FDA News Release

FDA approves first combination pill to treat hepatitis C

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Release

Español

The U.S. Food and Drug Administration today approved Harvoni (ledipasvir and sofosbuvir) to treat chronic hepatitis C virus (HCV) genotype 1 infection.

Harvoni is the first combination pill approved to treat chronic HCV genotype 1 infection. It is also the first approved regimen that does not require administration with interferon or ribavirin, two FDA-approved drugs also used to treat HCV infection.

Both drugs in Harvoni interfere with the enzymes needed by HCV to multiply. Sofosbuvir is a previously approved HCV drug marketed under the brand name Sovaldi. Harvoni also contains a new drug called ledipasvir.

"With the development and approval of new treatments for hepatitis C virus, we are changing the treatment paradigm for Americans living with the disease," said Edward Cox, M.D., M.P.H., director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research. "Until last year, the only available treatments for hepatitis C virus required administration with interferon and ribavirin. Now, patients and health care professionals have multiple treatment options, including a combination pill to help simplify treatment regimens."

Harvoni is the third drug approved by the FDA in the past year to treat chronic HCV infection. The FDA approved Olysio (simeprevir) in November 2013 and Sovaldi in December 2013.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take decades.

Some people with chronic HCV infection develop scarring and poor liver function (cirrhosis) over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections and liver cancer. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with HCV, and without proper treatment, 15-30 percent of these people will go on to develop cirrhosis.

Harvoni's efficacy was evaluated in three clinical trials enrolling 1,518 participants who had not previously received treatment for their infection (treatment-naive) or

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who had not previously received treatment for their infection (treatment-naive) or had not responded to previous treatment (treatment-experienced), including participants with cirrhosis. Participants were randomly assigned to receive Harvoni with or without ribavirin. The trials were designed to measure whether the hepatitis C virus was no longer detected in the blood at least 12 weeks after finishing treatment (sustained virologic response, or SVR), indicating that a participant's HCV infection has been cured.

In the first trial, comprised of treatment-naive participants, 94 percent of those who received Harvoni for eight weeks and 96 percent of those who received Harvoni for 12 weeks achieved SVR. The second trial showed 99 percent of such participants with and without cirrhosis achieved SVR after 12 weeks. And in the third trial, which examined Harvoni's efficacy in treatment-experienced participants with and without cirrhosis, 94 percent of those who received Harvoni for 12 weeks and 99 percent of those who received Harvoni for 24 weeks achieved SVR. In all trials, ribavirin did not increase response rates in the participants.

The most common side effects reported in clinical trial participants were fatigue and headache.

Harvoni is the seventh new drug with breakthrough therapy designation to receive FDA approval. The FDA can designate a drug as a breakthrough therapy at the request of the sponsor if preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapies for patients with serious or life-threatening diseases. Harvoni was reviewed under the FDA's priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness.

Harvoni and Sovaldi are marketed by Gilead, based in Foster City, California. Olysio is marketed by Janssen Pharmaceutical based in Raritan, New Jersey.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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