FDA Approves Hepatitis C Treatment Breakthrough for Children

May 3, 2017 By Connie M. Welch

April 7th 2017 the FDA approved supplemental applications for Sovaldi (sofosbuvir) and Harvoni (ledipasvir and sofosbuvir) both made by Gilead pharmaceuticals to treat the hepatitis C virus (HCV) in children ages 12 to 17 or weighing at least 77 pounds (35 kg).

The approvals provide pediatric Hep C treatment options for six major genotypes (virus strains) of the Hep C virus.

Harvoni is indicated for the treatment of children 12 years of age or older, or weighing at least 77 pounds (35 kg) having Hep C genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis (mild cirrhosis).

Sovaldi in combination with ribavirin is also approved for treatment for children 12 years or older or weighing at least 77 pounds (35 kg) with genotype 2 or 3 of Hep C without cirrhosis or with compensated cirrhosis (mild cirrhosis).

FDA news release states, “These are the first direct-acting antiviral treatments approved for children and adolescents with HCV (Hep C). Direct acting antiviral drugs reduce the amount of HCV in the body by preventing the virus from multiplying, and in most cases, they cure HCV (Hep C).”

According to the Centers for Disease Control and Prevention, an estimated 3.9 million people in the United States have chronic HCV, and children born to HCV-positive mothers are a risk for the Hep C infection. It’s estimated there are 23,000 to 46,000 children in the U.S. with Hep C.

Clinical Trial studies for Harvoni:
The safety and efficacy of Harvoni for treatment of Hepatitis C genotype (virus strain) 1 were established in an open label, multicenter clinical trial that included 100 pediatric patients 12 years and older. The results were comparable to those observed in adults and demonstrated 98 percent of patient showed no virus detected in the their blood 12 weeks after completing treatment, suggesting the patients were cured of Hep C.

For pediatric patients with Hep C genotypes 4, 5, and 6 who were 12 years and older the data showed similar exposures and efficacy to Harvoni in adults and adolescents with genotype 1.

The most common Hep C treatment side effects observed with Harvoni were fatigue and headache.

Treatment regimen with Harvoni is a once a day oral pill. Treatment duration is normally 12 weeks.

Clinical Trial studies for Sovaldi with Ribavrin:
FDA reports, “Sovaldi in combination with ribavirin was evaluated in an open-label clinical trial including 50 pediatric patients 12 years and older. The results were comparable to those in adults and 100 percent with Hep C genotype 2, and 97 percent of patients with Hep C genotype 3 showed no virus detected in their blood 12 weeks after completing treatment.”

The most common Hep C treatment side effects observed with Sovaldi in combination with ribavirin were fatigue and headache.

Treatment regimen with Sovaldi and Ribavirin are oral pills (the daily dosage of ribavirin is weight-based and is administered orally in two divided does with food.)
Treatment duration with Sovaldi and Ribavirin for genotype 2 patients (12 years or older and weighing at least 77 pounds or 35 kg) with without cirrhosis or with compensated (mild) cirrhosis was for 12 weeks.

Treatment duration with Sovaldi and Ribavirin for genotype 3 patients 12 years or older and weighing at least 77 pounds or 35 kg) without cirrhosis or with compensated (mild) cirrhosis was for 24 weeks.

All contraindications (a symptom or condition that makes a particular treatment inadvisable) to ribavirin also apply to Sovaldi in combination treatment.

Each patient and their condition will be evaluated by their physician upon recommendation to which treatment is safe and best suited for the patient.

FDA in addition reports that safety and efficacy of Harvoni have not been established in children younger than 12 years and weighing less than 77 pounds (35 kg) with decompensated cirrhosis or in pediatric liver transplant recipients.
Safety and efficacy of Sovadli have not been established in children younger than 12 years and weighing less than 77 pounds (35 kg) with Hep C genotype 2 or 3. The safety and efficacy of Sovaldi have not been established in children with Hep C genotype 1 or 4.

Additional Hep C treatments are in current clinical trials for a variety of genotypes and conditions. FDA approvals are expected for new Hep C treatment to be released in the summer of 2017. Stay tuned as we report further Hep C news.

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