An Integrated Analysis of Two Phase 3 Clinical Trials

OBJECTIVE

This integrated analysis of two Phase 3 clinical trials evaluated the safety and efficacy of glecaprevir/pibrentasvir in patients with HCV infection.

INTRODUCTION

People infected with hepatitis C virus (HCV) and human immunodeficiency virus (HIV) are at increased risk of liver-related complications and other health issues.

METHODS

- SO: 48-week extension of ENDURANCE-1 and ENDURANCE-2.
- SO: 24-week extension of ENDURANCE-1 and ENDURANCE-2.

KEY INCLUSION CRITERIA

- Individuals with chronic HCV infection
- Aged 18 years or older
- BMI ≥ 18 kg/m²
- HCV genotype 1a or 1b
- HCV RNA ≥ 150,000 IU/mL
- No prior treatment for HCV infection
- No concomitant use of HIV antiretroviral therapy (ART)

METHODS (CONTINUED)

- Interferon-free
- pegIFN ± RBV, or sofosbuvir (SOF) + RBV ± pegIFN
- No concomitant use of HIV antiretroviral therapy (ART)

SAFETY AND EFFICACY OF GLE/P

- Overall, 100% SVR12 rate with G/P
- 85% compliance
- No virologic failure
- 285 patients

ENDPOINTS AND ASSESSMENTS

- Primary Efficacy Endpoint: The proportion of patients with SVR12
- Secondary Efficacy Endpoint: The proportion of patients with on-treatment virologic failure and post-treatment response
- Safety Assessments: Adverse events (AEs) and laboratory abnormalities

RESULTS

- Overall, the majority of patients were white, male and HCV treatment-naive.
- 15% of patients were black, 33% had non-HCV genotype, 20% had F3–F4 fibrosis, and 25% reported or prior injection drug use
- One patient with HCV infection and cirrhosis experienced serious AEs unrelated to G/P, including a cerebrovascular accident, and an unrelated hematuria. On Day 10, the patient did not achieve SVR24, but had undetectable HCV RNA at last study visit (Day 15).
- All patients on stable ART maintained HIV-1 suppression (<200 copies/mL) during treatment

CONCLUSIONS

- Overall, 91% SVR24 with no relapses in HCV/HIV-1 coinfected patients with or without cirrhosis
- Achievement of SVR24 was not impacted by baseline viral load, presence of baseline polymorphisms, cirrhosis status, or any other factors
- G/P was well tolerated; serious adverse events, clinical significant laboratory abnormalities, and treatment discontinuations were rare

DISCLOSURES

The design, data analysis, writing, and editorial review of the study by DECOVIVIR and METABOLOLOGY, and all authors had access to all data and participated in writing, revising, and approving the final version. All the authors are employees of Gilead Sciences.

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REFERENCES

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