DISCUSSION AND CONCLUSION

- This analysis evaluated 1074 pregnant women in 5 RCTs
- There was no significant difference between DTG and EFV in the overall risk of neonatal deaths, stillbirths or MTCT cases
- This analysis includes outcomes after first-line treatment typically up to 6 months before birth
- Outcomes for women becoming pregnant after long term treatment could be different given higher risks of clinical obesity for DTG, especially if combined with TAF/FTC

REFERENCES:

1. Koff SJ, Bosvedi E, Hill AV, Verdeli KD, Farley L, Maseya M, Serenata C, Okoth S, Chandiwana N. The predicted risk of adverse pregnancy outcomes as a result of treatment associated obesity in a hypothetical population receiving line treatment with DTG leads to rapid suppression of HIV RNA which might lower the risk of mother-to-child HIV transmission (MTCT)
- World wide millions of women are taking DTG
- Hence, safety in pregnancy requires careful evaluation in RCTs
- Treatment associated obesity is linked to a wide range of adverse birth outcomes in women

RESULTS

- DolPHIN-1 and DolPHIN-2 trials were conducted in South Africa and Uganda, ADVANCE in South Africa, NAMSAL in Cameroon and IMPAACT-2010 internationally.
- DolPHIN-1, DolPHIN-2 and IMPAACT-2010 were conducted in women already pregnant at screening. ADVANCE and NAMSAL were conducted in women who were not already pregnant at baseline
- On combining the sum of stillbirths, MTCT and neonatal deaths there were 45 events in the DTG arm and 24 in the EFV arm (OR=1.20, P-value=0.49) (Figure 5).
- No cases of Neural Tube Defects (NTDs) were observed among infants born in any of the trials
- In ADVANCE, the risk of developing clinical obesity was significantly higher for women taking DTG/FTC/TAF for 4 years (42%) versus DTG/FTC/TDF (27%) or EFV/FTC/TAF (20%)

METHODS

- Data on adverse birth outcomes was included from 5 RCTs: DolPHIN-1, DolPHIN-2, ADVANCE, NAMSAL and IMPAACT-2010
- These trials compared DTG with EFV as first-line treatment
- Data for the outcomes of neonatal deaths, stillbirths and MTCT were extracted from each trial
- The meta-analysis was conducted using RevMan Software
- The odds ratio (OR) for each endpoint was calculated using the Mantel-Haenszel test (Random-effects model).

BACKGROUND

- First-line treatment with DTG leads to rapid suppression of HIV RNA which might lower the risk of mother-to-child HIV transmission (MTCT)

Figure 1: Forest plot for stillbirths

Figure 2: Forest plot for neonatal deaths

Figure 3: Forest plot for MTCT

Figure 4: Forest plot for combined sum of stillbirths, neonatal deaths and MTCT

Figure 5: Meta-analysis of adverse birth outcomes