FDA Approves Epclusa to Treat Hep C in Children Ages 6 and Up

Gilead Sciences' direct-acting antiviral regimen was previously approved for adults.

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The Food and Drug Administration (FDA) has extended its approval of Gilead Sciences' Epclusa (sofosbuvir/velpatasvir) to allow for treatment of all genotypes of hepatitis C virus (HCV) among children.

The federal agency first approved Epclusa for adults in 2016. The new approval applies to children ages six and older who weigh at least 37 pounds.

Gilead's application for the pediatric indication was based on an open-label study of 173 children with hep C including those with and without mild cirrhosis of the liver. The children were treated with 12 weeks of Epclusa.

The study authors found no difference in the way the children's bodies metabolized the medications in Epclusa compared with previous findings in adults.

Of the 102 participants who were 12 to 17 years old, 93% of those with genotype 1 and all of those with genotypes 2, 3, 4 and 6 of hep C achieved a sustained virologic response 12 weeks after completing therapy, considered a cure.

Of the 71 children between ages 6 and 11 years old, 93% of those with genotype 1, 91% of those with genotype 3 and all of those with genotypes 2 and 4 were cured.

To read an FDA press release about the approval, click here.

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