



# Long-Term Data Reinforce Safety and Efficacy Profile of Pfizer's New HIV Drug Selzentry(TM) (Maraviroc)

Tuesday, September 18, 2007 - 01:30am

Selzentry Now Available Throughout the U.S. for Use in Combination Therapy for Certain Treatment-Experienced HIV Patients

"These data continue to demonstrate that Selzentry provides significant benefit to certain treatment-experienced patients,"

(BUSINESS WIRE)--Nearly three times as many patients receiving Selzentry, in addition to an optimized background regimen, achieved undetectable levels of HIV virus compared with those receiving an optimized regimen alone, according to 48 week data presented today in late-breaking sessions at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting. This newly approved CCR5 antagonist – the first new class of oral HIV medicines introduced in more than ten years – is now available throughout the U.S.

"These data continue to demonstrate that Selzentry provides significant benefit to certain treatment-experienced patients," said Dr. Jacob Lalezari, director, Quest Clinical Research and Assistant Clinical Professor of Medicine, University of California, San Francisco. "The safety and durability of response seen with Selzentry out to one year in our study is reassuring. This drug is an important new weapon for clinicians who treat HIV."

Results from the planned 48-week analysis also demonstrated that Selzentry, along with an optimized background regimen, significantly increased CD4 cells, as compared to patients receiving an optimized regimen alone. The adverse event profile observed in this analysis in patients receiving Selzentry was similar to those receiving an optimized

regimen alone. The most common adverse events reported included diarrhea, nausea, fatigue and headache.

This longer-term analysis is consistent with the pre-planned 24-week analyses that formed the basis of Selzentry's accelerated U.S. approval in August for CCR5-tropic treatment-experienced patients. The 48-week data are under review by the U.S. Food and Drug Administration (FDA) for consideration of full approval of Selzentry for these patients.

Selzentry is now available in the U.S., and Pfizer is working with private and public payors to secure coverage and reimbursement for this novel and potentially life-saving medicine. Pfizer has also recently included Selzentry as part of a robust patient-assistance program to help patients who may experience difficulties accessing this medicine. For patients who qualify, the program offers a range of services, such as benefits verification and reimbursement case management, designed to meet the unique needs of those taking specialty products.

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.

In the U.S., Selzentry is indicated 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."

The company 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 is committed to bringing meaningful improvement to the lives of people living with HIV/AIDS. 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.

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, go to [www.Selzentry.com](http://www.Selzentry.com).

For more information on Pfizer's patient assistance program, call 1-888-327-RSVP (7787) or visit the RSVP section of [www.PfizerHelpfulAnswers.com](http://www.PfizerHelpfulAnswers.com).

Pfizer Inc Shreya Prudlo, 212-733-4889 (cell) 917-743-4349