US panel backs Gilead Sciences' hepatitis C drug (Update)

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U.S. Food and Drug Administration advisers on Friday unanimously voted in favor of a highly anticipated hepatitis C drug from Gilead Sciences that holds promise for millions infected with the liver-destroying virus.

All 15 members of the FDA's panel of virus experts voted to recommend approval of Gilead's pill, sofosbuvir, to treat several forms of hepatitis C. The FDA is not required to follow the group's advice, though it often does.

More than 3 million people in the U.S. have hepatitis C, a blood-borne disease that causes liver damage and is blamed for 15,000 deaths annually.

Current treatments can take up to a year of therapy and only cure about three out of four patients. Gilead's daily pill can cure up to 90 percent of patients infected with the most common form of the virus in just 12 weeks.

Gilead Sciences Inc. is one of a half-dozen companies racing to develop more effective treatments for hepatitis C. Many industry analysts predict the company's drug will eventually outperform its competitors. The FDA is expected to make a decision on the drug by Dec. 8.

Drugmakers see hepatitis treatments as a potentially lucrative market because the disease is expected to grow into a major public health problem as the baby-boom generation ages. People born between 1945 and 1965 are five times more likely to have the virus than people of other age groups, and the Centers for Disease Control and Prevention is urging all baby boomers to get tested for the disease. Many 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 has involved a grueling one-year regimen of pills and injections that causes flu-like symptoms and cures 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 appears to push the cure rate even higher.

In a company study of patients with the most common form of the disease, 90 percent of participants had undetectable levels of the virus after 12 weeks of treatment. The form of the disease studied in the trial accounts for about 75 percent of hepatitis C cases in the U.S.

Gilead's drug is less effective in treating two less common forms of the disease that account for about 25 percent of cases in the U.S. Among those patients, sofosbuvir cured about 67 percent of patients who had not previously taken other hepatitis C drugs.

But even for those patients, the FDA says Gilead's drug represents an important step forward.

The company's approach uses only pill-based medications—sofosbuvir and another antiviral drug—while excluding interferon, the injectable medication that is the backbone of standard treatment but causes nausea, diarrhea and other unpleasant side effects.

For patients with the less common subtypes of the disease, Gilead's approach provides the first all-oral approach to treating the disease, a goal long sought by drugmakers.