 (20.0)	8 (8.9)	10 (11.1)
Abdominal pain	15 (16.7)	4 (4.4)	11 (12.2)
Stomatitis	5 (5.6)	1 (1.1)	4 (4.4)
Haematemesis	3 (3.3)	3 (3.3)	0
Mouth haemorrhage	3 (3.3)	2 (2.2)	1 (1.1)
Abdominal distension	2 (2.2)	1 (1.1)	1 (1.1)
Ascites	2 (2.2)	1 (1.1)	1 (1.1)
Gingival erythema	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	49 (54.4)	25 (27.8)	24 (26.7)
Pyrexia	33 (36.7)	20 (22.2)	13 (14.4)
Fatigue	17 (18.9)	13 (14.4)	4 (4.4)
Chills	8 (8.9)	5 (5.6)	3 (3.3)
Face oedema	6 (6.7)	5 (5.6)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Oedema peripheral	6 (6.7)	6 (6.7)	0
Pain	5 (5.6)	1 (1.1)	4 (4.4)
Catheter site pain	4 (4.4)	1 (1.1)	3 (3.3)
Generalised oedema	4 (4.4)	2 (2.2)	2 (2.2)
Hepatobiliary disorders			
-Total	2 (2.2)	1 (1.1)	1 (1.1)
Cholelithiasis	1 (1.1)	0	1 (1.1)
Gallbladder enlargement	1 (1.1)	1 (1.1)	0
Immune system disorders			
-Total	59 (65.6)	10 (11.1)	49 (54.4)
Cytokine release syndrome	52 (57.8)	11 (12.2)	41 (45.6)
Hypogammaglobulinaemia	26 (28.9)	2 (2.2)	24 (26.7)
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)
Infections and infestations			
-Total	29 (32.2)	8 (8.9)	21 (23.3)
Upper respiratory tract infection	12 (13.3)	5 (5.6)	7 (7.8)
Conjunctivitis	8 (8.9)	3 (3.3)	5 (5.6)
Rhinovirus infection	7 (7.8)	0	7 (7.8)
Sinusitis	6 (6.7)	0	6 (6.7)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis	4 (4.4)	3 (3.3)	1 (1.1)
Otitis externa	1 (1.1)	0	1 (1.1)
Injury, poisoning and procedural complications			
-Total	8 (8.9)	4 (4.4)	4 (4.4)
Infusion related reaction	4 (4.4)	2 (2.2)	2 (2.2)
Procedural pain	2 (2.2)	1 (1.1)	1 (1.1)
Wound	2 (2.2)	1 (1.1)	1 (1.1)
Investigations			
-Total	39 (43.3)	8 (8.9)	31 (34.4)
Alanine aminotransferase increased	18 (20.0)	5 (5.6)	13 (14.4)
Platelet count decreased	14 (15.6)	7 (7.8)	7 (7.8)
Aspartate aminotransferase increased	12 (13.3)	3 (3.3)	9 (10.0)
White blood cell count decreased	11 (12.2)	4 (4.4)	7 (7.8)
International normalised ratio increased	9 (10.0)	5 (5.6)	4 (4.4)
Neutrophil count decreased	8 (8.9)	2 (2.2)	6 (6.7)
Blood bilirubin increased	6 (6.7)	2 (2.2)	4 (4.4)
Lymphocyte count decreased	6 (6.7)	2 (2.2)	4 (4.4)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood immunoglobulin m decreased	4 (4.4)	4 (4.4)	0
Weight increased	4 (4.4)	2 (2.2)	2 (2.2)
Blood immunoglobulin g decreased	3 (3.3)	1 (1.1)	2 (2.2)
Electrocardiogram qt prolonged	3 (3.3)	2 (2.2)	1 (1.1)
Blood creatinine increased	1 (1.1)	0	1 (1.1)
Lipase increased	1 (1.1)	1 (1.1)	0
Metabolism and nutrition disorders			
-Total	39 (43.3)	13 (14.4)	26 (28.9)
Decreased appetite	20 (22.2)	11 (12.2)	9 (10.0)
Hypokalaemia	13 (14.4)	4 (4.4)	9 (10.0)
Hypophosphataemia	11 (12.2)	4 (4.4)	7 (7.8)
Hypocalcaemia	10 (11.1)	2 (2.2)	8 (8.9)
Hypoalbuminaemia	9 (10.0)	0	9 (10.0)
Hypomagnesaemia	8 (8.9)	6 (6.7)	2 (2.2)
Hyperuricaemia	7 (7.8)	6 (6.7)	1 (1.1)
Hyperglycaemia	3 (3.3)	0	3 (3.3)
Hyponatraemia	2 (2.2)	2 (2.2)	0
Hypermagnesaemia	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	31 (34.4)	16 (17.8)	15 (16.7)
Pain in extremity	19 (21.1)	8 (8.9)	11 (12.2)
Arthralgia	12 (13.3)	6 (6.7)	6 (6.7)
Myalgia	9 (10.0)	5 (5.6)	4 (4.4)
Nervous system disorders			
-Total	31 (34.4)	16 (17.8)	15 (16.7)
Headache	27 (30.0)	13 (14.4)	14 (15.6)
Tremor	5 (5.6)	4 (4.4)	1 (1.1)
Somnolence	2 (2.2)	1 (1.1)	1 (1.1)
Neuropathy peripheral	1 (1.1)	1 (1.1)	0
Psychiatric disorders			
-Total	18 (20.0)	7 (7.8)	11 (12.2)
Anxiety	13 (14.4)	4 (4.4)	9 (10.0)
Confusional state	6 (6.7)	6 (6.7)	0
Sleep disorder	2 (2.2)	0	2 (2.2)
Renal and urinary disorders			
-Total	10 (11.1)	6 (6.7)	4 (4.4)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	6 (6.7)	3 (3.3)	3 (3.3)
Dysuria	4 (4.4)	3 (3.3)	1 (1.1)
Urinary retention	1 (1.1)	0	1 (1.1)
Respiratory, thoracic and mediastinal disorders			
-Total	35 (38.9)	25 (27.8)	10 (11.1)
Cough	25 (27.8)	20 (22.2)	5 (5.6)
Epistaxis	10 (11.1)	7 (7.8)	3 (3.3)
Nasal congestion	9 (10.0)	7 (7.8)	2 (2.2)
Oropharyngeal pain	8 (8.9)	6 (6.7)	2 (2.2)
Atelectasis	1 (1.1)	0	1 (1.1)
Skin and subcutaneous tissue disorders			
-Total	28 (31.1)	13 (14.4)	15 (16.7)
Pruritus	10 (11.1)	5 (5.6)	5 (5.6)
Rash	8 (8.9)	4 (4.4)	4 (4.4)
Dry skin	7 (7.8)	5 (5.6)	2 (2.2)
Erythema	5 (5.6)	4 (4.4)	1 (1.1)
Ingrowing nail	3 (3.3)	0	3 (3.3)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperhidrosis	2 (2.2)	0	2 (2.2)
Petechiae	2 (2.2)	1 (1.1)	1 (1.1)
Skin ulcer	2 (2.2)	1 (1.1)	1 (1.1)
Vascular disorders			
-Total	23 (25.6)	7 (7.8)	16 (17.8)
Hypertension	14 (15.6)	4 (4.4)	10 (11.1)
Hypotension	11 (12.2)	3 (3.3)	8 (8.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)
Endocrine disorders			
-Total	1 (50.0)	0	1 (50.0)
Delayed puberty	1 (50.0)	0	1 (50.0)
Hypothyroidism	1 (50.0)	0	1 (50.0)
Eye disorders			
-Total	1 (50.0)	1 (50.0)	0
Dry eye	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (100)	1 (50.0)	1 (50.0)
Diarrhoea	1 (50.0)	0	1 (50.0)
Nausea	1 (50.0)	1 (50.0)	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0
Vomiting	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Fatigue	1 (50.0)	0	1 (50.0)
Hepatobiliary disorders			
-Total	1 (50.0)	1 (50.0)	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	0	2 (100)
Cytokine release syndrome	2 (100)	0	2 (100)
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)
Seasonal allergy	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Device related bacteraemia	1 (50.0)	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypophosphataemia	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Growth retardation	1 (50.0)	0	1 (50.0)
Osteopenia	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	2 (100)	0	2 (100)
Cognitive disorder	1 (50.0)	0	1 (50.0)
Dysarthria	1 (50.0)	0	1 (50.0)
Memory impairment	1 (50.0)	0	1 (50.0)
Psychiatric disorders			
-Total	2 (100)	0	2 (100)
Anxiety	1 (50.0)	0	1 (50.0)
Sleep disorder	1 (50.0)	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	2 (100)
Cough	1 (50.0)	0	1 (50.0)
Lung disorder	1 (50.0)	1 (50.0)	0
Pleural effusion	1 (50.0)	0	1 (50.0)
Rhinorrhoea	1 (50.0)	0	1 (50.0)
Wheezing	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265f
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	81 (84.4)	3 (3.1)	78 (81.3)
Blood and lymphatic system disorders			
-Total	23 (24.0)	7 (7.3)	16 (16.7)
Anaemia	23 (24.0)	7 (7.3)	16 (16.7)
Cardiac disorders			
-Total	17 (17.7)	8 (8.3)	9 (9.4)
Tachycardia	17 (17.7)	8 (8.3)	9 (9.4)
Endocrine disorders			
-Total	2 (2.1)	0	2 (2.1)
Hypothyroidism	2 (2.1)	0	2 (2.1)
Gastrointestinal disorders			
-Total	64 (66.7)	29 (30.2)	35 (36.5)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	29 (30.2)	13 (13.5)	16 (16.7)
Vomiting	28 (29.2)	19 (19.8)	9 (9.4)
Diarrhoea	25 (26.0)	17 (17.7)	8 (8.3)
Constipation	19 (19.8)	9 (9.4)	10 (10.4)
Abdominal pain	17 (17.7)	6 (6.3)	11 (11.5)
General disorders and administration site conditions			
-Total	47 (49.0)	27 (28.1)	20 (20.8)
Pyrexia	38 (39.6)	20 (20.8)	18 (18.8)
Fatigue	18 (18.8)	15 (15.6)	3 (3.1)
Immune system disorders			
-Total	63 (65.6)	11 (11.5)	52 (54.2)
Cytokine release syndrome	55 (57.3)	13 (13.5)	42 (43.8)
Hypogammaglobulinaemia	27 (28.1)	2 (2.1)	25 (26.0)
Seasonal allergy	4 (4.2)	1 (1.0)	3 (3.1)
Infections and infestations			
-Total	15 (15.6)	5 (5.2)	10 (10.4)
Upper respiratory tract infection	13 (13.5)	5 (5.2)	8 (8.3)
Paronychia	3 (3.1)	1 (1.0)	2 (2.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Investigations			
-Total	39 (40.6)	8 (8.3)	31 (32.3)
Alanine aminotransferase increased	20 (20.8)	6 (6.3)	14 (14.6)
Platelet count decreased	15 (15.6)	8 (8.3)	7 (7.3)
Aspartate aminotransferase increased	14 (14.6)	4 (4.2)	10 (10.4)
White blood cell count decreased	14 (14.6)	5 (5.2)	9 (9.4)
Neutrophil count decreased	11 (11.5)	3 (3.1)	8 (8.3)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)
Metabolism and nutrition disorders			
-Total	42 (43.8)	14 (14.6)	28 (29.2)
Decreased appetite	23 (24.0)	13 (13.5)	10 (10.4)
Hypokalaemia	14 (14.6)	4 (4.2)	10 (10.4)
Hypocalcaemia	13 (13.5)	2 (2.1)	11 (11.5)
Hypoalbuminaemia	11 (11.5)	0	11 (11.5)
Hypophosphataemia	11 (11.5)	4 (4.2)	7 (7.3)
Musculoskeletal and connective tissue disorders			
-Total	34 (35.4)	18 (18.8)	16 (16.7)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain in extremity	20 (20.8)	9 (9.4)	11 (11.5)
Arthralgia	12 (12.5)	6 (6.3)	6 (6.3)
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)
Growth retardation	1 (1.0)	0	1 (1.0)
Nervous system disorders			
-Total	32 (33.3)	16 (16.7)	16 (16.7)
Headache	31 (32.3)	16 (16.7)	15 (15.6)
Cognitive disorder	2 (2.1)	0	2 (2.1)
Psychiatric disorders			
-Total	13 (13.5)	3 (3.1)	10 (10.4)
Anxiety	12 (12.5)	4 (4.2)	8 (8.3)
Sleep disorder	2 (2.1)	0	2 (2.1)
Respiratory, thoracic and mediastinal disorders			
-Total	39 (40.6)	29 (30.2)	10 (10.4)
Cough	25 (26.0)	21 (21.9)	4 (4.2)
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)
Epistaxis	10 (10.4)	7 (7.3)	3 (3.1)
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pleural effusion	6 (6.3)	4 (4.2)	2 (2.1)
Rhinorrhoea	5 (5.2)	4 (4.2)	1 (1.0)
Wheezing	1 (1.0)	0	1 (1.0)
Skin and subcutaneous tissue disorders			
-Total	18 (18.8)	9 (9.4)	9 (9.4)
Pruritus	11 (11.5)	5 (5.2)	6 (6.3)
Rash	10 (10.4)	5 (5.2)	5 (5.2)
Vascular disorders			
-Total	24 (25.0)	8 (8.3)	16 (16.7)
Hypertension	15 (15.6)	5 (5.2)	10 (10.4)
Hypotension	12 (12.5)	4 (4.2)	8 (8.3)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	0	1 (100)
Abdominal pain	1 (100)	1 (100)	0
Anal fissure	1 (100)	0	1 (100)
Anal haemorrhage	1 (100)	1 (100)	0
Diarrhoea	1 (100)	1 (100)	0
Nausea	1 (100)	1 (100)	0
Proctalgia	1 (100)	1 (100)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	1 (100)
Hypogammaglobulinaemia	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	1 (100)	0
Blood fibrinogen decreased	1 (100)	1 (100)	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0
Blood uric acid increased	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0
Metabolism and nutrition disorders			
-Total	1 (100)	1 (100)	0
Decreased appetite	1 (100)	1 (100)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (100)	1 (100)	0
Pain in extremity	1 (100)	1 (100)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Irritability	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Cough	1 (100)	1 (100)	0
Rhinorrhoea	1 (100)	1 (100)	0
Skin and subcutaneous tissue disorders			
-Total	1 (100)	1 (100)	0
Dry skin	1 (100)	1 (100)	0
Rash papular	1 (100)	1 (100)	0
Rash pruritic	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 265g
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	82 (84.5)	5 (5.2)	77 (79.4)
Blood and lymphatic system disorders			
-Total	22 (22.7)	6 (6.2)	16 (16.5)
Anaemia	22 (22.7)	6 (6.2)	16 (16.5)
Cardiac disorders			
-Total	17 (17.5)	8 (8.2)	9 (9.3)
Tachycardia	17 (17.5)	8 (8.2)	9 (9.3)
Gastrointestinal disorders			
-Total	64 (66.0)	27 (27.8)	37 (38.1)
Nausea	29 (29.9)	13 (13.4)	16 (16.5)
Vomiting	28 (28.9)	19 (19.6)	9 (9.3)
Diarrhoea	25 (25.8)	16 (16.5)	9 (9.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	19 (19.6)	9 (9.3)	10 (10.3)
Abdominal pain	16 (16.5)	5 (5.2)	11 (11.3)
Anal fissure	1 (1.0)	0	1 (1.0)
General disorders and administration site conditions			
-Total	48 (49.5)	27 (27.8)	21 (21.6)
Pyrexia	38 (39.2)	20 (20.6)	18 (18.6)
Fatigue	19 (19.6)	15 (15.5)	4 (4.1)
Immune system disorders			
-Total	63 (64.9)	11 (11.3)	52 (53.6)
Cytokine release syndrome	57 (58.8)	13 (13.4)	44 (45.4)
Hypogammaglobulinaemia	27 (27.8)	2 (2.1)	25 (25.8)
Infections and infestations			
-Total	13 (13.4)	5 (5.2)	8 (8.2)
Upper respiratory tract infection	13 (13.4)	5 (5.2)	8 (8.2)
Investigations			
-Total	40 (41.2)	7 (7.2)	33 (34.0)
Alanine aminotransferase increased	20 (20.6)	6 (6.2)	14 (14.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	14 (14.4)	4 (4.1)	10 (10.3)
Platelet count decreased	14 (14.4)	7 (7.2)	7 (7.2)
White blood cell count decreased	13 (13.4)	4 (4.1)	9 (9.3)
Neutrophil count decreased	11 (11.3)	3 (3.1)	8 (8.2)
International normalised ratio increased	10 (10.3)	6 (6.2)	4 (4.1)
Blood fibrinogen decreased	6 (6.2)	2 (2.1)	4 (4.1)
Blood immunoglobulin a decreased	5 (5.2)	4 (4.1)	1 (1.0)
Blood immunoglobulin m decreased	4 (4.1)	3 (3.1)	1 (1.0)
Blood uric acid increased	1 (1.0)	1 (1.0)	0
Metabolism and nutrition disorders			
-Total	42 (43.3)	13 (13.4)	29 (29.9)
Decreased appetite	22 (22.7)	12 (12.4)	10 (10.3)
Hypokalaemia	14 (14.4)	4 (4.1)	10 (10.3)
Hypocalcaemia	13 (13.4)	2 (2.1)	11 (11.3)
Hypophosphataemia	12 (12.4)	4 (4.1)	8 (8.2)
Hypoalbuminaemia	11 (11.3)	0	11 (11.3)
Musculoskeletal and connective tissue disorders			

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	32 (33.0)	17 (17.5)	15 (15.5)
Pain in extremity	19 (19.6)	8 (8.2)	11 (11.3)
Arthralgia	12 (12.4)	6 (6.2)	6 (6.2)
Myalgia	10 (10.3)	6 (6.2)	4 (4.1)
Nervous system disorders			
-Total	31 (32.0)	16 (16.5)	15 (15.5)
Headache	31 (32.0)	16 (16.5)	15 (15.5)
Psychiatric disorders			
-Total	15 (15.5)	6 (6.2)	9 (9.3)
Anxiety	13 (13.4)	4 (4.1)	9 (9.3)
Irritability	2 (2.1)	2 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	37 (38.1)	28 (28.9)	9 (9.3)
Cough	25 (25.8)	20 (20.6)	5 (5.2)
Nasal congestion	11 (11.3)	9 (9.3)	2 (2.1)
Epistaxis	10 (10.3)	7 (7.2)	3 (3.1)
Oropharyngeal pain	10 (10.3)	8 (8.2)	2 (2.1)
Rhinorrhoea	5 (5.2)	3 (3.1)	2 (2.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Skin and subcutaneous tissue disorders			
-Total	24 (24.7)	13 (13.4)	11 (11.3)
Pruritus	11 (11.3)	5 (5.2)	6 (6.2)
Rash	10 (10.3)	5 (5.2)	5 (5.2)
Dry skin	8 (8.2)	6 (6.2)	2 (2.1)
Rash papular	3 (3.1)	2 (2.1)	1 (1.0)
Vascular disorders			
-Total	25 (25.8)	9 (9.3)	16 (16.5)
Hypertension	15 (15.5)	5 (5.2)	10 (10.3)
Hypotension	13 (13.4)	5 (5.2)	8 (8.2)

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Table 265h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Lymphadenopathy	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Constipation	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	1 (33.3)
Pain	1 (33.3)	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pyrexia	1 (33.3)	0	1 (33.3)
Immune system disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypogammaglobulinaemia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)
Bronchitis	1 (33.3)	0	1 (33.3)
Cystitis	1 (33.3)	0	1 (33.3)
Gastroenteritis	1 (33.3)	1 (33.3)	0
Nasopharyngitis	1 (33.3)	1 (33.3)	0
Investigations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Lymphocyte count decreased	2 (66.7)	1 (33.3)	1 (33.3)
White blood cell count decreased	2 (66.7)	2 (66.7)	0
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood creatinine increased	1 (33.3)	1 (33.3)	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Platelet count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)
Hypocalcaemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
-Total	1 (33.3)	1 (33.3)	0
Acute kidney injury	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Cough	1 (33.3)	1 (33.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Dermatitis atopic	1 (33.3)	1 (33.3)	0
Rash vesicular	1 (33.3)	1 (33.3)	0

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accepted by the manufacturing facility
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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265h
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	81 (85.3)	5 (5.3)	76 (80.0)
Blood and lymphatic system disorders			
-Total	23 (24.2)	7 (7.4)	16 (16.8)
Anaemia	23 (24.2)	7 (7.4)	16 (16.8)
Lymphadenopathy	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	17 (17.9)	8 (8.4)	9 (9.5)
Tachycardia	17 (17.9)	8 (8.4)	9 (9.5)
Gastrointestinal disorders			
-Total	64 (67.4)	29 (30.5)	35 (36.8)
Nausea	30 (31.6)	14 (14.7)	16 (16.8)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	29 (30.5)	20 (21.1)	9 (9.5)
Diarrhoea	26 (27.4)	17 (17.9)	9 (9.5)
Constipation	18 (18.9)	9 (9.5)	9 (9.5)
Abdominal pain	17 (17.9)	6 (6.3)	11 (11.6)
General disorders and administration site conditions			
-Total	48 (50.5)	26 (27.4)	22 (23.2)
Pyrexia	37 (38.9)	20 (21.1)	17 (17.9)
Fatigue	19 (20.0)	15 (15.8)	4 (4.2)
Pain	5 (5.3)	1 (1.1)	4 (4.2)
Immune system disorders			
-Total	63 (66.3)	11 (11.6)	52 (54.7)
Cytokine release syndrome	57 (60.0)	13 (13.7)	44 (46.3)
Hypogammaglobulinaemia	27 (28.4)	2 (2.1)	25 (26.3)
Infections and infestations			
-Total	20 (21.1)	8 (8.4)	12 (12.6)
Upper respiratory tract infection	13 (13.7)	5 (5.3)	8 (8.4)
Nasopharyngitis	7 (7.4)	4 (4.2)	3 (3.2)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis	4 (4.2)	3 (3.2)	1 (1.1)
Bronchitis	2 (2.1)	0	2 (2.1)
Investigations			
-Total	38 (40.0)	7 (7.4)	31 (32.6)
Alanine aminotransferase increased	19 (20.0)	5 (5.3)	14 (14.7)
Platelet count decreased	14 (14.7)	7 (7.4)	7 (7.4)
Aspartate aminotransferase increased	13 (13.7)	3 (3.2)	10 (10.5)
White blood cell count decreased	12 (12.6)	3 (3.2)	9 (9.5)
Neutrophil count decreased	11 (11.6)	3 (3.2)	8 (8.4)
International normalised ratio increased	10 (10.5)	6 (6.3)	4 (4.2)
Lymphocyte count decreased	5 (5.3)	2 (2.1)	3 (3.2)
Blood creatinine increased	2 (2.1)	1 (1.1)	1 (1.1)
Metabolism and nutrition disorders			
-Total	42 (44.2)	14 (14.7)	28 (29.5)
Decreased appetite	23 (24.2)	13 (13.7)	10 (10.5)
Hypokalaemia	14 (14.7)	4 (4.2)	10 (10.5)
Hypocalcaemia	12 (12.6)	2 (2.1)	10 (10.5)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	12 (12.6)	4 (4.2)	8 (8.4)
Hypoalbuminaemia	10 (10.5)	0	10 (10.5)
Musculoskeletal and connective tissue disorders			
-Total	33 (34.7)	18 (18.9)	15 (15.8)
Pain in extremity	20 (21.1)	9 (9.5)	11 (11.6)
Arthralgia	12 (12.6)	6 (6.3)	6 (6.3)
Myalgia	10 (10.5)	6 (6.3)	4 (4.2)
Nervous system disorders			
-Total	31 (32.6)	16 (16.8)	15 (15.8)
Headache	31 (32.6)	16 (16.8)	15 (15.8)
Psychiatric disorders			
-Total	13 (13.7)	4 (4.2)	9 (9.5)
Anxiety	13 (13.7)	4 (4.2)	9 (9.5)
Renal and urinary disorders			
-Total	8 (8.4)	4 (4.2)	4 (4.2)
Acute kidney injury	8 (8.4)	4 (4.2)	4 (4.2)
Respiratory, thoracic and mediastinal disorders			

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	37 (38.9)	28 (29.5)	9 (9.5)
Cough	25 (26.3)	20 (21.1)	5 (5.3)
Nasal congestion	11 (11.6)	9 (9.5)	2 (2.1)
Epistaxis	10 (10.5)	7 (7.4)	3 (3.2)
Oropharyngeal pain	10 (10.5)	8 (8.4)	2 (2.1)
Skin and subcutaneous tissue disorders			
-Total	19 (20.0)	10 (10.5)	9 (9.5)
Pruritus	11 (11.6)	5 (5.3)	6 (6.3)
Rash	10 (10.5)	5 (5.3)	5 (5.3)
Dermatitis atopic	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	25 (26.3)	9 (9.5)	16 (16.8)
Hypertension	15 (15.8)	5 (5.3)	10 (10.5)
Hypotension	13 (13.7)	5 (5.3)	8 (8.4)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (50.0)	0	1 (50.0)
Photosensitivity reaction	1 (50.0)	0	1 (50.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265i
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	82 (85.4)	4 (4.2)	78 (81.3)
Blood and lymphatic system disorders			
-Total	23 (24.0)	7 (7.3)	16 (16.7)
Anaemia	23 (24.0)	7 (7.3)	16 (16.7)
Cardiac disorders			
-Total	17 (17.7)	8 (8.3)	9 (9.4)
Tachycardia	17 (17.7)	8 (8.3)	9 (9.4)
Gastrointestinal disorders			
-Total	65 (67.7)	29 (30.2)	36 (37.5)
Nausea	30 (31.3)	14 (14.6)	16 (16.7)
Vomiting	29 (30.2)	20 (20.8)	9 (9.4)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	26 (27.1)	17 (17.7)	9 (9.4)
Constipation	19 (19.8)	9 (9.4)	10 (10.4)
Abdominal pain	17 (17.7)	6 (6.3)	11 (11.5)
General disorders and administration site conditions			
-Total	47 (49.0)	26 (27.1)	21 (21.9)
Pyrexia	37 (38.5)	19 (19.8)	18 (18.8)
Fatigue	19 (19.8)	15 (15.6)	4 (4.2)
Immune system disorders			
-Total	64 (66.7)	11 (11.5)	53 (55.2)
Cytokine release syndrome	57 (59.4)	13 (13.5)	44 (45.8)
Hypogammaglobulinaemia	28 (29.2)	2 (2.1)	26 (27.1)
Infections and infestations			
-Total	14 (14.6)	5 (5.2)	9 (9.4)
Upper respiratory tract infection	13 (13.5)	5 (5.2)	8 (8.3)
Staphylococcal infection	2 (2.1)	0	2 (2.1)
Investigations			
-Total	38 (39.6)	7 (7.3)	31 (32.3)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	19 (19.8)	5 (5.2)	14 (14.6)
Platelet count decreased	15 (15.6)	8 (8.3)	7 (7.3)
Aspartate aminotransferase increased	14 (14.6)	4 (4.2)	10 (10.4)
White blood cell count decreased	14 (14.6)	5 (5.2)	9 (9.4)
Neutrophil count decreased	11 (11.5)	3 (3.1)	8 (8.3)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)
Metabolism and nutrition disorders			
-Total	43 (44.8)	14 (14.6)	29 (30.2)
Decreased appetite	23 (24.0)	13 (13.5)	10 (10.4)
Hypokalaemia	14 (14.6)	4 (4.2)	10 (10.4)
Hypocalcaemia	13 (13.5)	2 (2.1)	11 (11.5)
Hypophosphataemia	12 (12.5)	4 (4.2)	8 (8.3)
Hypoalbuminaemia	11 (11.5)	0	11 (11.5)
Musculoskeletal and connective tissue disorders			
-Total	33 (34.4)	18 (18.8)	15 (15.6)
Pain in extremity	20 (20.8)	9 (9.4)	11 (11.5)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	12 (12.5)	6 (6.3)	6 (6.3)
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)
Nervous system disorders			
-Total	31 (32.3)	16 (16.7)	15 (15.6)
Headache	31 (32.3)	16 (16.7)	15 (15.6)
Psychiatric disorders			
-Total	13 (13.5)	4 (4.2)	9 (9.4)
Anxiety	13 (13.5)	4 (4.2)	9 (9.4)
Respiratory, thoracic and mediastinal disorders			
-Total	38 (39.6)	29 (30.2)	9 (9.4)
Cough	26 (27.1)	21 (21.9)	5 (5.2)
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)
Epistaxis	10 (10.4)	7 (7.3)	3 (3.1)
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)
Skin and subcutaneous tissue disorders			
-Total	18 (18.8)	9 (9.4)	9 (9.4)
Pruritus	11 (11.5)	5 (5.2)	6 (6.3)

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash	10 (10.4)	5 (5.2)	5 (5.2)
Vascular disorders			
-Total	25 (26.0)	9 (9.4)	16 (16.7)
Hypertension	15 (15.6)	5 (5.2)	10 (10.4)
Hypotension	13 (13.5)	5 (5.2)	8 (8.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set

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

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	29 (96.7)	1 (3.3)	28 (93.3)
Blood and lymphatic system disorders			
-Total	10 (33.3)	3 (10.0)	7 (23.3)
Anaemia	7 (23.3)	3 (10.0)	4 (13.3)
Disseminated intravascular coagulation	3 (10.0)	0	3 (10.0)
Cardiac disorders			
-Total	4 (13.3)	2 (6.7)	2 (6.7)
Tachycardia	4 (13.3)	2 (6.7)	2 (6.7)
Eye disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Eyelid oedema	3 (10.0)	1 (3.3)	2 (6.7)

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	24 (80.0)	13 (43.3)	11 (36.7)
Diarrhoea	10 (33.3)	7 (23.3)	3 (10.0)
Abdominal pain	9 (30.0)	3 (10.0)	6 (20.0)
Nausea	9 (30.0)	5 (16.7)	4 (13.3)
Vomiting	8 (26.7)	7 (23.3)	1 (3.3)
Constipation	6 (20.0)	4 (13.3)	2 (6.7)
Abdominal pain upper	3 (10.0)	2 (6.7)	1 (3.3)
General disorders and administration site conditions			
-Total	16 (53.3)	10 (33.3)	6 (20.0)
Pyrexia	12 (40.0)	7 (23.3)	5 (16.7)
Fatigue	6 (20.0)	5 (16.7)	1 (3.3)
Oedema peripheral	4 (13.3)	4 (13.3)	0
Face oedema	3 (10.0)	2 (6.7)	1 (3.3)
Hepatobiliary disorders			
-Total	3 (10.0)	1 (3.3)	2 (6.7)
Hepatic function abnormal	3 (10.0)	1 (3.3)	2 (6.7)
Immune system disorders			

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	19 (63.3)	4 (13.3)	15 (50.0)
Cytokine release syndrome	17 (56.7)	4 (13.3)	13 (43.3)
Hypogammaglobulinaemia	8 (26.7)	1 (3.3)	7 (23.3)
Infections and infestations			
-Total	11 (36.7)	2 (6.7)	9 (30.0)
Conjunctivitis	5 (16.7)	1 (3.3)	4 (13.3)
Nasopharyngitis	4 (13.3)	3 (10.0)	1 (3.3)
Nail infection	3 (10.0)	2 (6.7)	1 (3.3)
Rhinovirus infection	3 (10.0)	0	3 (10.0)
Sinusitis	3 (10.0)	0	3 (10.0)
Upper respiratory tract infection	2 (6.7)	0	2 (6.7)
Investigations			
-Total	15 (50.0)	3 (10.0)	12 (40.0)
Alanine aminotransferase increased	6 (20.0)	2 (6.7)	4 (13.3)
Aspartate aminotransferase increased	6 (20.0)	1 (3.3)	5 (16.7)
Blood fibrinogen decreased	5 (16.7)	2 (6.7)	3 (10.0)
Lymphocyte count decreased	4 (13.3)	2 (6.7)	2 (6.7)
Platelet count decreased	4 (13.3)	2 (6.7)	2 (6.7)

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Serum ferritin increased	4 (13.3)	0	4 (13.3)
White blood cell count decreased	4 (13.3)	2 (6.7)	2 (6.7)
Blood bilirubin increased	3 (10.0)	1 (3.3)	2 (6.7)
Neutrophil count decreased	3 (10.0)	0	3 (10.0)
International normalised ratio increased	2 (6.7)	1 (3.3)	1 (3.3)
Metabolism and nutrition disorders			
-Total	16 (53.3)	7 (23.3)	9 (30.0)
Hypokalaemia	7 (23.3)	2 (6.7)	5 (16.7)
Decreased appetite	6 (20.0)	5 (16.7)	1 (3.3)
Hypoalbuminaemia	4 (13.3)	0	4 (13.3)
Hypocalcaemia	4 (13.3)	1 (3.3)	3 (10.0)
Hypophosphataemia	4 (13.3)	2 (6.7)	2 (6.7)
Hyperuricaemia	3 (10.0)	2 (6.7)	1 (3.3)
Hypomagnesaemia	2 (6.7)	2 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	14 (46.7)	8 (26.7)	6 (20.0)
Pain in extremity	10 (33.3)	5 (16.7)	5 (16.7)

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	4 (13.3)	2 (6.7)	2 (6.7)
Myalgia	2 (6.7)	1 (3.3)	1 (3.3)
Back pain	1 (3.3)	0	1 (3.3)
Nervous system disorders			
-Total	11 (36.7)	6 (20.0)	5 (16.7)
Headache	9 (30.0)	4 (13.3)	5 (16.7)
Dizziness	3 (10.0)	3 (10.0)	0
Tremor	3 (10.0)	2 (6.7)	1 (3.3)
Psychiatric disorders			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Delirium	3 (10.0)	2 (6.7)	1 (3.3)
Insomnia	3 (10.0)	1 (3.3)	2 (6.7)
Anxiety	2 (6.7)	0	2 (6.7)
Renal and urinary disorders			
-Total	4 (13.3)	3 (10.0)	1 (3.3)
Acute kidney injury	4 (13.3)	3 (10.0)	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	15 (50.0)	11 (36.7)	4 (13.3)

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

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Cough	7 (23.3)	6 (20.0)	1 (3.3)
Oropharyngeal pain	4 (13.3)	3 (10.0)	1 (3.3)
Pleural effusion	4 (13.3)	3 (10.0)	1 (3.3)
Epistaxis	3 (10.0)	1 (3.3)	2 (6.7)
Pulmonary oedema	3 (10.0)	2 (6.7)	1 (3.3)
Tachypnoea	3 (10.0)	2 (6.7)	1 (3.3)
Nasal congestion	2 (6.7)	1 (3.3)	1 (3.3)
Skin and subcutaneous tissue disorders			
-Total	10 (33.3)	4 (13.3)	6 (20.0)
Dry skin	4 (13.3)	3 (10.0)	1 (3.3)
Pruritus	4 (13.3)	1 (3.3)	3 (10.0)
Rash	4 (13.3)	0	4 (13.3)
Skin ulcer	3 (10.0)	2 (6.7)	1 (3.3)
Vascular disorders			
-Total	9 (30.0)	2 (6.7)	7 (23.3)
Hypertension	7 (23.3)	2 (6.7)	5 (16.7)
Hypotension	3 (10.0)	1 (3.3)	2 (6.7)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265j
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Complex Karyotypes
Enrolled set

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	54 (79.4)	1 (1.5)	53 (77.9)
Blood and lymphatic system disorders			
-Total	18 (26.5)	4 (5.9)	14 (20.6)
Anaemia	16 (23.5)	4 (5.9)	12 (17.6)
Disseminated intravascular coagulation	2 (2.9)	0	2 (2.9)
Cardiac disorders			
-Total	13 (19.1)	6 (8.8)	7 (10.3)
Tachycardia	13 (19.1)	6 (8.8)	7 (10.3)
Gastrointestinal disorders			
-Total	41 (60.3)	16 (23.5)	25 (36.8)
Nausea	21 (30.9)	9 (13.2)	12 (17.6)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Vomiting	21 (30.9)	13 (19.1)	8 (11.8)
Diarrhoea	16 (23.5)	10 (14.7)	6 (8.8)
Constipation	13 (19.1)	5 (7.4)	8 (11.8)
Abdominal pain	8 (11.8)	3 (4.4)	5 (7.4)
Abdominal pain upper	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	37 (54.4)	19 (27.9)	18 (26.5)
Pyrexia	26 (38.2)	13 (19.1)	13 (19.1)
Fatigue	13 (19.1)	10 (14.7)	3 (4.4)
Chills	9 (13.2)	5 (7.4)	4 (5.9)
Face oedema	4 (5.9)	3 (4.4)	1 (1.5)
Oedema peripheral	3 (4.4)	2 (2.9)	1 (1.5)
Hepatobiliary disorders			
-Total	2 (2.9)	0	2 (2.9)
Hepatic function abnormal	2 (2.9)	0	2 (2.9)
Immune system disorders			
-Total	45 (66.2)	7 (10.3)	38 (55.9)
Cytokine release syndrome	40 (58.8)	9 (13.2)	31 (45.6)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	20 (29.4)	1 (1.5)	19 (27.9)
Infections and infestations			
-Total	22 (32.4)	7 (10.3)	15 (22.1)
Upper respiratory tract infection	11 (16.2)	5 (7.4)	6 (8.8)
Rhinovirus infection	5 (7.4)	0	5 (7.4)
Conjunctivitis	4 (5.9)	2 (2.9)	2 (2.9)
Nasopharyngitis	4 (5.9)	2 (2.9)	2 (2.9)
Sinusitis	4 (5.9)	0	4 (5.9)
Nail infection	1 (1.5)	1 (1.5)	0
Investigations			
-Total	28 (41.2)	5 (7.4)	23 (33.8)
Alanine aminotransferase increased	14 (20.6)	4 (5.9)	10 (14.7)
Platelet count decreased	11 (16.2)	6 (8.8)	5 (7.4)
White blood cell count decreased	10 (14.7)	3 (4.4)	7 (10.3)
Aspartate aminotransferase increased	8 (11.8)	3 (4.4)	5 (7.4)
International normalised ratio increased	8 (11.8)	5 (7.4)	3 (4.4)
Neutrophil count decreased	8 (11.8)	3 (4.4)	5 (7.4)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood bilirubin increased	4 (5.9)	1 (1.5)	3 (4.4)
Lymphocyte count decreased	3 (4.4)	1 (1.5)	2 (2.9)
Serum ferritin increased	3 (4.4)	2 (2.9)	1 (1.5)
Blood fibrinogen decreased	2 (2.9)	1 (1.5)	1 (1.5)
Metabolism and nutrition disorders			
-Total	29 (42.6)	8 (11.8)	21 (30.9)
Decreased appetite	17 (25.0)	8 (11.8)	9 (13.2)
Hypocalcaemia	9 (13.2)	1 (1.5)	8 (11.8)
Hypophosphataemia	8 (11.8)	2 (2.9)	6 (8.8)
Hypoalbuminaemia	7 (10.3)	0	7 (10.3)
Hypokalaemia	7 (10.3)	2 (2.9)	5 (7.4)
Hypomagnesaemia	7 (10.3)	5 (7.4)	2 (2.9)
Hyperuricaemia	6 (8.8)	6 (8.8)	0
Musculoskeletal and connective tissue disorders			
-Total	25 (36.8)	11 (16.2)	14 (20.6)
Pain in extremity	10 (14.7)	4 (5.9)	6 (8.8)
Arthralgia	8 (11.8)	4 (5.9)	4 (5.9)
Myalgia	8 (11.8)	5 (7.4)	3 (4.4)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Back pain	7 (10.3)	2 (2.9)	5 (7.4)
Nervous system disorders			
-Total	25 (36.8)	15 (22.1)	10 (14.7)
Headache	22 (32.4)	12 (17.6)	10 (14.7)
Tremor	3 (4.4)	3 (4.4)	0
Dizziness	2 (2.9)	2 (2.9)	0
Psychiatric disorders			
-Total	12 (17.6)	4 (5.9)	8 (11.8)
Anxiety	11 (16.2)	4 (5.9)	7 (10.3)
Insomnia	3 (4.4)	1 (1.5)	2 (2.9)
Delirium	2 (2.9)	0	2 (2.9)
Renal and urinary disorders			
-Total	5 (7.4)	2 (2.9)	3 (4.4)
Acute kidney injury	5 (7.4)	2 (2.9)	3 (4.4)
Respiratory, thoracic and mediastinal disorders			
-Total	30 (44.1)	19 (27.9)	11 (16.2)
Cough	19 (27.9)	15 (22.1)	4 (5.9)
Nasal congestion	9 (13.2)	8 (11.8)	1 (1.5)

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

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	7 (10.3)	6 (8.8)	1 (1.5)
Oropharyngeal pain	6 (8.8)	5 (7.4)	1 (1.5)
Pleural effusion	3 (4.4)	1 (1.5)	2 (2.9)
Pulmonary oedema	3 (4.4)	1 (1.5)	2 (2.9)
Tachypnoea	3 (4.4)	2 (2.9)	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	16 (23.5)	11 (16.2)	5 (7.4)
Pruritus	7 (10.3)	4 (5.9)	3 (4.4)
Rash	6 (8.8)	5 (7.4)	1 (1.5)
Dry skin	5 (7.4)	4 (5.9)	1 (1.5)
Vascular disorders			
-Total	16 (23.5)	7 (10.3)	9 (13.2)
Hypotension	10 (14.7)	4 (5.9)	6 (8.8)
Hypertension	8 (11.8)	3 (4.4)	5 (7.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	28 (87.5)	2 (6.3)	26 (81.3)
Blood and lymphatic system disorders			
-Total	7 (21.9)	3 (9.4)	4 (12.5)
Anaemia	5 (15.6)	3 (9.4)	2 (6.3)
Disseminated intravascular coagulation	2 (6.3)	0	2 (6.3)
Gastrointestinal disorders			
-Total	20 (62.5)	7 (21.9)	13 (40.6)
Diarrhoea	8 (25.0)	3 (9.4)	5 (15.6)
Vomiting	8 (25.0)	6 (18.8)	2 (6.3)
Abdominal pain	6 (18.8)	1 (3.1)	5 (15.6)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nausea	6 (18.8)	1 (3.1)	5 (15.6)
Constipation	5 (15.6)	1 (3.1)	4 (12.5)
Stomatitis	2 (6.3)	0	2 (6.3)
Pancreatitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	15 (46.9)	8 (25.0)	7 (21.9)
Pyrexia	13 (40.6)	7 (21.9)	6 (18.8)
Face oedema	2 (6.3)	1 (3.1)	1 (3.1)
Fatigue	1 (3.1)	1 (3.1)	0
Influenza like illness	1 (3.1)	0	1 (3.1)
Oedema peripheral	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	19 (59.4)	4 (12.5)	15 (46.9)
Cytokine release syndrome	18 (56.3)	4 (12.5)	14 (43.8)
Hypogammaglobulinaemia	7 (21.9)	1 (3.1)	6 (18.8)
Infections and infestations			
-Total	13 (40.6)	6 (18.8)	7 (21.9)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nasopharyngitis	7 (21.9)	4 (12.5)	3 (9.4)
Conjunctivitis	5 (15.6)	1 (3.1)	4 (12.5)
Upper respiratory tract infection	3 (9.4)	3 (9.4)	0
Otitis media	1 (3.1)	0	1 (3.1)
Rhinovirus infection	1 (3.1)	0	1 (3.1)
Sinusitis	1 (3.1)	0	1 (3.1)
Investigations			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Platelet count decreased	4 (12.5)	3 (9.4)	1 (3.1)
Alanine aminotransferase increased	3 (9.4)	1 (3.1)	2 (6.3)
White blood cell count decreased	3 (9.4)	2 (6.3)	1 (3.1)
Aspartate aminotransferase increased	1 (3.1)	1 (3.1)	0
Neutrophil count decreased	1 (3.1)	0	1 (3.1)
Serum ferritin increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Decreased appetite	3 (9.4)	2 (6.3)	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypomagnesaemia	3 (9.4)	2 (6.3)	1 (3.1)
Hypokalaemia	2 (6.3)	1 (3.1)	1 (3.1)
Hyperuricaemia	1 (3.1)	0	1 (3.1)
Hypoalbuminaemia	1 (3.1)	0	1 (3.1)
Hypophosphataemia	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	11 (34.4)	4 (12.5)	7 (21.9)
Pain in extremity	6 (18.8)	1 (3.1)	5 (15.6)
Arthralgia	4 (12.5)	2 (6.3)	2 (6.3)
Back pain	4 (12.5)	1 (3.1)	3 (9.4)
Myalgia	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	11 (34.4)	6 (18.8)	5 (15.6)
Headache	11 (34.4)	6 (18.8)	5 (15.6)
Psychiatric disorders			
-Total	4 (12.5)	1 (3.1)	3 (9.4)
Anxiety	4 (12.5)	1 (3.1)	3 (9.4)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Agitation	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Cough	10 (31.3)	8 (25.0)	2 (6.3)
Oropharyngeal pain	3 (9.4)	3 (9.4)	0
Epistaxis	2 (6.3)	2 (6.3)	0
Pleural effusion	2 (6.3)	0	2 (6.3)
Skin and subcutaneous tissue disorders			
-Total	6 (18.8)	1 (3.1)	5 (15.6)
Pruritus	3 (9.4)	0	3 (9.4)
Rash	3 (9.4)	0	3 (9.4)
Dry skin	2 (6.3)	1 (3.1)	1 (3.1)
Vascular disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Hypotension	3 (9.4)	1 (3.1)	2 (6.3)
Hypertension	1 (3.1)	1 (3.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	48 (84.2)	0	48 (84.2)
Blood and lymphatic system disorders			
-Total	18 (31.6)	4 (7.0)	14 (24.6)
Anaemia	17 (29.8)	4 (7.0)	13 (22.8)
Disseminated intravascular coagulation	1 (1.8)	0	1 (1.8)
Cardiac disorders			
-Total	17 (29.8)	8 (14.0)	9 (15.8)
Tachycardia	17 (29.8)	8 (14.0)	9 (15.8)
Gastrointestinal disorders			
-Total	40 (70.2)	16 (28.1)	24 (42.1)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Nausea	22 (38.6)	11 (19.3)	11 (19.3)
Vomiting	21 (36.8)	14 (24.6)	7 (12.3)
Diarrhoea	17 (29.8)	14 (24.6)	3 (5.3)
Constipation	12 (21.1)	6 (10.5)	6 (10.5)
Abdominal pain	10 (17.5)	4 (7.0)	6 (10.5)
Stomatitis	3 (5.3)	0	3 (5.3)
Pancreatitis	1 (1.8)	0	1 (1.8)
Trichoglossia	1 (1.8)	0	1 (1.8)
General disorders and administration site conditions			
-Total	38 (66.7)	19 (33.3)	19 (33.3)
Pyrexia	24 (42.1)	12 (21.1)	12 (21.1)
Fatigue	18 (31.6)	14 (24.6)	4 (7.0)
Chills	9 (15.8)	5 (8.8)	4 (7.0)
Oedema peripheral	6 (10.5)	5 (8.8)	1 (1.8)
Pain	5 (8.8)	0	5 (8.8)
Face oedema	4 (7.0)	3 (5.3)	1 (1.8)
Hepatobiliary disorders			

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	1 (1.8)	0	1 (1.8)
Hepatic function abnormal	1 (1.8)	0	1 (1.8)
Immune system disorders			
-Total	39 (68.4)	5 (8.8)	34 (59.6)
Cytokine release syndrome	34 (59.6)	6 (10.5)	28 (49.1)
Hypogammaglobulinaemia	17 (29.8)	1 (1.8)	16 (28.1)
Infections and infestations			
-Total	18 (31.6)	2 (3.5)	16 (28.1)
Upper respiratory tract infection	8 (14.0)	2 (3.5)	6 (10.5)
Rhinovirus infection	6 (10.5)	0	6 (10.5)
Sinusitis	5 (8.8)	0	5 (8.8)
Conjunctivitis	4 (7.0)	2 (3.5)	2 (3.5)
Otitis media	2 (3.5)	0	2 (3.5)
Otitis externa	1 (1.8)	0	1 (1.8)
Tinea pedis	1 (1.8)	1 (1.8)	0
Urinary tract infection	1 (1.8)	0	1 (1.8)
Investigations			
-Total	30 (52.6)	5 (8.8)	25 (43.9)

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	17 (29.8)	5 (8.8)	12 (21.1)
Aspartate aminotransferase increased	13 (22.8)	3 (5.3)	10 (17.5)
Platelet count decreased	11 (19.3)	5 (8.8)	6 (10.5)
White blood cell count decreased	11 (19.3)	3 (5.3)	8 (14.0)
International normalised ratio increased	10 (17.5)	6 (10.5)	4 (7.0)
Neutrophil count decreased	9 (15.8)	3 (5.3)	6 (10.5)
Blood bilirubin increased	7 (12.3)	2 (3.5)	5 (8.8)
Blood immunoglobulin a decreased	6 (10.5)	5 (8.8)	1 (1.8)
Blood fibrinogen decreased	5 (8.8)	3 (5.3)	2 (3.5)
Serum ferritin increased	3 (5.3)	1 (1.8)	2 (3.5)
Metabolism and nutrition disorders			
-Total	36 (63.2)	12 (21.1)	24 (42.1)
Decreased appetite	20 (35.1)	11 (19.3)	9 (15.8)
Hypocalcaemia	13 (22.8)	2 (3.5)	11 (19.3)
Hypokalaemia	12 (21.1)	3 (5.3)	9 (15.8)
Hypophosphataemia	11 (19.3)	4 (7.0)	7 (12.3)
Hypoalbuminaemia	9 (15.8)	0	9 (15.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperuricaemia	8 (14.0)	8 (14.0)	0
Hypomagnesaemia	6 (10.5)	5 (8.8)	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	25 (43.9)	13 (22.8)	12 (21.1)
Pain in extremity	12 (21.1)	7 (12.3)	5 (8.8)
Myalgia	9 (15.8)	5 (8.8)	4 (7.0)
Arthralgia	7 (12.3)	3 (5.3)	4 (7.0)
Back pain	4 (7.0)	1 (1.8)	3 (5.3)
Nervous system disorders			
-Total	18 (31.6)	8 (14.0)	10 (17.5)
Headache	18 (31.6)	8 (14.0)	10 (17.5)
Seizure	3 (5.3)	0	3 (5.3)
Psychiatric disorders			
-Total	13 (22.8)	4 (7.0)	9 (15.8)
Anxiety	8 (14.0)	2 (3.5)	6 (10.5)
Agitation	6 (10.5)	3 (5.3)	3 (5.3)
Renal and urinary disorders			

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	10 (17.5)	6 (10.5)	4 (7.0)
Acute kidney injury	9 (15.8)	5 (8.8)	4 (7.0)
Haematuria	2 (3.5)	2 (3.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	26 (45.6)	17 (29.8)	9 (15.8)
Cough	16 (28.1)	13 (22.8)	3 (5.3)
Nasal congestion	11 (19.3)	9 (15.8)	2 (3.5)
Epistaxis	7 (12.3)	4 (7.0)	3 (5.3)
Oropharyngeal pain	6 (10.5)	4 (7.0)	2 (3.5)
Rhinorrhoea	6 (10.5)	4 (7.0)	2 (3.5)
Tachypnoea	6 (10.5)	4 (7.0)	2 (3.5)
Pleural effusion	3 (5.3)	3 (5.3)	0
Skin and subcutaneous tissue disorders			
-Total	17 (29.8)	12 (21.1)	5 (8.8)
Rash	7 (12.3)	5 (8.8)	2 (3.5)
Dry skin	6 (10.5)	5 (8.8)	1 (1.8)
Pruritus	6 (10.5)	3 (5.3)	3 (5.3)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin ulcer	2 (3.5)	2 (3.5)	0
Vascular disorders			
-Total	20 (35.1)	7 (12.3)	13 (22.8)
Hypertension	13 (22.8)	4 (7.0)	9 (15.8)
Hypotension	10 (17.5)	4 (7.0)	6 (10.5)

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Table 265k
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	9 (100)	0	9 (100)
Blood and lymphatic system disorders			
-Total	4 (44.4)	0	4 (44.4)
Disseminated intravascular coagulation	2 (22.2)	0	2 (22.2)
Anaemia	1 (11.1)	0	1 (11.1)
B-cell aplasia	1 (11.1)	0	1 (11.1)
Hypofibrinogenaemia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	2 (22.2)	2 (22.2)	0
Cardiac dysfunction	2 (22.2)	2 (22.2)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Gastrointestinal disorders			
-Total	7 (77.8)	2 (22.2)	5 (55.6)
Constipation	2 (22.2)	2 (22.2)	0
Nausea	2 (22.2)	2 (22.2)	0
Pancreatitis	2 (22.2)	0	2 (22.2)
Abdominal pain	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	0	1 (11.1)
Enteritis	1 (11.1)	0	1 (11.1)
Enterocolitis	1 (11.1)	0	1 (11.1)
Gastritis	1 (11.1)	0	1 (11.1)
Haemorrhoids	1 (11.1)	0	1 (11.1)
Stomatitis	1 (11.1)	1 (11.1)	0
Trichoglossia	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	1 (11.1)	1 (11.1)	0
Face oedema	1 (11.1)	1 (11.1)	0
Influenza like illness	1 (11.1)	1 (11.1)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pain	1 (11.1)	1 (11.1)	0
Pyrexia	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Hepatic function abnormal	4 (44.4)	1 (11.1)	3 (33.3)
Immune system disorders			
-Total	6 (66.7)	2 (22.2)	4 (44.4)
Cytokine release syndrome	5 (55.6)	3 (33.3)	2 (22.2)
Hypogammaglobulinaemia	4 (44.4)	0	4 (44.4)
Infections and infestations			
-Total	6 (66.7)	3 (33.3)	3 (33.3)
Upper respiratory tract infection	2 (22.2)	0	2 (22.2)
Bk virus infection	1 (11.1)	1 (11.1)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)
Nasopharyngitis	1 (11.1)	1 (11.1)	0
Otitis externa	1 (11.1)	0	1 (11.1)
Otitis media	1 (11.1)	0	1 (11.1)
Rhinovirus infection	1 (11.1)	0	1 (11.1)

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Sinusitis	1 (11.1)	0	1 (11.1)
Tinea pedis	1 (11.1)	1 (11.1)	0
Urinary tract infection	1 (11.1)	0	1 (11.1)
Urinary tract infection viral	1 (11.1)	1 (11.1)	0
Investigations			
-Total	4 (44.4)	0	4 (44.4)
Serum ferritin increased	3 (33.3)	0	3 (33.3)
Blood fibrinogen decreased	2 (22.2)	0	2 (22.2)
Blood creatine phosphokinase increased	1 (11.1)	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)
Tumour lysis syndrome	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Pain in extremity	2 (22.2)	1 (11.1)	1 (11.1)

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Arthralgia	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Headache	2 (22.2)	2 (22.2)	0
Seizure	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	1 (11.1)	0
Anxiety	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)
Haematuria	1 (11.1)	1 (11.1)	0
Proteinuria	1 (11.1)	1 (11.1)	0
Reproductive system and breast disorders			
-Total	1 (11.1)	0	1 (11.1)
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Pleural effusion	2 (22.2)	1 (11.1)	1 (11.1)
Epistaxis	1 (11.1)	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	5 (55.6)	4 (44.4)	1 (11.1)
Pruritus	2 (22.2)	2 (22.2)	0
Dry skin	1 (11.1)	1 (11.1)	0
Erythema nodosum	1 (11.1)	1 (11.1)	0
Palmar-plantar erythrodysaesthesia syndrome	1 (11.1)	1 (11.1)	0
Skin swelling	1 (11.1)	1 (11.1)	0
Skin ulcer	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypertension	1 (11.1)	0	1 (11.1)

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Table 265l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	49 (84.5)	2 (3.4)	47 (81.0)
Blood and lymphatic system disorders			
-Total	13 (22.4)	4 (6.9)	9 (15.5)
Anaemia	13 (22.4)	4 (6.9)	9 (15.5)
Cardiac disorders			
-Total	8 (13.8)	5 (8.6)	3 (5.2)
Tachycardia	8 (13.8)	5 (8.6)	3 (5.2)
Gastrointestinal disorders			
-Total	39 (67.2)	17 (29.3)	22 (37.9)
Nausea	19 (32.8)	10 (17.2)	9 (15.5)
Vomiting	19 (32.8)	12 (20.7)	7 (12.1)

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	18 (31.0)	11 (19.0)	7 (12.1)
Abdominal pain	11 (19.0)	4 (6.9)	7 (12.1)
Constipation	10 (17.2)	5 (8.6)	5 (8.6)
General disorders and administration site conditions			
-Total	28 (48.3)	18 (31.0)	10 (17.2)
Pyrexia	20 (34.5)	13 (22.4)	7 (12.1)
Fatigue	10 (17.2)	9 (15.5)	1 (1.7)
Chills	6 (10.3)	4 (6.9)	2 (3.4)
Oedema peripheral	2 (3.4)	2 (3.4)	0
Pain	2 (3.4)	1 (1.7)	1 (1.7)
Immune system disorders			
-Total	40 (69.0)	6 (10.3)	34 (58.6)
Cytokine release syndrome	34 (58.6)	7 (12.1)	27 (46.6)
Hypogammaglobulinaemia	18 (31.0)	0	18 (31.0)
Infections and infestations			
-Total	16 (27.6)	7 (12.1)	9 (15.5)
Conjunctivitis	7 (12.1)	3 (5.2)	4 (6.9)

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	7 (12.1)	3 (5.2)	4 (6.9)
Nasopharyngitis	6 (10.3)	4 (6.9)	2 (3.4)
Investigations			
-Total	23 (39.7)	6 (10.3)	17 (29.3)
Alanine aminotransferase increased	14 (24.1)	3 (5.2)	11 (19.0)
Platelet count decreased	9 (15.5)	5 (8.6)	4 (6.9)
Aspartate aminotransferase increased	8 (13.8)	3 (5.2)	5 (8.6)
Neutrophil count decreased	7 (12.1)	2 (3.4)	5 (8.6)
White blood cell count decreased	6 (10.3)	4 (6.9)	2 (3.4)
Blood fibrinogen decreased	3 (5.2)	2 (3.4)	1 (1.7)
International normalised ratio increased	3 (5.2)	3 (5.2)	0
Metabolism and nutrition disorders			
-Total	23 (39.7)	9 (15.5)	14 (24.1)
Decreased appetite	12 (20.7)	7 (12.1)	5 (8.6)
Hypokalaemia	8 (13.8)	3 (5.2)	5 (8.6)
Hypophosphataemia	8 (13.8)	4 (6.9)	4 (6.9)
Hypoalbuminaemia	5 (8.6)	0	5 (8.6)

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	4 (6.9)	2 (3.4)	2 (3.4)
Hypomagnesaemia	4 (6.9)	3 (5.2)	1 (1.7)
Hyperuricaemia	3 (5.2)	2 (3.4)	1 (1.7)
Hyperphosphataemia	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	24 (41.4)	11 (19.0)	13 (22.4)
Pain in extremity	12 (20.7)	5 (8.6)	7 (12.1)
Arthralgia	9 (15.5)	5 (8.6)	4 (6.9)
Back pain	6 (10.3)	2 (3.4)	4 (6.9)
Myalgia	5 (8.6)	3 (5.2)	2 (3.4)
Nervous system disorders			
-Total	16 (27.6)	9 (15.5)	7 (12.1)
Headache	16 (27.6)	9 (15.5)	7 (12.1)
Psychiatric disorders			
-Total	10 (17.2)	4 (6.9)	6 (10.3)
Anxiety	10 (17.2)	4 (6.9)	6 (10.3)
Renal and urinary disorders			

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (6.9)	3 (5.2)	1 (1.7)
Acute kidney injury	4 (6.9)	3 (5.2)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	26 (44.8)	20 (34.5)	6 (10.3)
Cough	20 (34.5)	16 (27.6)	4 (6.9)
Epistaxis	8 (13.8)	7 (12.1)	1 (1.7)
Nasal congestion	8 (13.8)	7 (12.1)	1 (1.7)
Oropharyngeal pain	4 (6.9)	4 (6.9)	0
Skin and subcutaneous tissue disorders			
-Total	15 (25.9)	9 (15.5)	6 (10.3)
Pruritus	6 (10.3)	3 (5.2)	3 (5.2)
Rash	6 (10.3)	3 (5.2)	3 (5.2)
Dry skin	5 (8.6)	3 (5.2)	2 (3.4)
Erythema	2 (3.4)	2 (3.4)	0
Vascular disorders			
-Total	15 (25.9)	6 (10.3)	9 (15.5)
Hypertension	8 (13.8)	3 (5.2)	5 (8.6)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypotension	8 (13.8)	3 (5.2)	5 (8.6)

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Table 265l
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	34 (85.0)	2 (5.0)	32 (80.0)
Blood and lymphatic system disorders			
-Total	10 (25.0)	3 (7.5)	7 (17.5)
Anaemia	10 (25.0)	3 (7.5)	7 (17.5)
Cardiac disorders			
-Total	9 (22.5)	3 (7.5)	6 (15.0)
Tachycardia	9 (22.5)	3 (7.5)	6 (15.0)
Gastrointestinal disorders			
-Total	26 (65.0)	12 (30.0)	14 (35.0)
Nausea	11 (27.5)	4 (10.0)	7 (17.5)
Vomiting	10 (25.0)	8 (20.0)	2 (5.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Constipation	9 (22.5)	4 (10.0)	5 (12.5)
Diarrhoea	8 (20.0)	6 (15.0)	2 (5.0)
Abdominal pain	6 (15.0)	2 (5.0)	4 (10.0)
General disorders and administration site conditions			
-Total	25 (62.5)	10 (25.0)	15 (37.5)
Pyrexia	18 (45.0)	7 (17.5)	11 (27.5)
Fatigue	9 (22.5)	6 (15.0)	3 (7.5)
Oedema peripheral	5 (12.5)	4 (10.0)	1 (2.5)
Pain	4 (10.0)	0	4 (10.0)
Chills	3 (7.5)	1 (2.5)	2 (5.0)
Immune system disorders			
-Total	24 (60.0)	5 (12.5)	19 (47.5)
Cytokine release syndrome	23 (57.5)	6 (15.0)	17 (42.5)
Hypogammaglobulinaemia	10 (25.0)	2 (5.0)	8 (20.0)
Infections and infestations			
-Total	8 (20.0)	2 (5.0)	6 (15.0)
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	2 (5.0)	0	2 (5.0)
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)
Investigations			
-Total	20 (50.0)	3 (7.5)	17 (42.5)
White blood cell count decreased	8 (20.0)	1 (2.5)	7 (17.5)
International normalised ratio increased	7 (17.5)	3 (7.5)	4 (10.0)
Alanine aminotransferase increased	6 (15.0)	3 (7.5)	3 (7.5)
Aspartate aminotransferase increased	6 (15.0)	1 (2.5)	5 (12.5)
Platelet count decreased	6 (15.0)	3 (7.5)	3 (7.5)
Blood fibrinogen decreased	4 (10.0)	1 (2.5)	3 (7.5)
Blood immunoglobulin g decreased	4 (10.0)	1 (2.5)	3 (7.5)
Electrocardiogram qt prolonged	4 (10.0)	2 (5.0)	2 (5.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	3 (7.5)
Metabolism and nutrition disorders			
-Total	23 (57.5)	7 (17.5)	16 (40.0)
Decreased appetite	11 (27.5)	6 (15.0)	5 (12.5)
Hypocalcaemia	9 (22.5)	0	9 (22.5)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	6 (15.0)	6 (15.0)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)
Hypokalaemia	6 (15.0)	1 (2.5)	5 (12.5)
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)
Hyperphosphataemia	4 (10.0)	4 (10.0)	0
Hypophosphataemia	4 (10.0)	0	4 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	15 (37.5)	8 (20.0)	7 (17.5)
Pain in extremity	8 (20.0)	4 (10.0)	4 (10.0)
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)
Arthralgia	3 (7.5)	1 (2.5)	2 (5.0)
Back pain	2 (5.0)	0	2 (5.0)
Nervous system disorders			
-Total	15 (37.5)	7 (17.5)	8 (20.0)
Headache	15 (37.5)	7 (17.5)	8 (20.0)
Psychiatric disorders			
-Total	3 (7.5)	0	3 (7.5)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Anxiety	3 (7.5)	0	3 (7.5)
Renal and urinary disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Acute kidney injury	5 (12.5)	2 (5.0)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (30.0)	9 (22.5)	3 (7.5)
Cough	6 (15.0)	5 (12.5)	1 (2.5)
Oropharyngeal pain	6 (15.0)	4 (10.0)	2 (5.0)
Nasal congestion	3 (7.5)	2 (5.0)	1 (2.5)
Epistaxis	2 (5.0)	0	2 (5.0)
Skin and subcutaneous tissue disorders			
-Total	12 (30.0)	7 (17.5)	5 (12.5)
Pruritus	5 (12.5)	2 (5.0)	3 (7.5)
Dry skin	4 (10.0)	4 (10.0)	0
Erythema	4 (10.0)	3 (7.5)	1 (2.5)
Rash	4 (10.0)	2 (5.0)	2 (5.0)
Vascular disorders			

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	10 (25.0)	3 (7.5)	7 (17.5)
Hypertension	7 (17.5)	2 (5.0)	5 (12.5)
Hypotension	5 (12.5)	2 (5.0)	3 (7.5)

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Table 265m
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Eligibility for SCT Enrolled set

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	13 (76.5)	0	13 (76.5)
Blood and lymphatic system disorders			
-Total	8 (47.1)	3 (17.6)	5 (29.4)
Anaemia	8 (47.1)	3 (17.6)	5 (29.4)
Cardiac disorders			
-Total	6 (35.3)	6 (35.3)	0
Tachycardia	6 (35.3)	6 (35.3)	0
Eye disorders			
-Total	2 (11.8)	2 (11.8)	0
Ocular hyperaemia	2 (11.8)	2 (11.8)	0
Gastrointestinal disorders			

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	11 (64.7)	5 (29.4)	6 (35.3)
Nausea	9 (52.9)	6 (35.3)	3 (17.6)
Vomiting	7 (41.2)	4 (23.5)	3 (17.6)
Diarrhoea	5 (29.4)	5 (29.4)	0
Abdominal pain	4 (23.5)	2 (11.8)	2 (11.8)
Constipation	3 (17.6)	3 (17.6)	0
Haematemesis	2 (11.8)	2 (11.8)	0
General disorders and administration site conditions			
-Total	7 (41.2)	6 (35.3)	1 (5.9)
Fatigue	7 (41.2)	6 (35.3)	1 (5.9)
Pyrexia	3 (17.6)	2 (11.8)	1 (5.9)
Hepatobiliary disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Hepatic function abnormal	2 (11.8)	1 (5.9)	1 (5.9)
Immune system disorders			
-Total	12 (70.6)	1 (5.9)	11 (64.7)
Cytokine release syndrome	10 (58.8)	1 (5.9)	9 (52.9)

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	6 (35.3)	0	6 (35.3)
Infections and infestations			
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Tinea pedis	2 (11.8)	2 (11.8)	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)
Injury, poisoning and procedural complications			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Transfusion reaction	2 (11.8)	1 (5.9)	1 (5.9)
Investigations			
-Total	10 (58.8)	1 (5.9)	9 (52.9)
International normalised ratio increased	6 (35.3)	5 (29.4)	1 (5.9)
Platelet count decreased	6 (35.3)	4 (23.5)	2 (11.8)
Blood immunoglobulin a decreased	5 (29.4)	5 (29.4)	0
Neutrophil count decreased	5 (29.4)	2 (11.8)	3 (17.6)
Alanine aminotransferase increased	4 (23.5)	0	4 (23.5)
Blood fibrinogen decreased	4 (23.5)	3 (17.6)	1 (5.9)
Blood immunoglobulin m decreased	4 (23.5)	4 (23.5)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
White blood cell count decreased	4 (23.5)	2 (11.8)	2 (11.8)
Activated partial thromboplastin time prolonged	3 (17.6)	2 (11.8)	1 (5.9)
Blood bilirubin increased	3 (17.6)	2 (11.8)	1 (5.9)
Lymphocyte count decreased	3 (17.6)	1 (5.9)	2 (11.8)
Aspartate aminotransferase increased	2 (11.8)	0	2 (11.8)
Serum ferritin increased	2 (11.8)	0	2 (11.8)
Metabolism and nutrition disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Decreased appetite	6 (35.3)	4 (23.5)	2 (11.8)
Hyperphosphataemia	3 (17.6)	3 (17.6)	0
Hyperuricaemia	2 (11.8)	2 (11.8)	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)
Hypokalaemia	1 (5.9)	0	1 (5.9)
Musculoskeletal and connective tissue disorders			
-Total	9 (52.9)	7 (41.2)	2 (11.8)
Pain in extremity	5 (29.4)	4 (23.5)	1 (5.9)

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	4 (23.5)	2 (11.8)	2 (11.8)
Arthralgia	3 (17.6)	3 (17.6)	0
Nervous system disorders			
-Total	5 (29.4)	4 (23.5)	1 (5.9)
Headache	5 (29.4)	4 (23.5)	1 (5.9)
Psychiatric disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Anxiety	2 (11.8)	1 (5.9)	1 (5.9)
Confusional state	2 (11.8)	2 (11.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (58.8)	9 (52.9)	1 (5.9)
Cough	5 (29.4)	5 (29.4)	0
Rhinorrhoea	4 (23.5)	4 (23.5)	0
Nasal congestion	3 (17.6)	3 (17.6)	0
Oropharyngeal pain	3 (17.6)	3 (17.6)	0
Pleural effusion	2 (11.8)	1 (5.9)	1 (5.9)
Tachypnoea	2 (11.8)	2 (11.8)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (5.9)	1 (5.9)	0
Skin and subcutaneous tissue disorders			
-Total	6 (35.3)	4 (23.5)	2 (11.8)
Dry skin	3 (17.6)	2 (11.8)	1 (5.9)
Rash papular	3 (17.6)	3 (17.6)	0
Pruritus	2 (11.8)	2 (11.8)	0
Skin ulcer	2 (11.8)	1 (5.9)	1 (5.9)
Vascular disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	1 (5.9)	0

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Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	70 (86.4)	3 (3.7)	67 (82.7)
Blood and lymphatic system disorders			
-Total	15 (18.5)	4 (4.9)	11 (13.6)
Anaemia	15 (18.5)	4 (4.9)	11 (13.6)
Cardiac disorders			
-Total	11 (13.6)	2 (2.5)	9 (11.1)
Tachycardia	11 (13.6)	2 (2.5)	9 (11.1)
Eye disorders			
-Total	1 (1.2)	1 (1.2)	0
Ocular hyperaemia	1 (1.2)	1 (1.2)	0
Gastrointestinal disorders			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	55 (67.9)	25 (30.9)	30 (37.0)
Vomiting	22 (27.2)	16 (19.8)	6 (7.4)
Diarrhoea	21 (25.9)	12 (14.8)	9 (11.1)
Nausea	21 (25.9)	8 (9.9)	13 (16.0)
Constipation	16 (19.8)	6 (7.4)	10 (12.3)
Abdominal pain	13 (16.0)	4 (4.9)	9 (11.1)
Haematemesis	2 (2.5)	2 (2.5)	0
General disorders and administration site conditions			
-Total	41 (50.6)	21 (25.9)	20 (24.7)
Pyrexia	35 (43.2)	18 (22.2)	17 (21.0)
Fatigue	12 (14.8)	9 (11.1)	3 (3.7)
Hepatobiliary disorders			
-Total	3 (3.7)	0	3 (3.7)
Hepatic function abnormal	3 (3.7)	0	3 (3.7)
Immune system disorders			
-Total	52 (64.2)	10 (12.3)	42 (51.9)
Cytokine release syndrome	47 (58.0)	12 (14.8)	35 (43.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	22 (27.2)	2 (2.5)	20 (24.7)
Infections and infestations			
-Total	11 (13.6)	4 (4.9)	7 (8.6)
Upper respiratory tract infection	11 (13.6)	4 (4.9)	7 (8.6)
Injury, poisoning and procedural complications			
-Total	1 (1.2)	0	1 (1.2)
Transfusion reaction	1 (1.2)	0	1 (1.2)
Investigations			
-Total	33 (40.7)	6 (7.4)	27 (33.3)
Alanine aminotransferase increased	16 (19.8)	6 (7.4)	10 (12.3)
Aspartate aminotransferase increased	12 (14.8)	4 (4.9)	8 (9.9)
White blood cell count decreased	10 (12.3)	3 (3.7)	7 (8.6)
Platelet count decreased	9 (11.1)	4 (4.9)	5 (6.2)
Neutrophil count decreased	6 (7.4)	1 (1.2)	5 (6.2)
Serum ferritin increased	5 (6.2)	2 (2.5)	3 (3.7)
Blood bilirubin increased	4 (4.9)	0	4 (4.9)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	4 (4.9)	1 (1.2)	3 (3.7)
Lymphocyte count decreased	4 (4.9)	2 (2.5)	2 (2.5)
Blood fibrinogen decreased	3 (3.7)	0	3 (3.7)
Activated partial thromboplastin time prolonged	2 (2.5)	1 (1.2)	1 (1.2)
Blood immunoglobulin a decreased	1 (1.2)	0	1 (1.2)
Blood immunoglobulin m decreased	1 (1.2)	0	1 (1.2)
Metabolism and nutrition disorders			
-Total	36 (44.4)	10 (12.3)	26 (32.1)
Decreased appetite	17 (21.0)	9 (11.1)	8 (9.9)
Hypocalcaemia	13 (16.0)	2 (2.5)	11 (13.6)
Hypokalaemia	13 (16.0)	4 (4.9)	9 (11.1)
Hypophosphataemia	12 (14.8)	4 (4.9)	8 (9.9)
Hypoalbuminaemia	10 (12.3)	0	10 (12.3)
Hyperuricaemia	7 (8.6)	6 (7.4)	1 (1.2)
Hyperphosphataemia	2 (2.5)	2 (2.5)	0
Musculoskeletal and connective tissue disorders			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	24 (29.6)	11 (13.6)	13 (16.0)
Pain in extremity	15 (18.5)	5 (6.2)	10 (12.3)
Arthralgia	9 (11.1)	3 (3.7)	6 (7.4)
Myalgia	6 (7.4)	4 (4.9)	2 (2.5)
Nervous system disorders			
-Total	26 (32.1)	12 (14.8)	14 (17.3)
Headache	26 (32.1)	12 (14.8)	14 (17.3)
Psychiatric disorders			
-Total	15 (18.5)	7 (8.6)	8 (9.9)
Anxiety	11 (13.6)	3 (3.7)	8 (9.9)
Confusional state	5 (6.2)	5 (6.2)	0
Renal and urinary disorders			
-Total	9 (11.1)	5 (6.2)	4 (4.9)
Acute kidney injury	9 (11.1)	5 (6.2)	4 (4.9)
Respiratory, thoracic and mediastinal disorders			
-Total	33 (40.7)	20 (24.7)	13 (16.0)
Cough	21 (25.9)	16 (19.8)	5 (6.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	9 (11.1)	6 (7.4)	3 (3.7)
Nasal congestion	8 (9.9)	6 (7.4)	2 (2.5)
Oropharyngeal pain	7 (8.6)	5 (6.2)	2 (2.5)
Pleural effusion	5 (6.2)	3 (3.7)	2 (2.5)
Tachypnoea	4 (4.9)	2 (2.5)	2 (2.5)
Rhinorrhoea	2 (2.5)	0	2 (2.5)
Skin and subcutaneous tissue disorders			
-Total	21 (25.9)	11 (13.6)	10 (12.3)
Rash	10 (12.3)	5 (6.2)	5 (6.2)
Pruritus	9 (11.1)	3 (3.7)	6 (7.4)
Dry skin	6 (7.4)	5 (6.2)	1 (1.2)
Rash papular	1 (1.2)	0	1 (1.2)
Skin ulcer	1 (1.2)	1 (1.2)	0
Vascular disorders			
-Total	22 (27.2)	7 (8.6)	15 (18.5)
Hypertension	14 (17.3)	4 (4.9)	10 (12.3)
Hypotension	11 (13.6)	4 (4.9)	7 (8.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	26 (92.9)	0	26 (92.9)
Blood and lymphatic system disorders			
-Total	7 (25.0)	3 (10.7)	4 (14.3)
Anaemia	7 (25.0)	3 (10.7)	4 (14.3)
Cardiac disorders			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Tachycardia	5 (17.9)	3 (10.7)	2 (7.1)
Eye disorders			
-Total	3 (10.7)	3 (10.7)	0
Ocular hyperaemia	3 (10.7)	3 (10.7)	0
Gastrointestinal disorders			
-Total	20 (71.4)	12 (42.9)	8 (28.6)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Diarrhoea	11 (39.3)	8 (28.6)	3 (10.7)
Vomiting	10 (35.7)	7 (25.0)	3 (10.7)
Nausea	8 (28.6)	3 (10.7)	5 (17.9)
Constipation	7 (25.0)	7 (25.0)	0
Abdominal pain	5 (17.9)	3 (10.7)	2 (7.1)
General disorders and administration site conditions			
-Total	19 (67.9)	8 (28.6)	11 (39.3)
Pyrexia	13 (46.4)	7 (25.0)	6 (21.4)
Fatigue	5 (17.9)	3 (10.7)	2 (7.1)
Face oedema	3 (10.7)	1 (3.6)	2 (7.1)
Pain	3 (10.7)	1 (3.6)	2 (7.1)
Chills	2 (7.1)	1 (3.6)	1 (3.6)
Immune system disorders			
-Total	22 (78.6)	3 (10.7)	19 (67.9)
Cytokine release syndrome	18 (64.3)	5 (17.9)	13 (46.4)
Hypogammaglobulinaemia	13 (46.4)	1 (3.6)	12 (42.9)
Infections and infestations			
-Total	13 (46.4)	3 (10.7)	10 (35.7)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Upper respiratory tract infection	6 (21.4)	3 (10.7)	3 (10.7)
Conjunctivitis	5 (17.9)	2 (7.1)	3 (10.7)
Sinusitis	4 (14.3)	0	4 (14.3)
Rhinovirus infection	3 (10.7)	0	3 (10.7)
Nasopharyngitis	1 (3.6)	0	1 (3.6)
Investigations			
-Total	14 (50.0)	1 (3.6)	13 (46.4)
White blood cell count decreased	7 (25.0)	1 (3.6)	6 (21.4)
Alanine aminotransferase increased	5 (17.9)	2 (7.1)	3 (10.7)
Platelet count decreased	5 (17.9)	2 (7.1)	3 (10.7)
Neutrophil count decreased	4 (14.3)	1 (3.6)	3 (10.7)
Aspartate aminotransferase increased	3 (10.7)	1 (3.6)	2 (7.1)
Blood immunoglobulin g decreased	3 (10.7)	1 (3.6)	2 (7.1)
International normalised ratio increased	3 (10.7)	3 (10.7)	0
Metabolism and nutrition disorders			
-Total	14 (50.0)	4 (14.3)	10 (35.7)
Decreased appetite	8 (28.6)	4 (14.3)	4 (14.3)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypocalcaemia	5 (17.9)	0	5 (17.9)
Hypophosphataemia	5 (17.9)	1 (3.6)	4 (14.3)
Hyperuricaemia	3 (10.7)	3 (10.7)	0
Hypokalaemia	3 (10.7)	1 (3.6)	2 (7.1)
Hypomagnesaemia	3 (10.7)	3 (10.7)	0
Hypoalbuminaemia	2 (7.1)	0	2 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	8 (28.6)	4 (14.3)	4 (14.3)
Pain in extremity	6 (21.4)	4 (14.3)	2 (7.1)
Myalgia	2 (7.1)	1 (3.6)	1 (3.6)
Arthralgia	1 (3.6)	0	1 (3.6)
Nervous system disorders			
-Total	9 (32.1)	6 (21.4)	3 (10.7)
Headache	9 (32.1)	6 (21.4)	3 (10.7)
Psychiatric disorders			
-Total	4 (14.3)	2 (7.1)	2 (7.1)
Anxiety	4 (14.3)	2 (7.1)	2 (7.1)
Renal and urinary disorders			

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	3 (10.7)	3 (10.7)	0
Dysuria	3 (10.7)	3 (10.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (42.9)	7 (25.0)	5 (17.9)
Cough	7 (25.0)	4 (14.3)	3 (10.7)
Nasal congestion	5 (17.9)	4 (14.3)	1 (3.6)
Epistaxis	3 (10.7)	2 (7.1)	1 (3.6)
Oropharyngeal pain	1 (3.6)	0	1 (3.6)
Skin and subcutaneous tissue disorders			
-Total	9 (32.1)	6 (21.4)	3 (10.7)
Rash	4 (14.3)	3 (10.7)	1 (3.6)
Erythema	3 (10.7)	2 (7.1)	1 (3.6)
Pruritus	3 (10.7)	2 (7.1)	1 (3.6)
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)
Vascular disorders			
-Total	8 (28.6)	3 (10.7)	5 (17.9)
Hypotension	6 (21.4)	3 (10.7)	3 (10.7)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypertension	3 (10.7)	1 (3.6)	2 (7.1)

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Table 265n
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	57 (81.4)	4 (5.7)	53 (75.7)
Blood and lymphatic system disorders			
-Total	16 (22.9)	4 (5.7)	12 (17.1)
Anaemia	16 (22.9)	4 (5.7)	12 (17.1)
Cardiac disorders			
-Total	12 (17.1)	5 (7.1)	7 (10.0)
Tachycardia	12 (17.1)	5 (7.1)	7 (10.0)
Gastrointestinal disorders			
-Total	45 (64.3)	17 (24.3)	28 (40.0)
Nausea	22 (31.4)	11 (15.7)	11 (15.7)
Vomiting	19 (27.1)	13 (18.6)	6 (8.6)
Diarrhoea	15 (21.4)	9 (12.9)	6 (8.6)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	12 (17.1)	3 (4.3)	9 (12.9)
Constipation	12 (17.1)	2 (2.9)	10 (14.3)
General disorders and administration site conditions			
-Total	33 (47.1)	18 (25.7)	15 (21.4)
Pyrexia	25 (35.7)	13 (18.6)	12 (17.1)
Fatigue	14 (20.0)	12 (17.1)	2 (2.9)
Chills	7 (10.0)	4 (5.7)	3 (4.3)
Face oedema	4 (5.7)	4 (5.7)	0
Pain	3 (4.3)	0	3 (4.3)
Immune system disorders			
-Total	42 (60.0)	8 (11.4)	34 (48.6)
Cytokine release syndrome	39 (55.7)	8 (11.4)	31 (44.3)
Hypogammaglobulinaemia	15 (21.4)	1 (1.4)	14 (20.0)
Infections and infestations			
-Total	20 (28.6)	6 (8.6)	14 (20.0)
Nasopharyngitis	7 (10.0)	5 (7.1)	2 (2.9)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	5 (7.1)
Rhinovirus infection	5 (7.1)	0	5 (7.1)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	4 (5.7)	1 (1.4)	3 (4.3)
Sinusitis	3 (4.3)	0	3 (4.3)
Investigations			
-Total	26 (37.1)	7 (10.0)	19 (27.1)
Alanine aminotransferase increased	15 (21.4)	4 (5.7)	11 (15.7)
Aspartate aminotransferase increased	11 (15.7)	3 (4.3)	8 (11.4)
Platelet count decreased	10 (14.3)	6 (8.6)	4 (5.7)
International normalised ratio increased	7 (10.0)	3 (4.3)	4 (5.7)
Neutrophil count decreased	7 (10.0)	2 (2.9)	5 (7.1)
White blood cell count decreased	7 (10.0)	4 (5.7)	3 (4.3)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	31 (44.3)	11 (15.7)	20 (28.6)
Decreased appetite	15 (21.4)	9 (12.9)	6 (8.6)
Hypokalaemia	11 (15.7)	3 (4.3)	8 (11.4)
Hypoalbuminaemia	9 (12.9)	0	9 (12.9)
Hypocalcaemia	8 (11.4)	2 (2.9)	6 (8.6)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	7 (10.0)	3 (4.3)	4 (5.7)
Hyperuricaemia	6 (8.6)	5 (7.1)	1 (1.4)
Hypomagnesaemia	6 (8.6)	4 (5.7)	2 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	25 (35.7)	14 (20.0)	11 (15.7)
Pain in extremity	14 (20.0)	5 (7.1)	9 (12.9)
Arthralgia	11 (15.7)	6 (8.6)	5 (7.1)
Myalgia	8 (11.4)	5 (7.1)	3 (4.3)
Nervous system disorders			
-Total	22 (31.4)	10 (14.3)	12 (17.1)
Headache	22 (31.4)	10 (14.3)	12 (17.1)
Psychiatric disorders			
-Total	14 (20.0)	4 (5.7)	10 (14.3)
Anxiety	9 (12.9)	2 (2.9)	7 (10.0)
Agitation	7 (10.0)	4 (5.7)	3 (4.3)
Renal and urinary disorders			
-Total	10 (14.3)	6 (8.6)	4 (5.7)
Acute kidney injury	9 (12.9)	5 (7.1)	4 (5.7)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Dysuria	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	26 (37.1)	22 (31.4)	4 (5.7)
Cough	19 (27.1)	17 (24.3)	2 (2.9)
Oropharyngeal pain	9 (12.9)	8 (11.4)	1 (1.4)
Epistaxis	7 (10.0)	5 (7.1)	2 (2.9)
Nasal congestion	6 (8.6)	5 (7.1)	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	18 (25.7)	10 (14.3)	8 (11.4)
Pruritus	8 (11.4)	3 (4.3)	5 (7.1)
Dry skin	7 (10.0)	6 (8.6)	1 (1.4)
Rash	6 (8.6)	2 (2.9)	4 (5.7)
Erythema	3 (4.3)	3 (4.3)	0
Vascular disorders			
-Total	17 (24.3)	6 (8.6)	11 (15.7)
Hypertension	12 (17.1)	4 (5.7)	8 (11.4)
Hypotension	7 (10.0)	2 (2.9)	5 (7.1)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	11 (100)	3 (27.3)	8 (72.7)
Blood and lymphatic system disorders			
-Total	1 (9.1)	0	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Constipation	4 (36.4)	2 (18.2)	2 (18.2)
Nausea	2 (18.2)	0	2 (18.2)
Abdominal pain	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	7 (63.6)	5 (45.5)	2 (18.2)
Pyrexia	6 (54.5)	5 (45.5)	1 (9.1)
Pain	2 (18.2)	1 (9.1)	1 (9.1)
Immune system disorders			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Cytokine release syndrome	6 (54.5)	2 (18.2)	4 (36.4)
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)
Infections and infestations			
-Total	3 (27.3)	0	3 (27.3)
Sinusitis	3 (27.3)	0	3 (27.3)
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Alanine aminotransferase increased	4 (36.4)	2 (18.2)	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	0	1 (9.1)

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Hypophosphataemia	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Back pain	2 (18.2)	1 (9.1)	1 (9.1)
Arthralgia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Headache	3 (27.3)	1 (9.1)	2 (18.2)
Psychiatric disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Anxiety	2 (18.2)	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Cough	1 (9.1)	0	1 (9.1)

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
Epistaxis	1 (9.1)	1 (9.1)	0
Nasal congestion	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pruritus	2 (18.2)	2 (18.2)	0
Rash	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Hypotension	2 (18.2)	1 (9.1)	1 (9.1)
Hypertension	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265o
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	72 (82.8)	2 (2.3)	70 (80.5)
Blood and lymphatic system disorders			
-Total	22 (25.3)	7 (8.0)	15 (17.2)
Anaemia	22 (25.3)	7 (8.0)	15 (17.2)
Cardiac disorders			
-Total	17 (19.5)	8 (9.2)	9 (10.3)
Tachycardia	17 (19.5)	8 (9.2)	9 (10.3)
Gastrointestinal disorders			
-Total	59 (67.8)	26 (29.9)	33 (37.9)
Nausea	28 (32.2)	14 (16.1)	14 (16.1)
Vomiting	28 (32.2)	19 (21.8)	9 (10.3)
Diarrhoea	25 (28.7)	16 (18.4)	9 (10.3)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Abdominal pain	16 (18.4)	5 (5.7)	11 (12.6)
Constipation	15 (17.2)	7 (8.0)	8 (9.2)
General disorders and administration site conditions			
-Total	43 (49.4)	20 (23.0)	23 (26.4)
Pyrexia	32 (36.8)	15 (17.2)	17 (19.5)
Fatigue	19 (21.8)	15 (17.2)	4 (4.6)
Chills	9 (10.3)	5 (5.7)	4 (4.6)
Pain	4 (4.6)	0	4 (4.6)
Immune system disorders			
-Total	57 (65.5)	10 (11.5)	47 (54.0)
Cytokine release syndrome	51 (58.6)	11 (12.6)	40 (46.0)
Hypogammaglobulinaemia	24 (27.6)	1 (1.1)	23 (26.4)
Infections and infestations			
-Total	15 (17.2)	5 (5.7)	10 (11.5)
Upper respiratory tract infection	12 (13.8)	5 (5.7)	7 (8.0)
Sinusitis	4 (4.6)	0	4 (4.6)
Investigations			
-Total	34 (39.1)	6 (6.9)	28 (32.2)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Alanine aminotransferase increased	16 (18.4)	4 (4.6)	12 (13.8)
Platelet count decreased	15 (17.2)	8 (9.2)	7 (8.0)
White blood cell count decreased	14 (16.1)	5 (5.7)	9 (10.3)
Aspartate aminotransferase increased	13 (14.9)	3 (3.4)	10 (11.5)
International normalised ratio increased	10 (11.5)	6 (6.9)	4 (4.6)
Neutrophil count decreased	10 (11.5)	3 (3.4)	7 (8.0)
Metabolism and nutrition disorders			
-Total	41 (47.1)	14 (16.1)	27 (31.0)
Decreased appetite	22 (25.3)	12 (13.8)	10 (11.5)
Hypokalaemia	14 (16.1)	4 (4.6)	10 (11.5)
Hypocalcaemia	13 (14.9)	2 (2.3)	11 (12.6)
Hypoalbuminaemia	11 (12.6)	0	11 (12.6)
Hypophosphataemia	10 (11.5)	4 (4.6)	6 (6.9)
Hyperuricaemia	9 (10.3)	8 (9.2)	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	36 (41.4)	18 (20.7)	18 (20.7)
Pain in extremity	20 (23.0)	9 (10.3)	11 (12.6)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Arthralgia	11 (12.6)	6 (6.9)	5 (5.7)
Myalgia	10 (11.5)	6 (6.9)	4 (4.6)
Back pain	6 (6.9)	1 (1.1)	5 (5.7)
Nervous system disorders			
-Total	28 (32.2)	15 (17.2)	13 (14.9)
Headache	28 (32.2)	15 (17.2)	13 (14.9)
Psychiatric disorders			
-Total	11 (12.6)	3 (3.4)	8 (9.2)
Anxiety	11 (12.6)	3 (3.4)	8 (9.2)
Renal and urinary disorders			
-Total	9 (10.3)	5 (5.7)	4 (4.6)
Acute kidney injury	9 (10.3)	5 (5.7)	4 (4.6)
Respiratory, thoracic and mediastinal disorders			
-Total	35 (40.2)	27 (31.0)	8 (9.2)
Cough	25 (28.7)	21 (24.1)	4 (4.6)
Nasal congestion	10 (11.5)	8 (9.2)	2 (2.3)
Oropharyngeal pain	10 (11.5)	8 (9.2)	2 (2.3)
Epistaxis	9 (10.3)	6 (6.9)	3 (3.4)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin and subcutaneous tissue disorders			
-Total	22 (25.3)	12 (13.8)	10 (11.5)
Dry skin	9 (10.3)	7 (8.0)	2 (2.3)
Pruritus	9 (10.3)	3 (3.4)	6 (6.9)
Rash	9 (10.3)	4 (4.6)	5 (5.7)
Vascular disorders			
-Total	22 (25.3)	8 (9.2)	14 (16.1)
Hypertension	14 (16.1)	5 (5.7)	9 (10.3)
Hypotension	11 (12.6)	4 (4.6)	7 (8.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	7 (100)	0	7 (100)
Blood and lymphatic system disorders			
-Total	4 (57.1)	0	4 (57.1)
Anaemia	2 (28.6)	0	2 (28.6)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)
Neutropenia	1 (14.3)	1 (14.3)	0
Splenomegaly	1 (14.3)	1 (14.3)	0
Cardiac disorders			
-Total	2 (28.6)	0	2 (28.6)
Bradycardia	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Tachycardia	1 (14.3)	0	1 (14.3)
Ear and labyrinth disorders			
-Total	1 (14.3)	1 (14.3)	0
Ear pruritus	1 (14.3)	1 (14.3)	0
Endocrine disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypothyroidism	1 (14.3)	0	1 (14.3)
Eye disorders			
-Total	2 (28.6)	2 (28.6)	0
Conjunctival haemorrhage	2 (28.6)	2 (28.6)	0
Ocular hyperaemia	1 (14.3)	1 (14.3)	0
Periorbital oedema	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	6 (85.7)	1 (14.3)	5 (71.4)
Constipation	3 (42.9)	2 (28.6)	1 (14.3)
Diarrhoea	3 (42.9)	3 (42.9)	0
Vomiting	2 (28.6)	2 (28.6)	0
Anal fissure	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Enterocolitis	1 (14.3)	0	1 (14.3)
Gastritis	1 (14.3)	0	1 (14.3)
Gingival erythema	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	0	1 (14.3)
Oral pain	1 (14.3)	0	1 (14.3)
Stomatitis	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Pyrexia	3 (42.9)	3 (42.9)	0
Face oedema	2 (28.6)	2 (28.6)	0
Fatigue	2 (28.6)	2 (28.6)	0
Generalised oedema	2 (28.6)	1 (14.3)	1 (14.3)
Catheter site pain	1 (14.3)	0	1 (14.3)
Chills	1 (14.3)	1 (14.3)	0
Complication associated with device	1 (14.3)	1 (14.3)	0
Localised oedema	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Hepatic function abnormal	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)
Hypertransaminasaemia	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Cytokine release syndrome	5 (71.4)	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)
Haemophagocytic lymphohistiocytosis	1 (14.3)	0	1 (14.3)
Seasonal allergy	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	4 (57.1)	0	4 (57.1)
Upper respiratory tract infection	4 (57.1)	1 (14.3)	3 (42.9)
Otitis media	2 (28.6)	0	2 (28.6)
Bronchitis	1 (14.3)	0	1 (14.3)
Cellulitis	1 (14.3)	0	1 (14.3)
Ear infection	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Folliculitis	1 (14.3)	0	1 (14.3)
Gastroenteritis viral	1 (14.3)	0	1 (14.3)
Nail infection	1 (14.3)	0	1 (14.3)
Nasopharyngitis	1 (14.3)	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)
Paronychia	1 (14.3)	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)
Rhinovirus infection	1 (14.3)	0	1 (14.3)
Sinusitis	1 (14.3)	0	1 (14.3)
Skin infection	1 (14.3)	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Abdominal injury	1 (14.3)	1 (14.3)	0
Contusion	1 (14.3)	1 (14.3)	0
Skin abrasion	1 (14.3)	1 (14.3)	0
Transfusion reaction	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Wound	1 (14.3)	0	1 (14.3)
Investigations			
-Total	6 (85.7)	0	6 (85.7)
Alanine aminotransferase increased	2 (28.6)	0	2 (28.6)
Platelet count decreased	2 (28.6)	0	2 (28.6)
Serum ferritin increased	2 (28.6)	0	2 (28.6)
Weight increased	2 (28.6)	1 (14.3)	1 (14.3)
White blood cell count decreased	2 (28.6)	0	2 (28.6)
Activated partial thromboplastin time prolonged	1 (14.3)	0	1 (14.3)
Blood bicarbonate decreased	1 (14.3)	0	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	0	1 (14.3)
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin a decreased	1 (14.3)	0	1 (14.3)
Blood immunoglobulin g decreased	1 (14.3)	1 (14.3)	0
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood thyroid stimulating hormone increased	1 (14.3)	1 (14.3)	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0
Cardiac murmur	1 (14.3)	1 (14.3)	0
International normalised ratio increased	1 (14.3)	0	1 (14.3)
Lymphocyte count decreased	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Oxygen saturation decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Hypocalcaemia	4 (57.1)	1 (14.3)	3 (42.9)
Hypokalaemia	3 (42.9)	2 (28.6)	1 (14.3)
Hypophosphataemia	3 (42.9)	1 (14.3)	2 (28.6)
Hyperphosphataemia	2 (28.6)	2 (28.6)	0
Hypoalbuminaemia	2 (28.6)	0	2 (28.6)
Decreased appetite	1 (14.3)	1 (14.3)	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperlipidaemia	1 (14.3)	0	1 (14.3)
Hypermagnesaemia	1 (14.3)	1 (14.3)	0
Hypervolaemia	1 (14.3)	0	1 (14.3)
Hyponatraemia	1 (14.3)	1 (14.3)	0
Metabolic syndrome	1 (14.3)	0	1 (14.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (42.9)	3 (42.9)	0
Bone pain	1 (14.3)	1 (14.3)	0
Muscle rigidity	1 (14.3)	1 (14.3)	0
Myalgia	1 (14.3)	1 (14.3)	0
Pain in extremity	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	0	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0
Generalised tonic-clonic seizure	1 (14.3)	0	1 (14.3)
Headache	1 (14.3)	0	1 (14.3)
Tremor	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Agitation	1 (14.3)	0	1 (14.3)
Automatism	1 (14.3)	1 (14.3)	0
Confusional state	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	0	1 (14.3)
Insomnia	1 (14.3)	0	1 (14.3)
Irritability	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Anuria	1 (14.3)	1 (14.3)	0
Azotaemia	1 (14.3)	0	1 (14.3)
Reproductive system and breast disorders			
-Total	1 (14.3)	0	1 (14.3)
Dysmenorrhoea	1 (14.3)	0	1 (14.3)
Perineal rash	1 (14.3)	0	1 (14.3)

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)
Cough	3 (42.9)	2 (28.6)	1 (14.3)
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)
Nasal congestion	2 (28.6)	1 (14.3)	1 (14.3)
Pleural effusion	2 (28.6)	2 (28.6)	0
Pulmonary oedema	2 (28.6)	0	2 (28.6)
Dyspnoea	1 (14.3)	0	1 (14.3)
Hypoxia	1 (14.3)	0	1 (14.3)
Nasal discomfort	1 (14.3)	0	1 (14.3)
Oropharyngeal pain	1 (14.3)	0	1 (14.3)
Pharyngeal haemorrhage	1 (14.3)	0	1 (14.3)
Respiratory distress	1 (14.3)	0	1 (14.3)
Rhinitis allergic	1 (14.3)	0	1 (14.3)
Rhinorrhoea	1 (14.3)	0	1 (14.3)
Sleep apnoea syndrome	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Wheezing	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	6 (85.7)	3 (42.9)	3 (42.9)
Rash	3 (42.9)	2 (28.6)	1 (14.3)
Blister	2 (28.6)	1 (14.3)	1 (14.3)
Erythema	2 (28.6)	2 (28.6)	0
Dermatitis diaper	1 (14.3)	0	1 (14.3)
Dry skin	1 (14.3)	1 (14.3)	0
Eczema	1 (14.3)	1 (14.3)	0
Ingrowing nail	1 (14.3)	0	1 (14.3)
Miliaria	1 (14.3)	1 (14.3)	0
Petechiae	1 (14.3)	0	1 (14.3)
Rash erythematous	1 (14.3)	1 (14.3)	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0
Scab	1 (14.3)	1 (14.3)	0
Skin discolouration	1 (14.3)	1 (14.3)	0
Skin swelling	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Skin ulcer	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Hypertension	3 (42.9)	2 (28.6)	1 (14.3)
Thrombosis	1 (14.3)	0	1 (14.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265p
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	78 (85.7)	2 (2.2)	76 (83.5)
Blood and lymphatic system disorders			
-Total	28 (30.8)	8 (8.8)	20 (22.0)
Anaemia	21 (23.1)	7 (7.7)	14 (15.4)
Disseminated intravascular coagulation	3 (3.3)	0	3 (3.3)
Splenomegaly	3 (3.3)	2 (2.2)	1 (1.1)
Neutropenia	2 (2.2)	0	2 (2.2)
Cardiac disorders			
-Total	16 (17.6)	8 (8.8)	8 (8.8)
Tachycardia	16 (17.6)	8 (8.8)	8 (8.8)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Bradycardia	2 (2.2)	2 (2.2)	0
Endocrine disorders			
-Total	2 (2.2)	0	2 (2.2)
Hypothyroidism	2 (2.2)	0	2 (2.2)
Eye disorders			
-Total	2 (2.2)	2 (2.2)	0
Ocular hyperaemia	2 (2.2)	2 (2.2)	0
Gastrointestinal disorders			
-Total	61 (67.0)	25 (27.5)	36 (39.6)
Nausea	29 (31.9)	14 (15.4)	15 (16.5)
Vomiting	27 (29.7)	18 (19.8)	9 (9.9)
Diarrhoea	23 (25.3)	14 (15.4)	9 (9.9)
Abdominal pain	17 (18.7)	6 (6.6)	11 (12.1)
Constipation	16 (17.6)	7 (7.7)	9 (9.9)
Stomatitis	5 (5.5)	1 (1.1)	4 (4.4)
Anal fissure	1 (1.1)	0	1 (1.1)
Gingival erythema	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	48 (52.7)	23 (25.3)	25 (27.5)
Pyrexia	35 (38.5)	17 (18.7)	18 (19.8)
Fatigue	17 (18.7)	13 (14.3)	4 (4.4)
Chills	8 (8.8)	4 (4.4)	4 (4.4)
Face oedema	5 (5.5)	3 (3.3)	2 (2.2)
Catheter site pain	4 (4.4)	2 (2.2)	2 (2.2)
Generalised oedema	3 (3.3)	1 (1.1)	2 (2.2)
Localised oedema	2 (2.2)	1 (1.1)	1 (1.1)
Hepatobiliary disorders			
-Total	9 (9.9)	3 (3.3)	6 (6.6)
Hepatic function abnormal	4 (4.4)	0	4 (4.4)
Hyperbilirubinaemia	3 (3.3)	1 (1.1)	2 (2.2)
Hypertransaminasaemia	2 (2.2)	2 (2.2)	0
Immune system disorders			
-Total	59 (64.8)	9 (9.9)	50 (54.9)
Cytokine release syndrome	52 (57.1)	11 (12.1)	41 (45.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypogammaglobulinaemia	26 (28.6)	2 (2.2)	24 (26.4)
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)
Haemophagocytic lymphohistiocytosis	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	31 (34.1)	6 (6.6)	25 (27.5)
Upper respiratory tract infection	9 (9.9)	4 (4.4)	5 (5.5)
Nasopharyngitis	7 (7.7)	4 (4.4)	3 (3.3)
Rhinovirus infection	7 (7.7)	0	7 (7.7)
Sinusitis	6 (6.6)	0	6 (6.6)
Nail infection	3 (3.3)	3 (3.3)	0
Paronychia	3 (3.3)	0	3 (3.3)
Bronchitis	2 (2.2)	0	2 (2.2)
Otitis media	2 (2.2)	0	2 (2.2)
Pneumonia	2 (2.2)	1 (1.1)	1 (1.1)
Skin infection	2 (2.2)	0	2 (2.2)
Staphylococcal infection	2 (2.2)	0	2 (2.2)
Ear infection	1 (1.1)	0	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Otitis externa	1 (1.1)	0	1 (1.1)
Injury, poisoning and procedural complications			
-Total	5 (5.5)	3 (3.3)	2 (2.2)
Transfusion reaction	2 (2.2)	1 (1.1)	1 (1.1)
Wound	2 (2.2)	1 (1.1)	1 (1.1)
Contusion	1 (1.1)	1 (1.1)	0
Skin abrasion	1 (1.1)	1 (1.1)	0
Investigations			
-Total	41 (45.1)	7 (7.7)	34 (37.4)
Alanine aminotransferase increased	18 (19.8)	6 (6.6)	12 (13.2)
Aspartate aminotransferase increased	14 (15.4)	4 (4.4)	10 (11.0)
Platelet count decreased	13 (14.3)	8 (8.8)	5 (5.5)
White blood cell count decreased	12 (13.2)	5 (5.5)	7 (7.7)
Neutrophil count decreased	10 (11.0)	3 (3.3)	7 (7.7)
International normalised ratio increased	9 (9.9)	6 (6.6)	3 (3.3)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Blood fibrinogen decreased	6 (6.6)	3 (3.3)	3 (3.3)
Lymphocyte count decreased	6 (6.6)	3 (3.3)	3 (3.3)
Blood immunoglobulin a decreased	5 (5.5)	5 (5.5)	0
Serum ferritin increased	5 (5.5)	2 (2.2)	3 (3.3)
Activated partial thromboplastin time prolonged	4 (4.4)	3 (3.3)	1 (1.1)
C-reactive protein increased	4 (4.4)	2 (2.2)	2 (2.2)
Blood immunoglobulin g decreased	3 (3.3)	0	3 (3.3)
Blood lactate dehydrogenase increased	3 (3.3)	2 (2.2)	1 (1.1)
Weight increased	3 (3.3)	1 (1.1)	2 (2.2)
Blood uric acid increased	1 (1.1)	1 (1.1)	0
Oxygen saturation decreased	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	39 (42.9)	14 (15.4)	25 (27.5)
Decreased appetite	22 (24.2)	12 (13.2)	10 (11.0)
Hypokalaemia	11 (12.1)	2 (2.2)	9 (9.9)
Hypoalbuminaemia	9 (9.9)	0	9 (9.9)
Hypocalcaemia	9 (9.9)	1 (1.1)	8 (8.8)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypophosphataemia	9 (9.9)	3 (3.3)	6 (6.6)
Hyperphosphataemia	3 (3.3)	3 (3.3)	0
Hypervolaemia	2 (2.2)	1 (1.1)	1 (1.1)
Hyponatraemia	2 (2.2)	2 (2.2)	0
Hyperchloraemia	1 (1.1)	1 (1.1)	0
Hypermagnesaemia	1 (1.1)	1 (1.1)	0
Musculoskeletal and connective tissue disorders			
-Total	33 (36.3)	15 (16.5)	18 (19.8)
Pain in extremity	19 (20.9)	8 (8.8)	11 (12.1)
Arthralgia	12 (13.2)	6 (6.6)	6 (6.6)
Myalgia	9 (9.9)	5 (5.5)	4 (4.4)
Bone pain	3 (3.3)	0	3 (3.3)
Nervous system disorders			
-Total	35 (38.5)	21 (23.1)	14 (15.4)
Headache	30 (33.0)	16 (17.6)	14 (15.4)
Tremor	5 (5.5)	5 (5.5)	0
Dizziness	4 (4.4)	4 (4.4)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Psychiatric disorders			
-Total	25 (27.5)	13 (14.3)	12 (13.2)
Anxiety	13 (14.3)	4 (4.4)	9 (9.9)
Agitation	6 (6.6)	4 (4.4)	2 (2.2)
Confusional state	6 (6.6)	6 (6.6)	0
Insomnia	5 (5.5)	2 (2.2)	3 (3.3)
Delirium	4 (4.4)	2 (2.2)	2 (2.2)
Irritability	2 (2.2)	2 (2.2)	0
Renal and urinary disorders			
-Total	8 (8.8)	5 (5.5)	3 (3.3)
Acute kidney injury	8 (8.8)	5 (5.5)	3 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	41 (45.1)	24 (26.4)	17 (18.7)
Cough	23 (25.3)	19 (20.9)	4 (4.4)
Nasal congestion	9 (9.9)	8 (8.8)	1 (1.1)
Oropharyngeal pain	9 (9.9)	8 (8.8)	1 (1.1)
Epistaxis	8 (8.8)	6 (6.6)	2 (2.2)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hypoxia	5 (5.5)	0	5 (5.5)
Pleural effusion	5 (5.5)	2 (2.2)	3 (3.3)
Rhinorrhoea	5 (5.5)	4 (4.4)	1 (1.1)
Tachypnoea	5 (5.5)	3 (3.3)	2 (2.2)
Pulmonary oedema	4 (4.4)	3 (3.3)	1 (1.1)
Dyspnoea	2 (2.2)	1 (1.1)	1 (1.1)
Respiratory distress	1 (1.1)	0	1 (1.1)
Rhinitis allergic	1 (1.1)	1 (1.1)	0
Sleep apnoea syndrome	1 (1.1)	1 (1.1)	0
Wheezing	1 (1.1)	0	1 (1.1)
Skin and subcutaneous tissue disorders			
-Total	28 (30.8)	14 (15.4)	14 (15.4)
Pruritus	11 (12.1)	5 (5.5)	6 (6.6)
Dry skin	8 (8.8)	6 (6.6)	2 (2.2)
Rash	7 (7.7)	3 (3.3)	4 (4.4)
Erythema	4 (4.4)	3 (3.3)	1 (1.1)
Ingrowing nail	3 (3.3)	1 (1.1)	2 (2.2)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Rash maculo-papular	3 (3.3)	1 (1.1)	2 (2.2)
Petechiae	2 (2.2)	2 (2.2)	0
Skin ulcer	2 (2.2)	2 (2.2)	0
Blister	1 (1.1)	1 (1.1)	0
Eczema	1 (1.1)	1 (1.1)	0
Skin discolouration	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	22 (24.2)	7 (7.7)	15 (16.5)
Hypotension	13 (14.3)	5 (5.5)	8 (8.8)
Hypertension	12 (13.2)	3 (3.3)	9 (9.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	40 (100)	2 (5.0)	38 (95.0)
Blood and lymphatic system disorders			
-Total	13 (32.5)	3 (7.5)	10 (25.0)
Anaemia	9 (22.5)	3 (7.5)	6 (15.0)
Disseminated intravascular coagulation	4 (10.0)	0	4 (10.0)
Cardiac disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)
Endocrine disorders			
-Total	2 (5.0)	0	2 (5.0)
Adrenal insufficiency	2 (5.0)	0	2 (5.0)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	27 (67.5)	13 (32.5)	14 (35.0)
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)
Vomiting	12 (30.0)	7 (17.5)	5 (12.5)
Nausea	10 (25.0)	6 (15.0)	4 (10.0)
Abdominal pain	7 (17.5)	1 (2.5)	6 (15.0)
Constipation	7 (17.5)	3 (7.5)	4 (10.0)
Stomatitis	4 (10.0)	1 (2.5)	3 (7.5)
General disorders and administration site conditions			
-Total	22 (55.0)	13 (32.5)	9 (22.5)
Pyrexia	17 (42.5)	10 (25.0)	7 (17.5)
Chills	5 (12.5)	2 (5.0)	3 (7.5)
Asthenia	4 (10.0)	3 (7.5)	1 (2.5)
Fatigue	4 (10.0)	4 (10.0)	0
Face oedema	3 (7.5)	2 (5.0)	1 (2.5)
Oedema peripheral	2 (5.0)	1 (2.5)	1 (2.5)
Pain	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Hepatic function abnormal	4 (10.0)	1 (2.5)	3 (7.5)
Immune system disorders			
-Total	31 (77.5)	8 (20.0)	23 (57.5)
Cytokine release syndrome	29 (72.5)	9 (22.5)	20 (50.0)
Hypogammaglobulinaemia	11 (27.5)	1 (2.5)	10 (25.0)
Seasonal allergy	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	18 (45.0)	6 (15.0)	12 (30.0)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	4 (10.0)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)
Gastroenteritis	5 (12.5)	4 (10.0)	1 (2.5)
Conjunctivitis	4 (10.0)	0	4 (10.0)
Sinusitis	3 (7.5)	0	3 (7.5)
Rhinovirus infection	2 (5.0)	0	2 (5.0)
Investigations			
-Total	18 (45.0)	4 (10.0)	14 (35.0)
Alanine aminotransferase increased	9 (22.5)	3 (7.5)	6 (15.0)
Platelet count decreased	8 (20.0)	5 (12.5)	3 (7.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Neutrophil count decreased	6 (15.0)	1 (2.5)	5 (12.5)
Serum ferritin increased	6 (15.0)	2 (5.0)	4 (10.0)
Aspartate aminotransferase increased	5 (12.5)	2 (5.0)	3 (7.5)
White blood cell count decreased	5 (12.5)	2 (5.0)	3 (7.5)
Blood bilirubin increased	3 (7.5)	0	3 (7.5)
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	17 (42.5)	6 (15.0)	11 (27.5)
Decreased appetite	8 (20.0)	5 (12.5)	3 (7.5)
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)
Hypokalaemia	4 (10.0)	2 (5.0)	2 (5.0)
Hypophosphataemia	4 (10.0)	1 (2.5)	3 (7.5)
Hypocalcaemia	3 (7.5)	1 (2.5)	2 (5.0)
Hyperuricaemia	2 (5.0)	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	19 (47.5)	10 (25.0)	9 (22.5)
Arthralgia	8 (20.0)	6 (15.0)	2 (5.0)
Pain in extremity	8 (20.0)	2 (5.0)	6 (15.0)
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)
Back pain	4 (10.0)	1 (2.5)	3 (7.5)
Nervous system disorders			
-Total	13 (32.5)	9 (22.5)	4 (10.0)
Headache	13 (32.5)	9 (22.5)	4 (10.0)
Psychiatric disorders			
-Total	8 (20.0)	5 (12.5)	3 (7.5)
Anxiety	6 (15.0)	3 (7.5)	3 (7.5)
Agitation	3 (7.5)	3 (7.5)	0
Confusional state	2 (5.0)	2 (5.0)	0
Renal and urinary disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Dysuria	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	24 (60.0)	17 (42.5)	7 (17.5)
Cough	15 (37.5)	13 (32.5)	2 (5.0)
Epistaxis	7 (17.5)	6 (15.0)	1 (2.5)
Oropharyngeal pain	5 (12.5)	5 (12.5)	0
Pleural effusion	5 (12.5)	2 (5.0)	3 (7.5)
Nasal congestion	4 (10.0)	4 (10.0)	0
Pulmonary oedema	1 (2.5)	1 (2.5)	0
Rhinorrhoea	1 (2.5)	1 (2.5)	0
Tachypnoea	1 (2.5)	0	1 (2.5)
Skin and subcutaneous tissue disorders			
-Total	11 (27.5)	8 (20.0)	3 (7.5)
Dry skin	4 (10.0)	4 (10.0)	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)
Rash	3 (7.5)	2 (5.0)	1 (2.5)
Erythema	2 (5.0)	1 (2.5)	1 (2.5)
Vascular disorders			

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 1 n (%)	 Grade 2 n (%)
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Hypertension	5 (12.5)	3 (7.5)	2 (5.0)
Hypotension	5 (12.5)	3 (7.5)	2 (5.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 265q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	40 (100)	0	40 (100)
Blood and lymphatic system disorders			
-Total	15 (37.5)	4 (10.0)	11 (27.5)
Anaemia	14 (35.0)	4 (10.0)	10 (25.0)
Disseminated intravascular coagulation	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	13 (32.5)	7 (17.5)	6 (15.0)
Tachycardia	13 (32.5)	7 (17.5)	6 (15.0)
Endocrine disorders			
-Total	4 (10.0)	0	4 (10.0)
Adrenal insufficiency	4 (10.0)	0	4 (10.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Gastrointestinal disorders			
-Total	37 (92.5)	15 (37.5)	22 (55.0)
Nausea	20 (50.0)	8 (20.0)	12 (30.0)
Vomiting	17 (42.5)	13 (32.5)	4 (10.0)
Diarrhoea	14 (35.0)	11 (27.5)	3 (7.5)
Constipation	12 (30.0)	6 (15.0)	6 (15.0)
Abdominal pain	9 (22.5)	5 (12.5)	4 (10.0)
Stomatitis	2 (5.0)	0	2 (5.0)
General disorders and administration site conditions			
-Total	32 (80.0)	17 (42.5)	15 (37.5)
Pyrexia	19 (47.5)	10 (25.0)	9 (22.5)
Fatigue	15 (37.5)	11 (27.5)	4 (10.0)
Oedema peripheral	5 (12.5)	5 (12.5)	0
Chills	4 (10.0)	3 (7.5)	1 (2.5)
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)
Pain	4 (10.0)	0	4 (10.0)
Hepatobiliary disorders			
-Total	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hepatic function abnormal	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	34 (85.0)	3 (7.5)	31 (77.5)
Cytokine release syndrome	28 (70.0)	4 (10.0)	24 (60.0)
Hypogammaglobulinaemia	17 (42.5)	1 (2.5)	16 (40.0)
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)
Infections and infestations			
-Total	16 (40.0)	3 (7.5)	13 (32.5)
Rhinovirus infection	6 (15.0)	0	6 (15.0)
Conjunctivitis	5 (12.5)	3 (7.5)	2 (5.0)
Upper respiratory tract infection	5 (12.5)	1 (2.5)	4 (10.0)
Sinusitis	4 (10.0)	0	4 (10.0)
Nasopharyngitis	1 (2.5)	1 (2.5)	0
Investigations			
-Total	24 (60.0)	3 (7.5)	21 (52.5)
Alanine aminotransferase increased	10 (25.0)	2 (5.0)	8 (20.0)
International normalised ratio increased	9 (22.5)	5 (12.5)	4 (10.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Aspartate aminotransferase increased	8 (20.0)	1 (2.5)	7 (17.5)
White blood cell count decreased	8 (20.0)	2 (5.0)	6 (15.0)
Platelet count decreased	7 (17.5)	3 (7.5)	4 (10.0)
Activated partial thromboplastin time prolonged	5 (12.5)	3 (7.5)	2 (5.0)
Blood fibrinogen decreased	5 (12.5)	3 (7.5)	2 (5.0)
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)
Blood immunoglobulin m decreased	5 (12.5)	4 (10.0)	1 (2.5)
Neutrophil count decreased	5 (12.5)	2 (5.0)	3 (7.5)
Blood bilirubin increased	4 (10.0)	2 (5.0)	2 (5.0)
Electrocardiogram qt prolonged	4 (10.0)	2 (5.0)	2 (5.0)
Serum ferritin increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	28 (70.0)	10 (25.0)	18 (45.0)
Decreased appetite	15 (37.5)	8 (20.0)	7 (17.5)
Hypokalaemia	10 (25.0)	2 (5.0)	8 (20.0)
Hypocalcaemia	9 (22.5)	1 (2.5)	8 (20.0)
Hypophosphataemia	8 (20.0)	3 (7.5)	5 (12.5)

Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)
Hyperphosphataemia	5 (12.5)	5 (12.5)	0
Hypoalbuminaemia	4 (10.0)	0	4 (10.0)
Hypomagnesaemia	4 (10.0)	3 (7.5)	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	20 (50.0)	9 (22.5)	11 (27.5)
Pain in extremity	12 (30.0)	7 (17.5)	5 (12.5)
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)
Arthralgia	4 (10.0)	0	4 (10.0)
Back pain	4 (10.0)	1 (2.5)	3 (7.5)
Nervous system disorders			
-Total	18 (45.0)	7 (17.5)	11 (27.5)
Headache	18 (45.0)	7 (17.5)	11 (27.5)
Psychiatric disorders			
-Total	15 (37.5)	6 (15.0)	9 (22.5)
Anxiety	7 (17.5)	1 (2.5)	6 (15.0)
Insomnia	6 (15.0)	2 (5.0)	4 (10.0)
Confusional state	5 (12.5)	5 (12.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Agitation	4 (10.0)	1 (2.5)	3 (7.5)
Renal and urinary disorders			
-Total	6 (15.0)	4 (10.0)	2 (5.0)
Dysuria	4 (10.0)	3 (7.5)	1 (2.5)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (50.0)	13 (32.5)	7 (17.5)
Cough	11 (27.5)	8 (20.0)	3 (7.5)
Nasal congestion	7 (17.5)	5 (12.5)	2 (5.0)
Oropharyngeal pain	5 (12.5)	3 (7.5)	2 (5.0)
Pulmonary oedema	5 (12.5)	2 (5.0)	3 (7.5)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)
Tachypnoea	4 (10.0)	4 (10.0)	0
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)
Pleural effusion	2 (5.0)	2 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	16 (40.0)	8 (20.0)	8 (20.0)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Pruritus	8 (20.0)	3 (7.5)	5 (12.5)
Rash	7 (17.5)	3 (7.5)	4 (10.0)
Dry skin	5 (12.5)	3 (7.5)	2 (5.0)
Erythema	4 (10.0)	4 (10.0)	0
Vascular disorders			
-Total	15 (37.5)	3 (7.5)	12 (30.0)
Hypertension	9 (22.5)	2 (5.0)	7 (17.5)
Hypotension	8 (20.0)	2 (5.0)	6 (15.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265q
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	3 (16.7)	0	3 (16.7)
Cardiac disorders			
-Total	1 (5.6)	0	1 (5.6)
Tachycardia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	2 (11.1)	0	2 (11.1)
Pyrexia	2 (11.1)	0	2 (11.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Pain	1 (5.6)	0	1 (5.6)
Investigations			
-Total	1 (5.6)	1 (5.6)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)
Hypocalcaemia	1 (5.6)	0	1 (5.6)
Renal and urinary disorders			
-Total	3 (16.7)	3 (16.7)	0
Acute kidney injury	3 (16.7)	3 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	0	1 (5.6)
Vascular disorders			

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
-Total	1 (5.6)	0	1 (5.6)
Hypertension	1 (5.6)	0	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	8 (100)	0	8 (100)
Blood and lymphatic system disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Anaemia	2 (25.0)	1 (12.5)	1 (12.5)
Lymphocytosis	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Tachycardia	3 (37.5)	1 (12.5)	2 (25.0)
Sinus tachycardia	1 (12.5)	1 (12.5)	0
Eye disorders			
-Total	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Eyelid oedema	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Abdominal pain	2 (25.0)	2 (25.0)	0
Nausea	2 (25.0)	2 (25.0)	0
Abdominal distension	1 (12.5)	0	1 (12.5)
Ascites	1 (12.5)	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)
Mouth haemorrhage	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Pyrexia	5 (62.5)	0	5 (62.5)
Fatigue	2 (25.0)	2 (25.0)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (12.5)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)
Face oedema	1 (12.5)	0	1 (12.5)
Generalised oedema	1 (12.5)	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)
Pain	1 (12.5)	0	1 (12.5)
Hepatobiliary disorders			
-Total	1 (12.5)	1 (12.5)	0
Cholelithiasis	1 (12.5)	1 (12.5)	0
Gallbladder enlargement	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Cytokine release syndrome	5 (62.5)	2 (25.0)	3 (37.5)
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)
Seasonal allergy	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	3 (37.5)	0	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Conjunctivitis	1 (12.5)	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0
Otitis externa	1 (12.5)	0	1 (12.5)
Rhinovirus infection	1 (12.5)	0	1 (12.5)
Sinusitis	1 (12.5)	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	3 (37.5)	0	3 (37.5)
Fibula fracture	1 (12.5)	0	1 (12.5)
Infusion related reaction	1 (12.5)	0	1 (12.5)
Procedural pain	1 (12.5)	0	1 (12.5)
Radius fracture	1 (12.5)	0	1 (12.5)
Skin injury	1 (12.5)	0	1 (12.5)
Skin wound	1 (12.5)	1 (12.5)	0
Wound	1 (12.5)	0	1 (12.5)
Investigations			

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)
Aspartate aminotransferase increased	2 (25.0)	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0
Blood bilirubin increased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)
International normalised ratio increased	1 (12.5)	1 (12.5)	0
Lipase increased	1 (12.5)	1 (12.5)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	1 (12.5)	0
Weight increased	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Metabolism and nutrition disorders			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)
Hypocalcaemia	3 (37.5)	0	3 (37.5)
Hyperuricaemia	2 (25.0)	2 (25.0)	0
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)
Acidosis	1 (12.5)	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0
Hyponatraemia	1 (12.5)	1 (12.5)	0
Hypophosphataemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Myalgia	1 (12.5)	1 (12.5)	0
Myositis	1 (12.5)	0	1 (12.5)
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	4 (50.0)	0	4 (50.0)
Headache	4 (50.0)	3 (37.5)	1 (12.5)
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)
Monoparesis	1 (12.5)	0	1 (12.5)
Neuropathy peripheral	1 (12.5)	0	1 (12.5)
Tremor	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Confusional state	1 (12.5)	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)
Sleep disorder	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Acute kidney injury	3 (37.5)	2 (25.0)	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Bladder dilatation	1 (12.5)	0	1 (12.5)
Dysuria	1 (12.5)	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Nasal congestion	2 (25.0)	2 (25.0)	0
Oropharyngeal pain	2 (25.0)	2 (25.0)	0
Atelectasis	1 (12.5)	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0
Skin and subcutaneous tissue disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Dry skin	2 (25.0)	2 (25.0)	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)
Decubitus ulcer	1 (12.5)	0	1 (12.5)
Erythema	1 (12.5)	1 (12.5)	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0
Ingrowing nail	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Petechiae	1 (12.5)	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)
Skin hypopigmentation	1 (12.5)	1 (12.5)	0
Skin ulcer	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	2 (25.0)	0
Hypotension	2 (25.0)	2 (25.0)	0
Hypertension	1 (12.5)	1 (12.5)	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	22 (73.3)	0	22 (73.3)
Blood and lymphatic system disorders			
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Anaemia	7 (23.3)	2 (6.7)	5 (16.7)
Splenomegaly	1 (3.3)	1 (3.3)	0
Cardiac disorders			
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Tachycardia	6 (20.0)	3 (10.0)	3 (10.0)
Endocrine disorders			
-Total	4 (13.3)	0	4 (13.3)
Adrenal insufficiency	3 (10.0)	0	3 (10.0)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypothyroidism	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	20 (66.7)	8 (26.7)	12 (40.0)
Vomiting	12 (40.0)	9 (30.0)	3 (10.0)
Nausea	9 (30.0)	3 (10.0)	6 (20.0)
Constipation	7 (23.3)	3 (10.0)	4 (13.3)
Diarrhoea	7 (23.3)	6 (20.0)	1 (3.3)
Abdominal pain	4 (13.3)	2 (6.7)	2 (6.7)
Haematemesis	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	15 (50.0)	7 (23.3)	8 (26.7)
Pyrexia	9 (30.0)	6 (20.0)	3 (10.0)
Fatigue	4 (13.3)	2 (6.7)	2 (6.7)
Oedema peripheral	4 (13.3)	4 (13.3)	0
Chills	3 (10.0)	2 (6.7)	1 (3.3)
Pain	3 (10.0)	0	3 (10.0)
Face oedema	2 (6.7)	2 (6.7)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Catheter site pain	1 (3.3)	0	1 (3.3)
Generalised oedema	1 (3.3)	0	1 (3.3)
Hepatobiliary disorders			
-Total	1 (3.3)	1 (3.3)	0
Gallbladder enlargement	1 (3.3)	1 (3.3)	0
Hypertransaminasaemia	1 (3.3)	1 (3.3)	0
Immune system disorders			
-Total	19 (63.3)	4 (13.3)	15 (50.0)
Cytokine release syndrome	15 (50.0)	4 (13.3)	11 (36.7)
Hypogammaglobulinaemia	9 (30.0)	1 (3.3)	8 (26.7)
Infections and infestations			
-Total	9 (30.0)	1 (3.3)	8 (26.7)
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)
Nasopharyngitis	2 (6.7)	1 (3.3)	1 (3.3)
Rhinovirus infection	2 (6.7)	0	2 (6.7)
Bronchitis	1 (3.3)	0	1 (3.3)
Gastroenteritis	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Otitis media	1 (3.3)	0	1 (3.3)
Staphylococcal infection	1 (3.3)	0	1 (3.3)
Investigations			
-Total	16 (53.3)	2 (6.7)	14 (46.7)
White blood cell count decreased	6 (20.0)	2 (6.7)	4 (13.3)
Alanine aminotransferase increased	5 (16.7)	1 (3.3)	4 (13.3)
Platelet count decreased	5 (16.7)	3 (10.0)	2 (6.7)
Blood fibrinogen decreased	4 (13.3)	2 (6.7)	2 (6.7)
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)
Aspartate aminotransferase increased	3 (10.0)	0	3 (10.0)
Blood bilirubin increased	3 (10.0)	1 (3.3)	2 (6.7)
Blood immunoglobulin a decreased	3 (10.0)	2 (6.7)	1 (3.3)
Blood immunoglobulin g decreased	3 (10.0)	1 (3.3)	2 (6.7)
International normalised ratio increased	3 (10.0)	1 (3.3)	2 (6.7)
Serum ferritin increased	3 (10.0)	1 (3.3)	2 (6.7)
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Electrocardiogram qt prolonged	2 (6.7)	1 (3.3)	1 (3.3)
Lymphocyte count decreased	2 (6.7)	0	2 (6.7)
Blood creatinine increased	1 (3.3)	0	1 (3.3)
C-reactive protein increased	1 (3.3)	1 (3.3)	0
Lipase increased	1 (3.3)	1 (3.3)	0
Weight increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	15 (50.0)	6 (20.0)	9 (30.0)
Decreased appetite	5 (16.7)	3 (10.0)	2 (6.7)
Hypocalcaemia	5 (16.7)	1 (3.3)	4 (13.3)
Hypokalaemia	4 (13.3)	1 (3.3)	3 (10.0)
Hyperphosphataemia	3 (10.0)	3 (10.0)	0
Hyperuricaemia	3 (10.0)	3 (10.0)	0
Hypoalbuminaemia	3 (10.0)	0	3 (10.0)
Hypomagnesaemia	3 (10.0)	2 (6.7)	1 (3.3)
Hypophosphataemia	3 (10.0)	1 (3.3)	2 (6.7)
Hyperglycaemia	2 (6.7)	0	2 (6.7)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	8 (26.7)	5 (16.7)	3 (10.0)
Pain in extremity	6 (20.0)	4 (13.3)	2 (6.7)
Arthralgia	1 (3.3)	0	1 (3.3)
Back pain	1 (3.3)	0	1 (3.3)
Myalgia	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	4 (13.3)	3 (10.0)	1 (3.3)
Headache	4 (13.3)	3 (10.0)	1 (3.3)
Psychiatric disorders			
-Total	6 (20.0)	2 (6.7)	4 (13.3)
Agitation	2 (6.7)	0	2 (6.7)
Anxiety	2 (6.7)	0	2 (6.7)
Confusional state	2 (6.7)	2 (6.7)	0
Delirium	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Acute kidney injury	1 (3.3)	1 (3.3)	0
Dysuria	1 (3.3)	1 (3.3)	0
Urinary retention	1 (3.3)	0	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (36.7)	8 (26.7)	3 (10.0)
Cough	7 (23.3)	7 (23.3)	0
Pulmonary oedema	4 (13.3)	2 (6.7)	2 (6.7)
Oropharyngeal pain	2 (6.7)	0	2 (6.7)
Tachypnoea	2 (6.7)	2 (6.7)	0
Epistaxis	1 (3.3)	0	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0
Rhinorrhoea	1 (3.3)	1 (3.3)	0
Skin and subcutaneous tissue disorders			
-Total	11 (36.7)	6 (20.0)	5 (16.7)
Pruritus	4 (13.3)	2 (6.7)	2 (6.7)
Dry skin	2 (6.7)	2 (6.7)	0
Erythema	2 (6.7)	1 (3.3)	1 (3.3)

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperhidrosis	1 (3.3)	0	1 (3.3)
Ingrowing nail	1 (3.3)	0	1 (3.3)
Petechiae	1 (3.3)	1 (3.3)	0
Rash	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	6 (20.0)	1 (3.3)	5 (16.7)
Hypertension	5 (16.7)	1 (3.3)	4 (13.3)
Hypotension	2 (6.7)	0	2 (6.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	17 (94.4)	1 (5.6)	16 (88.9)
Blood and lymphatic system disorders			
-Total	7 (38.9)	1 (5.6)	6 (33.3)
Anaemia	5 (27.8)	0	5 (27.8)
Neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Splenomegaly	2 (11.1)	2 (11.1)	0
Cardiac disorders			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Tachycardia	4 (22.2)	2 (11.1)	2 (11.1)
Sinus tachycardia	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	2 (11.1)	0	2 (11.1)
Hypothyroidism	2 (11.1)	0	2 (11.1)
Gastrointestinal disorders			
-Total	14 (77.8)	5 (27.8)	9 (50.0)
Diarrhoea	7 (38.9)	5 (27.8)	2 (11.1)
Nausea	7 (38.9)	4 (22.2)	3 (16.7)
Vomiting	5 (27.8)	4 (22.2)	1 (5.6)
Constipation	4 (22.2)	1 (5.6)	3 (16.7)
Abdominal pain	2 (11.1)	0	2 (11.1)
Haematemesis	2 (11.1)	2 (11.1)	0
Stomatitis	2 (11.1)	1 (5.6)	1 (5.6)
Gingival erythema	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	14 (77.8)	7 (38.9)	7 (38.9)
Pyrexia	8 (44.4)	4 (22.2)	4 (22.2)
Fatigue	7 (38.9)	5 (27.8)	2 (11.1)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Generalised oedema	2 (11.1)	2 (11.1)	0
Oedema peripheral	2 (11.1)	2 (11.1)	0
Catheter site pain	1 (5.6)	0	1 (5.6)
Face oedema	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypertransaminasaemia	2 (11.1)	1 (5.6)	1 (5.6)
Immune system disorders			
-Total	12 (66.7)	3 (16.7)	9 (50.0)
Cytokine release syndrome	11 (61.1)	3 (16.7)	8 (44.4)
Hypogammaglobulinaemia	5 (27.8)	1 (5.6)	4 (22.2)
Seasonal allergy	4 (22.2)	2 (11.1)	2 (11.1)
Infections and infestations			
-Total	8 (44.4)	1 (5.6)	7 (38.9)
Bronchitis	2 (11.1)	0	2 (11.1)
Nail infection	2 (11.1)	1 (5.6)	1 (5.6)
Oral herpes	2 (11.1)	0	2 (11.1)
Otitis media	2 (11.1)	0	2 (11.1)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory tract infection	2 (11.1)	1 (5.6)	1 (5.6)
Sinusitis	2 (11.1)	0	2 (11.1)
Staphylococcal infection	2 (11.1)	0	2 (11.1)
Upper respiratory tract infection	2 (11.1)	0	2 (11.1)
Conjunctivitis	1 (5.6)	1 (5.6)	0
Nasopharyngitis	1 (5.6)	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)
Injury, poisoning and procedural complications			
-Total	4 (22.2)	2 (11.1)	2 (11.1)
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)
Infusion related reaction	1 (5.6)	1 (5.6)	0
Wound	1 (5.6)	0	1 (5.6)
Investigations			
-Total	9 (50.0)	1 (5.6)	8 (44.4)
Alanine aminotransferase increased	5 (27.8)	2 (11.1)	3 (16.7)
Aspartate aminotransferase increased	4 (22.2)	1 (5.6)	3 (16.7)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
International normalised ratio increased	3 (16.7)	1 (5.6)	2 (11.1)
Activated partial thromboplastin time prolonged	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)
Platelet count decreased	2 (11.1)	0	2 (11.1)
Blood fibrinogen decreased	1 (5.6)	0	1 (5.6)
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0
Electrocardiogram qt prolonged	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Weight increased	1 (5.6)	0	1 (5.6)
White blood cell count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	7 (38.9)	2 (11.1)	5 (27.8)
Decreased appetite	5 (27.8)	2 (11.1)	3 (16.7)
Hypoalbuminaemia	3 (16.7)	0	3 (16.7)
Hypocalcaemia	3 (16.7)	0	3 (16.7)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Hypokalaemia	2 (11.1)	0	2 (11.1)
Hypophosphataemia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperphosphataemia	1 (5.6)	1 (5.6)	0
Hyperuricaemia	1 (5.6)	1 (5.6)	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0
Hyponatraemia	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	10 (55.6)	5 (27.8)	5 (27.8)
Arthralgia	5 (27.8)	3 (16.7)	2 (11.1)
Pain in extremity	4 (22.2)	2 (11.1)	2 (11.1)
Myalgia	2 (11.1)	0	2 (11.1)
Back pain	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Headache	8 (44.4)	2 (11.1)	6 (33.3)
Tremor	1 (5.6)	0	1 (5.6)
Psychiatric disorders			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	8 (44.4)	3 (16.7)	5 (27.8)
Anxiety	4 (22.2)	0	4 (22.2)
Confusional state	3 (16.7)	3 (16.7)	0
Delirium	3 (16.7)	1 (5.6)	2 (11.1)
Agitation	2 (11.1)	1 (5.6)	1 (5.6)
Renal and urinary disorders			
-Total	2 (11.1)	0	2 (11.1)
Acute kidney injury	2 (11.1)	0	2 (11.1)
Dysuria	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (44.4)	5 (27.8)	3 (16.7)
Cough	5 (27.8)	3 (16.7)	2 (11.1)
Nasal congestion	3 (16.7)	1 (5.6)	2 (11.1)
Rhinorrhoea	3 (16.7)	1 (5.6)	2 (11.1)
Oropharyngeal pain	2 (11.1)	2 (11.1)	0
Tachypnoea	2 (11.1)	2 (11.1)	0
Wheezing	2 (11.1)	0	2 (11.1)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Epistaxis	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Skin and subcutaneous tissue disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Dry skin	2 (11.1)	2 (11.1)	0
Pruritus	2 (11.1)	2 (11.1)	0
Erythema	1 (5.6)	1 (5.6)	0
Ingrowing nail	1 (5.6)	0	1 (5.6)
Petechiae	1 (5.6)	0	1 (5.6)
Rash	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	6 (33.3)	0	6 (33.3)
Hypertension	3 (16.7)	0	3 (16.7)
Hypotension	3 (16.7)	0	3 (16.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 265r
Non-severe adverse events (AE CTCAE Grade 1/2) that occurred in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term and maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Number of patients with at least one AE	37 (88.1)	3 (7.1)	34 (81.0)
Blood and lymphatic system disorders			
-Total	11 (26.2)	4 (9.5)	7 (16.7)
Anaemia	9 (21.4)	4 (9.5)	5 (11.9)
Neutropenia	1 (2.4)	0	1 (2.4)
Splenomegaly	1 (2.4)	0	1 (2.4)
Cardiac disorders			
-Total	5 (11.9)	2 (4.8)	3 (7.1)
Tachycardia	4 (9.5)	2 (4.8)	2 (4.8)
Sinus tachycardia	1 (2.4)	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Endocrine disorders			
-Total	3 (7.1)	0	3 (7.1)
Adrenal insufficiency	3 (7.1)	0	3 (7.1)
Eye disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Eyelid oedema	2 (4.8)	1 (2.4)	1 (2.4)
Gastrointestinal disorders			
-Total	28 (66.7)	12 (28.6)	16 (38.1)
Diarrhoea	12 (28.6)	6 (14.3)	6 (14.3)
Nausea	12 (28.6)	5 (11.9)	7 (16.7)
Vomiting	12 (28.6)	7 (16.7)	5 (11.9)
Abdominal pain	9 (21.4)	2 (4.8)	7 (16.7)
Constipation	7 (16.7)	4 (9.5)	3 (7.1)
Mouth haemorrhage	3 (7.1)	2 (4.8)	1 (2.4)
Stomatitis	3 (7.1)	0	3 (7.1)
Abdominal distension	2 (4.8)	1 (2.4)	1 (2.4)
Ascites	2 (4.8)	1 (2.4)	1 (2.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
General disorders and administration site conditions			
-Total	20 (47.6)	11 (26.2)	9 (21.4)
Pyrexia	16 (38.1)	10 (23.8)	6 (14.3)
Fatigue	6 (14.3)	6 (14.3)	0
Chills	5 (11.9)	3 (7.1)	2 (4.8)
Face oedema	3 (7.1)	2 (4.8)	1 (2.4)
Catheter site pain	2 (4.8)	1 (2.4)	1 (2.4)
Pain	2 (4.8)	1 (2.4)	1 (2.4)
Generalised oedema	1 (2.4)	0	1 (2.4)
Hepatobiliary disorders			
-Total	1 (2.4)	0	1 (2.4)
Cholelithiasis	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	28 (66.7)	3 (7.1)	25 (59.5)
Cytokine release syndrome	26 (61.9)	4 (9.5)	22 (52.4)
Hypogammaglobulinaemia	12 (28.6)	0	12 (28.6)
Infections and infestations			

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	20 (47.6)	5 (11.9)	15 (35.7)
Upper respiratory tract infection	6 (14.3)	3 (7.1)	3 (7.1)
Nasopharyngitis	5 (11.9)	3 (7.1)	2 (4.8)
Conjunctivitis	4 (9.5)	1 (2.4)	3 (7.1)
Rhinovirus infection	4 (9.5)	0	4 (9.5)
Sinusitis	4 (9.5)	0	4 (9.5)
Gastroenteritis	3 (7.1)	2 (4.8)	1 (2.4)
Oral herpes	3 (7.1)	1 (2.4)	2 (4.8)
Nail infection	2 (4.8)	2 (4.8)	0
Otitis externa	1 (2.4)	0	1 (2.4)
Otitis media	1 (2.4)	0	1 (2.4)
Respiratory tract infection	1 (2.4)	0	1 (2.4)
Injury, poisoning and procedural complications			
-Total	4 (9.5)	2 (4.8)	2 (4.8)
Infusion related reaction	3 (7.1)	1 (2.4)	2 (4.8)
Wound	1 (2.4)	1 (2.4)	0
Investigations			

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
-Total	18 (42.9)	4 (9.5)	14 (33.3)
Alanine aminotransferase increased	8 (19.0)	2 (4.8)	6 (14.3)
Neutrophil count decreased	7 (16.7)	1 (2.4)	6 (14.3)
Platelet count decreased	7 (16.7)	4 (9.5)	3 (7.1)
Aspartate aminotransferase increased	5 (11.9)	2 (4.8)	3 (7.1)
Lymphocyte count decreased	4 (9.5)	2 (4.8)	2 (4.8)
White blood cell count decreased	4 (9.5)	2 (4.8)	2 (4.8)
Blood bilirubin increased	3 (7.1)	1 (2.4)	2 (4.8)
International normalised ratio increased	3 (7.1)	3 (7.1)	0
Serum ferritin increased	3 (7.1)	0	3 (7.1)
Blood fibrinogen decreased	2 (4.8)	1 (2.4)	1 (2.4)
Blood immunoglobulin a decreased	2 (4.8)	2 (4.8)	0
C-reactive protein increased	2 (4.8)	1 (2.4)	1 (2.4)
Weight increased	2 (4.8)	1 (2.4)	1 (2.4)
Blood immunoglobulin m decreased	1 (2.4)	1 (2.4)	0
Metabolism and nutrition disorders			
-Total	18 (42.9)	6 (14.3)	12 (28.6)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Decreased appetite	10 (23.8)	6 (14.3)	4 (9.5)
Hypokalaemia	7 (16.7)	3 (7.1)	4 (9.5)
Hypophosphataemia	6 (14.3)	2 (4.8)	4 (9.5)
Hypomagnesaemia	4 (9.5)	3 (7.1)	1 (2.4)
Hyperuricaemia	3 (7.1)	2 (4.8)	1 (2.4)
Hypoalbuminaemia	3 (7.1)	0	3 (7.1)
Hypocalcaemia	2 (4.8)	1 (2.4)	1 (2.4)
Hyperglycaemia	1 (2.4)	0	1 (2.4)
Hypermagnesaemia	1 (2.4)	1 (2.4)	0
Hyperphosphataemia	1 (2.4)	1 (2.4)	0
Hyponatraemia	1 (2.4)	1 (2.4)	0
Musculoskeletal and connective tissue disorders			
-Total	19 (45.2)	7 (16.7)	12 (28.6)
Pain in extremity	9 (21.4)	2 (4.8)	7 (16.7)
Arthralgia	6 (14.3)	3 (7.1)	3 (7.1)
Back pain	6 (14.3)	2 (4.8)	4 (9.5)
Myalgia	6 (14.3)	4 (9.5)	2 (4.8)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Nervous system disorders			
-Total	19 (45.2)	11 (26.2)	8 (19.0)
Headache	15 (35.7)	8 (19.0)	7 (16.7)
Tremor	4 (9.5)	4 (9.5)	0
Somnolence	2 (4.8)	1 (2.4)	1 (2.4)
Neuropathy peripheral	1 (2.4)	1 (2.4)	0
Psychiatric disorders			
-Total	9 (21.4)	3 (7.1)	6 (14.3)
Anxiety	7 (16.7)	4 (9.5)	3 (7.1)
Agitation	3 (7.1)	3 (7.1)	0
Sleep disorder	2 (4.8)	0	2 (4.8)
Confusional state	1 (2.4)	1 (2.4)	0
Delirium	1 (2.4)	0	1 (2.4)
Renal and urinary disorders			
-Total	5 (11.9)	4 (9.5)	1 (2.4)
Acute kidney injury	3 (7.1)	2 (4.8)	1 (2.4)
Dysuria	2 (4.8)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	20 (47.6)	14 (33.3)	6 (14.3)
Cough	13 (31.0)	10 (23.8)	3 (7.1)
Epistaxis	8 (19.0)	7 (16.7)	1 (2.4)
Nasal congestion	5 (11.9)	5 (11.9)	0
Oropharyngeal pain	4 (9.5)	4 (9.5)	0
Rhinorrhoea	2 (4.8)	2 (4.8)	0
Tachypnoea	2 (4.8)	0	2 (4.8)
Atelectasis	1 (2.4)	0	1 (2.4)
Pulmonary oedema	1 (2.4)	1 (2.4)	0
Skin and subcutaneous tissue disorders			
-Total	14 (33.3)	5 (11.9)	9 (21.4)
Rash	6 (14.3)	3 (7.1)	3 (7.1)
Pruritus	4 (9.5)	1 (2.4)	3 (7.1)
Dry skin	3 (7.1)	1 (2.4)	2 (4.8)
Erythema	2 (4.8)	2 (4.8)	0
Skin ulcer	2 (4.8)	1 (2.4)	1 (2.4)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)
Hyperhidrosis	1 (2.4)	0	1 (2.4)
Ingrowing nail	1 (2.4)	0	1 (2.4)
Vascular disorders			
-Total	11 (26.2)	6 (14.3)	5 (11.9)
Hypertension	6 (14.3)	3 (7.1)	3 (7.1)
Hypotension	6 (14.3)	3 (7.1)	3 (7.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 266a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	Local assessment N=27	**IRC assessment N=27**
Events/Responders (%)	10/27 (37.0)	10/27 (37.0)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	7.49	7.49
Percentiles (95% CI) [1]		
25th	5.1 (2.5, 27.8)	5.1 (1.6, 27.8)
50th	27.8 (5.1, NE)	27.8 (5.1, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.1 (72.1, 98.0)	91.8 (71.1, 97.9)
Month 6	69.8 (46.7, 84.4)	69.4 (46.2, 84.2)
Month 9	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 12	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 15	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 18	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 21	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)

Age: <10 years	Local assessment N=27	IRC assessment N=27
Month 24	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 27	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 30	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 33	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 36	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 39	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 42	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)

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

Table 266a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	Local assessment N=29	**IRC assessment N=29**
Events/Responders (%)	11/29 (37.9)	11/29 (37.9)
Maximum follow-up (months)	60.5	59.6
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	8.3 (2.1, 46.8)	8.3 (2.1, 46.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	84.3 (63.4, 93.8)	84.3 (63.4, 93.8)
Month 9	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 12	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 15	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 18	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 21	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)

Age: >=10 years to <18 years

	Local assessment N=29	IRC assessment N=29
Month 24	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 27	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 30	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 33	62.7 (40.4, 78.7)	58.3 (36.1, 75.1)
Month 36	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 39	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 42	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)

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

Table 266a
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	Local assessment N=11	**IRC assessment N=11**
Events/Responders (%)	5/11 (45.5)	5/11 (45.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	17.77	17.77
Percentiles (95% CI) [1]		
25th	8.6 (8.6, 44.5)	8.8 (8.6, 44.5)
50th	44.5 (8.6, NE)	44.5 (8.6, NE)
75th	NE (17.8, NE)	NE (17.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 12	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 15	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 18	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)

Age: >=18

	Local assessment N=11	IRC assessment N=11
Month 21	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 24	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 27	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 30	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 33	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 36	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 39	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 42	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)

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

Table 266b
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	Local assessment N=38	**IRC assessment N=38**
Events/Responders (%)	16/38 (42.1)	16/38 (42.1)
Maximum follow-up (months)	60.5	59.5
Median follow-up (months)	8.82	8.82
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 22.7)	7.5 (4.0, 22.7)
50th	33.8 (8.3, NE)	32.9 (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.5, 98.6)	94.3 (79.0, 98.5)
Month 6	75.5 (56.9, 87.0)	75.3 (56.5, 86.8)
Month 9	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 12	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 15	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 18	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 21	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)

Gender: Male		
	Local assessment N=38	**IRC assessment N=38**
Month 24	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 27	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 30	53.3 (33.7, 69.5)	53.1 (33.5, 69.4)
Month 33	53.3 (33.7, 69.5)	49.0 (29.7, 65.8)
Month 36	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 39	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 42	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)

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

Table 266b
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female

	Local assessment N=29	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	11.40	11.40
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 44.5)	8.8 (2.1, 44.5)
50th	NE (8.6, NE)	NE (8.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	88.4 (68.1, 96.1)	88.4 (68.1, 96.1)
Month 9	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 12	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 15	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 18	66.4 (43.6, 81.8)	66.4 (43.6, 81.8)
Month 21	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)

Gender: Female		
	Local assessment N=29	**IRC assessment N=29**
Month 24	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 27	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 30	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 33	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 36	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 39	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 42	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)

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

Table 266c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	Local assessment N=51	**IRC assessment N=51**
Events/Responders (%)	16/51 (31.4)	16/51 (31.4)
Maximum follow-up (months)	60.5	59.8
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 33.8)	8.0 (4.6, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (84.3, 98.9)	95.8 (84.2, 98.9)
Month 6	81.5 (66.2, 90.3)	81.4 (66.0, 90.2)
Month 9	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 12	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 15	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 18	67.8 (50.8, 80.1)	67.7 (50.6, 80.0)
Month 21	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)

Race: White

	Local assessment N=51	IRC assessment N=51
Month 24	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 27	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 30	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 33	64.6 (47.2, 77.5)	61.3 (43.6, 74.9)
Month 36	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 39	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 42	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)

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

Table 266c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	Local assessment N=6	**IRC assessment N=6**
Events/Responders (%)	4/6 (66.7)	4/6 (66.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	18.33	18.33
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Race: Asian

	Local assessment N=6	IRC assessment N=6
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)

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

Table 266c
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	Local assessment N=10	**IRC assessment N=10**
Events/Responders (%)	6/10 (60.0)	6/10 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	9.86	9.95
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 27.8)	8.6 (2.1, 27.8)
50th	18.2 (2.1, NE)	18.3 (2.1, NE)
75th	NE (8.6, NE)	NE (8.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	80.0 (40.9, 94.6)	80.0 (40.9, 94.6)
Month 9	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 12	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 15	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 18	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)

Race: Other	Local assessment N=10	IRC assessment N=10
Month 21	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 24	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 27	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 30	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 33	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 36	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 39	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 42	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)

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

Table 266d
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino	**Local assessment N=13**	**IRC assessment N=13**
Events/Responders (%)	7/13 (53.8)	7/13 (53.8)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	8.61	8.64
Percentiles (95% CI) [1]		
25th	7.6 (2.1, 8.6)	7.6 (2.1, 8.6)
50th	8.6 (5.1, NE)	8.8 (5.1, NE)
75th	NE (8.6, NE)	NE (8.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.3 (56.6, 98.9)	92.3 (56.6, 98.9)
Month 6	76.2 (42.7, 91.7)	76.2 (42.7, 91.7)
Month 9	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 12	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 15	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 18	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 21	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)

Ethnicity: Hispanic or Latino		
	Local assessment N=13	**IRC assessment N=13**
Month 24	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 27	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 30	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 33	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 36	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 39	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 42	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)

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

Table 266d
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	Local assessment N=54	**IRC assessment N=54**
Events/Responders (%)	19/54 (35.2)	19/54 (35.2)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	11.24	11.24
Percentiles (95% CI) [1]		
25th	14.0 (4.6, 27.8)	14.0 (4.6, 27.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.0 (82.6, 98.0)	94.0 (82.4, 98.0)
Month 6	82.7 (68.3, 91.0)	82.6 (68.1, 90.9)
Month 9	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 12	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 15	72.6 (56.5, 83.5)	72.5 (56.4, 83.4)
Month 18	69.6 (53.0, 81.3)	69.4 (52.9, 81.2)
Month 21	66.5 (49.6, 78.9)	66.4 (49.5, 78.8)

Ethnicity: Other

	Local assessment N=54	IRC assessment N=54
Month 24	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 27	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 30	60.5 (43.2, 74.0)	60.4 (43.1, 73.9)
Month 33	60.5 (43.2, 74.0)	57.4 (40.1, 71.3)
Month 36	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 39	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 42	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)

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

Table 266e
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Response status at study entry: Primary refractory		
	Local assessment N=5	**IRC assessment N=5**
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

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

Table 266e
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease	**Local assessment N=62**	**IRC assessment N=62**
Events/Responders (%)	25/62 (40.3)	25/62 (40.3)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 20.0)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.3 (83.1, 97.4)	93.2 (82.9, 97.4)
Month 6	80.2 (66.9, 88.5)	80.0 (66.8, 88.4)
Month 9	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 12	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 15	65.8 (51.2, 77.0)	65.7 (51.1, 77.0)
Month 18	63.4 (48.5, 75.0)	63.3 (48.4, 75.0)
Month 21	60.9 (45.9, 73.0)	60.9 (45.8, 72.9)

Response status at study entry: Relapsed disease

	Local assessment N=62	IRC assessment N=62
Month 24	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 27	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 30	56.1 (40.9, 68.8)	56.0 (40.8, 68.7)
Month 33	56.1 (40.9, 68.8)	53.6 (38.4, 66.6)
Month 36	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 39	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 42	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)

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

Table 266f
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	Local assessment N=2	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	60.5	59.1
Median follow-up (months)	59.83	58.61
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive

	Local assessment N=2	IRC assessment N=2
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)

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

Table 266f
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Non-Positive

	Local assessment N=65	**IRC assessment N=65**
Events/Responders (%)	26/65 (40.0)	26/65 (40.0)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.5 (83.5, 97.5)	93.4 (83.4, 97.5)
Month 6	80.6 (67.6, 88.8)	80.5 (67.4, 88.7)
Month 9	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 12	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 15	64.6 (50.0, 75.9)	64.5 (49.9, 75.8)
Month 18	62.2 (47.4, 73.9)	62.1 (47.3, 73.8)
Month 21	59.8 (44.9, 71.8)	59.7 (44.8, 71.8)

Philadelphia chromosome/BCR-ABL: Non-Positive		
	Local assessment N=65	**IRC assessment N=65**
Month 24	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 27	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 30	55.0 (40.0, 67.7)	54.9 (39.9, 67.6)
Month 33	55.0 (40.0, 67.7)	52.5 (37.6, 65.5)
Month 36	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 39	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 42	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)

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

Table 266g
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	Local assessment N=1	IRC assessment N=1
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	4.9	4.9
Median follow-up (months)	4.86	4.86
Percentiles (95% CI) [1]		
25th	4.9 (NE, NE)	4.9 (NE, NE)
50th	4.9 (NE, NE)	4.9 (NE, NE)
75th	4.9 (NE, NE)	4.9 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	NE	NE
Month 9	NE	NE
Month 12	NE	NE
Month 15	NE	NE
Month 18	NE	NE
Month 21	NE	NE

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE

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

Table 266g
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	Local assessment N=66	**IRC assessment N=66**
Events/Responders (%)	25/66 (37.9)	25/66 (37.9)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.6 (4.6, 20.0)	8.6 (4.6, 20.0)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	82.8 (70.2, 90.4)	82.7 (70.1, 90.3)
Month 9	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 12	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 15	67.1 (52.8, 77.9)	67.0 (52.7, 77.9)
Month 18	64.8 (50.2, 76.0)	64.7 (50.1, 76.0)
Month 21	62.5 (47.8, 74.1)	62.4 (47.7, 74.0)

Mixed-lineage leukemia rearrangement: No

	Local assessment N=66	IRC assessment N=66
Month 24	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 27	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 30	57.8 (42.9, 70.1)	57.8 (42.9, 70.1)
Month 33	57.8 (42.9, 70.1)	55.5 (40.5, 68.0)
Month 36	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 39	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 42	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)

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

Table 266h
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	Local assessment N=1	**IRC assessment N=1**
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	59.0	59.0
Median follow-up (months)	58.97	58.97
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Hypodiploidy: Yes

	Local assessment N=1	IRC assessment N=1
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)

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

Table 266h
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No	**Local assessment N=66**	**IRC assessment N=66**
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 17.8)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	80.9 (68.1, 89.0)	80.8 (68.0, 88.9)
Month 9	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 12	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 15	65.2 (50.8, 76.3)	65.1 (50.8, 76.3)
Month 18	62.9 (48.3, 74.4)	62.8 (48.2, 74.3)
Month 21	60.6 (45.8, 72.4)	60.5 (45.8, 72.4)

Hypodiploidy: No

	Local assessment N=66	IRC assessment N=66
Month 24	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 27	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 30	55.9 (41.1, 68.4)	55.8 (41.0, 68.3)
Month 33	55.9 (41.1, 68.4)	53.5 (38.7, 66.3)
Month 36	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 39	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 42	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)

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

Table 266i
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	Local assessment N=1	IRC assessment N=1
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	1.6	1.5
Median follow-up (months)	1.58	1.54
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	NE	NE
Month 6	NE	NE
Month 9	NE	NE
Month 12	NE	NE
Month 15	NE	NE
Month 18	NE	NE
Month 21	NE	NE

BCR-ABL1-like: Yes

	Local assessment N=1	IRC assessment N=1
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE

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

Table 266i
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	Local assessment N=66	IRC assessment N=66
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.9, 17.8)	8.3 (4.9, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.9, 97.6)	93.6 (83.9, 97.6)
Month 6	81.2 (68.6, 89.2)	81.1 (68.5, 89.1)
Month 9	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 12	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 15	65.8 (51.6, 76.8)	65.8 (51.6, 76.7)
Month 18	63.6 (49.2, 74.9)	63.5 (49.1, 74.9)
Month 21	61.3 (46.7, 73.0)	61.2 (46.7, 72.9)

BCR-ABL1-like: No

	Local assessment N=66	IRC assessment N=66
Month 24	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 27	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 30	56.8 (42.1, 69.1)	56.7 (42.0, 69.0)
Month 33	56.8 (42.1, 69.1)	54.4 (39.7, 67.0)
Month 36	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 39	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 42	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)

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

Table 266j
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

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

	Local assessment N=22	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.44	8.44
Percentiles (95% CI) [1]		
25th	8.3 (2.5, 22.7)	8.3 (2.5, 22.7)
50th	22.7 (8.0, NE)	22.7 (8.0, NE)
75th	NE (22.7, NE)	NE (22.7, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (70.7, 99.3)	95.2 (70.7, 99.3)
Month 6	82.9 (55.4, 94.2)	82.9 (55.4, 94.2)
Month 9	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 12	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 15	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 18	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)
Month 21	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)

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

	Local assessment N=22	IRC assessment N=22
Month 24	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 27	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 30	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 33	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 36	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 39	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 42	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)

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

Table 266j
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

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

	Local assessment N=45	IRC assessment N=45
Events/Responders (%)	17/45 (37.8)	17/45 (37.8)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	13.96	13.96
Percentiles (95% CI) [1]		
25th	7.6 (4.0, 27.8)	7.6 (4.0, 27.8)
50th	NE (14.0, NE)	NE (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (79.6, 97.7)	92.9 (79.5, 97.6)
Month 6	80.2 (64.2, 89.6)	80.0 (63.9, 89.5)
Month 9	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 12	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 15	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 18	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 21	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)

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

	Local assessment N=45	IRC assessment N=45
Month 24	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 27	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 30	60.5 (43.0, 74.2)	60.4 (42.8, 74.1)
Month 33	60.5 (43.0, 74.2)	57.4 (39.8, 71.5)
Month 36	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 39	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 42	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)

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

Table 266k
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Europe

	Local assessment N=26	**IRC assessment N=26**
Events/Responders (%)	9/26 (34.6)	9/26 (34.6)
Maximum follow-up (months)	60.5	59.8
Median follow-up (months)	14.59	14.59
Percentiles (95% CI) [1]		
25th	17.8 (2.1, 46.8)	17.8 (2.1, 46.8)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (73.9, 99.4)	95.8 (73.9, 99.4)
Month 6	87.1 (65.0, 95.7)	87.1 (65.0, 95.7)
Month 9	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 12	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 15	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 18	71.5 (46.6, 86.2)	71.5 (46.6, 86.2)
Month 21	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)

Region: Europe

	Local assessment N=26	IRC assessment N=26
Month 24	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 27	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 30	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 33	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 36	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 39	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 42	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)

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

Table 266k
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	Local assessment N=36	**IRC assessment N=36**
Events/Responders (%)	13/36 (36.1)	13/36 (36.1)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	8.15	8.15
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 8.6)	7.5 (4.0, 8.6)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (78.7, 98.5)	94.2 (78.7, 98.5)
Month 6	77.0 (57.6, 88.4)	76.9 (57.4, 88.3)
Month 9	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 12	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 15	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 18	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 21	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)

Region: US

	Local assessment N=36	IRC assessment N=36
Month 24	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 27	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 30	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 33	58.7 (38.6, 74.2)	54.1 (33.9, 70.5)
Month 36	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 39	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 42	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)

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

Table 266k
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Rest of World

	Local assessment N=5	**IRC assessment N=5**
Events/Responders (%)	4/5 (80.0)	4/5 (80.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Region: Rest of World		
	Local assessment N=5	**IRC assessment N=5**
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)

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

Table 266l
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	Local assessment N=42	**IRC assessment N=42**
Events/Responders (%)	15/42 (35.7)	15/42 (35.7)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	15.87	15.87
Percentiles (95% CI) [1]		
25th	14.0 (4.9, 33.8)	14.0 (4.9, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.1, 98.8)
Month 6	81.9 (65.7, 91.0)	81.8 (65.5, 90.9)
Month 9	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 12	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 15	72.8 (55.0, 84.5)	72.7 (54.9, 84.4)
Month 18	69.3 (51.1, 81.9)	69.2 (51.0, 81.8)
Month 21	65.9 (47.3, 79.2)	65.8 (47.2, 79.2)

Prior SCT therapy: Yes

	Local assessment N=42	IRC assessment N=42
Month 24	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 27	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 30	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 33	62.4 (43.7, 76.5)	58.8 (40.1, 73.5)
Month 36	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 39	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 42	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)

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

Table 266l
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	11/25 (44.0)	11/25 (44.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	7.5 (1.6, 8.6)
50th	27.8 (7.5, NE)	27.8 (7.5, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.1, 97.6)	90.7 (67.6, 97.6)
Month 6	80.5 (55.7, 92.2)	80.3 (55.5, 92.1)
Month 9	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 12	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 15	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 18	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 21	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)

Prior SCT therapy: No		
	Local assessment N=25	**IRC assessment N=25**
Month 24	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 27	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 30	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 33	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 36	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 39	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 42	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)

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

Table 266m
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Events/Responders (%)	5/12 (41.7)	5/12 (41.7)
Maximum follow-up (months)	59.3	59.3
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	14.0 (1.6, 44.5)	14.0 (1.6, 44.5)
50th	22.7 (4.9, NE)	22.7 (4.9, NE)
75th	44.5 (14.0, NE)	44.5 (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 9	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 12	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 15	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 18	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 21	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 27	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 30	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 33	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 36	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 39	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 42	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)

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

Table 266m
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	Local assessment N=55	**IRC assessment N=55**
Events/Responders (%)	21/55 (38.2)	21/55 (38.2)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 20.0)	8.0 (4.6, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (83.1, 98.1)	94.2 (83.1, 98.1)
Month 6	81.5 (67.4, 89.9)	81.5 (67.4, 89.9)
Month 9	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 12	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 15	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 18	63.1 (47.3, 75.3)	63.1 (47.3, 75.3)
Month 21	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)

Eligibility for SCT: No

	Local assessment N=55	IRC assessment N=55
Month 24	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 27	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 30	57.8 (41.8, 70.9)	57.8 (41.8, 70.9)
Month 33	57.8 (41.8, 70.9)	55.2 (39.2, 68.6)
Month 36	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 39	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 42	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)

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

Table 266n
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low	**Local assessment N=25**	**IRC assessment N=25**
Events/Responders (%)	10/25 (40.0)	10/25 (40.0)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	16.62	16.62
Percentiles (95% CI) [1]		
25th	8.3 (1.6, 27.8)	8.3 (1.6, 27.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (70.6, 97.8)	91.7 (70.6, 97.8)
Month 6	82.7 (60.2, 93.2)	82.7 (60.2, 93.2)
Month 9	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 12	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 15	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 18	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 21	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)

Baseline bone marrow tumor burden: Low		
	Local assessment N=25	**IRC assessment N=25**
Month 24	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 27	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 30	56.7 (32.6, 75.0)	56.7 (32.6, 75.0)
Month 33	56.7 (32.6, 75.0)	51.0 (27.5, 70.4)
Month 36	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 39	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 42	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)

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

Table 266n
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	16/42 (38.1)	16/42 (38.1)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.85	8.95
Percentiles (95% CI) [1]		
25th	8.0 (4.2, 22.7)	8.0 (4.2, 22.7)
50th	46.8 (8.6, NE)	46.8 (8.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.9 (81.0, 98.7)	94.8 (80.8, 98.7)
Month 6	80.3 (62.9, 90.1)	80.1 (62.7, 90.0)
Month 9	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 12	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 15	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 18	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)
Month 21	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)

Baseline bone marrow tumor burden: High

	Local assessment N=42	IRC assessment N=42
Month 24	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 27	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 30	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 33	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 36	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 39	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 42	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)

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

Table 266o
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes	**Local assessment N=11**	**IRC assessment N=11**
Events/Responders (%)	3/11 (27.3)	3/11 (27.3)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	33.81	32.89
Percentiles (95% CI) [1]		
25th	33.8 (2.1, NE)	32.9 (2.1, NE)
50th	NE (2.1, NE)	NE (2.1, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 9	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 12	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 15	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 18	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 21	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)

Baseline extramedullary disease presence: Yes

	Local assessment N=11	IRC assessment N=11
Month 24	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 27	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 30	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 33	78.8 (38.1, 94.3)	65.6 (26.0, 87.6)
Month 36	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 39	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 42	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)

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

Table 266o
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No	**Local assessment N=56**	**IRC assessment N=56**
Events/Responders (%)	23/56 (41.1)	23/56 (41.1)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	44.5 (14.0, NE)	44.5 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.3 (83.5, 98.1)	94.3 (83.3, 98.1)
Month 6	81.6 (67.6, 90.0)	81.5 (67.4, 89.9)
Month 9	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 12	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 15	63.5 (47.8, 75.6)	63.4 (47.8, 75.6)
Month 18	60.8 (44.9, 73.4)	60.7 (44.8, 73.3)
Month 21	58.0 (42.0, 71.0)	57.9 (41.9, 71.0)

Baseline extramedullary disease presence: No

	Local assessment N=56	IRC assessment N=56
Month 24	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 27	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 30	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 33	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 36	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 39	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 42	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)

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

Table 266p
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	3/5 (60.0)	3/5 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	7.5 (4.6, NE)	7.5 (4.6, NE)
50th	22.7 (4.6, NE)	22.7 (4.6, NE)
75th	NE (4.6, NE)	NE (4.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 12	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Down syndrome: Yes

	Local assessment N=5	IRC assessment N=5
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)

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

Table 266p
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	Local assessment N=62	**IRC assessment N=62**
Events/Responders (%)	23/62 (37.1)	23/62 (37.1)
Maximum follow-up (months)	60.5	60.2
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.6 (4.9, 20.0)	8.6 (4.9, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (82.7, 97.4)	93.1 (82.6, 97.3)
Month 6	81.4 (68.1, 89.6)	81.3 (67.9, 89.5)
Month 9	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 12	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 15	66.4 (51.4, 77.8)	66.3 (51.3, 77.7)
Month 18	63.9 (48.6, 75.7)	63.8 (48.5, 75.6)
Month 21	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)

Down syndrome: No		
	Local assessment N=62	**IRC assessment N=62**
Month 24	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 27	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 30	58.8 (43.2, 71.4)	58.7 (43.1, 71.3)
Month 33	58.8 (43.2, 71.4)	56.1 (40.5, 69.1)
Month 36	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 39	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 42	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)

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

Table 266q
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	Local assessment N=34	**IRC assessment N=34**
Events/Responders (%)	14/34 (41.2)	14/34 (41.2)
Maximum follow-up (months)	60.5	59.8
Median follow-up (months)	18.91	18.91
Percentiles (95% CI) [1]		
25th	8.6 (3.4, 22.7)	8.8 (3.4, 22.7)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.8 (77.3, 98.4)	93.8 (77.3, 98.4)
Month 6	84.2 (66.0, 93.1)	84.2 (66.0, 93.1)
Month 9	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 12	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 15	70.2 (50.3, 83.3)	70.2 (50.3, 83.3)
Month 18	66.3 (46.1, 80.4)	66.3 (46.1, 80.4)
Month 21	62.4 (42.1, 77.3)	62.4 (42.1, 77.3)

Time since enrollment to CTL019 infusion: > Median

	Local assessment N=34	IRC assessment N=34
Month 24	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 27	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 30	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 33	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 36	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 39	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 42	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)

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

Table 266q
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	Local assessment N=33	**IRC assessment N=33**
Events/Responders (%)	12/33 (36.4)	12/33 (36.4)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	7.98	7.98
Percentiles (95% CI) [1]		
25th	7.5 (4.2, 33.8)	7.5 (4.2, 32.9)
50th	46.8 (8.0, NE)	46.8 (8.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (76.9, 98.4)	93.6 (76.9, 98.4)
Month 6	77.1 (55.6, 89.1)	77.1 (55.6, 89.1)
Month 9	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 12	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 15	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 18	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 21	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)

Time since enrollment to CTL019 infusion: <=Median

	Local assessment N=33	IRC assessment N=33
Month 24	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 27	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 30	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 33	60.0 (38.1, 76.3)	54.5 (32.4, 72.1)
Month 36	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 39	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 42	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)

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

Table 266r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0

	Local assessment N=5	IRC assessment N=5
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Number of previous relapses: 0

	Local assessment N=5	IRC assessment N=5
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

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

Table 266r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	Local assessment N=18	**IRC assessment N=18**
Events/Responders (%)	9/18 (50.0)	9/18 (50.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.90	7.90
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	4.9 (1.6, 8.6)
50th	14.0 (4.9, NE)	14.0 (4.9, NE)
75th	NE (14.0, NE)	NE (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	88.2 (60.6, 96.9)	88.2 (60.6, 96.9)
Month 6	75.1 (46.3, 89.9)	74.7 (45.5, 89.7)
Month 9	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 12	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 15	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 18	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 21	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)

Number of previous relapses: 1		
	Local assessment N=18	**IRC assessment N=18**
Month 24	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 27	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 30	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 33	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 36	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 39	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 42	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)

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

Table 266r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	Local assessment N=14	**IRC assessment N=14**
Events/Responders (%)	5/14 (35.7)	5/14 (35.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	9.82	9.82
Percentiles (95% CI) [1]		
25th	5.1 (4.2, NE)	5.1 (4.2, NE)
50th	NE (5.1, NE)	NE (5.1, NE)
75th	NE (44.5, NE)	NE (44.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 24	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 27	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 30	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 33	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 36	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 39	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 42	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

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

Table 266r
Relapse free survival (RFS) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	Local assessment N=30	**IRC assessment N=30**
Events/Responders (%)	11/30 (36.7)	11/30 (36.7)
Maximum follow-up (months)	60.5	59.8
Median follow-up (months)	21.37	21.37
Percentiles (95% CI) [1]		
25th	17.8 (4.0, 46.8)	17.8 (4.0, 46.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	85.7 (66.1, 94.4)	85.7 (66.1, 94.4)
Month 9	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 12	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 15	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 18	73.3 (51.7, 86.4)	73.3 (51.7, 86.4)

Number of previous relapses: >=3		
	Local assessment N=30	**IRC assessment N=30**
Month 21	68.7 (46.7, 83.1)	68.7 (46.7, 83.1)
Month 24	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 27	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 30	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 33	64.1 (41.9, 79.7)	59.5 (37.4, 76.1)
Month 36	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 39	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 42	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)

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

Table 304a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: <10 years	**Local assessment N=27**	**IRC assessment N=27**
Events/Responders (%)	10/27 (37.0)	10/27 (37.0)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	7.49	7.49
Percentiles (95% CI) [1]		
25th	5.1 (2.5, 27.8)	5.1 (1.6, 27.8)
50th	27.8 (5.1, NE)	27.8 (5.1, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.1 (72.1, 98.0)	91.8 (71.1, 97.9)
Month 6	69.8 (46.7, 84.4)	69.4 (46.2, 84.2)
Month 9	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 12	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 15	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 18	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 21	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)

Age: <10 years		
	Local assessment N=27	**IRC assessment N=27**
Month 24	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 27	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 30	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 33	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 36	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 39	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 42	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 45	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 48	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 51	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 54	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 57	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=10 years to <18 years	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	11/29 (37.9)	11/29 (37.9)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	8.3 (2.1, 46.8)	8.3 (2.1, 46.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	84.3 (63.4, 93.8)	84.3 (63.4, 93.8)
Month 9	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 12	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 15	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 18	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 21	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)

Age: >=10 years to <18 years

	Local assessment N=29	IRC assessment N=29
Month 24	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 27	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 30	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 33	62.7 (40.4, 78.7)	58.3 (36.1, 75.1)
Month 36	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 39	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 42	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 45	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 48	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 51	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 54	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 57	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 60	53.4 (31.5, 71.1)	NE
Month 63	NE	NE

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

Table 304a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=18	**Local assessment N=11**	**IRC assessment N=11**
Events/Responders (%)	5/11 (45.5)	5/11 (45.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	17.77	17.77
Percentiles (95% CI) [1]		
25th	8.6 (8.6, 44.5)	8.8 (8.6, 44.5)
50th	44.5 (8.6, NE)	44.5 (8.6, NE)
75th	NE (17.8, NE)	NE (17.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 12	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 15	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 18	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 21	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)

Age: >=18		
	Local assessment N=11	**IRC assessment N=11**
Month 24	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 27	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 30	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 33	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 36	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 39	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 42	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 45	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 48	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 51	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 54	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 57	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 60	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 63	NE	NE

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

Table 304b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Male	**Local assessment N=38**	**IRC assessment N=38**
Events/Responders (%)	16/38 (42.1)	16/38 (42.1)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	8.82	8.82
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 22.7)	7.5 (4.0, 22.7)
50th	33.8 (8.3, NE)	32.9 (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.5, 98.6)	94.3 (79.0, 98.5)
Month 6	75.5 (56.9, 87.0)	75.3 (56.5, 86.8)
Month 9	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 12	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 15	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 18	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 21	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)

Gender: Male

	Local assessment N=38	IRC assessment N=38
Month 24	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 27	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 30	53.3 (33.7, 69.5)	53.1 (33.5, 69.4)
Month 33	53.3 (33.7, 69.5)	49.0 (29.7, 65.8)
Month 36	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 39	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 42	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 45	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 48	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 51	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 54	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 57	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 60	44.8 (25.7, 62.2)	NE
Month 63	NE	NE

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

Table 304b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Female	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	11.40	11.40
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 44.5)	8.8 (2.1, 44.5)
50th	NE (8.6, NE)	NE (8.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	88.4 (68.1, 96.1)	88.4 (68.1, 96.1)
Month 9	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 12	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 15	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 18	66.4 (43.6, 81.8)	66.4 (43.6, 81.8)
Month 21	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)

Gender: Female		
	Local assessment N=29	**IRC assessment N=29**
Month 24	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 27	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 30	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 33	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 36	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 39	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 42	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 45	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 48	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 51	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 54	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 57	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 60	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 63	NE	NE

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

Table 304c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: White	**Local assessment N=51**	**IRC assessment N=51**
Events/Responders (%)	16/51 (31.4)	16/51 (31.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 33.8)	8.0 (4.6, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (84.3, 98.9)	95.8 (84.2, 98.9)
Month 6	81.5 (66.2, 90.3)	81.4 (66.0, 90.2)
Month 9	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 12	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 15	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 18	67.8 (50.8, 80.1)	67.7 (50.6, 80.0)
Month 21	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)

Race: White

	Local assessment N=51	IRC assessment N=51
Month 24	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 27	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 30	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 33	64.6 (47.2, 77.5)	61.3 (43.6, 74.9)
Month 36	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 39	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 42	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 45	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 48	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 51	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 54	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 57	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 60	57.9 (40.2, 72.2)	NE
Month 63	NE	NE

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

Table 304c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Asian

	Local assessment N=6	IRC assessment N=6
Events/Responders (%)	4/6 (66.7)	4/6 (66.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	18.33	18.33
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Race: Asian

	Local assessment N=6	IRC assessment N=6
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 48	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 51	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 54	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 57	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 60	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 63	NE	NE

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

Table 304c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Other	**Local assessment N=10**	**IRC assessment N=10**
Events/Responders (%)	6/10 (60.0)	6/10 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	9.95	9.95
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 27.8)	8.6 (2.1, 27.8)
50th	18.2 (2.1, NE)	18.3 (2.1, NE)
75th	NE (8.6, NE)	NE (8.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	80.0 (40.9, 94.6)	80.0 (40.9, 94.6)
Month 9	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 12	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 15	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 18	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 21	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)

Race: Other

	Local assessment N=10	IRC assessment N=10
Month 24	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 27	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 30	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 33	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 36	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 39	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 42	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 45	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 48	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 51	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 54	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 57	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino	**Local assessment N=13**	**IRC assessment N=13**
Events/Responders (%)	7/13 (53.8)	7/13 (53.8)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	8.62	8.62
Percentiles (95% CI) [1]		
25th	7.6 (2.1, 8.6)	7.6 (2.1, 8.6)
50th	8.6 (5.1, NE)	8.8 (5.1, NE)
75th	NE (8.6, NE)	NE (8.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.3 (56.6, 98.9)	92.3 (56.6, 98.9)
Month 6	76.2 (42.7, 91.7)	76.2 (42.7, 91.7)
Month 9	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 12	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 15	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 18	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 21	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)

Ethnicity: Hispanic or Latino		
	Local assessment N=13	**IRC assessment N=13**
Month 24	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 27	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 30	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 33	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 36	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 39	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 42	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 45	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 48	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 51	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 54	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 57	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Other	**Local assessment N=54**	**IRC assessment N=54**
Events/Responders (%)	19/54 (35.2)	19/54 (35.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	11.24	11.24
Percentiles (95% CI) [1]		
25th	14.0 (4.6, 27.8)	14.0 (4.6, 27.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.0 (82.6, 98.0)	94.0 (82.4, 98.0)
Month 6	82.7 (68.3, 91.0)	82.6 (68.1, 90.9)
Month 9	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 12	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 15	72.6 (56.5, 83.5)	72.5 (56.4, 83.4)
Month 18	69.6 (53.0, 81.3)	69.4 (52.9, 81.2)
Month 21	66.5 (49.6, 78.9)	66.4 (49.5, 78.8)

Ethnicity: Other

	Local assessment N=54	IRC assessment N=54
Month 24	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 27	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 30	60.5 (43.2, 74.0)	60.4 (43.1, 73.9)
Month 33	60.5 (43.2, 74.0)	57.4 (40.1, 71.3)
Month 36	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 39	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 42	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 45	54.3 (37.0, 68.7)	54.2 (36.9, 68.6)
Month 48	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 51	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 54	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 57	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 60	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 63	NE	NE

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

Table 304e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Response status at study entry: Primary refractory		
	Local assessment N=5	**IRC assessment N=5**
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 45	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 48	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 51	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 54	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 57	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease	**Local assessment N=62**	**IRC assessment N=62**
Events/Responders (%)	25/62 (40.3)	25/62 (40.3)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 20.0)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.3 (83.1, 97.4)	93.2 (82.9, 97.4)
Month 6	80.2 (66.9, 88.5)	80.0 (66.8, 88.4)
Month 9	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 12	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 15	65.8 (51.2, 77.0)	65.7 (51.1, 77.0)
Month 18	63.4 (48.5, 75.0)	63.3 (48.4, 75.0)
Month 21	60.9 (45.9, 73.0)	60.9 (45.8, 72.9)

Response status at study entry: Relapsed disease		
	Local assessment N=62	**IRC assessment N=62**
Month 24	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 27	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 30	56.1 (40.9, 68.8)	56.0 (40.8, 68.7)
Month 33	56.1 (40.9, 68.8)	53.6 (38.4, 66.6)
Month 36	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 39	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 42	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 45	51.1 (35.9, 64.4)	51.0 (35.8, 64.3)
Month 48	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 51	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 54	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 57	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 60	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 63	NE	NE

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

Table 304f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive	**Local assessment N=2**	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	59.14	59.14
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive		
	Local assessment N=2	**IRC assessment N=2**
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)
Month 45	100 (100, 100)	100 (100, 100)
Month 48	100 (100, 100)	100 (100, 100)
Month 51	100 (100, 100)	100 (100, 100)
Month 54	100 (100, 100)	100 (100, 100)
Month 57	100 (100, 100)	100 (100, 100)
Month 60	100 (100, 100)	NE
Month 63	NE	NE

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

Table 304f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive	**Local assessment N=65**	**IRC assessment N=65**
Events/Responders (%)	26/65 (40.0)	26/65 (40.0)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.5 (83.5, 97.5)	93.4 (83.4, 97.5)
Month 6	80.6 (67.6, 88.8)	80.5 (67.4, 88.7)
Month 9	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 12	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 15	64.6 (50.0, 75.9)	64.5 (49.9, 75.8)
Month 18	62.2 (47.4, 73.9)	62.1 (47.3, 73.8)
Month 21	59.8 (44.9, 71.8)	59.7 (44.8, 71.8)

Philadelphia chromosome/BCR-ABL: Non-Positive		
	Local assessment N=65	**IRC assessment N=65**
Month 24	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 27	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 30	55.0 (40.0, 67.7)	54.9 (39.9, 67.6)
Month 33	55.0 (40.0, 67.7)	52.5 (37.6, 65.5)
Month 36	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 39	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 42	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 45	50.1 (35.1, 63.3)	50.0 (35.1, 63.3)
Month 48	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 51	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 54	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 57	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 60	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 63	NE	NE

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

Table 304g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	4.9	4.9
Median follow-up (months)	4.86	4.86
Percentiles (95% CI) [1]		
25th	4.9 (NE, NE)	4.9 (NE, NE)
50th	4.9 (NE, NE)	4.9 (NE, NE)
75th	4.9 (NE, NE)	4.9 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	0.0 (NE, NE)	0.0 (NE, NE)
Month 9	0.0 (NE, NE)	0.0 (NE, NE)
Month 12	0.0 (NE, NE)	0.0 (NE, NE)
Month 15	0.0 (NE, NE)	0.0 (NE, NE)
Month 18	0.0 (NE, NE)	0.0 (NE, NE)
Month 21	0.0 (NE, NE)	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	0.0 (NE, NE)	0.0 (NE, NE)
Month 27	0.0 (NE, NE)	0.0 (NE, NE)
Month 30	0.0 (NE, NE)	0.0 (NE, NE)
Month 33	0.0 (NE, NE)	0.0 (NE, NE)
Month 36	0.0 (NE, NE)	0.0 (NE, NE)
Month 39	0.0 (NE, NE)	0.0 (NE, NE)
Month 42	0.0 (NE, NE)	0.0 (NE, NE)
Month 45	0.0 (NE, NE)	0.0 (NE, NE)
Month 48	0.0 (NE, NE)	0.0 (NE, NE)
Month 51	0.0 (NE, NE)	0.0 (NE, NE)
Month 54	0.0 (NE, NE)	0.0 (NE, NE)
Month 57	0.0 (NE, NE)	0.0 (NE, NE)
Month 60	0.0 (NE, NE)	0.0 (NE, NE)
Month 63	0.0 (NE, NE)	0.0 (NE, NE)

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

Table 304g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No	**Local assessment N=66**	**IRC assessment N=66**
Events/Responders (%)	25/66 (37.9)	25/66 (37.9)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.6 (4.6, 20.0)	8.6 (4.6, 20.0)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	82.8 (70.2, 90.4)	82.7 (70.1, 90.3)
Month 9	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 12	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 15	67.1 (52.8, 77.9)	67.0 (52.7, 77.9)
Month 18	64.8 (50.2, 76.0)	64.7 (50.1, 76.0)
Month 21	62.5 (47.8, 74.1)	62.4 (47.7, 74.0)

Mixed-lineage leukemia rearrangement: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 27	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 30	57.8 (42.9, 70.1)	57.8 (42.9, 70.1)
Month 33	57.8 (42.9, 70.1)	55.5 (40.5, 68.0)
Month 36	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 39	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 42	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 45	53.1 (38.2, 66.0)	53.0 (38.1, 65.9)
Month 48	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 51	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 54	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 57	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 60	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 63	NE	NE

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

Table 304h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	59.0	59.0
Median follow-up (months)	58.97	58.97
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Hypodiploidy: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)
Month 45	100 (100, 100)	100 (100, 100)
Month 48	100 (100, 100)	100 (100, 100)
Month 51	100 (100, 100)	100 (100, 100)
Month 54	100 (100, 100)	100 (100, 100)
Month 57	100 (100, 100)	100 (100, 100)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: No	**Local assessment N=66**	**IRC assessment N=66**
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 17.8)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	80.9 (68.1, 89.0)	80.8 (68.0, 88.9)
Month 9	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 12	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 15	65.2 (50.8, 76.3)	65.1 (50.8, 76.3)
Month 18	62.9 (48.3, 74.4)	62.8 (48.2, 74.3)
Month 21	60.6 (45.8, 72.4)	60.5 (45.8, 72.4)

Hypodiploidy: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 27	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 30	55.9 (41.1, 68.4)	55.8 (41.0, 68.3)
Month 33	55.9 (41.1, 68.4)	53.5 (38.7, 66.3)
Month 36	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 39	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 42	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 45	51.1 (36.3, 64.2)	51.1 (36.2, 64.1)
Month 48	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 51	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 54	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 57	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 60	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 63	NE	NE

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

Table 304i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	1.6	1.6
Median follow-up (months)	1.56	1.56
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	NE	NE
Month 6	NE	NE
Month 9	NE	NE
Month 12	NE	NE
Month 15	NE	NE
Month 18	NE	NE
Month 21	NE	NE

BCR-ABL1-like: Yes

	Local assessment N=1	IRC assessment N=1
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE
Month 51	NE	NE
Month 54	NE	NE
Month 57	NE	NE
Month 60	NE	NE
Month 63	NE	NE

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

Table 304i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	Local assessment N=66	IRC assessment N=66
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.9, 17.8)	8.3 (4.9, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.9, 97.6)	93.6 (83.9, 97.6)
Month 6	81.2 (68.6, 89.2)	81.1 (68.5, 89.1)
Month 9	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 12	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 15	65.8 (51.6, 76.8)	65.8 (51.6, 76.7)
Month 18	63.6 (49.2, 74.9)	63.5 (49.1, 74.9)
Month 21	61.3 (46.7, 73.0)	61.2 (46.7, 72.9)

BCR-ABL1-like: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 27	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 30	56.8 (42.1, 69.1)	56.7 (42.0, 69.0)
Month 33	56.8 (42.1, 69.1)	54.4 (39.7, 67.0)
Month 36	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 39	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 42	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 45	52.1 (37.4, 64.9)	52.1 (37.4, 64.9)
Month 48	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 51	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 54	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 57	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 60	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 63	NE	NE

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

Table 304j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.44	8.44
Percentiles (95% CI) [1]		
25th	8.3 (2.5, 22.7)	8.3 (2.5, 22.7)
50th	22.7 (8.0, NE)	22.7 (8.0, NE)
75th	NE (22.7, NE)	NE (22.7, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (70.7, 99.3)	95.2 (70.7, 99.3)
Month 6	82.9 (55.4, 94.2)	82.9 (55.4, 94.2)
Month 9	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 12	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 15	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 18	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)
Month 21	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)

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

	Local assessment N=22	IRC assessment N=22
Month 24	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 27	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 30	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 33	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 36	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 39	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 42	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 45	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 48	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 51	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 54	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 57	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No		
	Local assessment N=45	**IRC assessment N=45**
Events/Responders (%)	17/45 (37.8)	17/45 (37.8)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	13.96	13.96
Percentiles (95% CI) [1]		
25th	7.6 (4.0, 27.8)	7.6 (4.0, 27.8)
50th	NE (14.0, NE)	NE (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (79.6, 97.7)	92.9 (79.5, 97.6)
Month 6	80.2 (64.2, 89.6)	80.0 (63.9, 89.5)
Month 9	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 12	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 15	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 18	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 21	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)

Complex karyotypes II (>=5 unrelated abnormalities) : No		
	Local assessment N=45	**IRC assessment N=45**
Month 24	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 27	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 30	60.5 (43.0, 74.2)	60.4 (42.8, 74.1)
Month 33	60.5 (43.0, 74.2)	57.4 (39.8, 71.5)
Month 36	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 39	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 42	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 45	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 48	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 51	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 54	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 57	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 60	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 63	NE	NE

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

Table 304k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Europe	**Local assessment N=26**	**IRC assessment N=26**
Events/Responders (%)	9/26 (34.6)	9/26 (34.6)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	14.59	14.59
Percentiles (95% CI) [1]		
25th	17.8 (2.1, 46.8)	17.8 (2.1, 46.8)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (73.9, 99.4)	95.8 (73.9, 99.4)
Month 6	87.1 (65.0, 95.7)	87.1 (65.0, 95.7)
Month 9	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 12	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 15	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 18	71.5 (46.6, 86.2)	71.5 (46.6, 86.2)
Month 21	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)

Region: Europe

	Local assessment N=26	IRC assessment N=26
Month 24	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 27	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 30	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 33	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 36	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 39	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 42	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 45	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 48	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 51	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 54	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 57	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 60	53.6 (29.0, 73.0)	NE
Month 63	NE	NE

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

Table 304k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Enrolled set

Region: US	**Local assessment N=36**	**IRC assessment N=36**
Events/Responders (%)	13/36 (36.1)	13/36 (36.1)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	8.15	8.15
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 8.6)	7.5 (4.0, 8.6)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (78.7, 98.5)	94.2 (78.7, 98.5)
Month 6	77.0 (57.6, 88.4)	76.9 (57.4, 88.3)
Month 9	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 12	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 15	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 18	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 21	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)

Region: US

	Local assessment N=36	IRC assessment N=36
Month 24	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 27	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 30	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 33	58.7 (38.6, 74.2)	54.1 (33.9, 70.5)
Month 36	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 39	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 42	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 45	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 48	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 51	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 54	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 57	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 60	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 63	NE	NE

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

Table 304k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Rest of World	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	4/5 (80.0)	4/5 (80.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Region: Rest of World

	Local assessment N=5	IRC assessment N=5
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 48	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 51	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 54	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 57	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	15/42 (35.7)	15/42 (35.7)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	15.87	15.87
Percentiles (95% CI) [1]		
25th	14.0 (4.9, 33.8)	14.0 (4.9, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.1, 98.8)
Month 6	81.9 (65.7, 91.0)	81.8 (65.5, 90.9)
Month 9	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 12	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 15	72.8 (55.0, 84.5)	72.7 (54.9, 84.4)
Month 18	69.3 (51.1, 81.9)	69.2 (51.0, 81.8)
Month 21	65.9 (47.3, 79.2)	65.8 (47.2, 79.2)

Prior SCT therapy: Yes		
	Local assessment N=42	**IRC assessment N=42**
Month 24	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 27	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 30	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 33	62.4 (43.7, 76.5)	58.8 (40.1, 73.5)
Month 36	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 39	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 42	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 45	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 48	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 51	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 54	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 57	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 60	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 63	NE	NE

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

Table 304l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: No	**Local assessment N=25**	**IRC assessment N=25**
Events/Responders (%)	11/25 (44.0)	11/25 (44.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	7.5 (1.6, 8.6)
50th	27.8 (7.5, NE)	27.8 (7.5, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.1, 97.6)	90.7 (67.6, 97.6)
Month 6	80.5 (55.7, 92.2)	80.3 (55.5, 92.1)
Month 9	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 12	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 15	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 18	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 21	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)

Prior SCT therapy: No		
	Local assessment N=25	**IRC assessment N=25**
Month 24	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 27	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 30	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 33	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 36	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 39	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 42	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 45	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 48	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 51	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 54	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 57	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	5/12 (41.7)	5/12 (41.7)
Maximum follow-up (months)	59.3	59.3
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	14.0 (1.6, 44.5)	14.0 (1.6, 44.5)
50th	22.7 (4.9, NE)	22.7 (4.9, NE)
75th	44.5 (14.0, NE)	44.5 (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 9	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 12	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 15	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 18	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 21	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 27	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 30	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 33	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 36	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 39	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 42	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 45	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 48	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 51	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 54	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 57	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: No	**Local assessment N=55**	**IRC assessment N=55**
Events/Responders (%)	21/55 (38.2)	21/55 (38.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 20.0)	8.0 (4.6, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (83.1, 98.1)	94.2 (83.1, 98.1)
Month 6	81.5 (67.4, 89.9)	81.5 (67.4, 89.9)
Month 9	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 12	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 15	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 18	63.1 (47.3, 75.3)	63.1 (47.3, 75.3)
Month 21	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)

Eligibility for SCT: No		
	Local assessment N=55	**IRC assessment N=55**
Month 24	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 27	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 30	57.8 (41.8, 70.9)	57.8 (41.8, 70.9)
Month 33	57.8 (41.8, 70.9)	55.2 (39.2, 68.6)
Month 36	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 39	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 42	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 45	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 48	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 51	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 54	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 57	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 60	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 63	NE	NE

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

Table 304n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low		
	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	10/25 (40.0)	10/25 (40.0)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	16.62	16.62
Percentiles (95% CI) [1]		
25th	8.3 (1.6, 27.8)	8.3 (1.6, 27.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (70.6, 97.8)	91.7 (70.6, 97.8)
Month 6	82.7 (60.2, 93.2)	82.7 (60.2, 93.2)
Month 9	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 12	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 15	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 18	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 21	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)

Baseline bone marrow tumor burden: Low		
	Local assessment N=25	**IRC assessment N=25**
Month 24	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 27	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 30	56.7 (32.6, 75.0)	56.7 (32.6, 75.0)
Month 33	56.7 (32.6, 75.0)	51.0 (27.5, 70.4)
Month 36	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 39	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 42	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 45	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 48	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 51	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 54	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 57	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 60	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 63	NE	NE

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

Table 304n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	16/42 (38.1)	16/42 (38.1)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.95	8.95
Percentiles (95% CI) [1]		
25th	8.0 (4.2, 22.7)	8.0 (4.2, 22.7)
50th	46.8 (8.6, NE)	46.8 (8.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.9 (81.0, 98.7)	94.8 (80.8, 98.7)
Month 6	80.3 (62.9, 90.1)	80.1 (62.7, 90.0)
Month 9	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 12	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 15	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 18	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)
Month 21	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)

Baseline bone marrow tumor burden: High		
	Local assessment N=42	**IRC assessment N=42**
Month 24	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 27	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 30	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 33	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 36	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 39	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 42	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 45	53.1 (34.1, 69.0)	53.0 (34.0, 68.9)
Month 48	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 51	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 54	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 57	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes		
	Local assessment N=11	**IRC assessment N=11**
Events/Responders (%)	3/11 (27.3)	3/11 (27.3)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	33.35	33.35
Percentiles (95% CI) [1]		
25th	33.8 (2.1, NE)	32.9 (2.1, NE)
50th	NE (2.1, NE)	NE (2.1, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 9	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 12	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 15	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 18	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 21	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)

Baseline extramedullary disease presence: Yes		
	Local assessment N=11	**IRC assessment N=11**
Month 24	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 27	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 30	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 33	78.8 (38.1, 94.3)	65.6 (26.0, 87.6)
Month 36	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 39	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 42	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 45	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 48	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 51	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 54	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 57	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 60	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 63	NE	NE

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

Table 304o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No		
	Local assessment N=56	**IRC assessment N=56**
Events/Responders (%)	23/56 (41.1)	23/56 (41.1)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	44.5 (14.0, NE)	44.5 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.3 (83.5, 98.1)	94.3 (83.3, 98.1)
Month 6	81.6 (67.6, 90.0)	81.5 (67.4, 89.9)
Month 9	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 12	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 15	63.5 (47.8, 75.6)	63.4 (47.8, 75.6)
Month 18	60.8 (44.9, 73.4)	60.7 (44.8, 73.3)
Month 21	58.0 (42.0, 71.0)	57.9 (41.9, 71.0)

Baseline extramedullary disease presence: No		
	Local assessment N=56	**IRC assessment N=56**
Month 24	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 27	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 30	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 33	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 36	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 39	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 42	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 45	49.6 (33.6, 63.7)	49.5 (33.5, 63.6)
Month 48	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 51	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 54	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 57	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: Yes	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	3/5 (60.0)	3/5 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	7.5 (4.6, NE)	7.5 (4.6, NE)
50th	22.7 (4.6, NE)	22.7 (4.6, NE)
75th	NE (4.6, NE)	NE (4.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 12	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Down syndrome: Yes		
	Local assessment N=5	**IRC assessment N=5**
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 48	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 51	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 54	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 57	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: No	**Local assessment N=62**	**IRC assessment N=62**
Events/Responders (%)	23/62 (37.1)	23/62 (37.1)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.6 (4.9, 20.0)	8.6 (4.9, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (82.7, 97.4)	93.1 (82.6, 97.3)
Month 6	81.4 (68.1, 89.6)	81.3 (67.9, 89.5)
Month 9	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 12	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 15	66.4 (51.4, 77.8)	66.3 (51.3, 77.7)
Month 18	63.9 (48.6, 75.7)	63.8 (48.5, 75.6)
Month 21	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)

Down syndrome: No		
	Local assessment N=62	**IRC assessment N=62**
Month 24	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 27	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 30	58.8 (43.2, 71.4)	58.7 (43.1, 71.3)
Month 33	58.8 (43.2, 71.4)	56.1 (40.5, 69.1)
Month 36	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 39	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 42	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 45	53.5 (37.9, 66.9)	53.5 (37.8, 66.8)
Month 48	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 51	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 54	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 57	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 60	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 63	NE	NE

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

Table 304q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median	**Local assessment N=34**	**IRC assessment N=34**
Events/Responders (%)	14/34 (41.2)	14/34 (41.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	18.91	18.91
Percentiles (95% CI) [1]		
25th	8.6 (3.4, 22.7)	8.8 (3.4, 22.7)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.8 (77.3, 98.4)	93.8 (77.3, 98.4)
Month 6	84.2 (66.0, 93.1)	84.2 (66.0, 93.1)
Month 9	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 12	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 15	70.2 (50.3, 83.3)	70.2 (50.3, 83.3)
Month 18	66.3 (46.1, 80.4)	66.3 (46.1, 80.4)
Month 21	62.4 (42.1, 77.3)	62.4 (42.1, 77.3)

Time since enrollment to CTL019 infusion: > Median		
	Local assessment N=34	**IRC assessment N=34**
Month 24	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 27	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 30	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 33	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 36	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 39	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 42	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 45	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 48	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 51	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 54	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 57	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 60	50.4 (30.6, 67.2)	NE
Month 63	NE	NE

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

Table 304q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median	**Local assessment N=33**	**IRC assessment N=33**
Events/Responders (%)	12/33 (36.4)	12/33 (36.4)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	7.98	7.98
Percentiles (95% CI) [1]		
25th	7.5 (4.2, 33.8)	7.5 (4.2, 32.9)
50th	46.8 (8.0, NE)	46.8 (8.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (76.9, 98.4)	93.6 (76.9, 98.4)
Month 6	77.1 (55.6, 89.1)	77.1 (55.6, 89.1)
Month 9	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 12	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 15	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 18	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 21	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)

Time since enrollment to CTL019 infusion: <=Median		
	Local assessment N=33	**IRC assessment N=33**
Month 24	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 27	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 30	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 33	60.0 (38.1, 76.3)	54.5 (32.4, 72.1)
Month 36	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 39	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 42	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 45	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 48	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 51	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 54	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 57	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 60	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 63	NE	NE

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

Table 304r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 0	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Number of previous relapses: 0		
	Local assessment N=5	**IRC assessment N=5**
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 45	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 48	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 51	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 54	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 57	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 1		
	Local assessment N=18	**IRC assessment N=18**
Events/Responders (%)	9/18 (50.0)	9/18 (50.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.90	7.90
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	4.9 (1.6, 8.6)
50th	14.0 (4.9, NE)	14.0 (4.9, NE)
75th	NE (14.0, NE)	NE (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	88.2 (60.6, 96.9)	88.2 (60.6, 96.9)
Month 6	75.1 (46.3, 89.9)	74.7 (45.5, 89.7)
Month 9	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 12	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 15	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 18	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 21	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)

Number of previous relapses: 1		
	Local assessment N=18	**IRC assessment N=18**
Month 24	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 27	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 30	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 33	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 36	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 39	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 42	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 45	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 48	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 51	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 54	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 57	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 60	NE	NE
Month 63	NE	NE

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

Table 304r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Events/Responders (%)	5/14 (35.7)	5/14 (35.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	9.82	9.82
Percentiles (95% CI) [1]		
25th	5.1 (4.2, NE)	5.1 (4.2, NE)
50th	NE (5.1, NE)	NE (5.1, NE)
75th	NE (44.5, NE)	NE (44.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 24	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 27	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 30	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 33	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 36	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 39	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 42	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 45	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 48	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 51	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 54	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 57	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 60	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 63	NE	NE

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

Table 304r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: >=3	**Local assessment N=30**	**IRC assessment N=30**
Events/Responders (%)	11/30 (36.7)	11/30 (36.7)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	21.37	21.37
Percentiles (95% CI) [1]		
25th	17.8 (4.0, 46.8)	17.8 (4.0, 46.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	85.7 (66.1, 94.4)	85.7 (66.1, 94.4)
Month 9	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 12	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 15	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 18	73.3 (51.7, 86.4)	73.3 (51.7, 86.4)

Number of previous relapses: >=3

	Local assessment N=30	IRC assessment N=30
Month 21	68.7 (46.7, 83.1)	68.7 (46.7, 83.1)
Month 24	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 27	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 30	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 33	64.1 (41.9, 79.7)	59.5 (37.4, 76.1)
Month 36	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 39	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 42	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 45	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 48	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 51	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 54	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 57	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 60	54.6 (32.6, 72.1)	NE
Month 63	NE	NE

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

Table 305a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years	**Local assessment N=27**	**IRC assessment N=27**
Events/Responders (%)	10/27 (37.0)	10/27 (37.0)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	7.49	7.49
Percentiles (95% CI) [1]		
25th	5.1 (2.5, 27.8)	5.1 (1.6, 27.8)
50th	27.8 (5.1, NE)	27.8 (5.1, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.1 (72.1, 98.0)	91.8 (71.1, 97.9)
Month 6	69.8 (46.7, 84.4)	69.4 (46.2, 84.2)
Month 9	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 12	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 15	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 18	65.2 (42.1, 80.9)	64.8 (41.7, 80.7)
Month 21	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)

Age: <10 years		
	Local assessment N=27	**IRC assessment N=27**
Month 24	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 27	57.0 (31.9, 75.9)	56.7 (31.6, 75.6)
Month 30	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 33	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 36	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 39	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 42	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 45	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 48	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 51	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 54	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 57	48.9 (23.7, 70.1)	48.6 (23.5, 69.8)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	11/29 (37.9)	11/29 (37.9)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	8.3 (2.1, 46.8)	8.3 (2.1, 46.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	84.3 (63.4, 93.8)	84.3 (63.4, 93.8)
Month 9	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 12	71.7 (49.5, 85.4)	71.7 (49.5, 85.4)
Month 15	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 18	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)
Month 21	67.2 (44.8, 82.1)	67.2 (44.8, 82.1)

Age: >=10 years to <18 years		
	Local assessment N=29	**IRC assessment N=29**
Month 24	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 27	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 30	62.7 (40.4, 78.7)	62.7 (40.4, 78.7)
Month 33	62.7 (40.4, 78.7)	58.3 (36.1, 75.1)
Month 36	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 39	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 42	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 45	58.3 (36.1, 75.1)	58.3 (36.1, 75.1)
Month 48	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 51	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 54	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 57	53.4 (31.5, 71.1)	53.4 (31.5, 71.1)
Month 60	53.4 (31.5, 71.1)	NE
Month 63	NE	NE

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

Table 305a
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18	**Local assessment N=11**	**IRC assessment N=11**
Events/Responders (%)	5/11 (45.5)	5/11 (45.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	17.77	17.77
Percentiles (95% CI) [1]		
25th	8.6 (8.6, 44.5)	8.8 (8.6, 44.5)
50th	44.5 (8.6, NE)	44.5 (8.6, NE)
75th	NE (17.8, NE)	NE (17.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 12	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 15	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
Month 18	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 21	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)

Age: >=18		
	Local assessment N=11	**IRC assessment N=11**
Month 24	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 27	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 30	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 33	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 36	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 39	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 42	55.6 (20.4, 80.5)	55.6 (20.4, 80.5)
Month 45	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 48	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 51	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 54	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 57	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 60	44.4 (13.6, 71.9)	44.4 (13.6, 71.9)
Month 63	NE	NE

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

Table 305b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male	**Local assessment N=38**	**IRC assessment N=38**
Events/Responders (%)	16/38 (42.1)	16/38 (42.1)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	8.82	8.82
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 22.7)	7.5 (4.0, 22.7)
50th	33.8 (8.3, NE)	32.9 (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.4 (79.5, 98.6)	94.3 (79.0, 98.5)
Month 6	75.5 (56.9, 87.0)	75.3 (56.5, 86.8)
Month 9	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 12	65.4 (46.0, 79.2)	65.1 (45.8, 79.0)
Month 15	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 18	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)
Month 21	61.5 (42.0, 76.2)	61.3 (41.7, 76.0)

Gender: Male		
	Local assessment N=38	**IRC assessment N=38**
Month 24	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 27	57.4 (37.7, 72.9)	57.2 (37.5, 72.7)
Month 30	53.3 (33.7, 69.5)	53.1 (33.5, 69.4)
Month 33	53.3 (33.7, 69.5)	49.0 (29.7, 65.8)
Month 36	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 39	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 42	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 45	49.2 (29.8, 66.0)	49.0 (29.7, 65.8)
Month 48	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 51	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 54	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 57	44.8 (25.7, 62.2)	44.6 (25.5, 62.0)
Month 60	44.8 (25.7, 62.2)	NE
Month 63	NE	NE

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

Table 305b
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female	**Local assessment N=29**	**IRC assessment N=29**
Events/Responders (%)	10/29 (34.5)	10/29 (34.5)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	11.40	11.40
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 44.5)	8.8 (2.1, 44.5)
50th	NE (8.6, NE)	NE (8.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.6 (73.5, 98.1)	92.6 (73.5, 98.1)
Month 6	88.4 (68.1, 96.1)	88.4 (68.1, 96.1)
Month 9	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 12	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 15	71.5 (49.3, 85.3)	71.5 (49.3, 85.3)
Month 18	66.4 (43.6, 81.8)	66.4 (43.6, 81.8)
Month 21	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)

Gender: Female		
	Local assessment N=29	**IRC assessment N=29**
Month 24	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 27	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 30	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 33	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 36	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 39	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 42	61.3 (38.3, 77.9)	61.3 (38.3, 77.9)
Month 45	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 48	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 51	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 54	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 57	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 60	56.2 (33.4, 73.9)	56.2 (33.4, 73.9)
Month 63	NE	NE

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

Table 305c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White	**Local assessment N=51**	**IRC assessment N=51**
Events/Responders (%)	16/51 (31.4)	16/51 (31.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 33.8)	8.0 (4.6, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (84.3, 98.9)	95.8 (84.2, 98.9)
Month 6	81.5 (66.2, 90.3)	81.4 (66.0, 90.2)
Month 9	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 12	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 15	71.0 (54.5, 82.5)	70.9 (54.3, 82.4)
Month 18	67.8 (50.8, 80.1)	67.7 (50.6, 80.0)
Month 21	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)

Race: White		
	Local assessment N=51	**IRC assessment N=51**
Month 24	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 27	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 30	64.6 (47.2, 77.5)	64.5 (47.1, 77.5)
Month 33	64.6 (47.2, 77.5)	61.3 (43.6, 74.9)
Month 36	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 39	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 42	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 45	61.4 (43.7, 74.9)	61.3 (43.6, 74.9)
Month 48	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 51	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 54	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 57	57.9 (40.2, 72.2)	57.9 (40.1, 72.1)
Month 60	57.9 (40.2, 72.2)	NE
Month 63	NE	NE

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

Table 305c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian	**Local assessment N=6**	**IRC assessment N=6**
Events/Responders (%)	4/6 (66.7)	4/6 (66.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	18.33	18.33
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Race: Asian

	Local assessment N=6	IRC assessment N=6
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 48	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 51	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 54	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 57	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 60	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 63	NE	NE

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

Table 305c
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other	**Local assessment N=10**	**IRC assessment N=10**
Events/Responders (%)	6/10 (60.0)	6/10 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	9.95	9.95
Percentiles (95% CI) [1]		
25th	8.6 (2.1, 27.8)	8.6 (2.1, 27.8)
50th	18.2 (2.1, NE)	18.3 (2.1, NE)
75th	NE (8.6, NE)	NE (8.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	80.0 (40.9, 94.6)	80.0 (40.9, 94.6)
Month 9	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 12	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 15	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 18	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 21	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)

Race: Other		
	Local assessment N=10	**IRC assessment N=10**
Month 24	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 27	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)
Month 30	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 33	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 36	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 39	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 42	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 45	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 48	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 51	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 54	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 57	37.5 (9.9, 65.9)	37.5 (9.9, 65.9)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino	**Local assessment N=13**	**IRC assessment N=13**
Events/Responders (%)	7/13 (53.8)	7/13 (53.8)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	8.62	8.62
Percentiles (95% CI) [1]		
25th	7.6 (2.1, 8.6)	7.6 (2.1, 8.6)
50th	8.6 (5.1, NE)	8.8 (5.1, NE)
75th	NE (8.6, NE)	NE (8.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	92.3 (56.6, 98.9)	92.3 (56.6, 98.9)
Month 6	76.2 (42.7, 91.7)	76.2 (42.7, 91.7)
Month 9	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 12	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 15	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 18	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 21	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)

Ethnicity: Hispanic or Latino		
	Local assessment N=13	**IRC assessment N=13**
Month 24	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 27	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 30	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 33	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 36	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 39	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 42	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 45	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 48	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 51	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 54	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 57	42.3 (15.6, 67.1)	42.3 (15.6, 67.1)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305d
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other	**Local assessment N=54**	**IRC assessment N=54**
Events/Responders (%)	19/54 (35.2)	19/54 (35.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	11.24	11.24
Percentiles (95% CI) [1]		
25th	14.0 (4.6, 27.8)	14.0 (4.6, 27.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.0 (82.6, 98.0)	94.0 (82.4, 98.0)
Month 6	82.7 (68.3, 91.0)	82.6 (68.1, 90.9)
Month 9	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 12	75.5 (60.0, 85.7)	75.3 (59.8, 85.6)
Month 15	72.6 (56.5, 83.5)	72.5 (56.4, 83.4)
Month 18	69.6 (53.0, 81.3)	69.4 (52.9, 81.2)
Month 21	66.5 (49.6, 78.9)	66.4 (49.5, 78.8)

Ethnicity: Other		
	Local assessment N=54	**IRC assessment N=54**
Month 24	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 27	63.5 (46.4, 76.5)	63.4 (46.3, 76.4)
Month 30	60.5 (43.2, 74.0)	60.4 (43.1, 73.9)
Month 33	60.5 (43.2, 74.0)	57.4 (40.1, 71.3)
Month 36	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 39	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 42	57.5 (40.2, 71.4)	57.4 (40.1, 71.3)
Month 45	54.3 (37.0, 68.7)	54.2 (36.9, 68.6)
Month 48	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 51	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 54	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 57	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 60	51.1 (33.9, 65.9)	51.0 (33.8, 65.8)
Month 63	NE	NE

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

Table 305e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Response status at study entry: Primary refractory		
	Local assessment N=5	**IRC assessment N=5**
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 45	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 48	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 51	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 54	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 57	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305e
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease		
	Local assessment N=62	**IRC assessment N=62**
Events/Responders (%)	25/62 (40.3)	25/62 (40.3)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 20.0)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.3 (83.1, 97.4)	93.2 (82.9, 97.4)
Month 6	80.2 (66.9, 88.5)	80.0 (66.8, 88.4)
Month 9	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 12	68.2 (53.8, 78.9)	68.1 (53.6, 78.9)
Month 15	65.8 (51.2, 77.0)	65.7 (51.1, 77.0)
Month 18	63.4 (48.5, 75.0)	63.3 (48.4, 75.0)
Month 21	60.9 (45.9, 73.0)	60.9 (45.8, 72.9)

Response status at study entry: Relapsed disease		
	Local assessment N=62	**IRC assessment N=62**
Month 24	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 27	58.5 (43.4, 70.9)	58.4 (43.3, 70.8)
Month 30	56.1 (40.9, 68.8)	56.0 (40.8, 68.7)
Month 33	56.1 (40.9, 68.8)	53.6 (38.4, 66.6)
Month 36	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 39	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 42	53.6 (38.4, 66.6)	53.6 (38.4, 66.6)
Month 45	51.1 (35.9, 64.4)	51.0 (35.8, 64.3)
Month 48	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 51	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 54	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 57	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 60	48.5 (33.4, 62.1)	48.5 (33.4, 62.0)
Month 63	NE	NE

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

Table 305f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive		
	Local assessment N=2	**IRC assessment N=2**
Events/Responders (%)	0/2 (0.0)	0/2 (0.0)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	59.14	59.14
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive		
	Local assessment N=2	**IRC assessment N=2**
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)
Month 45	100 (100, 100)	100 (100, 100)
Month 48	100 (100, 100)	100 (100, 100)
Month 51	100 (100, 100)	100 (100, 100)
Month 54	100 (100, 100)	100 (100, 100)
Month 57	100 (100, 100)	100 (100, 100)
Month 60	100 (100, 100)	NE
Month 63	NE	NE

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

Table 305f
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Non-Positive	**Local assessment N=65**	**IRC assessment N=65**
Events/Responders (%)	26/65 (40.0)	26/65 (40.0)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.5 (83.5, 97.5)	93.4 (83.4, 97.5)
Month 6	80.6 (67.6, 88.8)	80.5 (67.4, 88.7)
Month 9	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 12	66.9 (52.5, 77.7)	66.8 (52.4, 77.7)
Month 15	64.6 (50.0, 75.9)	64.5 (49.9, 75.8)
Month 18	62.2 (47.4, 73.9)	62.1 (47.3, 73.8)
Month 21	59.8 (44.9, 71.8)	59.7 (44.8, 71.8)

Philadelphia chromosome/BCR-ABL: Non-Positive		
	Local assessment N=65	**IRC assessment N=65**
Month 24	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 27	57.4 (42.4, 69.8)	57.3 (42.3, 69.7)
Month 30	55.0 (40.0, 67.7)	54.9 (39.9, 67.6)
Month 33	55.0 (40.0, 67.7)	52.5 (37.6, 65.5)
Month 36	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 39	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 42	52.6 (37.6, 65.6)	52.5 (37.6, 65.5)
Month 45	50.1 (35.1, 63.3)	50.0 (35.1, 63.3)
Month 48	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 51	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 54	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 57	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 60	47.6 (32.7, 61.1)	47.5 (32.7, 61.0)
Month 63	NE	NE

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

Table 305g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	1/1 (100.0)	1/1 (100.0)
Maximum follow-up (months)	4.9	4.9
Median follow-up (months)	4.86	4.86
Percentiles (95% CI) [1]		
25th	4.9 (NE, NE)	4.9 (NE, NE)
50th	4.9 (NE, NE)	4.9 (NE, NE)
75th	4.9 (NE, NE)	4.9 (NE, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	0.0 (NE, NE)	0.0 (NE, NE)
Month 9	0.0 (NE, NE)	0.0 (NE, NE)
Month 12	0.0 (NE, NE)	0.0 (NE, NE)
Month 15	0.0 (NE, NE)	0.0 (NE, NE)
Month 18	0.0 (NE, NE)	0.0 (NE, NE)
Month 21	0.0 (NE, NE)	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	0.0 (NE, NE)	0.0 (NE, NE)
Month 27	0.0 (NE, NE)	0.0 (NE, NE)
Month 30	0.0 (NE, NE)	0.0 (NE, NE)
Month 33	0.0 (NE, NE)	0.0 (NE, NE)
Month 36	0.0 (NE, NE)	0.0 (NE, NE)
Month 39	0.0 (NE, NE)	0.0 (NE, NE)
Month 42	0.0 (NE, NE)	0.0 (NE, NE)
Month 45	0.0 (NE, NE)	0.0 (NE, NE)
Month 48	0.0 (NE, NE)	0.0 (NE, NE)
Month 51	0.0 (NE, NE)	0.0 (NE, NE)
Month 54	0.0 (NE, NE)	0.0 (NE, NE)
Month 57	0.0 (NE, NE)	0.0 (NE, NE)
Month 60	0.0 (NE, NE)	0.0 (NE, NE)
Month 63	0.0 (NE, NE)	0.0 (NE, NE)

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

Table 305g
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No	**Local assessment N=66**	**IRC assessment N=66**
Events/Responders (%)	25/66 (37.9)	25/66 (37.9)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.6 (4.6, 20.0)	8.6 (4.6, 20.0)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	82.8 (70.2, 90.4)	82.7 (70.1, 90.3)
Month 9	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 12	69.3 (55.2, 79.8)	69.2 (55.1, 79.7)
Month 15	67.1 (52.8, 77.9)	67.0 (52.7, 77.9)
Month 18	64.8 (50.2, 76.0)	64.7 (50.1, 76.0)
Month 21	62.5 (47.8, 74.1)	62.4 (47.7, 74.0)

Mixed-lineage leukemia rearrangement: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 27	60.2 (45.3, 72.1)	60.1 (45.2, 72.1)
Month 30	57.8 (42.9, 70.1)	57.8 (42.9, 70.1)
Month 33	57.8 (42.9, 70.1)	55.5 (40.5, 68.0)
Month 36	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 39	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 42	55.5 (40.6, 68.1)	55.5 (40.5, 68.0)
Month 45	53.1 (38.2, 66.0)	53.0 (38.1, 65.9)
Month 48	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 51	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 54	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 57	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 60	50.7 (35.8, 63.8)	50.6 (35.7, 63.7)
Month 63	NE	NE

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

Table 305h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	59.0	59.0
Median follow-up (months)	58.97	58.97
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	100 (100, 100)	100 (100, 100)
Month 12	100 (100, 100)	100 (100, 100)
Month 15	100 (100, 100)	100 (100, 100)
Month 18	100 (100, 100)	100 (100, 100)
Month 21	100 (100, 100)	100 (100, 100)

Hypodiploidy: Yes		
	Local assessment N=1	**IRC assessment N=1**
Month 24	100 (100, 100)	100 (100, 100)
Month 27	100 (100, 100)	100 (100, 100)
Month 30	100 (100, 100)	100 (100, 100)
Month 33	100 (100, 100)	100 (100, 100)
Month 36	100 (100, 100)	100 (100, 100)
Month 39	100 (100, 100)	100 (100, 100)
Month 42	100 (100, 100)	100 (100, 100)
Month 45	100 (100, 100)	100 (100, 100)
Month 48	100 (100, 100)	100 (100, 100)
Month 51	100 (100, 100)	100 (100, 100)
Month 54	100 (100, 100)	100 (100, 100)
Month 57	100 (100, 100)	100 (100, 100)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305h
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No	**Local assessment N=66**	**IRC assessment N=66**
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.3 (4.6, 17.8)	8.3 (4.6, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.8, 97.5)	93.5 (83.6, 97.5)
Month 6	80.9 (68.1, 89.0)	80.8 (68.0, 88.9)
Month 9	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 12	67.5 (53.3, 78.2)	67.4 (53.2, 78.1)
Month 15	65.2 (50.8, 76.3)	65.1 (50.8, 76.3)
Month 18	62.9 (48.3, 74.4)	62.8 (48.2, 74.3)
Month 21	60.6 (45.8, 72.4)	60.5 (45.8, 72.4)

Hypodiploidy: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 27	58.2 (43.4, 70.4)	58.2 (43.4, 70.4)
Month 30	55.9 (41.1, 68.4)	55.8 (41.0, 68.3)
Month 33	55.9 (41.1, 68.4)	53.5 (38.7, 66.3)
Month 36	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 39	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 42	53.6 (38.7, 66.3)	53.5 (38.7, 66.3)
Month 45	51.1 (36.3, 64.2)	51.1 (36.2, 64.1)
Month 48	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 51	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 54	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 57	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 60	48.7 (33.9, 62.0)	48.6 (33.9, 61.9)
Month 63	NE	NE

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

Table 305i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes	**Local assessment N=1**	**IRC assessment N=1**
Events/Responders (%)	0/1 (0.0)	0/1 (0.0)
Maximum follow-up (months)	1.6	1.6
Median follow-up (months)	1.56	1.56
Percentiles (95% CI) [1]		
25th	NE	NE
50th	NE	NE
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	NE	NE
Month 6	NE	NE
Month 9	NE	NE
Month 12	NE	NE
Month 15	NE	NE
Month 18	NE	NE
Month 21	NE	NE

BCR-ABL1-like: Yes

	Local assessment N=1	IRC assessment N=1
Month 24	NE	NE
Month 27	NE	NE
Month 30	NE	NE
Month 33	NE	NE
Month 36	NE	NE
Month 39	NE	NE
Month 42	NE	NE
Month 45	NE	NE
Month 48	NE	NE
Month 51	NE	NE
Month 54	NE	NE
Month 57	NE	NE
Month 60	NE	NE
Month 63	NE	NE

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

Table 305i
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	Local assessment N=66	IRC assessment N=66
Events/Responders (%)	26/66 (39.4)	26/66 (39.4)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	8.3 (4.9, 17.8)	8.3 (4.9, 17.8)
50th	46.8 (17.8, NE)	46.8 (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (83.9, 97.6)	93.6 (83.9, 97.6)
Month 6	81.2 (68.6, 89.2)	81.1 (68.5, 89.1)
Month 9	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 12	68.0 (54.0, 78.6)	68.0 (54.0, 78.5)
Month 15	65.8 (51.6, 76.8)	65.8 (51.6, 76.7)
Month 18	63.6 (49.2, 74.9)	63.5 (49.1, 74.9)
Month 21	61.3 (46.7, 73.0)	61.2 (46.7, 72.9)

BCR-ABL1-like: No		
	Local assessment N=66	**IRC assessment N=66**
Month 24	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 27	59.0 (44.4, 71.0)	59.0 (44.3, 71.0)
Month 30	56.8 (42.1, 69.1)	56.7 (42.0, 69.0)
Month 33	56.8 (42.1, 69.1)	54.4 (39.7, 67.0)
Month 36	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 39	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 42	54.5 (39.8, 67.0)	54.4 (39.7, 67.0)
Month 45	52.1 (37.4, 64.9)	52.1 (37.4, 64.9)
Month 48	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 51	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 54	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 57	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 60	49.8 (35.1, 62.8)	49.7 (35.0, 62.8)
Month 63	NE	NE

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

Table 305j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**Local assessment N=22**	**IRC assessment N=22**
Events/Responders (%)	9/22 (40.9)	9/22 (40.9)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.44	8.44
Percentiles (95% CI) [1]		
25th	8.3 (2.5, 22.7)	8.3 (2.5, 22.7)
50th	22.7 (8.0, NE)	22.7 (8.0, NE)
75th	NE (22.7, NE)	NE (22.7, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (70.7, 99.3)	95.2 (70.7, 99.3)
Month 6	82.9 (55.4, 94.2)	82.9 (55.4, 94.2)
Month 9	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 12	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 15	63.8 (36.1, 82.0)	63.8 (36.1, 82.0)
Month 18	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)
Month 21	54.7 (26.5, 76.0)	54.7 (26.5, 76.0)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes		
	Local assessment N=22	**IRC assessment N=22**
Month 24	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 27	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 30	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 33	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 36	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 39	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 42	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 45	45.6 (18.7, 69.2)	45.6 (18.7, 69.2)
Month 48	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 51	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 54	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 57	34.2 (10.0, 60.7)	34.2 (10.0, 60.7)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305j
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No		
	Local assessment N=45	**IRC assessment N=45**
Events/Responders (%)	17/45 (37.8)	17/45 (37.8)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	13.96	13.96
Percentiles (95% CI) [1]		
25th	7.6 (4.0, 27.8)	7.6 (4.0, 27.8)
50th	NE (14.0, NE)	NE (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	92.9 (79.6, 97.7)	92.9 (79.5, 97.6)
Month 6	80.2 (64.2, 89.6)	80.0 (63.9, 89.5)
Month 9	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 12	69.6 (52.6, 81.5)	69.4 (52.4, 81.4)
Month 15	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 18	66.6 (49.3, 79.1)	66.4 (49.1, 79.0)
Month 21	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)

Complex karyotypes II (>=5 unrelated abnormalities) : No		
	Local assessment N=45	**IRC assessment N=45**
Month 24	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 27	63.5 (46.1, 76.7)	63.4 (45.9, 76.6)
Month 30	60.5 (43.0, 74.2)	60.4 (42.8, 74.1)
Month 33	60.5 (43.0, 74.2)	57.4 (39.8, 71.5)
Month 36	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 39	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 42	57.5 (39.9, 71.6)	57.4 (39.8, 71.5)
Month 45	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 48	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 51	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 54	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 57	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 60	54.5 (37.0, 69.0)	54.3 (36.9, 68.9)
Month 63	NE	NE

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

Table 305k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Europe	**Local assessment N=26**	**IRC assessment N=26**
Events/Responders (%)	9/26 (34.6)	9/26 (34.6)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	14.59	14.59
Percentiles (95% CI) [1]		
25th	17.8 (2.1, 46.8)	17.8 (2.1, 46.8)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.8 (73.9, 99.4)	95.8 (73.9, 99.4)
Month 6	87.1 (65.0, 95.7)	87.1 (65.0, 95.7)
Month 9	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 12	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 15	77.4 (53.8, 90.0)	77.4 (53.8, 90.0)
Month 18	71.5 (46.6, 86.2)	71.5 (46.6, 86.2)
Month 21	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)

Region: Europe

	Local assessment N=26	IRC assessment N=26
Month 24	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 27	65.5 (40.2, 82.1)	65.5 (40.2, 82.1)
Month 30	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 33	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 36	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 39	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 42	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 45	59.5 (34.4, 77.7)	59.5 (34.4, 77.7)
Month 48	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 51	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 54	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 57	53.6 (29.0, 73.0)	53.6 (29.0, 73.0)
Month 60	53.6 (29.0, 73.0)	NE
Month 63	NE	NE

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

Table 305k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US	**Local assessment N=36**	**IRC assessment N=36**
Events/Responders (%)	13/36 (36.1)	13/36 (36.1)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	8.15	8.15
Percentiles (95% CI) [1]		
25th	7.5 (4.0, 8.6)	7.5 (4.0, 8.6)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (78.7, 98.5)	94.2 (78.7, 98.5)
Month 6	77.0 (57.6, 88.4)	76.9 (57.4, 88.3)
Month 9	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 12	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 15	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 18	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 21	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)

Region: US

	Local assessment N=36	IRC assessment N=36
Month 24	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 27	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 30	58.7 (38.6, 74.2)	58.6 (38.5, 74.1)
Month 33	58.7 (38.6, 74.2)	54.1 (33.9, 70.5)
Month 36	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 39	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 42	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 45	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 48	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 51	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 54	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 57	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 60	54.2 (34.0, 70.6)	54.1 (33.9, 70.5)
Month 63	NE	NE

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

Table 305k
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Rest of World	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	4/5 (80.0)	4/5 (80.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	14.0 (2.5, 44.5)	14.0 (2.5, 44.5)
50th	22.7 (2.5, NE)	22.7 (2.5, NE)
75th	44.5 (2.5, NE)	44.5 (2.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Region: Rest of World

	Local assessment N=5	IRC assessment N=5
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 48	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 51	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 54	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 57	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes	**Local assessment N=42**	**IRC assessment N=42**
Events/Responders (%)	15/42 (35.7)	15/42 (35.7)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	15.87	15.87
Percentiles (95% CI) [1]		
25th	14.0 (4.9, 33.8)	14.0 (4.9, 32.9)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	95.2 (82.3, 98.8)	95.2 (82.1, 98.8)
Month 6	81.9 (65.7, 91.0)	81.8 (65.5, 90.9)
Month 9	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 12	76.3 (59.2, 86.9)	76.2 (59.1, 86.9)
Month 15	72.8 (55.0, 84.5)	72.7 (54.9, 84.4)
Month 18	69.3 (51.1, 81.9)	69.2 (51.0, 81.8)
Month 21	65.9 (47.3, 79.2)	65.8 (47.2, 79.2)

Prior SCT therapy: Yes		
	Local assessment N=42	**IRC assessment N=42**
Month 24	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 27	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 30	62.4 (43.7, 76.5)	62.3 (43.6, 76.4)
Month 33	62.4 (43.7, 76.5)	58.8 (40.1, 73.5)
Month 36	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 39	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 42	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 45	58.9 (40.1, 73.6)	58.8 (40.1, 73.5)
Month 48	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 51	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 54	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 57	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 60	55.2 (36.5, 70.5)	55.2 (36.4, 70.5)
Month 63	NE	NE

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

Table 305l
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No	**Local assessment N=25**	**IRC assessment N=25**
Events/Responders (%)	11/25 (44.0)	11/25 (44.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	7.5 (1.6, 8.6)
50th	27.8 (7.5, NE)	27.8 (7.5, NE)
75th	NE (27.8, NE)	NE (27.8, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	90.9 (68.1, 97.6)	90.7 (67.6, 97.6)
Month 6	80.5 (55.7, 92.2)	80.3 (55.5, 92.1)
Month 9	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 12	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 15	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 18	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 21	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)

Prior SCT therapy: No		
	Local assessment N=25	**IRC assessment N=25**
Month 24	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 27	51.7 (27.4, 71.5)	51.6 (27.3, 71.4)
Month 30	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 33	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 36	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 39	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 42	45.3 (21.8, 66.2)	45.2 (21.8, 66.1)
Month 45	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 48	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 51	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 54	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 57	38.8 (16.8, 60.5)	38.7 (16.8, 60.4)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes	**Local assessment N=12**	**IRC assessment N=12**
Events/Responders (%)	5/12 (41.7)	5/12 (41.7)
Maximum follow-up (months)	59.3	59.3
Median follow-up (months)	10.91	10.91
Percentiles (95% CI) [1]		
25th	14.0 (1.6, 44.5)	14.0 (1.6, 44.5)
50th	22.7 (4.9, NE)	22.7 (4.9, NE)
75th	44.5 (14.0, NE)	44.5 (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (53.9, 98.8)	91.7 (53.9, 98.8)
Month 6	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 9	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 12	80.2 (40.3, 94.8)	80.2 (40.3, 94.8)
Month 15	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 18	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)
Month 21	64.2 (22.5, 87.6)	64.2 (22.5, 87.6)

Eligibility for SCT: Yes

	Local assessment N=12	IRC assessment N=12
Month 24	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 27	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 30	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 33	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 36	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 39	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 42	48.1 (11.9, 77.8)	48.1 (11.9, 77.8)
Month 45	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 48	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 51	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 54	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 57	24.1 (1.3, 62.7)	24.1 (1.3, 62.7)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305m
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No	**Local assessment N=55**	**IRC assessment N=55**
Events/Responders (%)	21/55 (38.2)	21/55 (38.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.38	10.38
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 20.0)	8.0 (4.6, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.2 (83.1, 98.1)	94.2 (83.1, 98.1)
Month 6	81.5 (67.4, 89.9)	81.5 (67.4, 89.9)
Month 9	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 12	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 15	65.7 (50.1, 77.5)	65.7 (50.1, 77.5)
Month 18	63.1 (47.3, 75.3)	63.1 (47.3, 75.3)
Month 21	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)

Eligibility for SCT: No		
	Local assessment N=55	**IRC assessment N=55**
Month 24	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 27	60.4 (44.5, 73.1)	60.4 (44.5, 73.1)
Month 30	57.8 (41.8, 70.9)	57.8 (41.8, 70.9)
Month 33	57.8 (41.8, 70.9)	55.2 (39.2, 68.6)
Month 36	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 39	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 42	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 45	55.2 (39.2, 68.6)	55.2 (39.2, 68.6)
Month 48	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 51	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 54	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 57	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 60	52.6 (36.6, 66.2)	52.6 (36.6, 66.2)
Month 63	NE	NE

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

Table 305n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low		
	Local assessment N=25	**IRC assessment N=25**
Events/Responders (%)	10/25 (40.0)	10/25 (40.0)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	16.62	16.62
Percentiles (95% CI) [1]		
25th	8.3 (1.6, 27.8)	8.3 (1.6, 27.8)
50th	NE (8.3, NE)	NE (8.3, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	91.7 (70.6, 97.8)	91.7 (70.6, 97.8)
Month 6	82.7 (60.2, 93.2)	82.7 (60.2, 93.2)
Month 9	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 12	73.2 (49.7, 87.0)	73.2 (49.7, 87.0)
Month 15	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 18	68.0 (44.0, 83.4)	68.0 (44.0, 83.4)
Month 21	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)

Baseline bone marrow tumor burden: Low		
	Local assessment N=25	**IRC assessment N=25**
Month 24	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 27	62.3 (38.1, 79.3)	62.3 (38.1, 79.3)
Month 30	56.7 (32.6, 75.0)	56.7 (32.6, 75.0)
Month 33	56.7 (32.6, 75.0)	51.0 (27.5, 70.4)
Month 36	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 39	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 42	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 45	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 48	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 51	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 54	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 57	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 60	51.0 (27.5, 70.4)	51.0 (27.5, 70.4)
Month 63	NE	NE

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

Table 305n
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High		
	Local assessment N=42	**IRC assessment N=42**
Events/Responders (%)	16/42 (38.1)	16/42 (38.1)
Maximum follow-up (months)	59.6	59.6
Median follow-up (months)	8.95	8.95
Percentiles (95% CI) [1]		
25th	8.0 (4.2, 22.7)	8.0 (4.2, 22.7)
50th	46.8 (8.6, NE)	46.8 (8.6, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.9 (81.0, 98.7)	94.8 (80.8, 98.7)
Month 6	80.3 (62.9, 90.1)	80.1 (62.7, 90.0)
Month 9	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 12	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 15	64.8 (46.3, 78.4)	64.7 (46.2, 78.3)
Month 18	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)
Month 21	61.0 (42.1, 75.4)	60.9 (42.0, 75.3)

Baseline bone marrow tumor burden: High		
	Local assessment N=42	**IRC assessment N=42**
Month 24	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 27	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 30	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 33	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 36	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 39	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 42	57.2 (38.2, 72.3)	57.1 (38.1, 72.2)
Month 45	53.1 (34.1, 69.0)	53.0 (34.0, 68.9)
Month 48	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 51	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 54	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 57	49.0 (30.1, 65.5)	48.9 (30.0, 65.4)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes		
	Local assessment N=11	**IRC assessment N=11**
Events/Responders (%)	3/11 (27.3)	3/11 (27.3)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	33.35	33.35
Percentiles (95% CI) [1]		
25th	33.8 (2.1, NE)	32.9 (2.1, NE)
50th	NE (2.1, NE)	NE (2.1, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	90.0 (47.3, 98.5)	90.0 (47.3, 98.5)
Month 6	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 9	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 12	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 15	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 18	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 21	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)

Baseline extramedullary disease presence: Yes		
	Local assessment N=11	**IRC assessment N=11**
Month 24	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 27	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 30	78.8 (38.1, 94.3)	78.8 (38.1, 94.3)
Month 33	78.8 (38.1, 94.3)	65.6 (26.0, 87.6)
Month 36	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 39	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 42	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 45	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 48	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 51	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 54	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 57	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 60	65.6 (26.0, 87.6)	65.6 (26.0, 87.6)
Month 63	NE	NE

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

Table 305o
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No		
	Local assessment N=56	**IRC assessment N=56**
Events/Responders (%)	23/56 (41.1)	23/56 (41.1)
Maximum follow-up (months)	59.8	59.8
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.0 (4.6, 17.8)	8.0 (4.6, 17.8)
50th	44.5 (14.0, NE)	44.5 (14.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	94.3 (83.5, 98.1)	94.3 (83.3, 98.1)
Month 6	81.6 (67.6, 90.0)	81.5 (67.4, 89.9)
Month 9	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 12	66.2 (50.7, 77.8)	66.1 (50.6, 77.7)
Month 15	63.5 (47.8, 75.6)	63.4 (47.8, 75.6)
Month 18	60.8 (44.9, 73.4)	60.7 (44.8, 73.3)
Month 21	58.0 (42.0, 71.0)	57.9 (41.9, 71.0)

Baseline extramedullary disease presence: No		
	Local assessment N=56	**IRC assessment N=56**
Month 24	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 27	55.2 (39.2, 68.7)	55.2 (39.1, 68.6)
Month 30	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 33	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 36	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 39	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 42	52.5 (36.4, 66.3)	52.4 (36.4, 66.2)
Month 45	49.6 (33.6, 63.7)	49.5 (33.5, 63.6)
Month 48	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 51	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 54	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 57	46.6 (30.8, 61.1)	46.6 (30.7, 61.0)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes	**Local assessment N=5**	**IRC assessment N=5**
Events/Responders (%)	3/5 (60.0)	3/5 (60.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	22.70	22.70
Percentiles (95% CI) [1]		
25th	7.5 (4.6, NE)	7.5 (4.6, NE)
50th	22.7 (4.6, NE)	22.7 (4.6, NE)
75th	NE (4.6, NE)	NE (4.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)
Month 9	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 12	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 15	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Down syndrome: Yes		
	Local assessment N=5	**IRC assessment N=5**
Month 24	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 27	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 30	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 33	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 36	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 39	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 42	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 45	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 48	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 51	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 54	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 57	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305p
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No	**Local assessment N=62**	**IRC assessment N=62**
Events/Responders (%)	23/62 (37.1)	23/62 (37.1)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	10.56	10.56
Percentiles (95% CI) [1]		
25th	8.6 (4.9, 20.0)	8.6 (4.9, 20.0)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (82.7, 97.4)	93.1 (82.6, 97.3)
Month 6	81.4 (68.1, 89.6)	81.3 (67.9, 89.5)
Month 9	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 12	68.9 (54.2, 79.7)	68.8 (54.1, 79.7)
Month 15	66.4 (51.4, 77.8)	66.3 (51.3, 77.7)
Month 18	63.9 (48.6, 75.7)	63.8 (48.5, 75.6)
Month 21	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)

Down syndrome: No		
	Local assessment N=62	**IRC assessment N=62**
Month 24	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 27	61.3 (45.9, 73.6)	61.2 (45.8, 73.5)
Month 30	58.8 (43.2, 71.4)	58.7 (43.1, 71.3)
Month 33	58.8 (43.2, 71.4)	56.1 (40.5, 69.1)
Month 36	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 39	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 42	56.2 (40.6, 69.2)	56.1 (40.5, 69.1)
Month 45	53.5 (37.9, 66.9)	53.5 (37.8, 66.8)
Month 48	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 51	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 54	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 57	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 60	50.9 (35.3, 64.5)	50.8 (35.2, 64.4)
Month 63	NE	NE

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

Table 305q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median	**Local assessment N=34**	**IRC assessment N=34**
Events/Responders (%)	14/34 (41.2)	14/34 (41.2)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	18.91	18.91
Percentiles (95% CI) [1]		
25th	8.6 (3.4, 22.7)	8.8 (3.4, 22.7)
50th	NE (17.8, NE)	NE (17.8, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.8 (77.3, 98.4)	93.8 (77.3, 98.4)
Month 6	84.2 (66.0, 93.1)	84.2 (66.0, 93.1)
Month 9	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 12	74.1 (54.7, 86.1)	74.1 (54.7, 86.1)
Month 15	70.2 (50.3, 83.3)	70.2 (50.3, 83.3)
Month 18	66.3 (46.1, 80.4)	66.3 (46.1, 80.4)
Month 21	62.4 (42.1, 77.3)	62.4 (42.1, 77.3)

Time since enrollment to CTL019 infusion: > Median		
	Local assessment N=34	**IRC assessment N=34**
Month 24	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 27	58.5 (38.2, 74.1)	58.5 (38.2, 74.1)
Month 30	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 33	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 36	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 39	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 42	54.6 (34.5, 70.8)	54.6 (34.5, 70.8)
Month 45	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 48	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 51	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 54	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 57	50.4 (30.6, 67.2)	50.4 (30.6, 67.2)
Month 60	50.4 (30.6, 67.2)	NE
Month 63	NE	NE

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

Table 305q
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median	**Local assessment N=33**	**IRC assessment N=33**
Events/Responders (%)	12/33 (36.4)	12/33 (36.4)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	7.98	7.98
Percentiles (95% CI) [1]		
25th	7.5 (4.2, 33.8)	7.5 (4.2, 32.9)
50th	46.8 (8.0, NE)	46.8 (8.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.6 (76.9, 98.4)	93.6 (76.9, 98.4)
Month 6	77.1 (55.6, 89.1)	77.1 (55.6, 89.1)
Month 9	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 12	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 15	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 18	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 21	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)

Time since enrollment to CTL019 infusion: <=Median		
	Local assessment N=33	**IRC assessment N=33**
Month 24	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 27	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 30	60.0 (38.1, 76.3)	60.0 (38.1, 76.3)
Month 33	60.0 (38.1, 76.3)	54.5 (32.4, 72.1)
Month 36	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 39	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 42	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 45	54.5 (32.4, 72.1)	54.5 (32.4, 72.1)
Month 48	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 51	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 54	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 57	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 60	49.1 (27.3, 67.7)	49.1 (27.3, 67.7)
Month 63	NE	NE

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

Table 305r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0		
	Local assessment N=5	**IRC assessment N=5**
Events/Responders (%)	1/5 (20.0)	1/5 (20.0)
Maximum follow-up (months)	59.1	59.1
Median follow-up (months)	7.62	7.62
Percentiles (95% CI) [1]		
25th	7.6 (7.6, NE)	7.6 (7.6, NE)
50th	NE (7.6, NE)	NE (7.6, NE)
75th	NE (7.6, NE)	NE (7.6, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	100 (100, 100)	100 (100, 100)
Month 9	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 12	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 15	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 18	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)

Number of previous relapses: 0		
	Local assessment N=5	**IRC assessment N=5**
Month 24	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 30	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 33	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 36	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 39	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 42	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 45	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 48	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 51	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 54	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 57	66.7 (5.4, 94.5)	66.7 (5.4, 94.5)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1	**Local assessment N=18**	**IRC assessment N=18**
Events/Responders (%)	9/18 (50.0)	9/18 (50.0)
Maximum follow-up (months)	59.4	59.4
Median follow-up (months)	7.90	7.90
Percentiles (95% CI) [1]		
25th	7.5 (1.6, 8.6)	4.9 (1.6, 8.6)
50th	14.0 (4.9, NE)	14.0 (4.9, NE)
75th	NE (14.0, NE)	NE (14.0, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	88.2 (60.6, 96.9)	88.2 (60.6, 96.9)
Month 6	75.1 (46.3, 89.9)	74.7 (45.5, 89.7)
Month 9	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 12	53.1 (25.5, 74.6)	52.8 (25.2, 74.4)
Month 15	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 18	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 21	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)

Number of previous relapses: 1		
	Local assessment N=18	**IRC assessment N=18**
Month 24	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 27	45.5 (19.6, 68.4)	45.2 (19.4, 68.2)
Month 30	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 33	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 36	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 39	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 42	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 45	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 48	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 51	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 54	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 57	36.4 (12.7, 61.0)	36.2 (12.6, 60.8)
Month 60	NE	NE
Month 63	NE	NE

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

Table 305r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Events/Responders (%)	5/14 (35.7)	5/14 (35.7)
Maximum follow-up (months)	60.2	60.2
Median follow-up (months)	9.82	9.82
Percentiles (95% CI) [1]		
25th	5.1 (4.2, NE)	5.1 (4.2, NE)
50th	NE (5.1, NE)	NE (5.1, NE)
75th	NE (44.5, NE)	NE (44.5, NE)
% Event-free probability estimates (95% CI) [2]		
Month 3	100 (100, 100)	100 (100, 100)
Month 6	73.3 (37.9, 90.6)	73.3 (37.9, 90.6)
Month 9	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 12	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 15	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 18	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)

Number of previous relapses: 2		
	Local assessment N=14	**IRC assessment N=14**
Month 21	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 24	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 27	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 30	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 33	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 36	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 39	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 42	64.2 (30.2, 84.8)	64.2 (30.2, 84.8)
Month 45	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 48	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 51	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 54	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 57	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 60	51.3 (18.4, 76.9)	51.3 (18.4, 76.9)
Month 63	NE	NE

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

Table 305r
Duration of remission (DOR) censoring HSCT by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

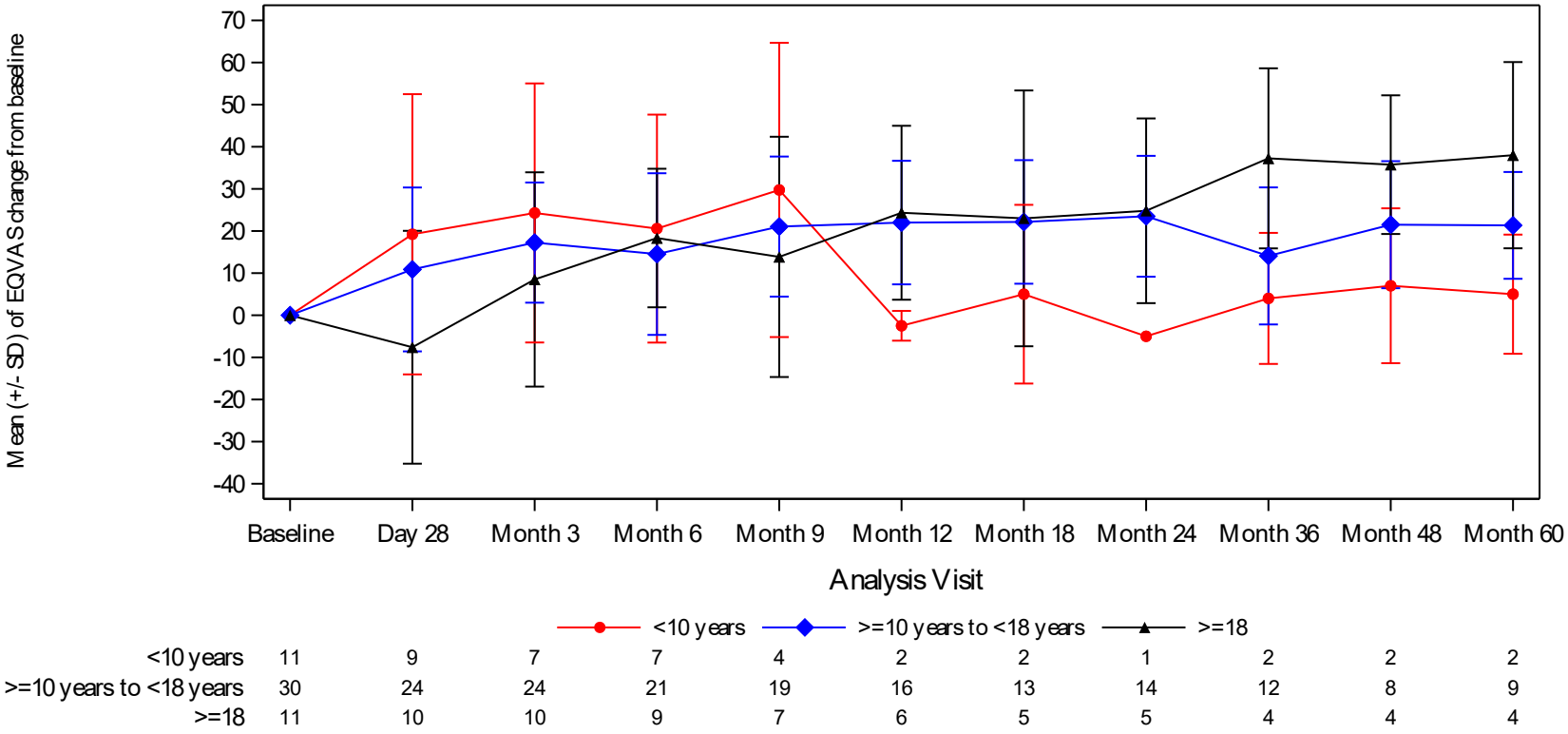
Number of previous relapses: >=3	**Local assessment N=30**	**IRC assessment N=30**
Events/Responders (%)	11/30 (36.7)	11/30 (36.7)
Maximum follow-up (months)	60.5	60.5
Median follow-up (months)	21.37	21.37
Percentiles (95% CI) [1]		
25th	17.8 (4.0, 46.8)	17.8 (4.0, 46.8)
50th	NE (20.0, NE)	NE (20.0, NE)
75th	NE	NE
% Event-free probability estimates (95% CI) [2]		
Month 3	93.1 (75.1, 98.2)	93.1 (75.1, 98.2)
Month 6	85.7 (66.1, 94.4)	85.7 (66.1, 94.4)
Month 9	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 12	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 15	77.9 (57.1, 89.4)	77.9 (57.1, 89.4)
Month 18	73.3 (51.7, 86.4)	73.3 (51.7, 86.4)

Number of previous relapses: >=3

	Local assessment N=30	IRC assessment N=30
Month 21	68.7 (46.7, 83.1)	68.7 (46.7, 83.1)
Month 24	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 27	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 30	64.1 (41.9, 79.7)	64.1 (41.9, 79.7)
Month 33	64.1 (41.9, 79.7)	59.5 (37.4, 76.1)
Month 36	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 39	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 42	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 45	59.5 (37.4, 76.1)	59.5 (37.4, 76.1)
Month 48	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 51	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 54	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 57	54.6 (32.6, 72.1)	54.6 (32.6, 72.1)
Month 60	54.6 (32.6, 72.1)	NE
Month 63	NE	NE

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

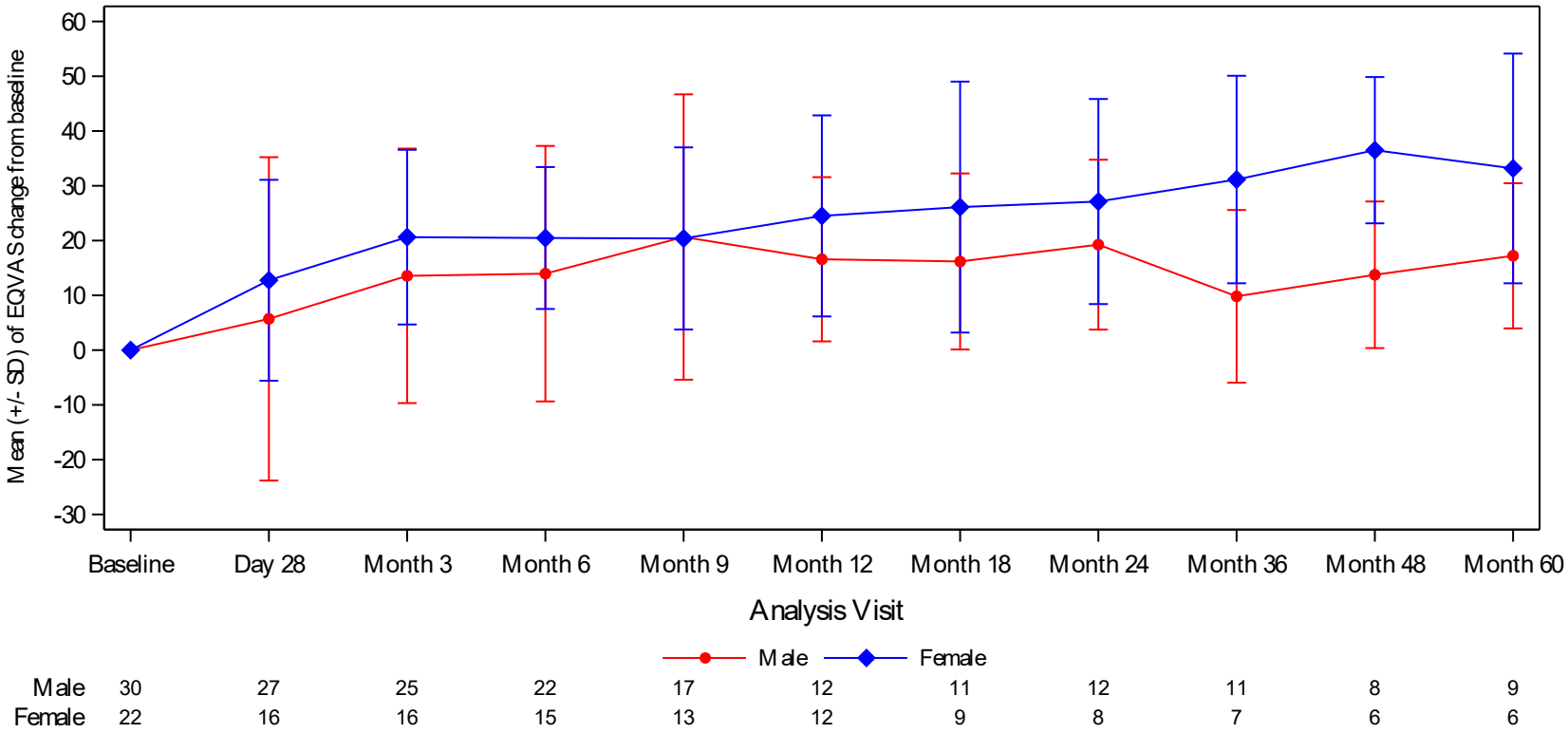
Figure 51a (Page 1 of 1)
Mean change in EQVAS total score over time by Age
Full analysis set - Patients >= 8 years at enrollment



<10 years	11	9	7	7	4	2	2	1	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	13	14	12	8	9
>=18	11	10	10	9	7	6	5	5	4	4	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

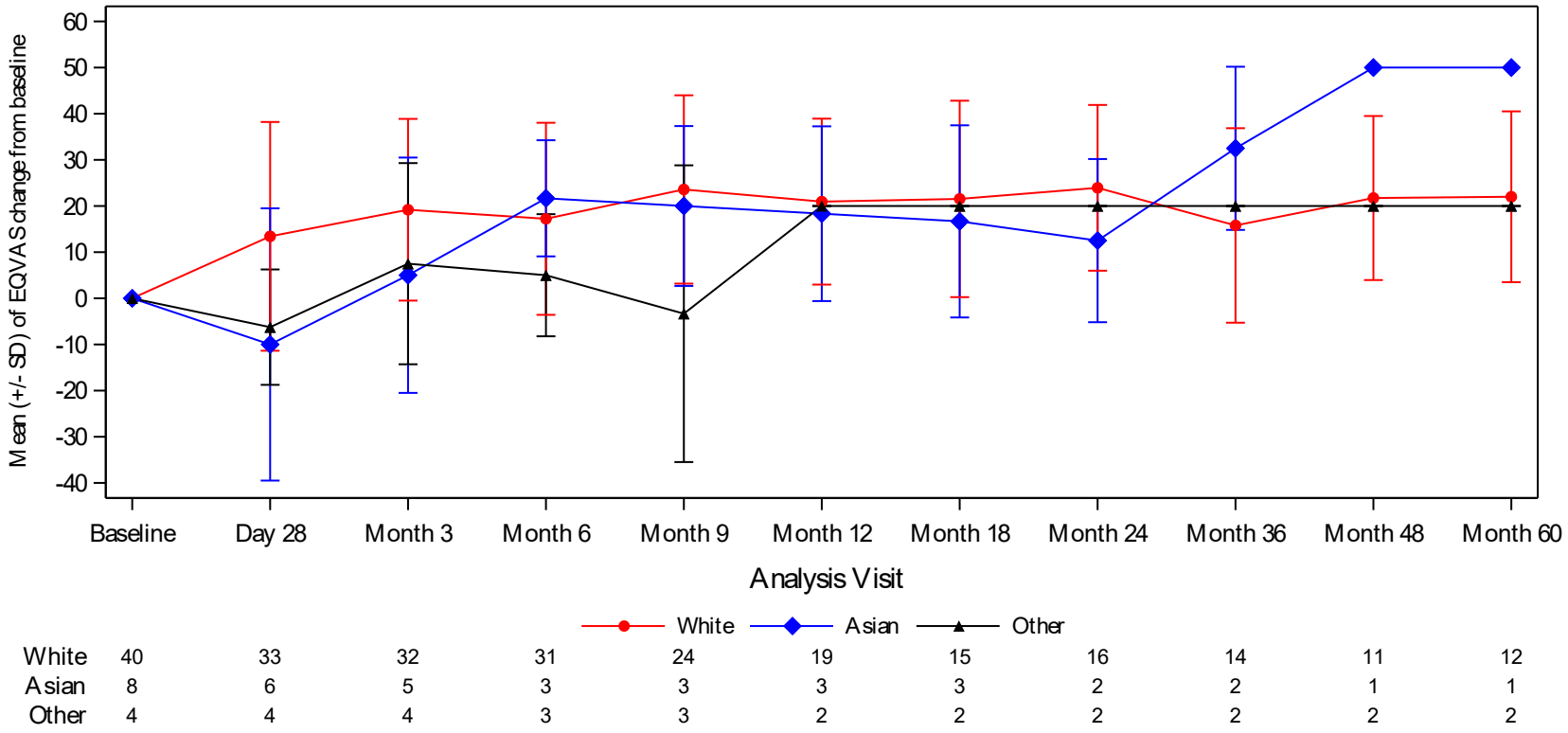
Figure 51b (Page 1 of 1)
Mean change in EQVAS total score over time by Gender
Full analysis set - Patients >= 8 years at enrollment



Male	30	27	25	22	17	12	11	12	11	8	9
Female	22	16	16	15	13	12	9	8	7	6	6

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

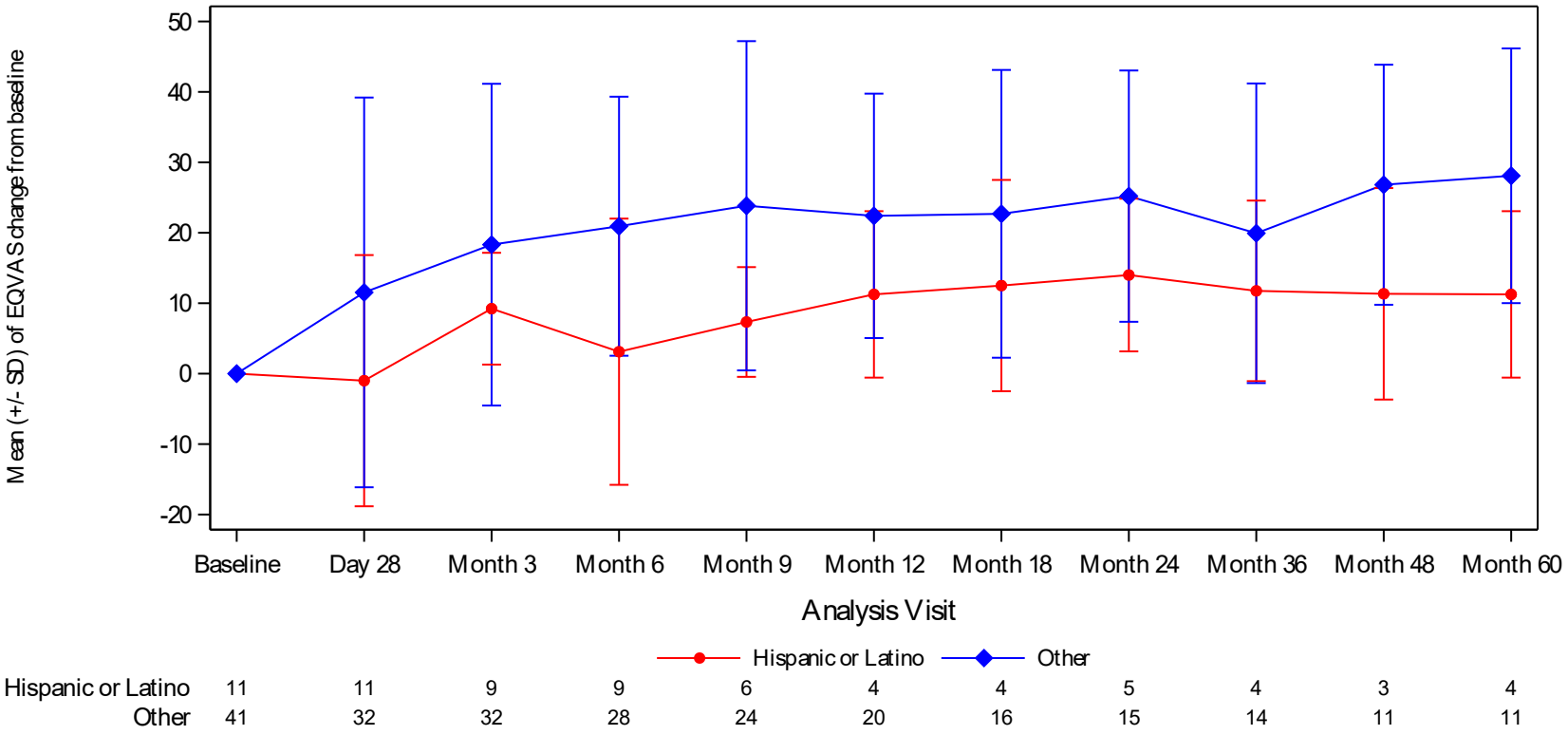
Figure 51c (Page 1 of 1)
Mean change in EQVAS total score over time by Race
Full analysis set - Patients >= 8 years at enrollment



White	40	33	32	31	24	19	15	16	14	11	12
Asian	8	6	5	3	3	3	3	2	2	1	1
Other	4	4	4	3	3	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

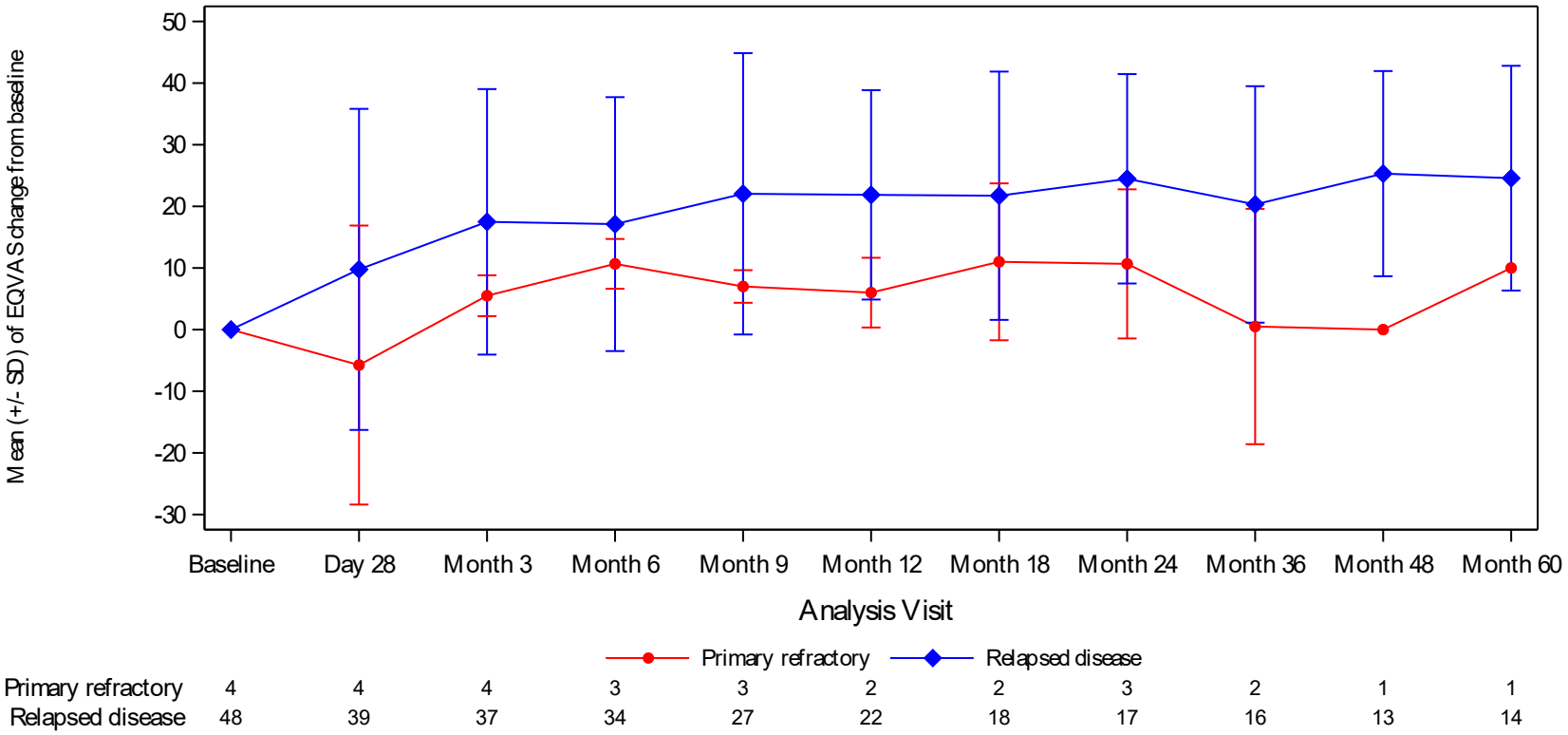
Figure 51d (Page 1 of 1)
Mean change in EQVAS total score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	11	11	9	9	6	4	4	5	4	3	4
Other	41	32	32	28	24	20	16	15	14	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

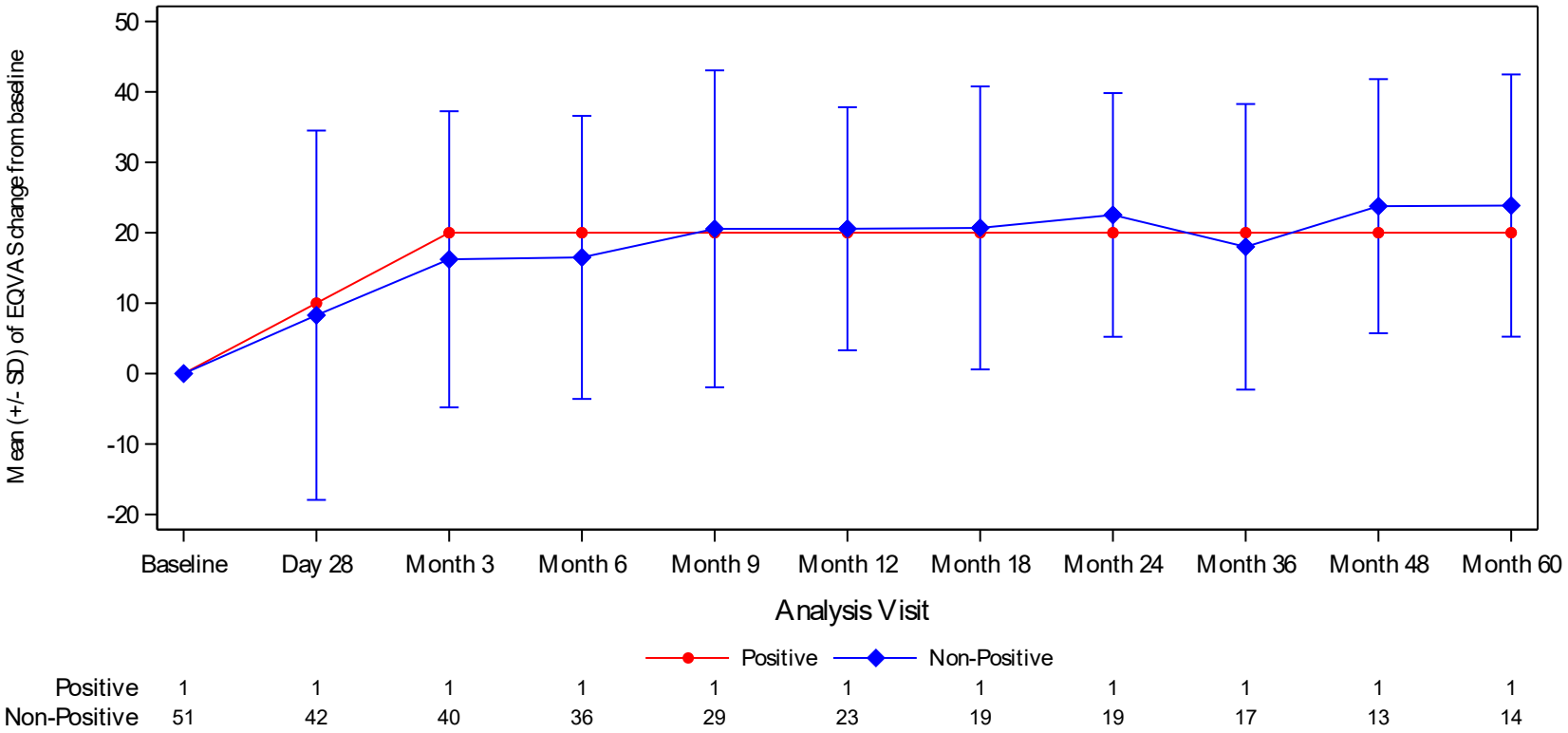
Figure 51e (Page 1 of 1)
Mean change in EQVAS total score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Primary refractory	4	4	4	3	3	2	2	3	2	1	1
Relapsed disease	48	39	37	34	27	22	18	17	16	13	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

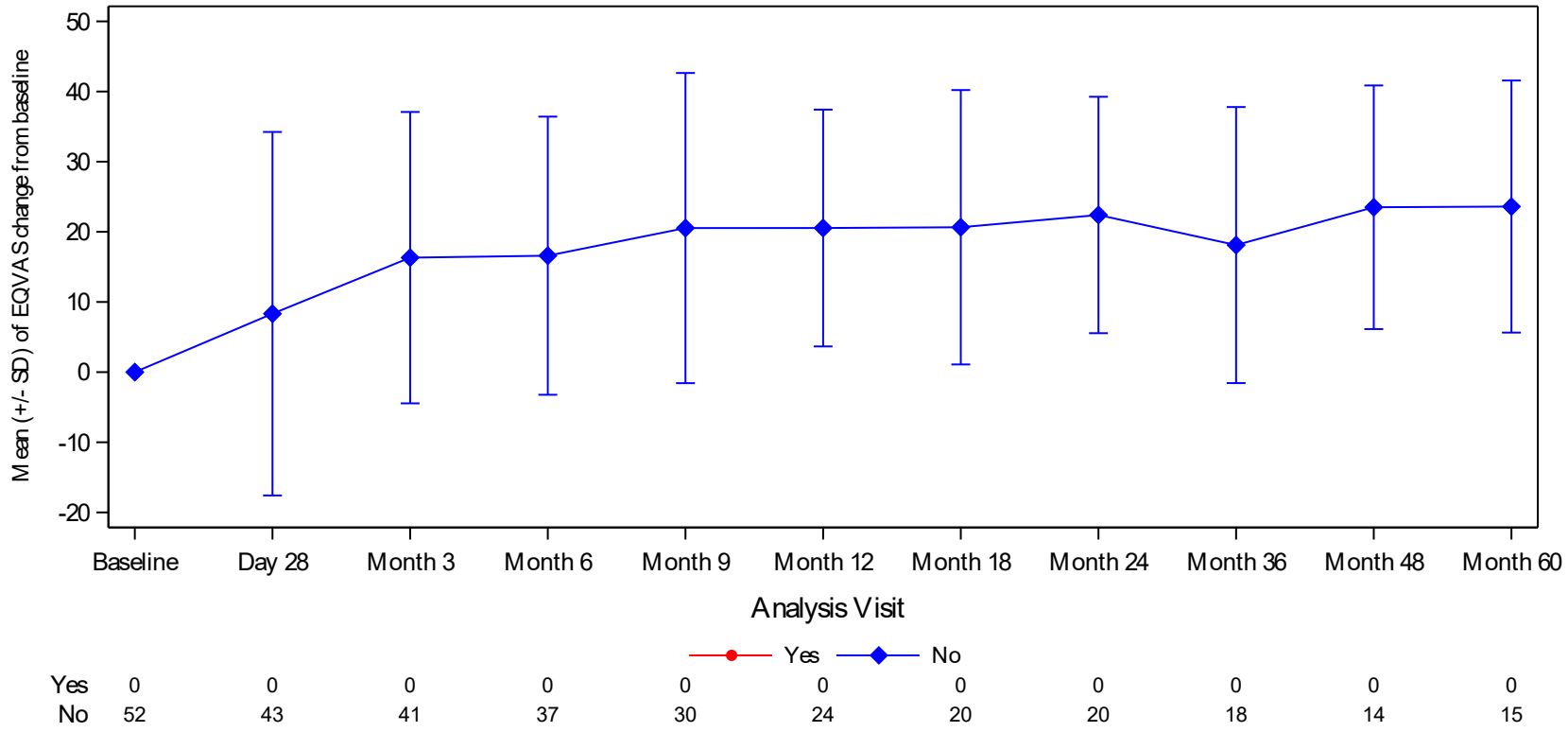
Figure 51f (Page 1 of 1)
Mean change in EQVAS total score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	42	40	36	29	23	19	19	17	13	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

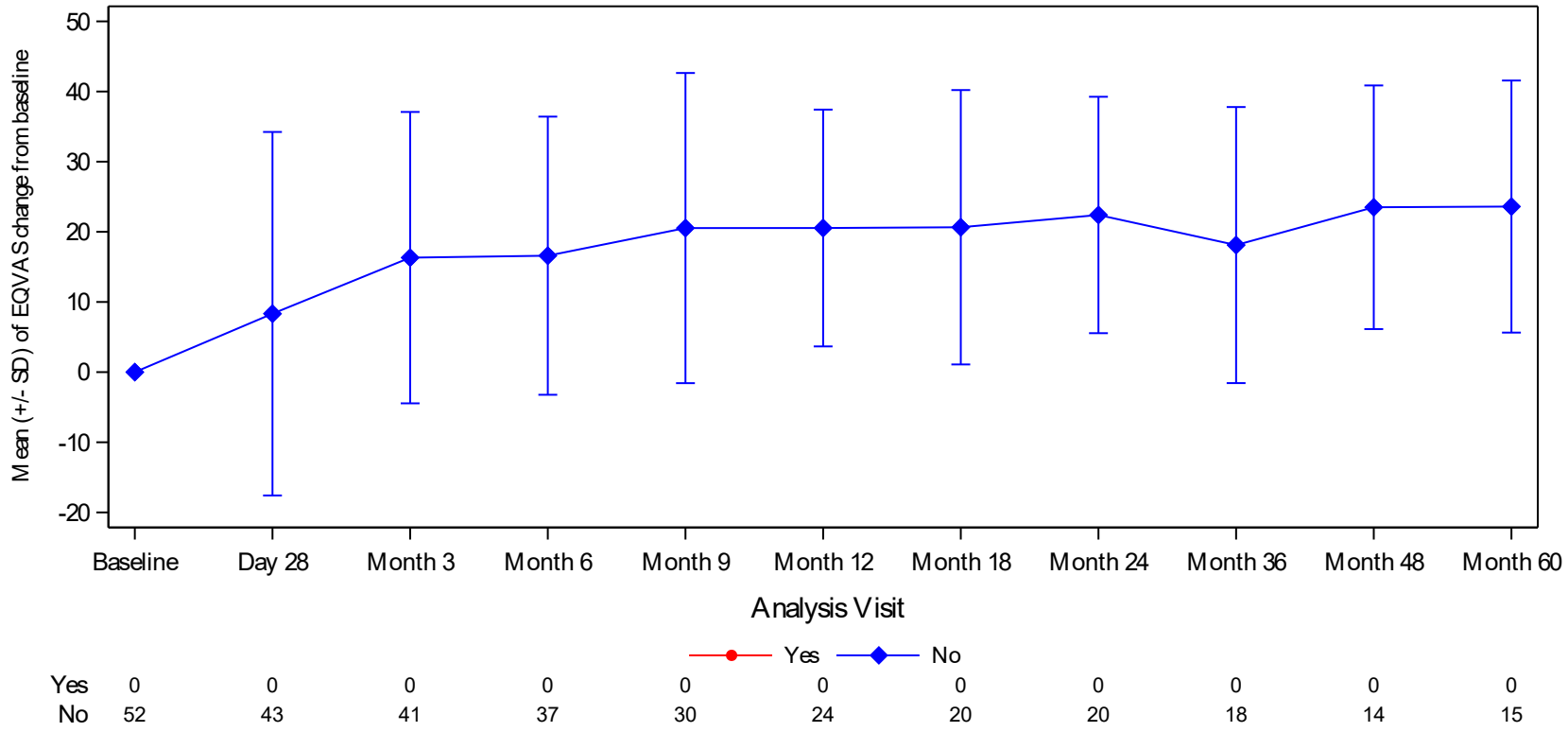
Figure 51g (Page 1 of 1)
Mean change in EQVAS total score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	43	41	37	30	24	20	20	18	14	15

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

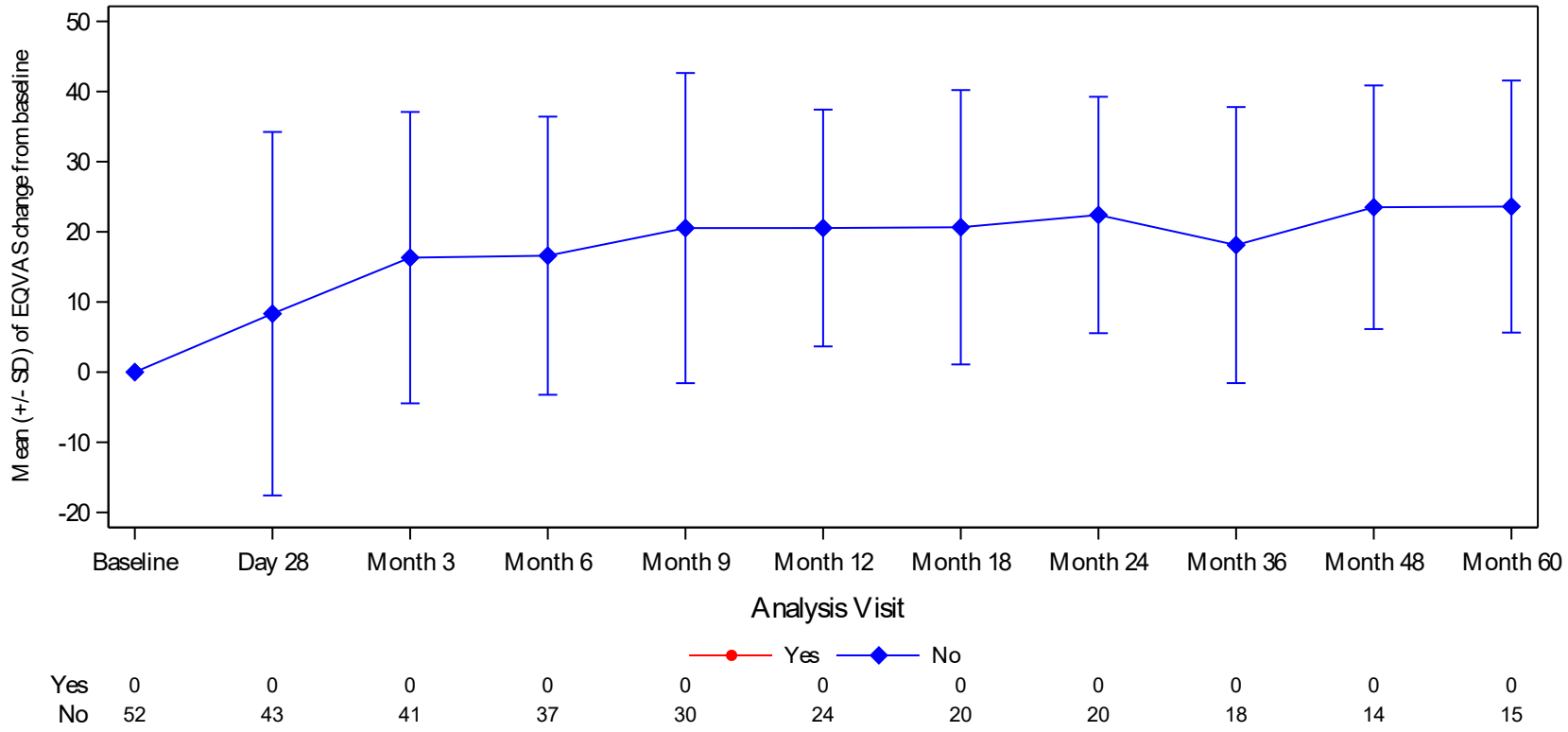
Figure 51h (Page 1 of 1)
Mean change in EQVAS total score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	43	41	37	30	24	20	20	18	14	15

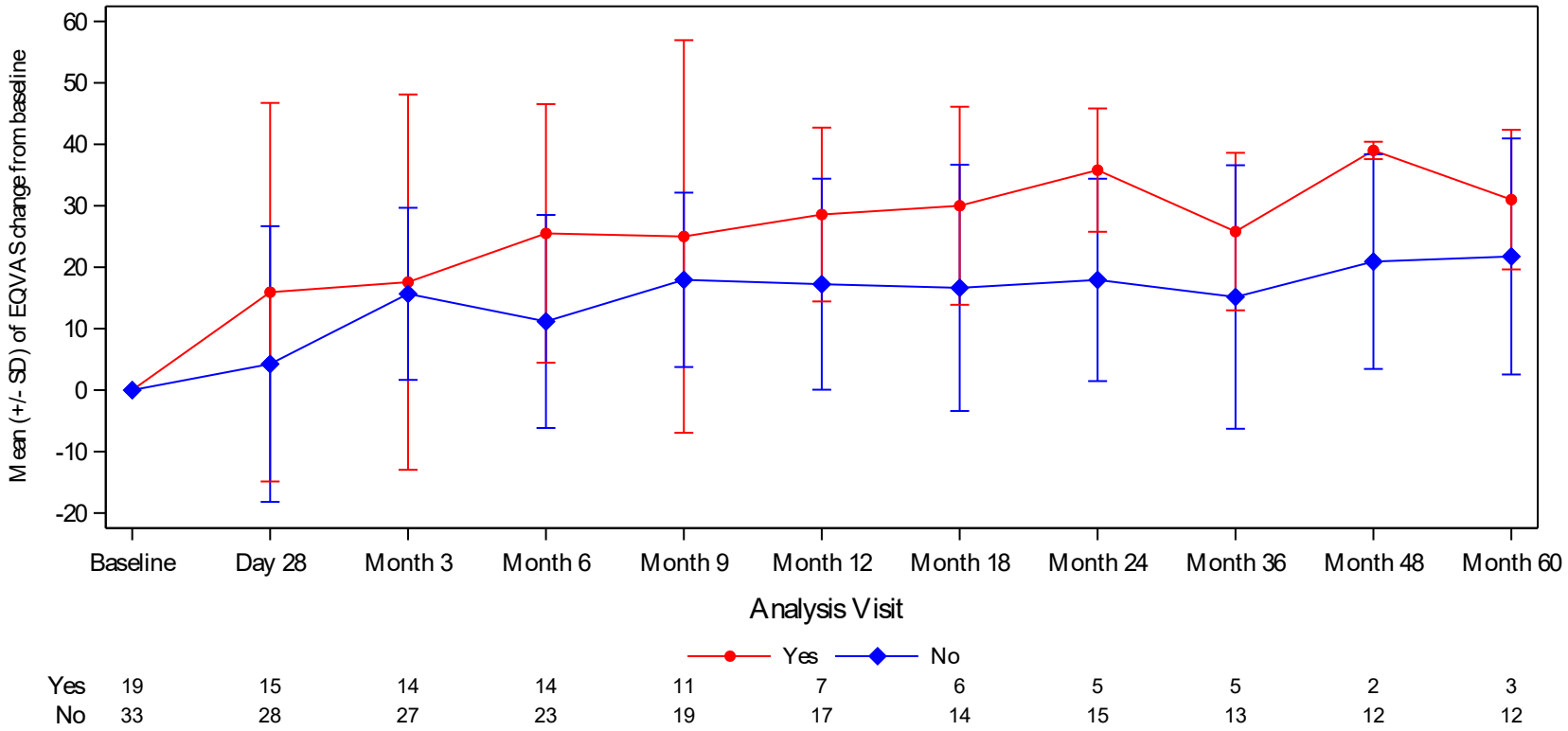
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 51i (Page 1 of 1)
Mean change in EQVAS total score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

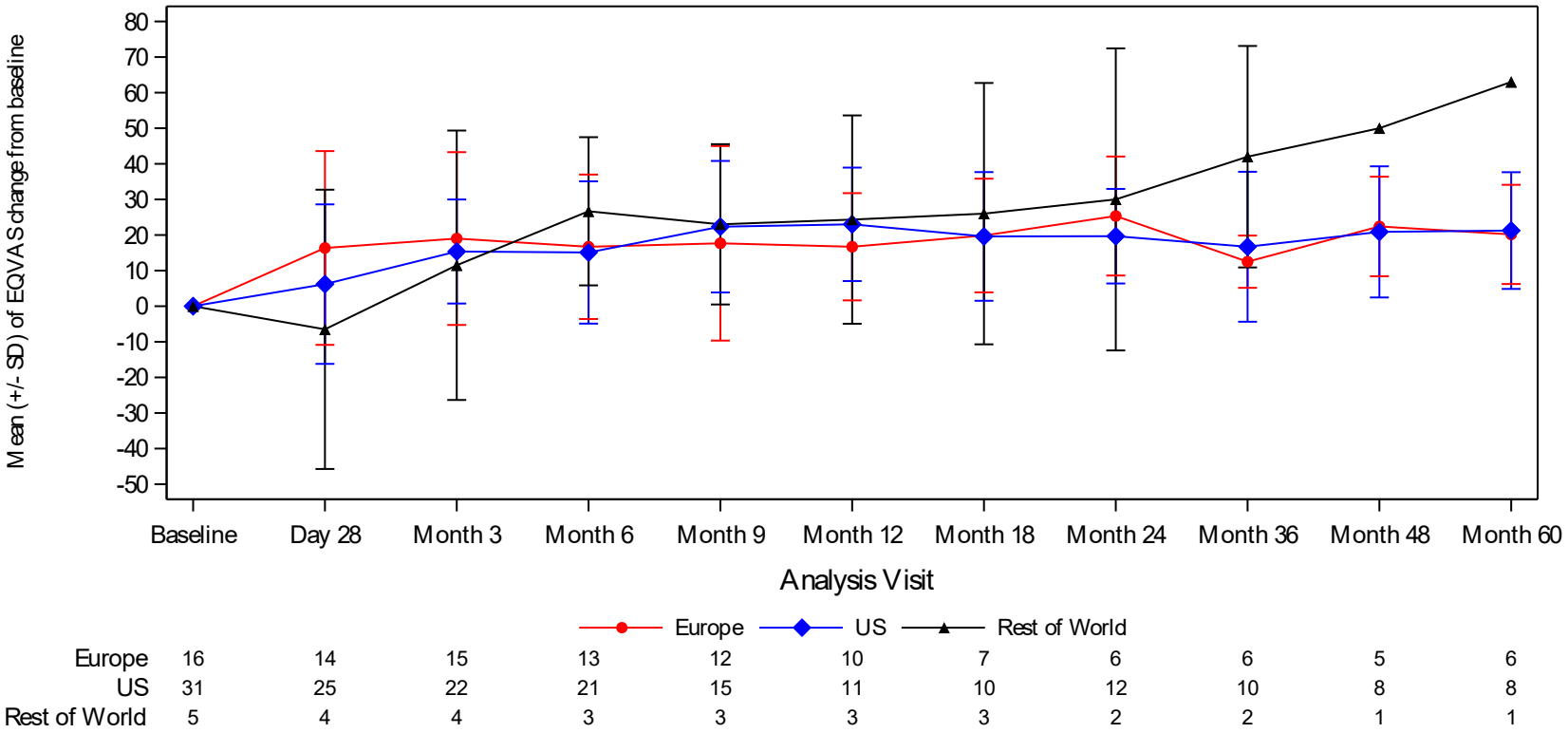
Figure 51j (Page 1 of 1)
Mean change in EQVAS total score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	19	15	14	14	11	7	6	5	5	2	3
No	33	28	27	23	19	17	14	15	13	12	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

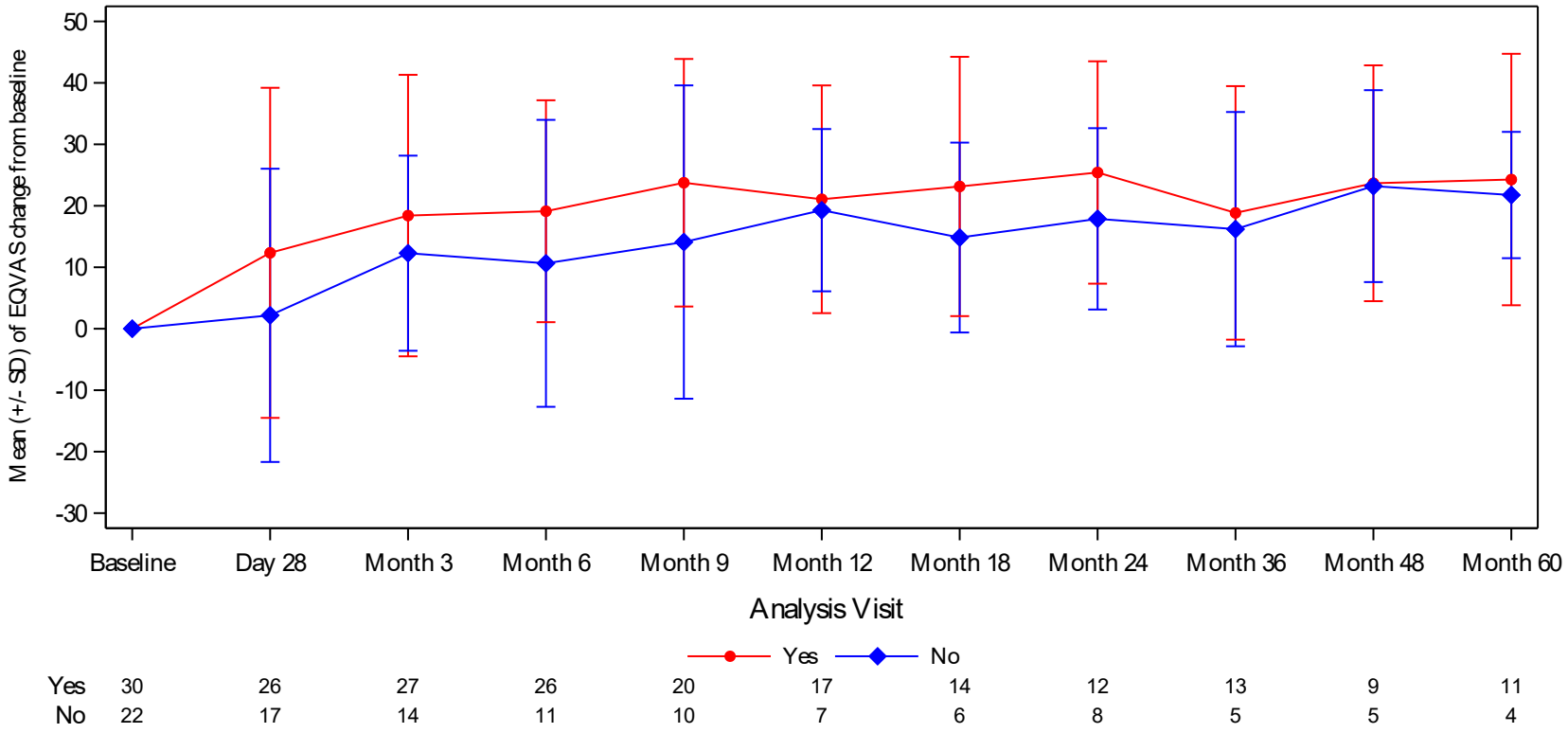
Figure 51k (Page 1 of 1)
Mean change in EQVAS total score over time by Region
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Europe	16	14	15	13	12	10	7	6	6	5	6
US	31	25	22	21	15	11	10	12	10	8	8
Rest of World	5	4	4	3	3	3	3	2	2	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

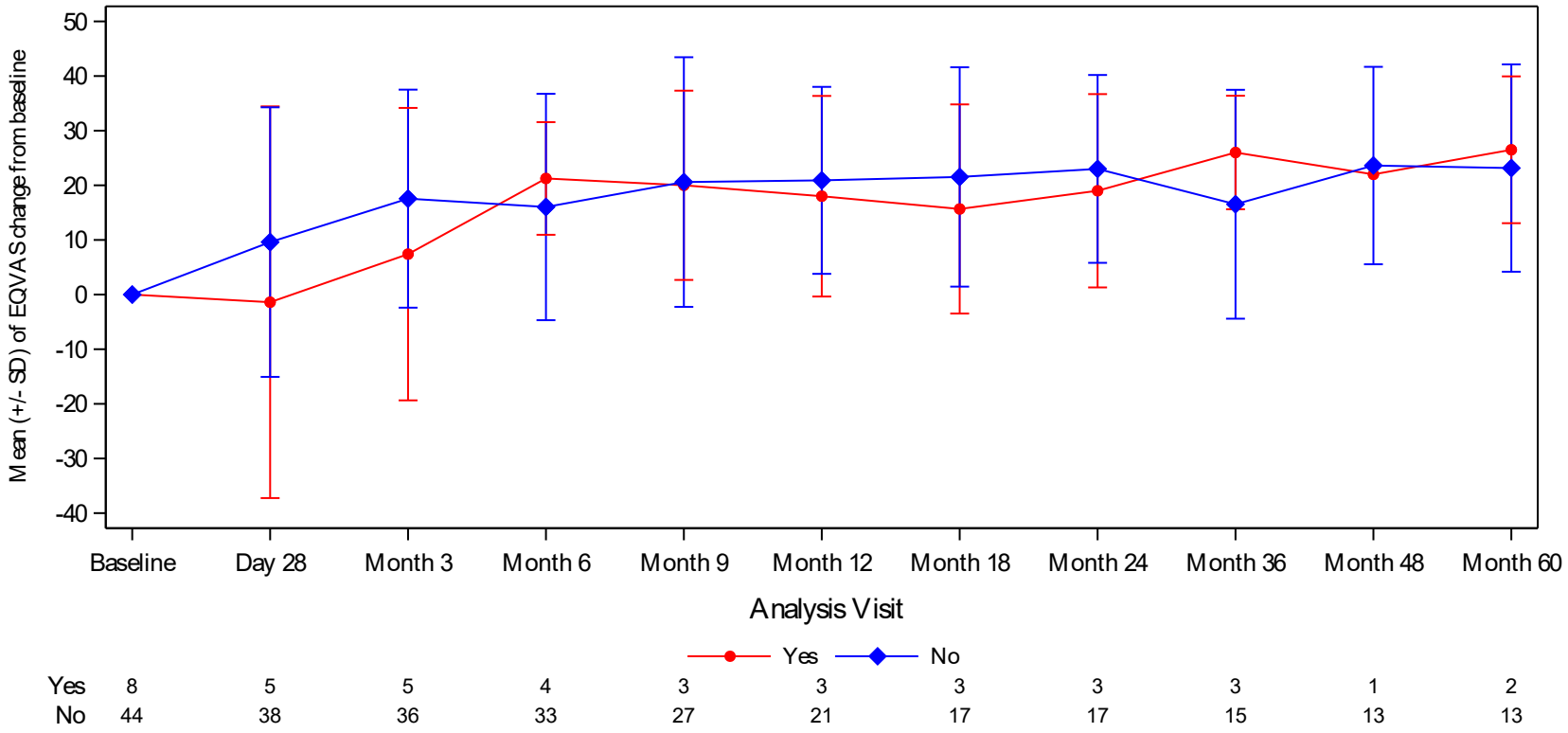
Figure 51l (Page 1 of 1)
Mean change in EQVAS total score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	30	26	27	26	20	17	14	12	13	9	11
No	22	17	14	11	10	7	6	8	5	5	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

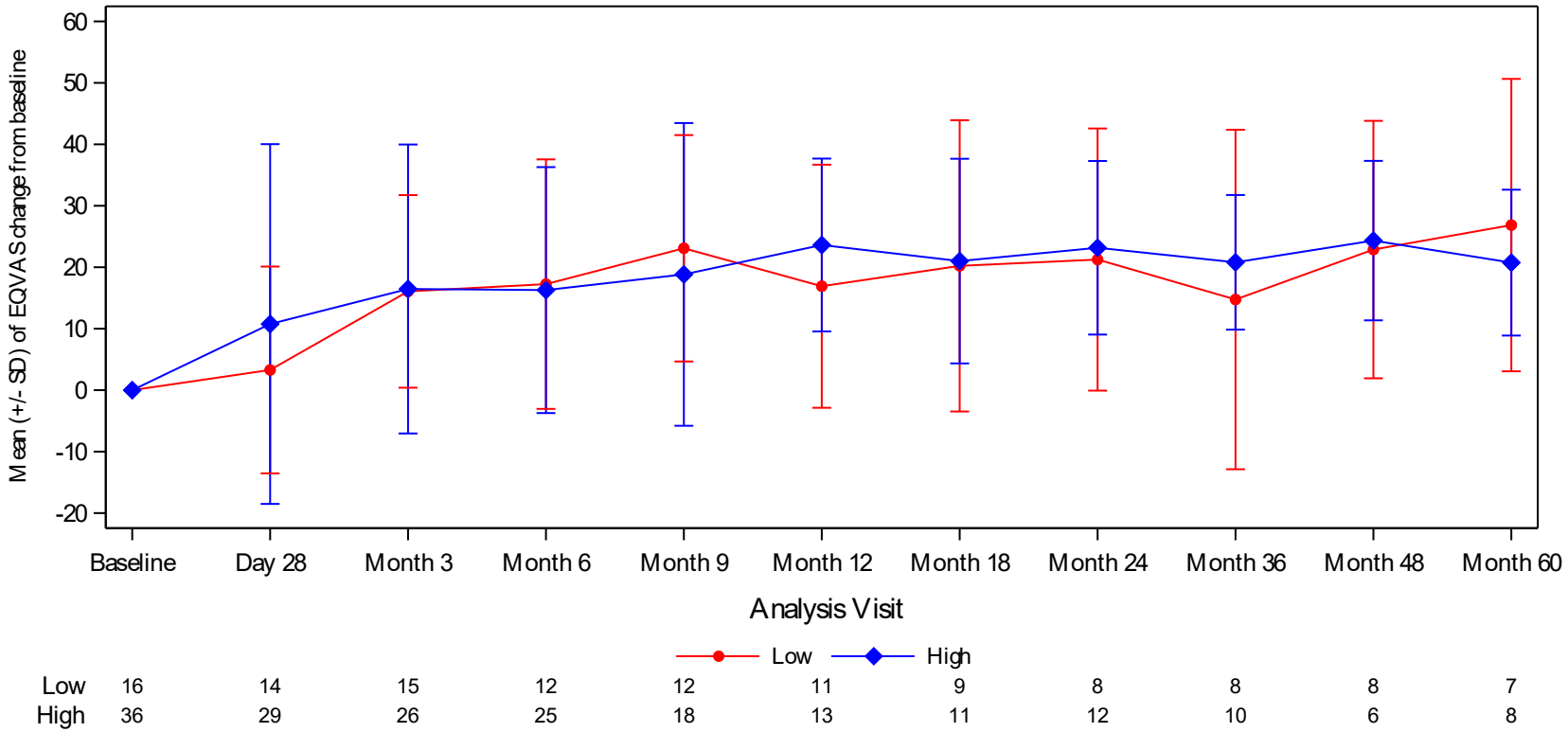
Figure 51m (Page 1 of 1)
Mean change in EQVAS total score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	8	5	5	4	3	3	3	3	3	1	2
No	44	38	36	33	27	21	17	17	15	13	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

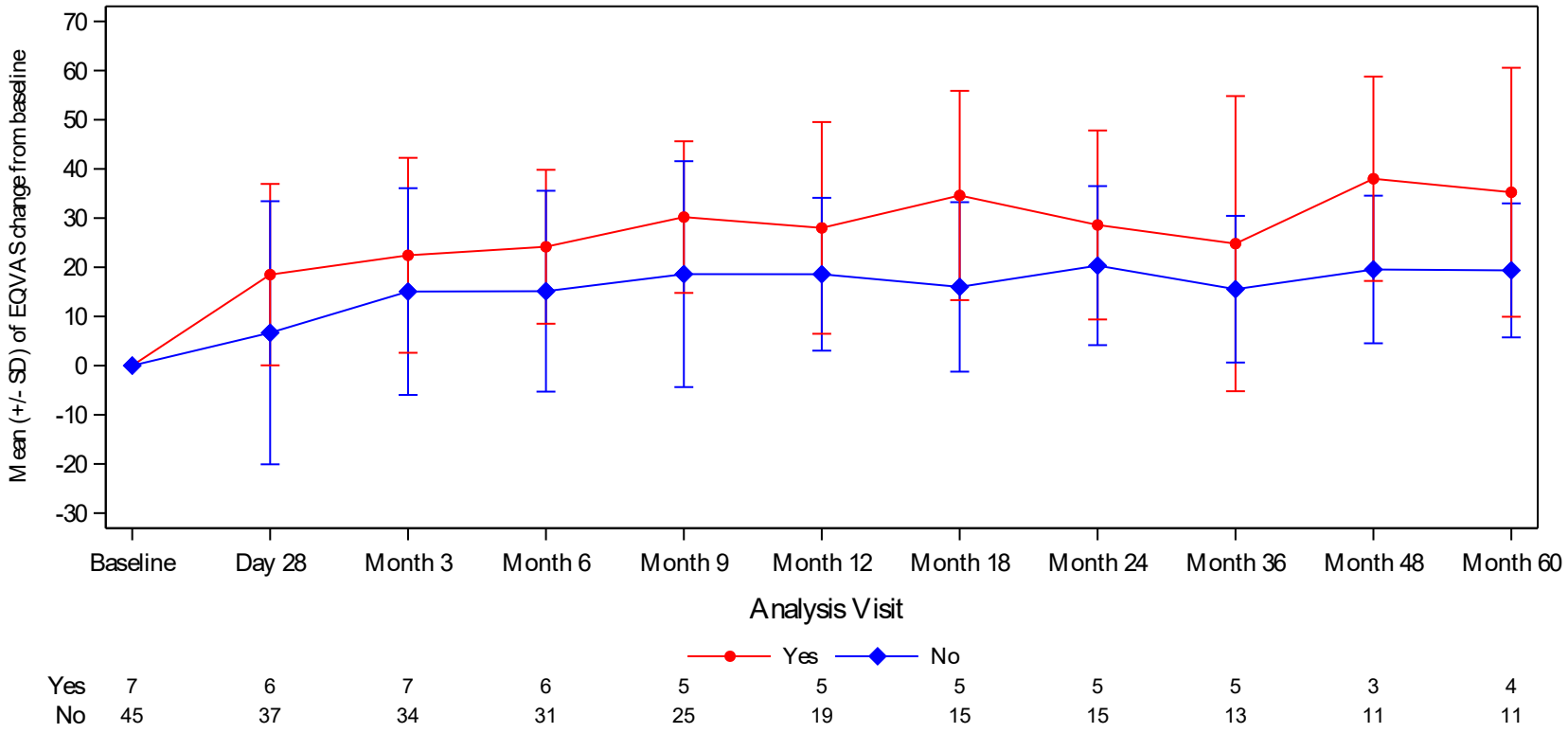
Figure 51n (Page 1 of 1)
Mean change in EQVAS total score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	14	15	12	12	11	9	8	8	8	7
High	36	29	26	25	18	13	11	12	10	6	8

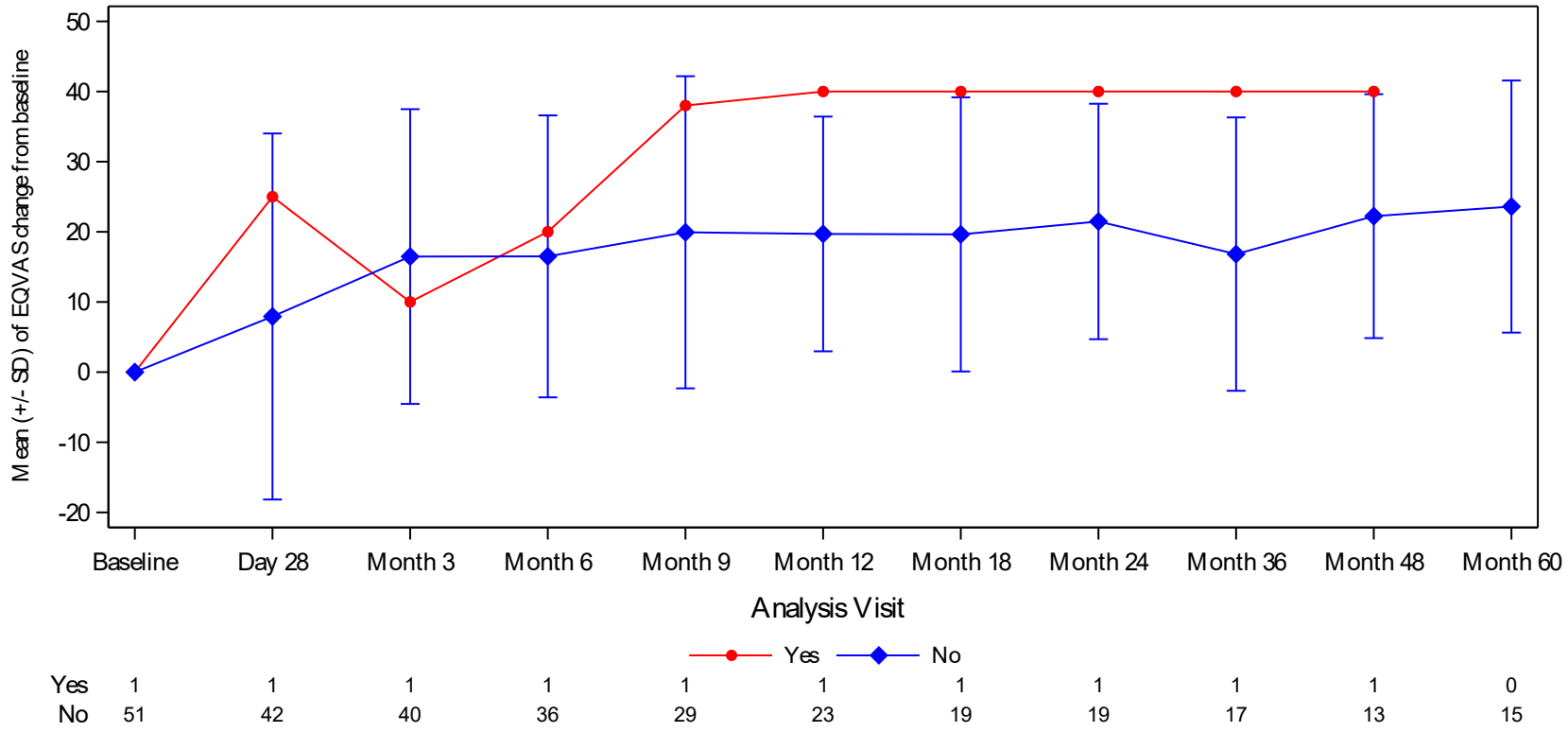
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 51o (Page 1 of 1)
Mean change in EQVAS total score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment



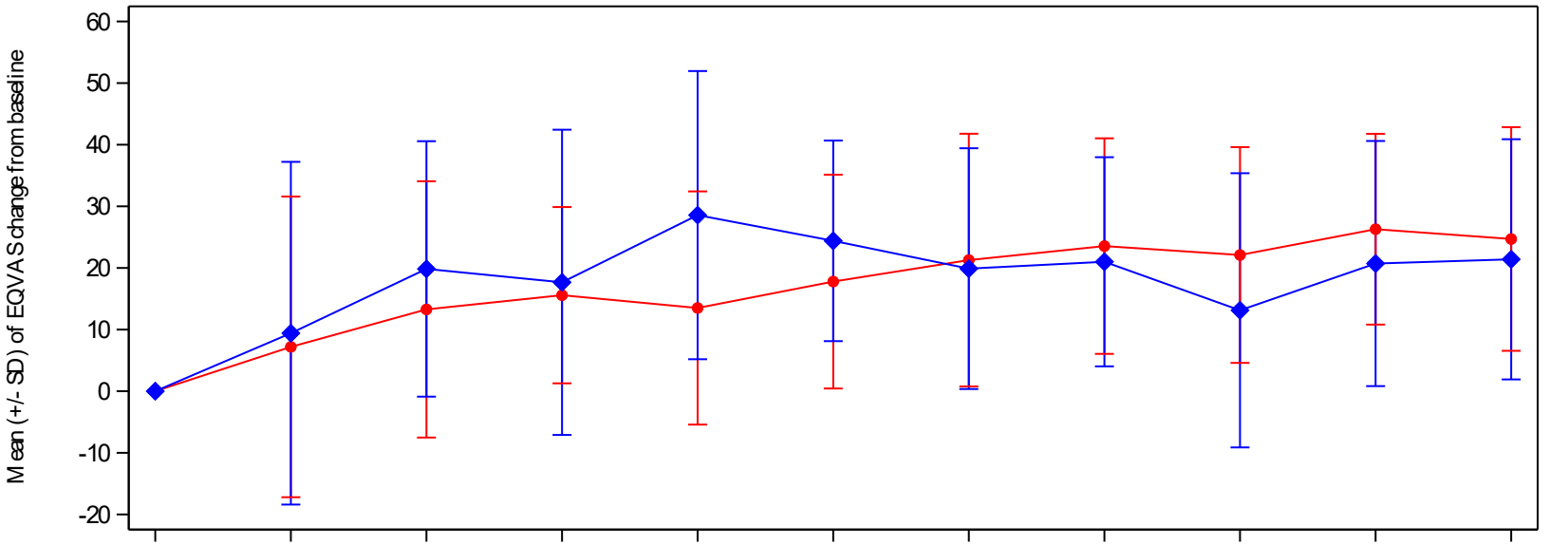
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 51p (Page 1 of 1)
Mean change in EQVAS total score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

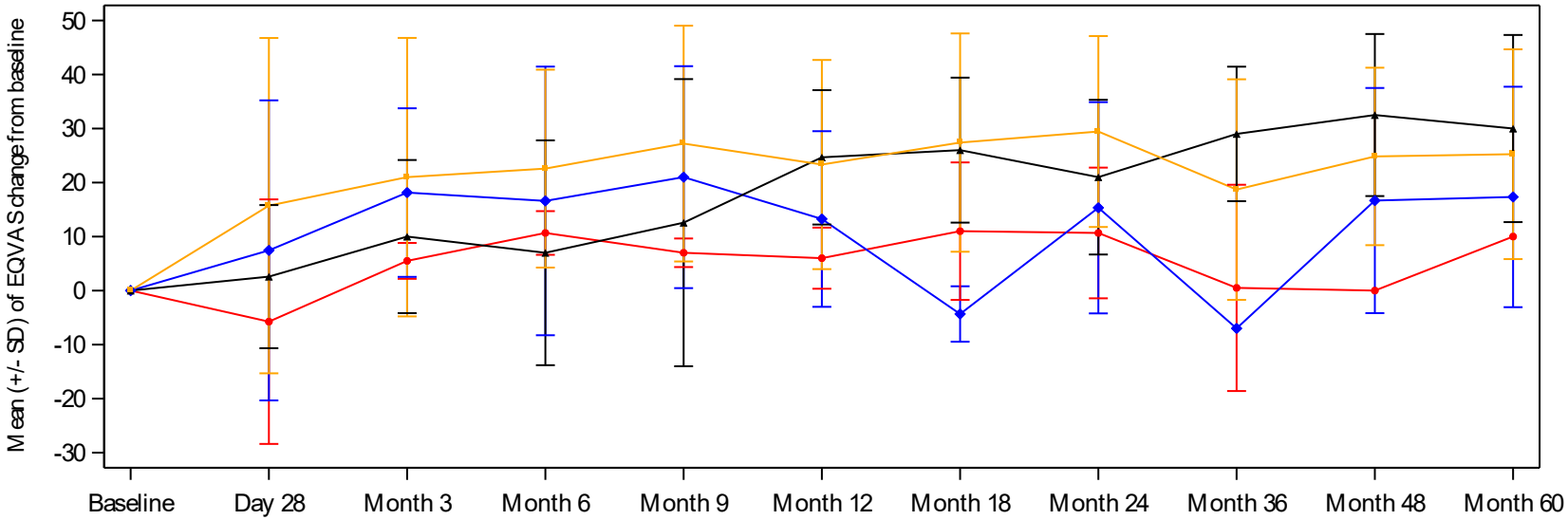
Figure 51q (Page 1 of 1)
Mean change in EQVAS total score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment



> Median	25	21	22	19	16	14	11	11	10	7	10
<=Median	27	22	19	18	14	10	9	9	8	7	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

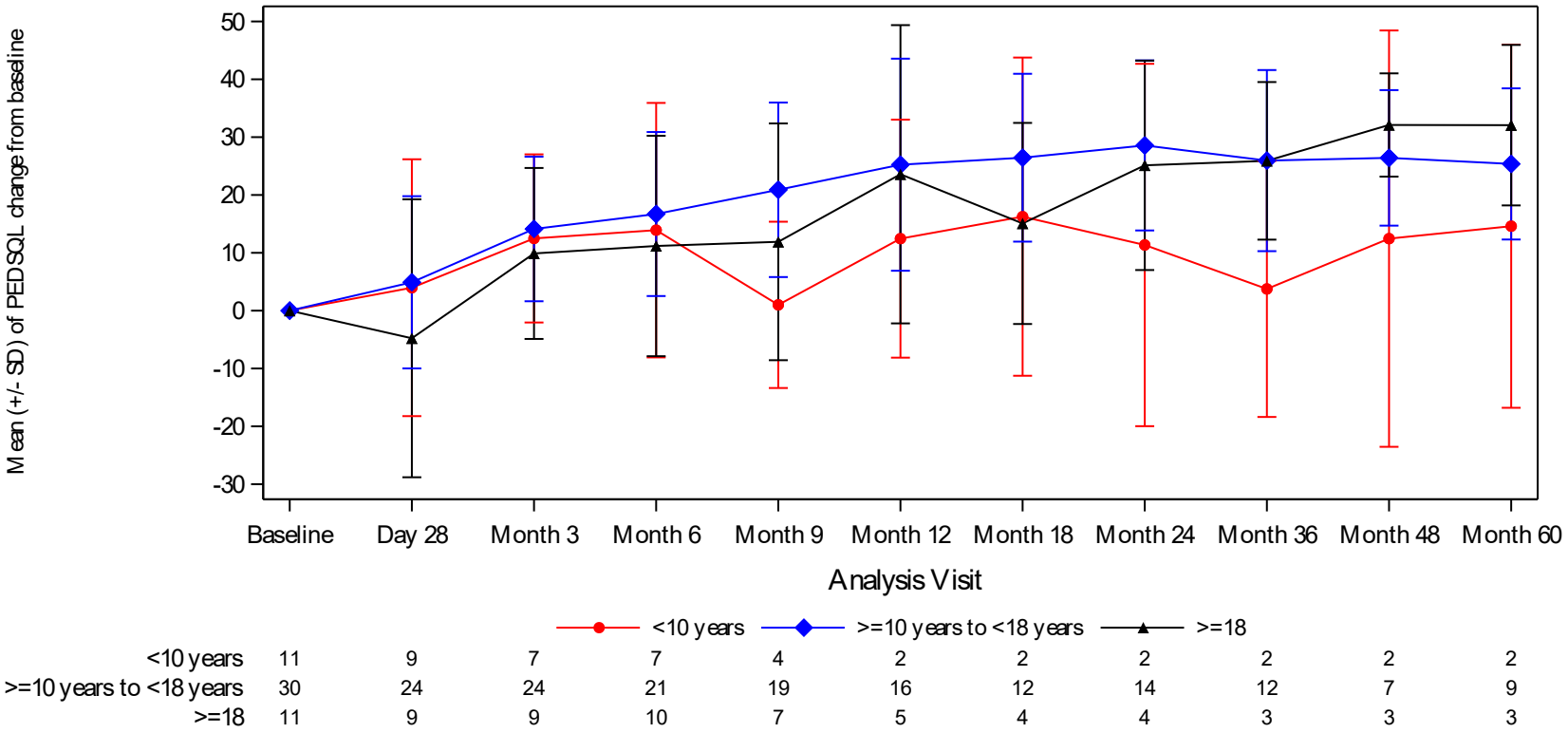
Figure 51r (Page 1 of 1)
Mean change in EQVAS total score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment



0	4	4	4	3	3	2	2	3	2	1	1
1	11	9	7	5	6	4	3	3	1	3	3
2	14	12	10	10	7	6	5	5	5	4	3
>=3	23	18	20	19	14	12	10	9	10	6	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

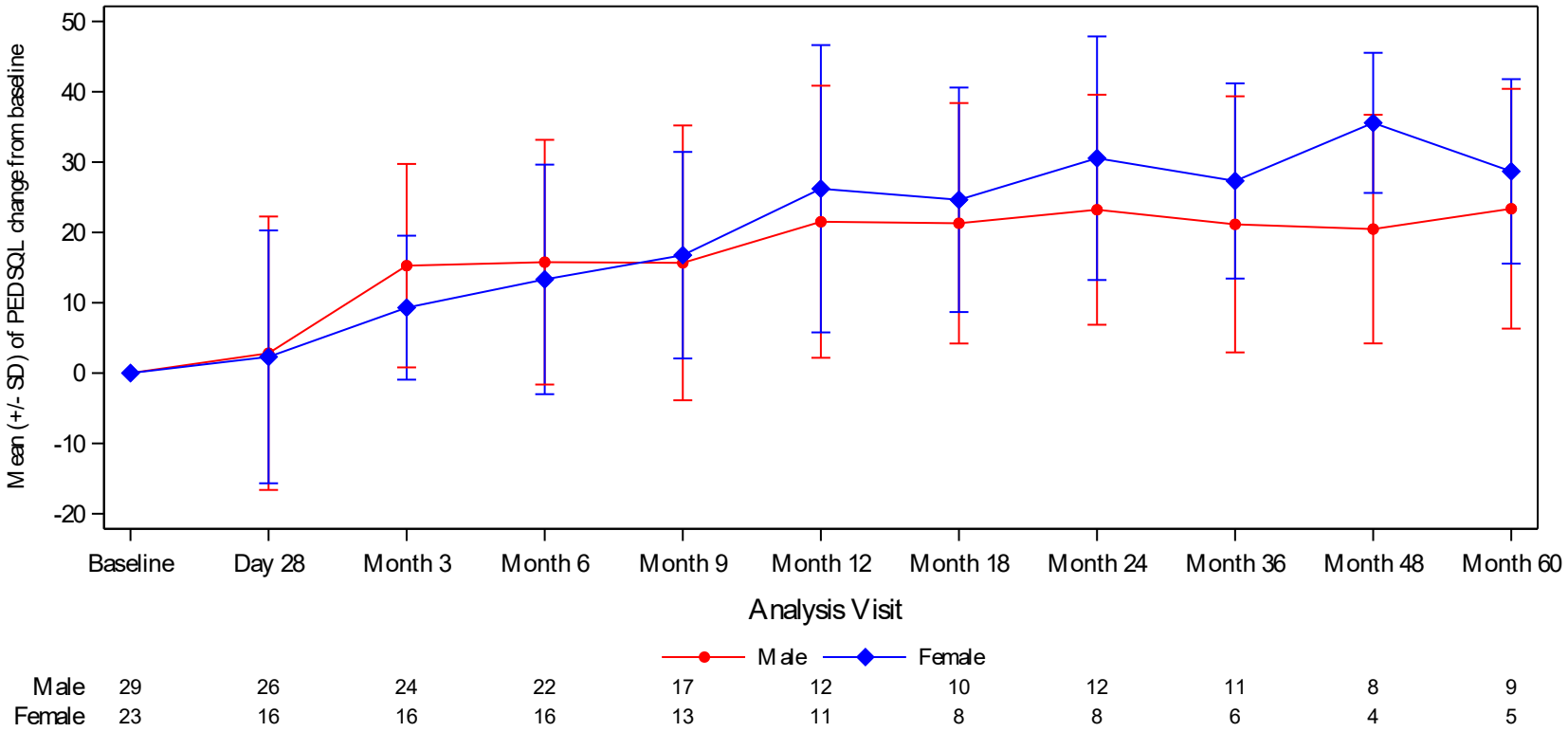
Figure 52a (Page 1 of 1)
Mean change in PedsQL score over time by Age
Full analysis set - Patients >= 8 years at enrollment



<10 years	11	9	7	7	4	2	2	2	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	12	14	12	7	9
>=18	11	9	9	10	7	5	4	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

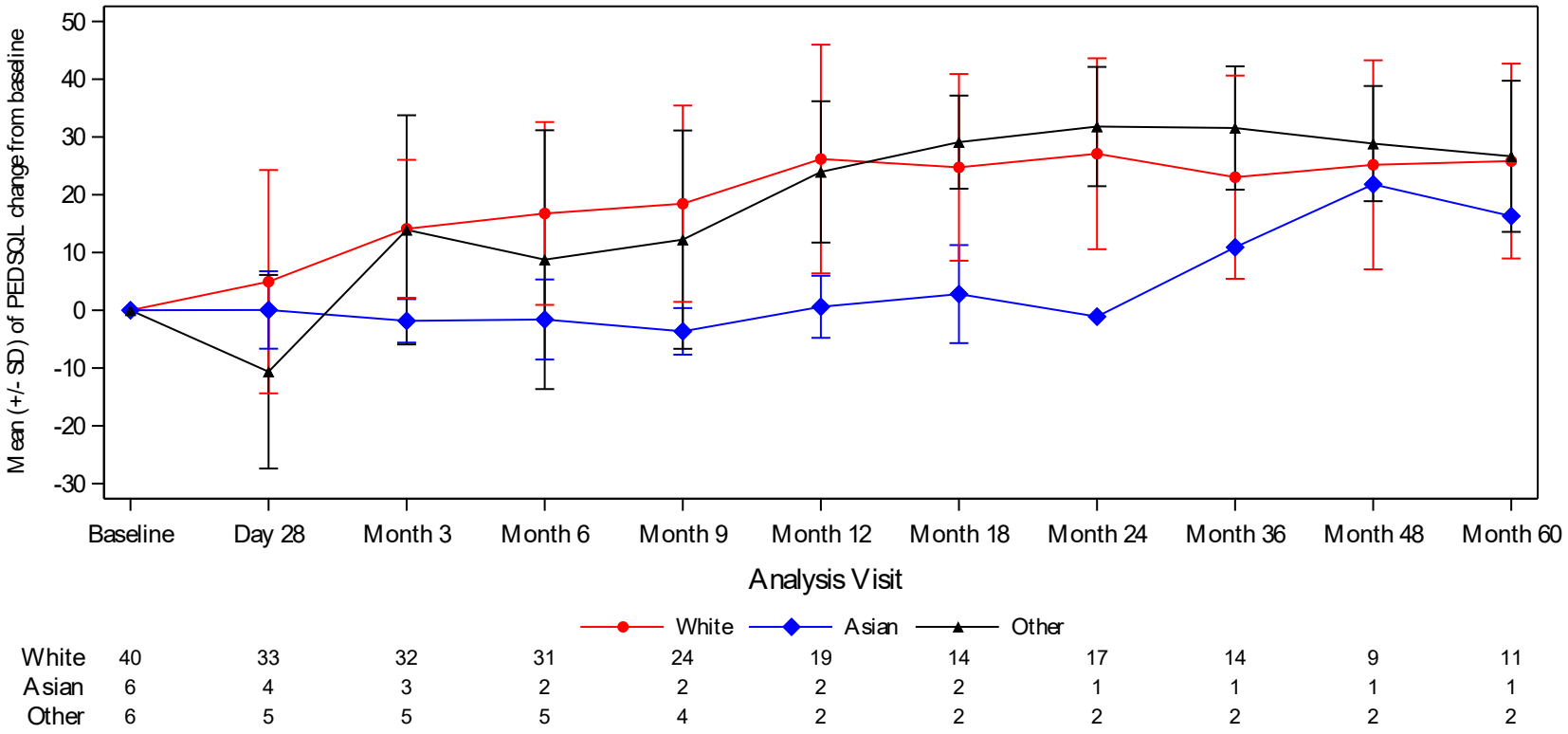
Figure 52b (Page 1 of 1)
Mean change in PedsQL score over time by Gender
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Male	29	26	24	22	17	12	10	12	11	8	9
Female	23	16	16	16	13	11	8	8	6	4	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

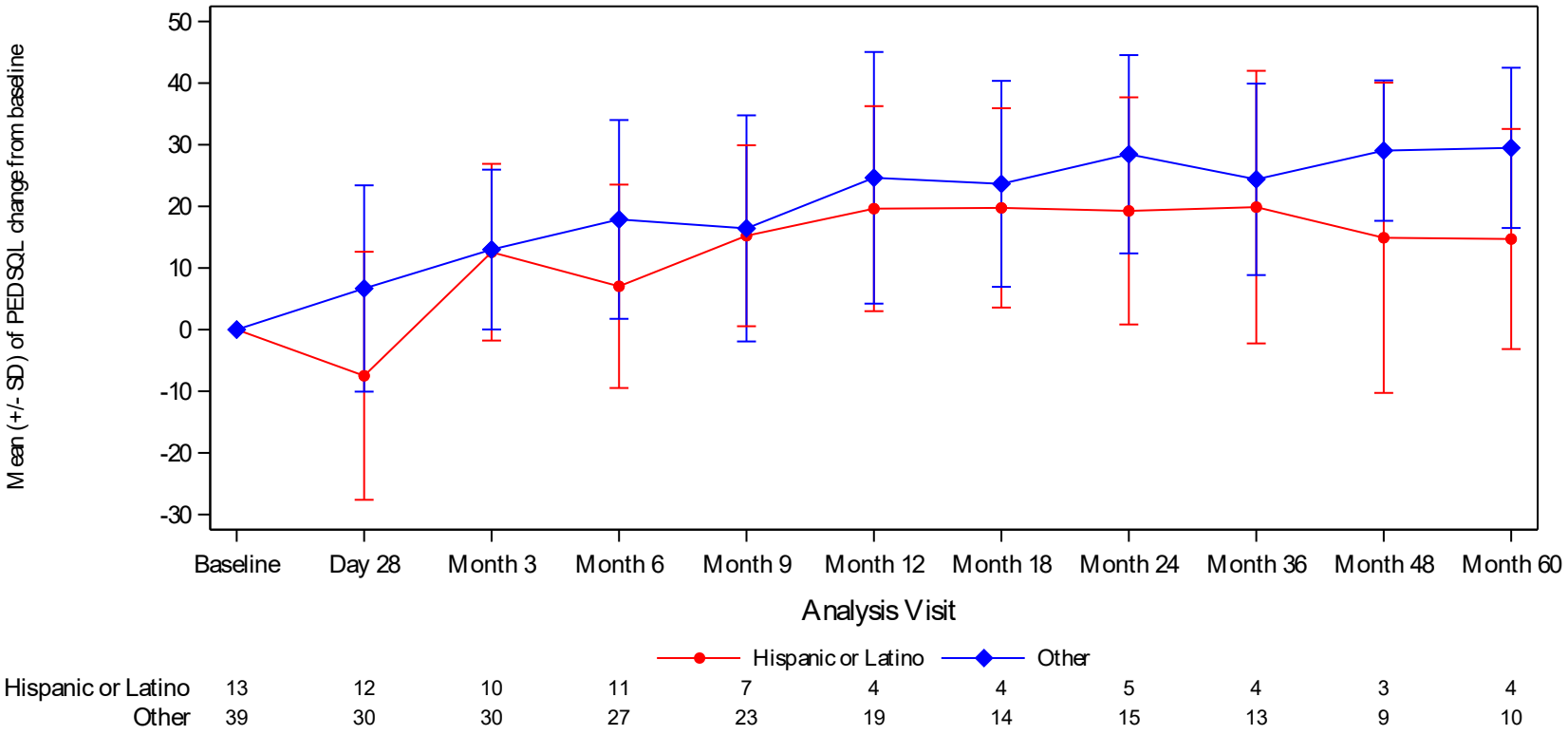
Figure 52c (Page 1 of 1)
Mean change in PedsQL score over time by Race
Full analysis set - Patients >= 8 years at enrollment



White	40	33	32	31	24	19	14	17	14	9	11
Asian	6	4	3	2	2	2	2	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

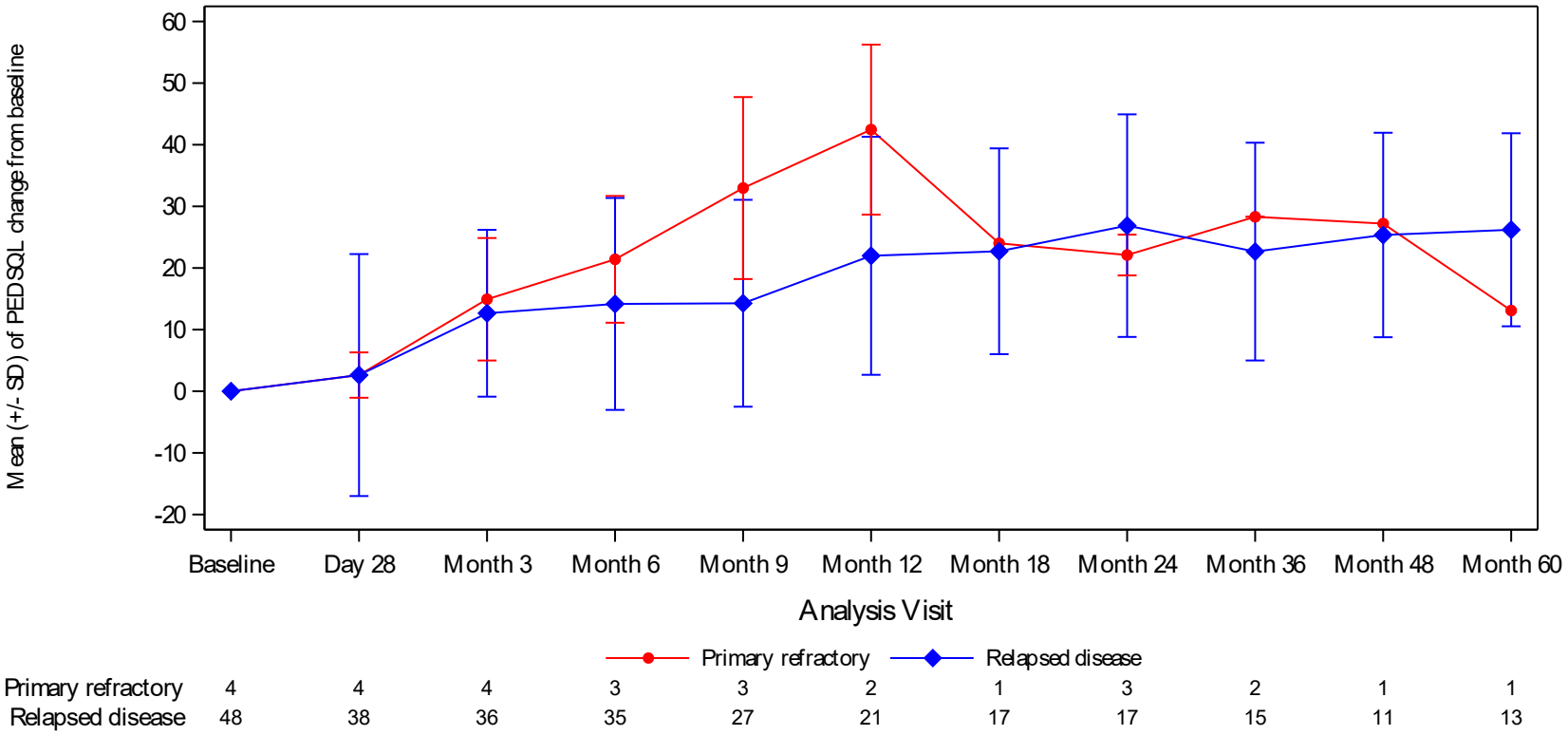
Figure 52d (Page 1 of 1)
Mean change in PedsQL score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	13	12	10	11	7	4	4	5	4	3	4
Other	39	30	30	27	23	19	14	15	13	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

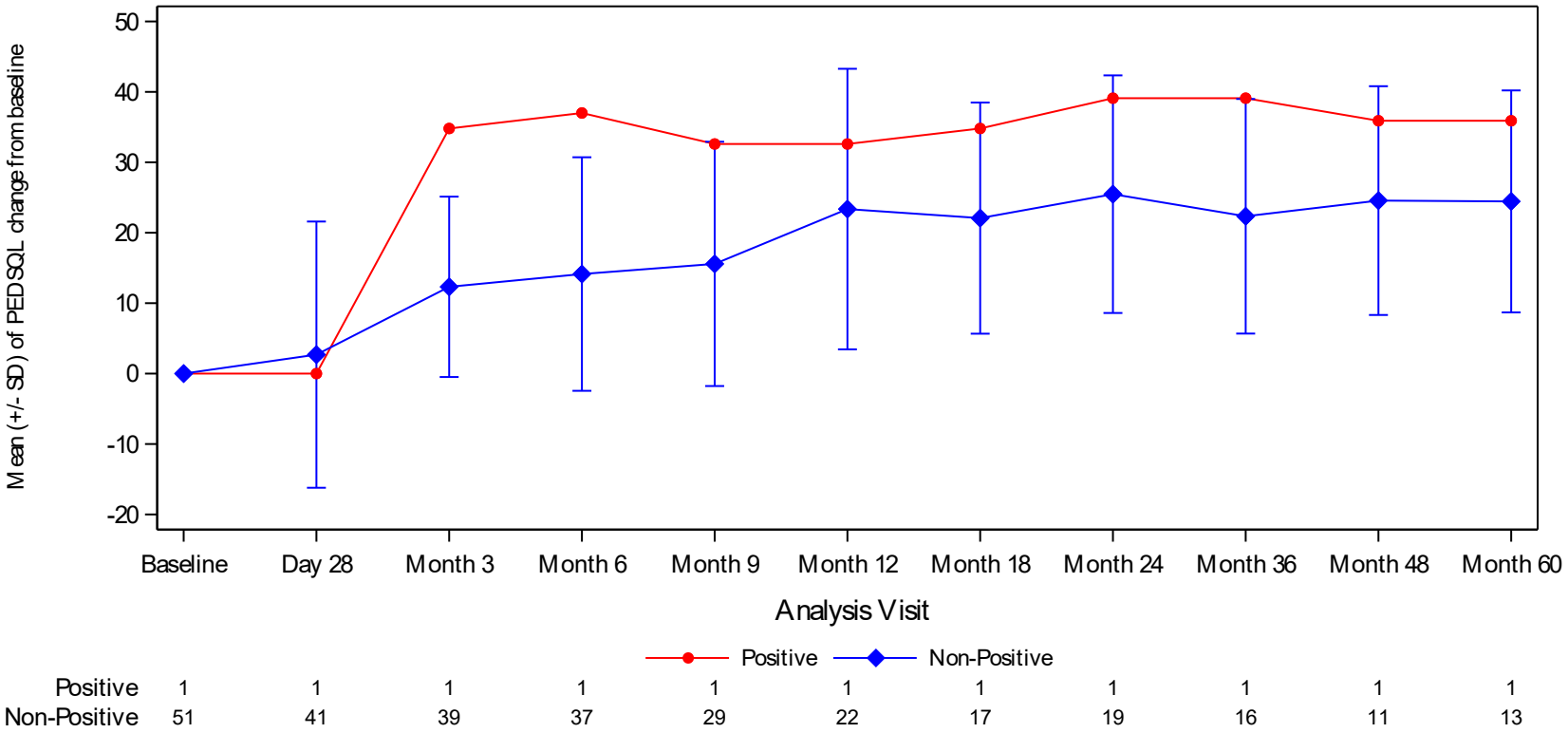
Figure 52e (Page 1 of 1)
Mean change in PedsQL score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Primary refractory	4	4	4	3	3	2	1	3	2	1	1
Relapsed disease	48	38	36	35	27	21	17	17	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

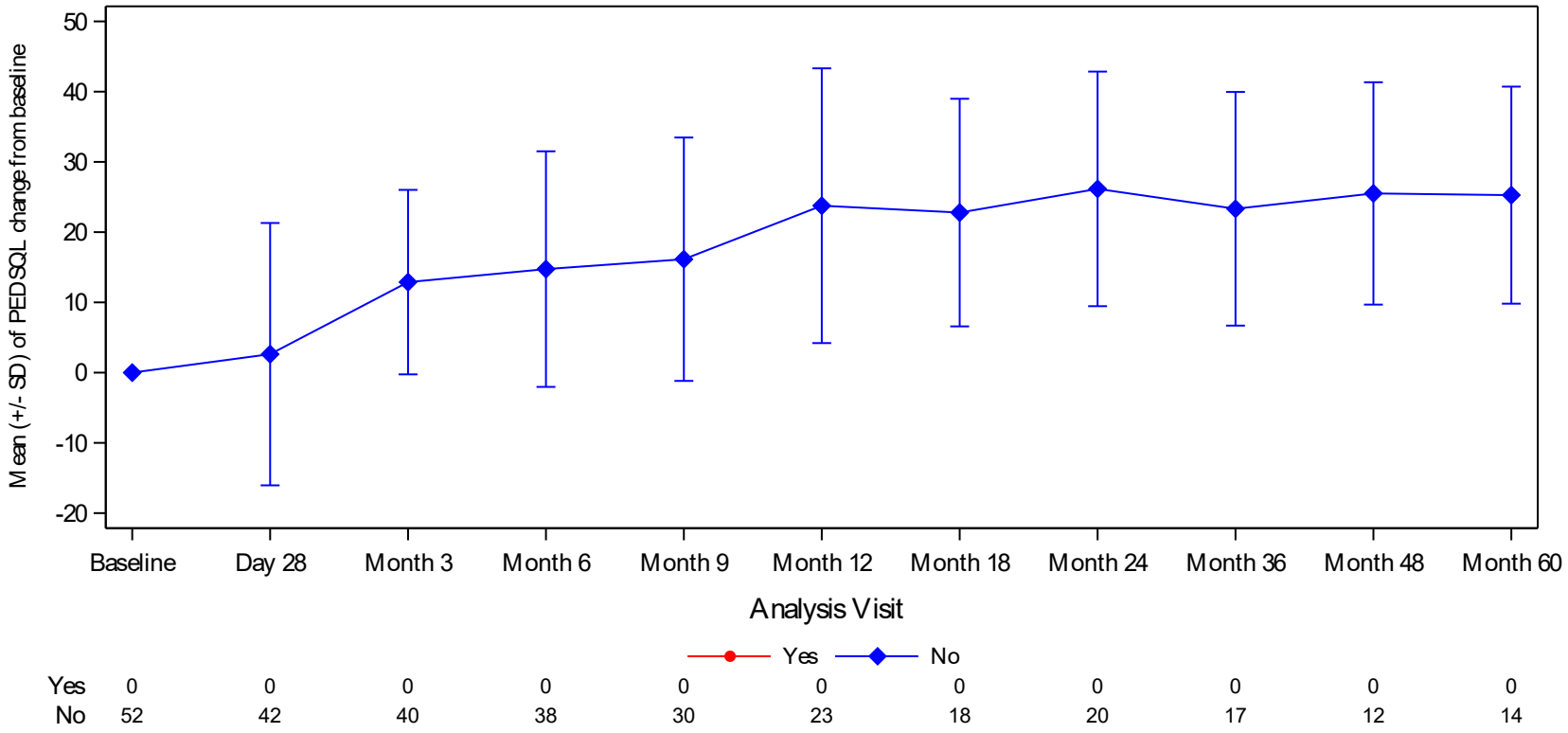
Figure 52f (Page 1 of 1)
Mean change in PedsQL score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	41	39	37	29	22	17	19	16	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

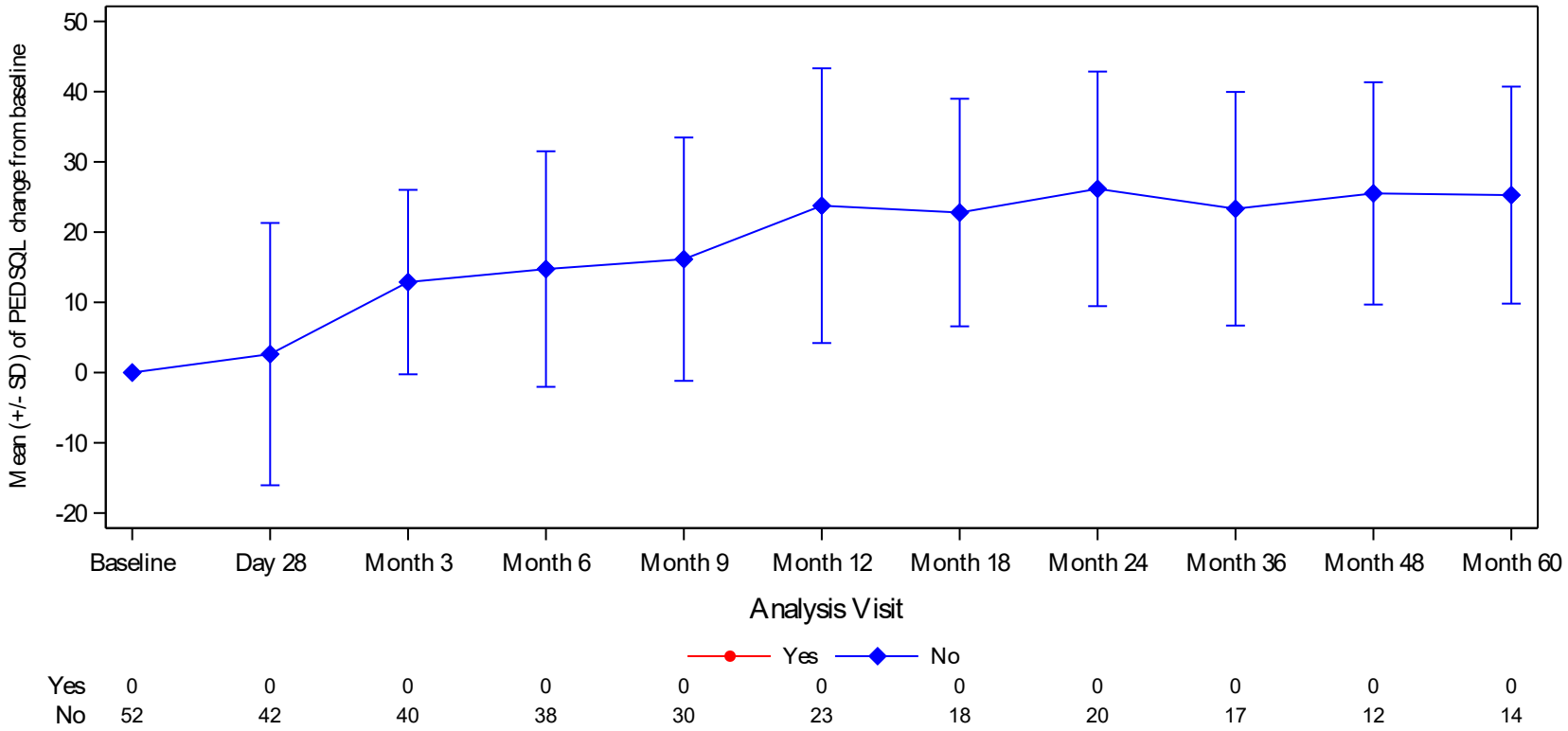
Figure 52g (Page 1 of 1)
Mean change in PedsQL score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

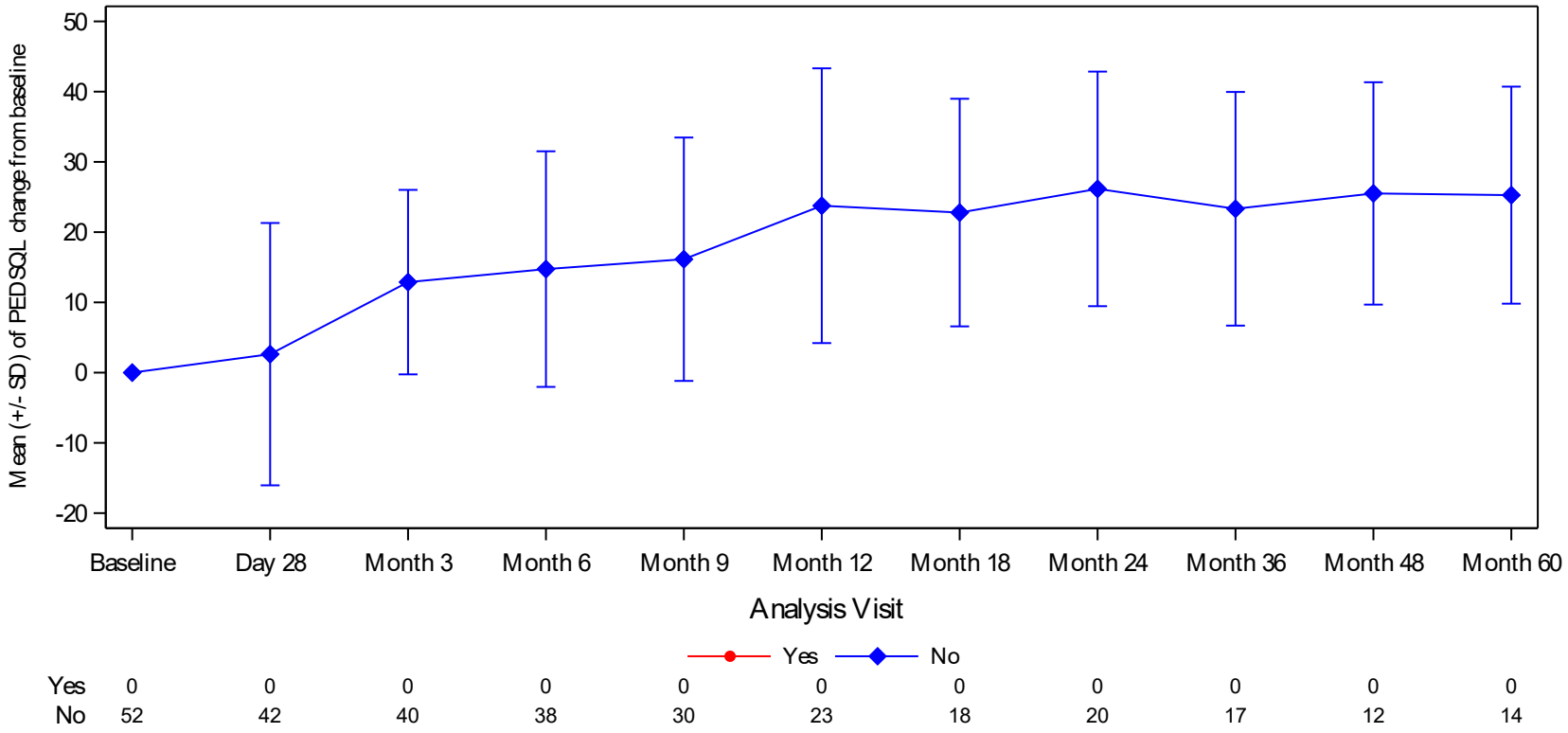
Figure 52h (Page 1 of 1)
Mean change in PedsQL score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

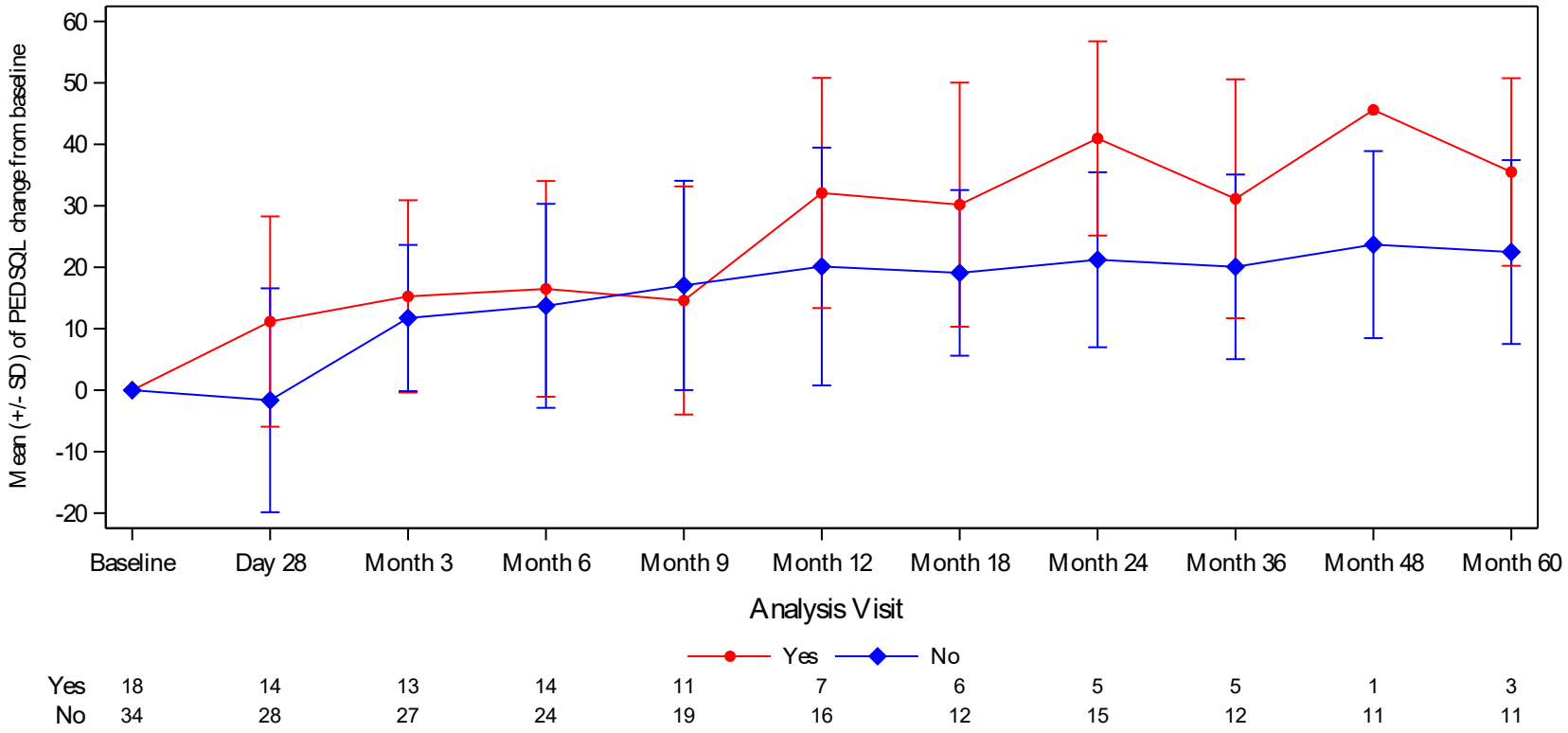
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 52i (Page 1 of 1)
Mean change in PedsQL score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

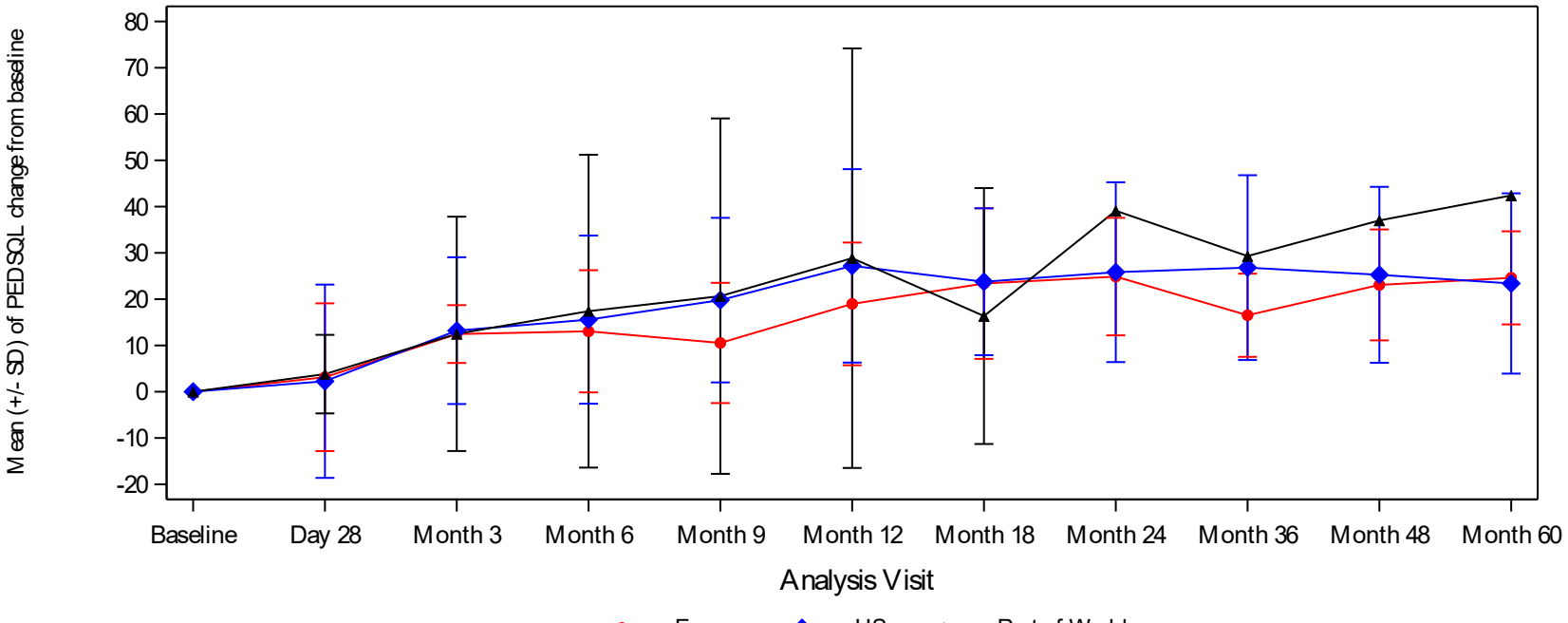
Figure 52j (Page 1 of 1)
Mean change in PedsQL score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	18	14	13	14	11	7	6	5	5	1	3
No	34	28	27	24	19	16	12	15	12	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

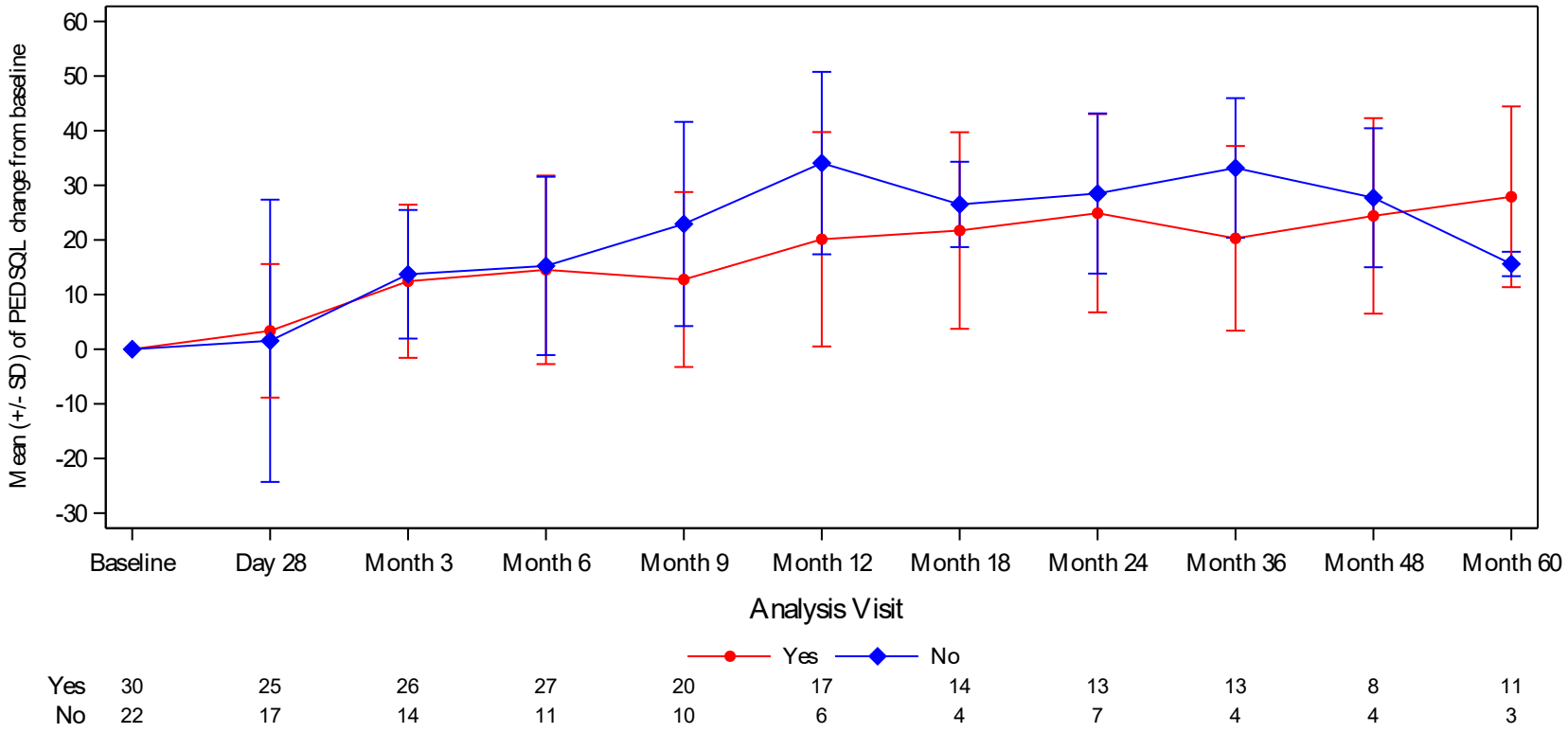
Figure 52k (Page 1 of 1)
Mean change in PedsQL score over time by Region
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Europe	17	14	15	14	12	10	7	7	6	4	6
US	32	26	23	22	16	11	9	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

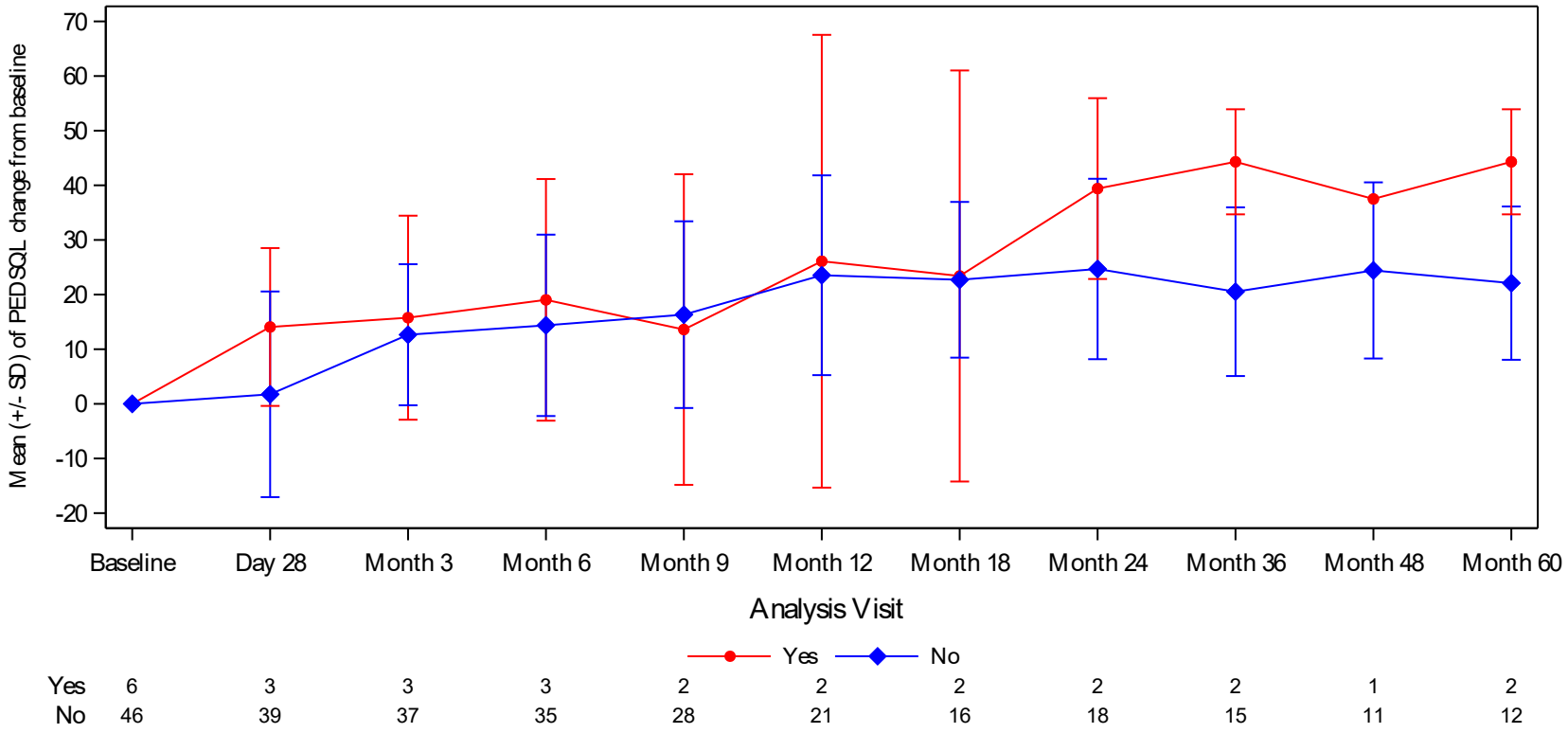
Figure 52l (Page 1 of 1)
Mean change in PedsQL score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment



Yes	30	25	26	27	20	17	14	13	13	8	11
No	22	17	14	11	10	6	4	7	4	4	3

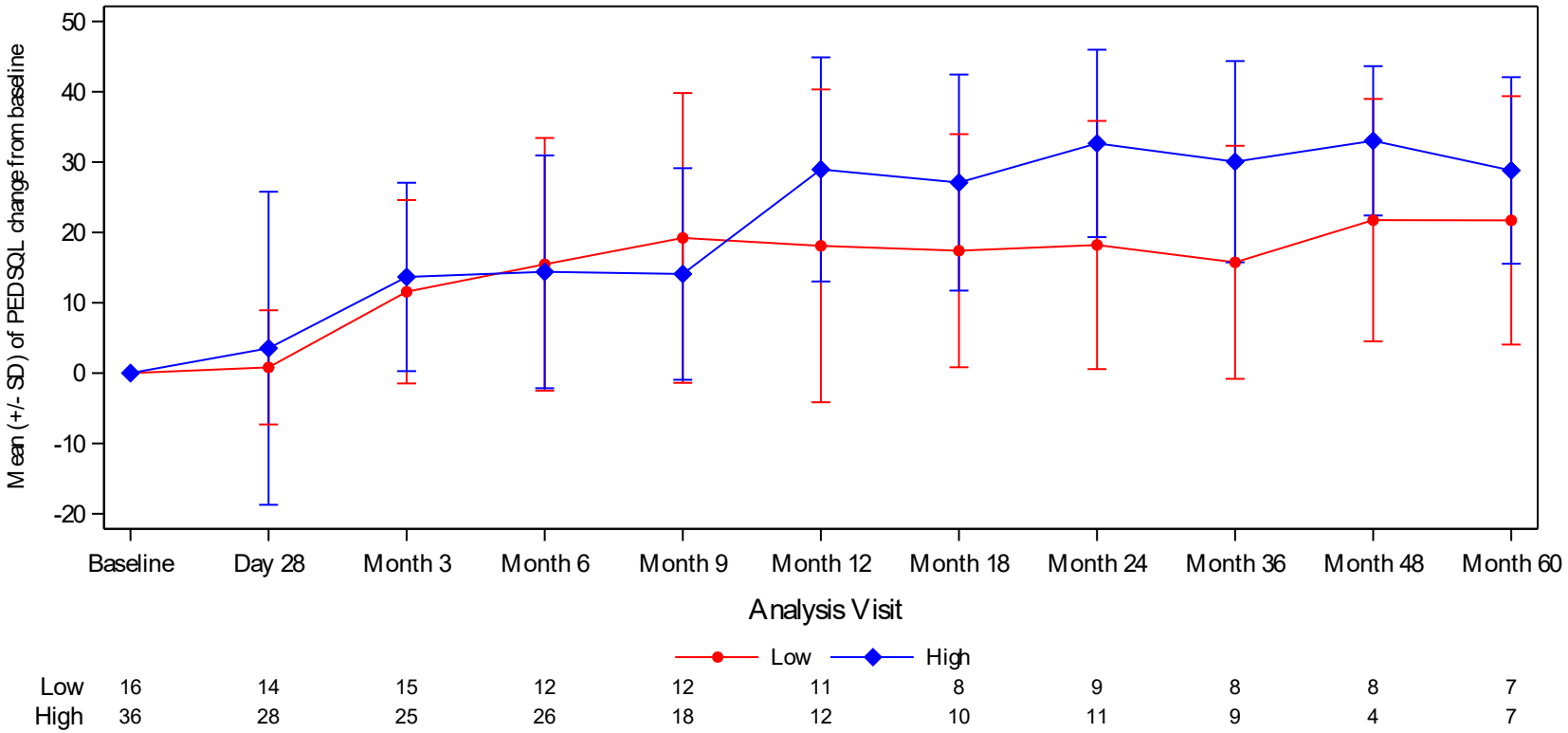
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 52m (Page 1 of 1)
Mean change in PedsQL score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

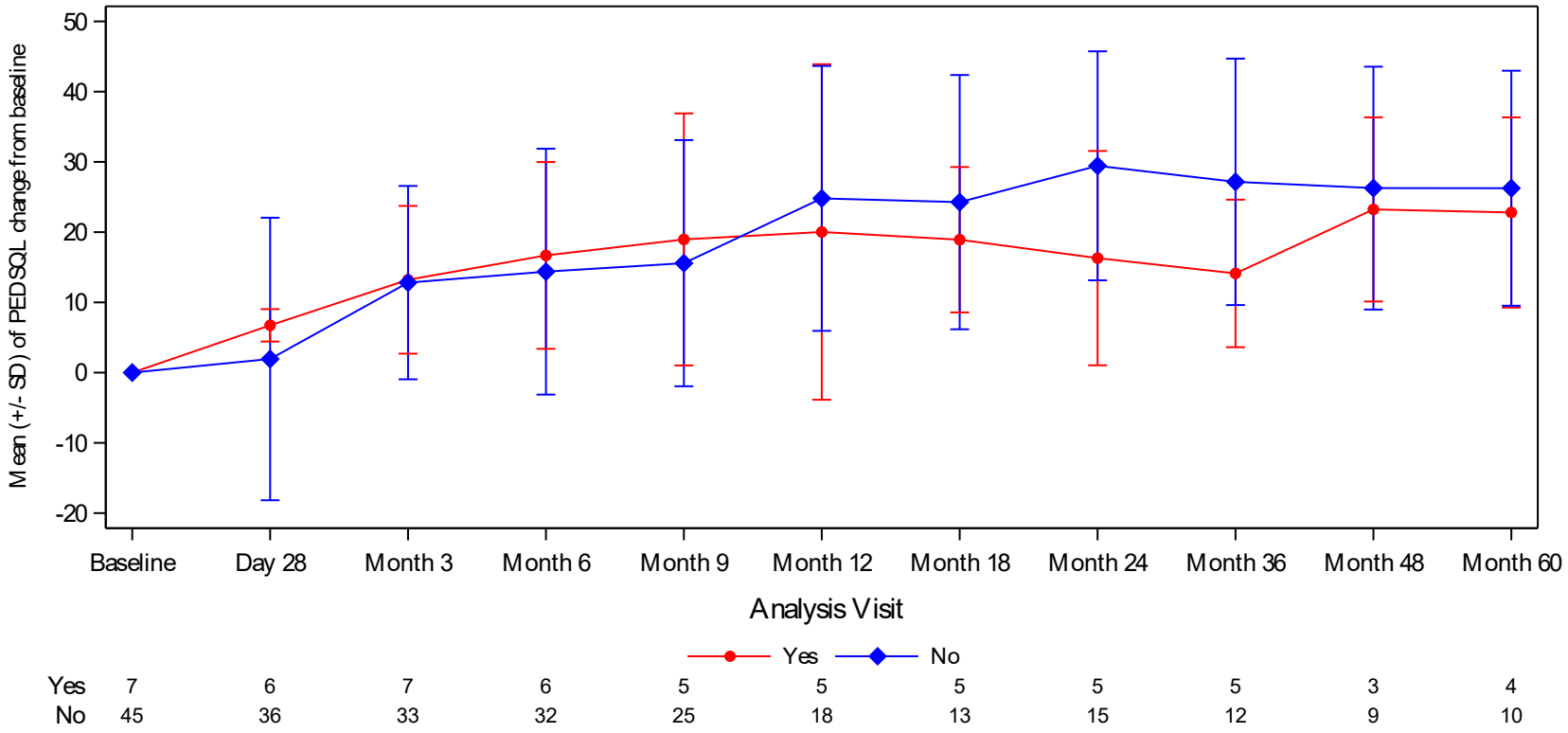
Figure 52n (Page 1 of 1)
Mean change in PedsQL score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	14	15	12	12	11	8	9	8	8	7
High	36	28	25	26	18	12	10	11	9	4	7

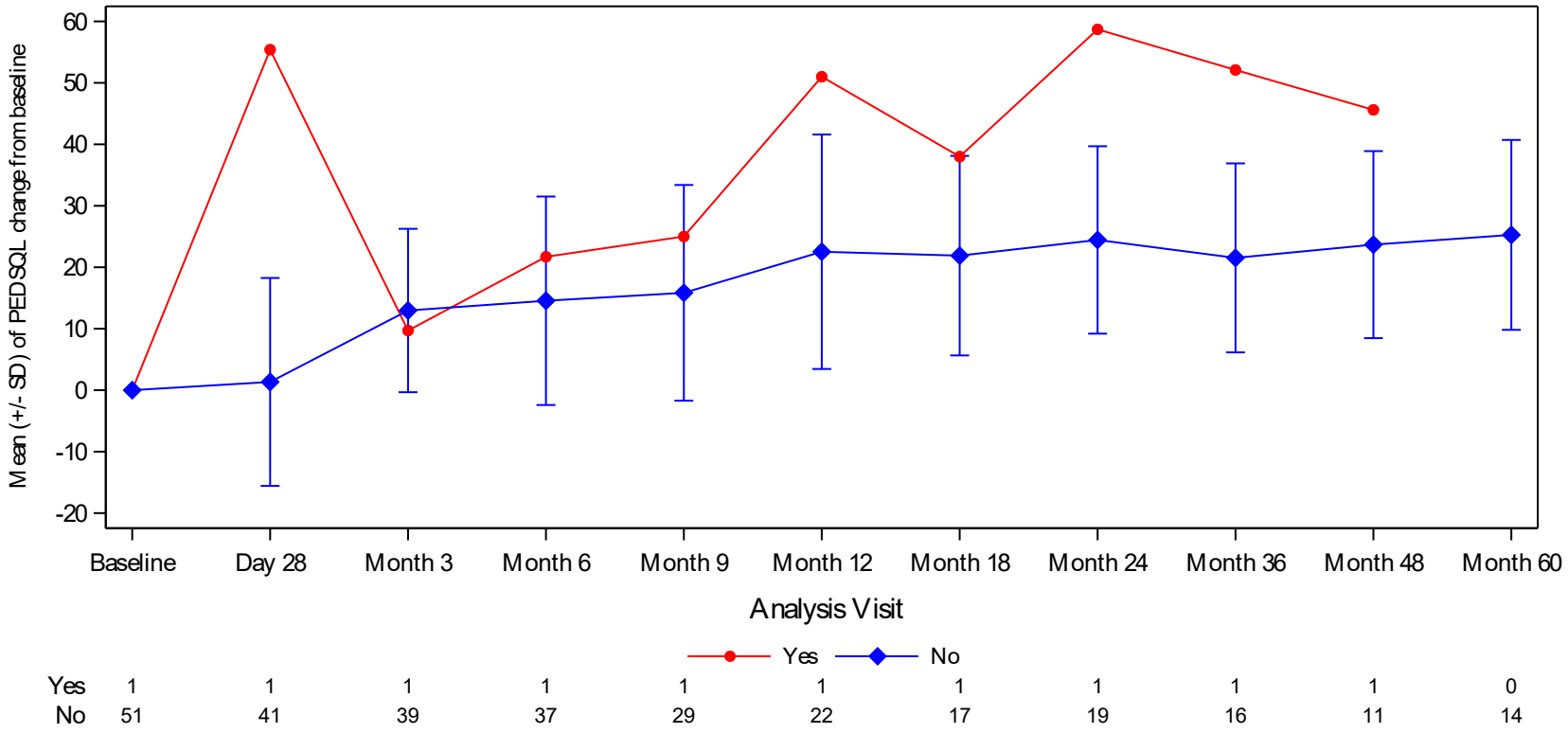
Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 52o (Page 1 of 1)
Mean change in PedsQL score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

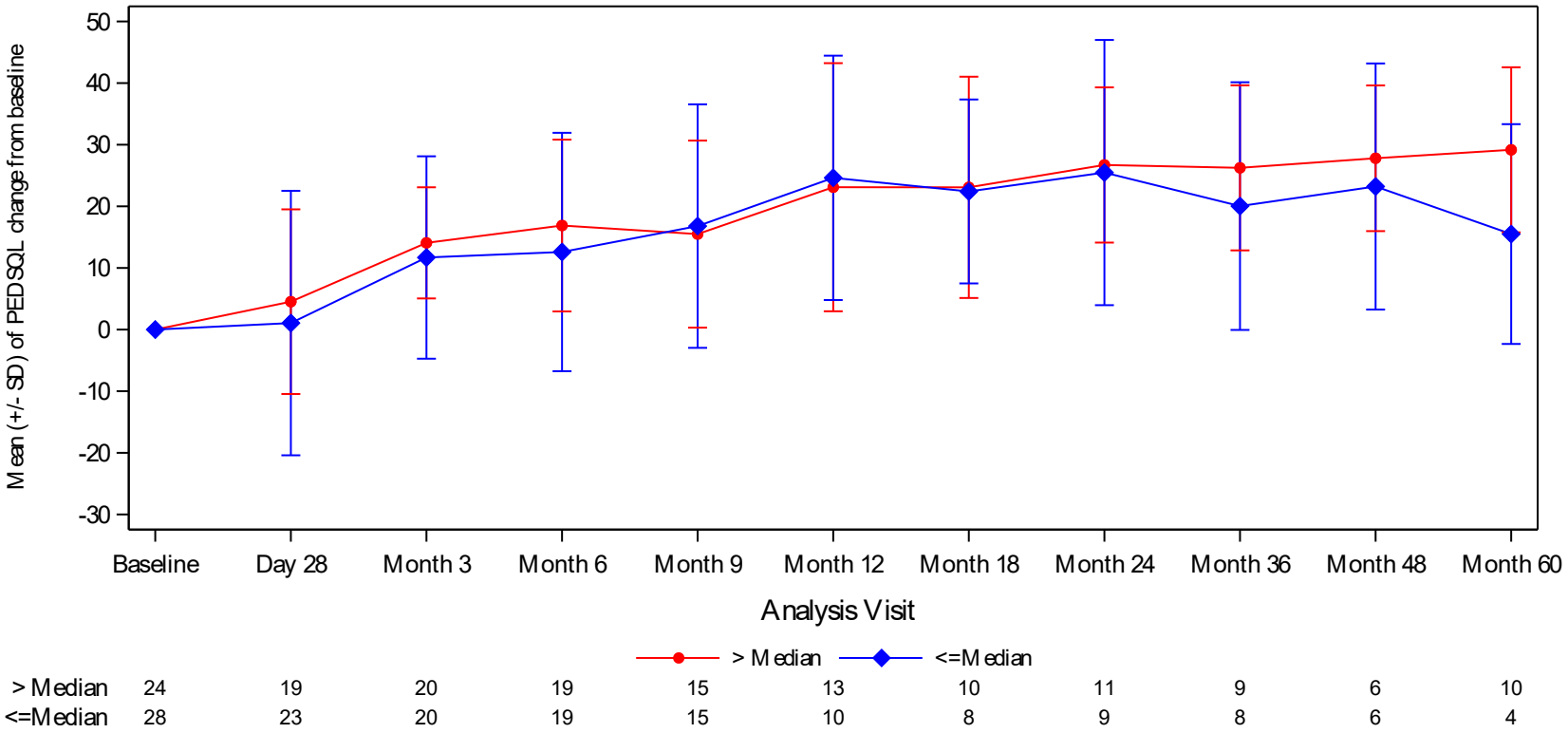
Figure 52p (Page 1 of 1)
Mean change in PedsQL score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment



	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	1	1	1	1	1	1	1	1	1	1	0
No	51	41	39	37	29	22	17	19	16	11	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

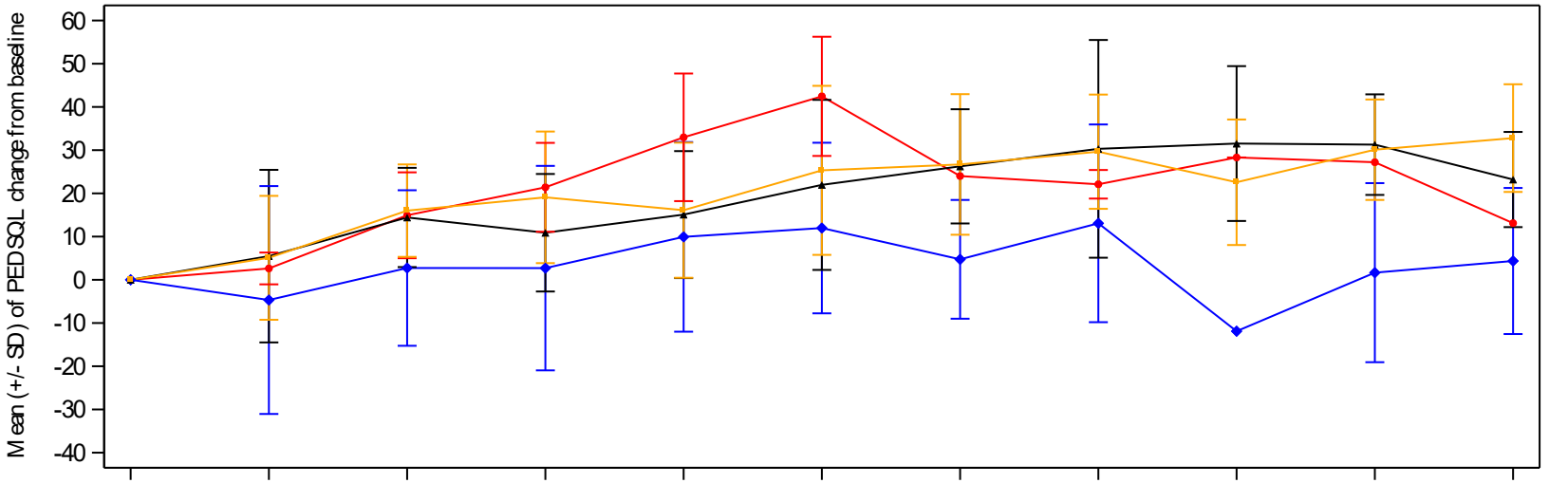
Figure 52q (Page 1 of 1)
Mean change in PedsQL score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment



> Median	24	19	20	19	15	13	10	11	9	6	10
<=Median	28	23	20	19	15	10	8	9	8	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 52r (Page 1 of 1)
Mean change in PedsQL score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

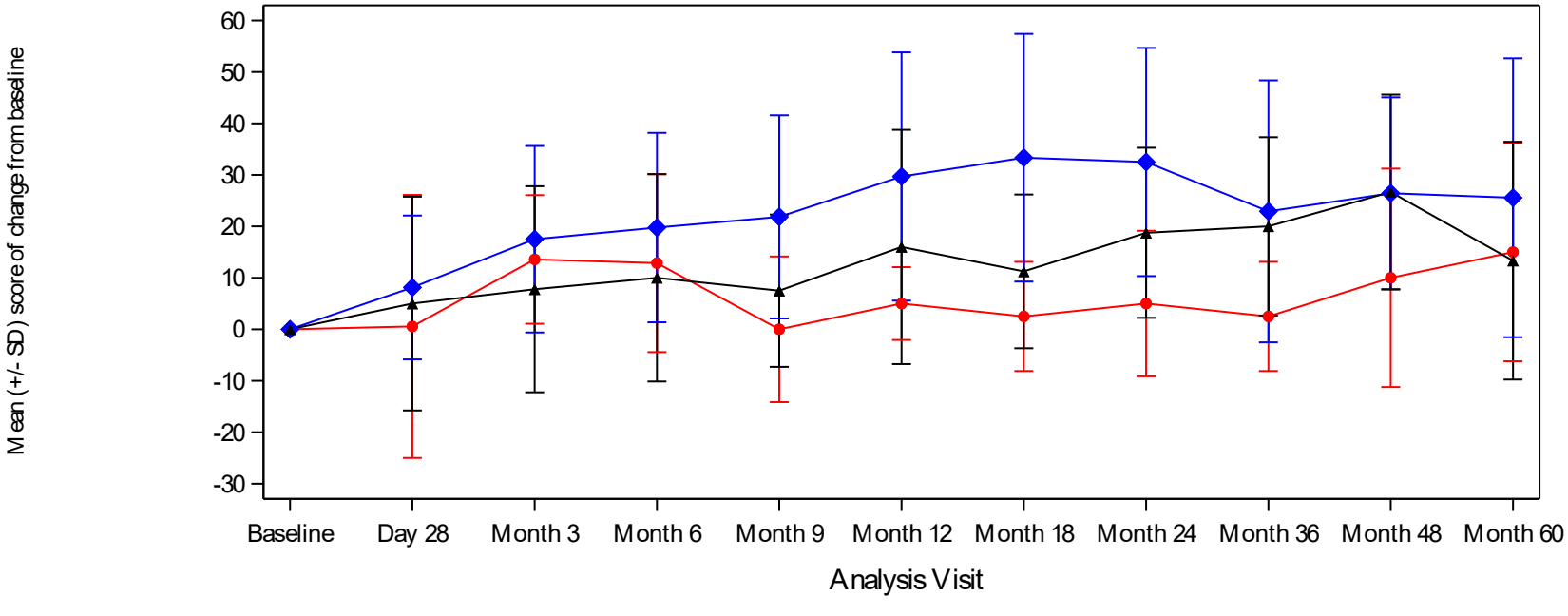


0	4	4	4	3	3	2	1	3	2	1	1
1	12	10	8	6	7	4	3	3	1	2	2
2	13	11	9	9	6	5	4	4	4	4	3
>=3	23	17	19	20	14	12	10	10	10	5	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53a (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

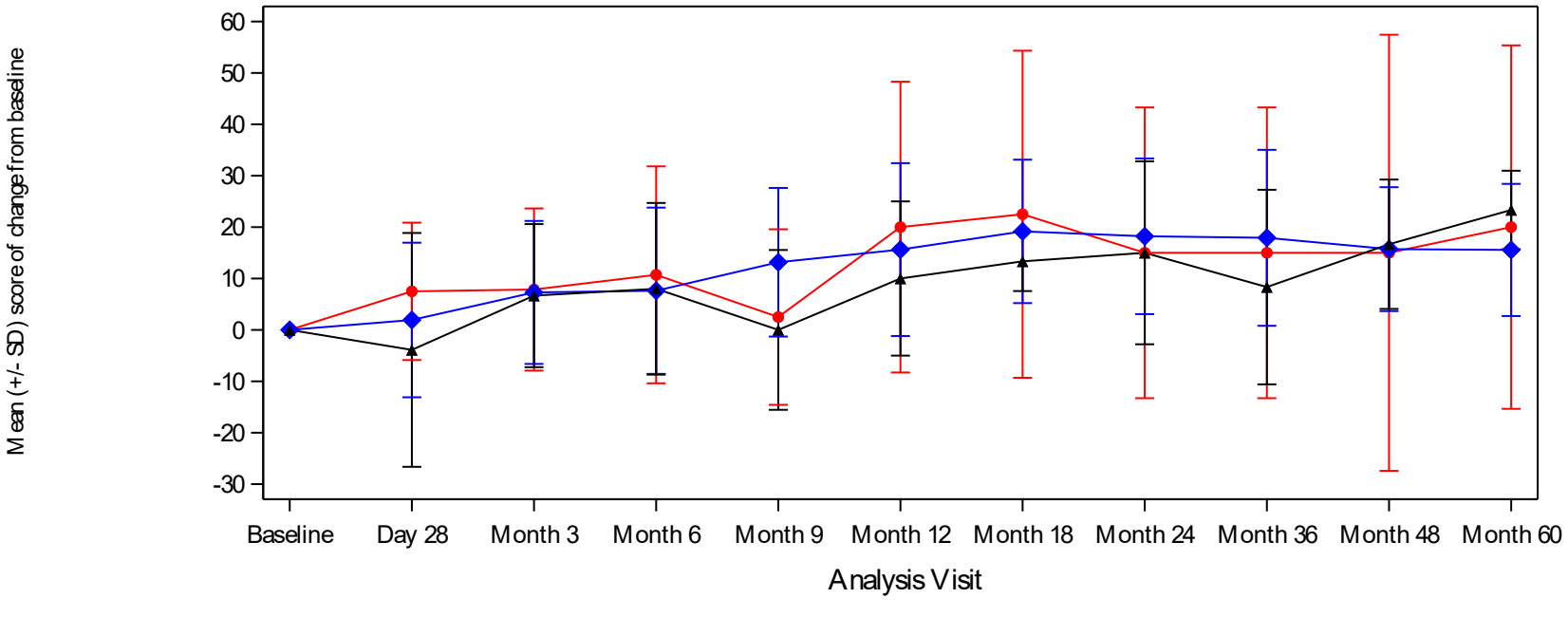


<10 years	11	9	7	7	4	2	2	2	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	12	14	12	7	9
>=18	11	9	9	10	7	5	4	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53a (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

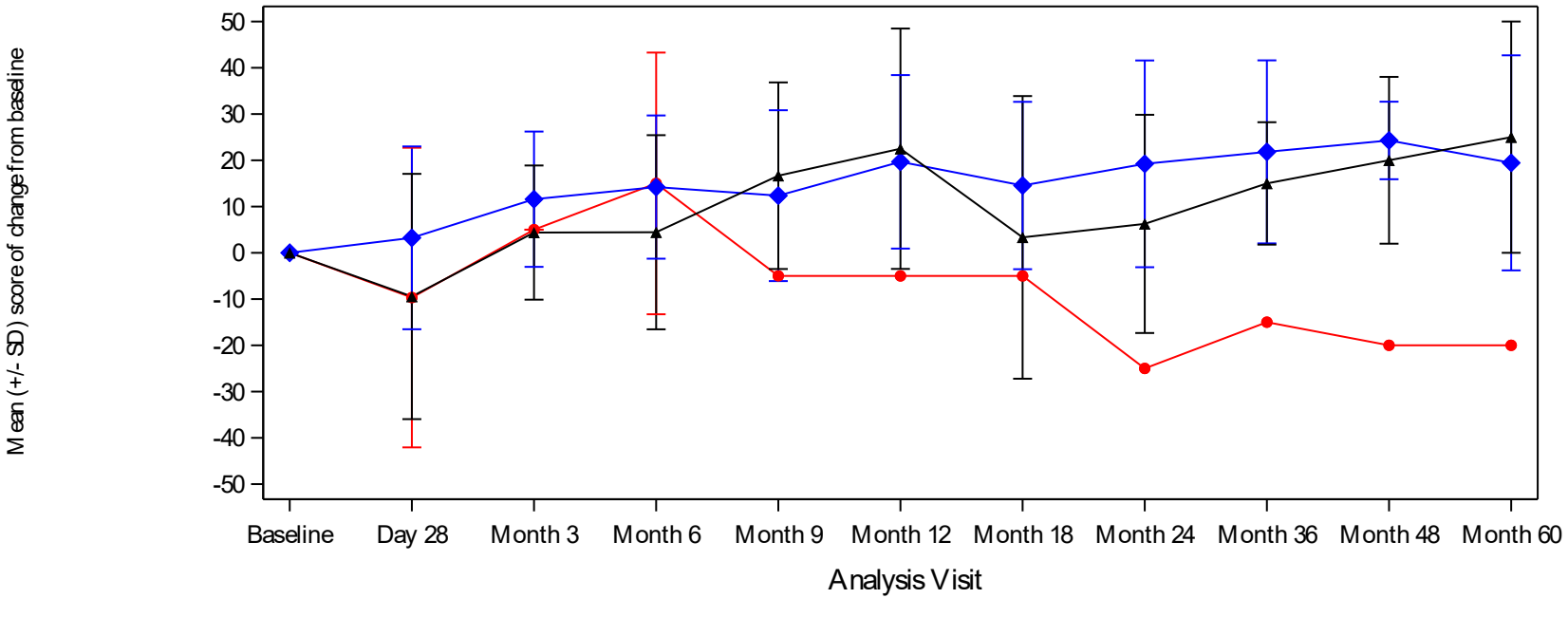


<10 years	11	8	7	7	4	2	2	2	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	12	14	12	7	9
>=18	11	9	9	10	7	5	3	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53a (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

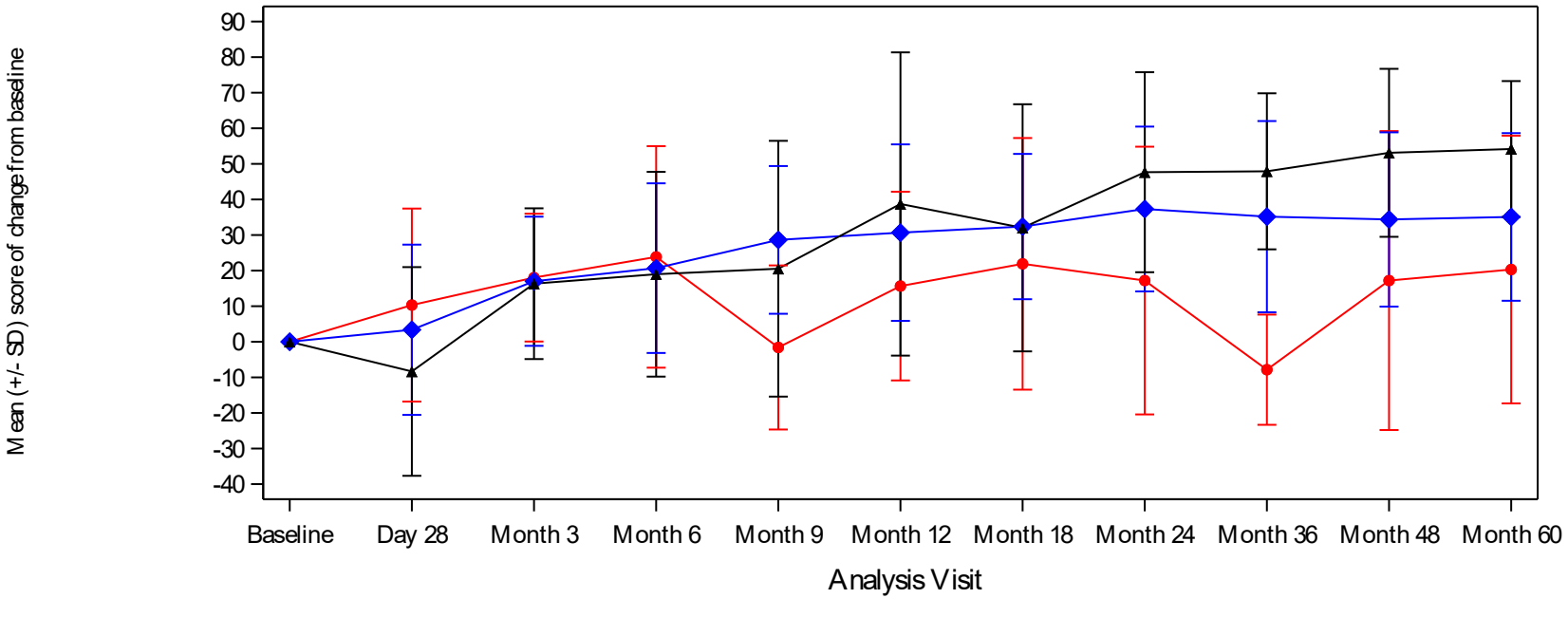


<10 years	7	4	2	2	1	1	1	1	1	1	1
>=10 years to <18 years	28	17	21	19	17	15	11	13	11	7	9
>=18	10	9	8	9	6	4	3	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53a (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

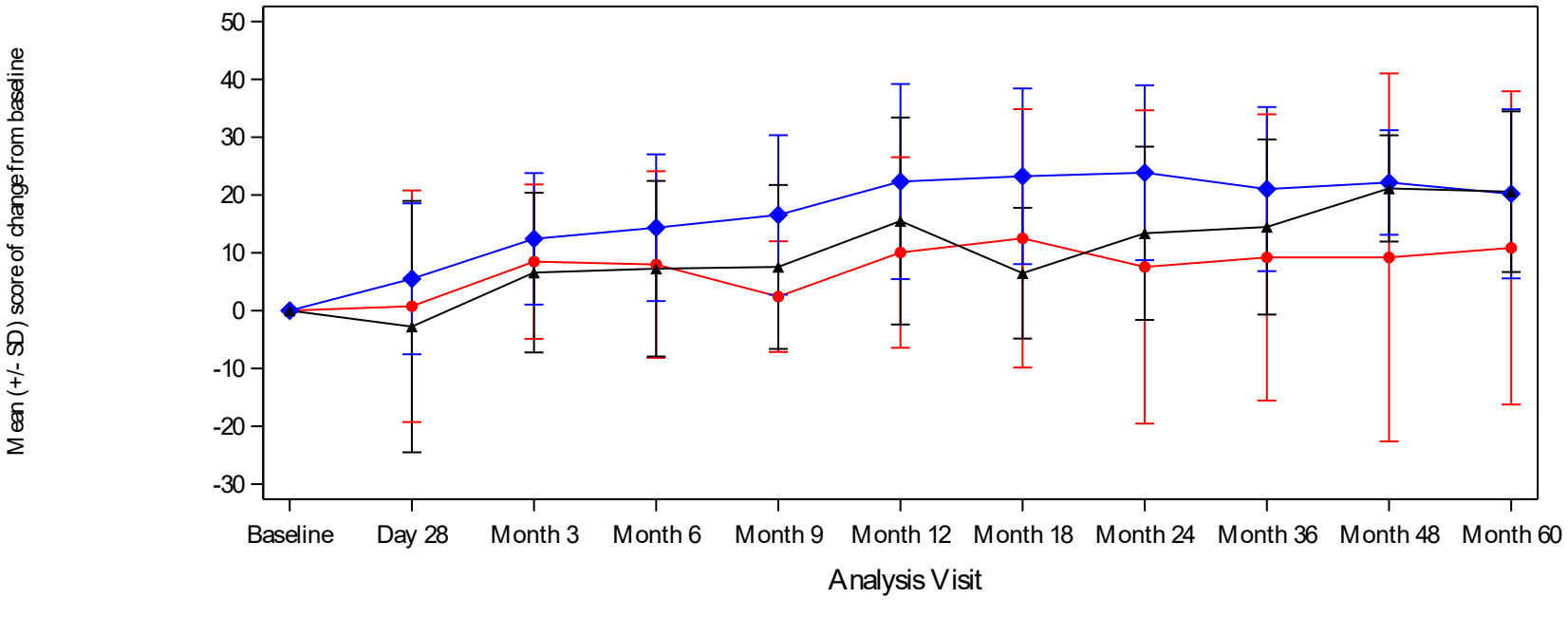


<10 years	11	9	7	7	4	2	2	2	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	12	14	12	7	9
>=18	11	9	9	10	7	5	4	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53a (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

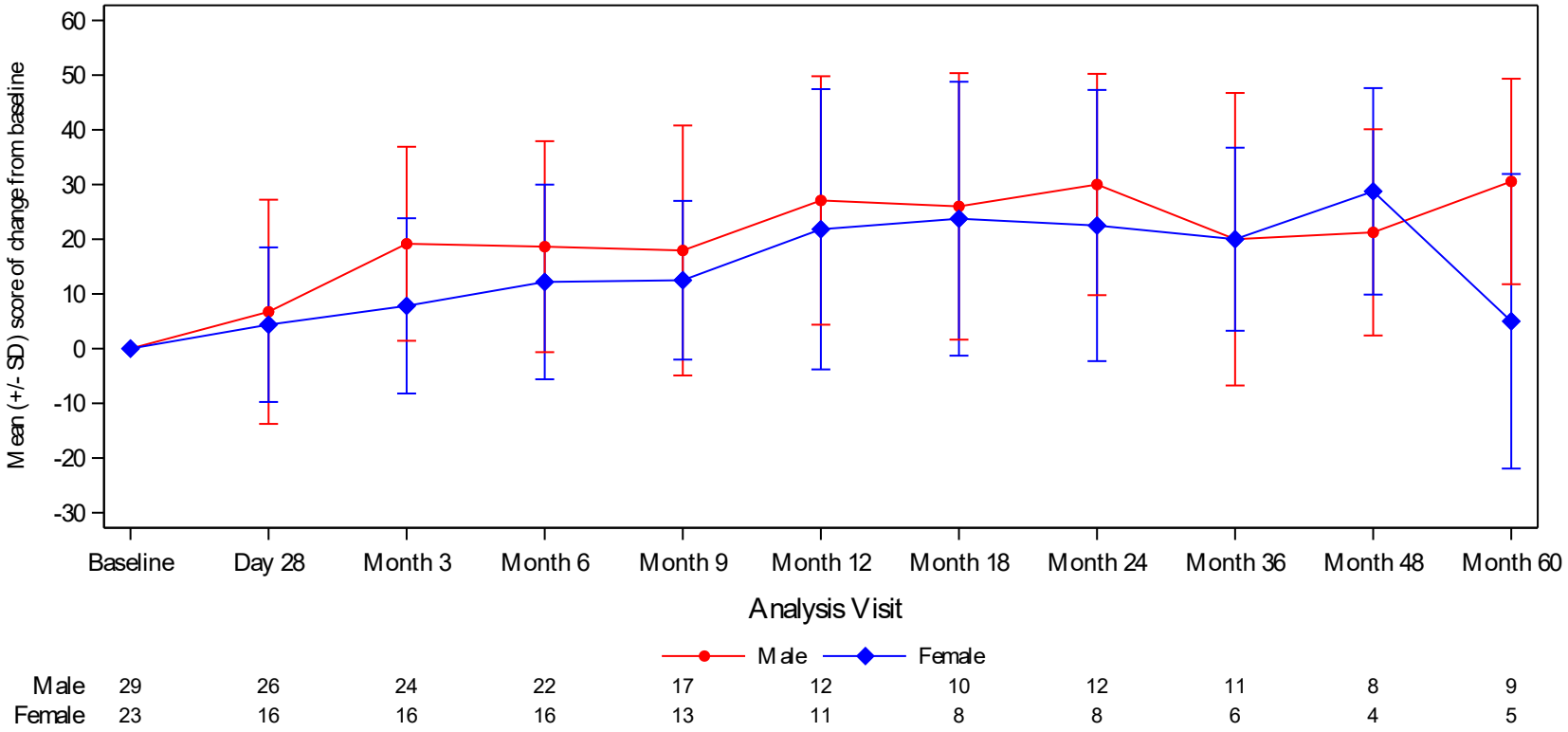


<10 years	11	9	7	7	4	2	2	2	2	2	2
>=10 years to <18 years	30	24	24	21	19	16	12	14	12	7	9
>=18	11	9	9	10	7	5	4	4	3	3	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53b (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Gender
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

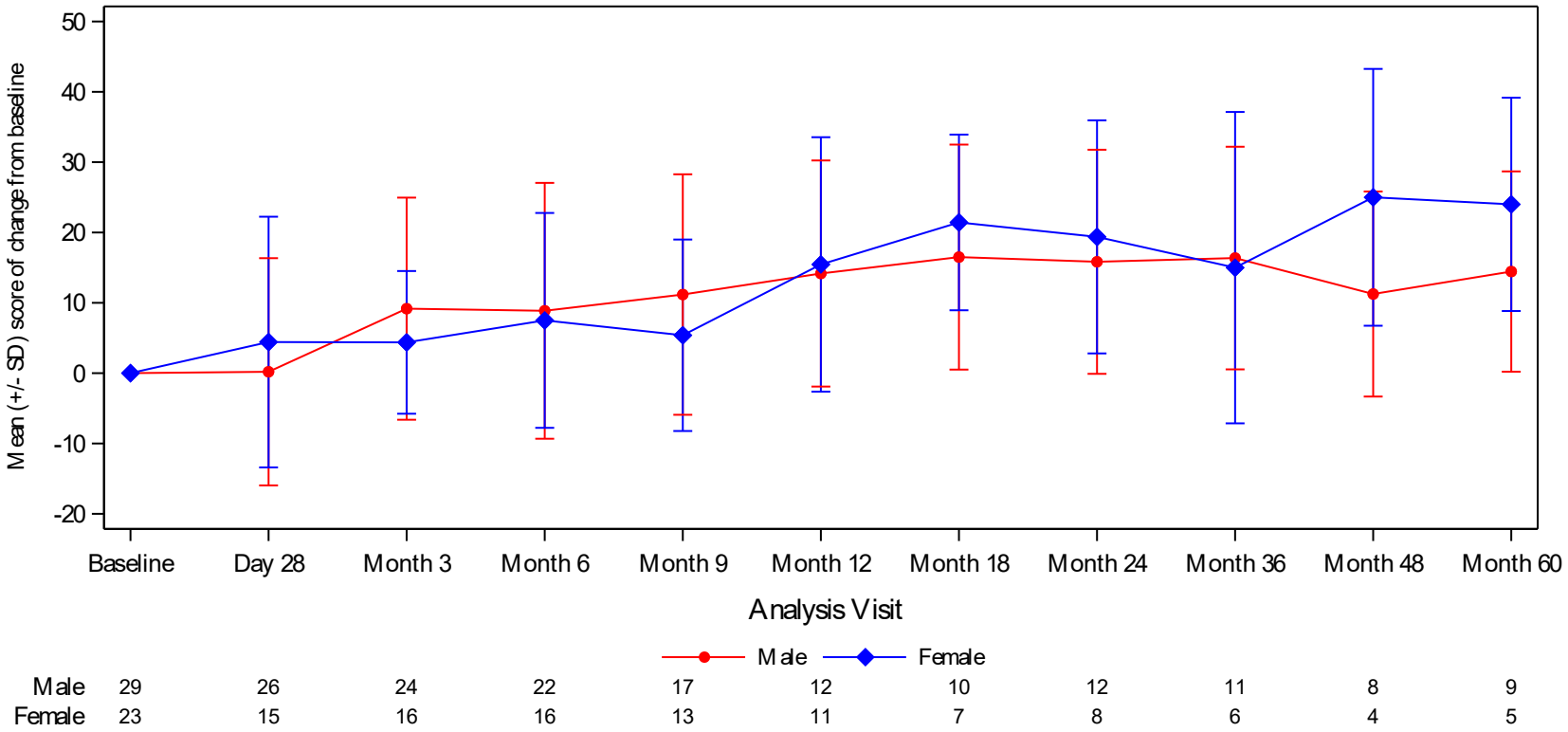


Male	29	26	24	22	17	12	10	12	11	8	9
Female	23	16	16	16	13	11	8	8	6	4	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53b (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Gender
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

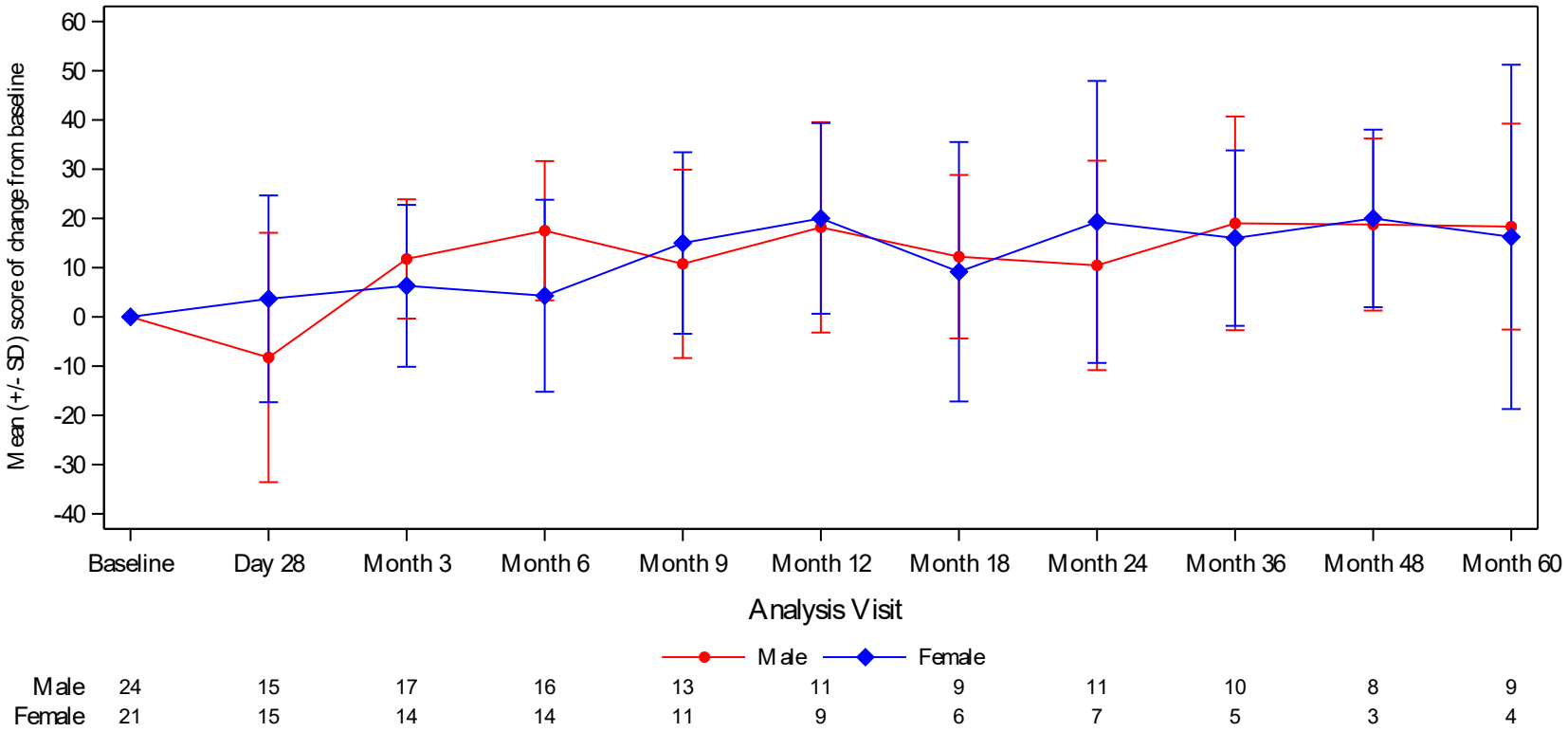


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Male	29	26	24	22	17	12	10	12	11	8	9
Female	23	15	16	16	13	11	7	8	6	4	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53b (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Gender
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

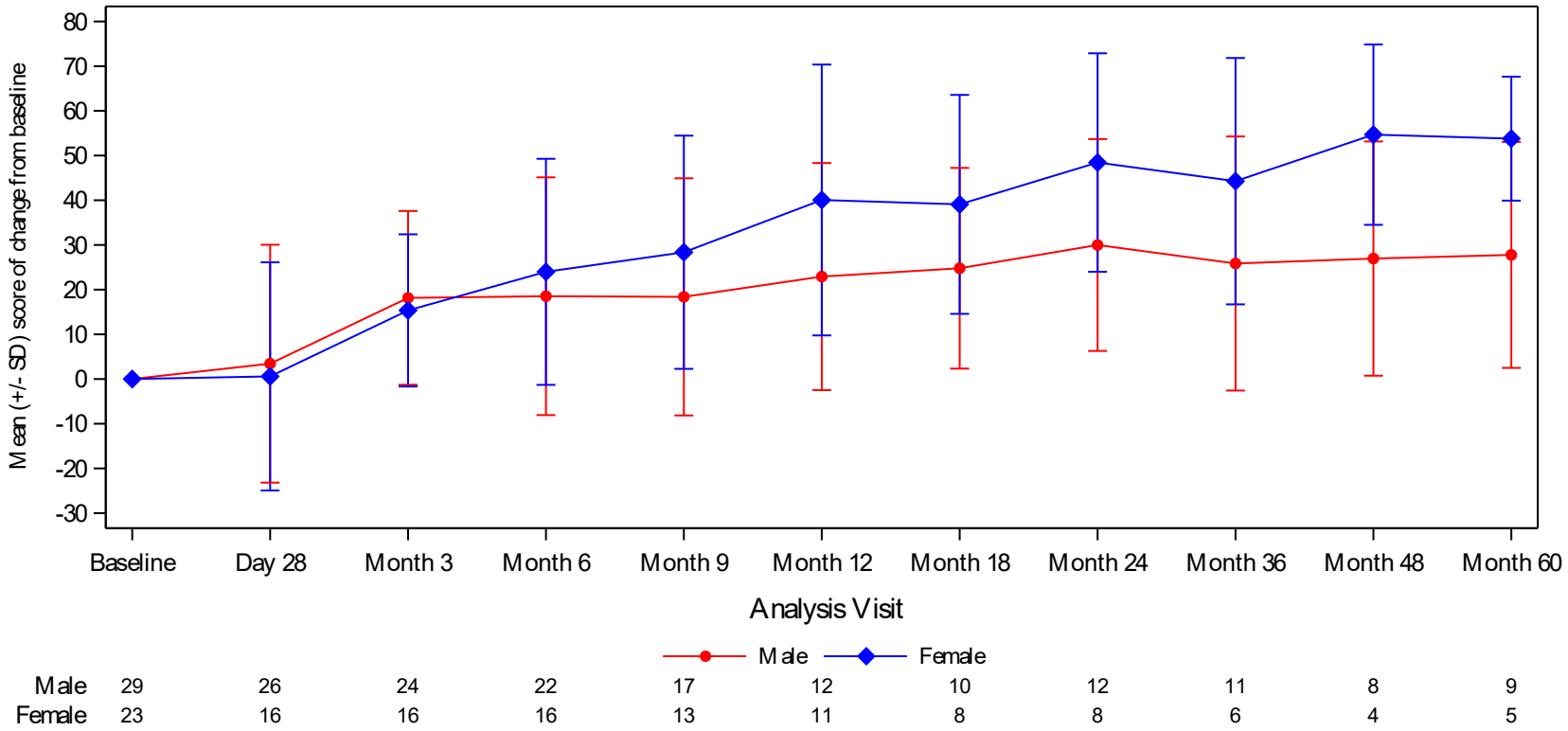


Male	24	15	17	16	13	11	9	11	10	8	9
Female	21	15	14	14	11	9	6	7	5	3	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53b (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Gender
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

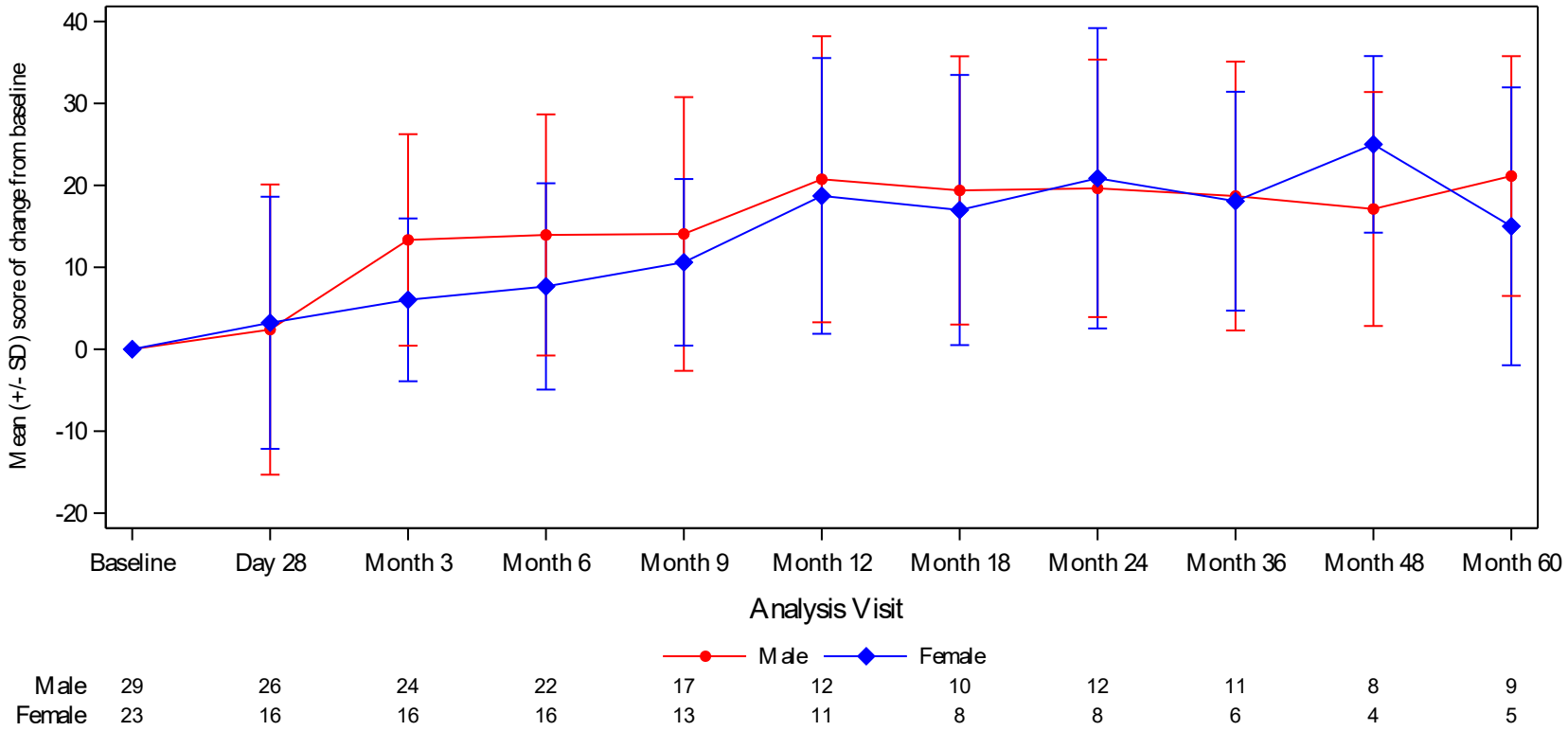


Male	29	26	24	22	17	12	10	12	11	8	9
Female	23	16	16	16	13	11	8	8	6	4	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53b (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Gender
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

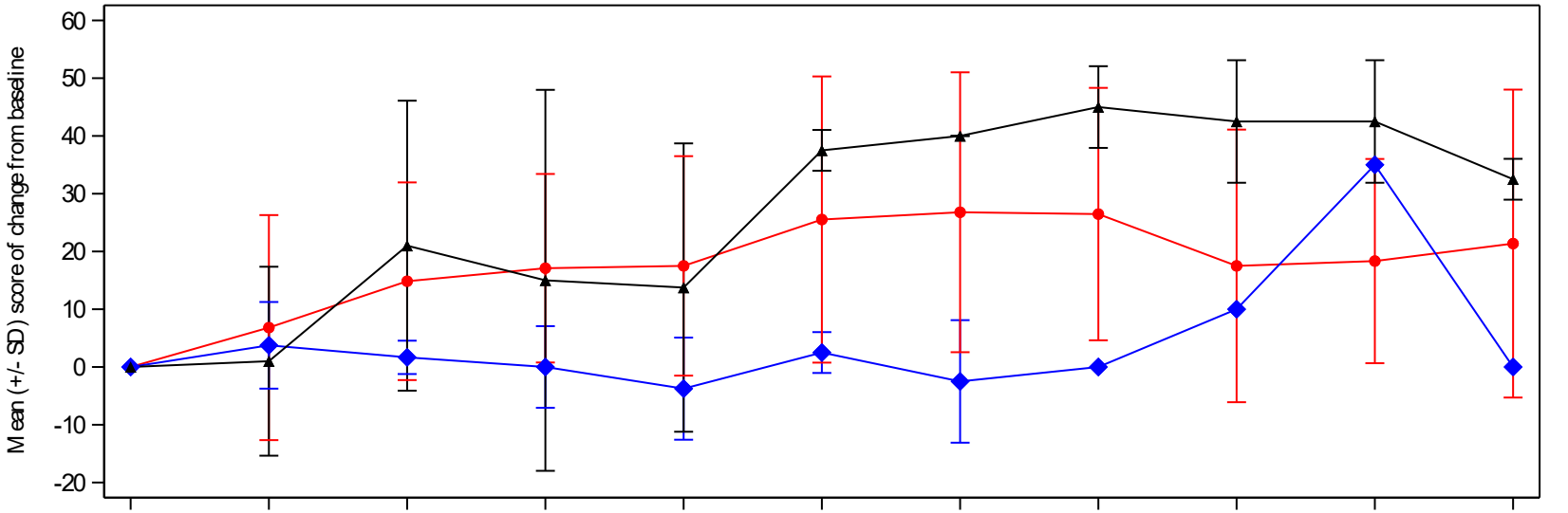


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Male	29	26	24	22	17	12	10	12	11	8	9
Female	23	16	16	16	13	11	8	8	6	4	5

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53c (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

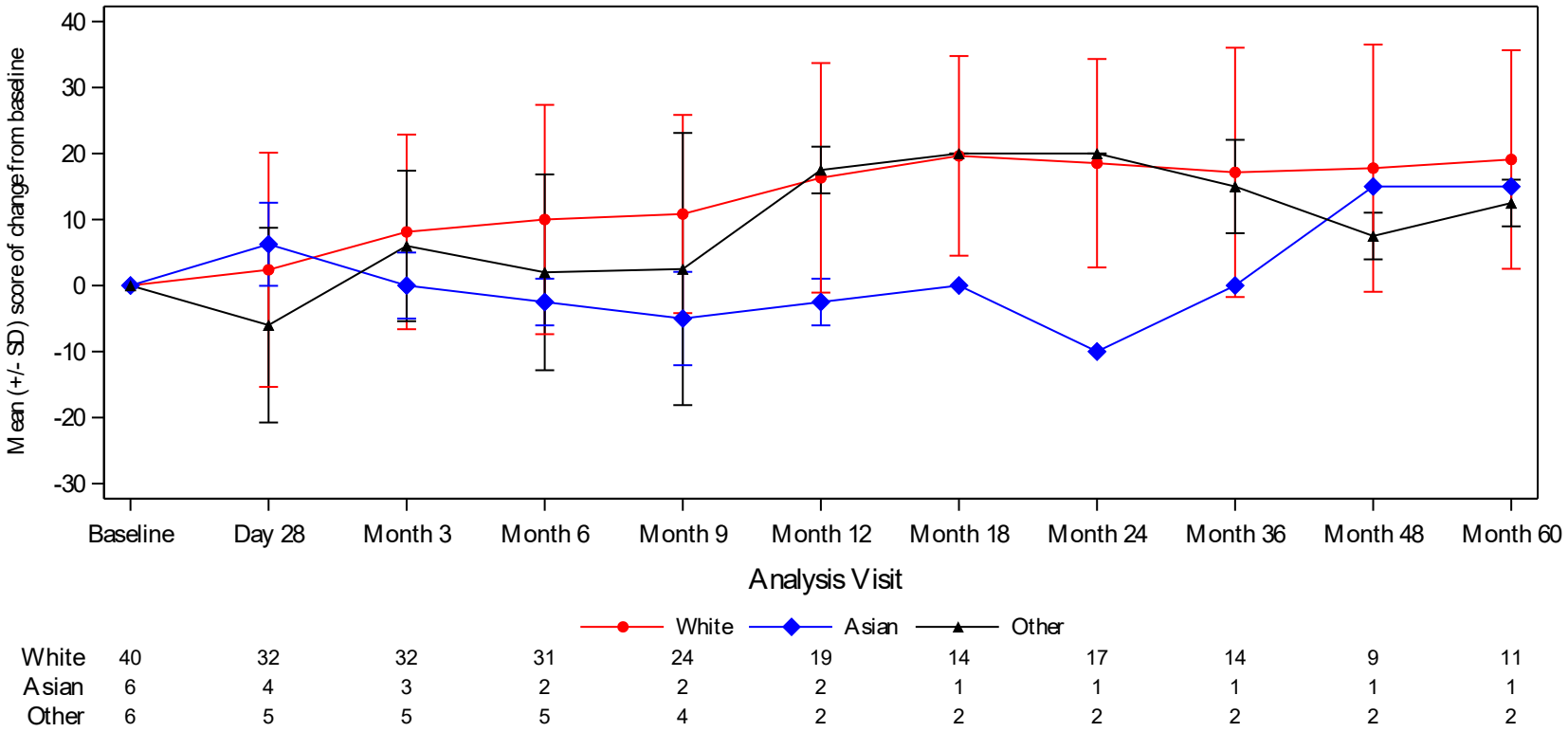


White	40	33	32	31	24	19	14	17	14	9	11
Asian	6	4	3	2	2	2	2	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53c (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

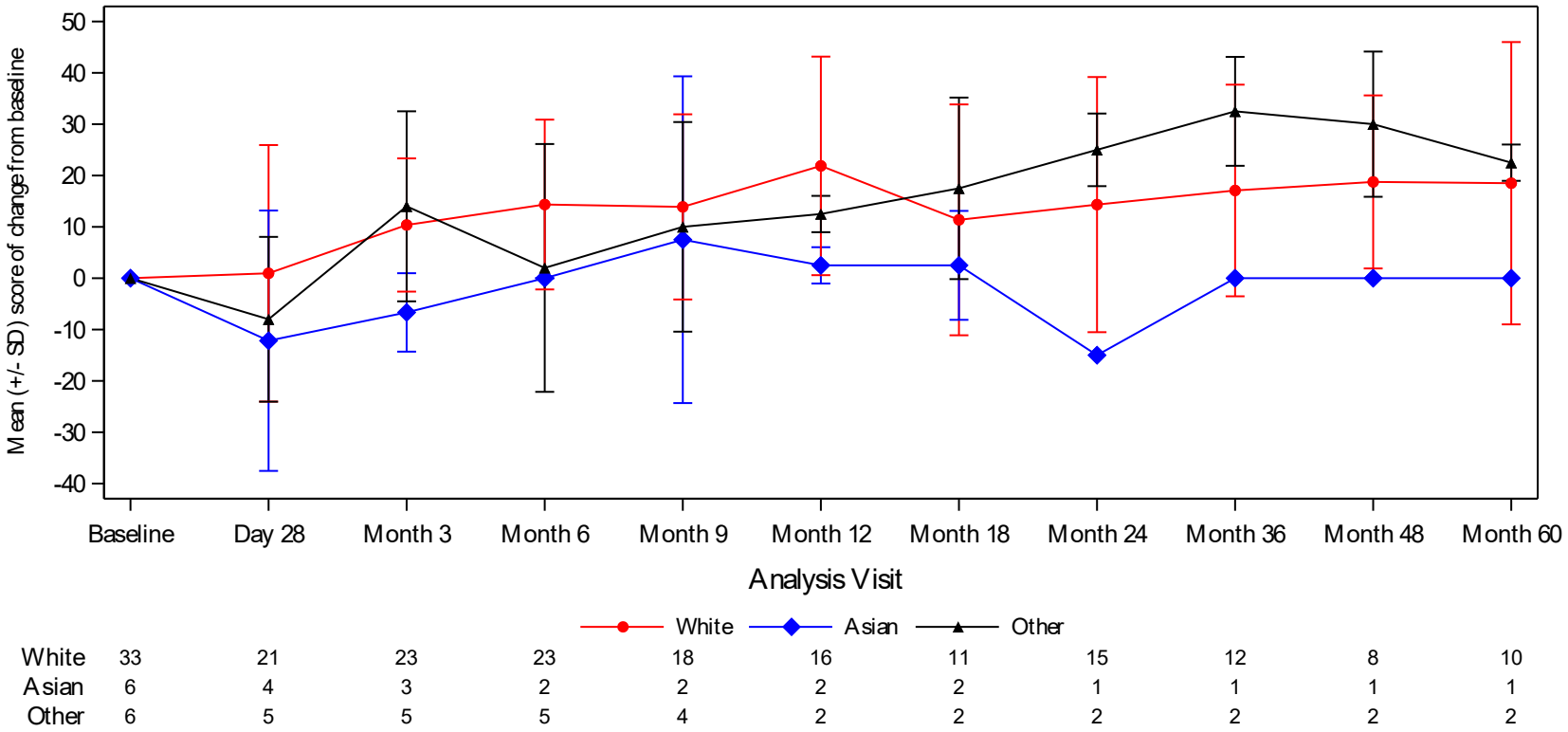


White	40	32	32	31	24	19	14	17	14	9	11
Asian	6	4	3	2	2	2	1	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53c (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

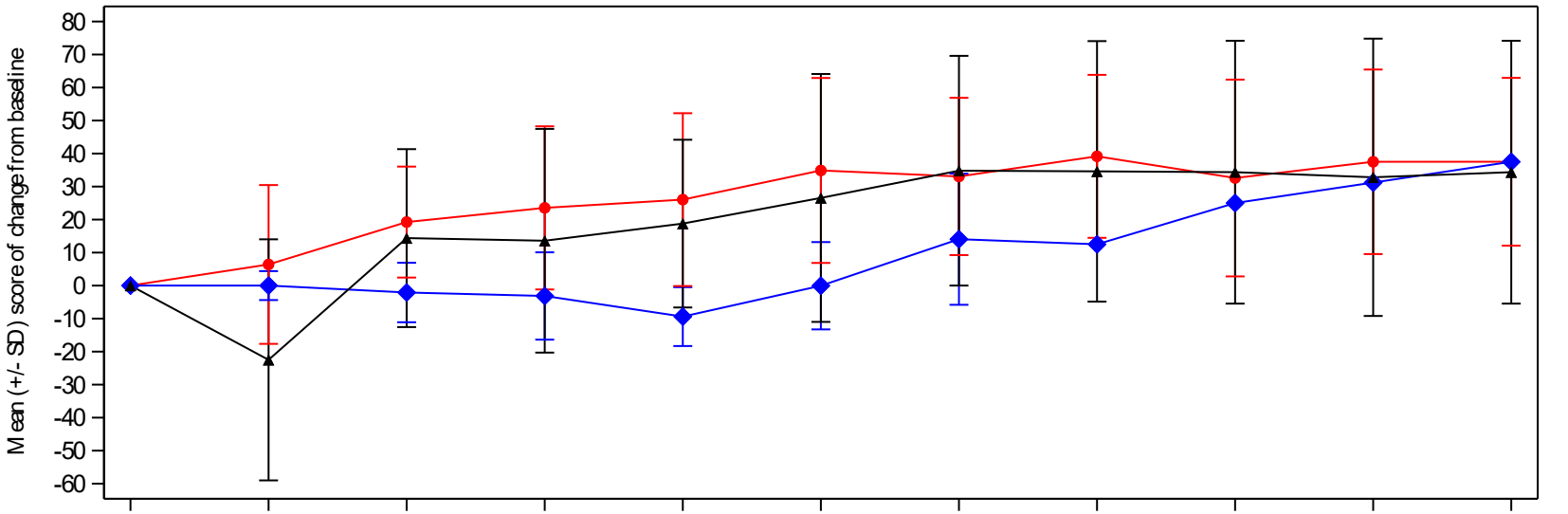


White	33	21	23	23	18	16	11	15	12	8	10
Asian	6	4	3	2	2	2	2	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53c (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

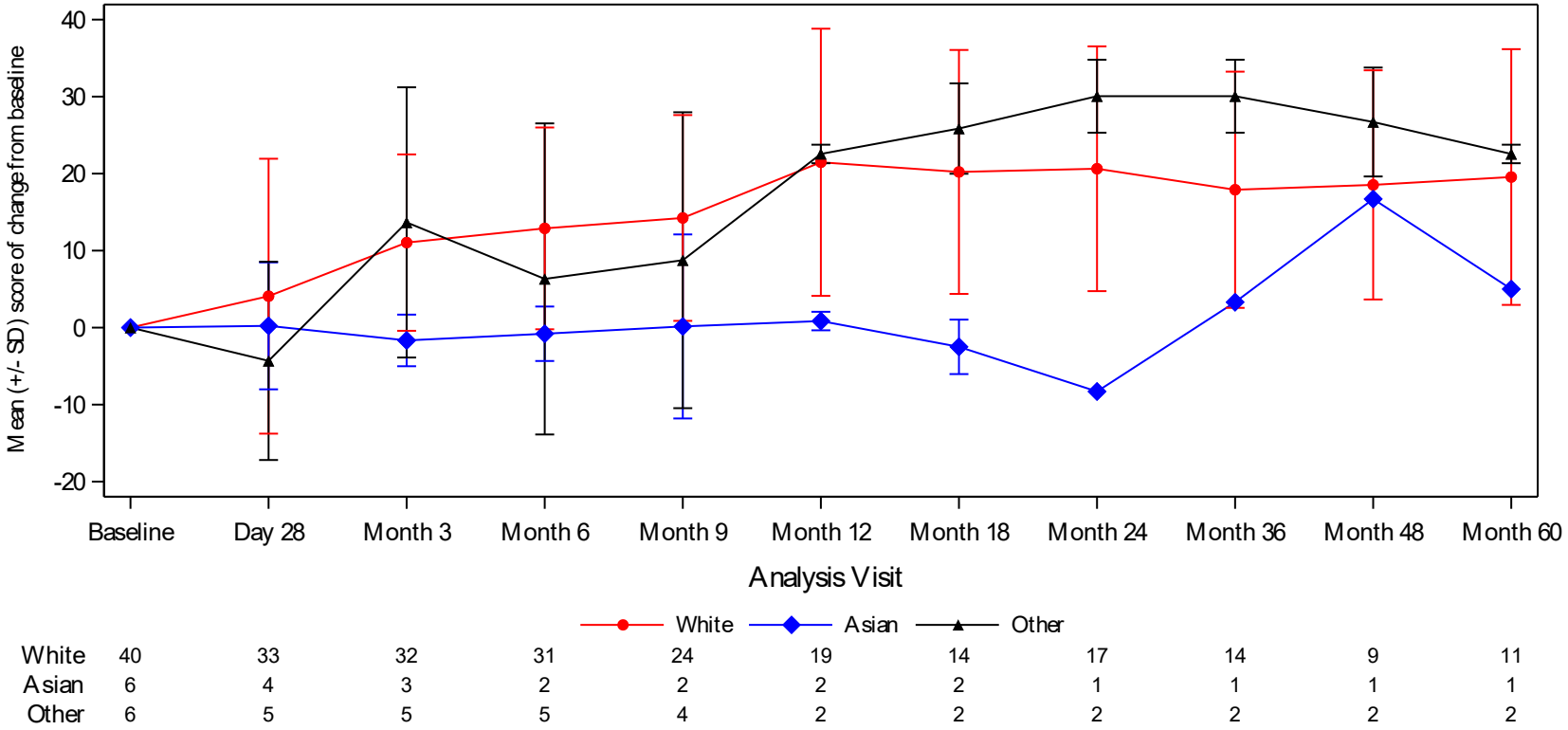


White	40	33	32	31	24	19	14	17	14	9	11
Asian	6	4	3	2	2	2	2	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53c (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

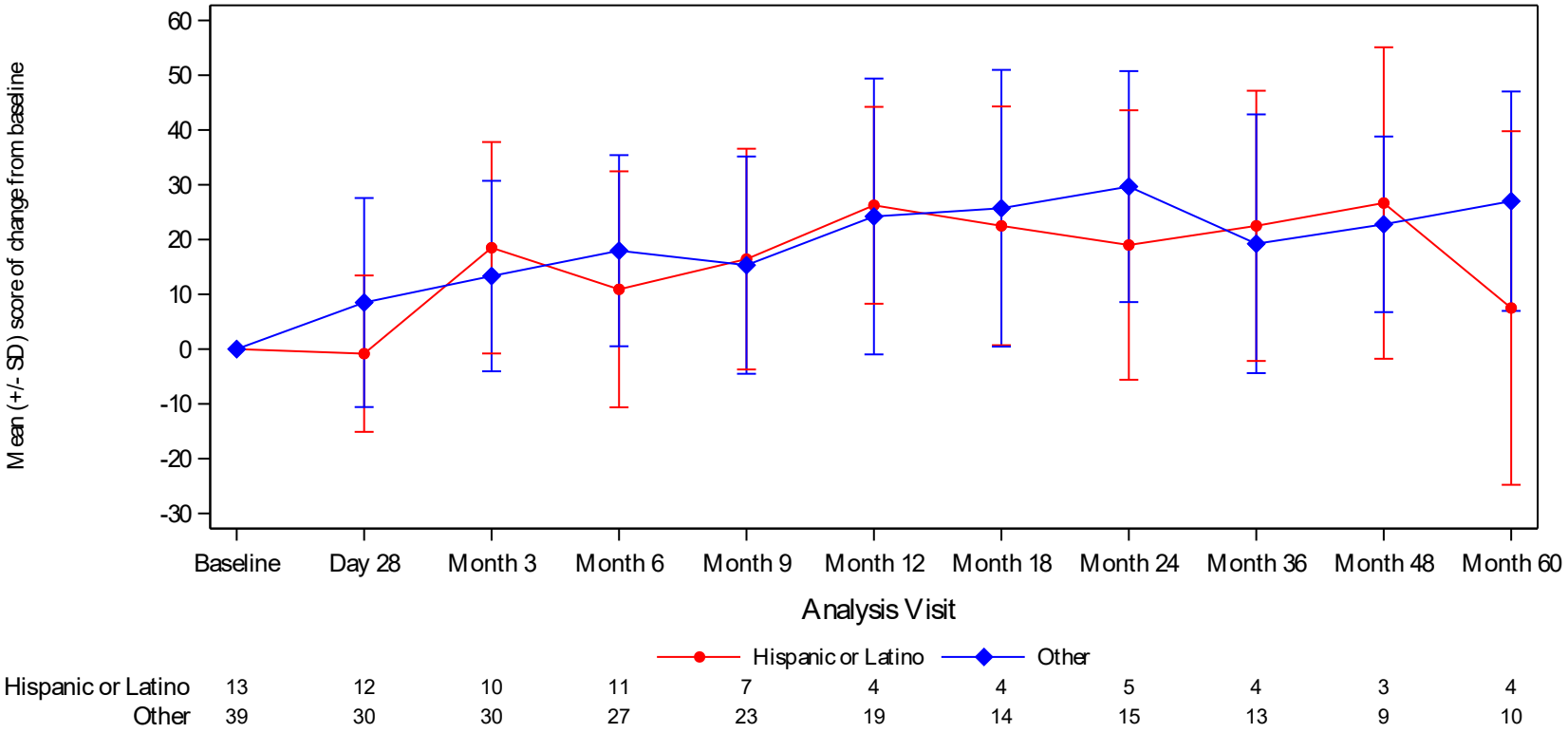


White	40	33	32	31	24	19	14	17	14	9	11
Asian	6	4	3	2	2	2	2	1	1	1	1
Other	6	5	5	5	4	2	2	2	2	2	2

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53d (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

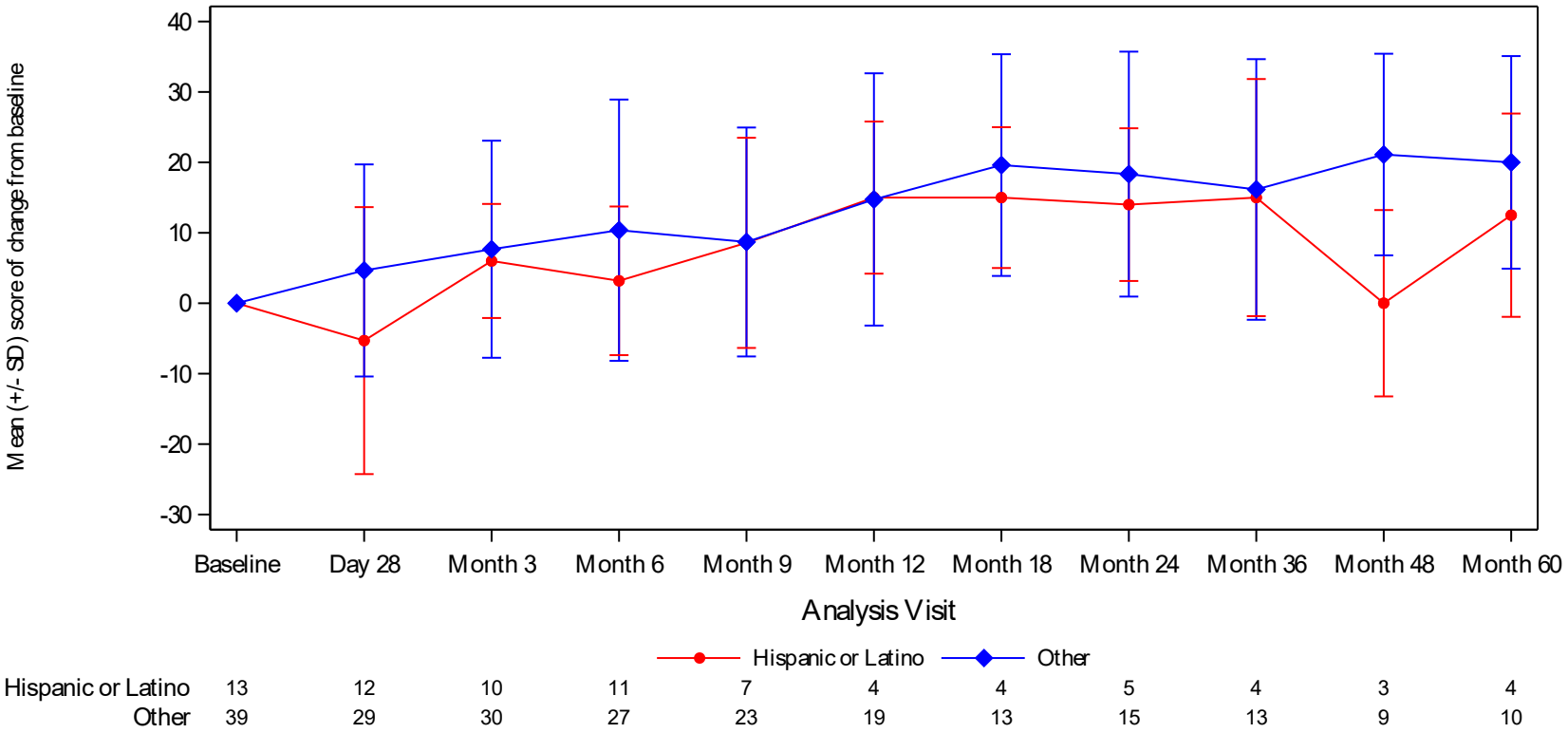


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	13	12	10	11	7	4	4	5	4	3	4
Other	39	30	30	27	23	19	14	15	13	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53d (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

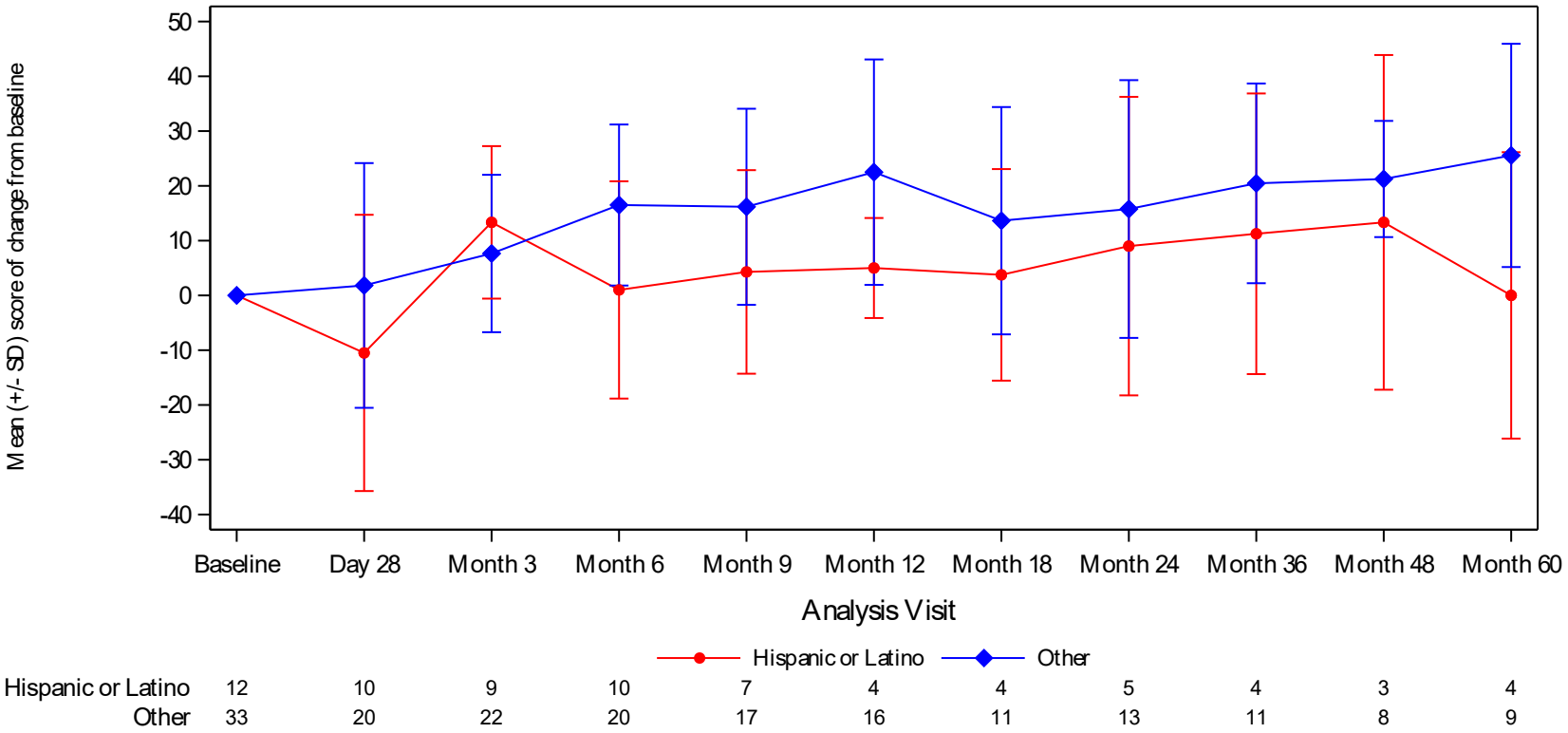


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	13	12	10	11	7	4	4	5	4	3	4
Other	39	29	30	27	23	19	13	15	13	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53d (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

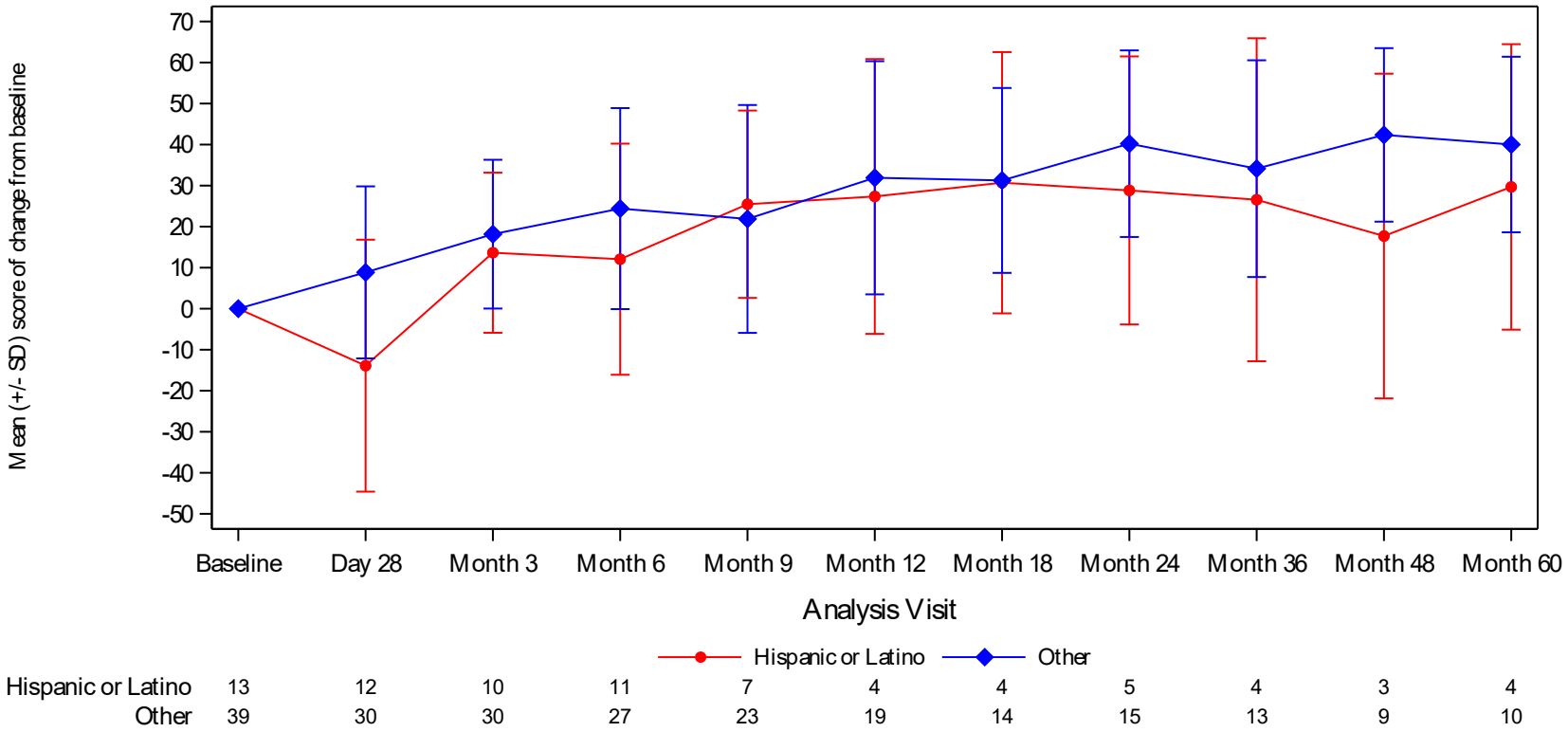


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	12	10	9	10	7	4	4	5	4	3	4
Other	33	20	22	20	17	16	11	13	11	8	9

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53d (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

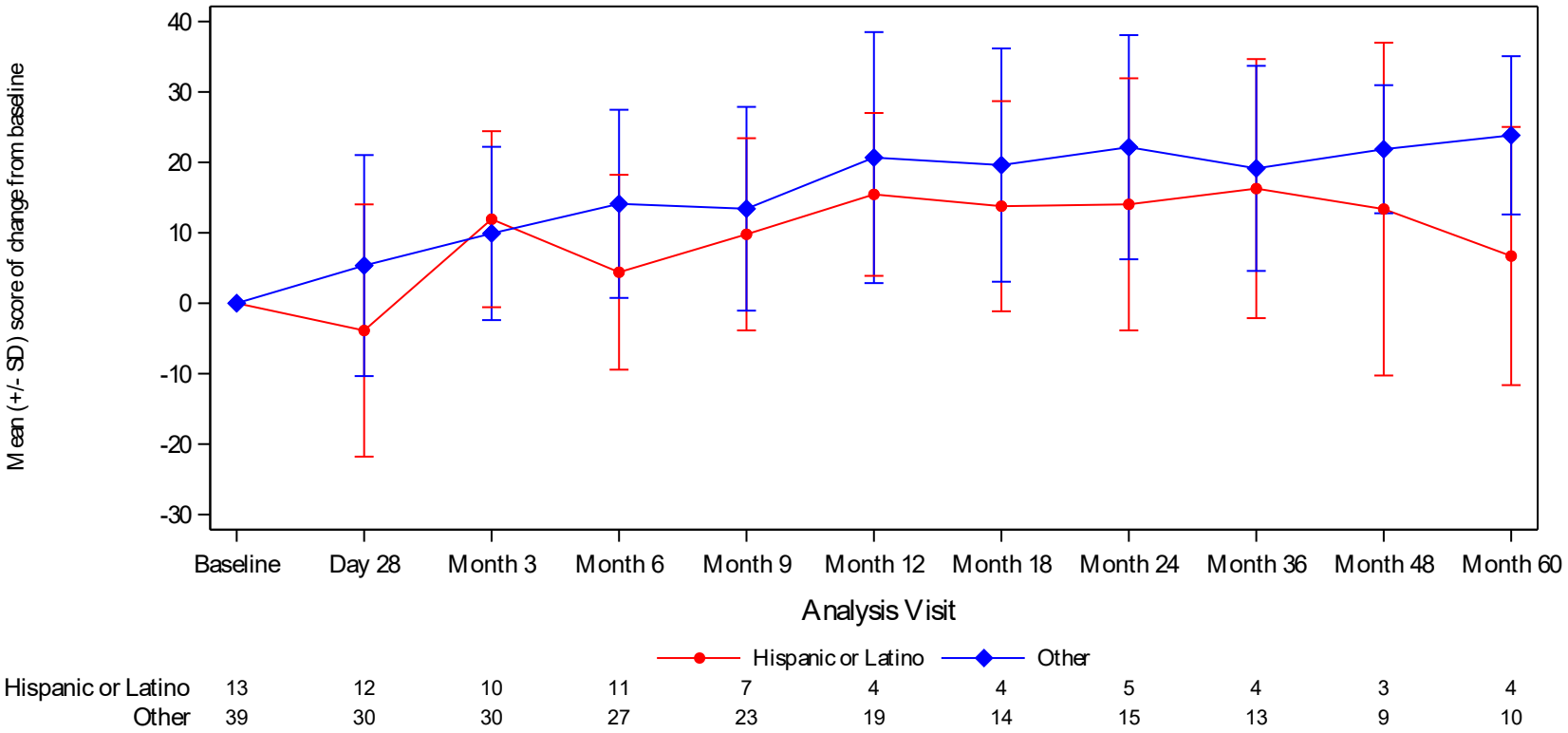


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	13	12	10	11	7	4	4	5	4	3	4
Other	39	30	30	27	23	19	14	15	13	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53d (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

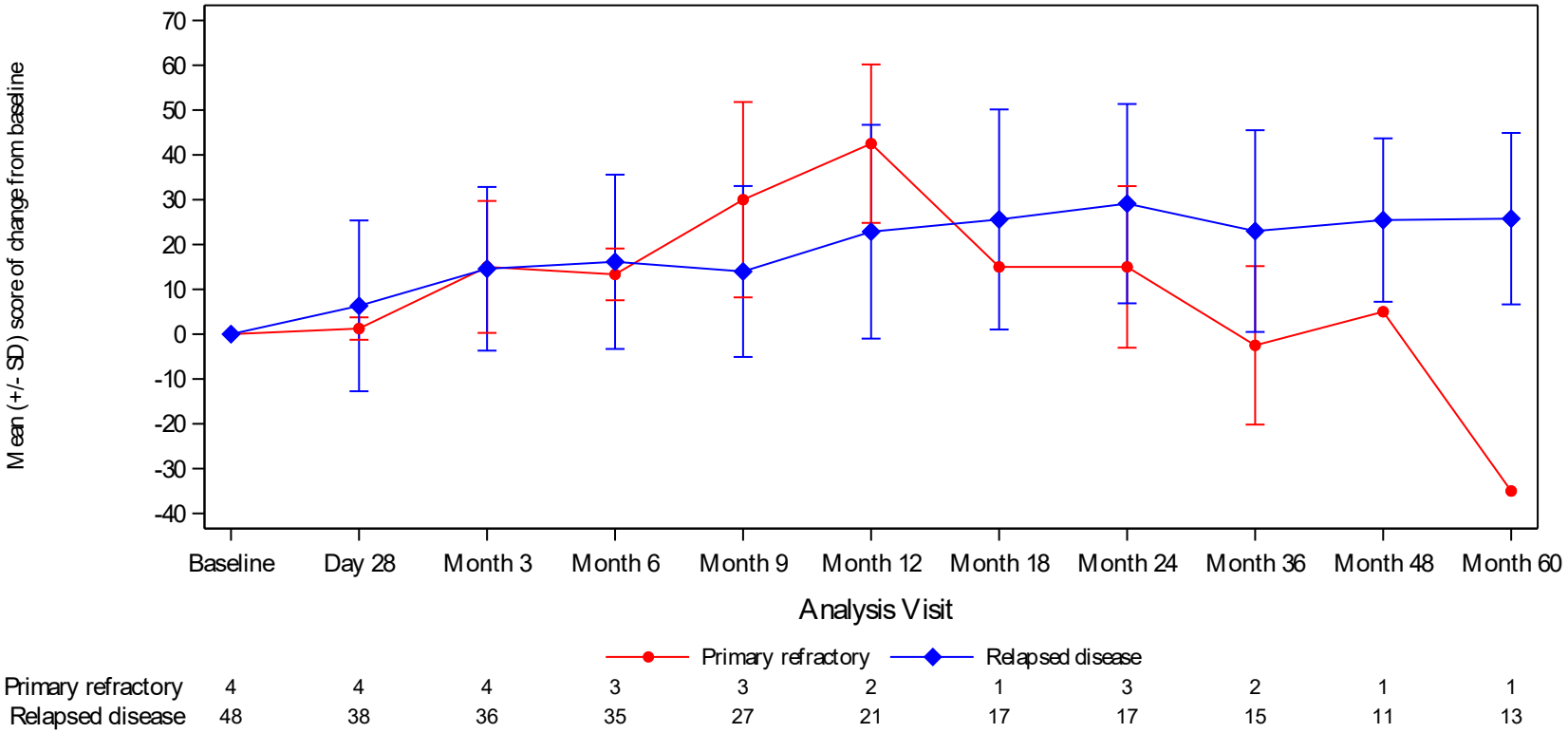


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Hispanic or Latino	13	12	10	11	7	4	4	5	4	3	4
Other	39	30	30	27	23	19	14	15	13	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53e (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

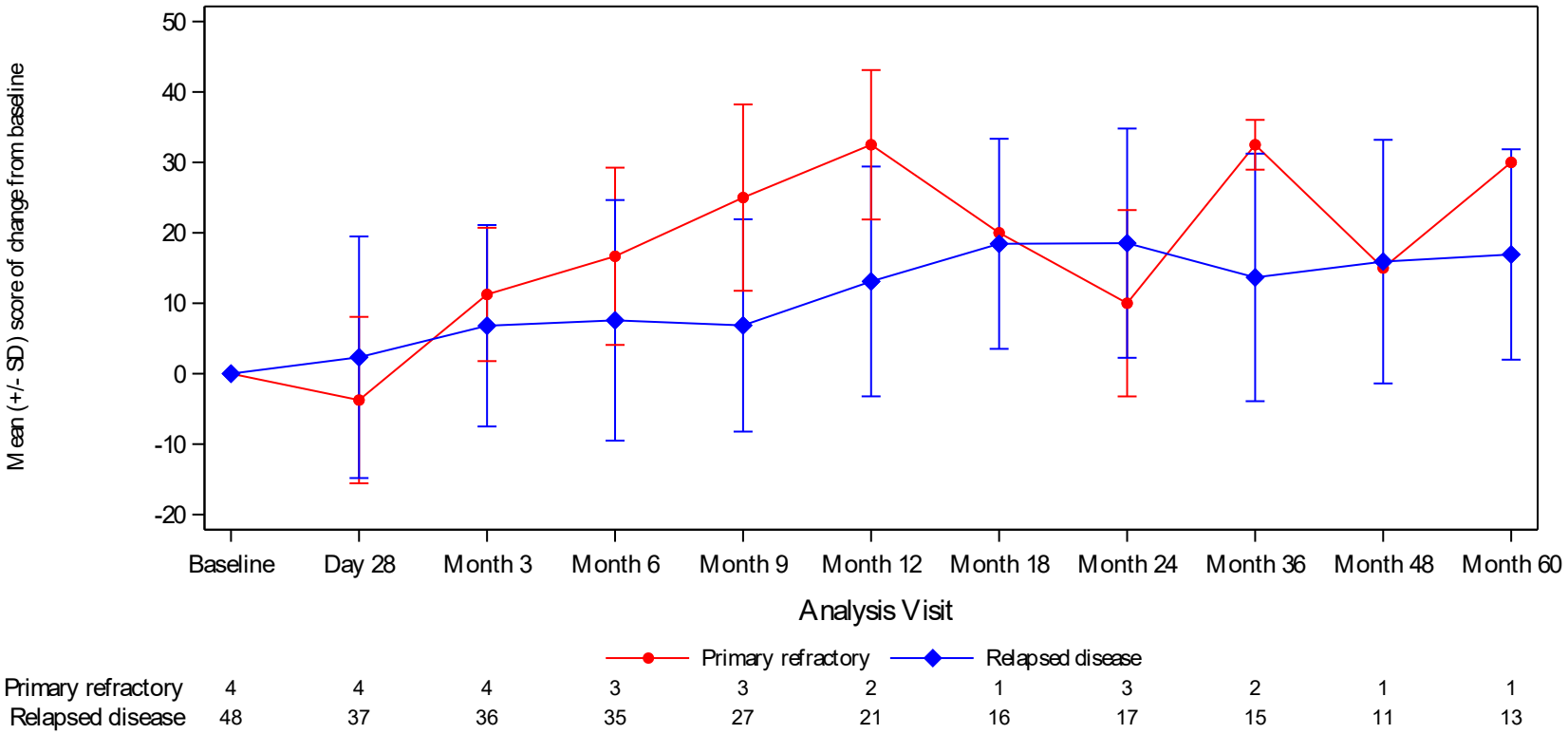


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Primary refractory	4	4	4	3	3	2	1	3	2	1	1
Relapsed disease	48	38	36	35	27	21	17	17	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53e (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

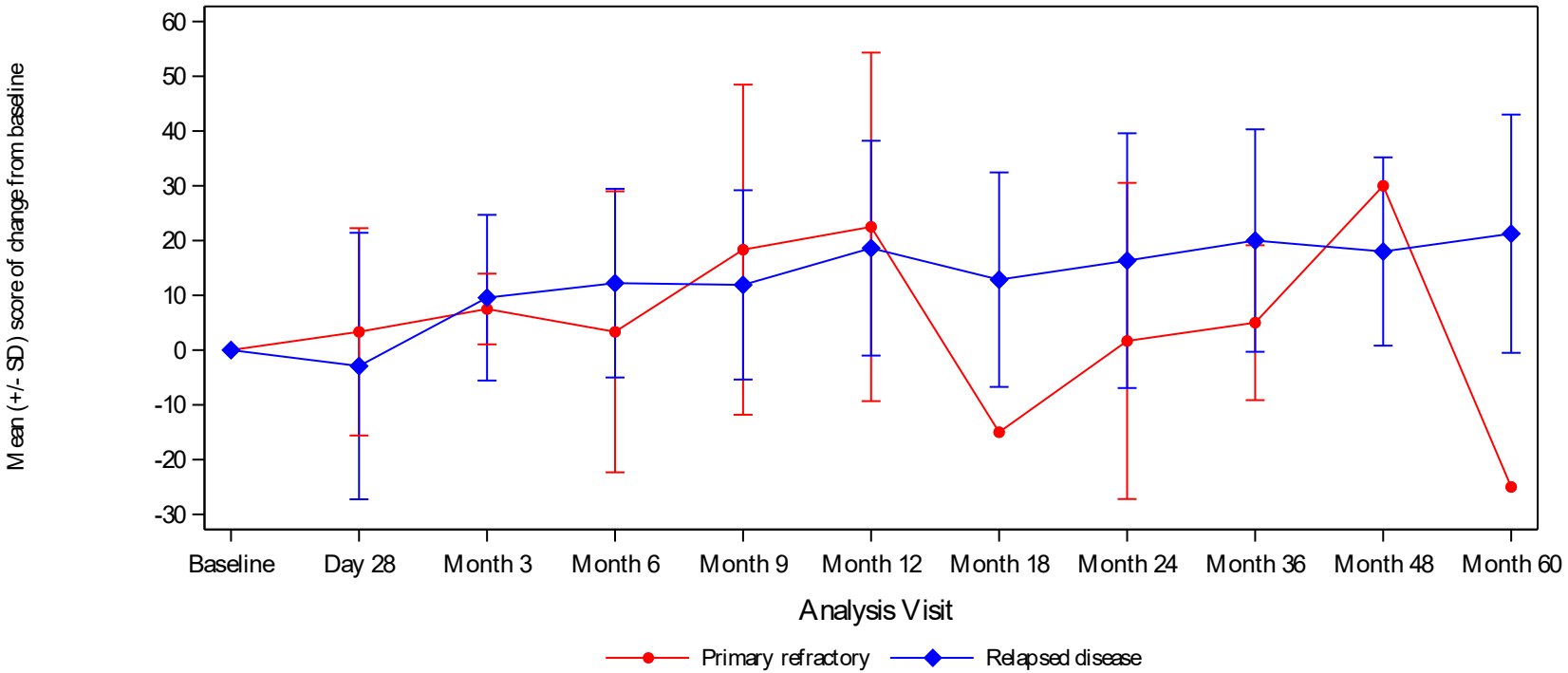


Primary refractory	4	4	4	3	3	2	1	3	2	1	1
Relapsed disease	48	37	36	35	27	21	16	17	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53e (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

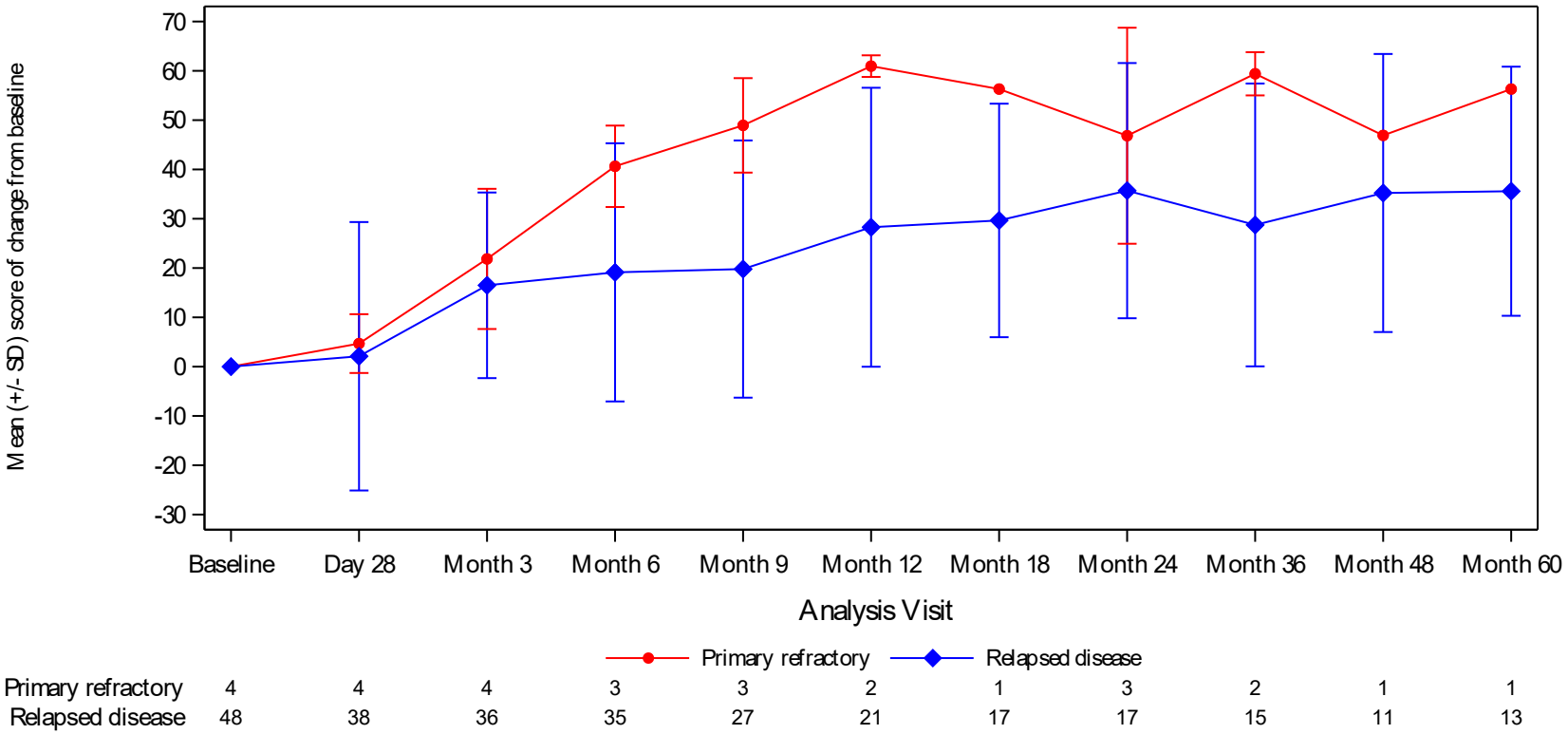


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Primary refractory	4	3	4	3	3	2	1	3	2	1	1
Relapsed disease	41	27	27	27	21	18	14	15	13	10	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53e (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

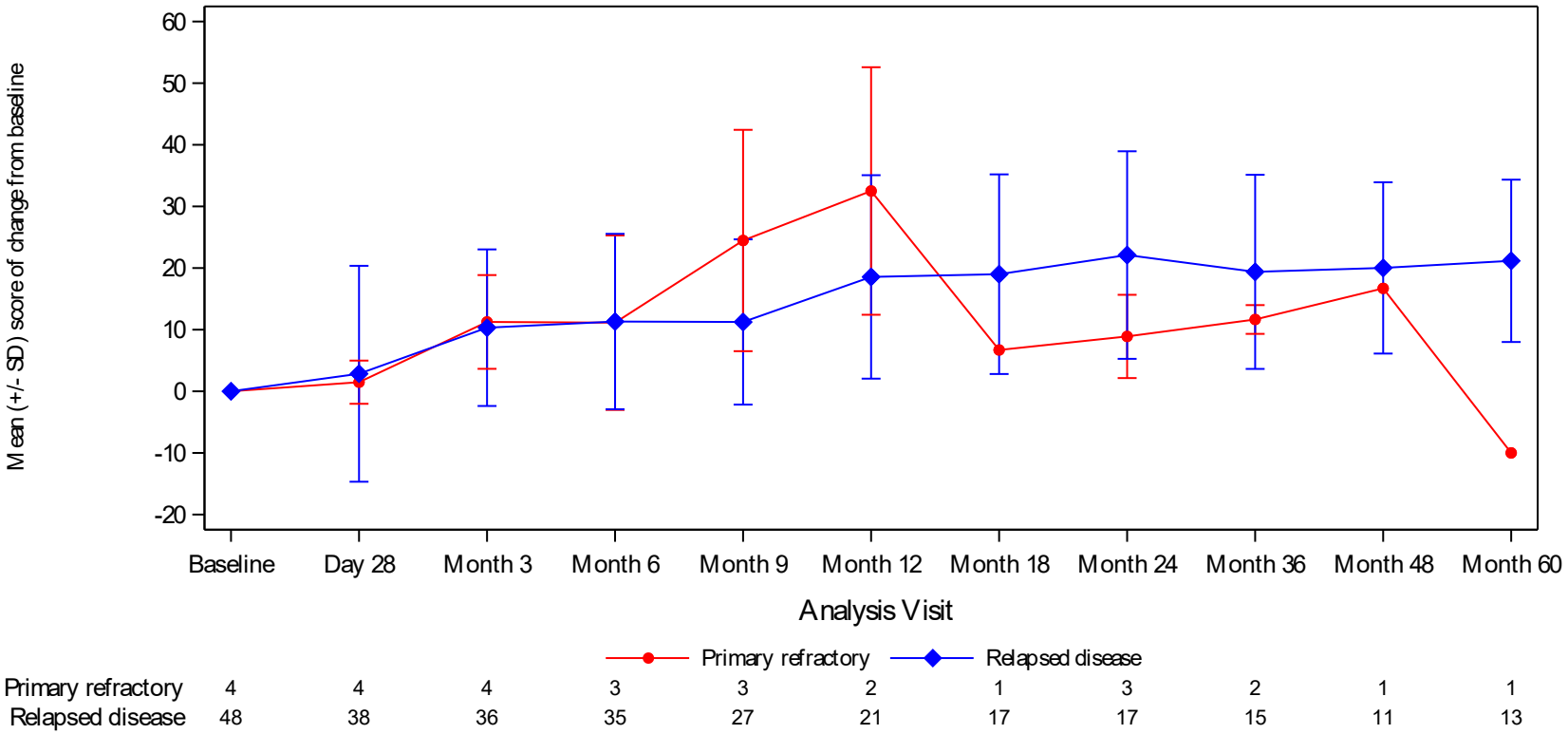


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Primary refractory	4	4	4	3	3	2	1	3	2	1	1
Relapsed disease	48	38	36	35	27	21	17	17	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53e (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

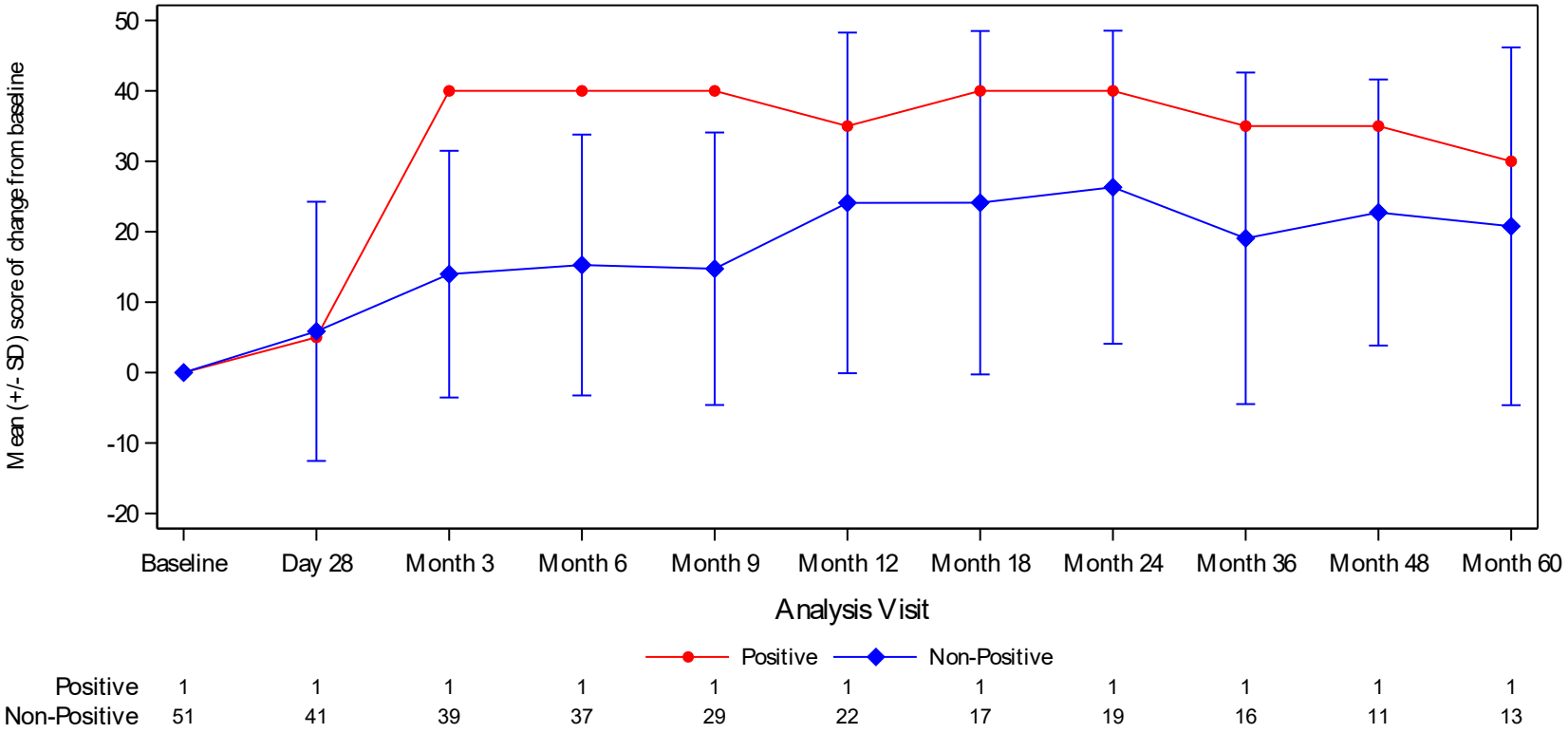


Primary refractory	4	4	4	3	3	2	1	3	2	1	1
Relapsed disease	48	38	36	35	27	21	17	17	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53f (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

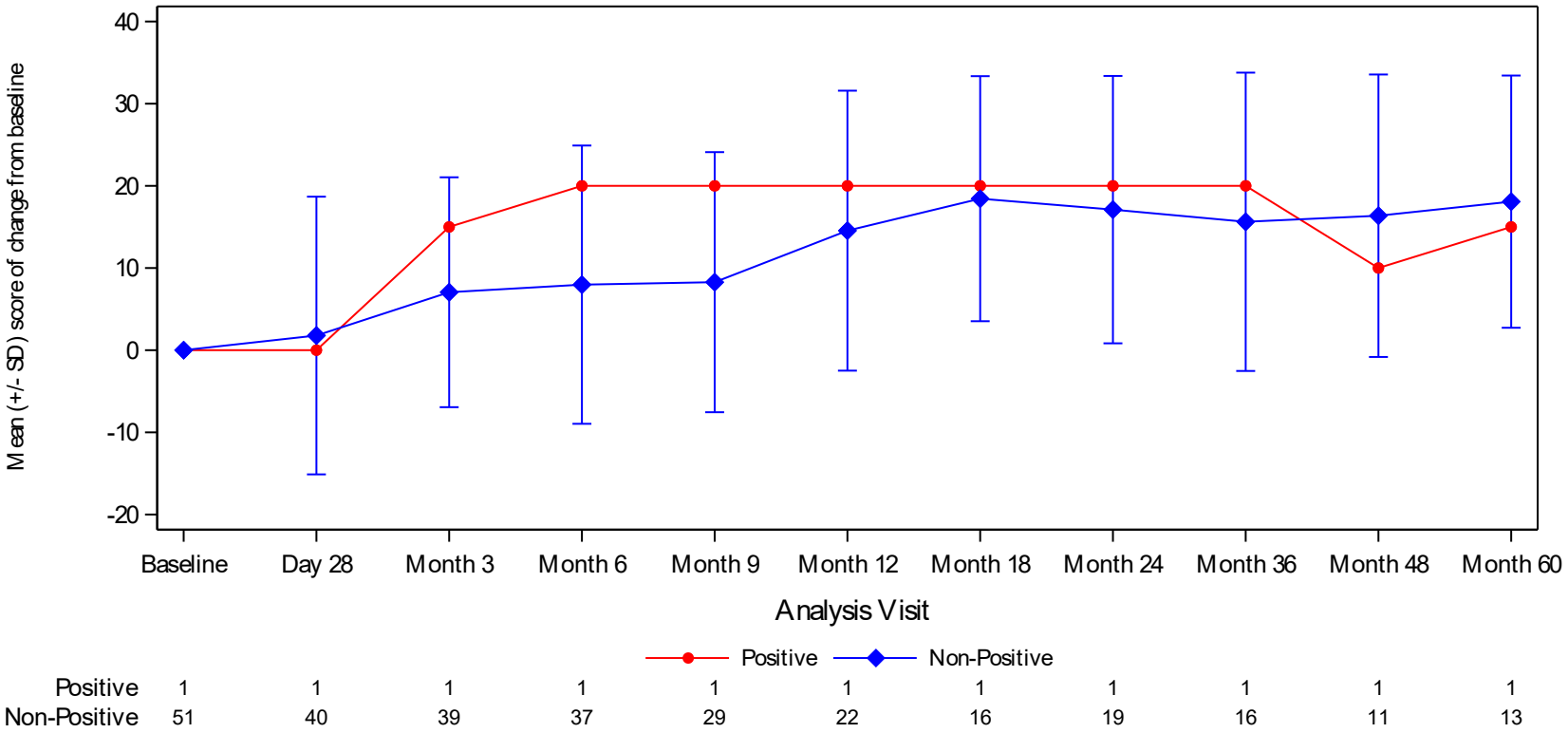


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	41	39	37	29	22	17	19	16	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53f (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

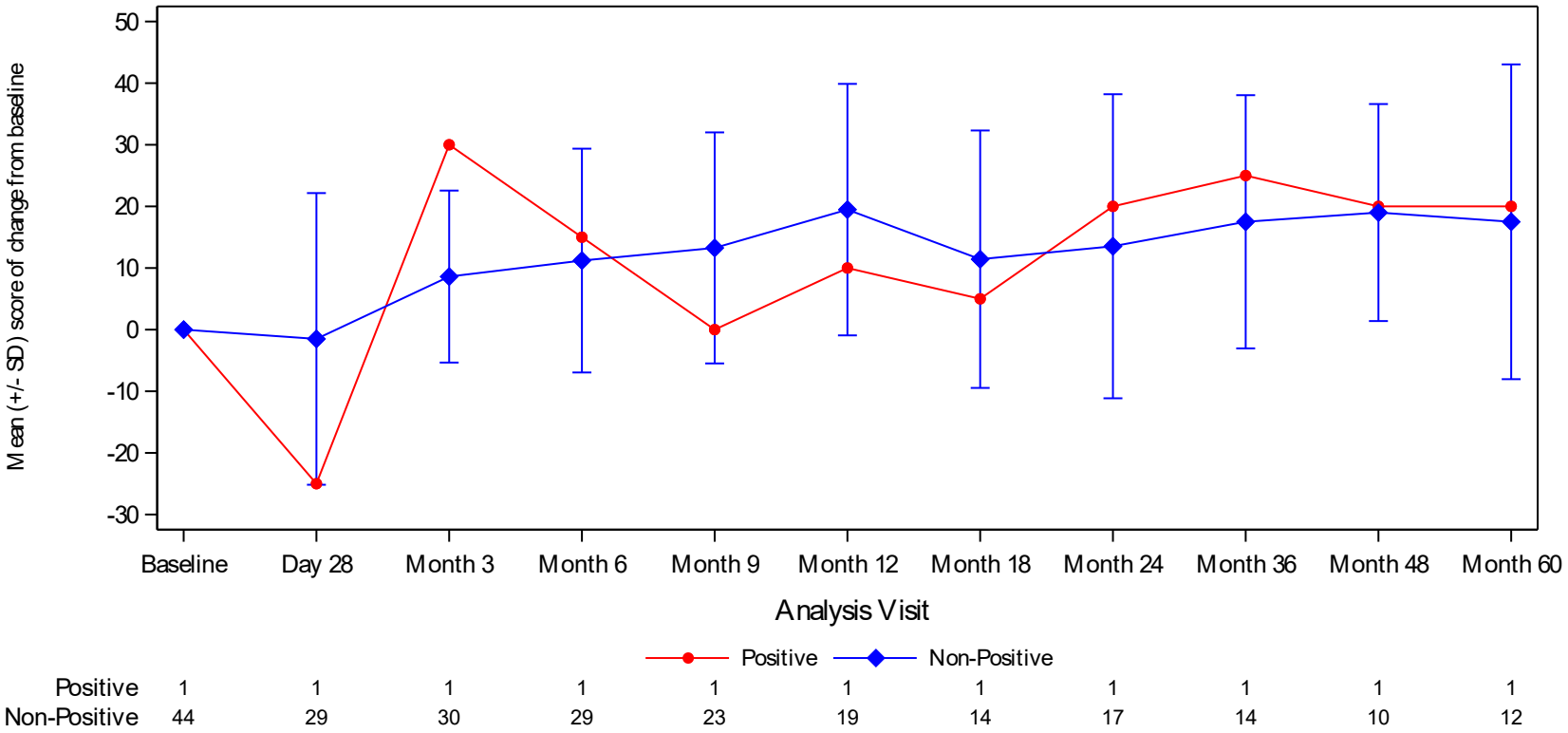


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	40	39	37	29	22	16	19	16	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53f (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

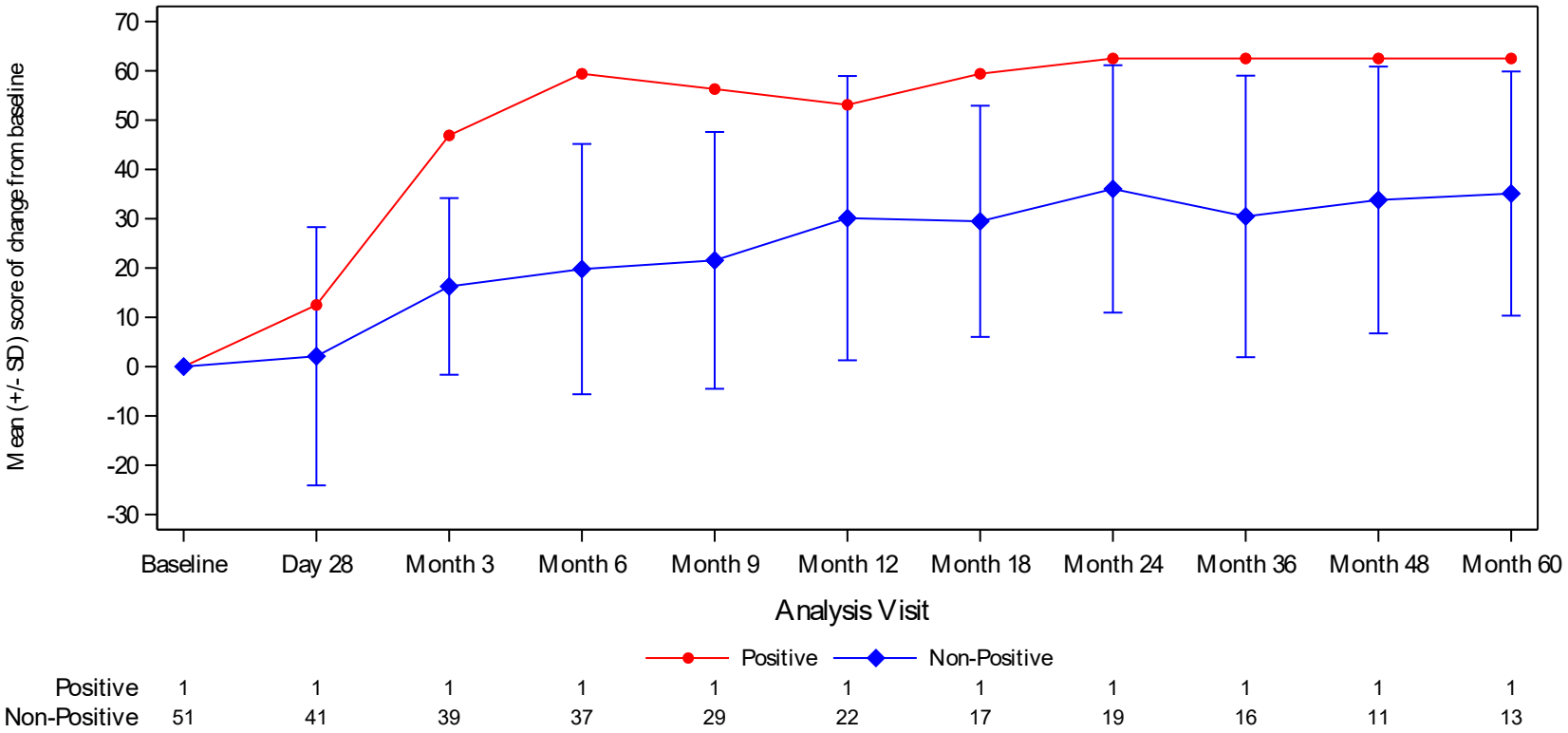


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	44	29	30	29	23	19	14	17	14	10	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53f (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

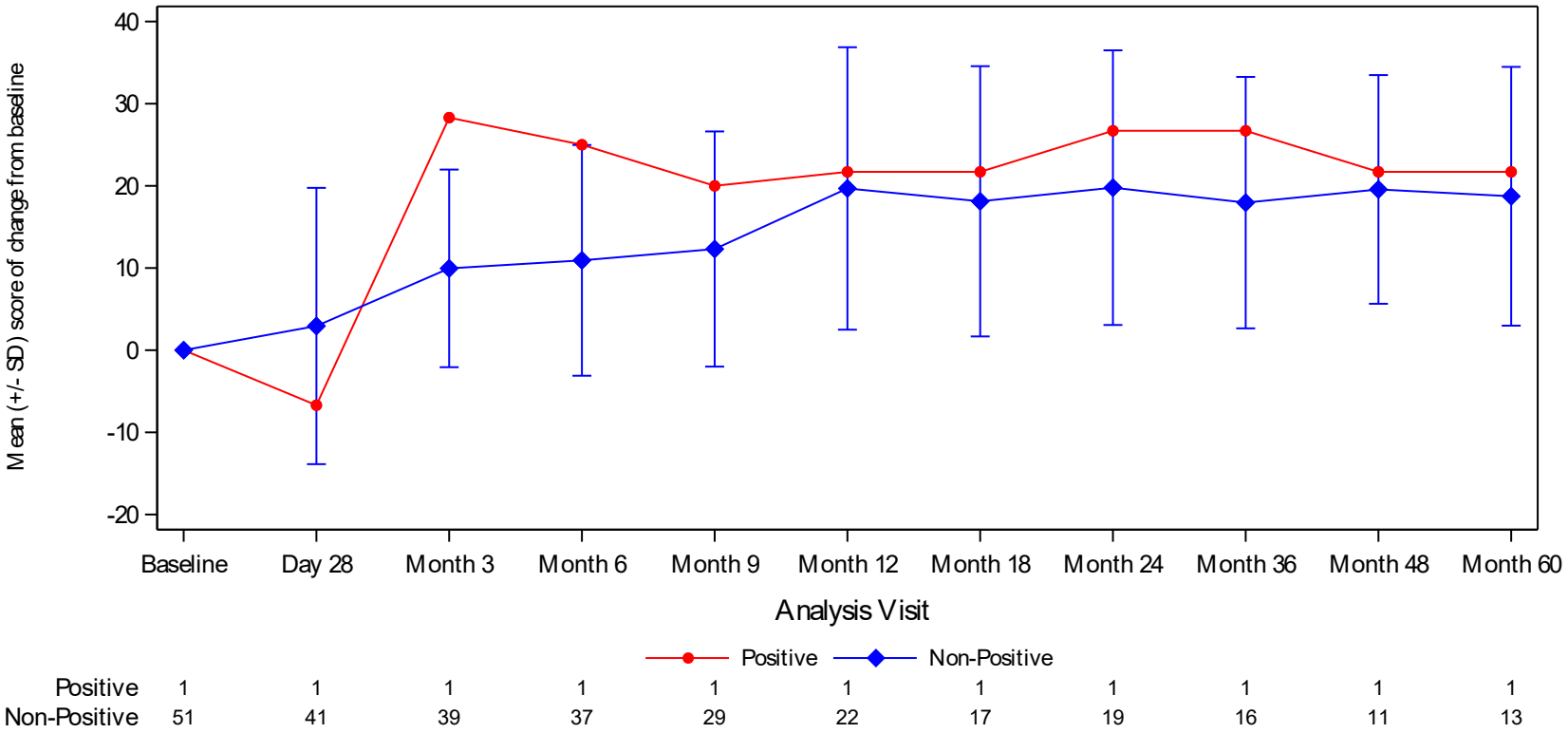


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	41	39	37	29	22	17	19	16	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53f (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

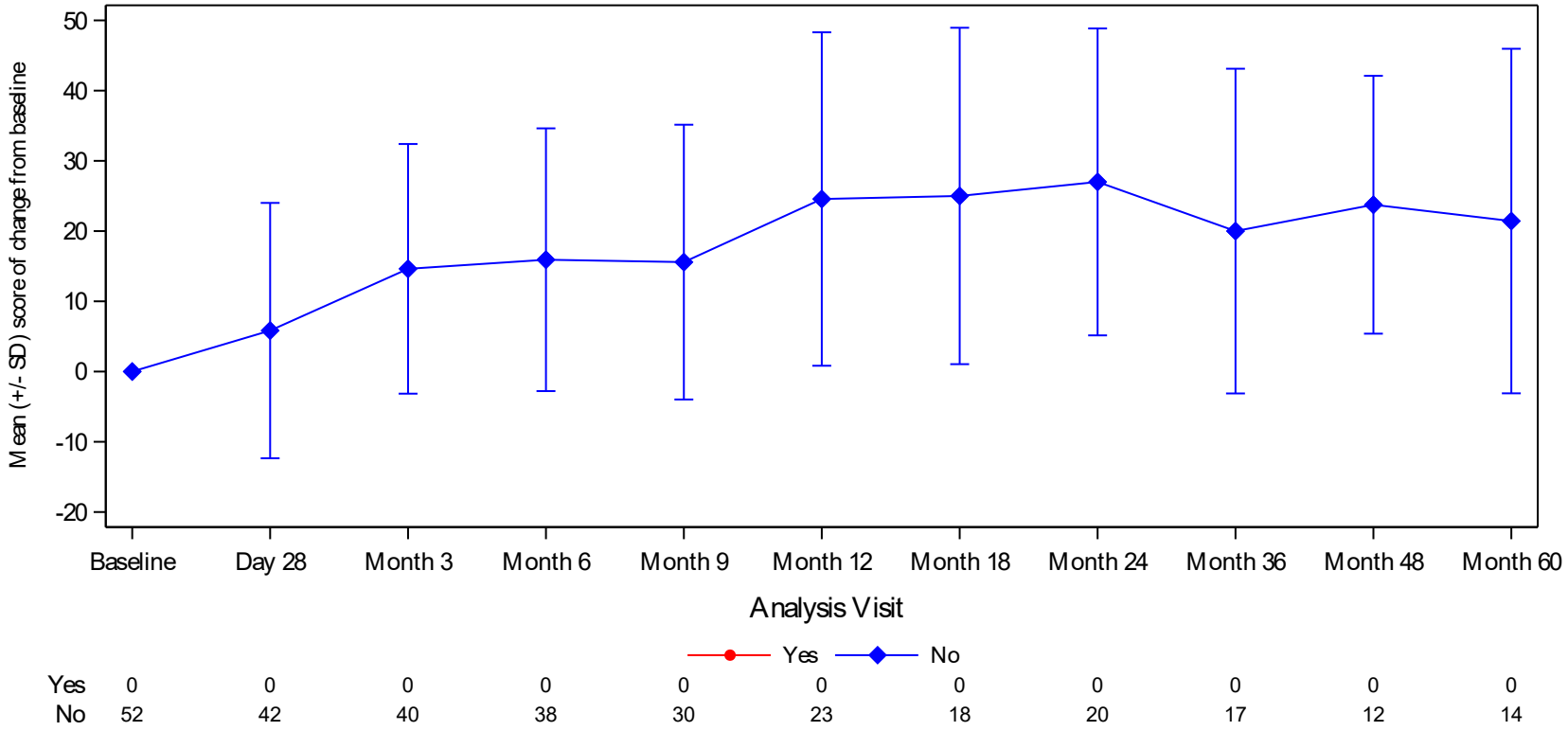


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Positive	1	1	1	1	1	1	1	1	1	1	1
Non-Positive	51	41	39	37	29	22	17	19	16	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53g (Page 1 of 5)
Mean change in each PedsQL subscales score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

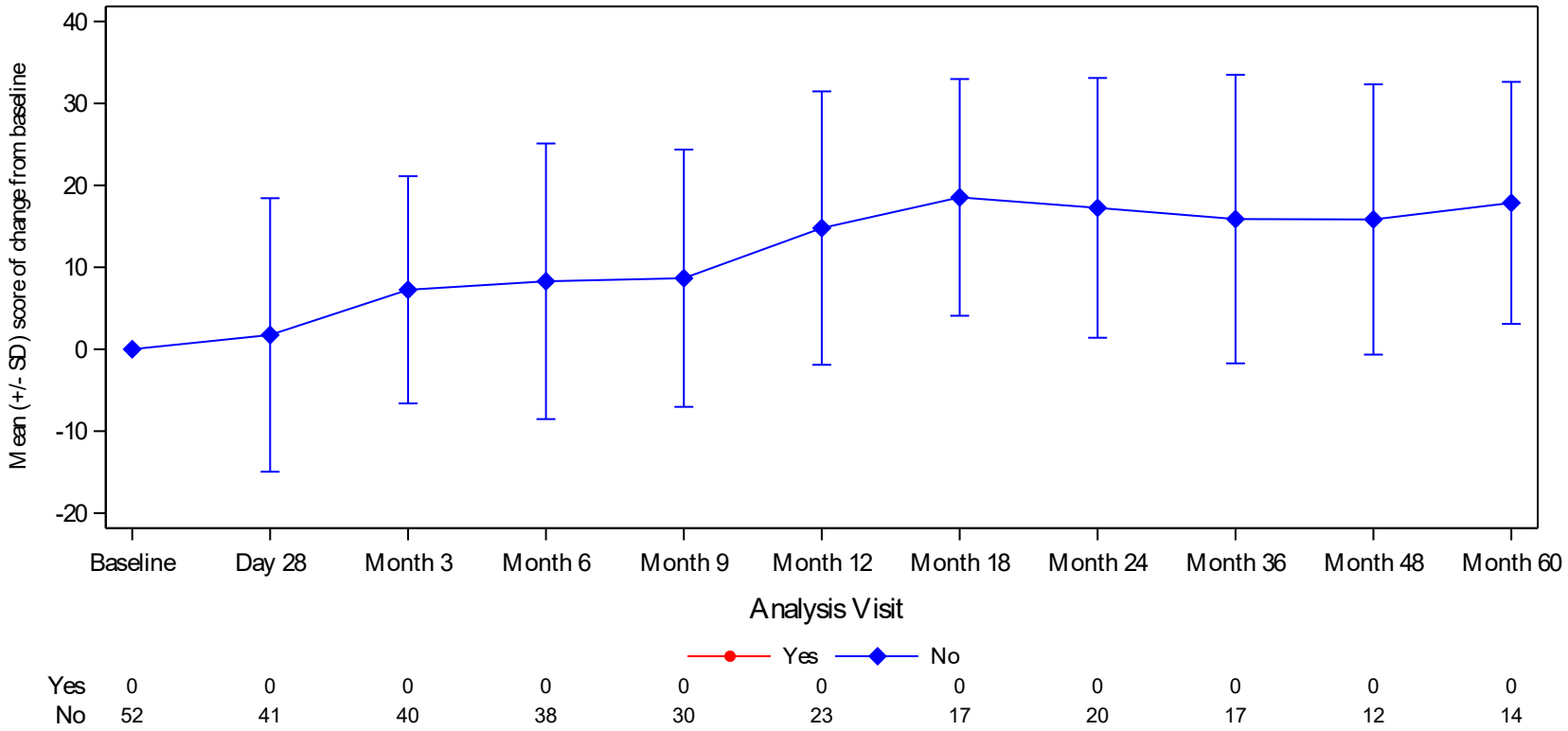


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53g (Page 2 of 5)
Mean change in each PedsQL subscales score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

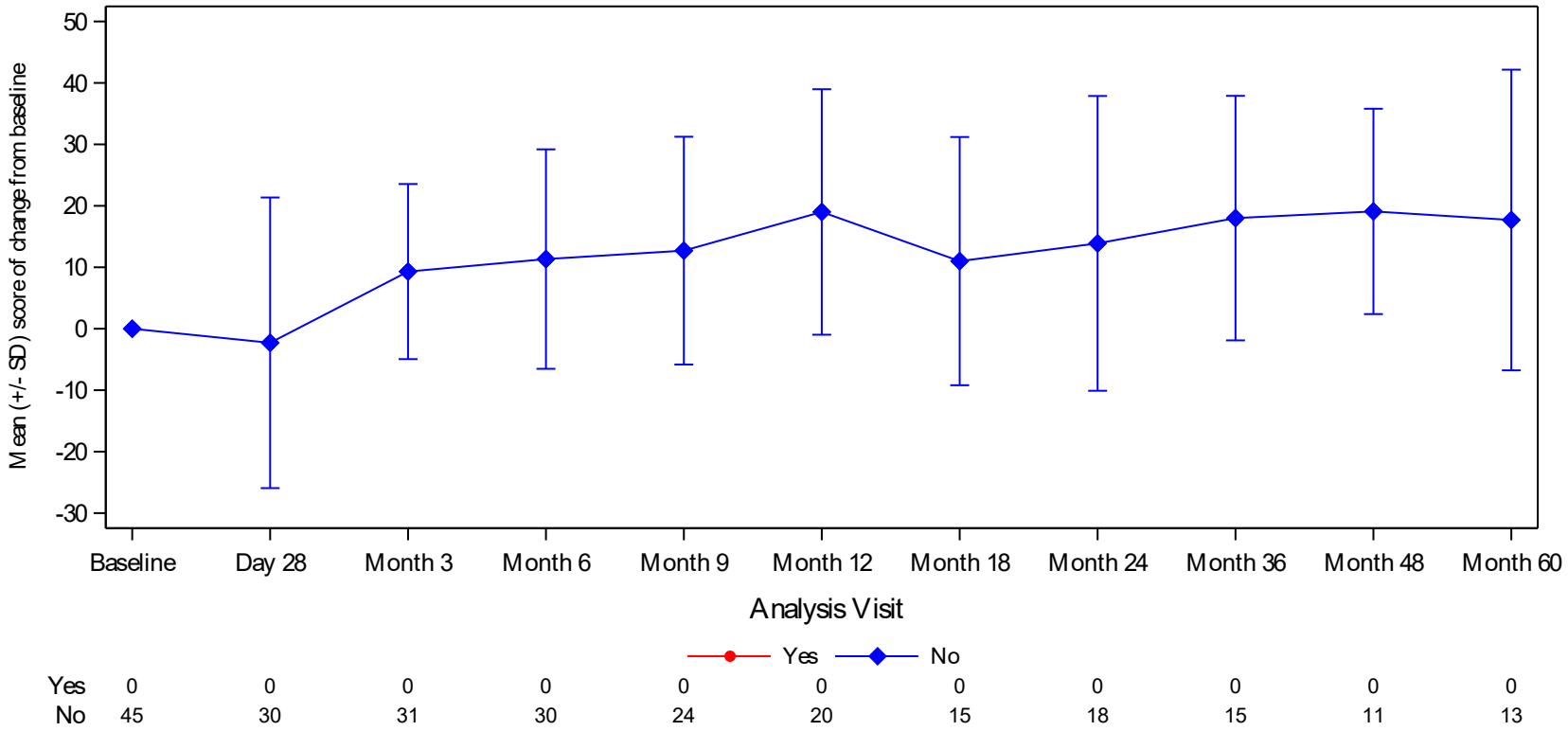


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	41	40	38	30	23	17	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53g (Page 3 of 5)
Mean change in each PedsQL subscales score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

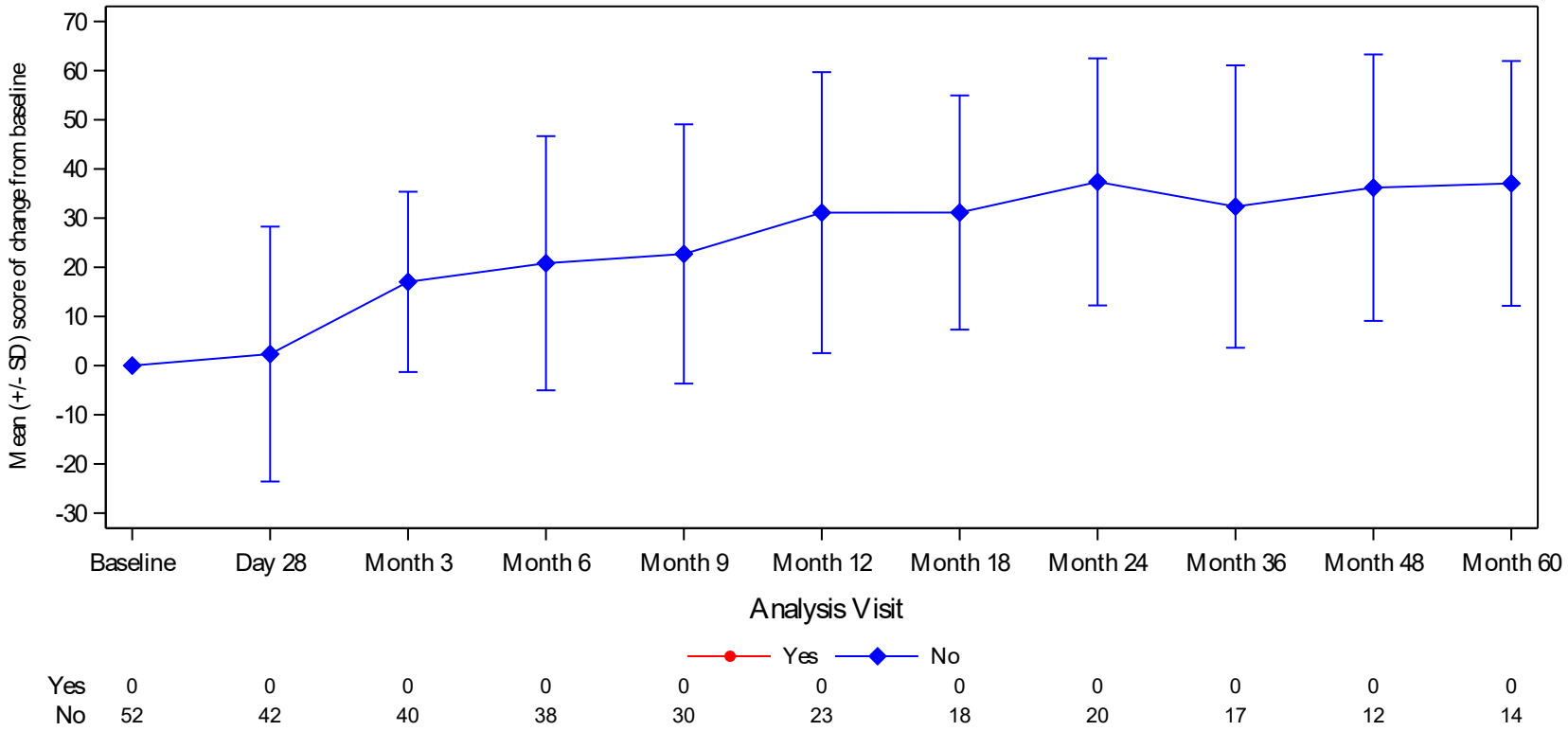


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	45	30	31	30	24	20	15	18	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53g (Page 4 of 5)
Mean change in each PedsQL subscales score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

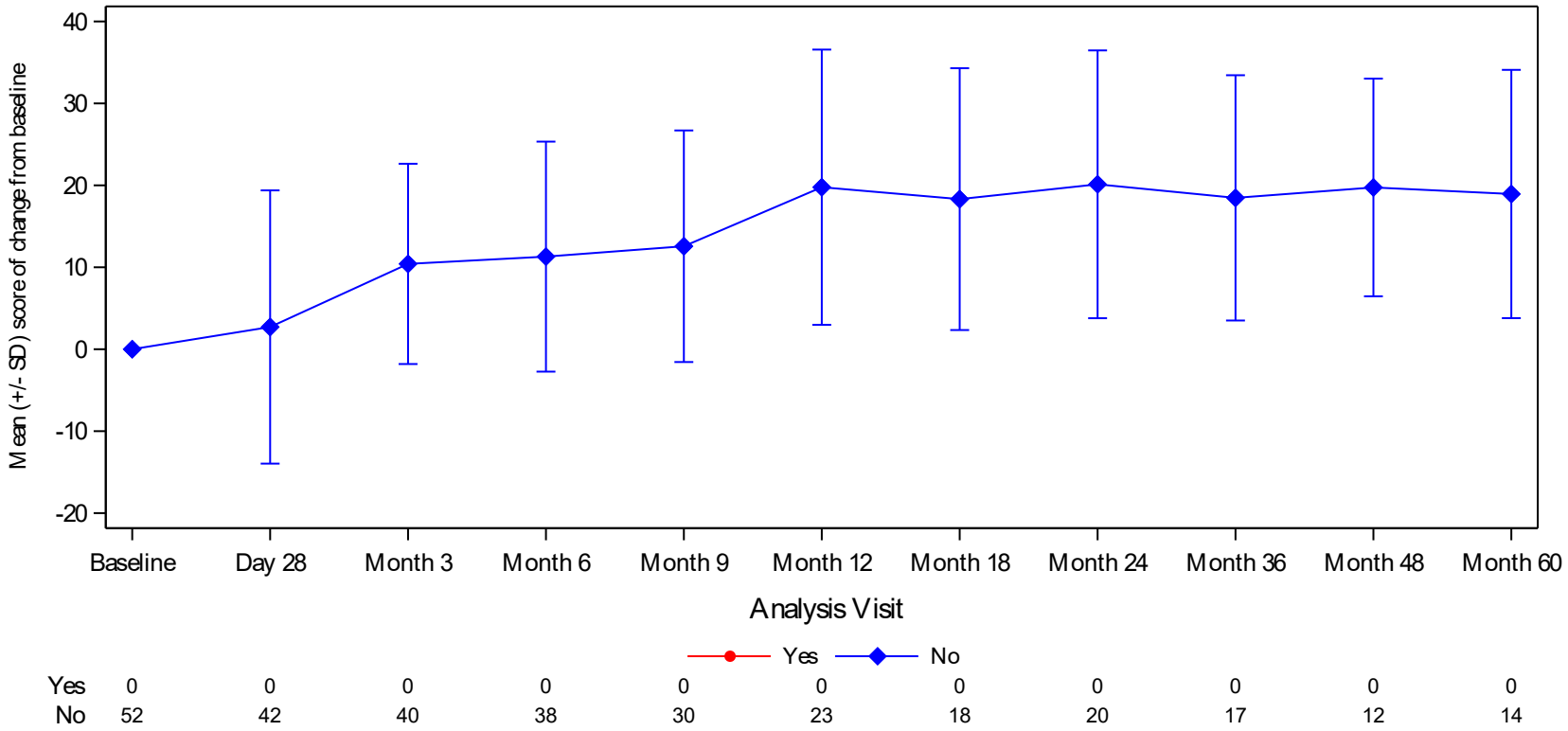


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53g (Page 5 of 5)
Mean change in each PedsQL subscales score over time by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

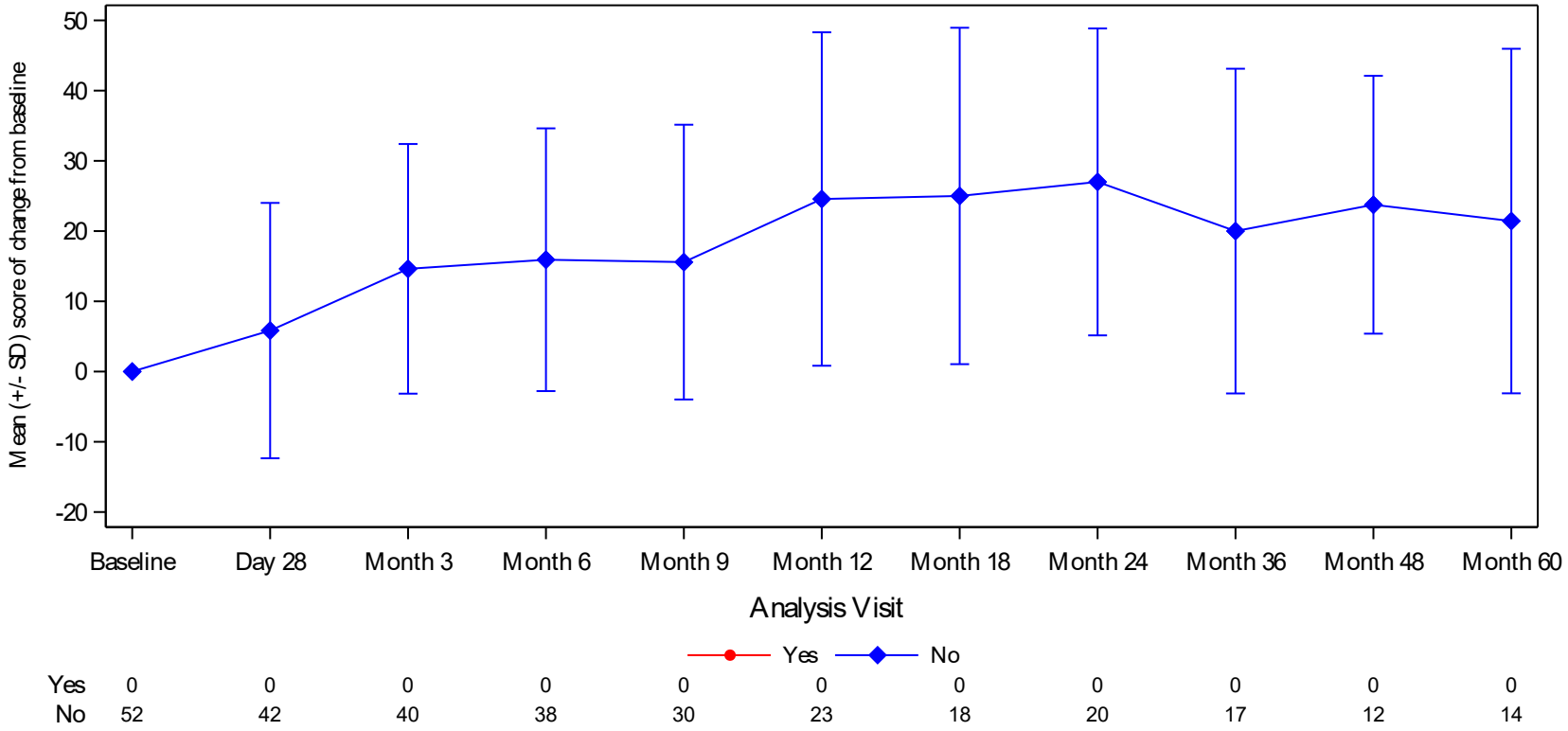


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53h (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

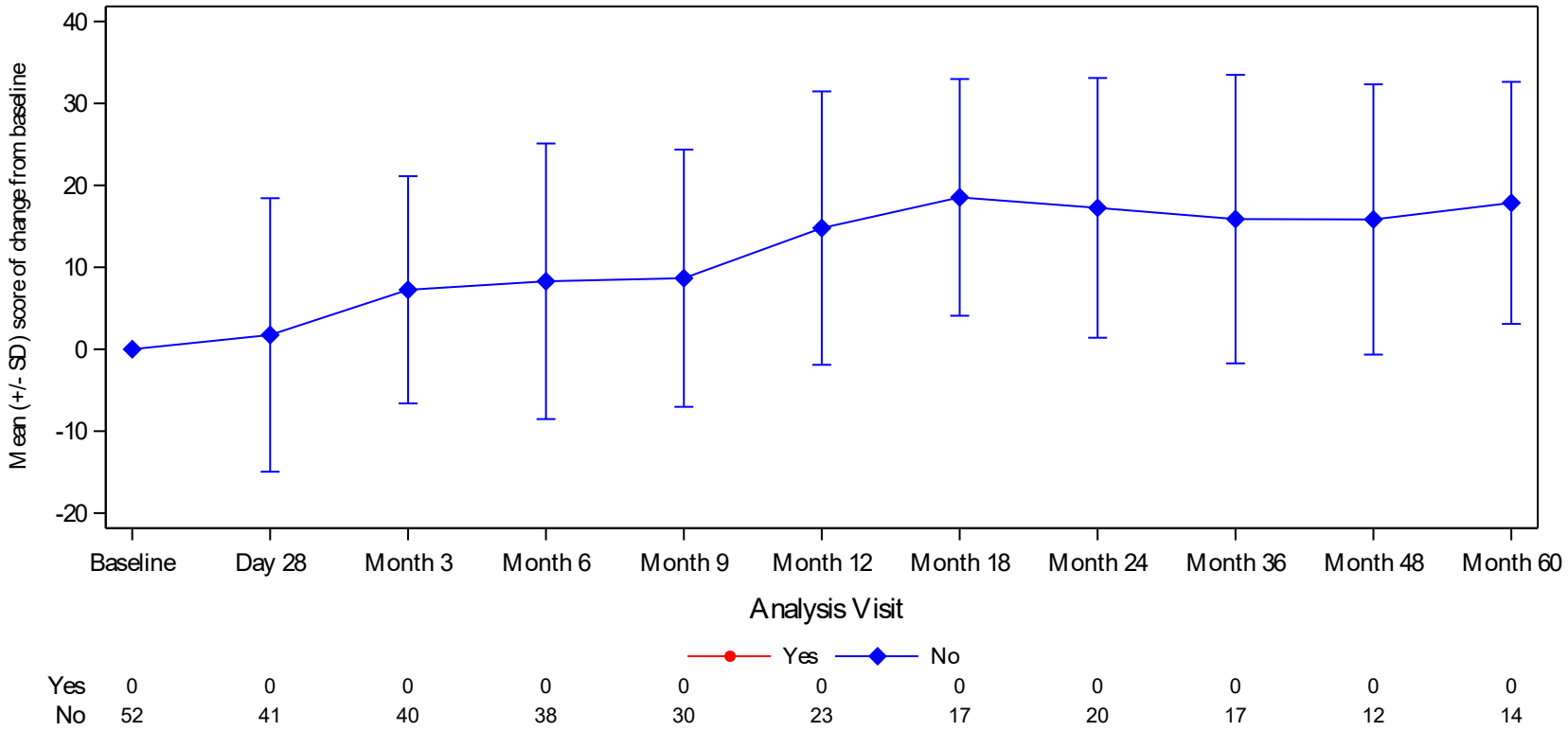


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53h (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

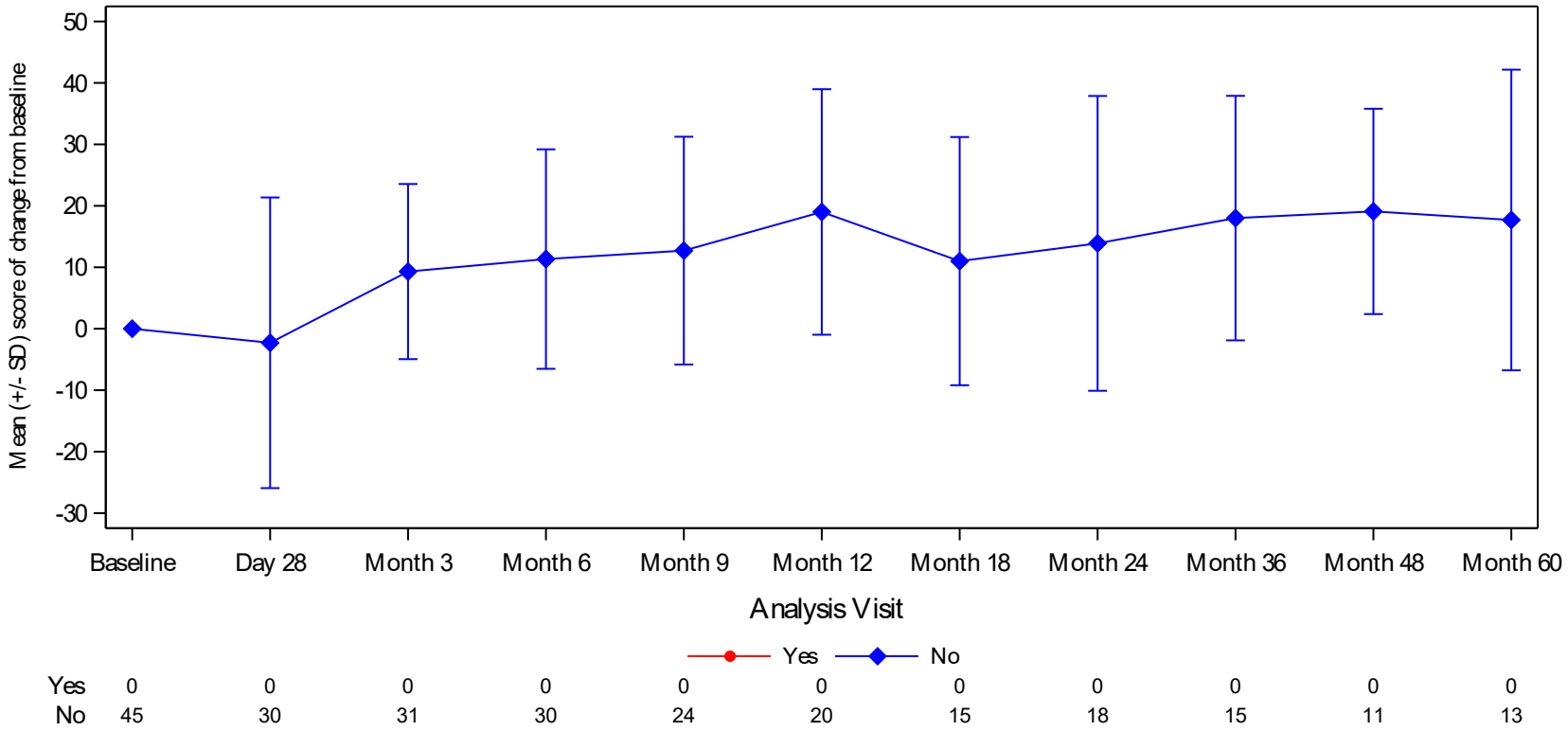


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	41	40	38	30	23	17	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53h (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

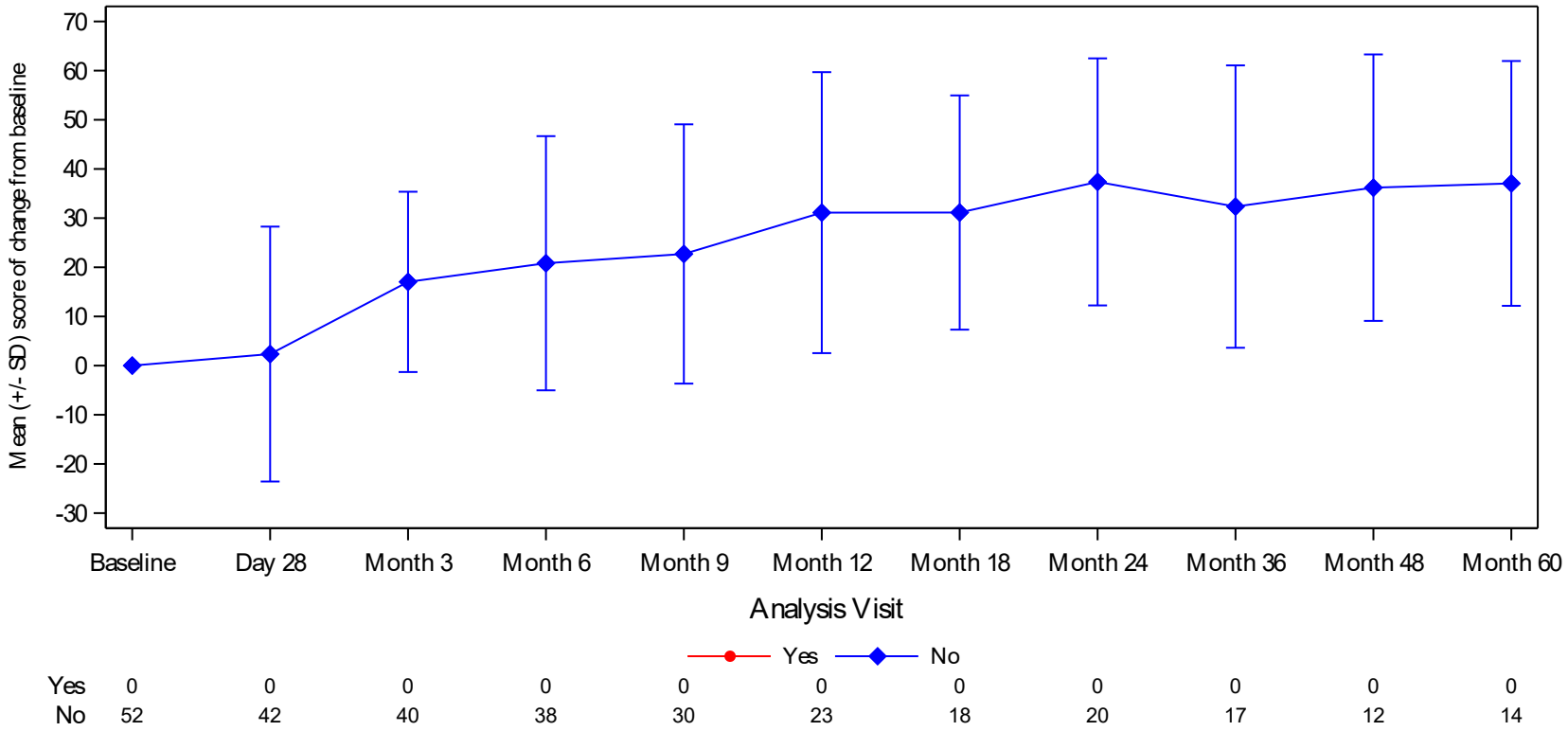
Parameter PedsQL Subscale: School Subscale



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53h (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

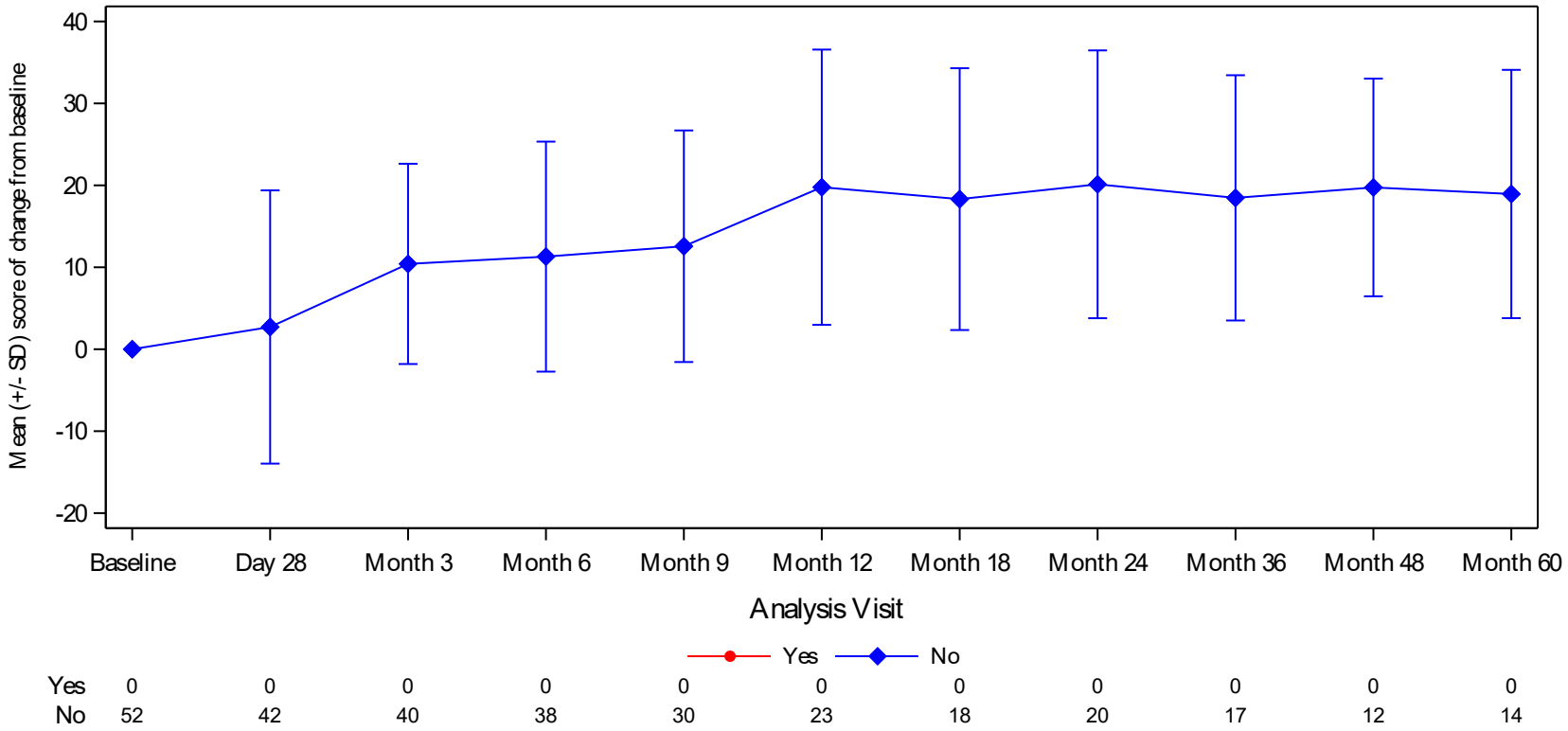


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53h (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

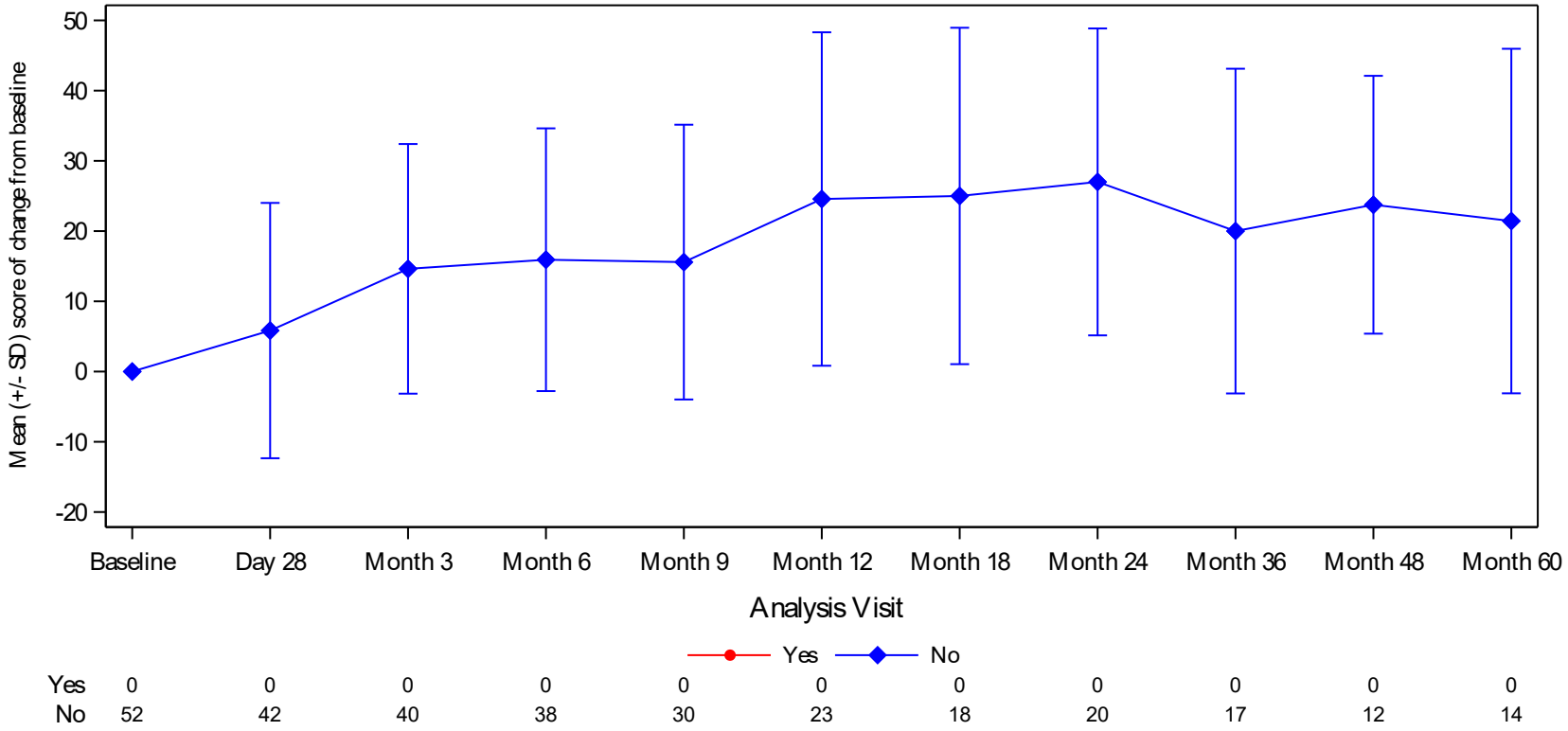


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53i (Page 1 of 5)
Mean change in each PedsQL subscales score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

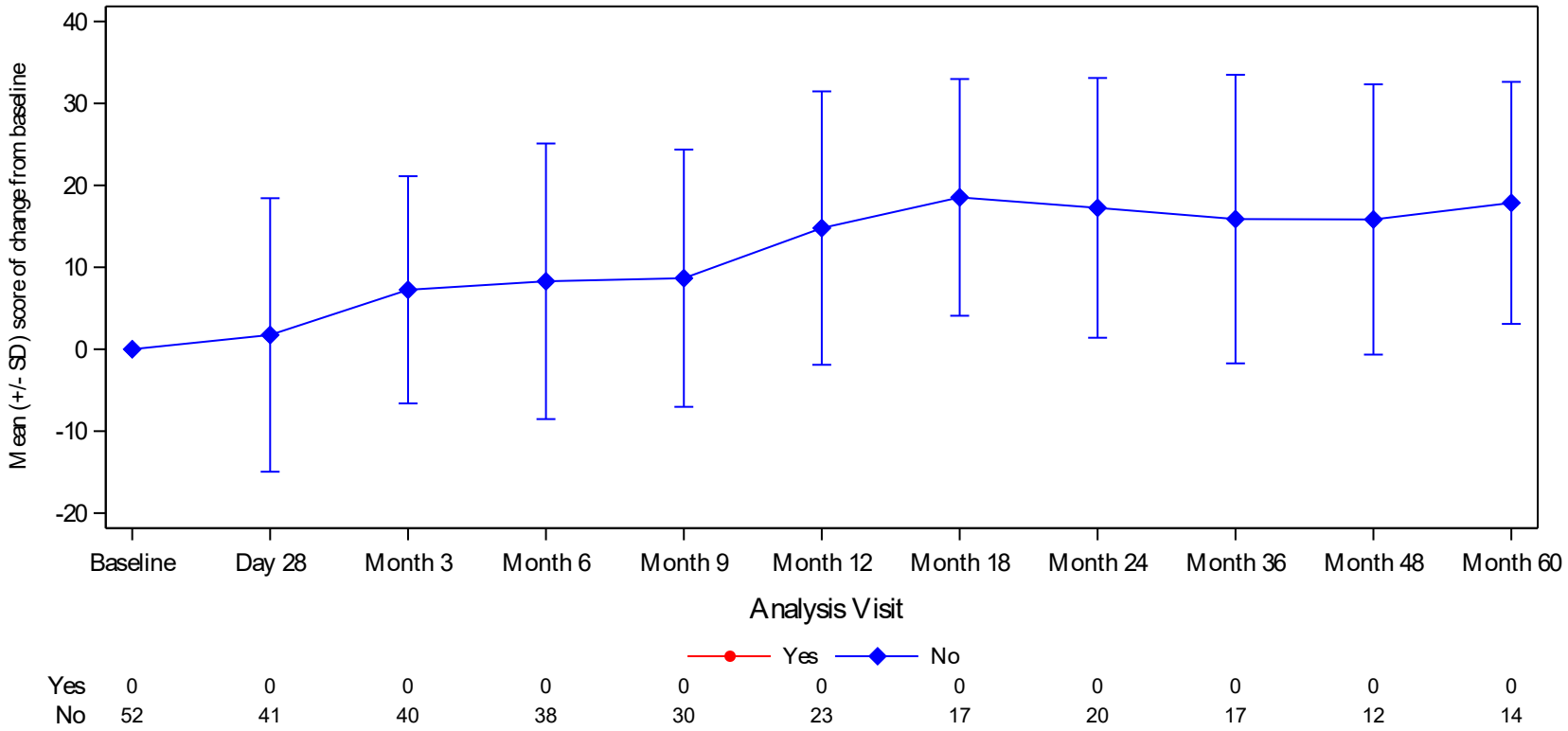


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53i (Page 2 of 5)
Mean change in each PedsQL subscales score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

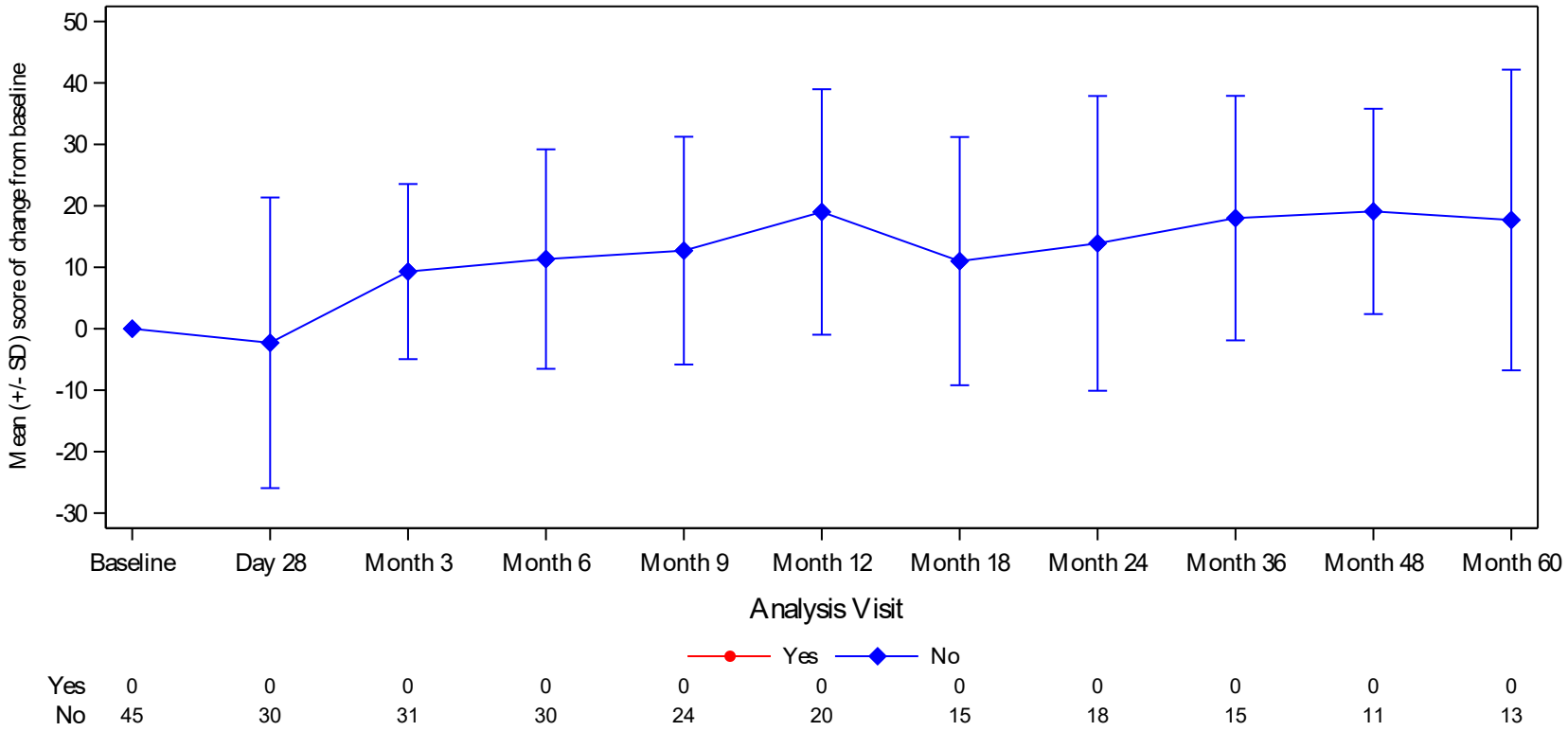


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	41	40	38	30	23	17	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53i (Page 3 of 5)
Mean change in each PedsQL subscales score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

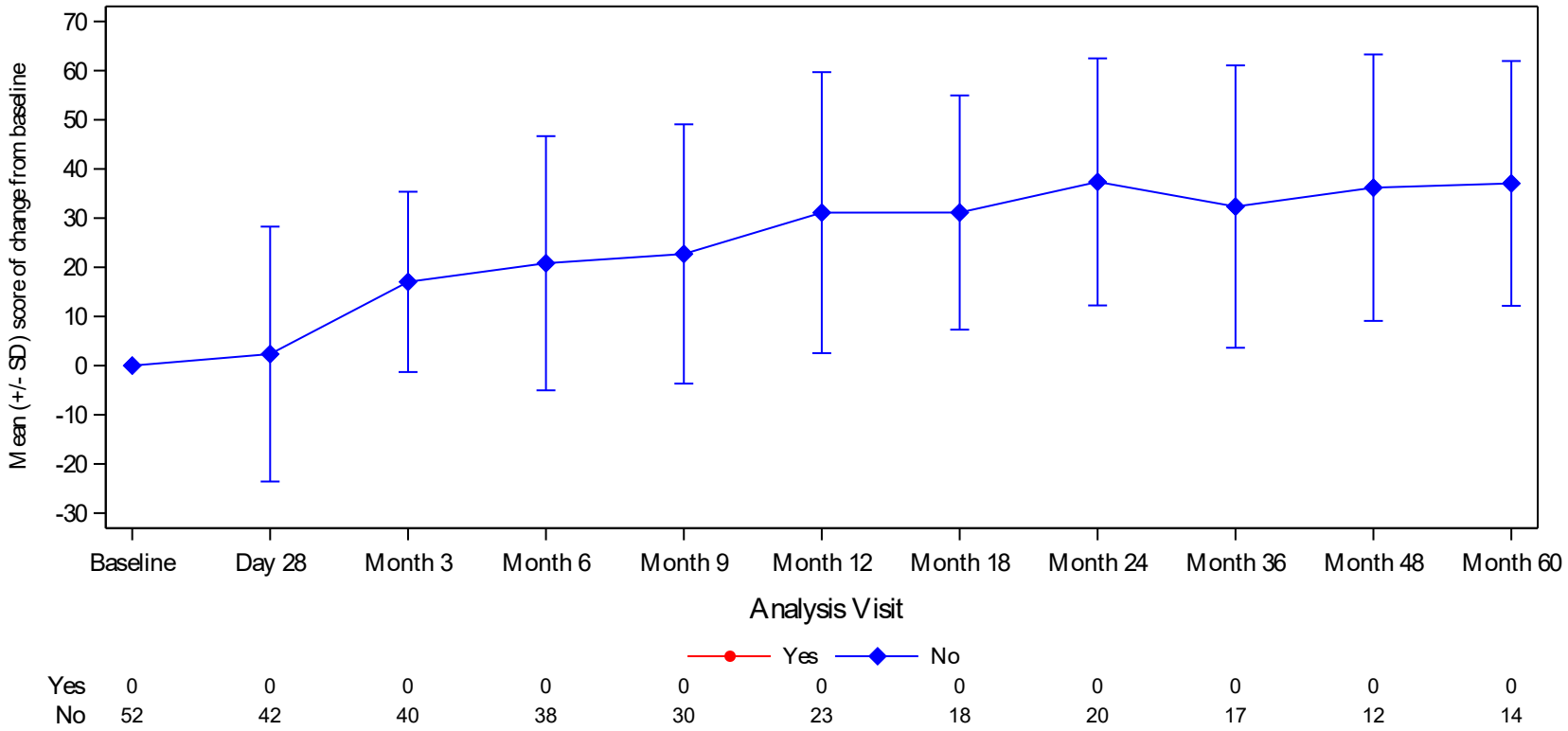


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	45	30	31	30	24	20	15	18	15	11	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53i (Page 4 of 5)
Mean change in each PedsQL subscales score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

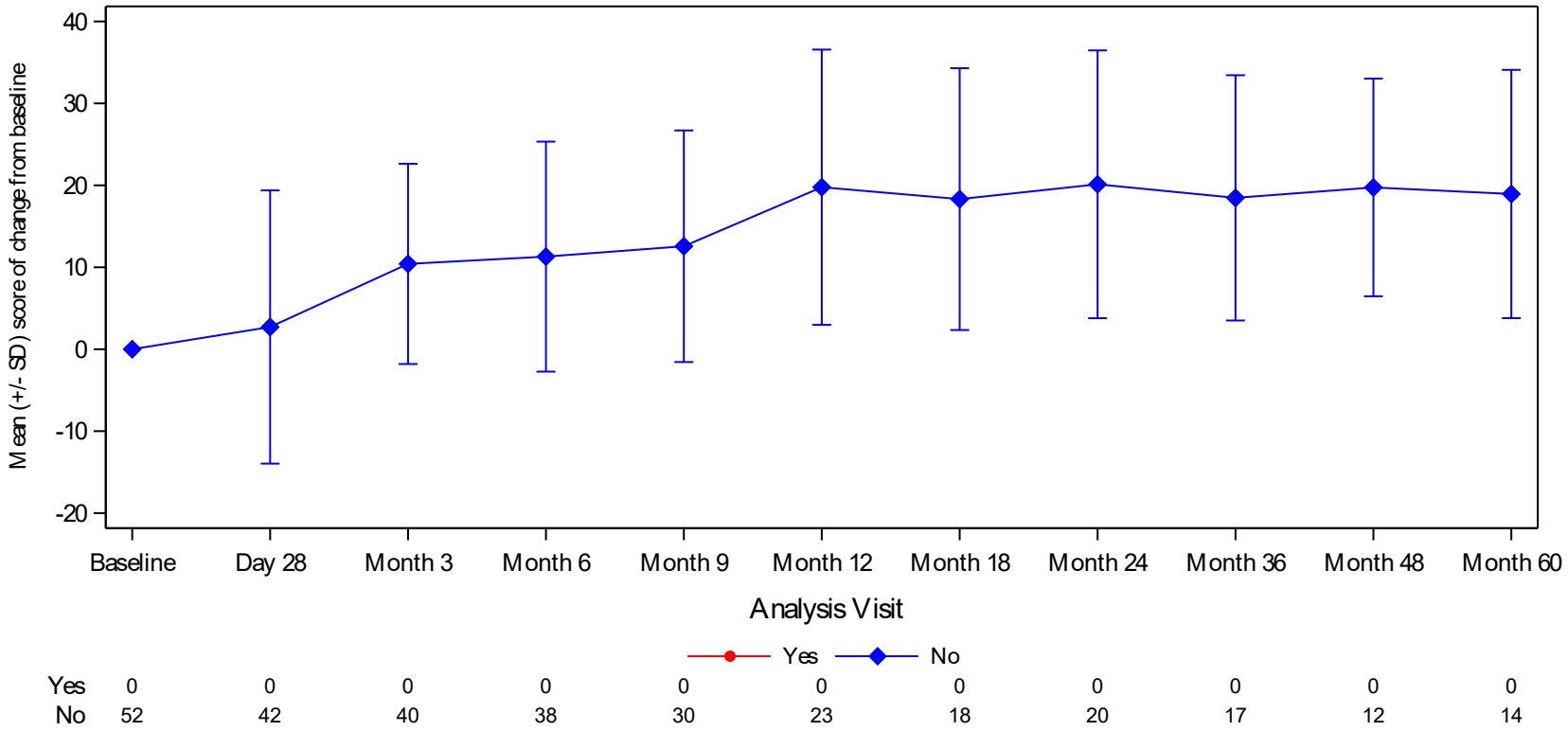


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53i (Page 5 of 5)
Mean change in each PedsQL subscales score over time by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

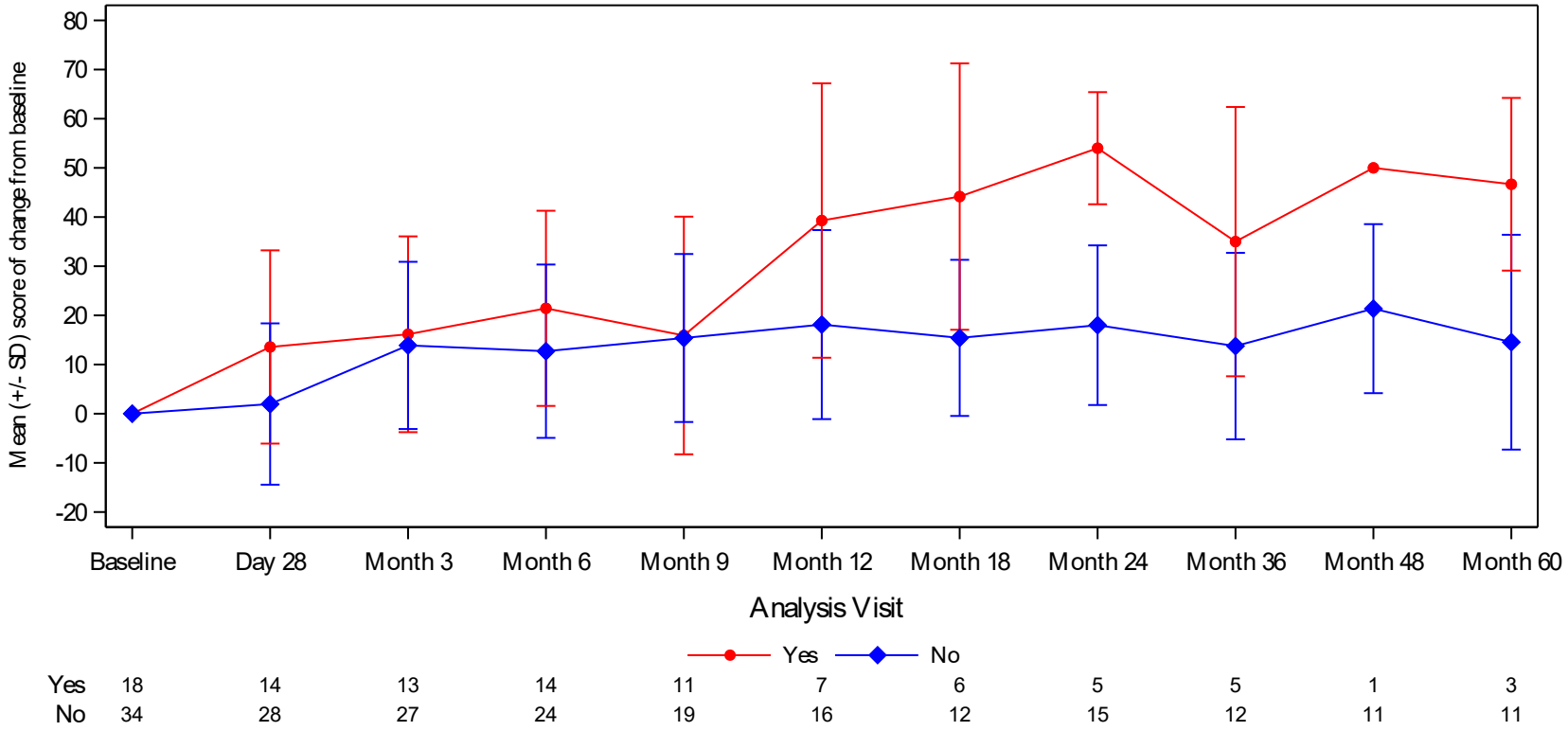


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	0	0	0	0	0	0	0	0	0	0	0
No	52	42	40	38	30	23	18	20	17	12	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53j (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

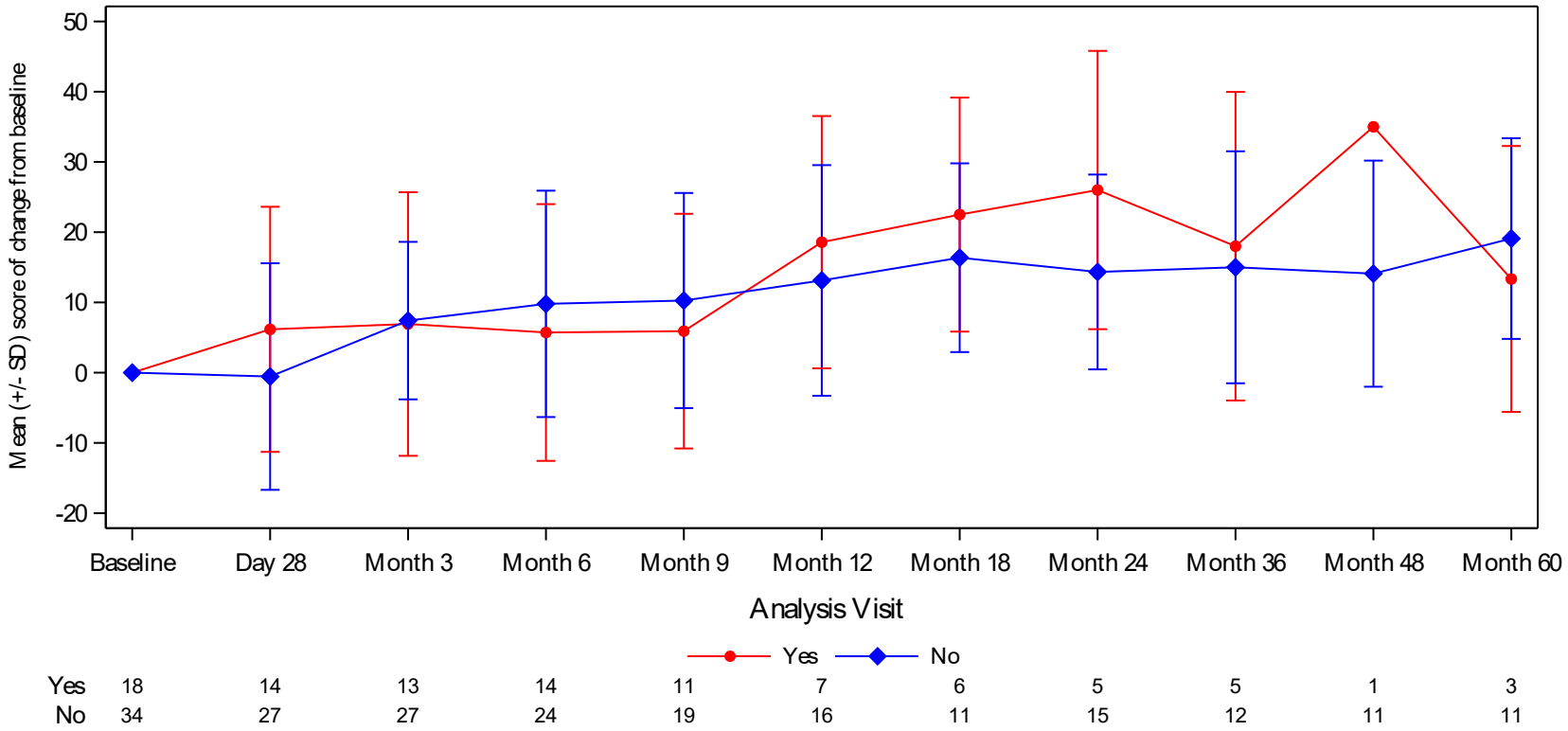


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	18	14	13	14	11	7	6	5	5	1	3
No	34	28	27	24	19	16	12	15	12	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53j (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

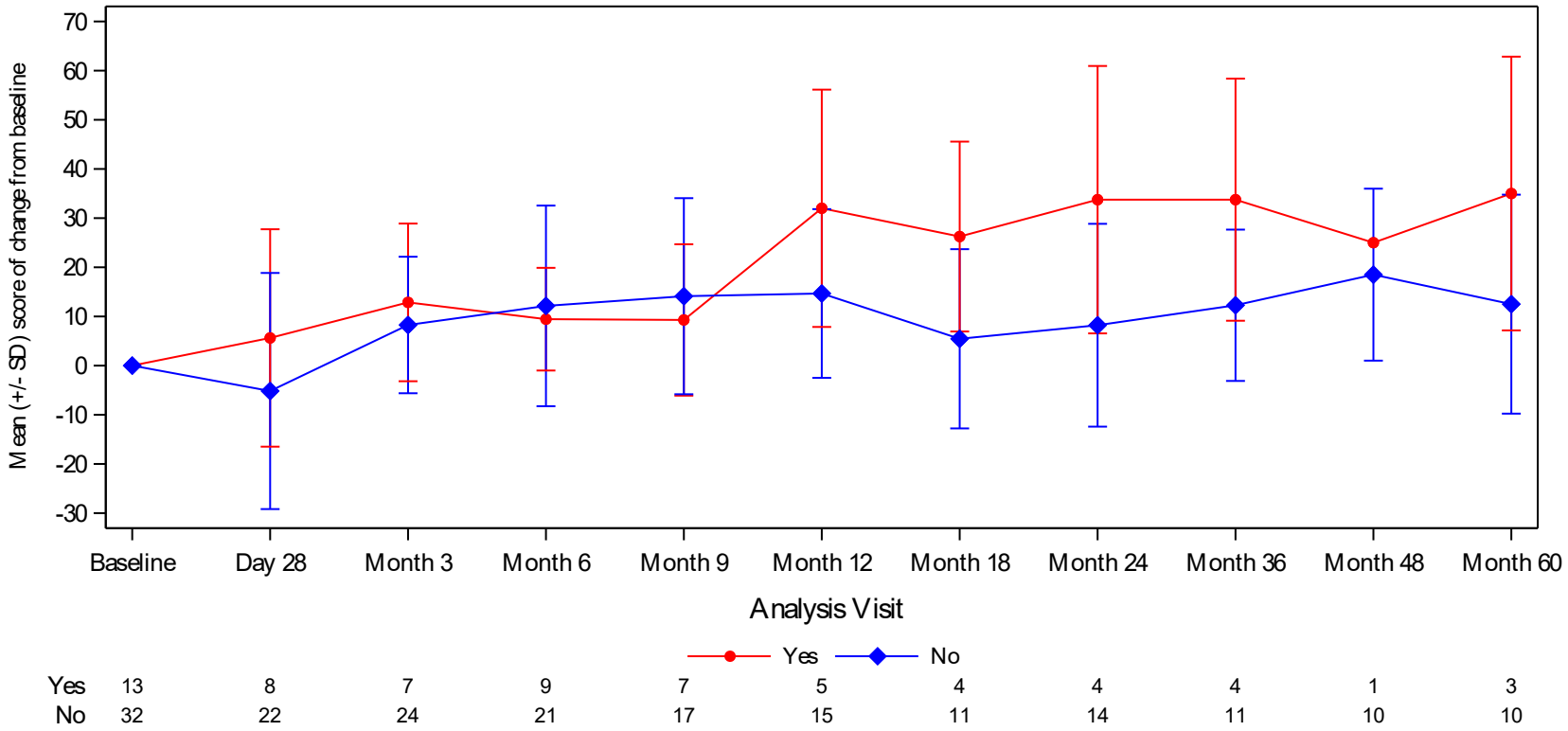


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	18	14	13	14	11	7	6	5	5	1	3
No	34	27	27	24	19	16	11	15	12	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53j (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

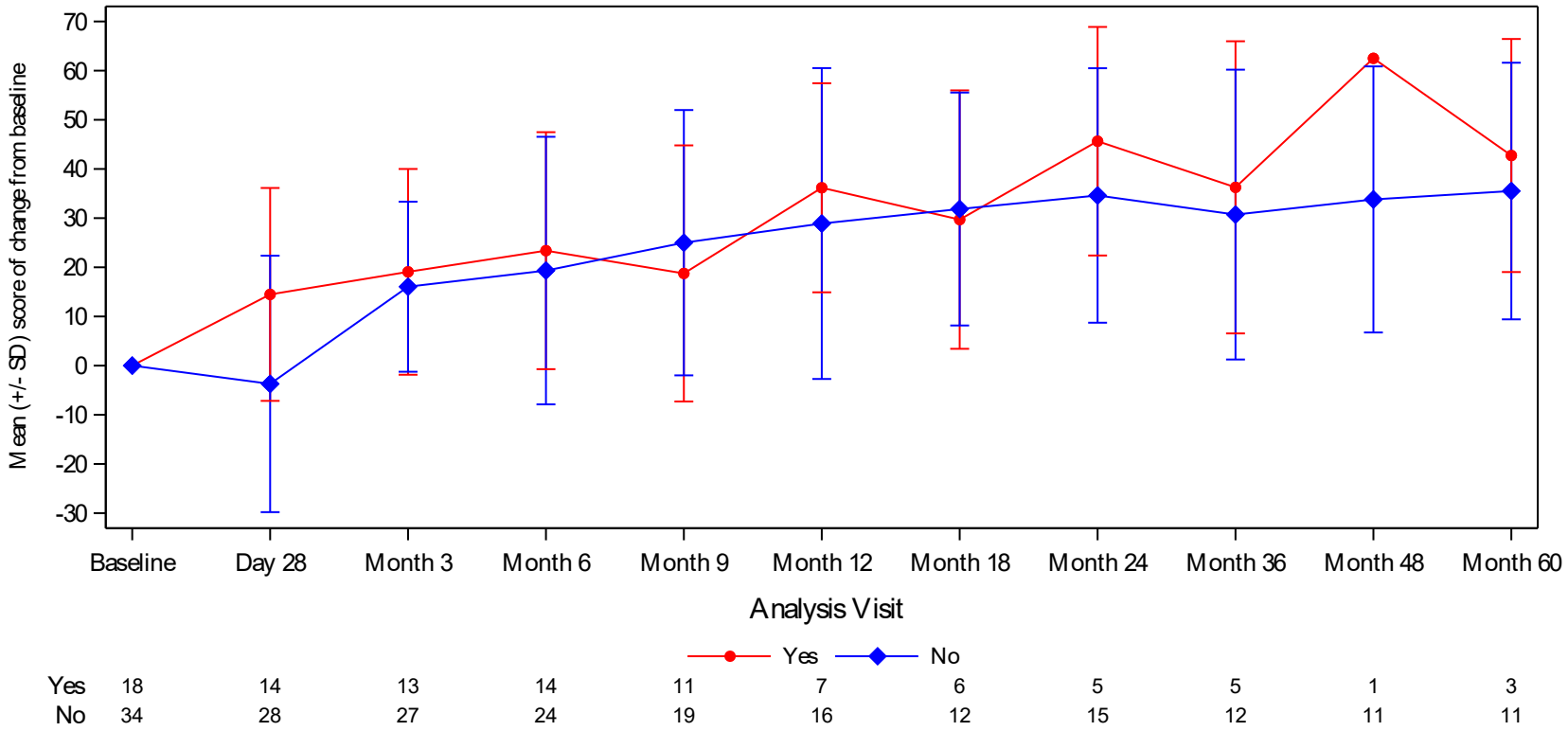


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	13	8	7	9	7	5	4	4	4	1	3
No	32	22	24	21	17	15	11	14	11	10	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53j (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

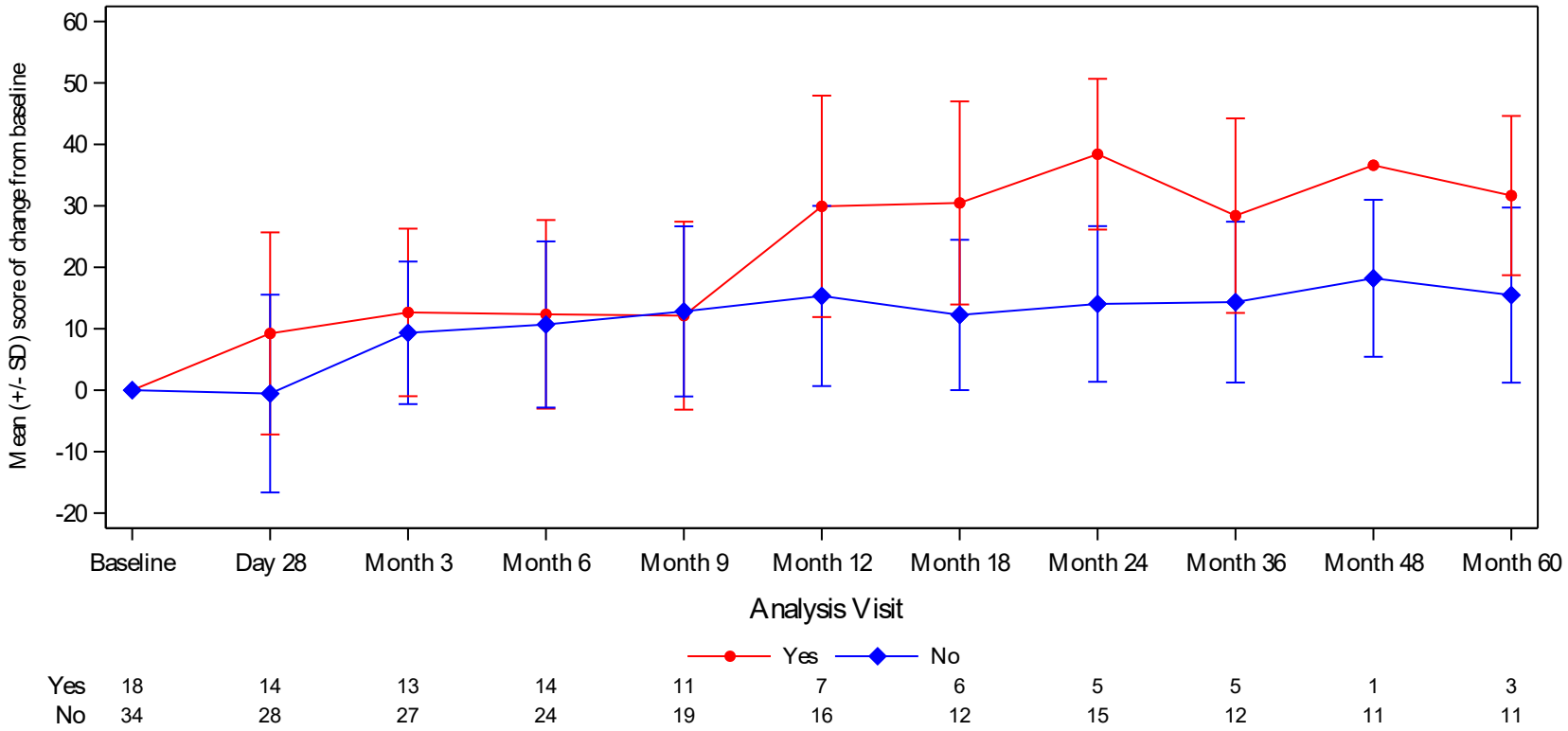


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	18	14	13	14	11	7	6	5	5	1	3
No	34	28	27	24	19	16	12	15	12	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53j (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Complex Karyotypes - >=5 unrelated abnormalities
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

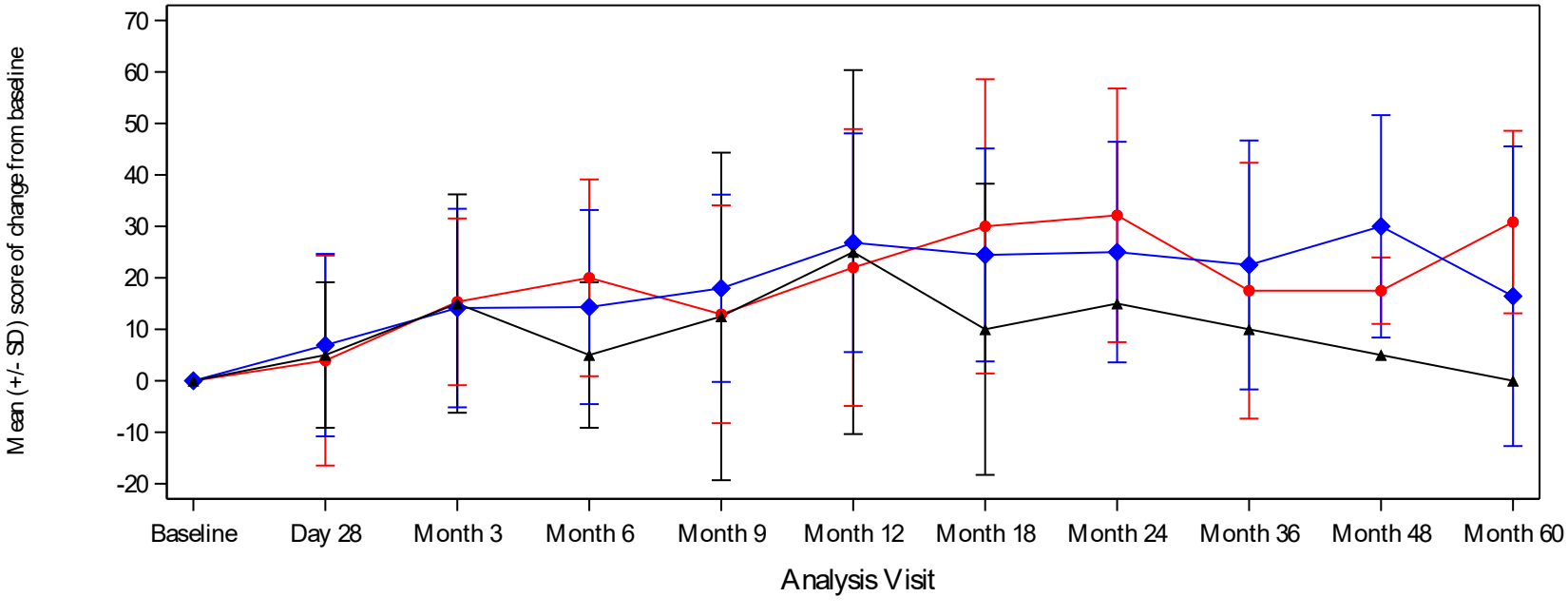


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	18	14	13	14	11	7	6	5	5	1	3
No	34	28	27	24	19	16	12	15	12	11	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53k (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Region
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

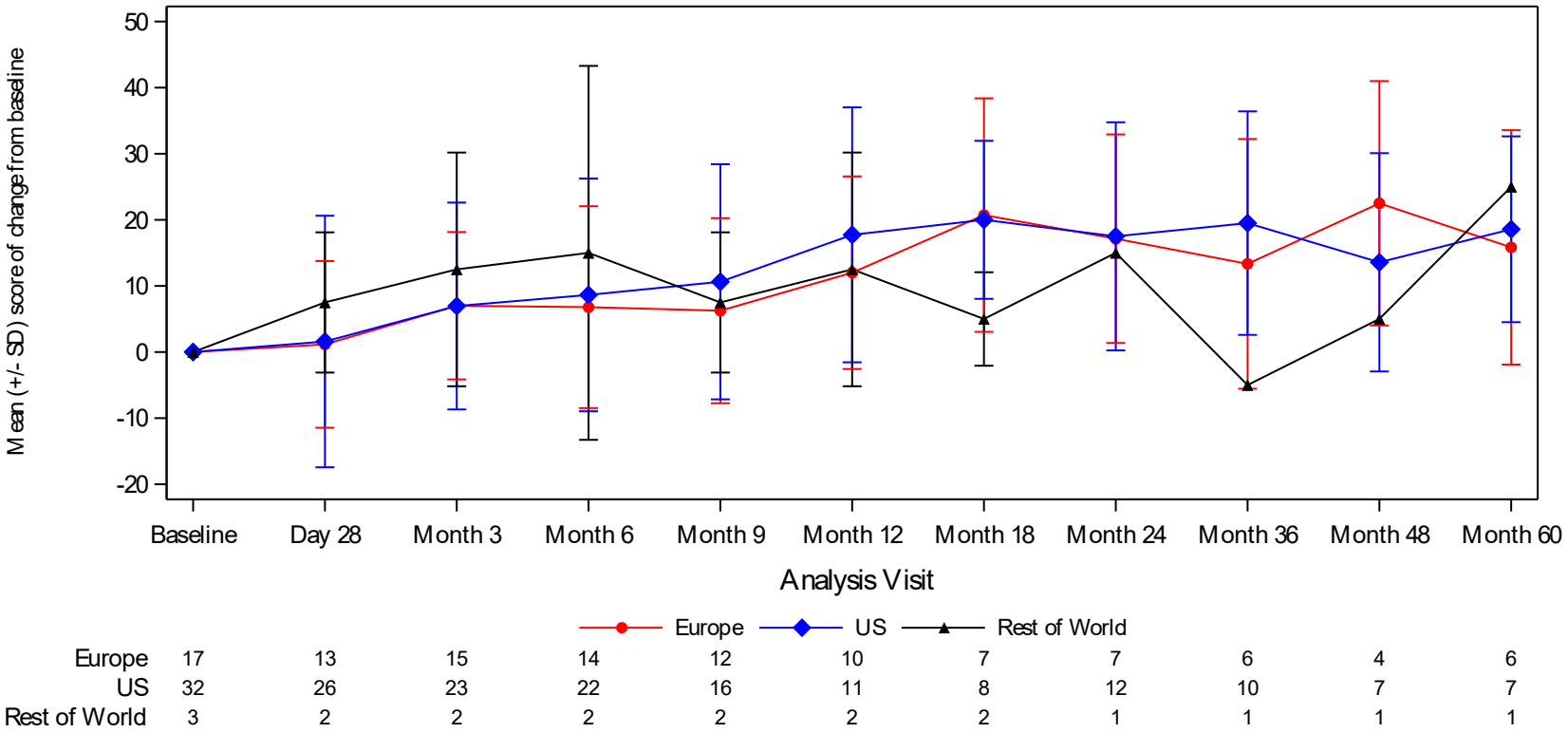


Europe	17	14	15	14	12	10	7	7	6	4	6
US	32	26	23	22	16	11	9	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53k (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Region
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

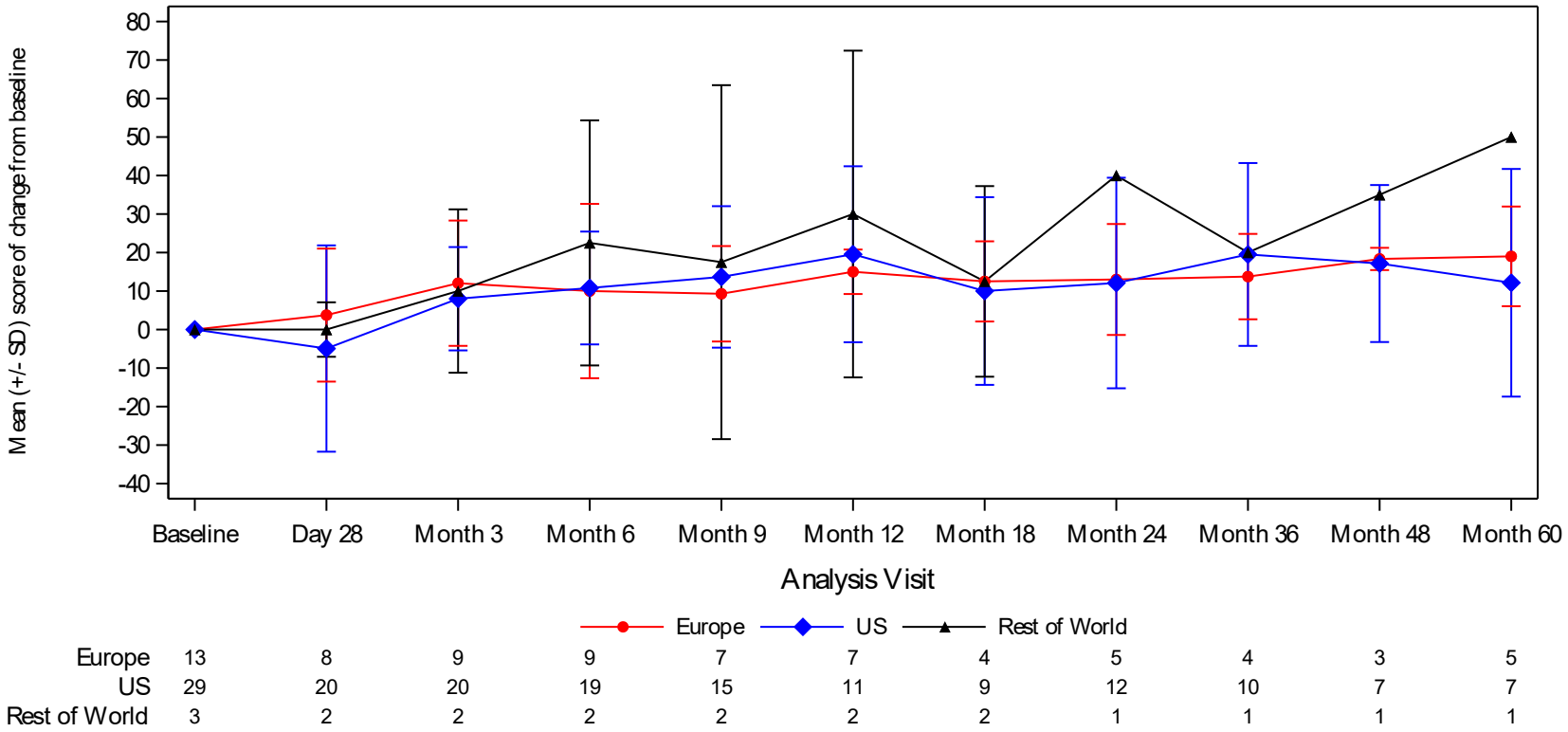


Europe	17	13	15	14	12	10	7	7	6	4	6
US	32	26	23	22	16	11	8	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53k (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Region
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

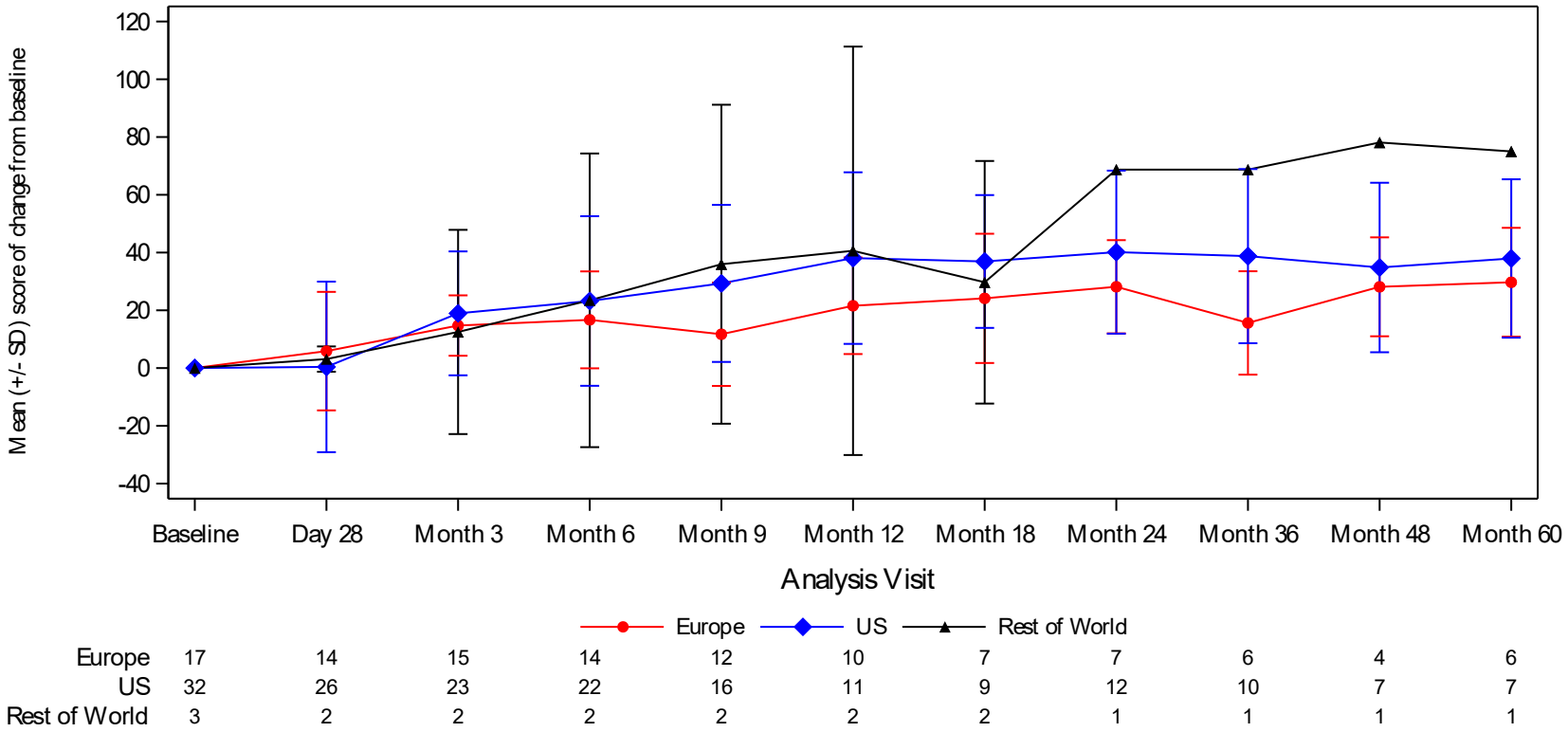


Europe	13	8	9	9	7	7	4	5	4	3	5
US	29	20	20	19	15	11	9	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53k (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Region
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

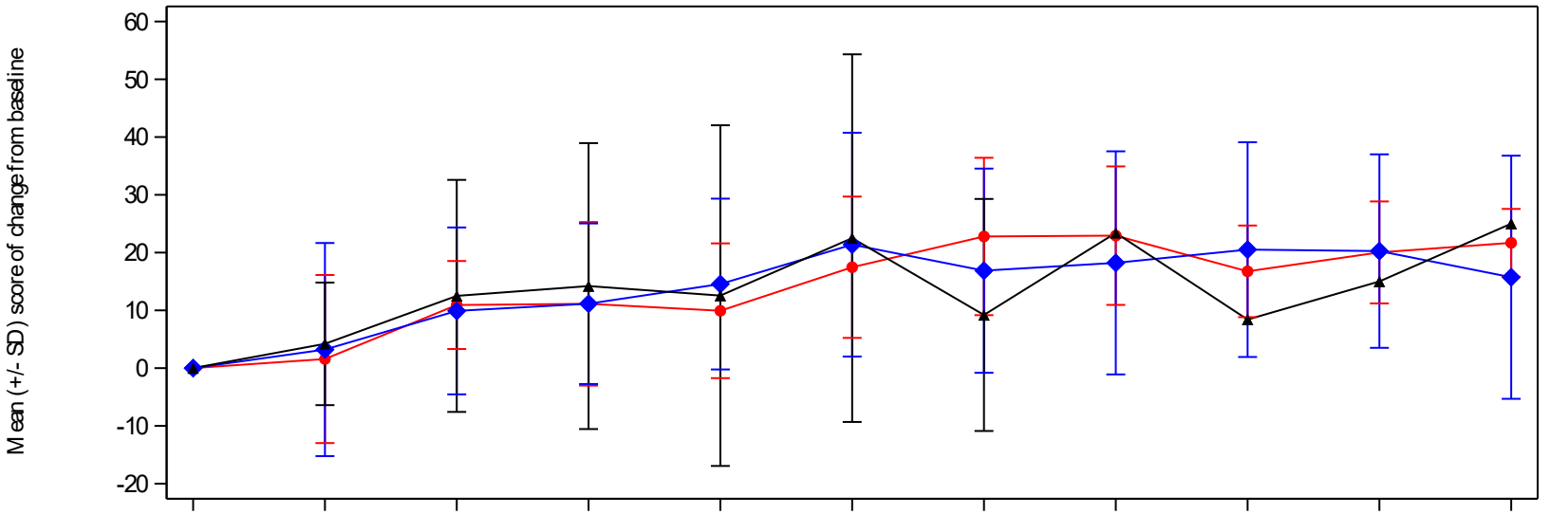


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Europe	17	14	15	14	12	10	7	7	6	4	6
US	32	26	23	22	16	11	9	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53k (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Region
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

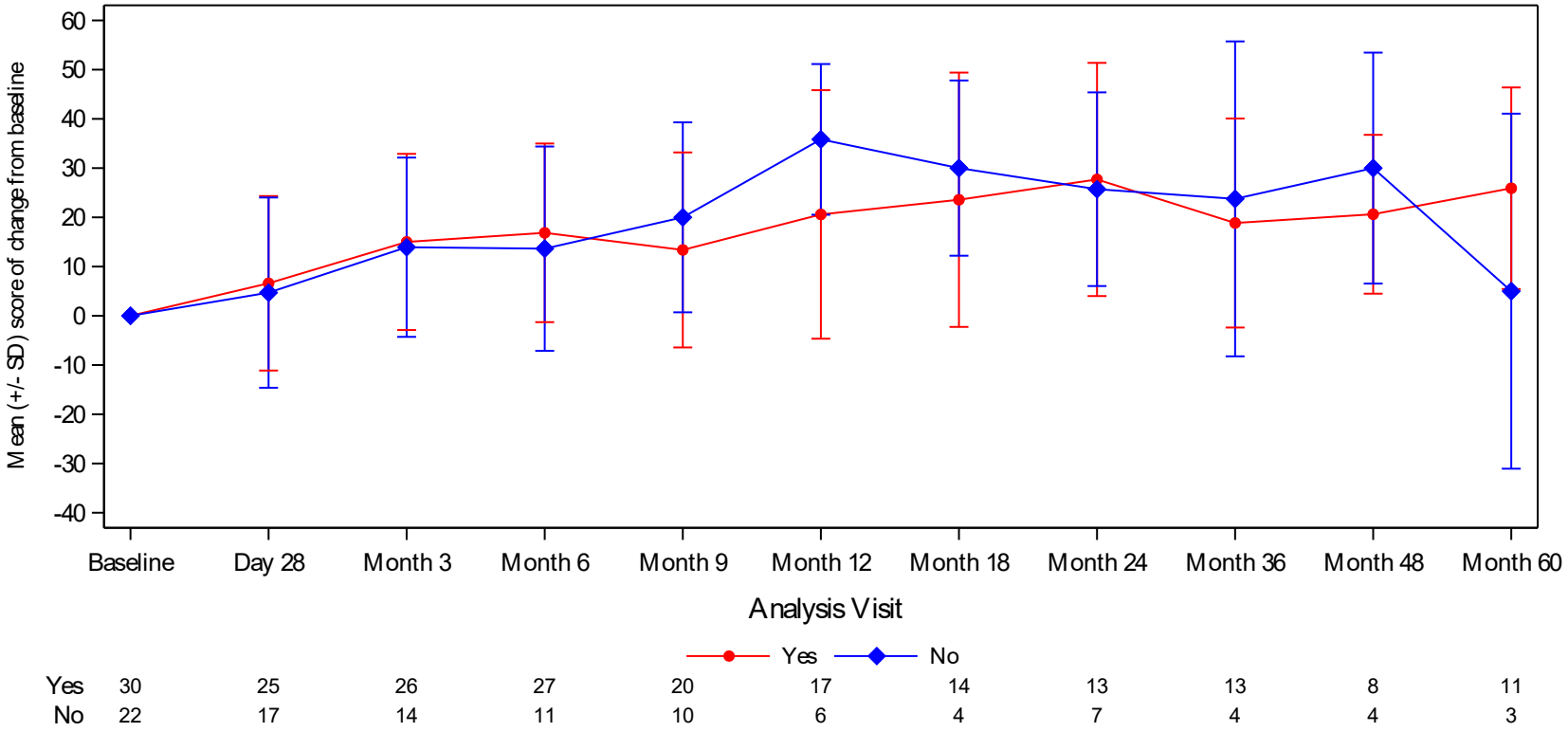


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Europe	17	14	15	14	12	10	7	7	6	4	6
US	32	26	23	22	16	11	9	12	10	7	7
Rest of World	3	2	2	2	2	2	2	1	1	1	1

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53l (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

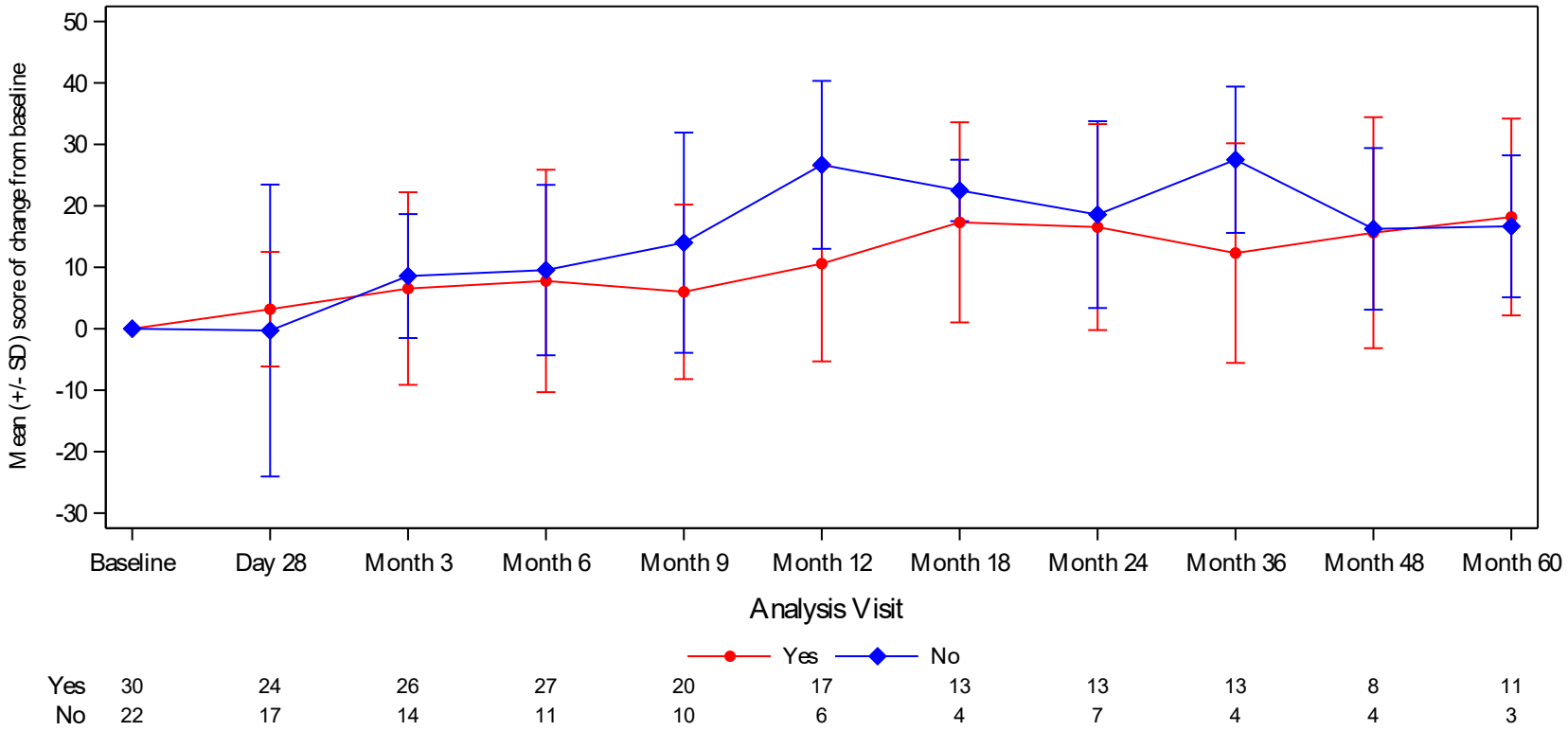


Yes	30	25	26	27	20	17	14	13	13	8	11
No	22	17	14	11	10	6	4	7	4	4	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53l (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

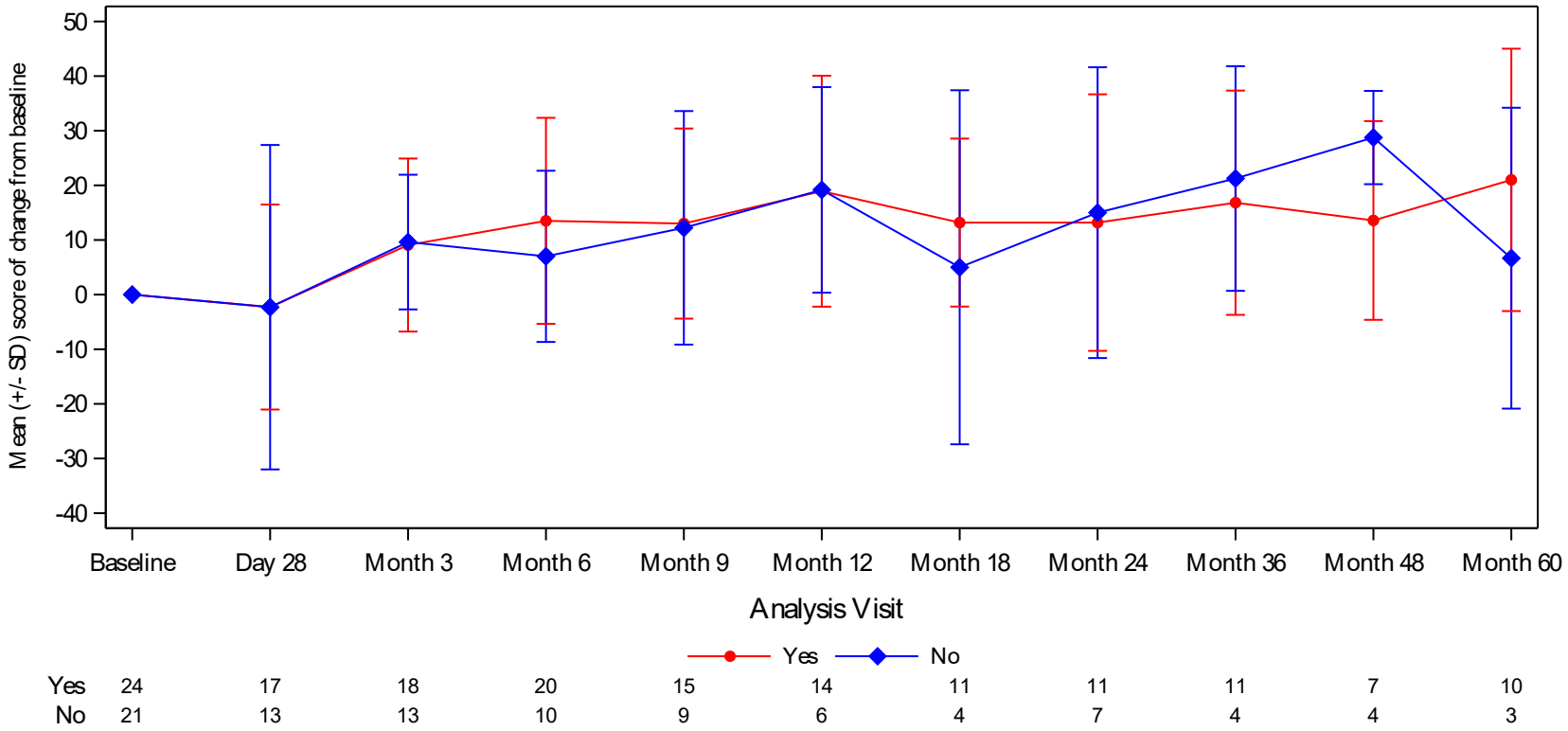


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	30	24	26	27	20	17	13	13	13	8	11
No	22	17	14	11	10	6	4	7	4	4	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53l (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

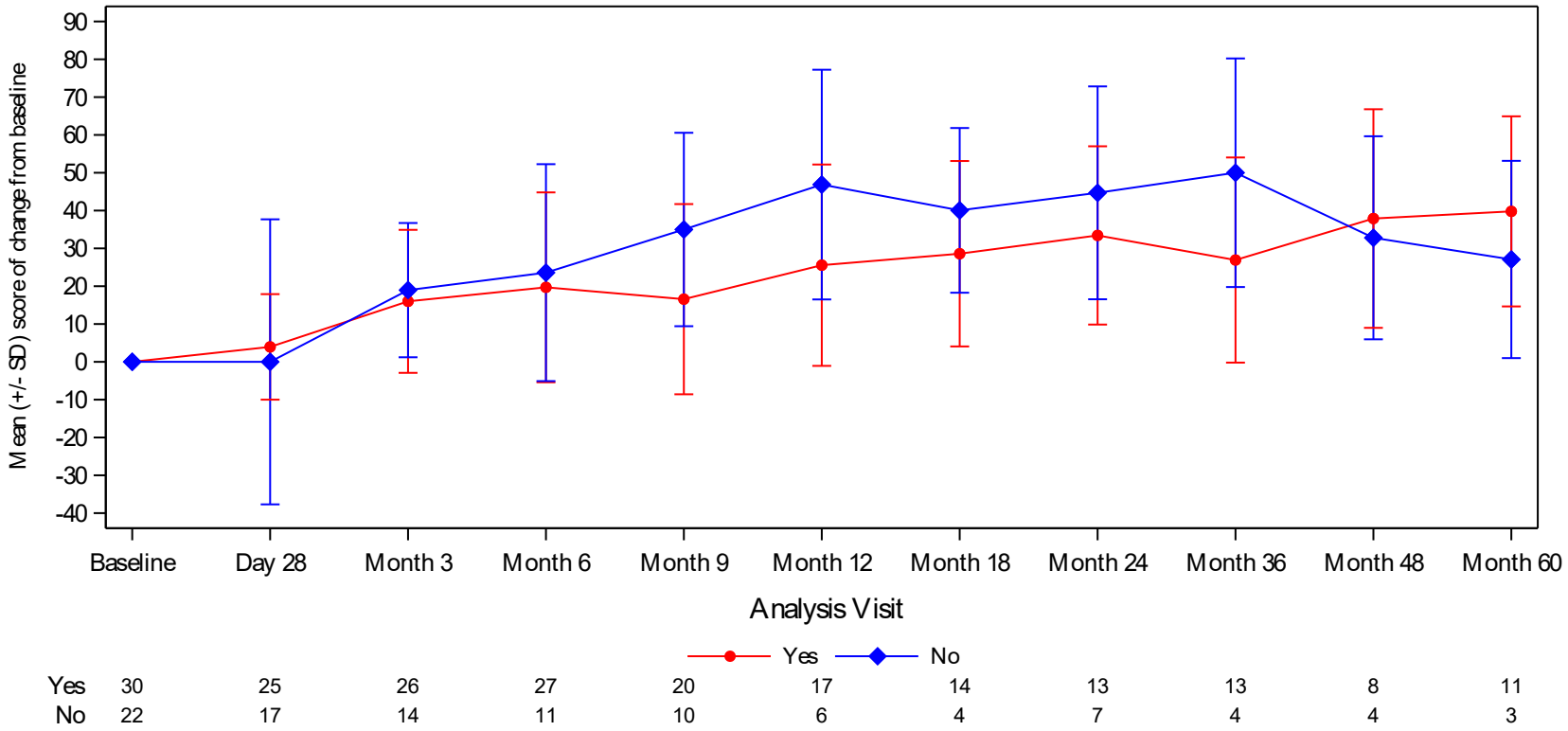


Yes	24	17	18	20	15	14	11	11	11	7	10
No	21	13	13	10	9	6	4	7	4	4	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53l (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

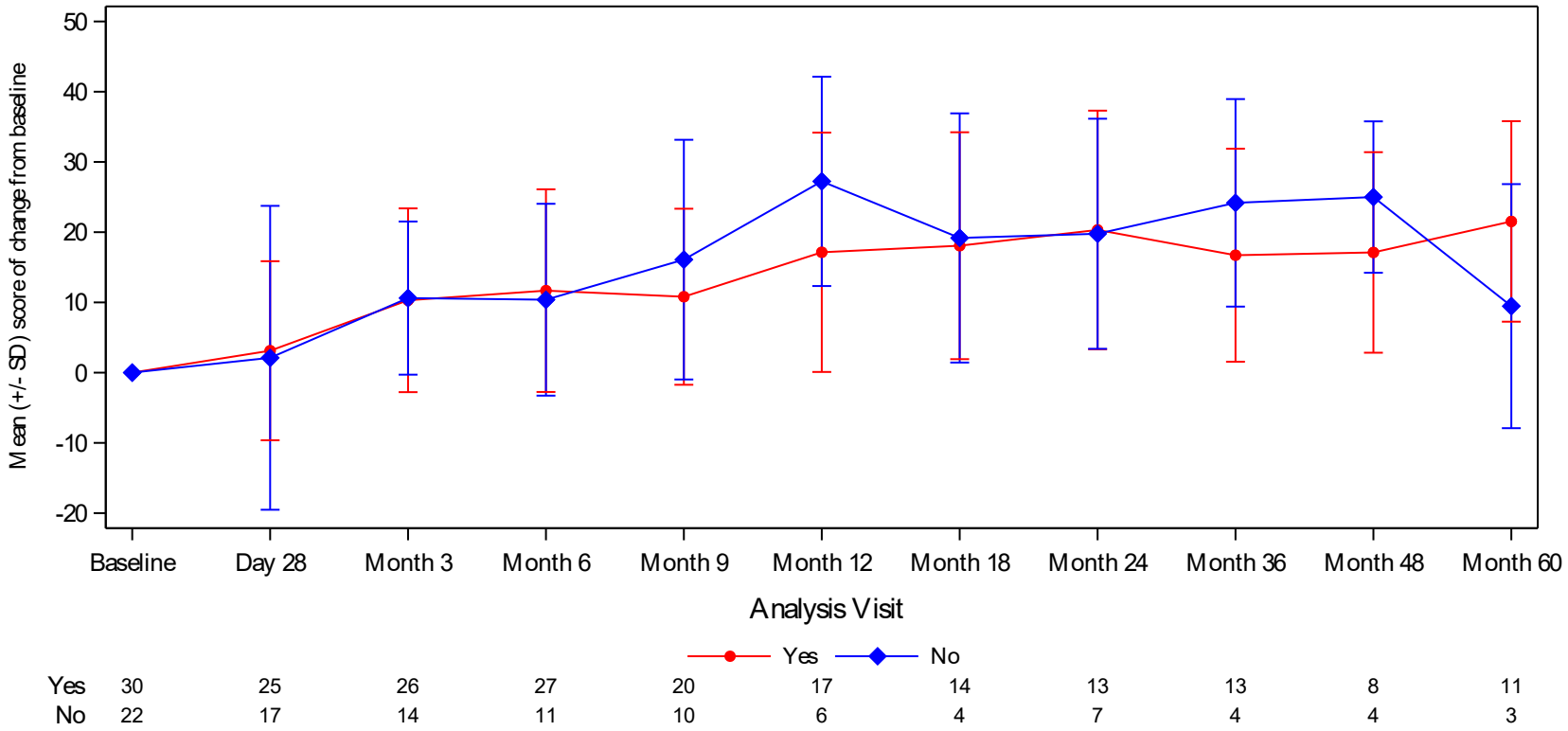


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	30	25	26	27	20	17	14	13	13	8	11
No	22	17	14	11	10	6	4	7	4	4	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53l (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

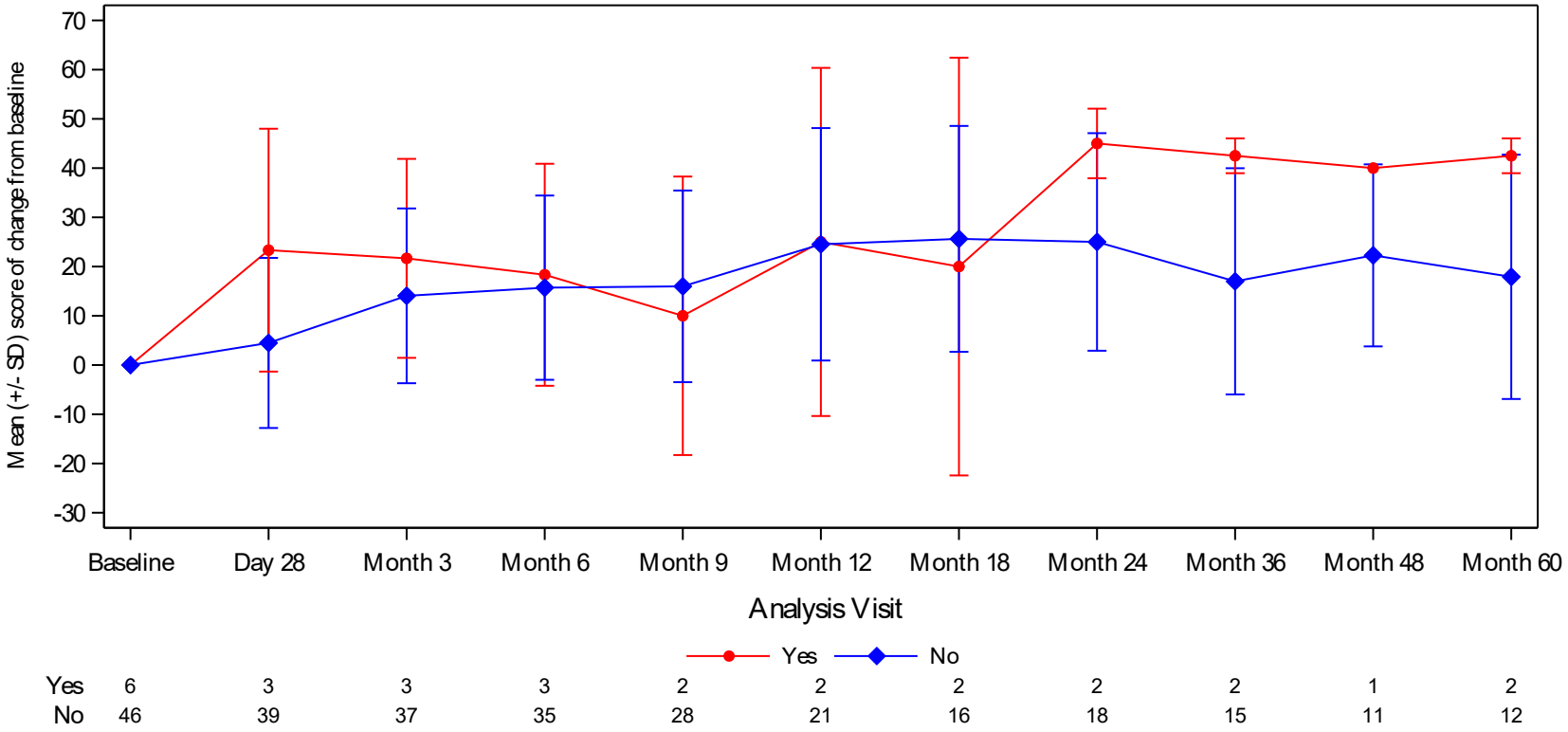


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	30	25	26	27	20	17	14	13	13	8	11
No	22	17	14	11	10	6	4	7	4	4	3

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53m (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

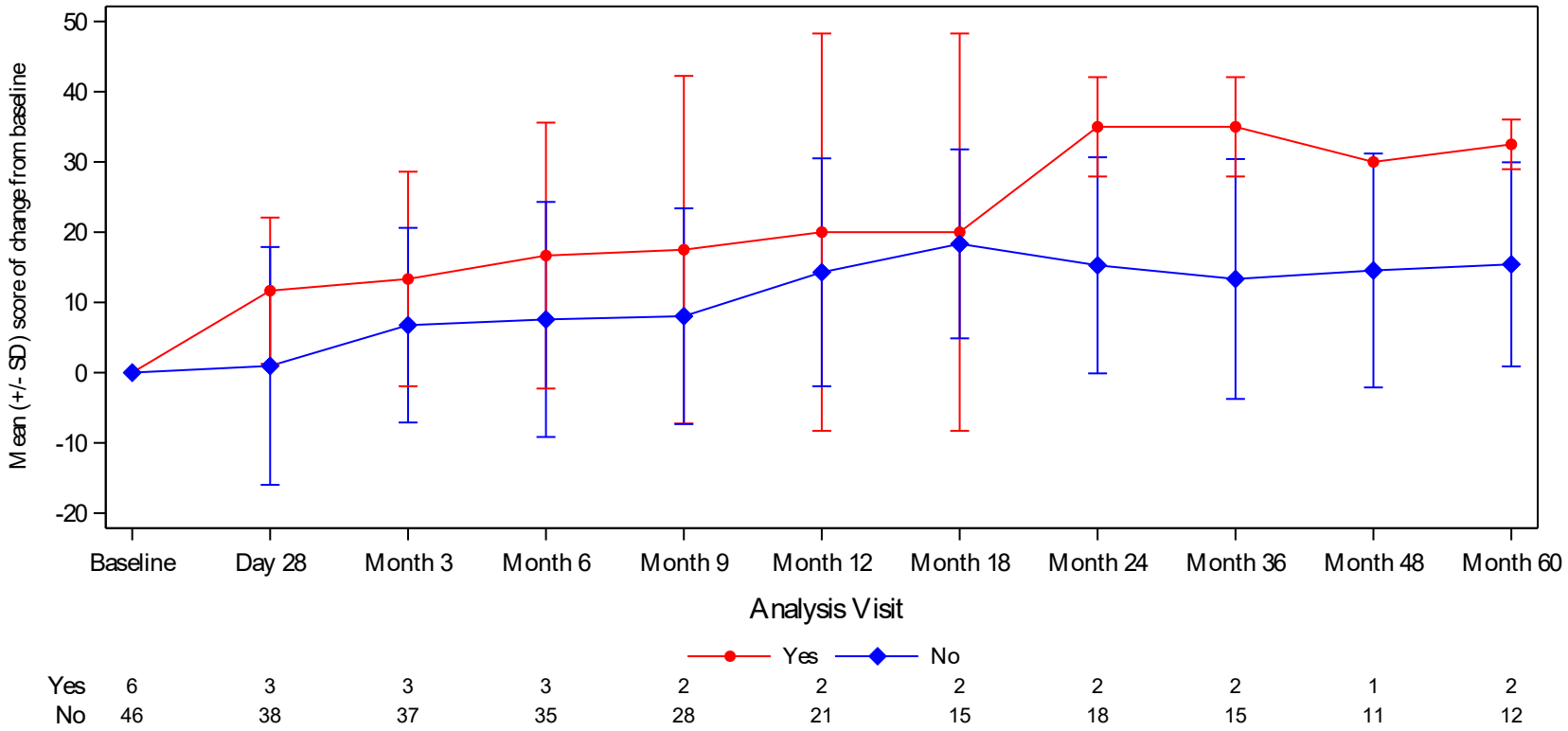


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	6	3	3	3	2	2	2	2	2	1	2
No	46	39	37	35	28	21	16	18	15	11	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53m (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

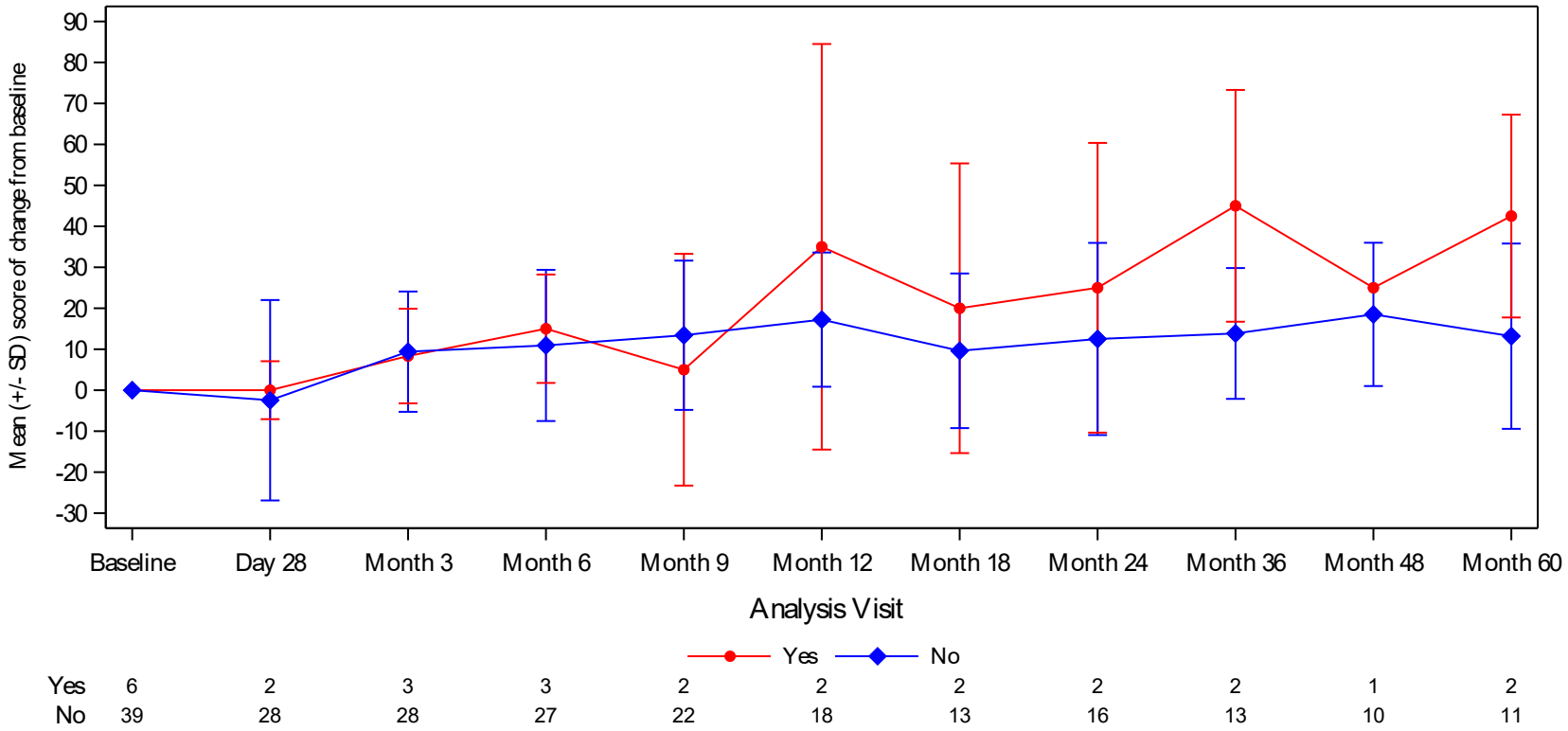


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	6	3	3	3	2	2	2	2	2	1	2
No	46	38	37	35	28	21	15	18	15	11	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53m (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

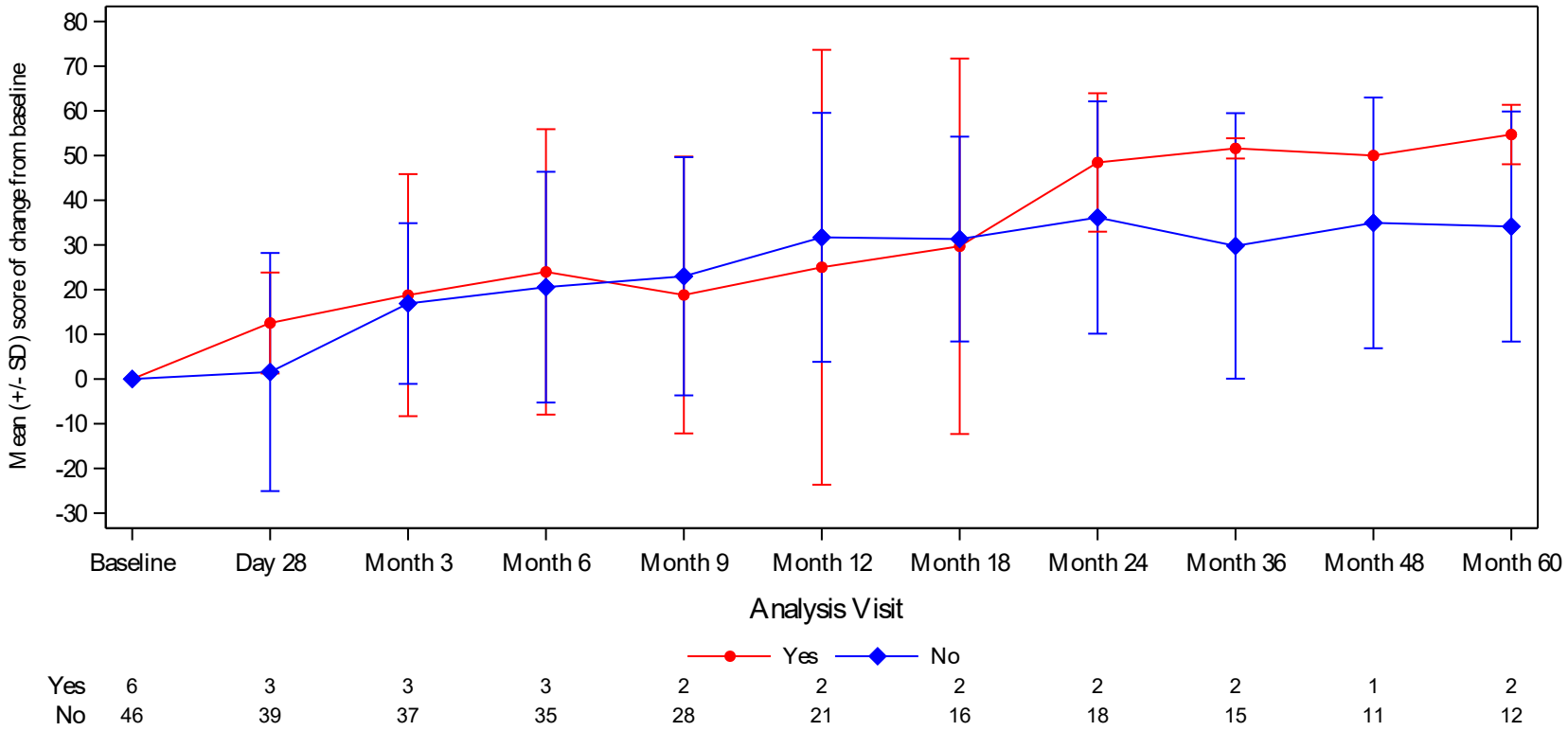


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	6	2	3	3	2	2	2	2	2	1	2
No	39	28	28	27	22	18	13	16	13	10	11

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53m (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

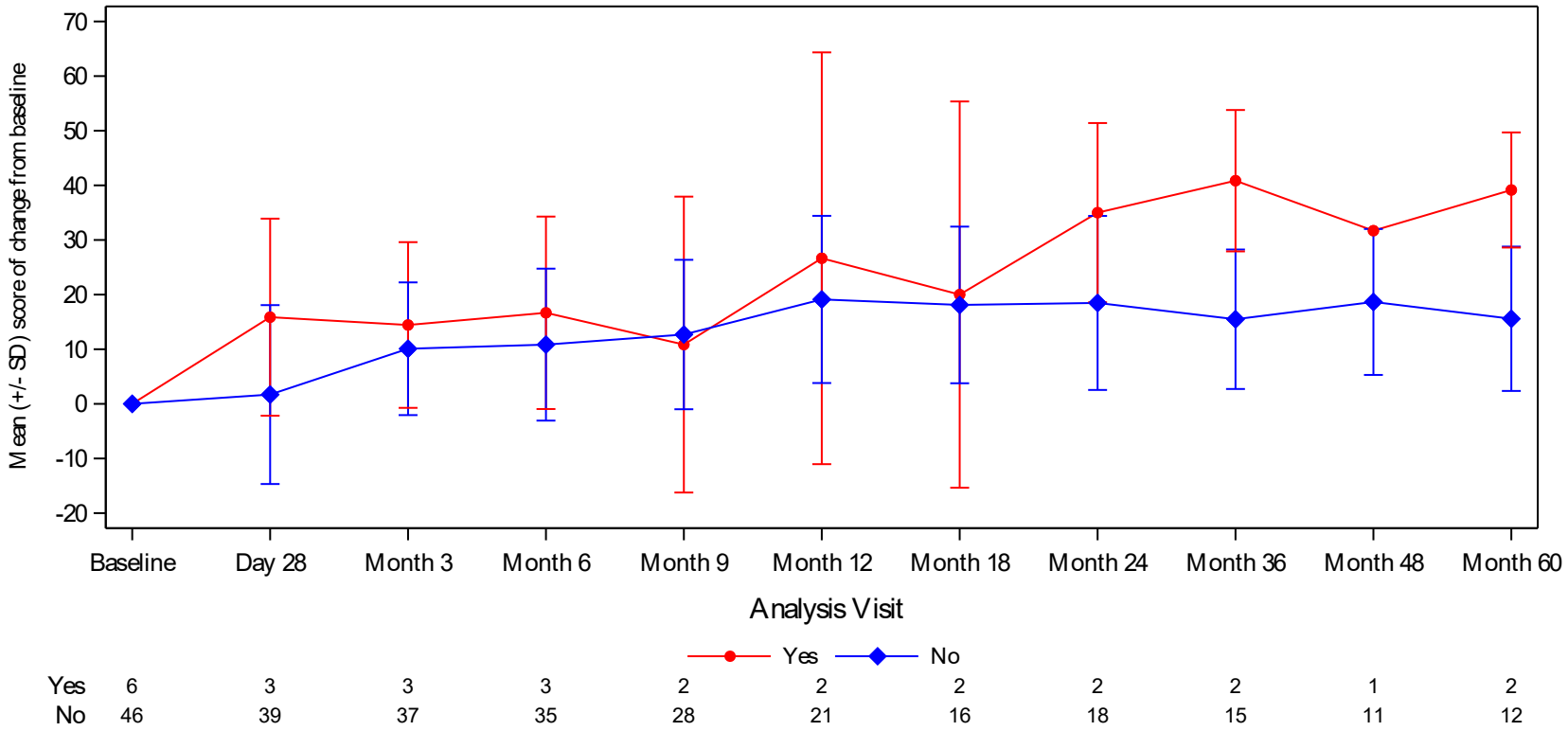


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	6	3	3	3	2	2	2	2	2	1	2
No	46	39	37	35	28	21	16	18	15	11	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53m (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

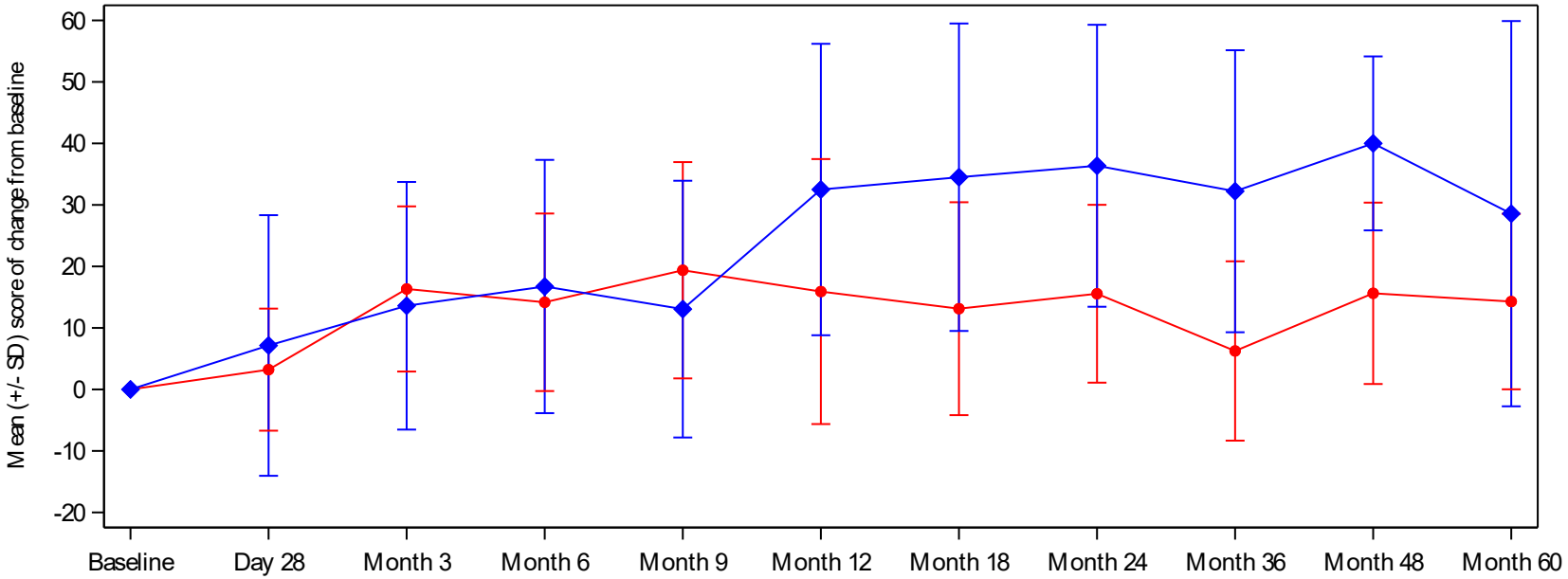


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	6	3	3	3	2	2	2	2	2	1	2
No	46	39	37	35	28	21	16	18	15	11	12

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53n (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

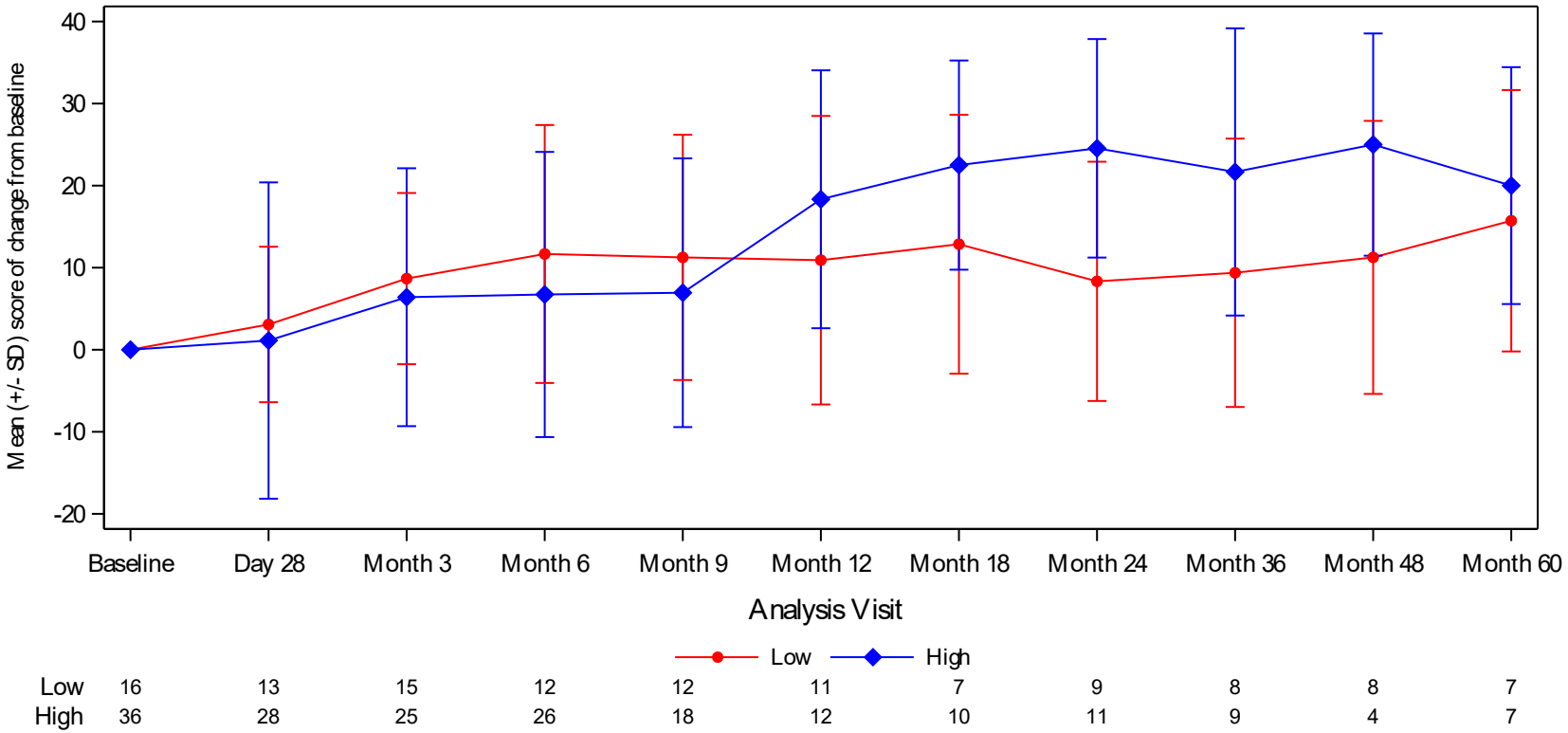


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	14	15	12	12	11	8	9	8	8	7
High	36	28	25	26	18	12	10	11	9	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53n (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

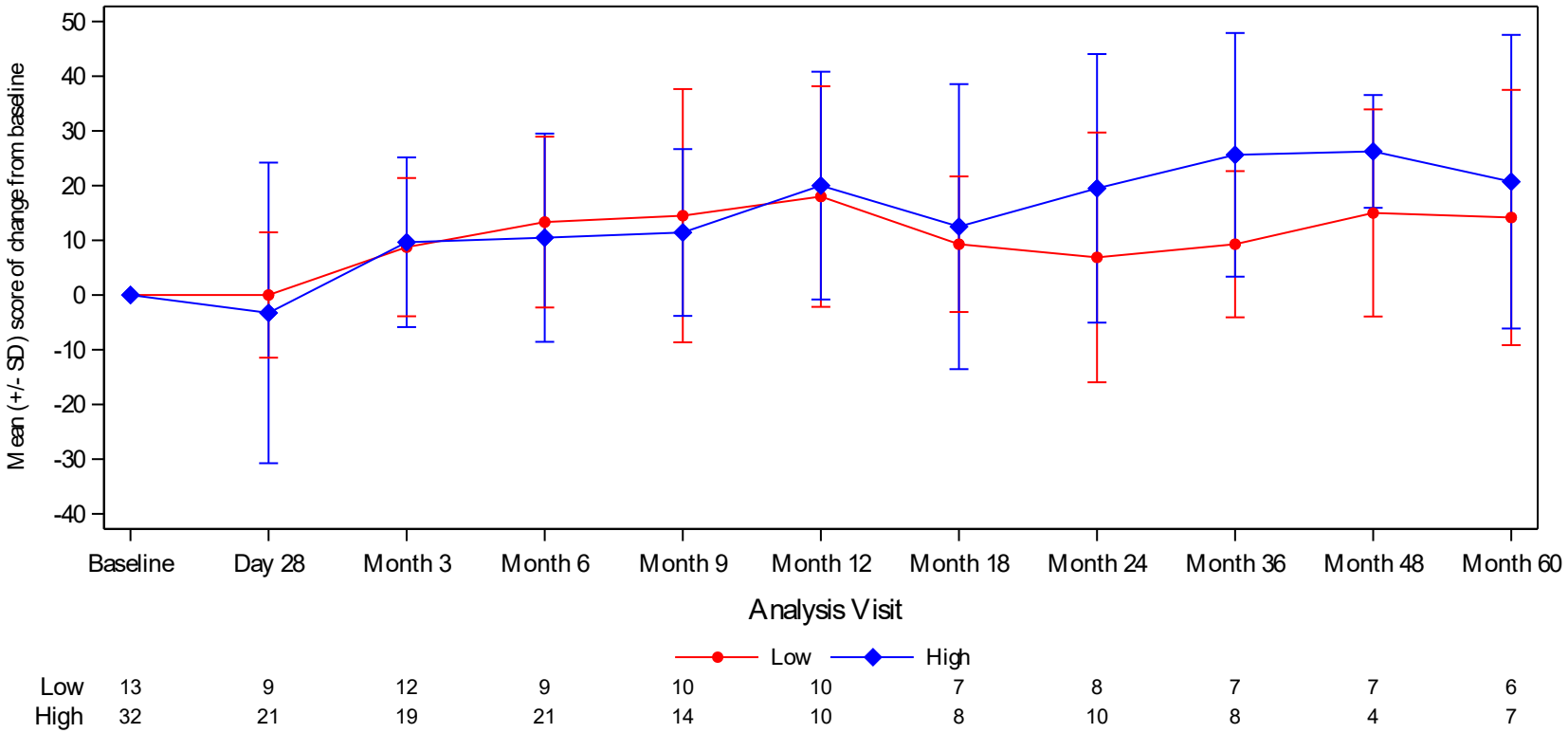


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	13	15	12	12	11	7	9	8	8	7
High	36	28	25	26	18	12	10	11	9	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53n (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

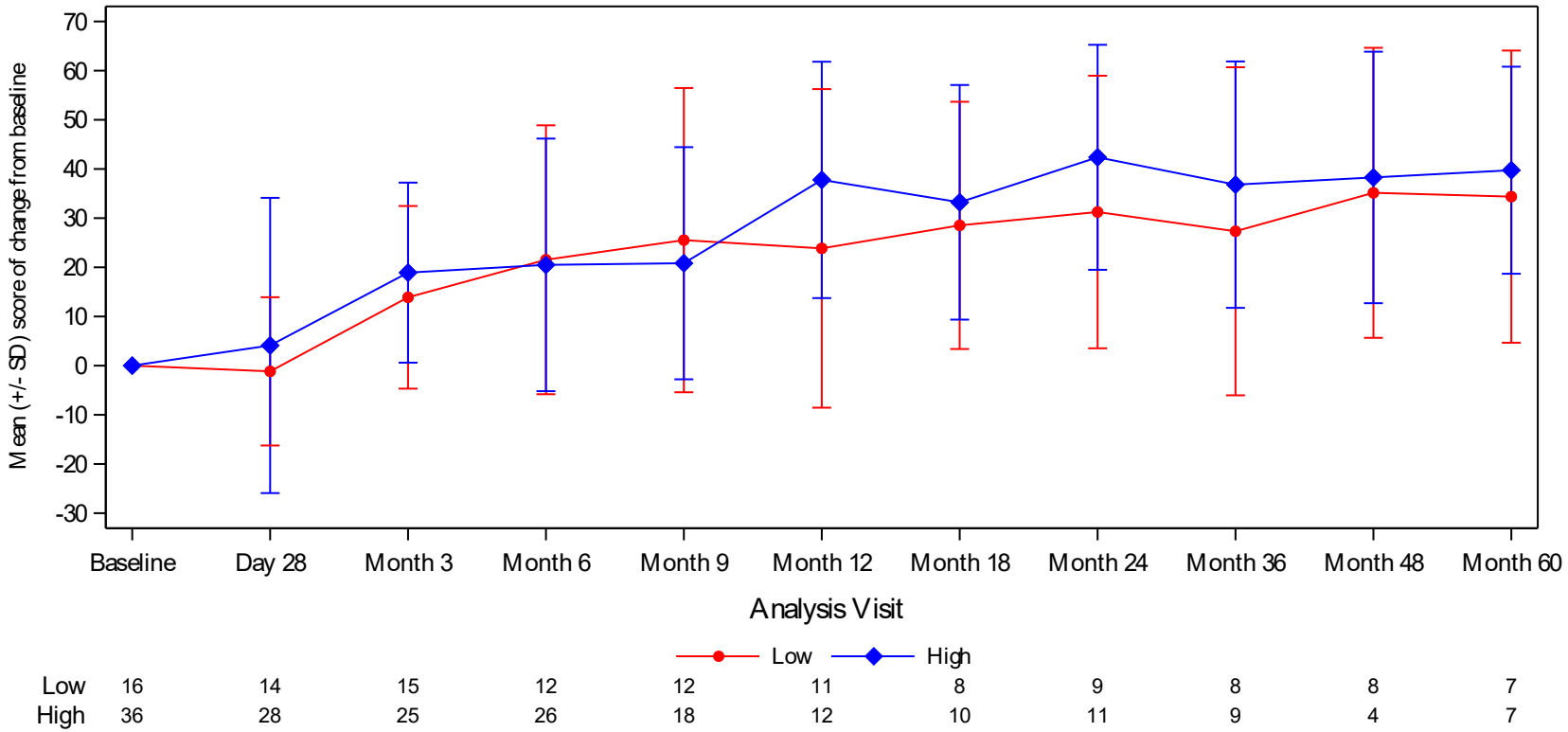


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	13	9	12	9	10	10	7	8	7	7	6
High	32	21	19	21	14	10	8	10	8	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53n (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

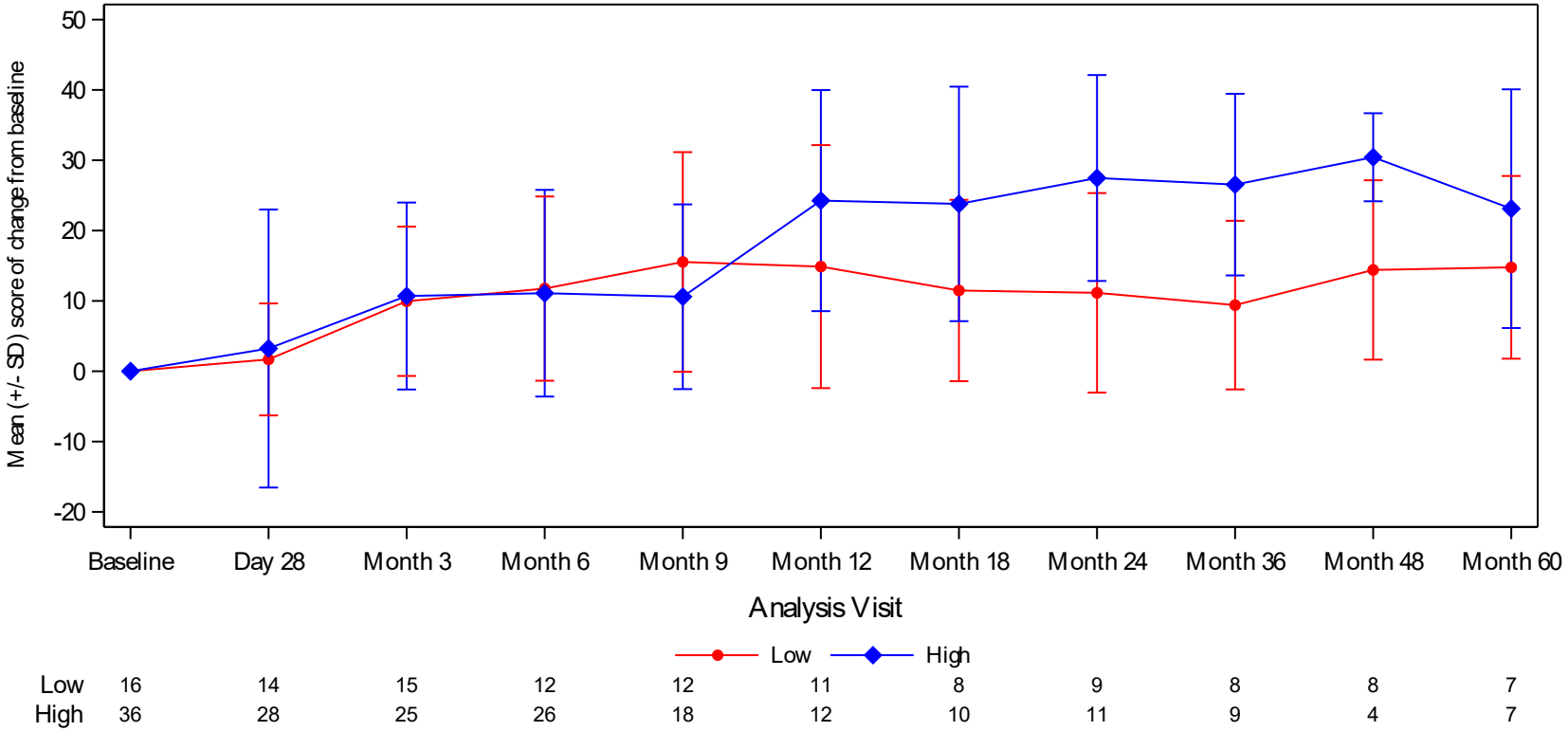


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	14	15	12	12	11	8	9	8	8	7
High	36	28	25	26	18	12	10	11	9	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53n (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

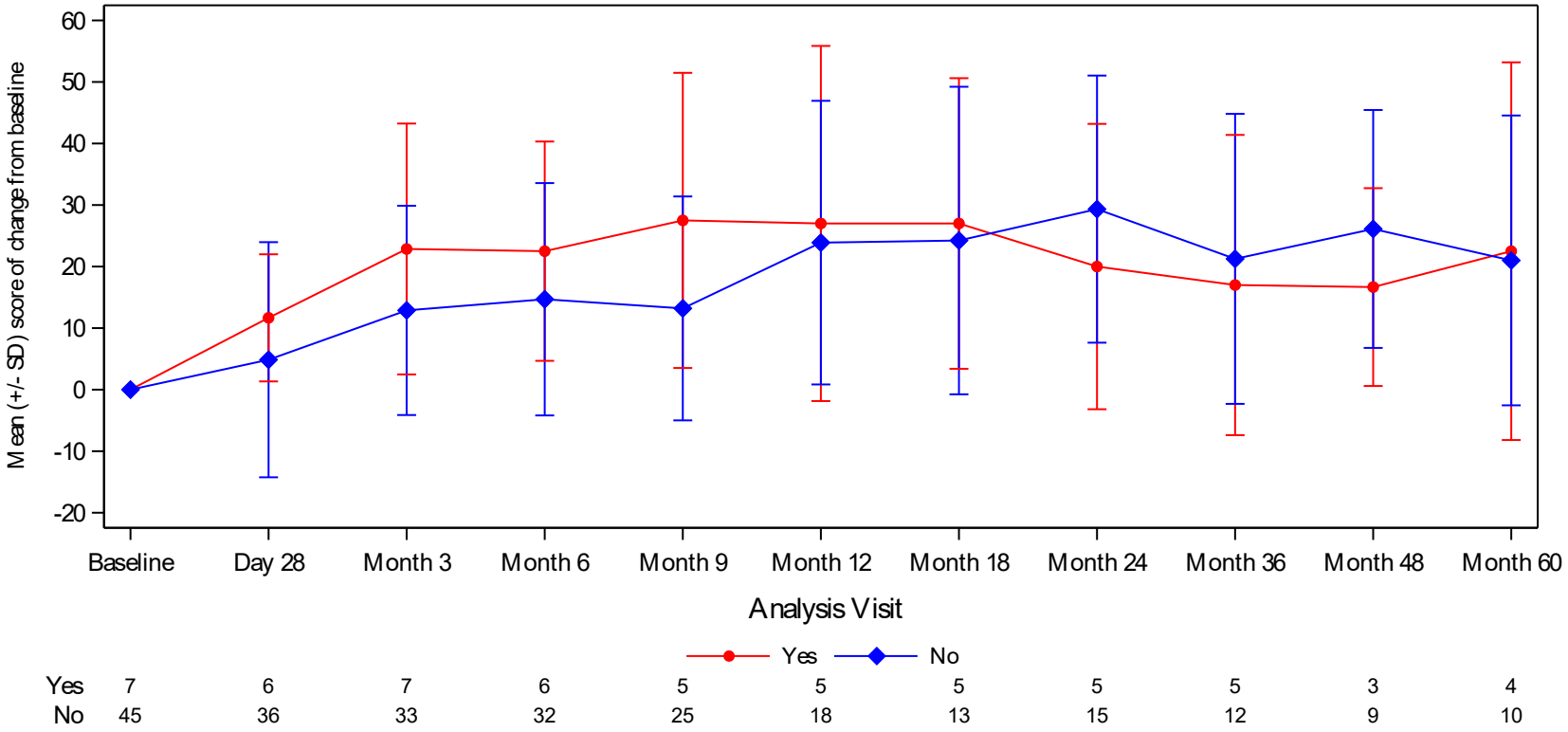


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Low	16	14	15	12	12	11	8	9	8	8	7
High	36	28	25	26	18	12	10	11	9	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53o (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

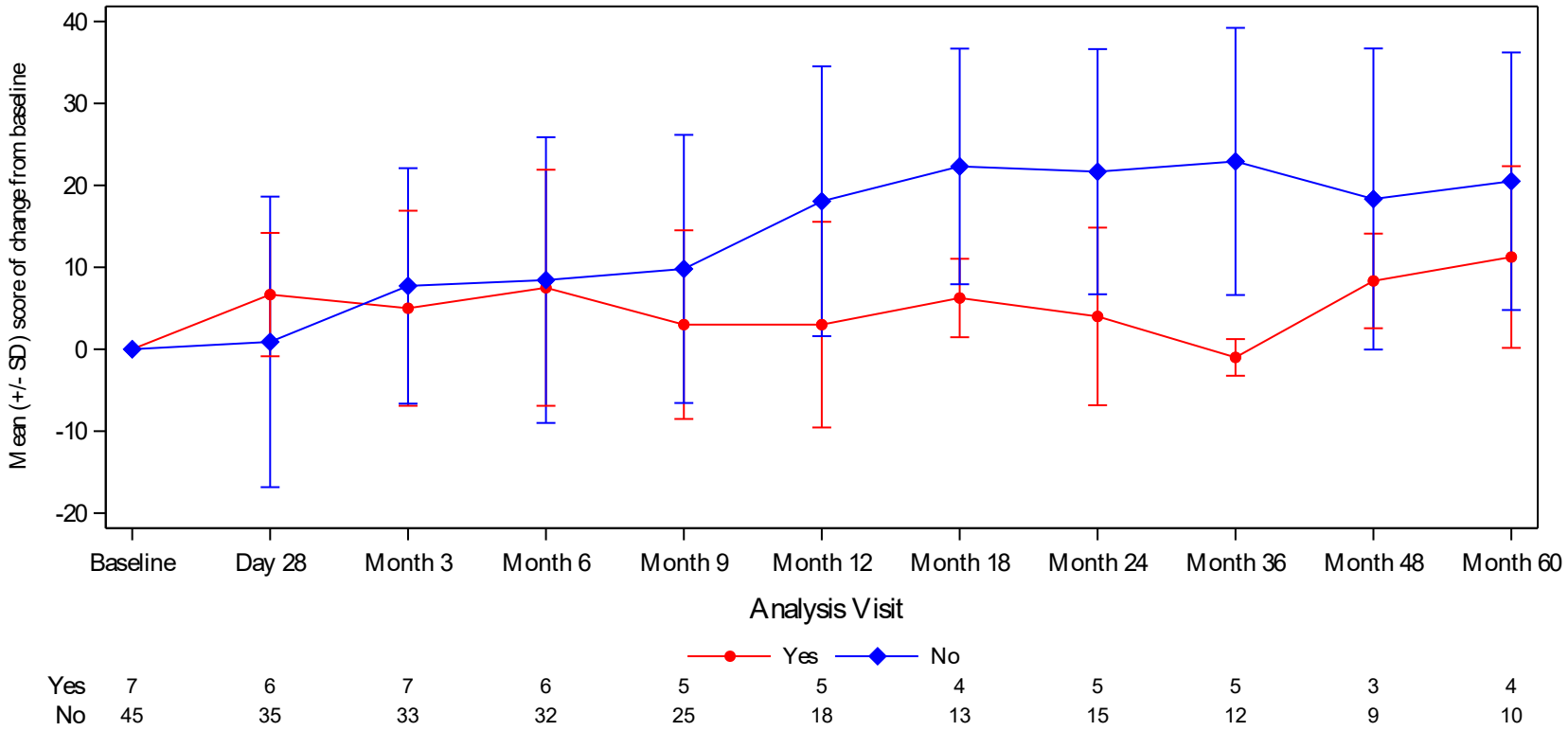


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	7	6	7	6	5	5	5	5	5	3	4
No	45	36	33	32	25	18	13	15	12	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53o (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

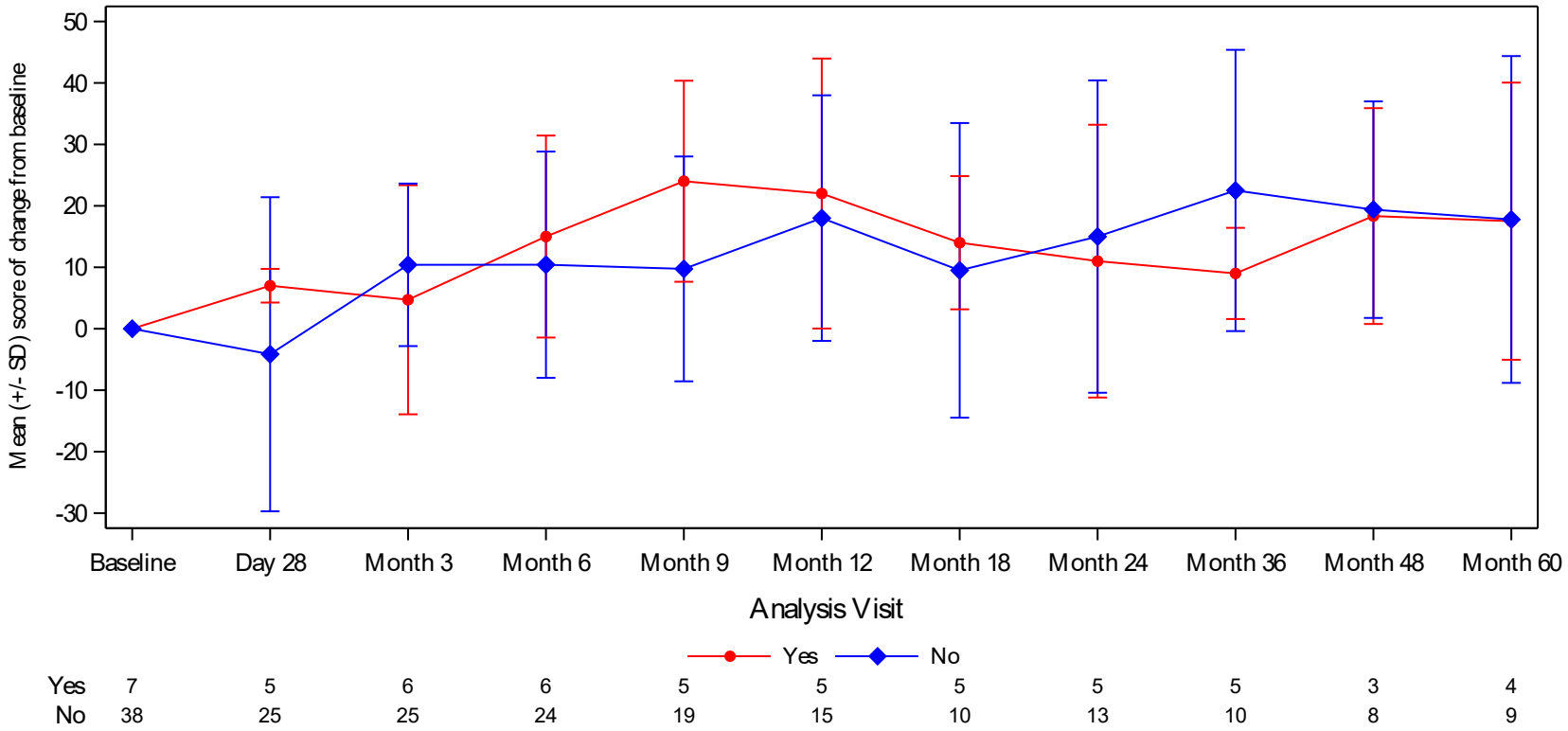


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	7	6	7	6	5	5	4	5	5	3	4
No	45	35	33	32	25	18	13	15	12	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53o (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

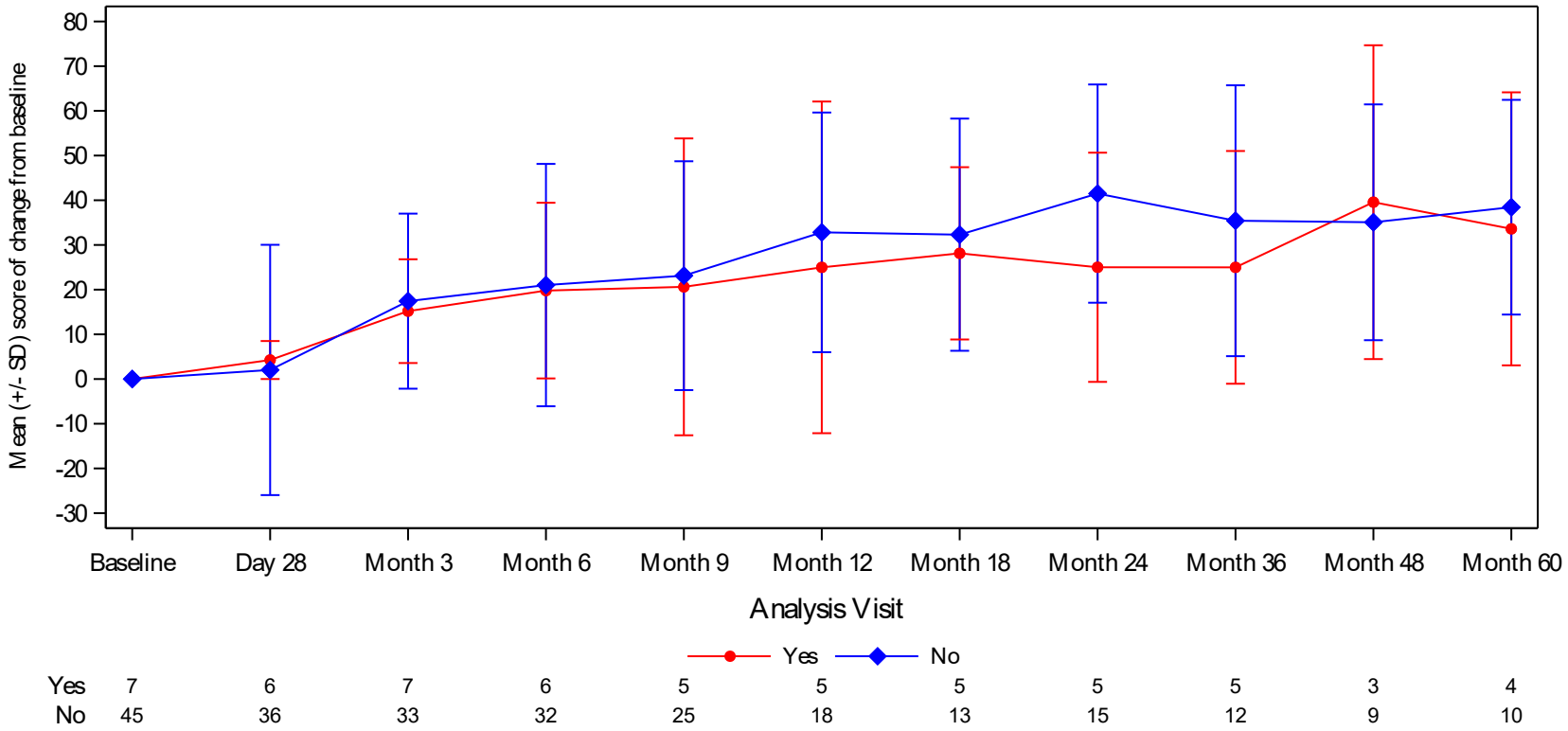


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	7	5	6	6	5	5	5	5	5	3	4
No	38	25	25	24	19	15	10	13	10	8	9

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53o (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment

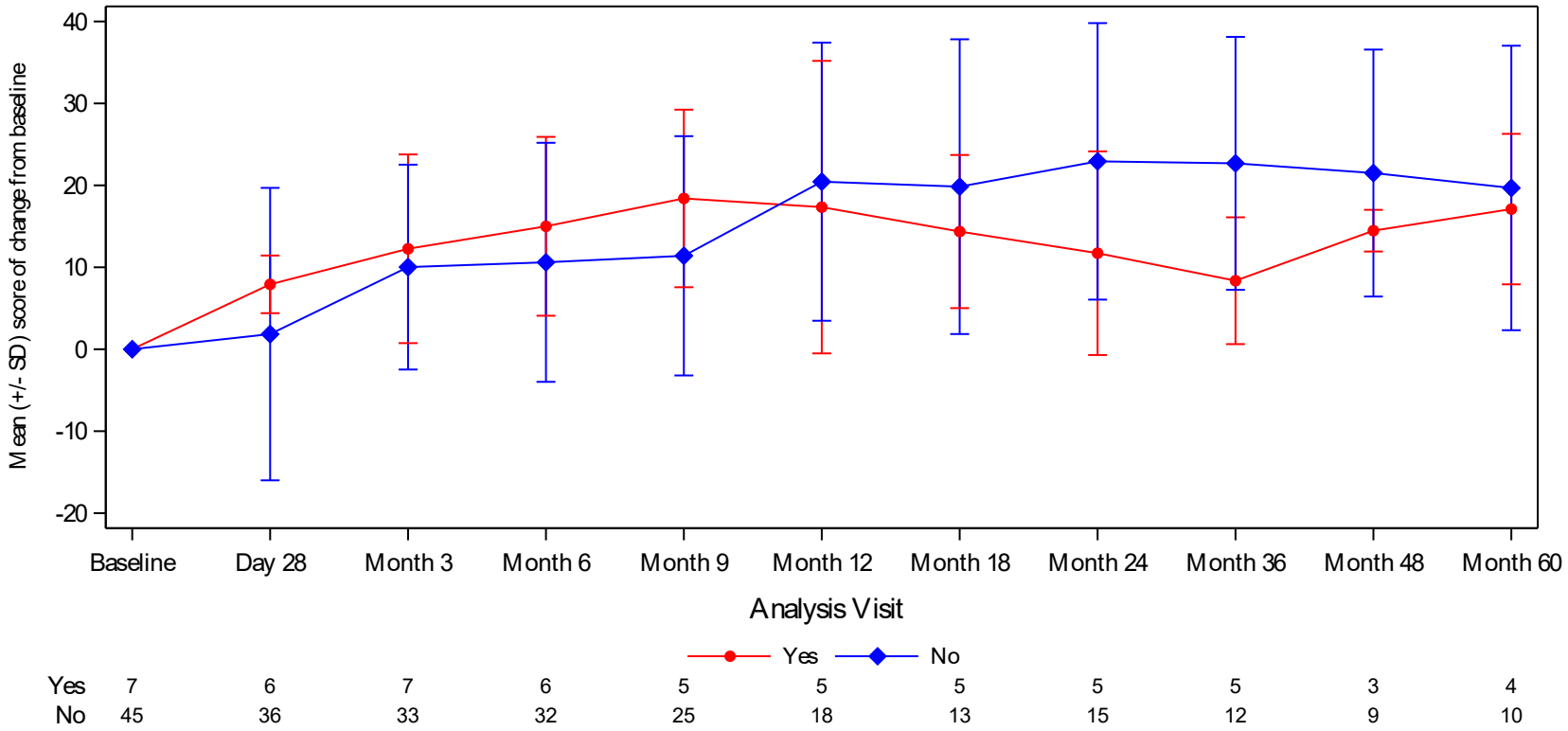
Parameter PedsQL Subscale: Physical Subscale



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53o (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

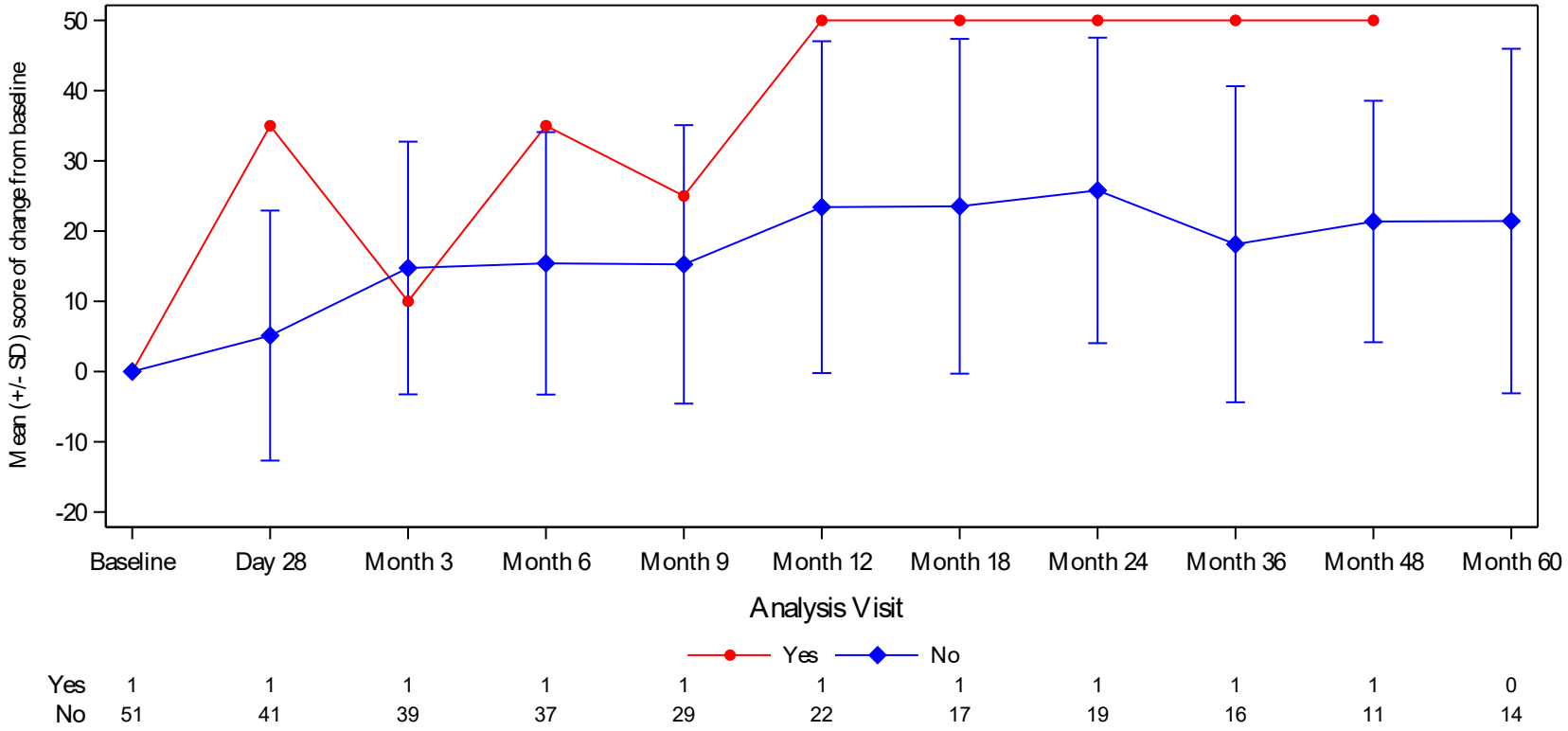


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	7	6	7	6	5	5	5	5	5	3	4
No	45	36	33	32	25	18	13	15	12	9	10

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53p (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

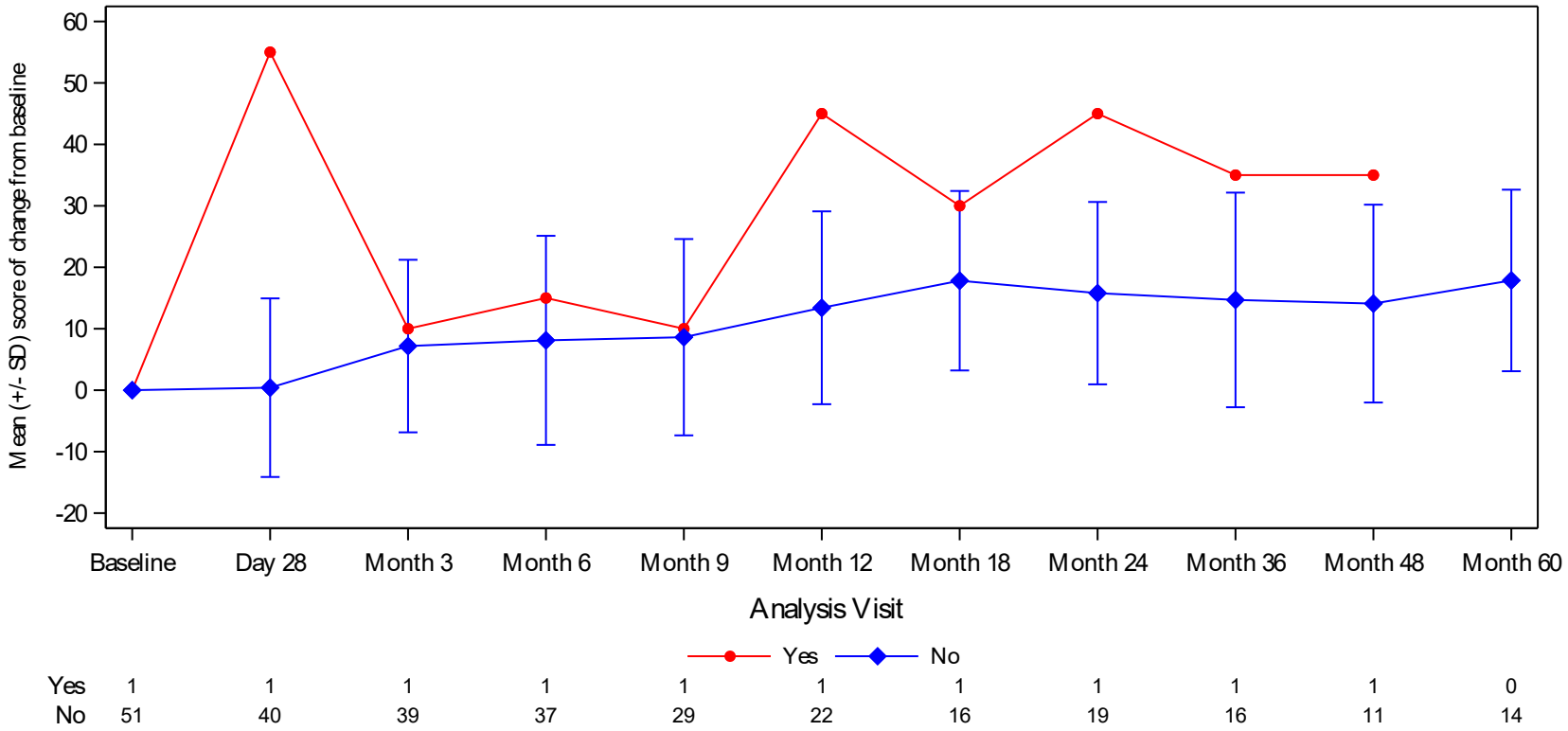


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	1	1	1	1	1	1	1	1	1	1	0
No	51	41	39	37	29	22	17	19	16	11	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53p (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

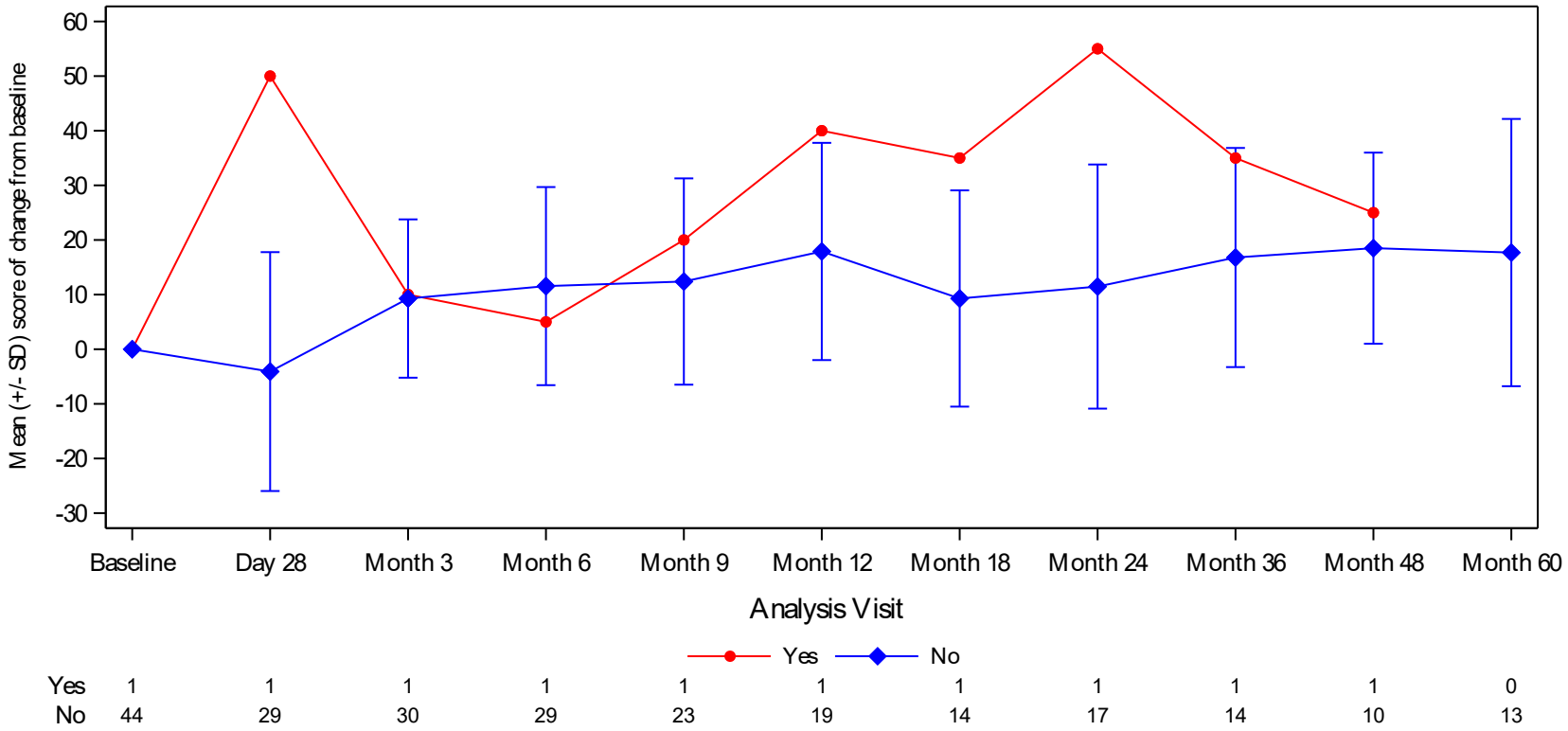
Parameter PedsQL Subscale: Social Subscale



Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53p (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

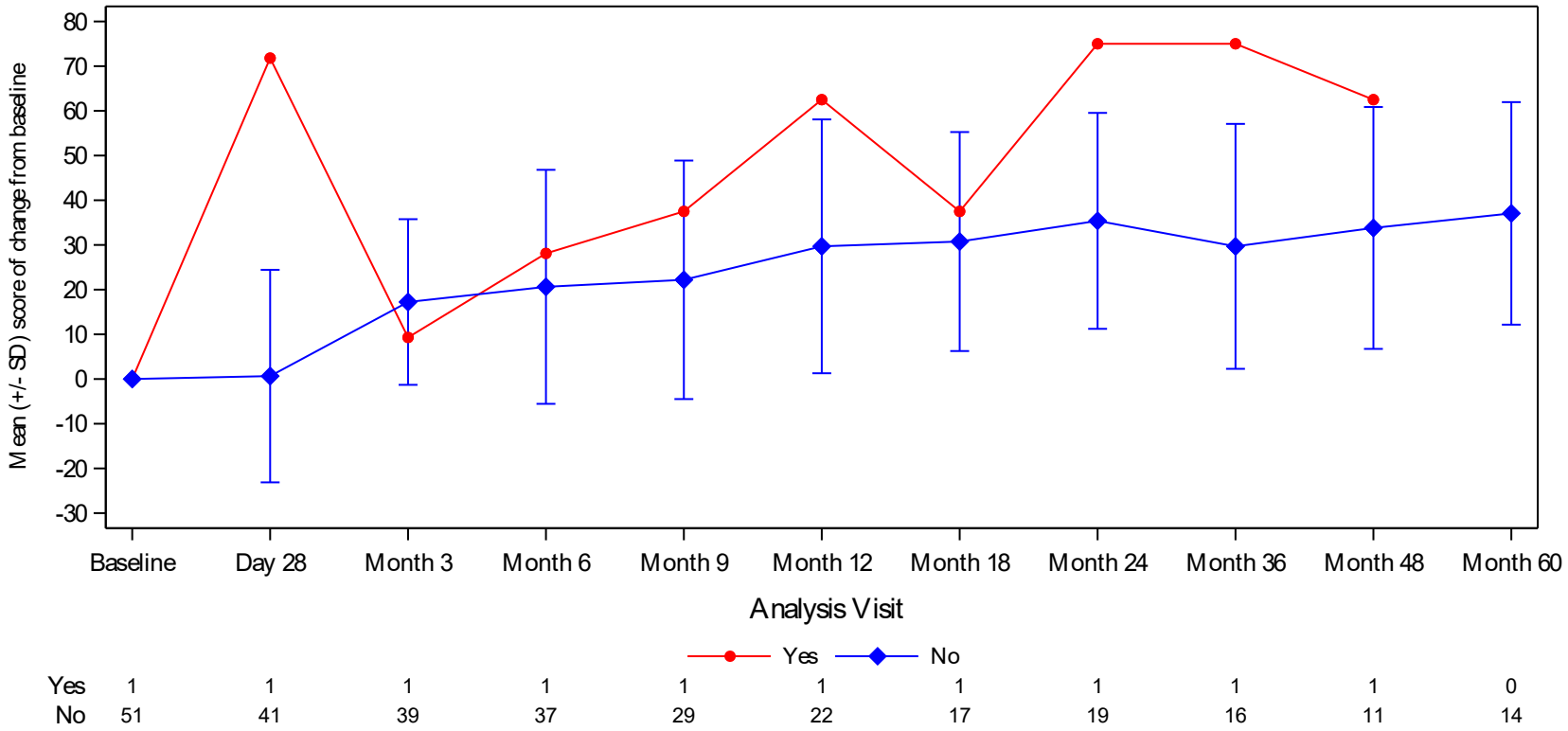


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	1	1	1	1	1	1	1	1	1	1	0
No	44	29	30	29	23	19	14	17	14	10	13

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53p (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

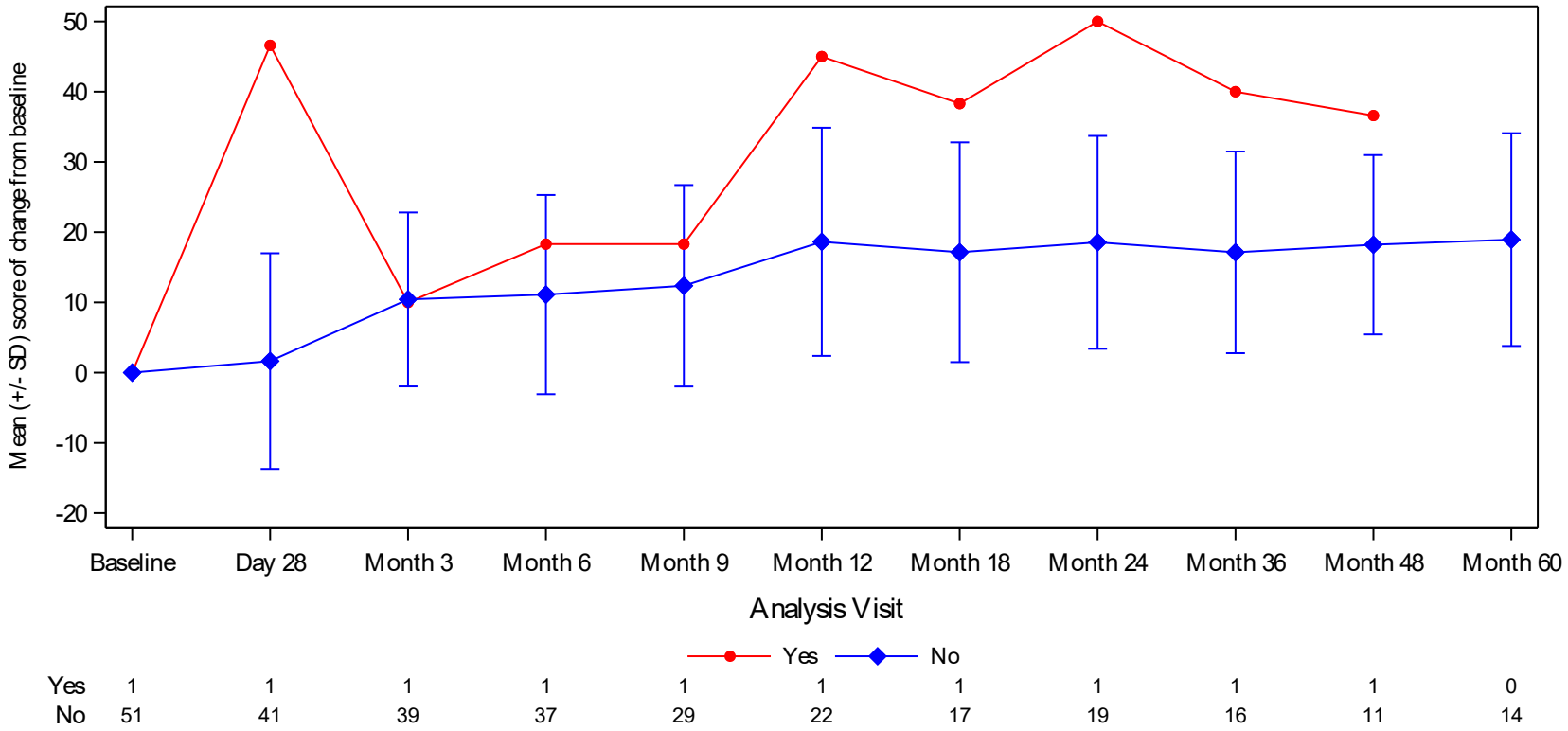


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	1	1	1	1	1	1	1	1	1	1	0
No	51	41	39	37	29	22	17	19	16	11	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53p (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

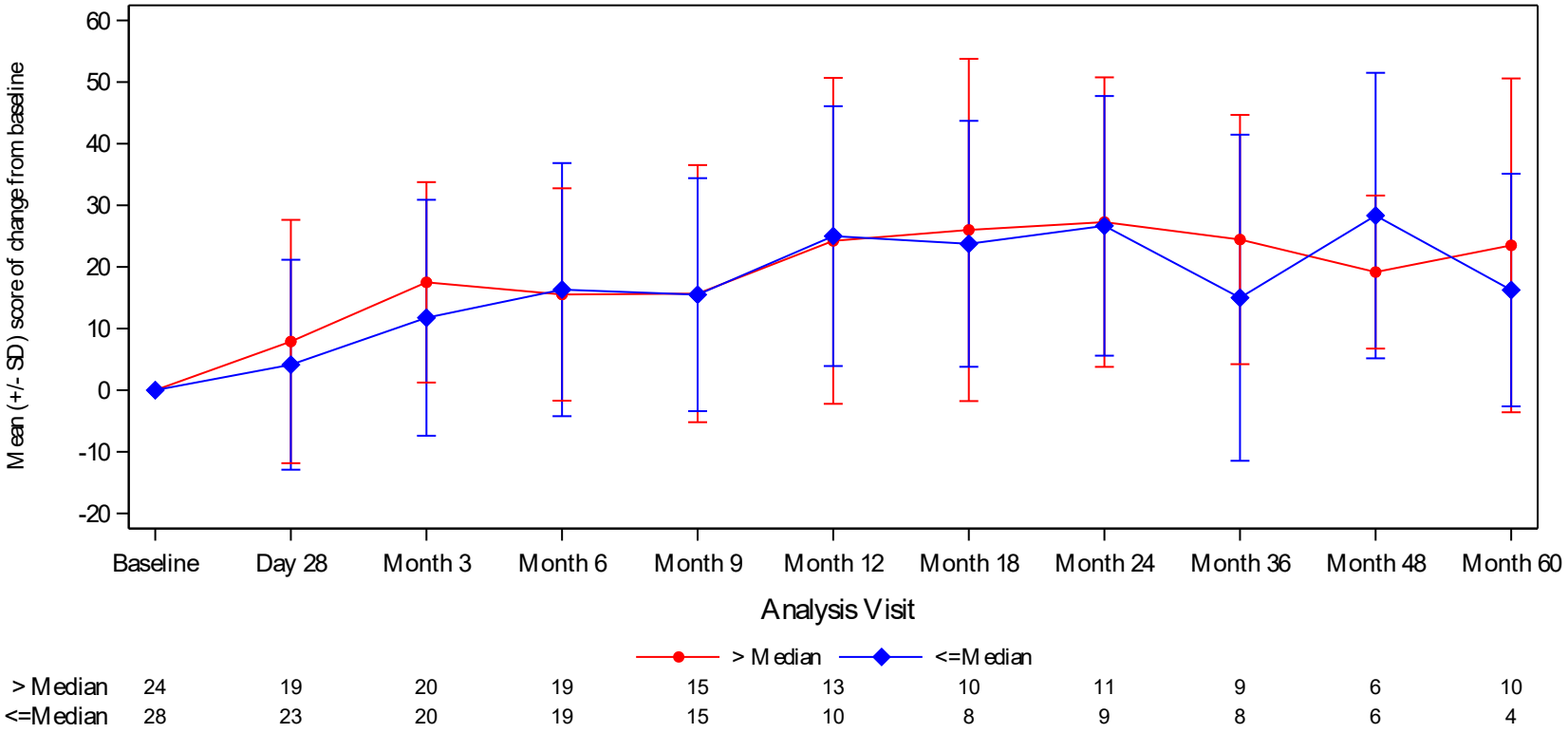


	Baseline	Day 28	Month 3	Month 6	Month 9	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Yes	1	1	1	1	1	1	1	1	1	1	0
No	51	41	39	37	29	22	17	19	16	11	14

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53q (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

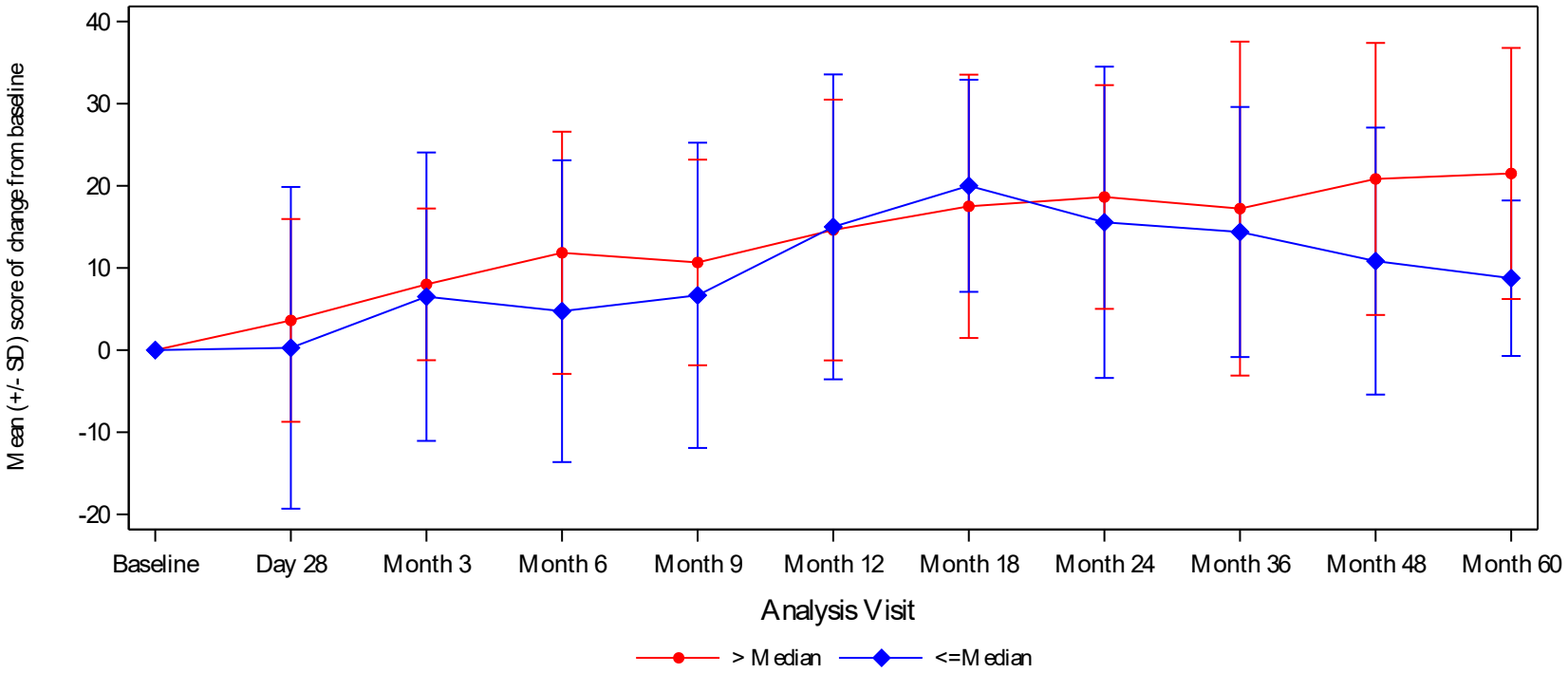


> Median	24	19	20	19	15	13	10	11	9	6	10
<=Median	28	23	20	19	15	10	8	9	8	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53q (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

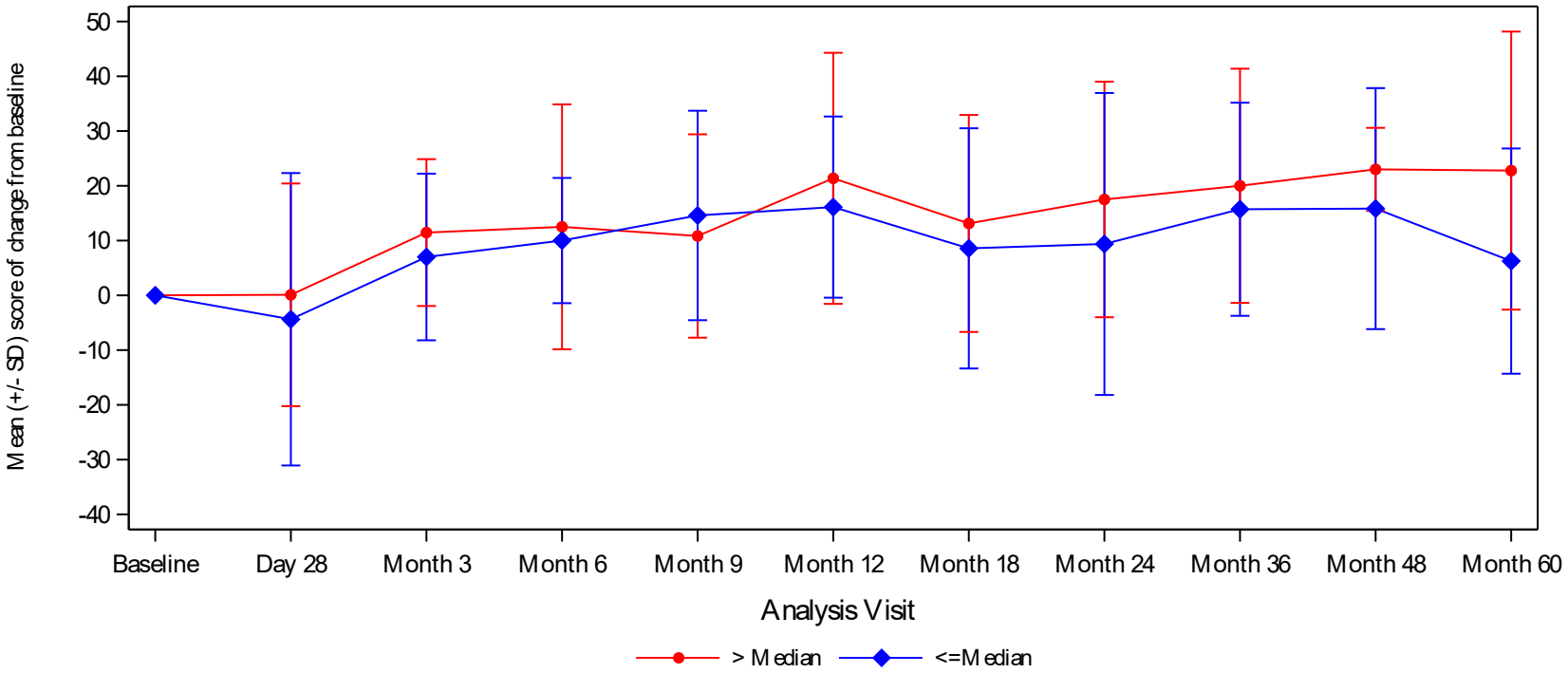


> Median	24	18	20	19	15	13	10	11	9	6	10
<=Median	28	23	20	19	15	10	7	9	8	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53q (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

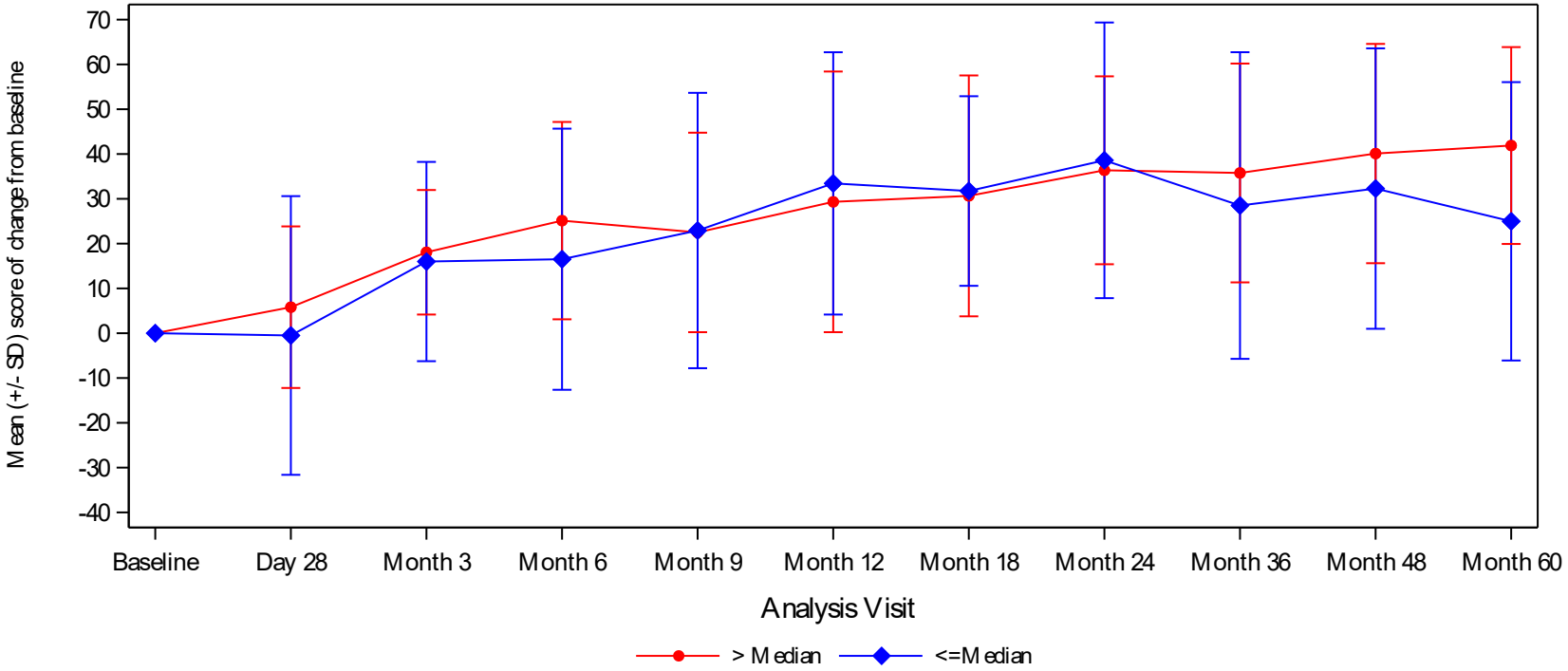


> Median	22	14	16	16	12	11	8	10	8	5	9
<=Median	23	16	15	14	12	9	7	8	7	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53q (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

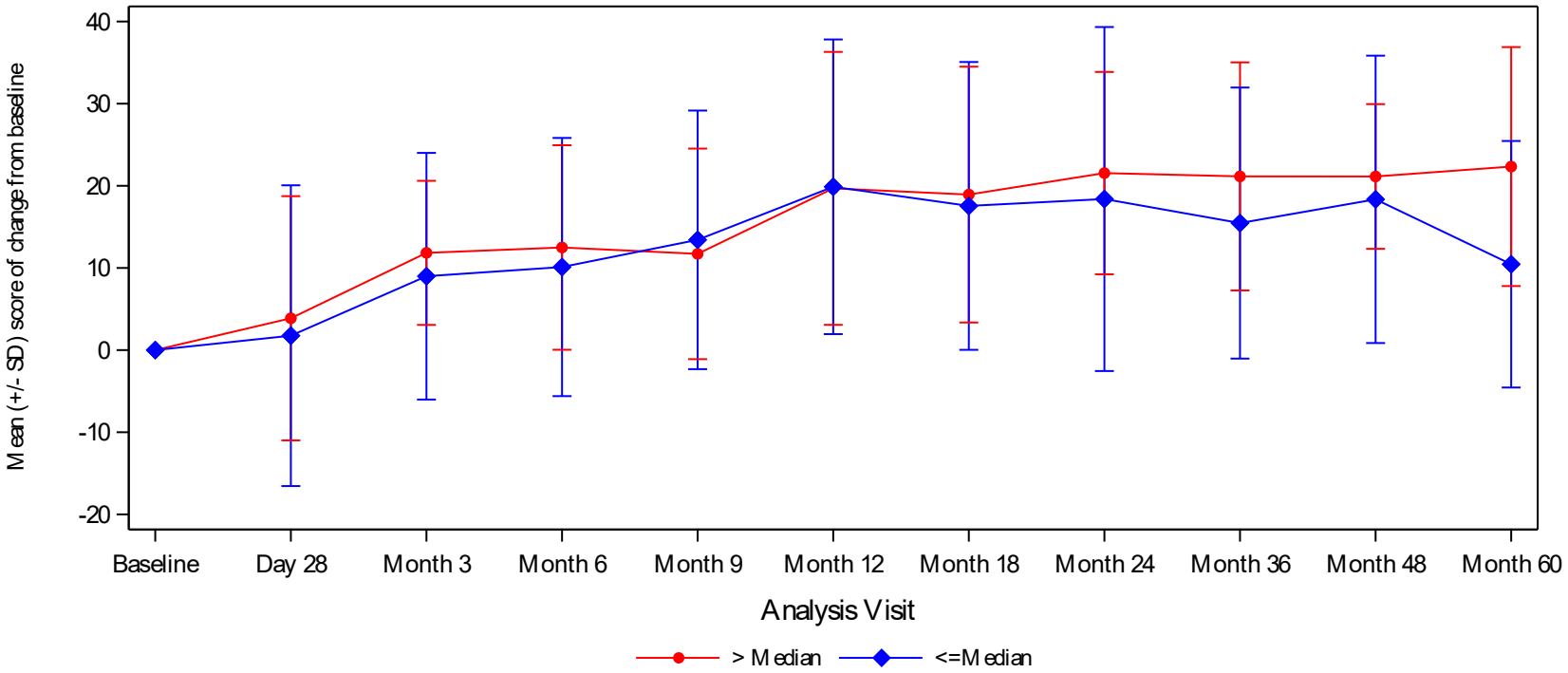


> Median	24	19	20	19	15	13	10	11	9	6	10
<=Median	28	23	20	19	15	10	8	9	8	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53q (Page 5 of)
Mean change in each PedsQL subscales score over time by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score

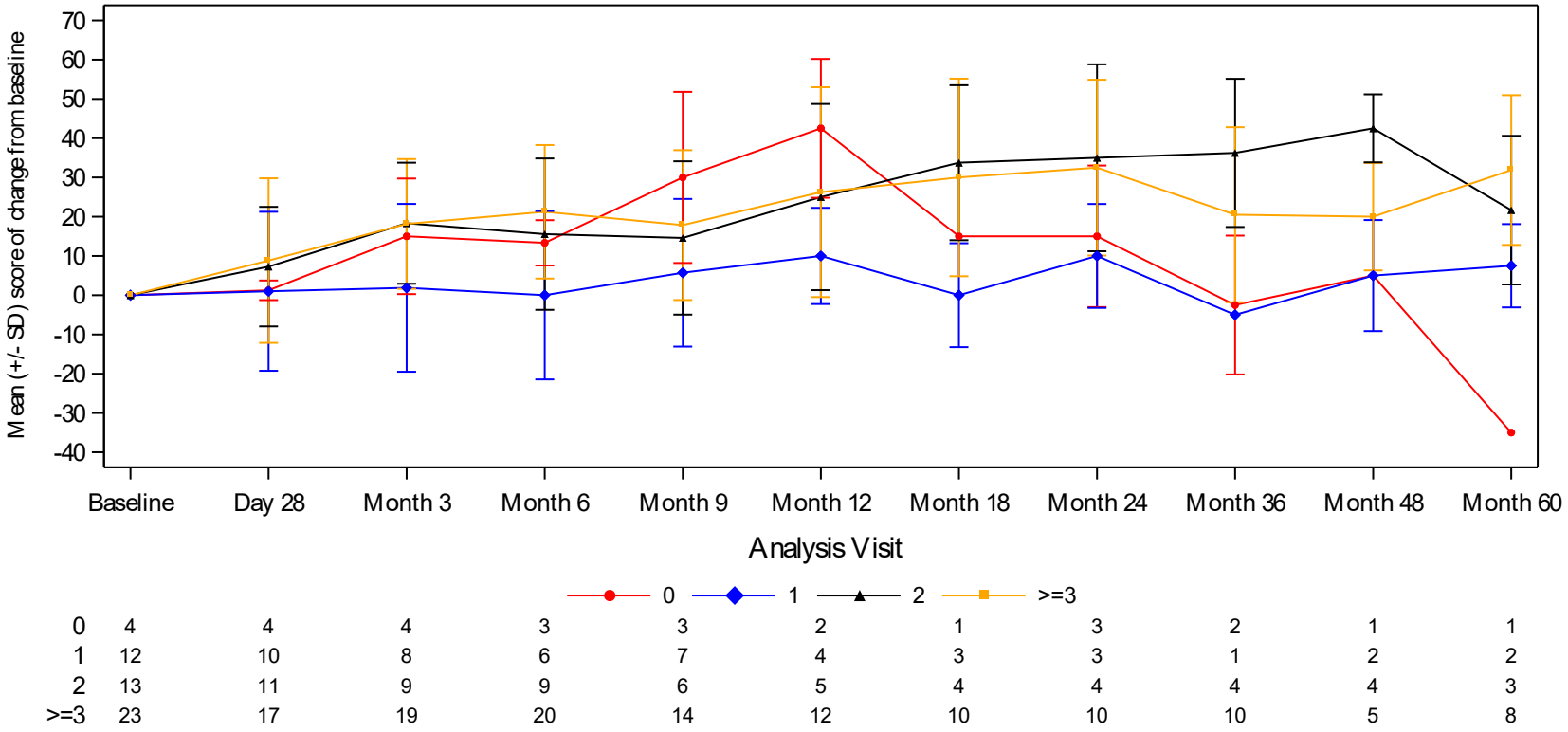


> Median	24	19	20	19	15	13	10	11	9	6	10
<=Median	28	23	20	19	15	10	8	9	8	6	4

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53r (Page 1 of 5)
Mean change in each PedsQL subscales score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Emotional Subscale

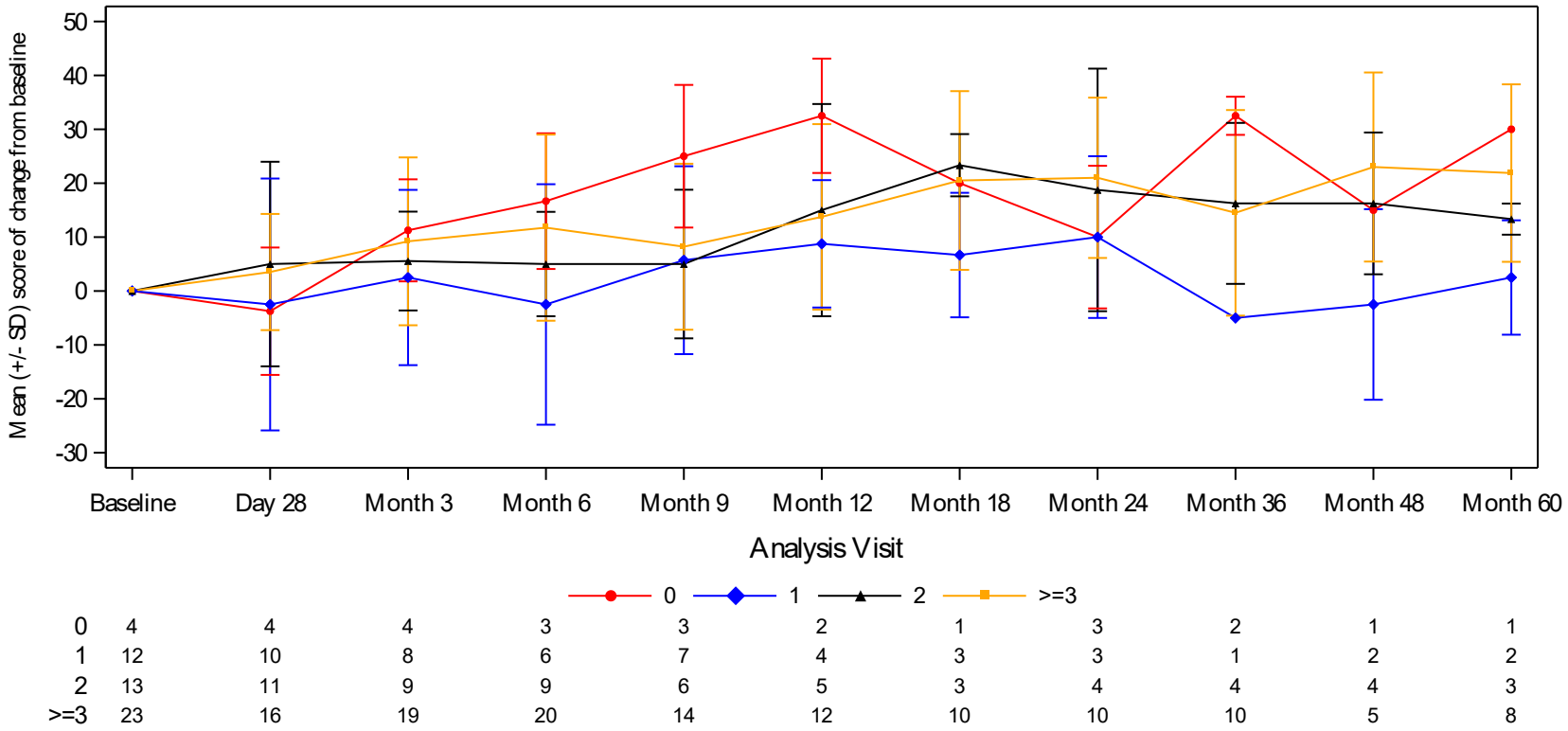


0	4	4	4	3	3	2	1	3	2	1	1
1	12	10	8	6	7	4	3	3	1	2	2
2	13	11	9	9	6	5	4	4	4	4	3
>=3	23	17	19	20	14	12	10	10	10	5	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53r (Page 2 of 5)
Mean change in each PedsQL subscales score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Social Subscale

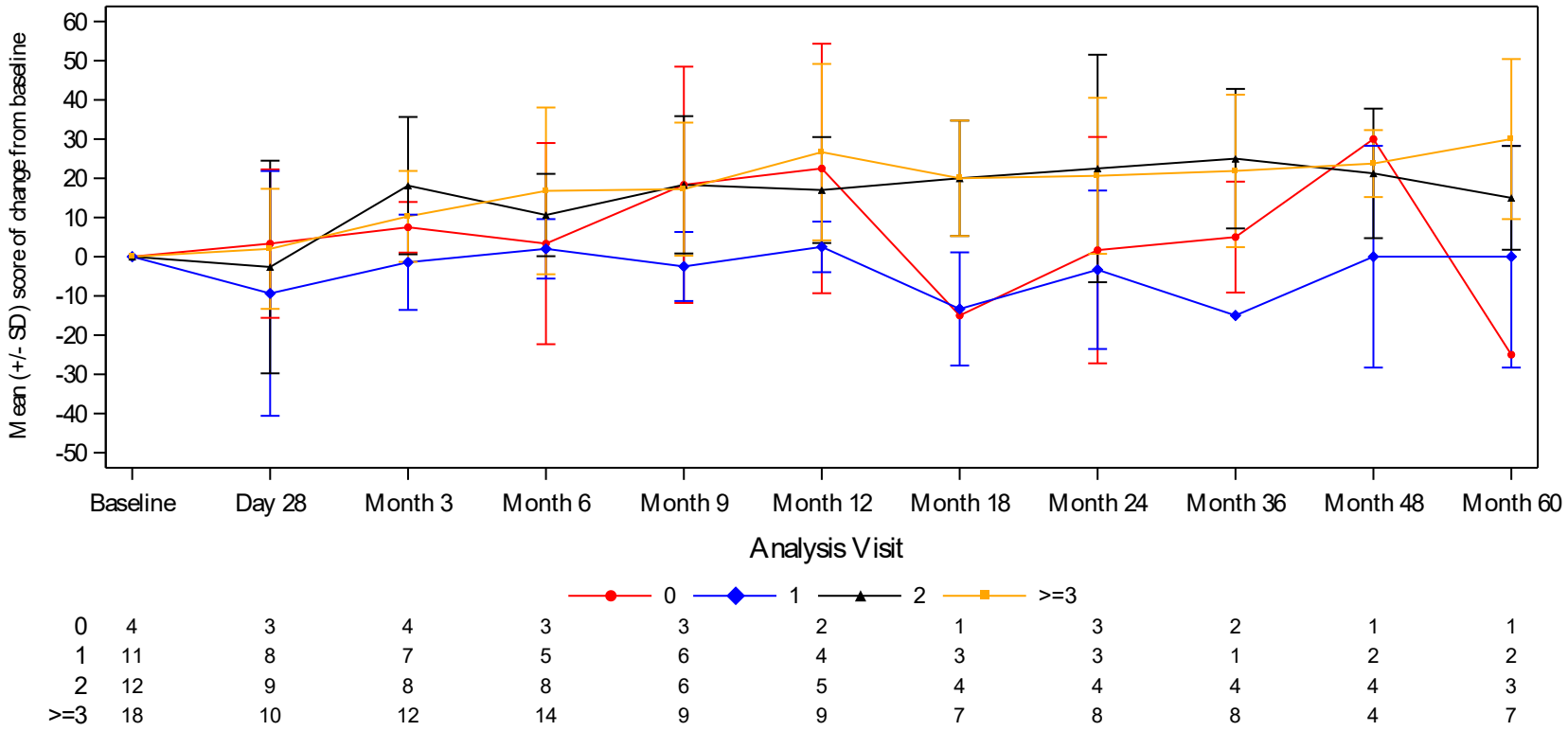


0	4	4	4	3	3	2	1	3	2	1	1
1	12	10	8	6	7	4	3	3	1	2	2
2	13	11	9	9	6	5	3	4	4	4	3
>=3	23	16	19	20	14	12	10	10	10	5	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53r (Page 3 of 5)
Mean change in each PedsQL subscales score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: School Subscale

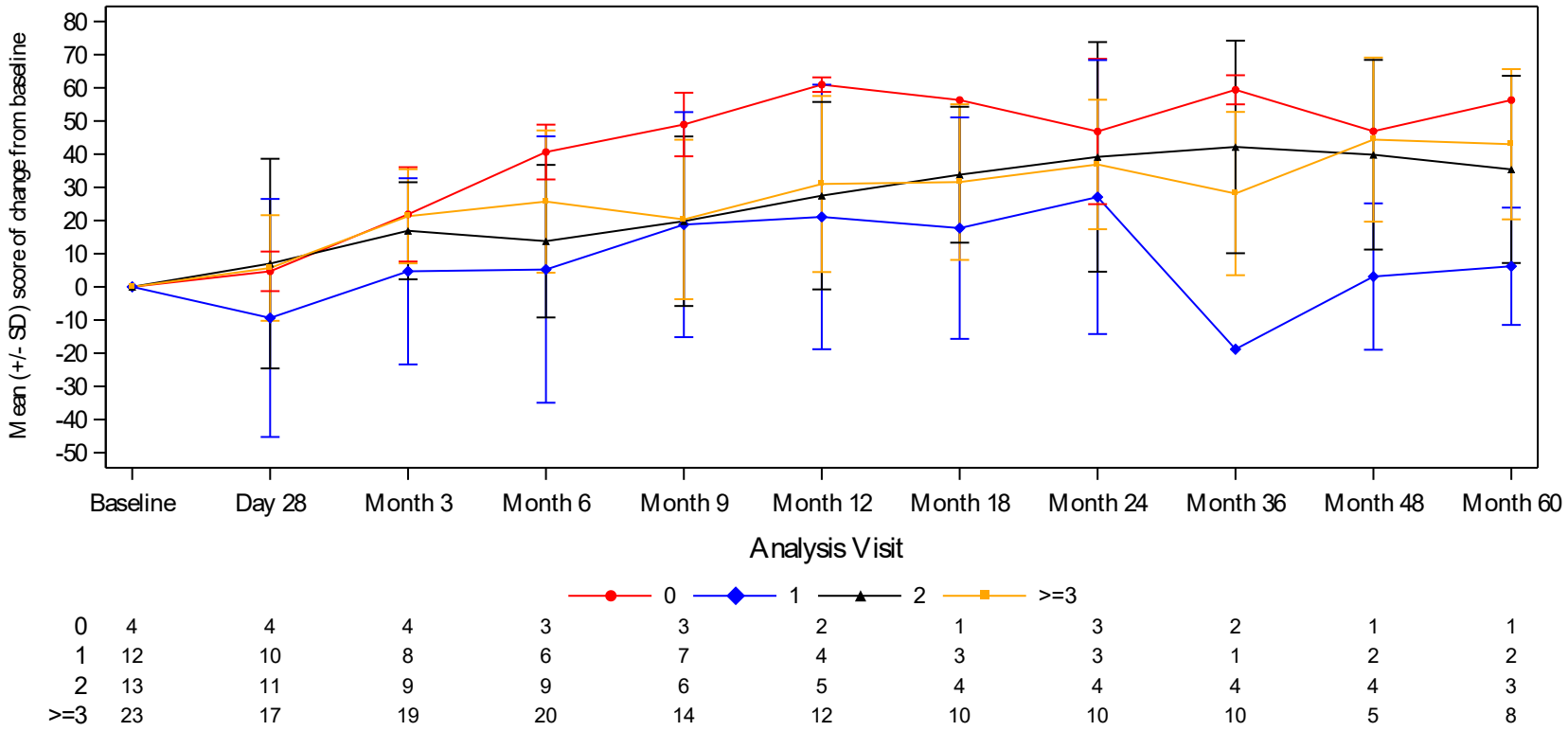


0	4	3	4	3	3	2	1	3	2	1	1
1	11	8	7	5	6	4	3	3	1	2	2
2	12	9	8	8	6	5	4	4	4	4	3
>=3	18	10	12	14	9	9	7	8	8	4	7

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53r (Page 4 of 5)
Mean change in each PedsQL subscales score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Physical Subscale

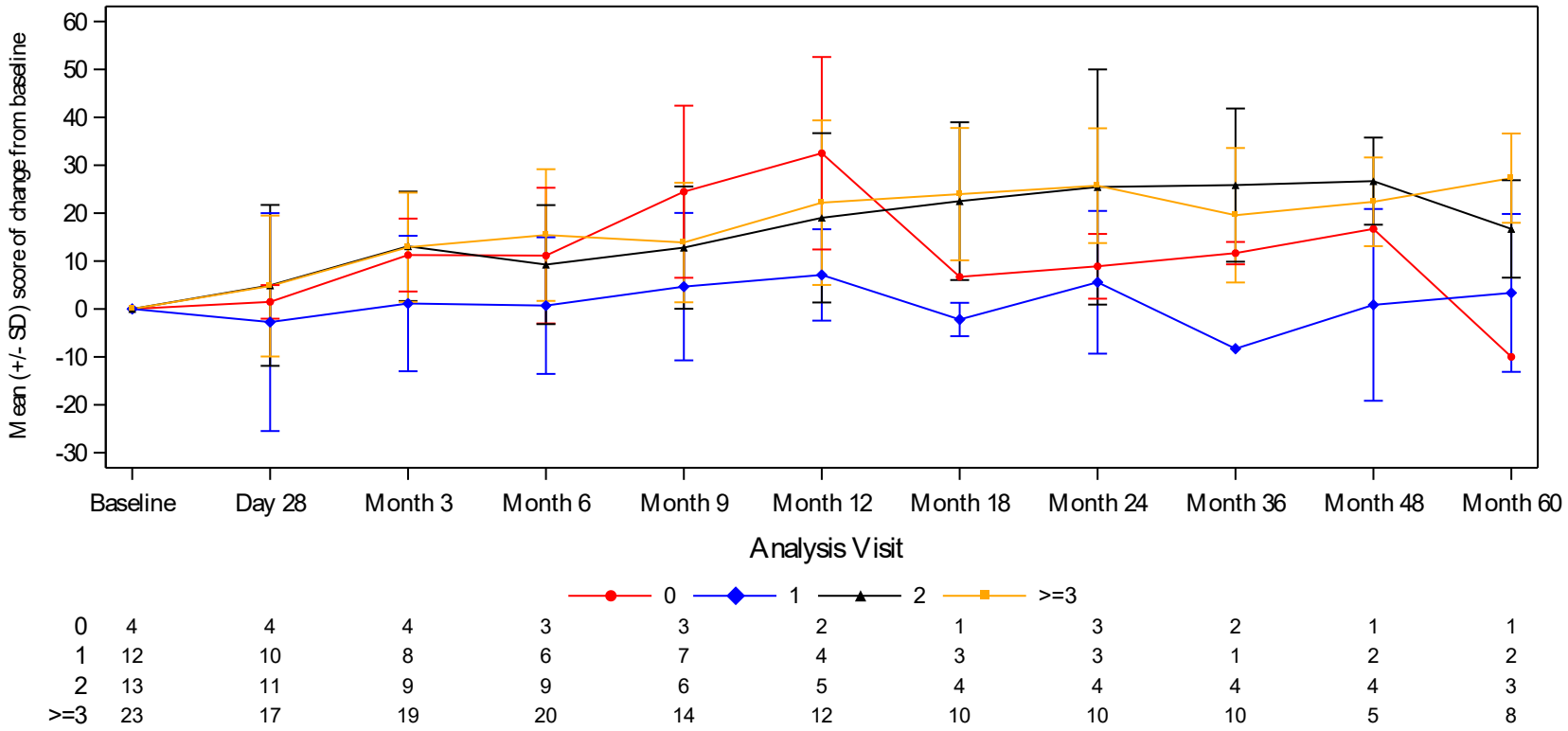


0	4	4	4	3	3	2	1	3	2	1	1
1	12	10	8	6	7	4	3	3	1	2	2
2	13	11	9	9	6	5	4	4	4	4	3
>=3	23	17	19	20	14	12	10	10	10	5	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.

Figure 53r (Page 5 of 5)
Mean change in each PedsQL subscales score over time by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Parameter PedsQL Subscale: Psychosocial Health Summary Score



0	4	4	4	3	3	2	1	3	2	1	1
1	12	10	8	6	7	4	3	3	1	2	2
2	13	11	9	9	6	5	4	4	4	4	3
>=3	23	17	19	20	14	12	10	10	10	5	8

Counts correspond to patients having filled both baseline and corresponding post-baseline analysis visit questionnaires.