U.S. FOOD & DRUG ADMINISTRATION

EPCLUSA: Labeling Updates for Pediatric Patients

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Today the U.S. Food and Drug Administration approved changes to the EPCLUSA (sofosbuvir and velpatasvir) labeling to provide for the use in pediatric patients with chronic hepatitis C virus (HCV) ages 6 years and older or weighing at least 37 pounds (17 kilograms) with any of the six HCV genotypes, or strains, without cirrhosis (liver disease) or with mild cirrhosis. Epclusa in combination with ribavirin is indicated for the treatment of pediatric patients 6 years and older or weighing at least 37 pounds with severe cirrhosis.

The pharmacokinetics, safety and efficacy of Epclusa, taken orally for 12 weeks, for the treatment of HCV genotypes 1, 2, 3, 4 or 6 infection was established in an open-label, multicenter clinical trial that included a total of 173 treatment-naïve and treatment-experienced pediatric patients ages 6 years and older without cirrhosis or with mild cirrhosis. No meaningful differences in pharmacokinetics were seen in pediatric patients compared to adults. The safety and efficacy results were comparable to those observed in adults. In 102 patients ages 12 through17, 93% of patients with genotype 1 and 100% of patients with genotypes 2, 3, 4 and 6 had no detectable virus in the blood 12 weeks after finishing treatment. Among the 71 patients ages 6 to 11 years with HCV genotypes 1, 2, 3 or 4, 93% with genotype 1, 91% with genotype 3 and 100% with genotypes 2 and genotype 4 had no virus detected in the blood 12 weeks after finishing treatment.

The safety and efficacy of Epclusa for treatment of HCV genotype 5 in pediatric patients 6 years and older or weighing at least 37 pounds without cirrhosis or with mild cirrhosis are supported by sofosbuvir and velpatasvir exposures in adults and pediatric patients with HCV genotype 1, 2, 3, 4 or 6 infection. Similar data were used to support dosing recommendations for pediatric patients with HCV genotype 1, 2, 3, 4, 5, or 6 infection who have severe cirrhosis.

The safety and effectiveness of Epclusa have not been established in pediatric patients less than 6 years of age.

The most common adverse reactions observed with treatment with Epclusa were fatigue and headache. The adverse reactions observed were consistent with those observed in clinical trials of Epclusa in adults.

The updated label will soon be available at Drugs@FDA or DailyMed.

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