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BACKGROUND

- For patients with chronic hepatitis C virus (HCV) infection, significant heterogeneity exists in access to direct acting antiviral (DAA) drugs and treatment patterns across different countries.

- GT1/a) is the most common genotype worldwide, representing ~30% of the global HCV population.

- The European Association for the Study of Liver (EASL) and others recommend the use of pangenotypic regimens as initial therapy for GT1–6 HCV infection.

- Open-label, real-world, and observational studies support the high efficacy and safety of the Glecaprevir/Pibrentasvir (G/P) combination.

- G/P is approved for use in Europe, the US and Canada.

- Efficacy and safety results from regional studies are expected to inform ongoing post-marketing studies.

METHODS

STUDY DESIGN

- Data from 8 countries participating in the PROMIS study (Austria, Belgium, France, Greece, Israel, Italy, Poland, and Switzerland) were included in this analysis.

- The study included 1,203 patients who were naïve to all antiviral therapies for HCV at the first post-treatment visit.

- Study population data were summarized for all patients, with subgroups of interest defined by the specific country analysis.

- This pooled analysis aimed to evaluate the real-world efficacy and safety evidence in pangenotypic HCV infection in non-biased, unselected, real-world clinical practice.

OBJECTIVE

- The primary objective was to explore the real-world effectiveness and safety of G/P according to baseline characteristics of treated HCV-infected patients in ongoing post-marketing observational studies (PMOs).

DATA SOURCES

- DAA-naïve GT1–6 HCV-infected patients were eligible to be included in the analysis if they had available data regarding baseline characteristics, virologic response, adherence, and safety.

- Data were collected for 1 February 2017 to 31 October 2019, and data were analyzed as of 24 November 2019.

- Adherence was calculated as a percentage of days covered relative to the total number of days expected to take the prescribed dose.

- Safety was measured by monitoring AEs and laboratory abnormalities.

RESULTS

STUDY POPULATION

- A total of 1,203 patients were included in the core population, and 1,203 patients were included in the core population (N = 1,203).

- The median age was 60 years (IQR 56–66), and the median BMI was 27.0 kg/m² (IQR 24.9–29.7).

- The proportion of patients receiving the tablet formulation was 62.7%.

- The most common AEs were headache (2.0%) and fatigue (2.8%).

- Arterial hypertension and compensated cirrhosis were the most common comorbidities.

- Patients with prior treatment history were included, and the most common cause for prior treatment failure was viral relapse.

- Treatment adherence was calculated as a percentage of days covered relative to the total number of days expected to take the prescribed dose.

- Safety was measured by monitoring AEs and laboratory abnormalities.

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CONCLUSIONS

- Real-world evidence supports the high efficacy and safety of the Glecaprevir/Pibrentasvir (G/P) combination in the treatment of chronic hepatitis C (HCV) infection in real-world practice.

- The high efficacy and safety of G/P in both randomized and real-world clinical settings affirm its non-inferiority to previous regimens.

- The Glecaprevir/Pibrentasvir (G/P) combination is well-tolerated and effective in real-world settings, supporting its use as a preferred treatment option for HCV-infected patients.

- The real-world evidence from this pooled analysis provides valuable insights into the efficacy and safety of G/P in various real-world settings, further supporting its use as a preferred treatment option for HCV-infected patients.

REFERENCES


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