Figure 4. SVR12 rates (ITT population)

FDV 240 mg QD 24 weeks

PR

Here, we report the results of STARTVerso3 (NCT01358864), a Phase III trial assessing the efficacy and safety of FDV plus PR in treatment-experienced patients with chronic HCV genotype-1 infection.

METHODS

Study Design

- Treatment-naïve, double-blind, placebo-controlled trial in HCV GT-1 patients
- Adults infected with chronic HCV GT-1 who had failed prior PR treatment, categorized as:
  - Null responders
  - Rapidly relapsing null responders
  - Relapse

Randomization

- At week 12: randomization to FDV 120 mg QD or placebo
- At week 24: randomization to FDV 240 mg QD or placebo
- All patients received PR throughout the study

Outcomes

- SVR12 (end of treatment and 12 weeks post treatment)
- Safety

RESULTS

Efficacy

- SVR12 rates for FDV 120 mg QD were 80% (FDV + PR) and 80% (FDV + PR), compared to 46% (PR) in patients with SVR12 for FDV 240 mg QD
- In concordance with treatment-naive studies, a favorable safety profile, with only slightly increased rates of AE over placebo, was observed at the tested higher dose (240 mg QD) of FDV 240 mg QD compared to the lower dose (120 mg QD).