FDA panel endorses Vertex hepatitis C drug

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(AP) -- Federal health experts say an experimental hepatitis C drug from Vertex Pharmaceuticals Inc. is a significant step forward in treating the virus, despite a high rate of rashes among patients taking the tablet.

The Food and Drug Administration's panel of experts voted unanimously, 18-0, that telaprevir is a safe and effective treatment for hepatitis C. The agency generally follows the recommendations of its panels. A final decision is expected by May 23.

Panelists commended the Massachusetts-based drugmaker for developing a drug that appears to raise the cure rate for hepatitis C from roughly 40 percent with current therapies to nearly 80 percent.

The most significant side effect with the drug was a rash, which affected more than half of all patients. Panelists said the issue could be addressed by educating patients and doctors through materials and a toll-free hotline.

The FDA convened its two-day meeting to review two new drugs that block the enzyme which allows the hepatitis virus to reproduce. On Wednesday the same panel unanimously recommended approval for Merck's drug boceprevir. Both Merck and Vertex have spent more than 15 years developing more effective therapies for the sometimes-fatal virus that infects about 3.2 million people in the U.S., or about 1.5 percent of the population.

Like HIV drugs, the new drugs from Merck and Vertex will be

prescribed as part of a cocktail with two older drugs to help lower viral levels.

Thursday's panel discussion highlighted several advantages of Vertex's drug over its Merck counterpart. The cure rate for new patients taking telaprevir ranged between 75 and 79 percent, compared with 60 and 65 percent for boceprevir. Additionally, most panelists said that patients who had previously failed treatment for the virus could likely achieve a cure within six months - half the time needed with older drugs - when taking telaprevir. When reviewing Merck's drug Wednesday, the panel said those patients would likely need a full year's worth of treatment.

Elsewhere in Thursday's discussion, Vertex executives said they were studying a twice-daily regimen of telaprevir. The drugs presented this week by both Vertex and Merck require patients to take three tablets a day.

Vertex Pharmaceuticals' telaprevir is expected to garner sales of up to $3 billion annually. That's more than the $700 to $800 million expected for Merck's boceprevir, based on analyst estimates.

Vertex is based in Cambridge, Mass., and was founded in 1989 by a former Merck & Co. scientist. If approved, telaprevir would be the company's first commercialized product in the U.S.

Trading in publicly-traded shares of the company was placed on hold Thursday ahead of the panel vote.

Vertex holds marketing rights for North America, while Johnson & Johnson will market the drug in other parts of the world. Eli Lilly and Co. will receive an undisclosed percent of royalties because of its collaborative work on the drug between 1997 and 2002.

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 can 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 after liver damage has occurred, which can cause abdominal pain, fatigue, itching and dark urine.

Current treatment for hepatitis C runs about $30,000. Neither Vertex nor Merck have discussed pricing for their drugs.