وزارة الصحة العامّة

Annex 4

معلومات عن ألدراسة سريريّة

دراسة رقم:

اسم الدراسة:

اسم المستشفى الجامعي:

رقم القرار:

للاستعمال من قبل وزارة الصحة	
رقم الدراسة في وزارة الصحّة	تاريخ تقديم الطلب:

معلومات عن مقدّم الطلب:

اسم المؤسسة المجازة:

اسم الصيدلي المسؤول:

العنوان:

رقم الهاتف:

البريد الإلكتروني:

معلومات عن صاحب البحث (Sponsor)

اسم المنظّمة / المؤسّسة:

اسم الصيدلي المسؤول:

العنوان:

رقم الهاتف:

البريد الإلكتروني:

CLINICAL TRIAL Summary **To be filled by Sponsor/CRO**

TESTED IMP
IMP with a market authorization? Yes □ No □
If yes, Date of MA: Therapeutic indication: IMP used in the trial according to its SPC? Yes □ No □
If non, specify:
IMP under development? Yes □ No □
If yes, Active substance name: Pharmacological class: Targeted indication:
IMP active substance origin: *specify (chemical, biological/ biotechnological, ..)*
Type of IMP: *specify (cell therapy, gene therapy, immunological, plasma derived,* *radiopharmaceutical, product containing genetically modified organism, ..)*

REFRENCE/COMPARATOR IMP
If any, name of IMP:
TRIAL INFORMATION
Trial scope: *specify (prophylaxis, therapy, safety, pharmacokinetic,* *dose-response, pharmacogenetic,..)*
Trial phase:
If phase I, is this a first administration to humans?
If the trial is not conducted on healthy volunteers, • Specify the medical condition being investigated: • Will patients under this medical condition be Yes □ No □ assigned to only a placebo treatment?
Has the trial been submitted to other countries authorities? Yes □ No □

If yes,

- Which country did authorize the trial?
- Which country did not authorize the trial?
- Reason for non-authorization:

Is the trial prepared to be submitted to other countries authorities?

Yes □ No □

If yes, specify which countries:

Does the trial have a data and/or safety monitoring

Yes □ No □

Committee independent from the sponsor?

Do pre-clinical toxicological, pharmacological and viral

Yes □ No □

studies (where applicable) show any result that may

Affect trial's subjects' safety?

If yes, specify:

POPULATION OF TRIAL SUBJECTS IN LEBANON

Subjects below 18 years?

Yes □ No □

If yes specify age:

Women of child baring potential with Yes □ No □ no efficient contraception imposed by the protocol?
Pregnant women? Yes □ No □
Other vulnerable population? Yes □ No □
If yes, specify:
TRIAL CENTRES AND INVESTIGATORS IN LEBANON
Number of trial's participating University Hospitals:
Has the IRB/EC of each of the participating Yes □ No □ Hospital given its approval for the trial? Date of approval: Duration of approval:
Give name of each Hospital and its participating Principal Investigator. In case of a multicentre trial in Lebanon, indicate the Coordinating Investigator: - -

Signature & Stamp