**Supplementary Tables**

**Table S1: Sensitivity analysis of primary endpoint: Imputation of missing primary endpoint**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | no/No (%) of patients with events) | | Estimate of relative risk (95% CI),P value | Estimate of risk difference (95% CI),P value |  | |
|  |  | Dolutegravir | Efavirenz | Dolutegravir vs Efavirenz | Dolutegravir vs Efavirenz |  | |
|  |  |  |  |  |  |  | |
|  |  |  |  |  |  |  | |
| Maternal HIV viral load <50 copies per mL at delivery(primary outcome) | Primary analysis\* | 89/120 (74·2) | 50/117 (42·7) | 1·64 (1·31,2·06), <0·0001 | 29·78 (18·18,41·37), <0·0001 | |  |
|  |  |  |  |  |  | |  |
|  | Scenario 1 | 89/125(71·20) | 50/125(40·00) | 1·70(1·34,2·15),<0·0001 | 29·85(18·44,41·27),<0·0001 | |  |
|  | Scenario 2 | 94/125(75·20) | 58/125(46·40) | 1·54(1·26,1·90),<0·0001 | 27·28(15·97,38·58),<0·0001 | |  |
|  | Scenario 3 | 89/125(71·20) | 58/125(46·40) | 1·47(1·19,1·81),0·0004 | 23·38(11·87,34·89),<0·0001 | |  |

Scenario 1: All subjects without outcome information did not achieve suppression

Scenario 2: All subjects without outcome information achieve suppression

Scenario 3: Subjects without outcome information did not achieve suppression for dolutegravir group but achieved suppression for efavirenz group

**Table S2**. Full listing of maternal serious adverse events (system organ class and preferred term) up to 6±2 weeks post-partum

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dolutegravir** | | **Efavirenz** | | **Total** | |
|  | **N = 137** | | **N = 131** | | **N = 268** | |
|  | **Mothers** | **Events** | **Mothers** | **Events** | **Mothers** | **Events** |
| **Blood and lymphatic system disorders** | **2** | **2** |  |  | **2** | **2** |
| Thrombocytopenia |  | 2 |  |  |  | 2 |
| **Gastrointestinal disorders** | **1** | **1** |  |  | **1** | **1** |
| Abdominal pain lower |  | 1 |  |  |  | 1 |
| **Infections and infestations** | **5** | **5** | **2** | **2** | **7** | **7** |
| Abdominal wall abscess & Post-partum sepsis |  | 1 |  |  |  | 1 |
| Escherichia pyelonephritis |  |  |  | 1 |  | 1 |
| Herpes zoster meningitis |  | 1 |  |  |  | 1 |
| Pneumonia pneumococcal |  | 1 |  |  |  | 1 |
| Post-partum sepsis |  | 1 |  |  |  | 1 |
| Sepsis |  |  |  | 1 |  | 1 |
| Wound sepsis |  | 1 |  |  |  | 1 |
| **Investigations or Pregnancy, puerperium and perinatal conditions1 excluding stillbirths** | **18** | **18** | **10** | **10** | **28** | **28** |
| Blood pressure increased & Foetal monitoring abnormal |  | 1 |  |  |  | 1 |
| Breech presentation & Foetal monitoring abnormal & Caesarean section |  | 1 |  |  |  | 1 |
| Cephalo-pelvic disproportion & Foetal distress syndrome |  | 1 |  |  |  | 1 |
| Foetal growth restriction |  | 1 |  |  |  | 1 |
| Foetal monitoring abnormal |  | 3 |  | 2 |  | 5 |
| Foetal monitoring abnormal & Caesarean section |  |  |  | 1 |  | 1 |
| Postpartum haemorrhage |  |  |  | 1 |  | 1 |
| Pre-eclampsia |  | 2 |  | 1 |  | 3 |
| Pre-eclampsia & Foetal monitoring abnormal |  | 1 |  |  |  | 1 |
| Pre-eclampsia & HELLP syndrome |  | 1 |  |  |  | 1 |
| Prolonged pregnancy |  | 2 |  | 2 |  | 4 |
| Prolonged pregnancy & Amniorrhoea |  | 1 |  |  |  | 1 |
| Prolonged pregnancy & Amniotic cavity infection |  | 1 |  |  |  | 1 |
| Prolonged pregnancy & Foetal biophysical profile score abnormal |  |  |  | 1 |  | 1 |
| Prolonged pregnancy & Foetal heart rate abnormal |  |  |  | 1 |  | 1 |
| Prolonged pregnancy & Foetal macrosomia |  | 1 |  |  |  | 1 |
| Prolonged pregnancy & Oligohydramnios |  | 1 |  |  |  | 1 |
| Prolonged rupture of membranes & Foetal distress syndrome |  | 1 |  |  |  | 1 |
| Urinary tract infection & False labour |  |  |  | 1 |  | 1 |
| **Pregnancy, puerperium and perinatal conditions2 including stillbirths** | **3** | **3** | **1** | **1** |  | **4** |
| Stillbirth |  | 2 |  |  |  | 2 |
| Stillbirth & Prolonged pregnancy & Foetal distress syndrome |  |  |  | 1 |  | 1 |
| Stillbirth & Uterine rupture |  | 1 |  |  |  | 1 |
| **Renal and urinary disorders** | **3** | **3** |  |  | **3** | **3** |
| Renal impairment |  | 1 |  |  |  | 1 |
| Urethral prolapse |  | 1 |  |  |  | 1 |
| Urogenital fistula |  | 1 |  |  |  | 1 |
| **Social circumstances** | **1** | **1** |  |  | **1** | **1** |
| Physical assault |  | 1 |  |  |  | 1 |
| **Vascular disorders** |  |  | **1** | **1** | **1** | **1** |
| Deep vein thrombosis |  |  |  | 1 |  | 1 |
| **Grand Total** | **30** | **33** | **14** | **14** | **44** | **47** |

1 These also include combinations with preferred terms assigned to the following system organ classes: **Infections and infestations; Surgical and medical procedures.**

2 These also include combinations with preferred terms assigned to the following system organ classes: **Injury, poisoning and procedural complications.**

**Table S3**. Full listing of infant serious adverse events (system organ class and preferred term) up to 6±2 weeks post-partum

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dolutegravir** | | **Efavirenz** | | **Total** | |
|  | **N = 124** | | **N = 120** | | **N = 242** | |
|  | **Infants** | **Events** | **Infants** | **Events** | **Infants** | **Events** |
| **Congenital, familial and genetic disorders** | **46** | **67** | **49** | **71** | **95** | **138** |
| Birth mark |  | 21 |  | 21 |  | 42 |
| Cleft palate |  |  |  | 1 |  | 1 |
| Congenital acrochordon |  | 2 |  | 3 |  | 5 |
| Congenital skin dimples |  | 3 |  |  |  | 3 |
| Congenital umbilical hernia |  | 37 |  | 41 |  | 78 |
| Heterochromia iridis |  | 1 |  |  |  | 1 |
| Laryngomalacia |  | 1 |  |  |  | 1 |
| Polydactyly |  |  |  | 2 |  | 2 |
| Strabismus congenital |  | 1 |  | 1 |  | 2 |
| Talipes |  | 1 |  | 2 |  | 3 |
| **Ear and labyrinth disorders** | **1** | **1** |  |  | **1** | **1** |
| Hypoacusis |  | 1 |  |  |  | 1 |
| **Hepatobiliary disorders** | **1** | **1** |  |  | **1** | **1** |
| Jaundice neonatal |  | 1 |  |  |  | 1 |
| **Infections and infestations** | **8** | **8** | **6** | **6** | **14** | **14** |
| Bullous impetigo |  | 1 |  |  |  | 1 |
| Pneumonia |  | 2 |  |  |  | 2 |
| Sepsis neonatal |  | 5 |  | 6 |  | 11 |
| **Injury, poisoning and procedural complications** | **1** | **1** |  |  | **1** | **1** |
| Humerus fracture |  | 1 |  |  |  | 1 |
| **Nervous system disorders** | **1** | **1** | **1** | **1** | **2** | **2** |
| Hypoxic-ischaemic encephalopathy & Seizure |  |  |  | 1 |  | 1 |
| Seizure & Hypoxic-ischaemic encephalopathy |  | 1 |  |  |  | 1 |
| **Pregnancy, puerperium and perinatal conditions1** | **4** | **4** | **7** | **7** | **11** | **11** |
| Low birth weight baby |  | 1 |  |  |  | 1 |
| Premature baby |  | 2 |  | 5 |  | 7 |
| Premature baby & Infantile apnoea & Jaundice neonatal & Meconium ileus |  |  |  | 1 |  | 1 |
| Premature baby & Jaundice neonatal & Sepsis neonatal & Neonatal respiratory distress |  |  |  | 1 |  | 1 |
| Foetal growth restriction & Growth retardation & Developmental delay & Brain scan abnormal |  | 1 |  |  |  | 1 |
| **Respiratory, thoracic and mediastinal disorders2** | **8** | **8** | **4** | **4** | **12** | **12** |
| Choking |  | 1 |  |  |  | 1 |
| Neonatal asphyxia |  | 5 |  | 3 |  | 8 |
| Transient tachypnoea of the newborn |  | 1 |  |  |  | 1 |
| Hiccups & Sudden death |  |  |  | 1 |  | 1 |
| Neonatal hypoxia & Hypoxic-ischaemic encephalopathy |  | 1 |  |  |  | 1 |
| **Grand Total** | **61** | **91** | **56** | **89** | **117** | **180** |

1 These also include combinations with preferred terms assigned to the following system organ classes: **Gastrointestinal disorders; General disorders and administration site conditions; Infections and infestations; Investigations; Metabolism and nutrition disorders; Respiratory, thoracic and mediastinal disorders.**

2 These also include combinations with preferred terms assigned to the following system organ classes: **General disorders and administration site conditions; Nervous system disorders.**

**Table S4**. Infant deaths up to 6±2 weeks post-partum

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infant ID** | **Gestation** | **Age** | **Arm** | **Maternal** | **Relation to maternal** | | **Primary Cause** | **Other factors** |
|  | **(w)** | **(d)** |  | **Antiretrovirals (d)** | **Antiretrovirals** | **IRIS** |  |  |
| 10135-01-01 | 28 | 1 | Efavirenz | 0 | Not related | Not related | Premature (28w) twin pregnancy |  |
| 10091-01-01 | 32 | 19 | Dolutegravir | 30 | Unlikely | Not related | Premature infant (32w) | Antepartum  haemorrhage |
| 25118-01-02 | 35 | 14 | Efavirenz | 7 | Unlikely | Not related | Respiratory distress | Neonatal sepsis/grunting 10d before |
| 10040-01-02 | 37 | 88 | Dolutegravir | 13 | Unlikely | Not related | Sudden Infant Death  (nasal discharge 1w) | Disengaged (22d Dolutegravir), switched to Efavirenz (17d), fu for safety |
| 25025-01-01 | 38 | 47 | Dolutegravir | 28 | Not related | Not related | Infant choking |  |
| 10037-01-01 | 39 | 2 | Dolutegravir | 52 | Not related | Not related | Neonatal asphyxia |  |