Pfizer's SelzentryTM (Maraviroc) Tablets, Novel Treatment for HIV, Approved by FDA

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First in a New Class of Oral HIV Medicines in More Than a Decade

(BUSINESS WIRE)--Pfizer Inc announced today that the U.S. Food and Drug Administration (FDA) has approved SelzentryTM (maraviroc) tablets, the first in a new class of oral HIV medicines in more than 10 years. Selzentry blocks viral entry into white blood cells, significantly reducing viral load and increasing T-cell counts in treatment-experienced patients infected with a specific type of HIV.

“There is a profound need for new medicines to treat HIV. In the United States, thousands of patients living with HIV are running out of effective medications that can control their virus,” said Dr. Joseph Feczko, Pfizer’s chief medical officer. “The approval of Selzentry for treatment-experienced patients is a significant breakthrough, and we continue its development in a spectrum of other patients living with HIV/AIDS.”

The FDA granted accelerated approval to Selzentry for combination antiretroviral treatment of adults infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and have HIV-1 strains resistant to multiple antiretroviral agents. A diagnostic test confirms whether a patient is infected with CCR5-tropic HIV-1, which is also known as “R5 virus.”

An accelerated approval allows for earlier approval of drugs that provide a meaningful therapeutic advantage over existing treatment for serious or life-threatening diseases. This approval is based on 24-week data. Longer-term data will be required before the FDA can consider traditional approval for Selzentry.

Selzentry is the first in a class of drugs known as CCR5 antagonists, which block the CCR5 co-receptor, the virus' predominant entry route into T-cells. Selzentry stops the R5 virus on the outside surface of the cells before it enters, rather than fighting the virus inside as do all other classes of oral HIV medicines.

Selzentry is expected to be available in the U.S. by the middle of September.

Pfizer is currently submitting marketing applications around the world and recently received a positive opinion from the CHMP in the EU. Pfizer intends to commercialize the product with the name Celsentri outside of the U.S.

Pfizer has established a multi-national expanded access program (EAP), a clinical study that provides Selzentry in countries where it is not yet commercially available to patients who have limited treatment options due to resistance or intolerance to existing therapies.

Pfizer's Ongoing Commitment to HIV/AIDS

Pfizer scientists discovered Selzentry in 1997. Selzentry's clinical program initiated the first combined phase 2b/3 trial design in HIV to efficiently characterize its clinical profile and submit data to regulatory authorities as quickly as possible.

Pfizer is committed to bringing meaningful improvement to the lives of people living with HIV/AIDS and those at risk around the world. This commitment is embodied in Pfizer's products, partnerships, pipeline and philanthropy.

Current initiatives include the Southern HIV/AIDS Prevention Initiative, the building of the Infectious Disease Institute in Kampala, Uganda, the Pfizer Global Health Fellows Program and the Diflucan Partnership Program.

Most recently in April 2007, Pfizer launched ConnectHIV, a three year initiative that will provide $7.5 million in grants and capacity building to twenty community-based AIDS Service Organizations in communities of greatest need in the U.S. ConnectHIV grantee organizations were chosen based on a demonstrated commitment to comprehensive approaches to improving HIV prevention efforts in underserved populations.

Data Supporting Selzentry Approval

The FDA approval of Selzentry is based on 24-week data from the ongoing double-blind, controlled MOTIVATE clinical trials. In the MOTIVATE trials, approximately twice as many patients receiving Selzentry combined with an optimized background therapy (OBT) achieved undetectable viral load at 24 weeks compared with those receiving OBT alone.

In the trials, patients receiving Selzentry with OBT also experienced significantly greater viral load reductions and increases in CD4 cell counts compared with those receiving OBT alone.

Patients in the MOTIVATE trials were highly treatment-experienced, with 69.7% receiving Selzentry and OBT and 66% receiving OBT alone having two or fewer active drugs in their optimized background regimen.

Patients receiving Selzentry in the studies had a rate of discontinuation due to adverse events (3.8%) which was similar to the group receiving OBT plus placebo (3.8%). The most common adverse reactions (>8% incidence and greater than placebo) are cough, pyrexia (fever), upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness.

Important Safety Information

Selzentry does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

Although there was no overall increase in serious liver function test abnormalities in patients treated with Selzentry, hepatotoxicity has been reported with Selzentry use. Evidence of a systemic allergic reaction (e.g., pruritic rash, eosinophilia or elevated IgE) prior to the development of hepatotoxicity may occur. Patients with signs or symptoms of hepatitis or allergic reaction following use of Selzentry should be evaluated immediately.

The safety and efficacy of Selzentry have not been specifically studied in patients with significant underlying liver disorders. However, caution should be used when administering Selzentry to patients with pre-existing liver dysfunction or who are co-infected with viral hepatitis B or C.

In clinical studies, more cardiovascular events, including myocardial ischemia and/or infarction, were observed in patients who received Selzentry as compared to placebo. Selzentry should be used with caution in patients at increased risk for cardiovascular events.

Caution should be used when administering Selzentry in patients with a history of postural hypotension or who receive concomitant medication known to lower blood pressure. Patients should be advised that if they experience dizziness while receiving Selzentry, they should avoid driving or operating machinery.

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.

Selzentry antagonizes the CCR5 co-receptor located on some immune cells, and therefore could potentially increase the risk of developing infections and malignancy.

For full prescribing information for Selzentry, including boxed warning, or for more information on these and other Pfizer initiatives, go to www.pfizer.com.

To preview and request free broadcast-standard video about this announcement digitally or by tape please log onto www.thenewsmarket.com/pfizer.

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