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 | |