26 June 2023

EMA/250553/2023

*Parallel EMA/HTA body (HTAb) Scientific Advice during the Interim Period*

*Short study information*

Date of the information provided: YYYY-MM-DD

Please specify/delete as necessary.

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| **(Planned) phase-II/III-study NAME – Short Study Information** |
| Short description | Open/(double)blind, randomized, placebo/active control, Intervention, study population |
| Study objective | Comparison of effectiveness and safety of intervention vs. comparator in description of study population, quality of previous specific therapy |
| Centers | Number of Centers, nations/continents |
| Size of study | estimated number of randomized patients |
| Inclusion criteria | ---- |
| Exclusion criteria | ---- |
| Design | Parallel-group/cross over/factorial design |
| Randomization | N:M |
| Stratification | Disease severity, prior therapy, ethnicity, geographic region |
| Blinding | Blinding for Intervention, outcome assessment |
| Intervention | Substance INN, Dose, application, duration |
| Additional intervention | Substance INN, Dose, application, duration |
| Comparator | Substance INN, Dose, application, duration |
| Additional Comparator | Substance INN, Dose, application, duration |
| Start/End Date | (Planned) start and end date of patient inclusion and of study treatment. (Planned) date of analysis of primary outcome |
| Study periods | Duration of pre-randomization, study, post-treatment periods |
| Interim analyses | Methods and Procedures used |
| primary hypothesis to be tested  | superiority/non-inf/equivalence; which arms will be compared |
| Outcome measures |
| Primary | Primary outcome measure (and timing of assessments) |
| Secondary | Secondary outcome measure (and timing of assessments) |
| Quality of life | All QoL measures not yet listed (and timing of assessments) |
| Supplementary | Additional outcome measure (and timing of assessments) |