SAFETY AND EFFICACY OF GLECAPREVIR/PIBRENTASVIR IN PATIENTS WITH CHRONIC HEPATITIS C GENOTYPES 1–6 RECEIVING OPIOID SUBSTITUTION THERAPY

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Background: International guidelines recommend prioritizing hepatitis C virus (HCV) treatment in injection drug users, including those on opioid substitution therapy (OST). The once-daily, all-oral, ribavirin-free, pangenotypic combination of glecaprevir (identified by AbbVie and Enanta) and pibrentasvir has shown high sustained virologic response at post-treatment week 12 (SVR12) in clinical trials. In this analysis, we evaluate the safety and efficacy of glecaprevir/pibrentasvir in people receiving OST.

Methods: Data were pooled from patients with HCV genotypes (GT) 1–6 who were enrolled in 8 Phase 2 or 3 trials of glecaprevir/pibrentasvir for 8, 12, or 16 weeks. Concomitant medications at study enrolment were reviewed for OST use. Treatment completion, adherence (≥90% compliance by pill count), SVR12, adverse events (AEs), and laboratory abnormalities were evaluated for patients receiving OST versus non-OST patients.

Results: Among 2256 patients, 157 (7%) were receiving OST. Compared with non-OST patients, OST patients were more often male (69% vs 54%), <65 years of age (96% vs 85%), treatment naïve (86% vs 72%), had HCV GT3a (60% vs 26%), or had a history of depression or bipolar disorder (43% vs 19%). Most patients completed (OST: 98% [n/N=154/157]; non-OST: 99% [n/N=2070/2099]) and were adherent to (OST: 98% [n/N=121/123]; non-OST: 99% [n/N=1884/1905] among patients with available data) glecaprevir/pibrentasvir treatment. SVR12 rates in OST and non-OST patients were: ITT, 96% (n/N=151/157) and 98% (n/N=2055/2099); mITT (excluding nonvirologic failures), 99% (n/N=151/152) and 99% (n/N=2055/2077). For OST patients, reasons for nonresponse included relapse (n=1), premature study drug discontinuation (n=1), and missing SVR12 data (n=4). AEs occurring in ≥10% of patients were headache, fatigue, and nausea. Drug-related serious AEs, AEs leading to study drug discontinuation, and grade 3 or higher laboratory abnormalities were infrequent (<1%). No HCV reinfections occurred through post-treatment week 12.

Conclusion: Glecaprevir/pibrentasvir is highly efficacious and well tolerated in HCV-infected patients receiving OST.

Disclosure of interest statement:
AbbVie sponsored the studies; contributed to their design and to data collection, analysis, and interpretation; and participated in the writing, review, and approval of

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