# FDA Approves Merck's New Hepatitis C Treatment

Zepatier will compete with expensive drugs from Gilead and AbbVie

By Peter Loftus, Wall Street Journal
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The U.S. Food and Drug Administration approved Merck & Co.'s new treatment for hepatitis C, the latest entrant in a booming market for drugs for the viral infection—a market now dominated by Gilead Sciences Inc.

Merck's treatment, Zepatier, is a once-daily, single-tablet combination of two drugs, grazoprevir and elbasvir. It is approved for patients infected with the most common type of hepatitis C in the U.S., known as genotype 1, and a less common type, genotype 4.

Merck's treatment will compete with expensive drugs from Gilead and AbbVie Inc.

Gilead's Sovaldi and Harvoni had combined sales of $14.2 billion for the first nine months of 2015, helped by high price tags—about $84,000 for a typical course of Sovaldi and $94,500 for Harvoni.

Gilead has provided rebates and discounts that lower the net price, but many insurers and government health programs have restricted use of Gilead's drugs in an effort to contain costs.

AbbVie was the first to challenge Gilead by launching of Viekira Pak in late 2014. But it hasn't taken much of Gilead's market share; Viekira sales were $1.1 billion for the first nine months of 2015. Viekira costs about $83,000 a patient for a standard course.

The new drug has a list price of $54,600 for a 12-week regimen, which Merck said is in the range of net prices for other competing drugs, after discounts.

Merck said it chose that price after considering that the majority of patients with chronic hepatitis C haven't been treated, in some cases due to cost constraints. The company said it plans to seek broad coverage of the drug across commercial and public insurers.

Bernstein analyst Tim Anderson estimates Merck can capture an 11% share of the hepatitis C market in 2017 with its new product, which would amount to about $2.2 billion in sales.

Clinical studies showed that 12 or 16 weeks of treatment with Merck's therapy reduced the virus to undetectable levels, which doctors say amounts to a cure, in more than 94% of patients, the FDA said in a news release Thursday.

An estimated 3.5 million Americans have chronic hepatitis C infection, according to the U.S. Centers for Disease Control and Prevention. The virus is spread through contact with the blood of an infected person, including by sharing needles. If left untreated it can lead to serious liver disease over time.

Merck also is developing a triple-drug combination that could be used to treat additional subtypes of hepatitis C, potentially in shorter durations. That could hit the market in 2018, Bernstein estimates.

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