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 Kuwait

Keywords

Chronic hepatitis C (CHC), non-interventional study, paritaprevir, ritonavir (r), ombitasvir, dasabuvir, ribavirin (RBV), sustained virological response (SVR), genotype 4, Patient Support Program (PSP)

Background

The interferon-free combination regimen of paritaprevir/ritonavir (r) 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 Kuwait in a clinical practice patient population.

Methods

In this prospective, multi-center observational study a total of 40 adult patients chronically infected with hepatitis C virus (HCV) were enrolled by 5 centers in Kuwait.

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 end of treatment (SVR12).

Results

The majority of the core population (CP, n=39) had genotype 4 (69.2%) and was receiving paritaprevir/r plus ombitasvir (2DAA) with RBV. The remaining patients had genotype 1a or 1b and were treated with paritaprevir/r plus ombitasvir plus dasabuvir (3DAA) ± RBV.

All patients of the CP achieved SVR12 including 2 patients with cirrhosis. There were no virological failures. No treatment emergent serious adverse events (SAEs) were reported, no deaths occurred and no patient discontinued the ABBVIE REGIMEN for safety reasons.

Conclusion

Overall the present study provides evidence for the very high effectiveness, resembling results from pivotal trials, and excellent tolerability of the ABBVIE REGIMEN under real world conditions in the CHC population in Kuwait. Since the study population was small with 40 patients, results have to be interpreted with caution. No new safety signals were detected during this study.

Marketing Authorisation Holder(s)

Names and Affiliations of Principal Investigators