FDA Approves Two Hepatitis C Treatments for Younger Children

The Epclusa and Mavyret combination pills are now indicated for kids as young as age 3.

June 11, 2021 By Liz Highleyman

On June 10, the Food and Drug Administration (FDA) extended its approval of

Epclusa (sofosbuvir/velpatasvir) and Mavyret (glecaprevir/pibrentasvir) for the treatment of hepatitis C in children ages 3 and older. Both combination pills are effective against all genotypes of hepatitis C virus (HCV).

Hepatitis C is uncommon among children, affecting an estimated 50,000 kids in the United States and some 3 to 5 million children worldwide, but it is a growing concern due to rising hep C rates among women of childbearing age. Pregnant women can transmit HCV to their infants during gestation or delivery, and experts recommend that they should be tested for the virus during each pregnancy. Most children born with HCV will develop chronic infection, which can lead to serious liver disease.

The FDA first approved Gilead Sciences' Epclusa for adults in 2016 and extended the indication to children ages 6 and older in 2020. Now, the 12-week treatment is approved for pediatric patients ages 3 and up without cirrhosis or with compensated cirrhosis; those with decompensated cirrhosis can take Epclusa in combination with ribavirin. The latest approval covers two strengths of an oral pellet formulation of Epclusa developed for young children who can't swallow tablets; the recommended dosage is based on body weight.

The approval was based on findings from a Phase II clinical trial that included 41 children ages 3 to 6 years who were treated with Epclusa for 12 weeks. Overall, 83% achieved sustained virological response (SVR), or continued undetectable HCV after the completion of treatment. The SVR rates were 100% for the three children with HCV genotypes 3 or 4, 88% (28 out of 32) for those with genotype 1and 50% (three out of six) for those with genotype 2. However, seven of the children who were not cured stopped treatment early.

The FDA first approved AbbVie's Mavyret for adults in 2017 and extended the indication to children ages 12 and up in 2019. The new approval is for pediatric patients ages 3 and older without cirrhosis or with compensated cirrhosis. Mavyret is also now available in an oral pellet formulation.

This approval was supported by results from the Phase II/III DORA Part 2 trial, in which 62 children ages 3 to 12 without cirrhosis were treated with Mavyret for eight, 12 or 16 weeks, depending on their HCV genotype and prior treatment history. The overall cure rate was 98%; the one child who did not achieve SVR stopped treatment early. The approved duration is eight weeks for children being treated for the first time.

Both Epclusa and Mavyret were safe and well tolerated in the pediatric trials, and side effects were generally consistent with those seen in adults. In the Epclusa study, 15% of participants experienced vomiting, and 10% spit up the drug. In the Mavyret trial, vomiting (8%), upper abdominal pain (4%) and rash (4%) were more common in children compared with adults.

Click here for full prescribing information for Epclusa.

Click here for full prescribing information for Mavyret.
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