Mavyret approved for hepatitis C

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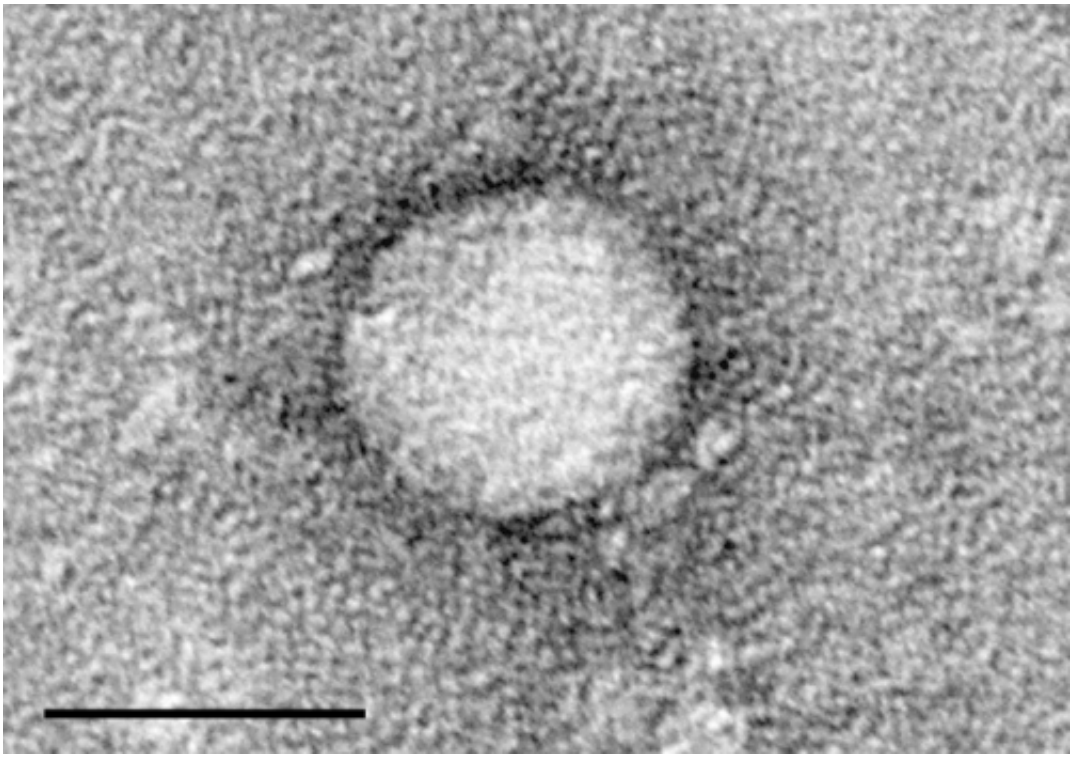

Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

(HealthDay) —Mavyret (glecaprevir and pibrentasvir) has been approved by the U.S. Food and Drug Administration to treat adults with certain types of chronic hepatitis C virus (HCV).

The combination drug is the first approved therapy for hepatitis C to

require as few as eight weeks of treatment, the FDA said in a news release. Other therapies require treatment of 12 weeks or longer.

"This approval provides a shorter treatment duration for many patients, and also a treatment option for certain patients . . . who were not successfully treated with other direct-acting antiviral treatments," said Dr. Edward Cox, director of the FDA's Office of Antimicrobial Products.

HCV causes liver inflammation, potentially leading to reduced liver function or liver failure, the agency said. Symptoms and complications may include jaundice, a yellowing of the skin; bleeding; abdominal fluid accumulation; infections; liver cancer and death.

There are at least six distinct genotypes (strains). About three-quarters of Americans have genotype 1. As many as 3.9 million people in the United States have chronic HCV, according to the U.S. Centers for Disease Control and Prevention.

Mavyret was evaluated in clinical studies of some 2,300 adults with all six genotypes. At least 92 percent of people who took the drug had no HCV detected in the blood 12 weeks after completing treatment, the FDA said.

The most common side effects of the drug included headache, fatigue and nausea.

The drug shouldn't be taken by people with severe liver scarring (cirrhosis), or by those taking the antiviral drugs atazanavir and firampin. People who are simultaneously infected with hepatitis B virus should be monitored carefully while taking Mavyret, the agency added.

Approval for Mavyret was given to AbbVie Inc., based in Chicago.

More information: Visit the FDA to learn more.