Please specify/delete as necessary.

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| **(Planed) phase-II/III-study – 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 No. of randomized patients |
| Inclusion criteria |  |
| Exclusion criteria |  |
| Randomization | N:M |
| Stratification | Disease severity, prior therapy, ethnicity, geographic region |
| Blinding | Blinding for Intervention, outcome assessment |
| 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 |
| Design | Parallel-group/cross over/factorial design |
| Outcome measures |  |
|  Primary | Primary outcome measure |
|  Secondary | Secondary outcome measure |
|  supplementary | Additional outcomes measures  |

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