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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.
- It is therefore crucial to evaluate the effectiveness and safety of DAA drugs in real-world settings.

METHODS

- G/P, as interferon-free, twice-daily, fixed-dose combination, was approved in the United States and Europe in 2017 for the treatment of patients chronically infected with HCV genotype (GT) 1–6.
- AbbVie sponsored the study; contributed to its design; and participated in its analysis.
- AbbVie, MSD, Gilead, Gore, and Alfasigma.

OBJECTIVE

- To assess the real-world effectiveness and safety of G/P in patients with chronic HCV infections in real-world post-marketing observational studies (PMOS).

RESULTS

- Total population: 1760. Excluded N = 73. Of 1687 patients, 1203 were included in the core population. 454 patients had less than 12 weeks of follow-up and were excluded from the real-world analysis.
- SVR12 rate for GT3 patients was 96.4%.
- There were no DAA-related deaths.
- The most common adverse events were gastrointestinal.

CONCLUSIONS

- G/P was generally well tolerated with no serious or life-threatening adverse events.
- SVR12 rates were consistent with the labeled G/P-panendrines DAA treatment regimens in real-world settings.
- G/P is the first DAA option not associated with interferon.
- G/P is the first panendrines DAA option developed in a patient with prior exposure to HCV in whom more than 2200 patients in real-world observational studies.

REFERENCES


METHODS (CONCLUDED)

- Safety

- The most common adverse events were gastrointestinal.
- G/P was generally well tolerated with no serious or life-threatening adverse events.
- SVR12 rates were consistent with the labeled G/P-panendrines DAA treatment regimens in real-world settings.
- G/P is the first DAA option not associated with interferon.
- G/P is the first panendrines DAA option developed in a patient with prior exposure to HCV in whom more than 2200 patients in real-world observational studies.

DISCLOSURES

- Consultant: AbbVie, Bristol-Myers Squibb, Gilead, Merck, and Roche.
- The authors had full access to the study data and take full responsibility for the decision to submit for publication.

EFFECTIVENESS

- Overall, the SVR12 rate was 96.4% (73/772) (Figure 1A) – There were 5 patients with virologic failure (1) on treatment withdrawal (1), virological drop (1), drug-related (1), and a case of potential non-compliance (1). – The mean ± standard deviation (SD) time since diagnosis of HCV infection was 62 (± 70) years.
- In 1125 patients with available data, reference to treatment was 58.9% in phase 1, 33.8% in phase 2, and 7.3% in phase 3.

SAFETY

- Treatment with G/P was well tolerated with no G/P-related serious adverse events. – The most common adverse events were fatigue (42% vs 26%), diarrhea (5% vs 2%), and headache (1% vs 2%). – G/P-mediated inhibition of fibrate transport and inhibition of upregulation of fibrate-inducible genes was associated with 2 patients. – G/P-mediated upregulation of fibrate-inducible genes was associated with 2 patients. – G/P-mediated upregulation of fibrate-induced genes was associated with 2 patients.

ACKNOWLEDGMENTS

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