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FDA approves Mavyret for treating all Hep C genotypes in children

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FDA granted the approval of Mavyret to AbbVie Inc.

The U.S. Food and Drug Administration has approved Mavyret (glecaprevir and pibrentasvir) tablets to treat all six genotypes of hepatitis C virus (HCV) in children ages 12 to 17. Mavyret was previously approved to treat HCV in adults in 2017.

With this approval, dosing information is provided for Mavyret for the treatment of adult or pediatric patients 12 years and older, or weighing at least 99 pounds, who are infected with any of six identified HCV genotypes either without cirrhosis or with compensated cirrhosis.

The safety and efficacy of Mavyret in pediatric patients was evaluated during clinical trials of 47 patients with genotype 1, 2, 3 or 4 HCV infection without cirrhosis or with mild cirrhosis. Results of the trials demonstrated that 100 percent of patients who received Mavyret for eight or 16 weeks had no virus detected in the blood 12 weeks after finishing treatment, suggesting that patients' infection had been cured. In pediatric patients with cirrhosis, history of a kidney and/or liver transplant, or genotype 5 or 6 HCV infection, the safety and efficacy of Mavyret are supported by previous studies observed in glecaprevir and pibrentasvir in adults. The adverse reactions observed were consistent with those observed in clinical studies of Mavyret in adults.

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 and fatigue. 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.