|  |  |
| --- | --- |
| **Eligibility criteria for a fast-track process [1]** | |
| **Molecule or association of molecules**  **already evaluated in France** | Yes  No |
| **and in the same indication [2] as for the previous trial** | Yes  No |

**[1] non-eligibility criteria (for information) especially:** **:** First CT in France**,** complex design, ATMP

[2] same disease, target population, treatment (symptomatic, curative, preventive, diagnostic); Furthermore pharmaceutical and non clinical data must have already been assessed (no new data submitted in this CT application)

|  |  |
| --- | --- |
| **Clinical trial identification** | |
| **Title** |  |
| **Sponsor** |  |
| **EudraCT number** |  |
| **CPP concerned (if identified)** |  |
| **Protocol** | **Date/version :** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study documentation** | | | | | |
| **Name IMP [2]**  **dosage, pharmaceutical form** | Chemical | Biological | **Document** | **Submitted**  **Version & date** | **Last authorized by ANSM**  **Version & Date**  ***(If applicable)*** |
| IMP1 |  |  | IMPD (Quality) |  |  |
| IB |  |  |
| IMP2 |  |  | IMPD (Quality) |  |  |
| IB |  |  |
| IMP3 |  |  | IMPD (Quality) |  |  |
| IB |  |  |
| IMP4 |  |  | SmPC |  |  |

**[2] tested, comparator and placebo**

*(Duplicate as necessary)*

| **Clinical trial information** | |
| --- | --- |
| **Active Substance** | **Code & [INN] :** |
| **Study treatments** Description of planned therapeutic schemes | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **IMP** | **Starting Dose** | **Maximum Daily dose** | **Route of administration** | **Schedule** | **Maximal treatment duration** | | Therapeutic scheme 1 : | | | | | | | IMP1 |  |  |  |  |  | | IMP2 |  |  |  |  |  | |  |  |  |  |  |  | | Therapeutic scheme 2 : | | | | | | | IMP3 |  |  |  |  |  | | IMP4 |  |  |  |  |  | |  |  |  |  |  |  |   *(Duplicate as necessary)* |
| **Study population & Contraception** | **Study Population :** male  female  **Age range :**  **Description of contraceptive measures** and justification in case of non-compliance with current recommendations issued by the CTFG :   |  |  |  |  | | --- | --- | --- | --- | | **IMP** | **T ½**  ***(half-life of elimination)*** | **Profile**  ***(genotoxic, teratogen)*** | **Type and duration of contraception *(women and men)*** | |  |  |  |  | |  |  |  |  |   *(Duplicate as necessary)*  Justification in case of non-compliance with current recommendations issued by the CTFG: |
| **Study plan** |  |
| **Scientific advice** | **Has a scientific advice been given for the IMP or trial? :** Yes  No  (by the EMA or another competent authority of the EU or a third country)  **Are there discrepancies between the submitted protocol and the recommendations provided in the scientific advice?:** Yes  No  If yes, please justify : |
| **Pediatric investigation plan** | **Is the trial part of a paediatric investigation plan (PIP) submitted to the EMA?**  Yes  No  **Are there discrepancies between the submitted protocol and the PIP?**  Yes  No  If yes, please justify : |
| **ICH S9** | Yes  No  If Yes, please indicate if the trial covers several indications/pathologies and if all are S9 : |

|  |
| --- |
| **CLINICAL SECTION** |

|  |
| --- |
| 1. **Justification of the study population and line of treatment** |

[Possible references: SmPC, national and international recommendations, relevant bibliographical articles…]

**Justification of the study population in relation to the presumption of clinical efficacy of the IMP**

**Description of the therapeutic alternatives available in France in the proposed indication**

**Justification of the proposed line of treatment in regard to the existing therapeutic alternatives**

**Justification of the choice of the control arm (if applicable)**

|  |
| --- |
| 1. **Study treatments** |

**Justification of planned therapeutic schemes and doses**

**Identification of each expected adverse effect and planned risk minimization measures**

(for each treatment arm, including the comparator arm)

|  |  |  |
| --- | --- | --- |
|  | **Expected adverse effect** | **Planned risk minimization measures** |
| Therapeutic scheme 1 : | | |
| A |  |  |
| B |  |  |
| Therapeutic scheme 2 : | | |
| C |  |  |
| D |  |  |
|  |  |  |

**Identification of potential toxicities and planned risk minimization measures**

(for each treatment arm, including the comparator arm)

|  |  |  |
| --- | --- | --- |
|  | Potential toxicities | Planned risk minimization measures |
| Therapeutic scheme 1 : | | |
|  |  |  |
|  |  |  |
|  |  |  |
| Therapeutic scheme 2 : | | |
|  |  |  |
|  |  |  |
|  |  |  |

**The eligibility and non-eligibility criteria planned in the protocol are in accordance with the recommendations detailed in the documents provided in support of the clinical trial request for authorization (IB / SmPC):**  Yes  No

Any discrepancy is to be justified below:

**The safety monitoring scheduled in the protocol (including type and frequency of examination) is in accordance with the recommendations detailed in the documents provided in support of the clinical trial request for authorization (IB / SmPC):**

Yes  No

Any discrepancy (in terms of type and/or frequency of examination) is to be justified below:

**Sampling volume**

Indicate the volume of sampling at each visit:

|  |
| --- |
| 1. **Associated medications** |

**Description of planned auxiliary medicinal products**

|  |  |
| --- | --- |
| **Auxiliary medicinal product** | **Indication** |
| Treatment X |  |
| Treatment Y |  |
|  |  |
|  |  |

**Concomitant therapies**

The planned concomitant therapies (permitted and prohibited) are in accordance with the recommendations detailed in the documents provided in support of the clinical trial request for authorization (IB / SmPC):  Yes  No

Any discrepancy is to be justified below:

|  |
| --- |
| 1. **Conditions of use** |

The patient management planned in the protocol in case of toxicity (toxicities management, guidelines for dose modifications, including reductions, delays, interruptions, and discontinuation) is in accordance with the recommendations detailed in the documents provided in support of the clinical trial request for authorization (IB / SmPC):  Yes  No

Any discrepancy is to be justified below:

|  |  |  |
| --- | --- | --- |
| I hereby certify that the information provided in this document is accurate and consistent with the constituent elements of the CT application and attached to this document | | |
| **Do it :** | **Name and surname of the signatory** |  |
| **Signature** | |

**\* \***

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