A Pharmacokinetic Drug-Drug Interaction Study Between Raltegravir and Atorvastatin

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ABSTRACT

OBJECTIVES - Raltegravir, a potent integrase inhibitor for the treatment of HIV-1 infection, is co-administered with other antiretroviral agents as well as with statins for the prevention or treatment of cardiovascular disease. This study describes the pharmacokinetics of raltegravir and atorvastatin with and without co-administration.

METHODS - The study was a randomized, open-label, parallel-group, three-period, three-treatment, 12-day, single-dose study in healthy volunteers. Subjects received raltegravir 400 mg BID, atorvastatin 20 mg QD or raltegravir 400 mg BID and atorvastatin 20 mg QD for 7 days. On day 8, a washout period of 7 days was followed by treatment with the alternate combination for 7 days.

RESULTS - Raltegravir AUC and Cmax were increased by 32% and 67%, respectively, when co-administered with atorvastatin compared with raltegravir alone. Atorvastatin AUC and Cmax were decreased by 15% and 9%, respectively, when co-administered with raltegravir compared with atorvastatin alone. The pharmacokinetics of atorvastatin and raltegravir were not affected by co-administration of the other drug.

CONCLUSIONS - Raltegravir and atorvastatin can be co-administered without adjustment of the doses.

3. METHODS

4. RESULTS

5. CONCLUSIONS

Table 1: Pharmacokinetic parameters raltegravir

Table 2: Pharmacokinetic parameters atorvastatin equivalents

Figure 1: Raltegravir mean plasma concentrations vs. time curves

Figure 2: Atorvastatin mean plasma concentrations vs. time curves

Figure 3: Individual AUC

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