

# **Approval of Sovaldi (sofosbuvir) and Olysio (simeprevir) for treatment of hepatitis C by the Food and Drug Administration (FDA)**

The FDA has announced the approval of 2 new medications for the treatment of Hepatitis C. The research on these medications is very promising as a significant advance in the treatment of this disease. Further details can be found below.

## **FDA NEWS RELEASE**

**Consumer Inquiries:** 888-INFO-FDA

### **FDA approves Sovaldi for chronic hepatitis C**

The U.S. Food and Drug Administration approved Sovaldi (sofosbuvir) to treat chronic hepatitis C virus (HCV) infection. Sovaldi is the first drug that has demonstrated safety and efficacy to treat certain types of HCV infection without the need for co-administration of interferon.

“Today’s approval represents a significant shift in the treatment paradigm for some patients with chronic hepatitis C,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research.

Sovaldi is the second drug approved by the FDA in the past two weeks to treat chronic HCV infection. On November 22, the FDA approved Olysio (simeprevir).

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 several years. 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 or liver cancer. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with HCV.

Sovaldi is a nucleotide analog inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. Sovaldi is to be used as a component of a combination antiviral treatment regimen for chronic HCV infection. There are several different types of HCV infection. Depending on the type of HCV infection a patient has, the treatment regimen could include Sovaldi and ribavirin or Sovaldi, ribavirin and peginterferon-alfa. Ribavirin and peginterferon-alfa are two drugs also used to treat HCV infection.

Sovaldi’s effectiveness was evaluated in six clinical trials consisting of 1,947 participants who had not previously received treatment for their disease (treatment-naive) or had not responded to previous treatment (treatment-experienced), including participants co-infected with HCV and HIV. 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), suggesting a participant's HCV infection has been cured.

Results from all clinical trials showed a treatment regimen containing Sovaldi was effective in treating multiple types of the hepatitis C virus. Additionally, Sovaldi demonstrated efficacy in participants who could not tolerate or take an interferon-based treatment regimen and in participants with liver cancer awaiting liver transplantation, addressing unmet medical needs in these populations.

The most common side effects reported in clinical study participants treated with Sovaldi and ribavirin were fatigue and headache. In participants treated with Sovaldi, ribavirin and peginterferon-alfa, the most common side effects reported were fatigue, headache, nausea, insomnia and anemia.

Sovaldi is the third 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. Sovaldi 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.

Sovaldi is marketed by Gilead, based in Foster City, Calif. Olysio is marketed by Raritan, N.J.-based Janssen Pharmaceuticals.

## **FDA NEWS RELEASE**

**Consumer Inquiries:** 888-INFO-FDA

### **FDA approves new treatment for hepatitis C virus**

The U.S. Food and Drug Administration approved Olysio (simeprevir), a new therapy to treat chronic hepatitis C virus infection.

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 the hepatitis C virus have no symptoms of the disease until liver damage becomes apparent, which may take several years. Most of these people then go on to develop chronic hepatitis C. Some will also 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 or liver cancer. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with the hepatitis C virus.

Olysio is a protease inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. It is to be used as a component of a combination antiviral treatment regimen. In clinical studies, Olysio was evaluated in combination with peginterferon-alfa and ribavirin, two drugs also used to treat hepatitis C

virus infection. Olysio is intended for adults with compensated liver disease (a diseased liver that is still functioning), including cirrhosis, who have not received treatment for their infection (treatment naïve) or for whom previous treatment has not been effective (treatment experienced).

“Olysio is the third FDA-approved protease inhibitor to treat chronic hepatitis C virus infection, and provides health professionals and patients with a new, effective treatment for this serious disease,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research.

In 2011, the FDA approved Victrelis (boceprevir) and Incivek (telaprevir) for the treatment of hepatitis C. Olysio was reviewed under the FDA’s priority review program, which provides for an expedited review of drugs that, if approved, would provide safe and effective therapy when no satisfactory alternative therapy exists, or offer significant improvement compared to available therapies.

The safety and effectiveness of Olysio were evaluated in five clinical studies of 2,026 treatment-naïve and treatment-experienced participants randomly assigned to receive Olysio plus peginterferon-alfa and ribavirin or placebo plus peginterferon-alfa and ribavirin. The studies were designed to measure whether a participant’s hepatitis C virus was no longer detected in the blood at least 12 weeks after finishing treatment (sustained virologic response), suggesting a participant’s infection had been cured.

Results showed 80 percent of treatment-naïve participants given Olysio plus peginterferon-alfa and ribavirin achieved sustained virologic response, compared to 50 percent of participants receiving peginterferon-alfa and ribavirin alone. In one of the studies with treatment-experienced participants whose infection returned (prior relapsers), 79 percent receiving Olysio plus peginterferon-alfa and ribavirin achieved sustained virologic response compared to 37 percent of participants receiving peginterferon-alfa and ribavirin alone.

Another study examined Olysio’s safety and effectiveness in treatment-experienced participants, including prior relapsers, those who partially responded to prior therapy (partial responders) and those who did not respond to prior therapy (null responders). Adding Olysio improved response rates in each of these subgroups compared to peginterferon-alfa and ribavirin alone.

A reduction in Olysio’s effectiveness was observed in participants infected with the genotype 1a hepatitis C virus with an NS3 Q80K polymorphism, a strain of the hepatitis C virus commonly found in the United States. Olysio’s drug label includes a recommendation to screen for the presence of the strain prior to beginning therapy and to consider alternative therapy if the strain is detected.

The most common side effects reported in clinical study participants treated with Olysio in combination with peginterferon-alfa and ribavirin were rash (including photosensitivity), itching (pruritis) and nausea. Serious photosensitivity reactions resulting in hospitalization were reported. Patients will be advised to limit sun exposure and to use sun protective measures during treatment with Olysio in combination with peginterferon alfa and ribavirin. Olysio should not be used alone to treat chronic hepatitis C infection.

Olysio is marketed by Janssen Pharmaceuticals, based in Raritan, N.J. Victrelis is marketed by Whitehouse Station, N.J.-based Merck, and Incivek is marketed by Cambridge, Mass.-based Vertex Pharmaceuticals.

For more information:

[FDA: Approved Drugs: Questions and Answers](#)

[FDA: Drug Innovation](#) 

[FDA: What's New at FDA in Hepatitis](#)

[CDC: Hepatitis C Information for the Public](#) 