# FDA says Merck drug successfully fights hepatitis

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Federal health officials said Monday a highly-anticipated drug to treat hepatitis C made by Merck appears to cure more patients in less time than established drugs that have been used for 20 years. But the agency has questions about how the drug should be combined with older medicines for the maximum effect.

The Food and Drug Administration posted its review of Merck & Co. Inc.'s boceprevir ahead of a public meeting Wednesday to consider whether to approve the medication. The meeting brings to a head more than 15 years of research to find a better therapy for a virus that infects about 3.2 million people in the U.S.

On Thursday Vertex Pharmaceuticals Inc. will bring a similar drug before the FDA's panel. Both drugs are considered breakthrough medications with the potential to rack up over a billion dollars in annual sales.

Both new drugs works by blocking the enzyme protease, which allows the hepatitis virus to reproduce. The tablet-based drugs differ from the older medications - ribavirin pills and interferon-alpha injections - that are designed to boost the immune system.

Like HIV drugs, the new drugs from Merck and Vertex will be prescribed as part of a cocktail with the two older drugs to help lower viral levels.

FDA scientists said the two studies submitted by Merck achieved their goal of showing patients had undetectable virus levels six months after completing treatment with boceprevir.

The current two-drug treatment for the virus cures only about 40 percent of people and causes side effects like nausea, fatigue and vomiting.

Merck & Co.'s boceprevir has been shown to boost cure rates as high as 75 percent when combined with the older drugs. Merck's studies were designed to show that the drug combination could cure most patients in six months - cutting the standard treatment time in half and reducing exposure to negative side effects from the older drugs.

But the FDA said in its review that some late-responding patients may need to take the drugs for eight months to eliminate the virus. The agency also suggested that other groups of patients should receive longer therapy, including African Americans, who did not respond as well as other racial groups. African Americans make up more than 20 percent of hepatitis C carriers in the U.S., according to the Centers for Disease Control and Prevention.

The FDA said the primary side effect with Merck's drug was anemia, or weakness and fatigue caused by a lack of oxygen-carrying red blood cells.

An outside panel of viral experts will vote on the safety and efficacy of the drug Wednesday. The FDA often follows the guidance of its panels, though it is not required to do so.

Hepatitis C is a major cause of liver transplants, and it kills about 12,000 U.S. patients a year, a number expected to triple by 2030 as baby boomers succumb to the disease.

The disease is often associated with users of illegal injectable drugs like heroin, though it could also be picked up from blood transfusions before 1992, when testing of the blood supply began.

Most people with hepatitis C don't even know they have the virus until years later when liver damage has occurred, which can cause abdominal pain, fatigue, itching and dark urine.

"The liver has a huge capacity of going about its business until it fails," said Dr. Eliav Barr, Merck's vice president for infectious diseases. "So you have chronic damage that gets worse and worse but you yourself can't tell until a fair bit of damage is done."

Whitehouse Station, N.J.-based Merck was the first company to market a drug for hepatitis C in 1991 when it launched interferon-alpha. The company began developing boceprevir soon thereafter.