BUSINESS DAY

F.D.A. Approves Pill to Treat Hepatitis C

By ANDREW POLLACK DEC. 6, 2013

Tom Espinosa, a building inspector in Oakland, Calif, has tried the existing drugs for hepatitis C and some experimental ones, without success. Thor Swift for The New York Times

The Food and Drug Administration on Friday approved a pill that is expected to make the treatment of hepatitis C less onerous, shorter in duration and more effective.

The drug, Sovaldi, from Gilead Sciences, will allow at least some patients infected with the liver-destroying virus to be treated with pills only, doing away with weekly injections of a drug that can have debilitating side effects.

"Today's approval represents a significant shift in the treatment paradigm for some patients with chronic hepatitis C," said Dr. Edward Cox, director of the office of antimicrobial products at the F.D.A.

But the greater convenience and effectiveness comes at a price.

Gilead said the wholesale cost of Sovaldi, which is known generically as sofosbuvir, would be $28,000 for four weeks — or $1,000 per daily pill. That translates to $84,000 for the 12 weeks of treatment recommended for most patients, and $168,000 for the 24 weeks needed for a hard-to-treat strain of the virus.

"This is unbearable to the health care system and it is completely unjustified," said Michael Weinstein, president of the AIDS Healthcare Foundation, which runs treatment clinics in the United States and

abroad and has previously clashed with Gilead on the price of its drugs for H.I.V.

The Initiative for Medicines, Access and Knowledge, a legal group based in New York, recently filed a motion to try to block patenting of the drug in India. If it succeeds, generic manufacturers in India will be able to manufacture cheap copies of the drug for distribution there and in some other developing countries.

Gilead said the price was fair given the drug's higher cure rate and that the total cost for the 12-week regimen was "consistent with, and in some cases lower than" the cost of some other regimens for hepatitis C. It said it would offer financial assistance to some patients.

Some three million to four million Americans, many of them in middle age, are believed to have a chronic hepatitis C infection, though many do not know it. The virus slowly damages the liver, leading to cirrhosis and in some cases to liver cancer. But it often takes decades before any damage is noticeable, and many people never experience a problem.

Globally, at least 150 million people have hepatitis C.

Sovaldi was obtained by Gilead in an $11 billion acquisition of a smaller company, Pharmasset. The high purchase price raised eyebrows when the deal was announced in 2011, but it has vaulted Gilead to the lead in a heated race to develop all-oral treatments for hepatitis C.

AbbVie, Bristol-Myers Squibb, Merck, Johnson & Johnson and others are also developing all-oral regimens for hepatitis C that could reach the market in the next one to three years.

Some analysts expect Sovaldi to become one of the best-selling drugs in the world. Matthew Roden, an analyst at UBS, said in a note on Friday that annual sales could surpass the record of around $13 billion achieved by Lipitor, from Pfizer, in its peak year.

Sales are expected to be strong from the start, because many patients, on the advice of their doctors, have been putting off starting treatment until Sovaldi became available.

One person waiting is Tom Espinosa, a building inspector in Oakland, Calif. He has tried the existing drugs and some experimental ones, without success, so this drug might be his last chance. His liver is already deteriorating badly, but he is hoping the new drug will stop the progression.

Other companies are trying to get at least a little piece of Gilead's bounty. Merck, Roche and Idenix Pharmaceuticals are separately claiming that Sovaldi infringes on patents they hold. Should any of those companies prevail, it is expected they will receive royalties, not keep the drug off the market.

Until two years ago, the treatment for hepatitis C consisted of 24 to 48 weeks of weekly injections of interferon alfa combined with daily tablets of ribavirin. Neither drug was developed specifically to treat hepatitis C. The combination cured about half of patients, but the side effects, including flulike symptoms, anemia and depression, could be severe.

Sovaldi and newer drugs work by inhibiting enzymes produced by the hepatitis C virus. This is the same approach that was used to make drugs for H.I.V. As in H.I.V., two or more of these drugs for hepatitis C

must be used together, to prevent the virus from developing resistance.

Cure rates with Sovaldi, a polymerase inhibitor, are over 80 percent, though success and treatment duration depend in part on which strain, or genotype, of the virus is involved.

For genotypes 2 and 3, which together account for about 20 to 25 percent of cases in the United States, Sovaldi's label recommends the drug be used with ribavirin. This will constitute the first all-oral, interferon-free treatment for hepatitis C. Genotype 2 will require 12 weeks of treatment and genotype 3 will need 24 weeks.

For genotype 1, which accounts for more than 70 percent of American cases, Sovaldi is supposed to be used with injected interferon and ribavirin. But the treatment is for only 12 weeks instead of 24 or 48, and the cure rate is about 90 percent for newly treated patients.

The label, however, says that genotype 1 patients who are ineligible for interferon can be treated for 24 weeks with Sovaldi and ribavirin. Wall Street analysts had not been expecting an all-oral regimen to be endorsed for genotype 1 patients.

The side effects seem mild, though the clinical trials to date have not been able to distinguish the effects of Sovaldi from the drugs it was taken with.

Ribavirin requires several pills taken more than once a day. Gilead hopes to combine Sovaldi with another drug it is developing into a single pill that can be taken once a day and cure most cases of genotype 1.

Results of clinical trials testing how that combination pill works are expected in the coming weeks. If all goes well, that drug could get to market by the end of next year.

A version of this article appears in print on December 7, 2013, on page B1 of the New York edition with the headline: New Hope In Hepatitis As F.D.A. Allows Pill. Order Reprints | Today's Paper | Subscribe

NEWS

World

U.S.

Politics

New York

Business

Technology

Science

Health

Sports

Education

Obituaries

Today's Paper

Corrections

OPINION

Today's Opinion

Op-Ed Columnists

Editorials

Contributing Writers

Op-Ed Contributors

Opinionator

Letters

Sunday Review

Taking Note

Room for Debate

Public Editor

Video: Opinion

ARTS

Today's Arts

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.