HEALTH

FDA Approves Gilead's Hepatitis C Drug

Sovaldi Shown to Cure More Patients in Less Time

By JONATHAN D. ROCKOFF and JOSEPH C. WALKER

Updated Dec. 6, 2013 6:53 p.m. ET

The U.S. Food and Drug Administration approved on Friday a new treatment for hepatitis C infections that promises to cure more patients in a fraction of the time required by current therapies while giving Gilead Sciences Inc. (GILD +0.54%) a potential blockbuster.

The drug, Sovaldi, is the first pill approved to treat some types of hepatitis C without interferon, an injected drug that can cause flulike symptoms.

The hepatitis C virus is most often transmitted through the sharing of needles and other equipment used to inject drugs. More than three million Americans and about 170 million world-wide are infected with the disease, which if untreated can lead to liver damage and death. The disease is the leading cause of liver transplants in many countries.

The current treatment regimen of three drugs can require close to a year of injections which often cause side effects, and which don't work in a large number of patients, according to liver doctors.

In clinical testing, Sovaldi was shown to cure about 90 % of patients when taken in combination with at least one other drug for 12 or 24 weeks, depending on the form of the disease they had. "It's a monstrous advance," said Douglas Dieterich, a liver specialist at Mount Sinai's Icahn School of Medicine in New York City who participated in the Sovaldi clinical testing.

In clinical trials, the most commonly used regimens cured 60% or more of patients, but doctors say that in medical practice, the regimens are curing less than half of patients.

Analysts estimate Sovaldi's annual sales could surpass $7 billion in several years, making it one of the biggest selling drugs in the world. But Gilead will face rivals, including AbbVie Inc. (ABBV +3.72%) and Johnson & Johnson, (JNJ +0.57%) which are also developing new hepatitis pills. Last month, the FDA approved a new hepatitis C pill from J&J called Olysio.

Many patients have been holding off on treatment in anticipation of the drug's approval. "It is the kind of product that can launch to very high numbers," Gilead President John Milligan said in an interview. He said Gilead was prepared for "a mad rush."

Sovaldi will cost about $84,000 for patients with the most common form of hepatitis C taking a pill a day for 12 weeks, Gilead said. Dr. Milligan said he doesn't expect insurers will try to stymie use of the drug, although he anticipates that health plans will ask doctors to justify their prescription in writing before reimbursing, a process called prior authorization.

The drug is a so-called nucleotide analogue, or nuc, that blocks a protein needed by the hepatitis C virus to replicate.

It was the crown jewel of Gilead's $11 billion purchase of Pharmasset in 2012. Gilead, of Foster City, Calif., paid a high, 90% premium to beat out rivals, but the drug gives the company an entree into a multibillion-dollar market that is rapidly growing as patients learn they have the disease and opt for treatments that are getting easier to take.

Gilead is known for its treatments for HIV/AIDS, but it has been looking to diversify its portfolio.

Many doctors and patients have been waiting for new hepatitis C drugs that can be taken without interferon injections.

For the most common type of hepatitis C, known as Genotype 1, the FDA approved Sovaldi for use in combination with interferon and a pill called ribavirin. Gilead is still studying Sovaldi's use without interferon in Genotype 1 patients. Dr. Milligan said the results of these clinical trials will become available starting later this year.

For two less common types of the virus, known as Genotypes 2 and 3, the FDA approved Sovaldi's use alongside ribavirin and without interferon.

The FDA also approved Sovaldi's use in patients who are either awaiting a liver transplant or received one; these patients are vulnerable to fast-moving infections.

Write to Jonathan D. Rockoff at jonathan.rockoff@wsj.com and Joseph Walker at joseph.walker@wsj.com

Justin Hamlin

Great! Expected, but definitely good news!

Now if we can just get them to ban tattoos, we can make some headway against this disease.

Dec 6, 2013

Subscribe / Login Back to Top

Customer Service
Customer Center
New! Live Help
Contact Us
WSJ Weekend
Contact Directory
Corrections

Policy
Privacy Policy
Cookie Policy
Data Policy
Copyright Policy
Subscriber Agreement & Terms of Use
Your Ad Choices

Ads
Advertise
Place a Classified Ad
Sell Your Home
Sell Your Business
Commercial Real Estate Ads
Recruitment & Career Ads
Franchising
Advertise Locally

Tools & Features
Apps
Emails & Alerts
Graphics & Photos
Columns
Topics
Guides
Portfolio
Old Portfolio

More
Register for Free
Reprints
Content Partnerships
Conferences
SafeHouse
Mobile Site
News Archive

Jobs at WSJ