FDA Approved AbbVie’s Technivie for Hep C Treatment Genotype 4

September 16, 2015 By Connie M. Welch

The U.S. Food and Drug Administration (FDA) approved AbbVie’s Technivie (ombitasvir, paritaprevir and ritonavir) for Hep C Treatment Genotype 4 in combination with ribavirin, on July 24, 2015. Technivie is for Hep C patients without cirrhosis.

Technivie in combination with ribavirin is the first drug that has demonstrated safety and efficacy to treat genotype 4 Hep C without the need for Interferon. Dr. Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research, stated in the FDA press release, “Today’s approval provides the first treatment option for patients with genotype 4 HCV infections without requiring the use of Interferon.”

According to the Centers for Disease Control and Prevention, genotype 4 is one of the least common genotypes in the United States.

Dosage Recommended for Adults:
Two tablets taken orally once daily (in the morning) with a meal without regard to fat or calorie content.

Used in Combination and Treatment Length:
Technivie is intended to be used in combination with Ribavirin for 12 weeks.

Treatment Option:
Technivie can be used without Ribavirin for 12 weeks for treatment-naÃ¯ve patients who cannot take or tolerate Ribavirin.

Restriction:
Not recommended for use in patients with cirrhosis.

Cure Rate Results:
Results showed 100 percent of the participants who received Technivie with ribavirin achieved a sustained virologic response. Of those who received Technivie without ribavirin, 91 percent achieved sustained virologic response.

Most Common Side Effects:
The most common side effects of Technivie with Ribavirin were Fatigue, Weakness (asthenia), nausea, insomnia, itching (pruritus) and other skin reactions. The majority of adverse reactions were mild in severity.

Results reported:
The safety and efficacy of Technivie with ribavirin were evaluated in a clinical trial of 135 participants with chronic HCV genotype 4 infections without cirrhosis. Ninety-one participants received Technivie with ribavirin once daily for 12 weeks. Forty-four participants received Technivie once daily without ribavirin for 12 weeks. The studies were designed to measure whether a participant's hepatitis C virus was no longer detected in the blood 12 weeks after finishing treatment (sustained virologic response), suggesting a participant's infection had been cured.

Safety information was available for 316 participants with HCV treated with the recommended dose of Technivie in combination with other anti-HCV drugs in clinical trials. The three drugs included in Technivie are also included in Viekira Pak, previously approved for the treatment of HCV genotype 1 infection. Additional safety information for those drugs was available from the Viekira Pak trials.

Warning reported:
Technivie carries a warning alerting patients and health care providers that elevations of liver enzymes to greater than five times the upper limit of normal occurred in approximately 1 percent of clinical trial participants. The elevations occurred more frequently in females taking contraceptives containing ethinyl estradiol. Contraceptives containing ethinyl estradiol must be discontinued prior to starting Technivie. Hepatic laboratory testing should be performed during the first four weeks of starting treatment, and as clinically indicated thereafter.

To read more see the FDA press release for Technivie.

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