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Bristol-Myers: FDA blocks hepatitis C drug for now

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U.S. regulators have declined to approve Bristol-Myers Squibb's daclatasvir as part of a combination hepatitis C treatment with another antiviral drug called asunaprevir.

The company said Wednesday that data it submitted to the Food and Drug Administration to win approval of daclatasvir focused on that drug's use with asunaprevir.

However, the New York-based drugmaker in October withdrew its application for approval of asunaprevir, citing "the rapidly evolving hepatitis C ... treatment landscape in the U.S." The FDA then requested more data on the effects of daclatasvir in combination with other drugs for treating hepatitis C, currently one of the hottest areas in drug research.

Bristol-Myers Squibb Co., which has a strong focus on drugs for viruses, cancer, heart disease and gene-related disorders, said it's now discussing with the FDA the scope of additional data needed.

Meanwhile, the company said it is committed to further testing of daclatasvir, part of a drug class called NS5A inhibitors. Multiple studies of the drug are being conducted around the world, including ones on patients who have had or are facing a liver transplant, and on patients who also have HIV.

"Despite the recent advances in the treatment of hepatitis C there remain

significant areas of unmet high need," Francis Cuss, the company's head of research and development, said in a statement. "We will continue to collaborate with the FDA to bring daclatasvir to patients in the U.S. as quickly as possible."

Daclatasvir was approved in July in Japan for use in patients with one strain of the virus that's common in that country. It was approved in August in Europe for use along with other medicines in adult patients who have one of four strains of hepatitis C.

Multiple drugmakers have been trying to grab a piece of the hepatitis C drug market, given the millions of patients needing treatment for the liver-destroying virus and the ultra-high prices new drugs in the category are commanding.

Those include market leader Gilead Science Inc.'s Sovaldi and Harvoni. Their price tags—$1,125-per-pill for the newest one, Harvoni—have drawn criticism, but they spare patients the decades-old combination of months and months of antiviral pills and shots that cause flu-like side effects, yet barely cure half of patients.

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