3. RESULTS (continued)

For 14 HIV infected women who used raltegravir 400 mg twice daily during pregnancy,
Pharmacokinetics were determined in 11/14 women (79%), of which 5 started in the 3rd trimester (36%), see Table 1. In 6/14 patients (43%) raltegravir was part of quadruple CART. These patients had concomitant ARVs in the 2nd or 3rd trimester.

Pharmacokinetics

- Evaluated paired PK curves (3rd trimester and postpartum) for 12 patients. Two patients had 3rd trimester only and for one patient the postpartum curve was incomplete and therefore not evaluable.
- Exposure (AUC0-12h) to raltegravir during pregnancy (3rd trimester) was 33% lower than postpartum (see Figure 1 and Table 1).
- Exposure (AUC0-12h) to raltegravir in 3rd trimester and postpartum shows considerable intra- and inter-subject variability (see Figure 2).
- Concomitant use of PI and NRTI in 3rd trimester and postpartum was approximately 50% lower compared to postpartum (GMR: 0.91; 0.54-1.92).
- One patient in the 3rd trimester (and none postpartum) had a Cmax below the suggested therapeutic range (0.54 mg/L), which was associated with failure to achieve an undetectable HIV RNA load in ODM9R study. This patient had an HIV RNA load of 74 copies/mL at pregnancy 3rd trimester assessment and an undetectable HIV RNA load at the day of delivery.
- Geometric mean (GM) of raltegravir plasma concentrations in 3rd trimester and postpartum was 1.24 (0.13-4.53).

Figure 1: Mean raltegravir concentrations

Table 3: Pharmacokinetic parameters

4. CONCLUSIONS

The slight decrease observed in exposure to raltegravir during 3rd trimester compared to postpartum is not considered to be of clinical importance given the large inter- and intra-subject variability in raltegravir pharmacokinetics.

• Raltegravir was well tolerated during pregnancy without causing congenital abnormalities.

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3. RESULTS (continued)

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