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IN THIS ISSUE

In Brief: *Technivie* for HCV Genotype 4 Infection ..... online only

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IN BRIEF

Technivie for HCV Genotype 4 Infection

The FDA has approved *Technivie* (Abbvie), a fixed-dose combination of the direct-acting antiviral agents ombitasvir and paritaprevir and the pharmacokinetic enhancer ritonavir, for oral treatment of chronic hepatitis C virus (HCV) genotype 4 infection in patients without cirrhosis. It is indicated for use in combination with ribavirin. Ombitasvir/paritaprevir/ritonavir copackaged with dasabuvir, an HCV RNA polymerase inhibitor that has little activity against HCV genotype 4, is approved as *Viekira Pak* for treatment of HCV genotype 1 infection.[1]

HCV genotype 4 is uncommon in the US and Canada. It is the most prevalent strain of HCV in Central sub-Saharan Africa, North Africa, and the Middle East.[2] *Technivie* plus ribavirin was the first all-oral treatment approved for treatment of HCV genotype 4. Ledipasvir/sofosbuvir *(Harvoni)*[3] was also recently approved for this indication; it does not require coadministration with ribavirin and can be used in patients with or without cirrhosis. Its use for this and other new indications will be reviewed in a future issue.

FDA approval of *Technivie* was based on an open-label trial (PEARL-I) in 86 treatment-naive and 49 treatment-experienced non-cirrhotic patients with HCV genotype 4 infection. Treatment-naive patients were randomized to receive *Technivie* with or without ribavirin for 12 weeks; all treatment-experienced patients received the combination plus ribavirin for 12 weeks. The rate of sustained virologic response 12 weeks after stopping treatment (SVR12), the primary endpoint, was 91% (40/44) in treatment-naive patients not receiving ribavirin and was 100% in both treatment-naive (42/42) and treatment-experienced (49/49) patients receiving the combination plus ribavirin.[4]

Adverse effects observed with *Technivie* in the clinical trial included asthenia, fatigue, nausea, insomnia, pruritus, and skin reactions. Like *Viekira Pak*, *Technivie* has been associated with serious, sometimes fatal cases of hepatic decompensation and is contraindicated in patients with moderate to severe (Child-Pugh B/C) hepatic impairment.[5] It is also contraindicated in patients taking ethinyl estradiol (because of a risk of ALT elevation), CYP3A4 inducers such as rifampin, or certain sensitive CYP3A4 substrates such as midazolam or simvastatin.[6]

Each *Technivie* tablet contains 12.5 mg of ombitasvir, 75 mg of paritaprevir, and 50 mg of ritonavir. The recommended dosage is two tablets taken once daily in the morning with a meal for 12 weeks. Ribavirin should be coadministered with *Technivie* at a daily dose of 1000 mg in patients weighing <75 kg or 1200 mg in those weighing ≥75 kg. Use of *Technivie* alone may be considered in treatment-naive patients who cannot take or tolerate ribavirin. A 12-week supply of *Technivie* costs $76,653.[7] ■

1. A 4-drug combination (Viekira Pak) for hepatitis C. Med Lett Drugs Ther 2015; 57:15.
2. JP Messina et al. Global distribution and prevalence of hepatitis C virus genotypes. Hepatology 2015; 61:77.
3. A combination of ledipasvir plus sofosbuvir (Harvoni) for hepatitis C. Med Lett Drugs Ther 2014; 56:11.
4. C Hézode et al. Ombitasvir plus paritaprevir plus ritonavir with or without ribavirin in treatment-naive and treatment-experienced patients with genotype 4 chronic hepatitis C virus infection (PEARL-I): a randomised, open-label trial. Lancet 2015; 385:2502.
5. In brief: hepatic injury with hepatitis C drugs. Med Lett Drugs Ther 2015; 57:156.
6. Inhibitors and inducers of CYP enzymes and P-glycoprotein. Med Lett Drugs Ther 2013; 55:e44.
7. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. November 5, 2015. Reprinted with permission by First Databank, Inc. All rights reserved. ©2015 www.fdbhealth.com/policies/drug-pricing-policy.

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