| **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** | |

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | | Treatment  start  (week of pregnancy) | | | Treatment  stop  (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 known  If yes, please specify test date and results: | | | | | | | | | | | | | | | | |
| **6: PREGNANCY OUTCOME** | | | | | | | | | | | | | | | | |
| Abortion:  Therapeutic  Planned  Spontaneous  Please specify the reason and any abnormalities (if known):  Date of abortion | | | | | | | | | | Delivery:  Normal  Forceps/Ventouse  Caesarean  Maternal 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 scores  1 min  5 mins  10 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 | | | | | |  | | | | | | | | | | |