

INTEGRATED EFFICACY AND SAFETY OF GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH PSYCHIATRIC DISORDERS

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Background:

Herein we report the integrated efficacy and safety of glecaprevir (NS3/4A protease inhibitor; developed by AbbVie/Enanta) and pibrentasvir (NS5A inhibitor; coformulated as G/P) from ten Phase 2/3 studies in patients with psychiatric disorders.

Methods:

Data were pooled from SURVEYOR-I and -II, MAGELLAN-I, ENDURANCE-1, -2, -3, and -4, and EXPEDITION-1, -2 and -4 studies. Treatment-naïve and -experienced patients were classified as having a psychiatric disorder if they were taking a psychiatric medication at G/P initiation or had a medical history of a psychiatric disorder. Efficacy was assessed as percent of patients achieving post-treatment week-12 (SVR12: HCV RNA < lower limit of quantification) using an intent-to-treat analysis. Safety was assessed in all patients.

Results:

Of the 2,522 HCV-infected patients included, 789 (31%) were classified as having a psychiatric disorder most commonly due to history of (n, %) depression (506, 64%), anxiety (216, 47%), and/or bipolar disorder (57, 7%). Patients with psychiatric disorders were more often male (403, 51%), white (685, 87%), >65 years old (703, 89%). The most common psychiatric drugs taken concomitantly by patients with psychiatric disorders were antidepressants (396, 50%), opioids (272, 34%), anxiolytics (244, 31%), antiepileptics (217, 28%), hypnotics/sedatives (159, 20%), and antipsychotics (117, 15%). Overall SVR12 rates (%; n/N) were 97% for both patients with (97.3%; 768/789; 95% CI=96.2–98.5) and without psychiatric disorders (97.5%; 1689/1733; 95% CI=96.7–98.2). Among patients with psychiatric disorders, SVR12 rates were >96% regardless of the number of diagnosed psychiatric disorders or concomitant psychiatric drugs used. Overall, G/P was well-tolerated in patients with psychiatric disorders with no DAA-related serious adverse events (0/789) and <1% (5/789) adverse events leading to discontinuation of G/P.

Conclusion: Use of G/P in chronic HCV genotype 1-6 infected patients who were either receiving concomitant CNS drugs or had a history of a psychiatric disorder was well-tolerated and achieved high SVR12 rates

Disclosures:

David Back: Advisory board member/speakers bureau and receives honorarium from: Gilead, Merck, Abbvie, Bristol-Myers Squibb, Janssen; received research grant funding from: Gilead, Merck, Abbvie, Bristol-Myers Squibb, Janssen; received travel sponsorship from: Abbvie.

Pamela Belperio: Nothing to disclose.

Fiona Marra: Consulting or grants from Abbvie, Gilead, MSD, Janssen, BMS.

Francesco Negro: Advisor to Gilead, AbbVie, Merck. Unrestricted research grant from AbbVie. Investigator initiated study supported by Gilead.

Andrew Talal: Research grants: AbbVie, Merck, Gilead, Intercept, Conatus, Abbott Laboratories; Advisor: AbbVie, Merck, Abbott Laboratories.

Mark Bondin, Caroline Park, Yang Lei, Federico Mensa, Eric Crown are employees of AbbVie, Inc. and may hold stock or stock options.