FDA Approves the First Treatment for All Hepatitis C Genotypes in Pediatric Patients

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The U.S. Food and Drug Administration (FDA) announced the approval of Mavyret (glecaprevir and pibrentasvir) tablets to treat all six genotypes of hepatitis C virus (HCV) in children ages 12 to 17. Mavyret is part of a relatively new class of medications called "direct acting antivirals" (DAAs) that are designed to prevent the HCV virus from multiplying, and in most cases, DAAs cure HCV infection. The introduction of DAA therapy has resulted in high rates of disease cure along with a well-tolerated, short course of treatment (usually 8-12 weeks) that has raised the opportunities for widespread treatment, cure, and even the elimination of HCV. The approval follows review of data from clinical trials that included 47 pediatric patients with genotype 1, 2, 3, or 4 HCV infection who had mild cirrhosis or no cirrhosis. It was previously approved in 2017 to treat HCV in adults.

HCV is a blood-borne virus that causes inflammation of the liver that can lead to reduced liver function and liver failure. About 2.4 million persons in the United States were living with HCV from 2013 through 2016, according to estimates from the U.S. Centers for Disease Control and Prevention (CDC). About half of people with HCV do not know they are infected. Children born to HCV-positive mothers are at risk for HCV infection and it is estimated that there are 23,000 to 46,000 children in the U.S. with HCV infection. According to Jeffrey Murray, M.D., M.P.H., deputy director of the Division of Antiviral Products in the FDA's Center for Drug Evaluation and Research, "today's approval represents another treatment option for children and adolescents with HCV infection, but for the first time, in all genotypes of HCV."

Treating adults and children for HCV supports the strategies and actions set forth in the National Viral Hepatitis Action Plan that calls for access to affordable hepatitis C treatment. Elimination of viral hepatitis – and its mounting toll on lives and resources – is the ultimate goal. The new FDA-approved HCV treatment can help us take a step closer to our goals.

New #HepC treatment can now be used for all children with chronic infection! Using these treatments for children will prevent liver disease and #livercancer and help keep them healthy for life! https://go.usa.gov/xmmfK

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