

## **FDA approves Epclusa**

June 2016

The U.S. Food and Drug Administration approved Epclusa to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis (advanced liver disease). For patients with moderate to severe cirrhosis (decompensated cirrhosis), Epclusa is approved for use in combination with the drug ribavirin. Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV.

“This approval offers a management and treatment option for a wider scope of patients with chronic hepatitis C,” 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. There are at least six distinct HCV genotypes, or strains, which are genetically distinct groups of the virus. Knowing the genotype helps inform treatment recommendations and the duration of treatment. Approximately 75 percent of Americans with HCV have genotype 1; 20-25 percent have genotypes 2 or 3; and a small numbers of patients are infected with genotypes 4, 5 or 6. According to the Centers for Disease Control and Prevention, HCV infection becomes chronic in approximately 75 to 85 percent of cases. Patients who suffer from chronic HCV infection over many years may have complications, such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections, liver cancer and death.

The safety and efficacy of Epclusa for 12 weeks was evaluated in three Phase III clinical trials of 1,558 subjects without cirrhosis or with compensated cirrhosis (mild cirrhosis). Results demonstrated that 95–99 percent of patients who received Epclusa had no virus detected in the blood 12 weeks after finishing treatment, suggesting the patients’ infections had been cured. The safety and efficacy of Epclusa was also evaluated in a clinical trial of 267 subjects with decompensated cirrhosis (moderate to severe cirrhosis), of whom 87 subjects received Epclusa in combination with ribavirin for 12 weeks, and 94 percent of these patients had no virus detected in the blood 12 weeks after finishing treatment.

The most common side effects of Epclusa include headache and fatigue. Epclusa and ribavirin combination regimens are contraindicated for patients for whom ribavirin is contraindicated.

Epclusa carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone is used with sofosbuvir in combination with another HCV direct-acting antiviral. Co-administration of amiodarone with Epclusa is not recommended. Epclusa also carries a warning not to use with certain drugs that may reduce the amount of Epclusa in the blood which could lead to reduced efficacy of Epclusa.

Epclusa 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.

Epclusa is manufactured and marketed by Gilead Sciences, Inc., of Foster City, California.