Applicant request to the Egyptian Drug Authority For Clinical Trial Authorization on a medicinal product for Human use

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

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:**	**Authorization/ positive opinion:** **Give date:**
		Withdrawal of application **Give date:**
Checkech By: **Signature** **Date:**		

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

1. Trial identification

1.1 Full title of the trial:

1.2 Sponsor's protocol code number, version, date and Eudra-CT:

1.3 Other countries in which the submission is being made:

1.4 Is this a resubmission? Yes ☐ No ☐
If yes, indicate the resubmission letter :

[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.

2- Sponsor Identification:

2.0 Sponsor

2.0.1 Name of organization:
2.0.2 Full Name of the contact person:
2.0.3 Address:
2.0.4 Telephone number:
2.0.5 Fax number:
2.0.6 E-mail:

2.1 Legal representative of the sponsor

2.1.1 Name of organization:	
2.1.2 Full Name of the person to contact:	
2.1.3 Address:	
2.1.4 Telephone number:	
2.1.5 Fax number:	
2.1.6 E-mail:	
2.1.7 All tasks of the sponsor	yes ☐ no ☐
2.1.7.1 Monitoring	yes ☐ no ☐
2.1.7.2 Regulatory (e.g. preparation of applications to EDA and ethics committee)	yes ☐ no ☐
2.1.7.3 Investigator recruitment	yes ☐ no ☐
2.1.7.4 IVRS9 – treatment randomization	yes ☐ no ☐
2.1.7.5 Data management	yes ☐ no ☐
2.1.7.6 -data capture	yes ☐ no ☐
2.1.7.7 SUSAR (Suspecting unexpected Serious Adverse Reaction) reporting	yes ☐ no ☐
2.1.7.8 Quality assurance auditing	yes ☐ no ☐
2.1.7.9 Statistical analysis	yes ☐ no ☐
2.1.7.10 Medical writing	yes ☐ no ☐
2.1.7.11 Other duties subcontracted	yes ☐ no ☐
2.1.7.11.1 If yes to other please specify:	

2.2 Status of the sponsor:

Commercial	☐
Non commercial	☐

3.0 IMP identification

3.0.1 Name /Number of IMP to be tested.

3.0.2 Name /Number of IMP used as a comparator.

3.1 Status of the IMP

3.1.1 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:
Trade name:
Name of the Marketing Authorization holder:

3.1.2 IMPD (**Investigational Medicinal Product Dossier**) submitted: yes ☐ no ☐

3.1.3 Was this IMP previously authorized in the market of any other countries?
Yes☐ no ☐
Specify which countries?

3.1.4 Has the IMP been subjected of any scientific advice related to this clinical trial? Yes ☐ no ☐

3.2 IMP Description

3.2.1 Product name:

3.2.2 Product code:

3.2.3 Pharmaceutical form:

Is this a specific pediatric formulation? Yes ☐ no ☐

3.2.4 Maximum duration of treatment of a subject according to the protocol:

3.2.5 Dose allowed:

First dose for first-in-human clinical trial:

Maximum dose allowed:

3.2.6 Route of administration:

3.2.7 active substance(s): Name, Other available name for each active substance, Chemical/biological description of the Active Substance

3.2.8 Strength (s):

[2]To 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.

3.3 Type of IMP

	Yes	No
3.3.1 Does the IMP contain an active substance of chemical origin?		
3.3.2 Does the IMP contain an active substance of biological / biotechnological origin (other than Advanced Therapy IMP (ATIMP)?		
3.3.3 Is this an Advanced Therapy IMP (ATIMP)?		
3.3.4 Is this a Somatic cell therapy medicinal product?		
3.3.5 Is this a Gene therapy medicinal product?		
3.3.6 Is this a Tissue Engineered Product?		
3.3.7 Is this a Radiopharmaceutical medicinal product?		
3.3.8 Is this an Immunological medicinal product (such as vaccine, allergen, immune serum)?		
3.3.9 Is this a Plasma derived medicinal product?		
3.3.10 Is this an Extractive medicinal product?		
3.3.11 Is this a Recombinant medicinal product?		
3.3.12 Is this a Herbal medicinal product?		
3.3.13 Is this Another type of medicinal product? , If yes, specify:		

3.4 Mode of action[4]

[4]The mode of action should briefly describe the chemical, biochemical, immunological or biological means the IMP uses to effect its pharmaceutical action.

3.5 Placebo Information

3.5.1 Is there a placebo: yes ☐ no ☐
3.5.2 Pharmaceutical form:
3.53 Route of administration:
3.5.4 Composition:
3.5.5 Rationale for the use of placebo:
3.6 Who is responsible for the certification of the finished IMP?
Manufacturer ☐
Importer ☐
3.6.1 Name of the organization:
3.6.2 Address
3.6.3 Give the manufacturing authorization number:

4. General Information on the trial

4.0.1 Medical condition or disease under investigation

4.0.2 Therapeutic area

4.0.3 Is any of the conditions being studied a rare disease? yes ☐ no ☐

4.1 Objective of the trial

4.1.1 Main objective:

4.1.2 Secondary objectives:

4.1.3 Is there a sub-study? yes ☐ no ☐

, If yes give the full title, date and version of each sub-study and their related objectives:

4.2 Scope of the trial – (Tick all boxes where applicable)

	Yes	No
Diagnosis		
Prophylaxis		

Therapy		
Safety		
Efficacy		
Pharmacokinetic		
Pharmacodynamic		
Bioequivalence		
Dose Response		

Others

, If others, specify:

4.3 Trial type[7]

4.3.1 First administration to human (Phase I)	☐
4.3.2 Therapeutic exploratory (Phase II)	☐
4.3.3 Therapeutic confirmatory (Phase III)	☐
4.3.4 Therapeutic use (Phase IV)	☐

4.4 Design of the trial

Controlled	☐
Randomized	☐
Open:	☐
Single blind:	☐
Double blind:	☐
Parallel group:	☐
Cross over:	☐
Other:	☐

,If yes to other specify:

4.4.1 If controlled, specify the comparator:

Other medicinal product(s)	☐
Placebo	☐

Other	☐
, If yes to other, specify:	
4.4.2 Number of treatment arms in the trial:	
4.4.3 Number of sites anticipated in Egypt	
4.4.4 Trial involving sites outside Egypt:	☐
If yes, specify the number of sites anticipated outside EGYPT:	
4.4.5 Trial having an independent data monitoring committee:	☐
4.4.6 Initial estimate of the duration of the trial[5] (years, months and days):	
In Egypt concerned years, months, days	
In all countries concerned by the trial years, months, days	
4.4.7 Proposed date of start of recruitment	
In EGYPT concerned	
In all countries concerned	
4.4.8 Proposed Completion date of the study	

[5] From the first inclusion until the last visit of the last subject.

5 Population of trial subjects

5.0.1 Age range

Preterm Newborn Infants (up to gestational age < 37 weeks)	☐
Newborns (0-27 days)	☐
Infants and toddlers (28 days - 23 months)	☐
Children (2-11 years)	☐
Adolescents (12-17 years)	☐
Adults (18-64 years)	☐
Elderly (>= 65 years)	☐
Specify" how many" for each group selected	

5.0.2 Gender

Female	☐
Male	☐

Specify" how many" for each group selected

5.0.3 Group of trial subjects	
Healthy volunteers	☐
Patients	☐
Specific vulnerable populations	
1 Women of child bearing potential not using contraception	☐
2 Women of child bearing potential using contraception	☐
3 Pregnant women	☐
4 Nursing women	☐
5 Emergency situation	☐
6 Subjects incapable of giving consent personally	☐
If yes, specify:	
7 Others:	☐
If yes, specify	

5.0.4 Planned number of subjects to be included:
In Egypt ( )
-In the other countries in case of multinational clinical trial ( )

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

5.0.6 Please specify any incentives, compensation or treatment the participants will receive through participation in this study

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

6.0.1 Principal investigator(s)for the trial (enumerate each Principle Investigator for each study site **)**

Name	**Title**	**Institution Name /Department**	**E-mail**	**Contact number**

6.0.2. Co-investigator(s) and study site staff(s)

Name	Title	Institution Name /Department	E-mail	Contact number

6.1 Name of the all-designated laboratory (ies):

Local ☐

Central ☐

6.1.1 Name of Organization:

6.1.2 Department

6.1.3 Name of contact person:

6.1.4 Address:

6.1.5 Telephone number:

6.1.6 E-mail:

6.1.7 Duties subcontracted:

7.0 Information on of Institutional Review Board Ethics Committee

7.0.1 Institution Name:
7.0.2 Address:
7.0.3 Approval Date
7.0.4 Validity

7.1 National security decision in case of traveling patients samples outside EGYPT

Pending ☐
Given ☐
If 'Given', specify the Date of approval:

8.0 Signature of the applicant:

9.1 I hereby confirm that:

☐ 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:**