

US approves pricey new pill against hepatitis C

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US regulators on Friday approved Harvoni, a daily pill to treat hepatitis C that is simpler to administer than long-standing treatments but that carries a steep price tag.

The [combination pill](#) made by California-based Gilead Sciences was shown in trials to cure up to 99 percent of patients within two to three months.

But Harvoni's price is set at \$94,500 for a 12-week course of treatment, or \$1,125 per pill.

The pill combines two agents—ledipasvir and sofosbuvir, a previously approved hepatitis C drug marketed by Gilead under the brand name Sovaldi.

Sovaldi had already stoked criticism for its high price tag of \$1,000 per pill, or \$84,000 per treatment course.

Gilead CEO John Martin said the company was "working to ensure rapid and broad access."

"Unlike other serious chronic diseases, hepatitis C can be cured, and Harvoni offers patients the potential for a cure in as little as eight weeks," added Martin.

Harvoni is the first treatment for hepatitis C that does not require administration with interferon or ribavirin, which can cause side effects like headache, fatigue and nausea.

Edward Cox, director of the Office of Antimicrobial Products at the Food and Drug Administration said the new treatments were "changing the treatment paradigm" for people with hepatitis C.

"Now, patients and [health care professionals](#) have multiple treatment options, including a combination pill to help simplify treatment regimens," he said.

Harvoni is the third drug approved by the FDA in the past year to treat chronic hepatitis C infection.

Others include Olysio (simeprevir), marketed by Janssen Therapeutics in New Jersey and approved in November 2013 and Gilead's Sovaldi which was approved in December 2013.

Hepatitis C, or HCV, is a viral infection that affects the liver, and may cause no symptoms for years until liver damage becomes apparent in the form of cirrhosis, jaundice or cancer.

Between 130 million and 150 million people worldwide are infected with HCV, which kills as many as 500,000 each year, according to the World Health Organization.

"This is a giant step forward for people with HCV. One [pill](#), once daily, no interferon, no ribavirin and 94-99 percent cure," said Douglas Dieterich, professor of medicine in the Division of Liver Diseases at The Mount Sinai Hospital in New York.

"It moves the risk-benefit ratio needle way over toward benefit."

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