Efficacy and Safety of Glecaprevir/Pibrentasvir Treatment for 8 Weeks in Treatment-Naïve Patients With Chronic Hepatitis C Virus Infection Without Cirrhosis or With Compensated Cirrhosis: Analysis of Data Pooled From Phase 2 and 3 Studies


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BACKGROUND

Glecaprevir/pibrentasvir (G/P), a once-daily, all-oral, pan-genotypic, and pan-subtype HCV regimen, has been approved for the treatment of adults with HCV infection. The presence of virologic failure at week 4 in patients who fulfill the criteria for treatment failure is an indication for the use of a salvage therapy option. Currently, Glecaprevir/pibrentasvir is approved for 8 weeks of treatment in treatment-naïve patients with HCV genotype (GT) 1–6 infection (G/P, N = 372).

METHODOLOGY

Methods

Patients were randomized to G/P or placebo (PBO). For the APRI study, cirrhosis assessment was based only on APRI (APRI ≥ 0.75, or APRI > 2).

Efficacy

The most common adverse event (AE) 10% or more was headache (11%) and fatigue (10%)(Table 3).

SAFETY

One or more of these events occurred in less than 1% of patients of all events occurred in non-cirrhotic patients

Table 3. Treatment-Emergent AEs and Post-Baseline Clinical Laboratory Abnormalities

CONCLUSIONS

At 12 weeks of treatment, SVR12 rates were 97.9% in patients with compensated cirrhosis.

REFERENCES


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