Evaluation of Drug-Drug Interaction Between Asunaprevir and Methadone or Buprenorphine/Naloxone


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**BACKGROUND**

Asunaprevir (ASV) is an oral HCV NS3/4A protease inhibitor (PI) that is under development for the treatment of chronic hepatitis C virus (HCV) genotype 1 infection. ASV is being developed in combination with B-sofa virus NS5A replication complex inhibitor (RCI) asunaprevir with or without NS5B RCI daclatasvir.

**METHODS (cont)**

A review of the literature on design recommendations for coadministration of ASV and BUP was conducted to identify target exposure and effects of ASV on BUP based on its, a lack of clinically significant effect of ASV on the steady state peak (Cmax) or area under the curve (AUC) of BUP was concluded if the 80% confidence intervals (CI) for the geometric mean ratios (GMR) of both Cmax and AUC were contained within the pre-specified bounds of 0.85 to 1.15 for both Cmax and AUC.

Phase 1 of 10 and 100 mg BUP softgel capsules for use with R088299-02 placebo

Methadone (MET) and buprenorphine (BUP) are opioid analgesics commonly prescribed for pain management.

Methadone (MET) is a fully synthetic opioid analog derived from 2,6-methano[1,3]dioxan-3-one (1-DOM) and 2,6-dimethylecyclohexane-1,4-diol. It is a weak opioid agonist with some antagonist properties.

BUP is a partial opioid agonist that is maintained in the form of a CI. The high selectivity of BUP for the δ-opioid receptor and its relative lack of affinity for the μ-opioid receptor, which is responsible for the typical euphoric effects of other opioids, make it a highly effective tool for the treatment of opioid-dependent patients.

**RESULTS**

In part 1, 6 (40%) subjects experienced AEs. Two subjects withdrew due to AEs. One subject had severe diarrhea and three subjects had mild opioid withdrawal. Overall, did not result in discontinuations from study drug due to AEs.

Study powered for 14 subjects per part with a mean treatment period of 14 days. The ASV dose was 200 mg BID for 14 days. The BUP dose was 100 mg BID for 14 days. The ASV dose was 100 mg BID for 14 days. The BUP dose was 100 mg BID for 14 days.

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**REFERENCES**


