Efficacy and Safety of Glecaprevir/Pibrentasvir in Patients With HCV Genotype 5 or 6 Infection: An Integrated Analysis of Phase 2 and 3 Studies

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INTRODUCTION

Hepatitis C Virus (HCV) infection affects approximately 230 million individuals worldwide1,2. HCV genotype (GT) 5 and 6 infections account for 1% of infections worldwide1,2.

- HCV is characterized by high genetic diversity, and the prevalence of each GT varies by geography3. GT5 has a single known subtype GT5a, whereas GT6 exhibits high subtype diversity with 24 confirmed subtypes (GT6a–x)4. The efficacy data for GT6 subtypes are pending.

- To help further the WHO goal of achieving HCV elimination by 2030, a potent pan-genotypic short treatment regimen that is active across the diverse array of HCV subtypes is necessary.

G/P is approved for patients with HCV GT1–6 infection.

METHODS

- The integrated data across 2b, 3a, and 3b studies represent the largest number of patients with GT5 or GT6 infection; however, patients with cirrhosis without or with compensated cirrhosis were excluded from analysis.

- Patients with chronic HCV GT5 or GT6 infection received oral GLE + PIB once daily for either 8 or 12 weeks depending on the design of the original study.

- To evaluate efficacy and safety of GLE + PIB co-administration or GLE co-administration with placebo in patients with HCV GT5 or GT6 infection, patients with cirrhosis or with compensated cirrhosis were excluded from analysis.

- Any G/P related AE leading to study discontinuation or any AE with a reasonable possibility of being related to G/P was assessed by the investigator.

- The integrated data across 2b, 3a, and 3b studies represent the largest number of patients with GT5 or GT6 infection; however, patients with cirrhosis without or with compensated cirrhosis were excluded from analysis.

RESULTS

- One HCV GT5 subtype (5a) and six GT6 subtypes (6a–e, 6h, 6j) were identified by phylogenetic analysis among 2b/GT5-infected patients. Among HCV GT6-infected patients, the predominant subtypes were 6a (35%) and 6e (24%).

- A single patient was lost to follow-up due to a lack of homology in any of the known HCV GT6 subtypes.

- There were missing sub-structural information for phylogenetic analysis due to technical reason. Of these, 17 were HCV GT5s and 14 were HCV GT6s as determined by the in silico U2.0 assay.

REFERENCES


ACKNOWLEDGMENTS

AbbVie is grateful to the patients and their families, investigators, and coordinators who made these studies possible. Medical writing support was provided by Gold Bursch, PhD, Weybridge, UK.