

# Pfizer's Novel HIV/AIDS Treatment Selzentry(TM) (Maraviroc) Demonstrates Increased Efficacy Rate In Treatment-Naive HIV Patients

Sunday, October 26, 2008 - 01:46am

Results from MERIT ES Data Reanalysis Using Enhanced Sensitivity Tropism Test at 48 Weeks

[\(BUSINESS WIRE\)](#)--Patients taking Selzentry, in combination with Combivir® (zidovudine/lamivudine) and selected by an enhanced sensitivity tropism test to screen patients, experienced a 68 percent rate of virologic suppression to undetectable levels, according to the MERIT ES (Reanalysis of the MERIT Study with the Enhanced Trofile Assay) reanalysis presented at the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC™)/ 46th Annual Meeting of the Infectious Diseases Society of America (IDSA) in Washington D.C., USA.

MERIT ES is a reanalysis of 48-week efficacy and safety data from the MERIT (Maraviroc versus Efavirenz Regimens as Initial Therapy) study following retesting of screening samples using the newly launched enhanced sensitivity Trofile™ assay. This therefore represents a subset of the MERIT 48-week primary analysis population. The enhanced sensitivity test was not available at the time of the MERIT study and is the only version of Trofile currently available.

In the MERIT ES reanalysis 68 percent of patients in the Selzentry arm, and 68 percent of patients in the efavirenz arm – a current standard of care – achieved suppression of the virus to undetectable levels (less than 50 copies/ml). When the criterion of less than 400 copies/ml was used, the results were 73 percent with Selzentry, and 72 percent with efavirenz.

“The results of MERIT ES are exciting as they show that with an enhanced sensitivity tropism assay the efficacy rate of Selzentry shown in MERIT with the original Trofile assay is improved further,” said Michael Saag, Professor of Medicine and Director of the Center for AIDS Research at the University of Alabama at Birmingham, who presented the results. “These findings are important for patients and physicians and offer guidance for clinical practice with the only version of Trofile currently available.”

In the MERIT ES population, 14.2 percent of patients taking efavirenz discontinued due to adverse events compared to 4.2 percent of patients taking Selzentry. This was largely driven by a greater number of cases of CNS toxicity (13 vs. 2), rash (9 vs. 0), and tuberculosis (6 vs. 1) in the efavirenz arm versus the Selzentry arm. In MERIT ES, there were fewer discontinuations in the Selzentry arm due to lack of efficacy than the rate seen for the MERIT full study population. In MERIT ES, 9.3 percent of patients taking Selzentry discontinued due to lack of efficacy, compared to 4 percent of patients taking efavirenz.

The enhanced sensitivity Trofile assay is able to detect dual/mixed or CXCR4-tropic variants of the HIV virus when they are present in patients in 70.3 percent of the total viral population, a 30-fold improvement in sensitivity.

### **About the MERIT Study**

MERIT was a Phase 3 study designed to evaluate the antiretroviral activity of Selzentry (300 mg twice daily) compared to efavirenz (600 mg once daily), a current standard of care, in combination with Combivir (zidovudine/lamivudine) in CCR5-tropic HIV-1 infected patients who had never received antiretroviral therapy and had no evidence of resistance to any of the drugs used in the study.

In MERIT, rates of virologic suppression in patients receiving Selzentry compared to efavirenz were 70.6 percent vs. 73.1 percent for <400 copies/ml and 65.3 percent vs. 69.3 percent at <50 copies/ml. Fewer patients experienced grade 3 or 4 adverse events in the Selzentry arm than in the efavirenz arm.

At 48 weeks, the most common adverse events reported during the study in both arms were nausea, headaches, diarrhea, dizziness and fatigue. When the incidence of adverse events was adjusted for exposure to study drug, there was a higher incidence of nasopharyngitis and bronchitis in the Selzentry treatment group and a higher incidence of dizziness, diarrhea, vomiting, upper respiratory tract infection, cough, abdominal pain, rash and abnormal dreams in the efavirenz treatment group.

### **About Selzentry**

Selzentry is referred to as Celsentri® in countries outside the U.S. Discovered by Pfizer scientists in 1997, Selzentry is an oral medicine that blocks viral entry to human cells. Rather than fighting HIV inside white blood cells, Selzentry prevents the virus from entering uninfected cells by blocking its predominant entry route, the CCR5 co-receptor.

Selzentry has been approved for use in several markets around the world including the U.S. and European Union in combination with other antiretroviral medicinal products, for the treatment of experienced adult patients with only CCR5-tropic HIV-1 detectable.

### **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.

*DISCLOSURE NOTICE: The information contained in this release is as of October 26, 2008. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about a potential additional indication for Selzentry, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any supplemental drug applications that may be filed for*

*such additional indication as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such additional indication; and competitive developments.*

*A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in its reports on Form 10-Q and Form 8-K.*

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