

Abbvie Drugs Approved by FDA

December 19, 2014

The U.S. Food and Drug Administration today approved Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets) to treat patients with chronic hepatitis C virus (HCV) genotype 1 infection, including those with a type of advanced liver disease called cirrhosis.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to reduced liver function, liver failure or liver cancer. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take decades. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with HCV, and without proper treatment, 15-30 percent of these people will go on to develop cirrhosis.

Viekira Pak contains three new drugs—ombitasvir, paritaprevir and dasabuvir—that work together to inhibit the growth of HCV. It also contains ritonavir, a previously approved drug, which is used to increase blood levels of paritaprevir. Viekira Pak can be used with or without ribavirin, but it is not recommended for patients whose liver is unable to function properly (decompensated cirrhosis).

“The new generation of therapeutics for hepatitis C virus is changing the treatment paradigm for Americans living with the disease,” said Edward Cox, M.D., M.P.H., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research. “We continue to see the development of new all-oral treatments with very high virologic response rates and improved safety profiles compared to some of the older interferon-based drug regimens.”

Viekira Pak is the fourth drug product approved by the FDA in the past year to treat chronic HCV infection. The FDA approved Olysio (simeprevir) in November 2013, Sovaldi (sofosbuvir) in December 2013 and Harvoni (ledipasvir and sofosbuvir) in October 2014.

Viekira Pak’s efficacy was evaluated in six clinical trials enrolling 2,308 participants with chronic HCV infection with and without cirrhosis. In different trials, participants were randomly assigned to receive Viekira Pak or placebo (sugar pill); Viekira Pak with or without ribavirin; or Viekira Pak with ribavirin for 12 or 24 weeks.

The trials were designed to measure whether the hepatitis C virus was no longer detected in the blood at least 12 weeks after finishing treatment (sustained virologic response, or SVR), indicating that a participant’s HCV infection has been cured. Results from multiple populations, including those considered difficult to treat, showed 91 to 100 percent of participants who received Viekira Pak at the recommended dosing achieved SVR. The recommended dosing for Viekira Pak is two ombitasvir, paritaprevir, ritonavir 12.5 milligrams (mg)/75 mg/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily.

The most common side effects reported in clinical trial participants were feeling tired, itching, feeling weak or lack of energy, nausea and trouble sleeping.

Viekira Pak is the eleventh new drug product with breakthrough therapy designation to receive FDA approval. The FDA can designate a drug as a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients with serious or life-threatening diseases. Viekira Pak was reviewed under

the FDA's priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness.