US approves breakthrough hepatitis C drug (Update)

6 December 2013, by Matthew Perrone

U.S. health officials have approved a highly anticipated hepatitis C drug from Gilead Sciences Inc. that is expected to offer a faster, more palatable cure to millions of people infected with the liver-destroying virus.

The Food and Drug Administration said Friday it approved the pill Sovaldi in combination with older drugs to treat the main forms of hepatitis C that affect U.S. patients.

Current treatments for hepatitis C can take up to a year of therapy and involve weekly injections of a drug that causes flu-like side effects. That approach only cures about three out of four patients. Sovaldi is a daily pill that in clinical trials cured roughly 90 percent of patients in just 12 weeks, when combined with the older drug cocktail.

Between 3 million and 4 million Americans are estimated to carry the blood-borne virus, though most do not even know they are infected. Others have tested positive but are waiting for more effective treatments to become available. Hepatitis C symptoms may not appear until two or three decades after infection, though the virus can cause liver failure, cirrhosis and cancer if left untreated.

Dr. Donald Jensen of the University of Chicago said he's optimistic that new drugs like Sovaldi will increase treatment of the disease, which is blamed for 15,000 U.S. deaths per year.

"I'm hoping that these new, less toxic therapies will drive more people to get tested and more primary care physicians to test their patients, knowing that the therapy is going to be more effective and easier," said Jensen, who directs the university's center for liver diseases.

Gilead Sciences Inc., based in Foster City, California, is one of a half-dozen companies battling over the market more effective treatments for hepatitis C. Many industry analysts expect Sovaldi to quickly dominate the field with sales of over $1.6 billion next year.

Gilead said Friday it would price the drug at $84,000 for one 12-week supply. Patients with a less common subtype of the disease may need to take the drug for 24 weeks, raising the cost to $168,000 for one course of treatment. Drugs already on the market run between $25,000 and $50,000 for a course of treatment.

The approval comes as the U.S. government urges all baby boomers to get tested for the disease. People born between 1945 and 1965 are five times more likely than other age groups to have hepatitis C, with many having contracted the virus by sharing needles or having sex with an infected person in their youth.

For most of the last 20 years, the standard treatment for hepatitis C involved a grueling one-year regimen of pills and injections that caused nausea, fever and headaches and cured fewer than half of patients. Then in 2011, the FDA approved two new drugs from Merck and Vertex Pharmaceuticals that raised the cure rate to about 65 and 75 percent, respectively, when combined with the older treatments.

Gilead's once-a-day pill pushes the cure rate much higher.

In a company study of patients with the most common forms of the disease, 90 percent of participants had undetectable levels of the virus after 12 weeks taking Sovaldi plus the older pill-and-injection cocktail. The forms of the disease studied in the trial account for more than 75 percent of hepatitis C cases in the U.S.

Gilead's drug is less effective in treating a less common form of the disease that accounts for about 10 percent of U.S. cases. Patients with that

strain of the virus had to take the drug for 24 weeks, twice the normal duration, to achieve an 85 percent cure rate.

But even for those patients, experts say Gilead's drug represents an important step forward.

The company's approach for those patients—Sovaldi plus another antiviral pill—is the first all-oral regimen to treat hepatitis C, eliminating the need for interferon, the injectable medication that is the backbone of standard treatment and causes diarrhea and other taxing side effects.

Next year Gilead expects to file for FDA approval of a combination pill containing sofosbuvir and ledipasvir, another antiviral drug, that could become the first all-oral regimen for the most common form of hepatitis C, long viewed as the holy grail of treatments by drugmakers. Similar development efforts are underway from competitors like Abbott Laboratories, Bristol-Myers Squibb Co., Vertex Pharmaceuticals and others.