Pfizer’s Novel HIV/AIDS Treatment SELZENTRY™ Becomes the Latest Fully Approved Antiretrovial for Treatment-Experienced HIV Patients

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(BUSINESS WIRE)--The U.S. Food and Drug Administration (FDA) has granted SELZENTRY™ (maraviroc) full (traditional) approval for use in treatment-experienced adults with CCR5-tropic HIV-1 in combination with other antiretrovirals. SELZENTRY was originally granted accelerated conditional approval in August 2007 based on 24-week data from pivotal Phase 3 studies. SELZENTRY now becomes the latest fully approved treatment for HIV.

“New, effective and well-tolerated treatment options are critical for treatment-experienced persons living with HIV infection,” said W. David Hardy, MD, Chief of the Division of Infectious Diseases, Cedars-Sinai Medical Center and Associate Professor of Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA). “Selzentry, the first oral entry inhibitor, has proven to be an effective and well-tolerated treatment option for treatment-experienced patients whose HIV has become resistant to other treatments, but remains susceptible to this new class of medications.”

The full approval of SELZENTRY is based on 48-week data from the MOTIVATE (Maraviroc Plus Optimized Therapy in Viremic Antiretrovial Treatment Experienced Patients) studies. The studies compared the safety and effectiveness of SELZENTRY plus optimized background therapy to placebo plus optimized background therapy in treatment-experienced CCR5-tropic HIV-1 patients.

Accelerated conditional approval is granted to medicines that provide a meaningful therapeutic advantage over existing treatments for serious or life-threatening diseases. FDA grants full approval status once it is satisfied with longer-term safety and efficacy data. Once full approval is granted, restrictions on promotion and/or distribution that apply to conditionally approved medicines are removed.

“SELZENTRY has been on a long journey, from its initial discovery by Pfizer scientists in 2000 to this full FDA approval,” said Dr. Howard Mayer, Pfizer’s executive director, and development team leader for HIV/AIDS. “We are extremely excited with this important milestone in SELZENTRY’s lifecycle and the potential improvement it may bring to treatment-experienced people living with HIV/AIDS.”

Results at Week 48 from the MOTIVATE studies were recently published in the October 2, 2008 edition of the New England Journal of Medicine.

About SELZENTRY

SELZENTRY is part of a new class of drugs called CCR5 antagonists, providing a new approach to HIV treatment. A diagnostic test confirms whether a patient is infected with CCR5-tropic HIV-1, which is also known as “R5 virus”. SELZENTRY blocks viral entry into CD4 T-cells that express the CCR5 co-receptor, stopping the R5 virus on the outside surface of the cells before it enters, rather than fighting the virus inside the cell, as do all other classes of oral HIV medicines.

Data Supporting SELZENTRY Full Approval

The full approval is based on 48-week data which showed that a greater log reduction in viral load from baseline was seen in patients receiving SELZENTRY plus optimized background therapy, compared to those patients receiving placebo plus optimized background therapy (MOTIVATE 1 and 2 pooled data = –1.68 log10 copies and –1.84 log10 copies/mL for SELZENTRY once-daily and twice-daily, respectively, compared with –0.79 log10 copies/mL for placebo).

More than twice as many patients receiving SELZENTRY plus optimized background therapy over 48-weeks achieved undetectable viral loads (<50 copies/mL HIV RNA) compared with those receiving placebo plus optimized background therapy in treatment-experienced CCR5-tropic HIV-1-infected patients (MOTIVATE 1 and 2 pooled data = 43 percent and 46 percent for SELZENTRY once-daily and twice-daily, respectively, compared with 17 percent for placebo).

Patients treated with SELZENTRY plus optimized background therapy achieved a significantly higher increase in CD4 cells than those receiving placebo plus optimized background therapy (MOTIVATE 1 and 2 pooled data = +116 and +124 cells/mm3 for SELZENTRY once-daily and twice-daily, respectively, vs. +61 cells/mm3 for placebo).

Results analyzed at 48-weeks showed no clinically relevant differences in the safety profile between the study treatment groups and remained consistent with 24-week results. The most common adverse events included upper respiratory tract infections, cough, pyrexia, rash, and dizziness.

About Pfizer

Founded in 1849, Pfizer is the world's largest research-based pharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

Indication

SELZENTRY, in combination with other antiretroviral agents, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

This indication is based on analyses of plasma HIV-1 RNA levels in two controlled studies of SELZENTRY of 48 weeks duration. Both studies were conducted in clinically advanced, 3-class antiretroviral (NRTI, NNRTI, PI, or enfuvirtide) treatment-experienced adults with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

The following points should be considered when initiating therapy with SELZENTRY: (1) tropism testing is required for the appropriate use of SELZENTRY; (2) use of SELZENTRY is not recommended in patients with dual/mixed or CXCR4-tropic HIV-1 as efficacy was not demonstrated in a Phase 2 study of this patient group; and (3) the safety and efficacy of SELZENTRY have not been established in treatment-naive adult patients or pediatric patients.

For more information on the approved U.S. label, including a boxed warning, please see full prescribing information available at www.SELZENTRY.com.

Pfizer IncMedia:Sally Beatty, 212-733-6566sally.beatty@pfizer.comorInvestors:Suzanne Harnett, 212-733-8009suzanne.harnett@pfizer.com