BACKGROUND

FDV, a protease inhibitor, has antiviral activity against HCV genotypes (GT) 1, 4, 5, and 6 in vitro.1

METHODS

STUDY DESIGN

- Multicenter, open-label, parallel-randomized. Phase IIIb study in patients co-infected with HCV GT-1 and HIV-1 (N=310; 308 evaluable).
- Patients randomized (1:1) or assigned to:
  - FDV 120 mg, 24 weeks + PR
  - FDV 240 mg, 24 weeks + PR
  - FDV 240 mg, 48 weeks + PR
- Randomizations (day 1, week 12, and week 24) were stratified by HCV GT-1 subtype and region.
- Patients randomized to continue ART if ETS was achieved prior to the planned end of treatment.

RESULTS

Efficacy

- SVR rates were similar across FDV dose (120 mg vs 240 mg) and duration (24 weeks vs 48 weeks).
- SVR rates were comparable across FDV doses and durations of treatment.

SAFETY

- Most frequent AEs were nausea and fatigue (44% and 43% respectively).
- The results confirm the value of using ETS to guide PR treatment duration of 24 weeks.

CONCLUSIONS

- FDV + PR resulted in sustained virologic response 12 weeks after the planned end of treatment (SVR12) across all treatment groups (N=185).
- SVR12 rates were high in all patient subgroups, regardless of HCV genotype, IL28B allele status, and therapy background.
- FDV + PR may become an important option for the treatment of HCV and HIV co-infection.


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DISCLOSURES

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