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| **Applicant request to the "General Administration of Clinical Trials" For Clinical Trial Authorization on a medicinal product for Human use** |

**These Information (to be fulfill by the Egyptain Drug Authority).**

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| **Date of receiving the request:**  **Date of request for information:** | **Date of request for additional**  **information:** | **Grounds for non-acceptance/**  **negative opinion:**  **Give date** |
| **Date of start of procedure:** | **Date of receipt of additional / amended information:** | **Authorisation/ positive opinion: Give date:** |
| **Withdrawal of application**  **Give date:** |
| **Checkech By:**  **Signature**  **Date:** | | |

**These Information *(*to be fulfilled by the applicant)**

**A. Trial identification**

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| A.1 Full title of the trial:  A.2 Sponsor’s protocol code number, version, and date:  A.3 Other countries in which the submission is being made:  A.4 Is this a resubmission? Yes No  If yes, indicate the resubmission letter1 |
| 1 For a resubmission following previous withdrawal of an application or unfavorable opinion of an ethics committee, or previous withdrawal of an application or refusal of a request by the competent authority. |

**B- Identification of the sponsor responsible for the request**

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| **B.1 Sponsor** |
| B.1.1 Name of organization:  B.1.2 Full Name of the contact person:  B.1.3 Address:  B.1.4 Telephone number:  B.1.5 Fax number:  B.1.6 E-mail: |
| **B.2 Legal representative of the sponsor in the community for the purpose of this trial**  **(If different from the sponsor) e.g. Contract Research Organization (CRO) / Principle Investigator(PI)** |
| B.2.1 Name of organization:  B.2.2 Full Name of the person to contact:  B.2.3 Address:  B.2.4 Telephone number:  B.2.5 Fax number:  B.2.6 E-mail: |

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| **B.3 Status of the sponsor:** |
| B.3.1 Commercial  B.3.2 Non commercial |
| **B.4 Source(s) of Monetary or Material Support for the clinical trial:** |
| B.4.1 Name of organization:  B.4.2 Country: |

**C. Information on each IMP**

Information should be provided in this section for each investigational medicinal product (IMP) being tested including each comparator and each placebo

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| **C.1 IMP identification**  Indicate the numbers of IMPs to be used in the trial (assign numbers from 1-n): |
| C.1.1 IMP being tested , Name /Number    C.1.2 IMP used as a comparator , Name /Number |

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| **C.2 Status of the IMP** |
| C.2.1 Is the IMP to be used in the trial has a marketing authorization in Egypt?: yes no  , If yes specify for the product to be used in the trial:  C.2.1.1 Trade name:  C.2.1.2 Name of the Marketing Authorisation holder:  C.2.1.3 Is the IMP modified in relation to its Marketing Authorisation? Yes no  , If yes, please specify: |
| C.2.2 IMPD( **Investigational Medicinal Product Dossier**) submitted:  C.2.2.1 Full IMPD yes no  C.2.2.2 Simplified IMPD yes no  C.2.2.3 Summary of product characteristics (SmPC) only yes no |
| C.2.3 Has the use of the IMP been previously authorized in a clinical trial conducted by the sponsor in other countries? yes no  C.2.3.1 If yes specify which countries: |
| C.2.4 Has the IMP been subjected of any scientific advice related to this clinical trial? Yes no  , if yes please indicate the source of advice and provide a copy in the CTA request: |
| **C.3 Description of the IMP** |
| C.3.1 Product name where applicable2:  C.3.2 Product code where applicable3:  C.3.3 Pharmaceutical form:  C.3.3.1 Is this a specific pediatric formulation? Yes no  C.3.4 Maximum duration of treatment of a subject according to the protocol:  C.3.5 Dose allowed:  C.3.5.1 First dose for first-in-human clinical trial (specify; per day or total dose; units and route of administration):  C.3.5.2 Maximum dose allowed (specify; per day or total dose; units and route of administration):  C.3.6 Route of administration :  C.3.7 Name of each active substance:  C.3.8 Other available name for each active substance ( provide all available):  C.3.8.1 Current sponsor code  C.3.8.2 Chemical/biological description of the Active Substance  C.3.9 Strength (specify all strengths to be used):  C.3.9.1 Concentration unit: |

2To be provided only when there is no trade name. This is the name routinely used by a sponsor to identify the IMP in the CT documentation (protocol, IB…).

3 To be provided only when there is no trade name. This is a code designated by the sponsor which represents the name routinely used by the sponsor to identify the product in the CT documentation. For example, a code may be used for combinations of drugs or drugs and devices.

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| **C.4 Type of IMP**   |  |  |  | | --- | --- | --- | | **Does the IMP contain an active substance:**  C.4.1 Of chemical origin? | **Yes** | **No** | |  |  | | C.4.2 Of biological / biotechnological origin (other than Advanced Therapy IMP (ATIMP)? |  |  | | **Is this a:**   * Advanced Therapy IMP (ATIMP)? |  |  | | Somatic cell therapy medicinal product? |  |  | | Gene therapy medicinal product? |  |  | | Tissue Engineered Product? |  |  | | * Radiopharmaceutical medicinal product? |  |  | | * Immunological medicinal product (such as vaccine, allergen, immune serum)? |  |  | | * Plasma derived medicinal product? |  |  | | * Extractive medicinal product? |  |  | | * Recombinant medicinal product? |  |  | | * Another type of medicinal product?   ,If yes, specify: |  |  | | **C.5 Mode of action 4** | | | | **C.6 Is it an IMP to be used in a first-in-human clinical trial** yes no  If yes, are there risk factors identified according to the guidance FIH?5 yes no | | | |
| 4 The mode of action should briefly describe the chemical, biochemical, immunological or biological means the IMP uses to effect its pharmaceutical action.  5 Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products. EMEA/CHMP/SWP/28367/2007 19 July 2007 |

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| **C.7 Information on Placebo** |
| C.7.1 Is there a placebo: yes no  C.7.2 Pharmaceutical form:  C.7.3 Route of administration:  C.7.4 Composition: |

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| **C.8 Site(s) where the qualified person certifies batch release (**this section is dedicated to the finished IMPs, i.e. medicinal products randomized, packaged, labeled and certified for use in the clinical trial.) |
| C.8.1 Who is responsible for the certification of the finished IMP?  (This site is responsible for certification of each IMP including placebo.)  please tick the appropriate box:  C.8.1.1 Manufacturer  C.8.1.2 Importer   * Name of the organization: * Address: * Give the manufacturing authorisation number: |

**D General Information on the trial**

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| **D.1 Medical condition or disease under investigation** |
| D.1.1 Specify the medical condition(s) to be investigated:  D.1.2 Therapeutic area  D.1.3 Is any of the conditions being studied a rare disease? yes no |

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| **D.2 Objective of the trial** |
| D.2.1 Main objective:  D.2.2 Secondary objectives:  D.2.3 Is there a sub-study? yes no  , If yes give the full title, date and version of each sub-study and their related objectives: |

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| **D.3 Principal Inclusion Criteria (list the most important )** |
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| **D.4 Principal Exclusion Criteria (list the most important)** |
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| **D.5 End point(s):** |
| D.5.1 Primary End Point 6  D.5.1.1 Time point(s) of evaluation of this endpoint  D.5.2 Secondary End Point  D.5.2.1 Time point(s) of evaluation of this endpoint |

6 The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points

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| **D.6 Scope of the trial – (**Tick all boxes where applicable**)** |
| |  |  |  | | --- | --- | --- | |  | **Yes** | **No** | | D.6.1 Diagnosis |  |  | | D.6.2 Prophylaxis |  |  | | D.6.3 Therapy |  |  | | D.6.4 Safety |  |  | | D.6.5 Efficacy |  |  | | D.6.6 Pharmacokinetic |  |  | | D.6.7 Pharmacodynamic |  |  | | D.6.8 Bioequivalence |  |  | | D.6.9 Dose Response |  |  |   **D.6.10 Others**  , If others, specify: |

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| **D.7 Trial type7** |
| D.7.1 Human pharmacology (Phase I) yes no  Is it:  D.7.1.1 First administration to humans yes no  D.7.1.2 Bioequivalence study yes no  D.7.1.3 Other: yes no  If other, please specify  D.7.2 Therapeutic exploratory (Phase II) yes no  D.7.3 Therapeutic confirmatory (Phase III) yes no  D.7.4 Therapeutic use (Phase IV) yes no |

7 The descriptions of the trial types provided are those recommended in preference to Phases. See page 5 of Community guideline CPMP/ICH/291/95. The development of a new indication after initial approval of a medicine should be considered as a new development plan.

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| **D.8 Design of the trial** |
| D.8.1 Controlled yes no  If yes, specify:  D.8.1.1 Randomized yes no  D.8.1.2 Open: yes no  D.8.1.3 Single blind: yes no  D.8.1.4 Double blind: yes no  D.8.1.5 Parallel group: yes no  D.8.1.6 Cross over: yes no  D.8.1.7 Other: yes no  ,If yes to other specify:  D.8.2 If controlled, specify the comparator:  D.8.2.1 Other medicinal product(s) yes no  D.8.2.2 Placebo yes no  D.8.2.3 Other yes no  , If yes to other, specify:  D.8.3 Number of treatment arms in the trial:  D.8.4 Single site in Egypt concerned yes no  D.8.5 Multiple sites in Egypt concerned yes no  D.8.5.1 Number of sites anticipated in Egypt concerned ( )  D.8.6 Trial involving sites outside Egypt:  D.8.6.1 Trial being conducted both within and outside EGYPT: yes no  If yes, specify the regions in which trial sites are planned outside EGYPT:  If yes, specify the number of sites anticipated outside EGYPT: ( )  D.8.7 Trial having an independent data monitoring committee: yes no  D.8.8 Initial estimate of the duration of the trial8 (years ,months and days):  D.8.8.1In Egypt concerned years, months ,days  D.8.8.2 In all countries concerned by the trial years, months, days  E.8.9 Proposed date of start of recruitment  D.8.9.1 In EGYPT concerned  D.8.9.2 In any country  D.8.10 Proposed Completion date of the study |
| 8 From the first inclusion until the last visit of the last subject. |

**E Population of trial subjects**

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| **E.1** **Age range** |
| E.1.1 Less than 18 years yes no  ,If yes specify the estimated number of subjects planned in each age range for the whole trial:  Approx. no. of patients  E.1.1.1 Preterm Newborn Infants (up to gestational age < 37 weeks) ( ) yes no  E.1.1.2 Newborns (0-27 days) ( ) yes no  E.1.1.3 Infants and toddlers (28 days - 23 months) ( ) yes no  E.1.1.4 Children (2-11 years) ( ) yes no  E.1.1.5 Adolescents (12-17 years) ( ) yes no  E.1.1.6 Adults (18-64 years) ( ) yes no  E.1.1.7 Elderly (>= 65 years) ( ) yes no |

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| **E.2 Gender** |
| E.2.1 Female  E.2.2 Male |

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| **E.3 Group of trial subjects** |
| E.3.1 Healthy volunteers yes no  E.3.2 Patients yes no  E.3.3 Specific vulnerable populations yes no  E.3.3.1 Women of child bearing potential not using contraception yes no  E.3.3.2 Women of child bearing potential using contraception yes no  E.3.3.3 Pregnant women yes no  E.3.3.4 Nursing women yes no  E.3.3.5 Emergency situation yes no  E.3.3.6 Subjects incapable of giving consent personally yes no  If yes, specify:  E.3.3.7 Others: yes no  If yes, specify |

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| **E.4 Planned number of subjects to be included:** |
| E.4.1 In Egypt ( )  E.4.2 For a multinational trial:  E.4.2.1 In the Egypt ( )  E.4.2.2 In the whole clinical trial ( ) |

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| **E.5 Plans for treatment or care after a subject has ended his/her participation in the trial.** please specify |

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| **E.6 Please specify any incentives, compensation or treatment the participants will receive through participation in this study** |

**F. Clinical trial sites/investigators in Egypt concerned by this request**

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| **F.1 Principal investigator(s) for the trial (** enumerate each Principle Investigator for each study site **)** |
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| **F.2. Co-investigator(s) and study site staff(s)** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Name/title** | **Designation role in the study** | **Institution Name**  **/Department** | **E-mail** | **Contact number** | **Fax number** | |  |  |  |  |  |  | |  |  |  |  |  |  | |

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| **F.3 Central technical facilities to be used in the conduct of the trial Laboratory or other technical facility, in which the measurement or assessment of the main evaluation criteria are centralized (**repeat as needed for multiple organizations**).** |
| F.3.1 Name of Organization:  F.3.2 Department  F.3.3 Name of contact person ::  F.3.4 Address:  F.3.5 Telephone number:  F.3.6 Fax number:  F.3.7 E-mail:  F.3.8 Duties subcontracted: |

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| **F.4 Organizations to whom the sponsor has transferred trial related duties and functions (**repeat as needed for multiple organizations**)** |
| G.4.1 Has the sponsor transferred any major or all the sponsor’s trial related duties and functions to  another organization or third party? yes no  Repeat as necessary for multiple organizations:  F.4.1.1 Name of Organization:  F.4.1.2 Department  F.4.1.3 Name of contact person:  F.4.1.4 Address:  F.4.1.5 Telephone number:  F.4.1.6 Fax number:  F.4.1.7 E-mail:  F.4.1.8 All tasks of the sponsor yes no  F.4.1.9 Monitoring yes no  F.4.1.10 Regulatory (e.g. preparation of applications to EDA and ethics committee) yes no  F.4.1.11 Investigator recruitment yes no  F.4.1.12 IVRS9 – treatment randomization yes no  F.4.1.13 Data management yes no  F.4.1.14 -data capture yes no F.4.1.15 SUSAR ( Suspecting unexpected Serious Adverse Reaction ) reporting yes no  F.4.1.16 Quality assurance auditing yes no  F.4.1.17 Statistical analysis yes no  F.4.1.18 Medical writing yes no  F.4.1.19 Other duties subcontracted yes no  F.4.1.19.1 If yes to other please specify: |

9Interactive Voice Response System: commonly used for randomization of treatment and controlling the

shipment of stock of product.

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| **G.1 Information on of Institutional Review Board Ethics Committee** |
| G.1.1 Institution Name :  G.1.2 Address:  G.1.3 Approval Date  G.1.4 Validity  G.1.5 Date of submission: |

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| **H.2 Ethics opinion: Research Ethics Committee; Research & Health Development at Ministry of Health and Population (REC-RHD/MoHp)** |
| H.2.1 Date of /opinion:  H.2.2 Accepted / favorable opinion |
| **H.3 National security decision in case of traveling patients samples outside EGYPT** |
| H.3.1 Pending  H.3.2 Given  If ‘Given’, specify the Date of approval: |

**I Signature of the applicant:**

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| I.1 I hereby confirm that:   the information provided is complete;   the attached documents contain an accurate account of the information available;   the clinical trial will be conducted in accordance with the protocol; and   the clinical trial will be conducted, and SUSARs and result-related information will be reported, in accordance with the applicable legislation. |
| **Date:**  **Signature:**  **Print name**: |