

FDA News Release

FDA approves treatment for adults and children with all genotypes of hepatitis C and compensated cirrhosis that shortens duration of treatment to eight weeks

For Immediate Release:

September 26, 2019

The U.S. Food and Drug Administration today expanded the approval of Mavyret (glecaprevir and pibrentasvir) tablets for an eight-week duration for the treatment of adults and children ages 12 years and older or weighing at least 99 pounds who have chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection and compensated cirrhosis and have not been previously treated for HCV (treatment-naïve). Mavyret is now the first eight-week treatment approved for all treatment-naïve adult and certain pediatric patients with HCV genotypes 1-6 both without cirrhosis and with compensated cirrhosis. Standard treatment length for patients with compensated cirrhosis was previously 12 weeks or more.

“This approval provides a treatment duration of eight weeks for both pediatric and adult patients with compensated cirrhosis regardless of HCV genotype; meaning that an eight-week treatment regimen is available for any treatment-naïve HCV patient, regardless of cirrhosis status or genotype,” said Jeffrey Murray, M.D., deputy director of the Division of Antiviral Products in the FDA’s Center for Drug Evaluation and Research. “Mavyret is a combination of direct-acting antiviral drugs that reduce the amount of HCV in the body to undetectable levels by preventing the virus from multiplying, and in most cases, curing HCV infection.”

HCV is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. According to the U.S. Centers for Disease Control and Prevention, an estimated 2.7 to 3.9 million people in the U.S. have chronic HCV, and children born to HCV-positive mothers are at risk for HCV infection. Researchers estimate there are [23,000 to 46,000 children](#) in the U.S. with HCV infection.

The efficacy and safety of Mavyret was established in clinical trials, which cumulatively evaluated more than 2,500 people with HCV genotype 1, 2, 3, 4, 5 or 6 infection who received Mavyret for eight, 12 or 16 weeks duration. The trials included patients with HIV-co-infection, kidney or liver transplant recipients and patients with advanced kidney disease, including those requiring hemodialysis.

The efficacy of HCV treatment regimens are measured by the proportion of people in clinical trials achieving virologic cure. Virologic cure is the lack of detectable HCV in the blood at certain time points after completion of HCV therapy, known as sustained virologic response (SVR). SVR at 12 weeks post-treatment (SVR 12) is the standard measure of virologic cure. SVR 12 rates for Mavyret have ranged from 91-100 percent across clinical trials.

The most common adverse reactions in patients taking Mavyret are headache and fatigue. Mavyret is contraindicated in patients with moderate or severe liver impairment (Child-Pugh B or C) or in those with any history of liver decompensation. It is also contraindicated in patients taking the drugs atazanavir and rifampin.

The FDA granted the approval of Mavyret to AbbVie Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.