



Gilead's Harvoni Boasts Near-Perfect Hepatitis Cure Rates Among Young Children

The single-tablet regimen was just approved for adolescent pediatric use in the United States.

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Gilead Sciences' Harvoni (ledipasvir/sofosbuvir) offers similarly excellent hepatitis C virus (HCV) cure rates to young children as those seen in adults.

In April, the U.S. Food and Drug Administration (FDA) [approved](#) Harvoni and another of Gilead's HCV treatments, Sovaldi (sofosbuvir), for use among children 12 to 17 years old. Currently, the standard of care for children 6 to 11 years of age who weigh less than 35 kilograms (77 pounds) is interferon plus ribavirin for up to 48 weeks.

The open-label Phase II study, known as #PS-101, included 90 children with hep C between the ages of 6 and 11. All received an experimental dose of Harvoni, including 45 milligrams of ledipasvir and 200 mg of sofosbuvir.

Of the 86 participants with genotype 1 of hep C, 85 received 12 weeks of treatment, while the one other, who had cirrhosis and had failed a previous treatment with interferon and ribavirin, received 24 weeks of Harvoni. Otherwise, the two children with genotype 3 received Harvoni plus ribavirin for 24 weeks, and the two children with genotype 4 received Harvoni for 12 weeks.

Overall, 99 percent (89 of 90) of the participants were cured. One child with genotype 1, who had not been treated before, experienced viral relapse.

The most common adverse health events, occurring in more than 10 percent of participants, all of which were mild to moderate in severity, were abdominal pain, headache, diarrhea, vomiting, nausea, fever, cough and sore throat. None of the participants stopped treatment early.

To read a press release about the study, [click here](#).
