

FDA Approves Novel Antiretroviral Drug

August 7, 2007 -- The U.S. Food and Drug Administration (FDA) today approved maraviroc, an antiretroviral drug for use in adult HIV patients. Maraviroc, sold under the trade name Selzentry, is the first in a new class of drugs designed to slow the advancement of HIV and received priority review by the FDA.

Maraviroc is approved for use in combination with other antiretroviral drugs for the treatment of adults with CCR5-tropic HIV-1, who have been treated with other HIV medications and who have evidence of elevated levels of HIV in their blood (viral load). Rather than fighting HIV inside white blood cells, maraviroc prevents the virus from entering uninfected cells by blocking the predominant route of entry, the CCR5 co-receptor. CCR5 is a protein on the surface of some types of immune cells. Among patients who have previously received HIV medications, approximately 50 percent to 60 percent have circulating CCR5-tropic HIV-1. "This is an important new product for many HIV-infected patients who have not responded to other treatments and have few options," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research.

The product label includes a boxed warning about liver toxicity (hepatotoxicity) and a statement in the Warnings/Precautions section about the possibility of heart attacks. The FDA's approval of maraviroc is based on safety and effectiveness data from two double-blind, placebo-controlled studies. The 1,076 clinical trial participants were selected because they still showed evidence of HIV-1 in their blood, despite treatment with other HIV medications. A blood test for CCR5 tropic HIV-1 was used during clinical trials to identify patients appropriate for

The safety and effectiveness of maraviroc have not been established in adult and pediatric patients who have never been treated with any other HIV drug. Additionally, the drug has not been tested or studied in pregnant women. The FDA recommends that HIV positive women should not breast feed, whether or not they are on antiretroviral medications.

The most common adverse events reported with maraviroc were cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness.

Maraviroc is distributed by New York-based Pfizer Inc.

Source: Food and Drug Administration

