

Gilead to license generic version of Sovaldi (Update)

September 15 2014, by Tom Murphy



This undated file photo provided by Gilead Sciences shows the hepatitis C medication Sovaldi. Gilead Sciences says it has reached a deal with several generic drugmakers to produce cheaper versions of its popular, expensive hepatitis C drug Sovaldi for use in developing countries. (AP Photo/Courtesy of Gilead Sciences, File)

Gilead Sciences has reached a deal with several generic drugmakers to produce a cheaper version of its popular, \$1,000-per-pill hepatitis C drug Sovaldi for use in developing countries.

Gilead said Monday that the India-based companies will make a generic version of Sovaldi, also known as sofosbuvir, and another investigational drug for distribution in 91 countries.

Sovaldi hit the U.S. market late last year and has been hailed as a breakthrough treatment. But Gilead has taken criticism over its cost, which can amount to \$84,000 for a full course of treatment.

Hepatitis C is a liver-destroying virus carried by an estimated 3 million to 4 million Americans. Until late last year, the standard treatments required taking up to 12 pills a day, alongside antiviral drug injections that can cause flu-like symptoms. That approach cured only about 75 percent of patients.

U.S. regulators approved Sovaldi last December, and it was quickly embraced by physicians based on its once-a-day pill regimen and increased effectiveness, curing between 80 percent and 90 percent of patients.

The drug is expected to generate several billion dollars in sales this year alone for Foster City, California-based Gilead. The drugmaker has said that Sovaldi's costs for payers will be recouped over the long term as fewer patients suffer liver failure and transplant complications. It also has said it offers financial assistance to patients who cannot afford the drug and related insurance costs.

Even so, Congressional leaders have criticized the drug's pricing, and some state-based Medicaid plans are scaling back access to the treatment.



This Thursday, March 12, 2009, file photo, shows Gilad Sciences Inc. headquarters in Foster City, Calif. Gilad Sciences says it has reached a deal with several generic drugmakers to produce cheaper versions of its popular, expensive hepatitis C drug Sovaldi for use in developing countries. (AP Photo/Paul Sakuma, File)

Gilad Sciences Inc. did not detail the price on the generic version of Sovaldi to be sold in developing markets. It said countries covered by the agreement account for more than 100 million people living with hepatitis C. That represents more than half of the total global, infected population.

"These agreements are essential to advancing the goals of our humanitarian program in these countries," Gilad Executive Vice President Gregg H. Alton said in a statement from the company.

One of the generic drugmakers involved, Mylan Inc., said the deal will allow its subsidiary to offer access to "a more affordable version" of the drug to help meet the unmet medical needs of millions of patients.

The seven India-based companies—a list that also includes Ranbaxy Laboratories Ltd. and Cadila Healthcare Ltd.—will pay sales royalties to Gilead and receive a technology transfer that helps them start production quickly.

Gilead's agreement also covers another treatment, a single tablet combination of sofosbuvir and another antiviral drug, ledipasvir. Regulators in both the United States and Europe are currently reviewing that combination.

Shares of Gilead dropped \$2.83, or 2.7 percent, to \$100.83 in morning trading Monday. But the stock had already climbed 38 percent so far this year, as of Friday's close.

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