**Investigator Initiated Study – IIS**

**Abbreviated Study Outline**

**Substance (INN) / Product:**

**Indication:**

|  |  |
| --- | --- |
| Principal Sponsor-Investigator |  |
| Address |  |
| Phone/Fax |  |
| E-mail |  |
| Planned number of study sites Only for multi-center studies |  |
| **Study Title** |  |
| Keywords Up to seven study specific keywords  should be listed |  |
| **Study Type**   * interventional study or * non-interventional study or * pre-clinical study |  |
| **Medical Study Rationale** Description of evidence and medical need Definition of study hypothesis |  |
| **Study Design**   * single-center // multi-center * prospective // retrospective * controlled // non-controlled * open // single-blind or double-blind * randomized // non-randomized * *n* arm parallel // *n* arm cross-over * interventional // observational * confirmatory // exploratory pilot * *other* |  |
| **Primary Objective**  Major goal of the study |  |
| **Secondary Objectives** Most important to be listed |  |
| **Evaluation Criteria**   * Primary analysis variable/endpoint * Most important secondary analysis variables/endpoints * Safety variables * Quality of life (*if applicable*) * Health economics (*if applicable*) |  |
| Treatments and Visits  * Treatment plan and therapeutic goals * Schedule of visits displayed in a graph * Dosage and dosing regimen for all study periods * Formulation and strength(s) for study products * Route of administration for study products * Blinding techniques (*if applicable*) | *Please describe the study design and display a graph including study treatment arms and visit schedule* |
| **Study Population**  Brief description of major inclusion criteria and major exclusion criteria | **Inclusion criteria**   * nn   **Exclusion criteria**   * nn |
| **Sample Size** | Plan is to recruit up to n = xxx subjects  *For hypothesis generating exploratory clinical studies  the sample size calculation and justification should refer  to the primary objective/primary endpoint solely* |
| Safety Reporting Classification requested | ❑ Solicited reporting  *Safety data reporting should be performed in   accordance with BI pharmacovigilance requests*  ❑ Spontaneous stimulated reporting |
| Required Support | ❑ Financial Support  ❑ Study medicinal product originated by BI:  - Compound 1 (in total n = x pills)  - Compound 2 (in total n = y pills)  ❑ Other (*please specify*): ............................ |
| **Additional information**  on the study concept to support IIS application | *Please add additional information if applicable* |