1.0 Abstract

Title

Real World Evidence of the Effectiveness of Paritaprevir/r – Ombitasvir, + Dasabuvir, ± Ribavirin in Patients with Chronic Hepatitis C -
An Observational Study in Romania

Keywords

Chronic hepatitis C (CHC), non-interventional study, paritaprevir/ritonavir (r), ombitasvir, dasabuvir, ribavirin (RBV), sustained virological response (SVR), Patient Reported Outcome (PRO), EuroQol 5 dimension 5 level (EQ-5D-5L), Work Productivity and Activity Impairment (WPAI)

Background

The interferon-free combination regimen of paritaprevir/ritonavir and ombitasvir with or without dasabuvir (ABBVIE REGIMEN) ± ribavirin (RBV) for the treatment of chronic hepatitis C (CHC) has been shown to be safe and effective in randomized controlled clinical trials with strict inclusion and exclusion criteria under well controlled conditions.

The rationale for this observational study was to determine how the efficacy and safety of the ABBVIE REGIMEN as demonstrated in pivotal trials translates into real world everyday clinical settings when used according to local label in Romania in a clinical practice patient population.

Methods

In this prospective, multi-center observational study a total of 522 adult patients chronically infected with hepatitis C virus (HCV) were enrolled by 22 centers in Romania.

Patients were receiving the interferon-free ABBVIE REGIMEN ± RBV at the discretion of the physician in accordance with local clinical practice and label.

The primary objective was effectiveness as evidenced by sustained virological response 12 weeks after the end of treatment (SVR12).

Results

The vast majority of the core population (CP, n = 519) had genotype 1b (99.0%) and was suffering from cirrhosis (92.1%). Almost half of the patients were treatment experienced with interferon-based therapy (46.2%). The combination of paritaprevir/r plus ombitasvir plus dasabuvir with RBV for 12 weeks was prescribed to 84.4% of the CP.

SVR12 was achieved in 98.1% of the CP overall and in 98.1% and 97.6% of patients with and without cirrhosis, respectively. Four patients (0.8%) relapsed and there was one on-treatment virological failure.

Treatment emergent serious adverse events (SAEs) were reported by 3.8% of the patients, one patient discontinued the ABBVIE REGIMEN early for safety reasons and three patients died (hepatic failure, pyonephrosis and rectal adenocarcinoma, the latter around 2.5 months after EOT). The safety profile overall was dominated by effects well known for RBV, e.g., anemia and rash.

Discussion and Conclusion

Overall the present study provides evidence for the very high effectiveness - resembling results from pivotal trials - of the ABBVIE REGIMEN under real-world conditions in the Romanian CHC population. Tolerability was good with adverse events (AEs) well known for RBV prevailing, however, the current label does no longer recommend the addition of RBV for patients with genotype 1b including cirrhosis. No new safety signals were detected during this study.