| **Study Title:** | **Centre no.:** |
| --- | --- |
| **R&D no.:** |
| **EudraCT no.:** | **Participant number:** |
| **Sponsor:** | **Participant initials:** |
| **DO NOT SEND IDENTIFIABLE DATA OR SOURCE DOCUMENTS WITH THIS REPORT** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Initial Report**  |  |  | **Follow Up Report** |  |  |

|  |  |
| --- | --- |
| **REPORT TYPE:** | [ ]  Notification of pregnancy in female participant **(please complete all sections of the form)** |
| [ ]  Notification of pregnancy in partner of male participant **(please complete sections 6,9,10 and include any other relevant information in section 11)** |
| **1: MATERNAL INFORMATION** |
| DOB (dd/mm/yyyy) | Date of last menstrual period | Expected date of delivery |
| Method of contraception | Contraception used as instructed?[ ]  Yes [ ]  No [ ]  Uncertain |
| **2: MEDICAL HISTORY**  (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy. If none, mark as N/A) |
|  |
| **3: PREVIOUS OBSTETRIC HISTORY** (provide details on all previous pregnancies, including termination or stillbirth) |
|  | Gestation week | Outcome including any abnormalities |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| **4: DRUG INFORMATION** (including study, list all therapies taken prior to and during pregnancy) |
| Name of drug | Daily dose | Route | Date started | Date stopped | Indication | Treatmentstart(week of pregnancy) | Treatmentstop(week of pregnancy) |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |
| **5: PRENATAL INFORMATION** |
| Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far?[ ]  No [ ]  Yes [ ]  Not knownIf yes, please specify test date and results: |
| **6: PREGNANCY OUTCOME** |
| Abortion:[ ]  Therapeutic [ ]  Planned [ ]  SpontaneousPlease specify the reason and any abnormalities (if known):Date of abortion | Delivery:[ ]  Normal [ ]  Forceps/Ventouse [ ]  CaesareanMaternal complications or problems related to birth:Date of delivery |
| **7: MATERNAL PREGNANCY ASSOCIATED EVENTS** If the mother experiences an SAE during the pregnancy, please indicate here and complete a SAE form and email to trial office immediately – *<trial office email >* |
|  |
| **8: CHILD OUTCOME** |
| [ ]  Normal [ ]  Abnormal [ ]  Stillbirth | If any abnormalities, please specify and provide dates |
| Sex[ ]  Male[ ]  Female | Height cm | Weight  kg | Apgar scores1 min5 mins10 mins | Head circumference  cm |
| **9: ASSESSMENT OF SERIOUSNESS (OF PREGNANCY OUTCOME)** |
| [ ]  Non serious [ ]  Involved prolonged participant [ ]  Results in persistent or significant Hospitalisation disability/incapacity[ ]  Life-threatening [ ]  Mother died [ ]  Stillbirth/neonate died Please provide date Please provide date Other seriousness criteria [ ]  Congenital anomaly/birth defect [ ]  Other significant medical events |
| **10: ASSESSMENT OF CAUSALITY (OF PREGNANCY OUTCOME)** |
| Please indicate the relationship between pregnancy outcome  |
| [ ]  Unrelated | [ ]  Possibly\* | [ ]  Probably\* | [ ]  Definitely\* |
| If any of the \*fields have been checked, the outcome is considered to be **RELATED** to the study drug. |
| **11: ADDITIONAL INFORMATION** |
|  |
| **12: INFORMATION SOURCE** |
| Name, address and telephone number of PI at site or CI |  |
| Date of report  |  |
| PI at site or CI signature |  |
| **ALL REPORTS MUST BE SIGNED AND DATED BY THE PRINCIPAL INVESTIGATOR.****PLEASE E-MAIL ALL REPORTS TO THE TRIAL OFFICE <*Trial Office email*>** |
| **13: TRACKING (STU USE ONLY)** |
| Report received by |  |
| Report received on  |  |
| Action Taken |  |