(نموذج رقم 1) (Form No. 1)

**ANNUAL PROGRESS REPORT TO SFDA**

(This report should be completed by an authorized personal)

**1. Sponsor Details**

|  |  |
| --- | --- |
| Name of sponsor/CRO: |  |
| Address: |  |
| City: |  |
| Contact person: |  |
| Contact number: |  |

**2. Study Details**

|  |  |
| --- | --- |
| Study title: |  |
| Protocol number: |  |
| Current study status: | □ Completed □ Terminated □ Ongoing □ Other (please specify): |
| SCTR number (if applicable) : |  |

#### **3. Start and Completion Dates**

|  |  |
| --- | --- |
| Did the study begin in Saudi Arabia? | **Yes / No** |
| If yes, what was the actual start date in Saudi Arabia? |  |
| If no, what are the reasons for not beginning the study in Saudi Arabia?  What is the expected start date? |  |
| Has the study concluded? | **Yes / No** |
| If no, what is the expected completion date? |  |
| If you do not expect the study to be completed, give reason(s) |  |

**4. Investigational Site Information**

4.1

|  |  |
| --- | --- |
| Total number of participants globally (if applicable): |  |
| Total number of participants in Saudi Arabia: |  |
| Number of sites proposed in original application: |  |
| Number of sites recruited to date: |  |
| Do you plan to increase the total number of sites proposed for the study? | **Yes / No** |

4.2

|  |  |
| --- | --- |
| Name of site: |  |
| Name of principal investigator: |  |
| Number of participants on this site: |  |
| Number of withdrawals, to date, from trial due to: |  |
| (a) withdrawal of consent: \_\_\_\_\_\_ |  |
| (b) loss to follow-up: \_\_\_\_\_\_ |  |
| (c) death (where not the primary outcome): \_\_\_\_\_\_ |  |
| Total study withdrawals: \_\_\_\_\_\_ |  |
| Number of treatment failures to date (prior to reaching primary outcome) due to: |  |
| (a) adverse events: \_\_\_\_\_\_ |  |
| (b) lack of efficacy: \_\_\_\_\_\_ |  |
| Total treatment failures: \_\_\_\_\_\_ |  |

\**(For 4.2, fill out each site of the study separately)*

4.3

|  |  |
| --- | --- |
| Have there been any serious difficulties in recruiting participants? | **Yes / No** |
| If yes, provide details: |  |
| Do you plan to increase the planned recruitment of study participants? | **Yes / No** |

5. Safety Reports

|  |  |
| --- | --- |
| Have there been any suspected unexpected serious adverse reactions (SUSARs) in this trial in Saudi Arabia? | **Yes / No** |
| Have these SUSARs been reported to the SFDA within 7 or 15 days in accordance with the SFDA’s Regulations and Requirements for Conducting Clinical Drug Trials?  If no, please arrange urgently and provide give reasons for late notification. | **Yes / No** |
| Has a DSUR been submitted? | **Yes / No / Not yet due** |
| When is the next DSUR due? |  |

**6. Amendments**

|  |  |
| --- | --- |
| Have any substantial amendments been made to the trial? | **Yes / No** |
| If yes, please give the date and amendment number for each substantial amendment made. |  |

**7. Serious Deviations in Protocol or Good Clinical Practice**

|  |  |
| --- | --- |
| Have any serious protocol or GCP deviations occurred in relation to this trial? | **Yes / No** |
| If yes, please give the date of each notification to the SFDA.  Please provide the IRB/EC with a copy of each notification of information (unless previously done). |  |

**8. Other Issues**

|  |  |
| --- | --- |
| Are there any other developments in the trial that you wish to report to the SFDA? | **Yes / No** |
| Are there any ethical issues regarding which further advice is required?  *If yes to either, please attach a separate statement with details.* | **Yes / No** |

**9. Declaration**

|  |  |
| --- | --- |
| Name and title of authorized person: |  |
| Signature: |  |
| Date of submission: |  |