

## **Merck Gets FDA Approval For New HIV Treatment**

Wall St Jnl

By JENNIFER CORBETT DOOREN

October 12, 2007 5:50 p.m.

WASHINGTON -- A U.S. Food and Drug Administration panel Friday approved a new type of HIV drug from Merck & Co., a company spokeswoman said.

The drug, known by the brand name Isentress, was approved for use in patients who have failed treatment with other HIV drugs.

Isentress was approved as part of the FDA's accelerated-approval mechanism, which is aimed at getting life-saving treatments to market faster by allowing companies to submit less clinical data than usually required. Companies obtaining accelerated approval must keep studying drugs after they are on the market to gain full approval.

Isentress is designed to target one of three enzymes needed by HIV to reproduce. Current drugs on the market attack the other two enzymes, reverse transcriptase and protease. If approved, Isentress would be the only drug to target the third enzyme, known as integrase. Amy Rose, a Merck spokeswoman, said treatment with Isentress would cost about \$9,850 a year.

Patients with HIV typically are treated with a "cocktail" of two or three types of drugs. However, over time, most HIV viruses mutate and stop responding to certain drugs, creating the need for new ones. Isentress is meant to be used in combination with other HIV drugs.

### **Merck's Isentress HIV Medicine Approved by U.S. FDA**

By Shannon Pettypiece and Rob Waters

Oct. 12 (Bloomberg) -- Merck & Co.'s HIV drug Isentress was approved by U.S. regulators, offering a new option for the thousands of AIDS patients whose virus has developed resistance to other medicines.

Adding Isentress to drugs already on the market can slow the advance of HIV, the virus that causes AIDS, the Food and Drug Administration said today in a statement announcing the approval.

Isentress, Merck's first HIV therapy since 1999, may generate as much as \$1 billion in annual sales worldwide, analysts said. About 150,000 Americans taking HIV medicines have a hard-to-treat form of the virus and may benefit from the new drug, said Robert Rode, Merck's vice president for infectious disease and hospital products.

"This is the first of a class of agents that should show growth for many years," said Robert Hazlett, an analyst with BMO Capital Markets in New York, in a telephone interview. "We expect this drug to be widely considered in conjunction with other therapies for patients where existing therapies are failing."

Hazlett said he expects sales of \$400 million next year, rising to \$950 million in 2010.

Merck rose 47 cents to \$53.51 at 4 p.m. in New York Stock Exchange composite trading and have risen 23 percent this year.

Analysts had expected the FDA to approve Isentress after a panel of advisers recommended in August that the agency do so.

## \$27 a Day

ISENTRESS, taken twice daily, will cost \$27 a day, or almost \$10,000 a year, similar to AIDS drugs developed in recent years, Merck spokeswoman Amy Rose said in a phone interview.

"We're pleased that the FDA recognizes the clinical profile of ISENTRESS and the benefits it will bring to patients and physicians who are struggling to keep this disease under control," Rose said.

The new medicine uses a different method from other AIDS drugs to block the HIV virus from inserting its genetic material into human DNA, allowing replication. ISENTRESS targets an enzyme called integrase that HIV uses to accomplish the task. Studies have shown the medicine helps patients with resistant strains of HIV when used in combination with other drugs.

### **Pfizer's Selzentry**

This is the second new form of HIV medicine to come on the market this year. Pfizer Inc., the world's biggest drugmaker, won FDA approval in August for Selzentry, the first drug to block a chemical portal the HIV virus uses to enter cells.

Merck's studies found that ISENTRESS reduced the virus to less than could be detected after four months in 61 to 62 percent of patients who got the medicine in combination with other anti-HIV drugs. That compares with 33 to 36 percent of those who got a placebo along with their most effective therapies.

Side effects included rashes, diarrhea, nausea and headaches. Although more patients taking ISENTRESS developed cancers, the drug didn't appear to pose an increased risk, according to regulatory advisers.

Thirty AIDS treatments are approved in the U.S., according to the FDA. AIDS patients take so-called cocktails of anti-HIV drugs each day, typically three or more medicines. The drugs can't cure HIV, and people with the infections still have the virus in their bodies. Eventually, HIV develops resistance to treatment. Once a drug fails, the combination loses effectiveness.

### **Further Studies**

Merck is also studying the drug in children and patients who haven't been on any other HIV medicines.

All HIV drugs are designed to interfere with a part of the HIV life cycle of infection and replication. HIV attacks and destroys white blood cells, which the immune system uses to fend off invasions from viruses and bacteria.

GlaxoSmithKline Plc's Lexiva and Pfizer's Viracept interfere with the action of the protease enzyme, while drugs such as Gilead Sciences Inc.'s Viread inactivate another viral enzyme, reverse transcriptase.

A third class of medications, called entry inhibitors, works by blocking HIV from entering target white cells. These drugs include Roche Holding AG and Trimeris Inc.'s Fuzeon, which reached the market in 2003.

Merck sold the U.S. rights to its previous AIDS drug, Stocrin, to Bristol-Myers Squibb Co., which markets it under the name Sustiva. Merck continues to market Stocrin outside the U.S. and sells another older AIDS drug, Crixivan.