Background

This phase IIb study evaluated the antiretroviral efficacy, safety, and tolerability of BMS-663068 (Attachment Inhibitor Prodrug) in antiretroviral-experienced subjects. The study aimed to determine whether a companion phenotypic assay is necessary in the future.

Methods

The study was a randomized, open-label, active-controlled, Phase Ib/IIb study (NCT00677400). Subjects were randomized 2:1 to receive BMS-663068 1200 mg QD or ATV/r 300/100 mg QD. At Week 48, BMS-663068 1200 mg QD was to be added to the ATV/r arm. Both arms also received TDF 300 mg QD.

RESULTS

Virologic response rates (HIV-1 RNA <50 c/mL) appear to be generally similar across the BMS-663068 and ATV/r arms. There were no new or unexpected safety signals for RAL.

CONCLUSIONS

BMS-663068 1200 mg QD was generally well tolerated. A retrospective analysis will be conducted to determine whether a companion phenotypic assay is necessary in the future.

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REFERENCES

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