FDA News Release

FDA approves Mavyret for Hepatitis C

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved Mavyret (glecaprevir and pibrentasvir) to treat adults with chronic hepatitis C virus (HCV) genotypes 1-6 without cirrhosis (liver disease) or with mild cirrhosis, including patients with moderate to severe kidney disease and those who are on dialysis. Mavyret is also approved for adult patients with HCV genotype 1 infection who have been previously treated with a regimen either containing an NS5A inhibitor or an NS3/4A protease inhibitor but not both.

Mavyret is the first treatment of eight weeks duration approved for all HCV genotypes 1-6 in adult patients without cirrhosis who have not been previously treated. Standard treatment length was previously 12 weeks or more.

“This approval provides a shorter treatment duration for many patients, and also a treatment option for certain patients with genotype 1 infection, the most common HCV genotype in the United States, who were not successfully treated with other direct-acting antiviral treatments in the past,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. According to the Centers for Disease Control and Prevention, an estimated 2.7 to 3.9 million people in the United States have chronic HCV. Some patients who suffer from chronic HCV infection over many years may have jaundice (yellowish eyes or skin) and complications, such as bleeding, fluid accumulation in the abdomen, infections, liver cancer and death.

There are at least six distinct HCV genotypes, or strains, which are genetically distinct groups of the virus. Knowing the strain of the virus can help inform treatment recommendations. Approximately 75 percent of Americans with HCV have genotype 1; 20-25 percent have genotypes 2 or 3; and a small number of patients are infected with genotypes 4, 5 or 6.

The safety and efficacy of Mavyret were evaluated during clinical trials enrolling approximately 2,300 adults with genotype 1, 2, 3, 4, 5 or 6 HCV infection without cirrhosis or with mild cirrhosis. Results of the trials demonstrated that 92-100 percent of patients who received Mavyret for eight, 12 or 16 weeks duration had

no virus detected in the blood 12 weeks after finishing treatment, suggesting that patients' infection had been cured.

Treatment duration with Mavyret differs depending on treatment history, viral genotype, and cirrhosis status.

The most common adverse reactions in patients taking Mavyret were headache, fatigue and nausea.

Mavyret is not recommended in patients with moderate cirrhosis and contraindicated in patients with severe cirrhosis. It is also contraindicated in patients taking the drugs atazanavir and rifampin.

Hepatitis B virus (HBV) reactivation has been reported in HCV/HBV coinfected adult patients who were undergoing or had completed treatment with HCV direct-acting antivirals, and who were not receiving HBV antiviral therapy. HBV reactivation in patients treated with direct-acting antiviral medicines can result in serious liver problems or death in some patients. Health care professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with Mavyret.

The FDA granted this application **Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm)** and **Breakthrough Therapy (/ForPatients/Approvals/Fast/ucm405397.htm)** designations.

The FDA granted 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.

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Related Information

- **FDA: Hepatitis B & C (/ForPatients/Illness/HepatitisBC/default.htm)**

- **FDA Guidance for Industry: Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment (PDF) (PDF - 666KB) (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM225333.pdf)**

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