96-Week MERIT ES Analysis Shows Efficacy Of Pfizer’s HIV/AIDS Treatment Celsentri/Selzentry (Maraviroc) In Treatment-Naïve HIV Patients; Results Consistent With 48-Week Analysis

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NEW YORK--(BUSINESS WIRE)--At 96-week follow up, data from the MERIT ES analysis show that treatment-naïve HIV patients taking Celsentri/Selzentry (maraviroc), in combination with Combivir® (zidovudine/lamivudine) experienced comparable virologic suppression to undetectable levels and significantly greater increases in CD4 T-cell count through 96-weeks, compared to patients taking efavirenz in combination with zidovudine/lamivudine. The data also show the favorable tolerability of Celsentri/Selzentry, which was associated with fewer discontinuations due to adverse events.1

The 96-week results from MERIT ES were presented today at the 5th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Cape Town, South Africa. MERIT ES is an analysis of the data from the MERIT (Maraviroc versus E favirenz Regimens as Initial Therapy) study following retesting of screening samples using the enhanced sensitivity Trofile™ assay - therefore representing a subset of the MERIT primary analysis population. This enhanced sensitivity test was not available at the time of the MERIT study and is the only version of Trofile currently available.

Results from the MERIT ES population show that, at 96 weeks, a similar number of patients taking Celsentri/Selzentry achieved undetectable viral load compared to those taking efavirenz (<50 copies/mL = 58.5 percent and 62.4 percent, respectively). Comparable results were seen based on a Time to Loss of Virologic Response* (TLOVR)

analysis (<50 copies/mL = 60.5 percent on Celsentri/Selzentry versus 60.7 percent on efavirenz). Results also show that, at the end of almost two years, a similar number of patients taking Celsentri/Selzentry remained on therapy compared to those taking efavirenz (66.9 percent and 66.0 percent, respectively).

“Durable HIV treatments are critical as they better ensure that patients remain on therapy, which can delay disease progression and help patients live considerably longer lives,” said Dr. 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 results further support maraviroc’s durability and safety profile and, therefore, offer the potential to enhance currently available treatment options for treatment-naïve HIV patients.”

For patients from the MERIT ES population with higher viral loads at screening (>100,000 copies/mL), a similar number of patients taking Celsentri/Selzentry maintained undetectable viral load compared to those taking efavirenz (56.0 percent and 56.7 percent, respectively, based on TLOVR analysis). Additionally, at Week 96 the increase in CD4 T-cell count was significantly greater with Celsentri/Selzentry than with efavirenz (median change from baseline was +212 cells/mm3 and +171 cells/mm3, respectively, a difference of 41 cells/mm3 [95 percent CI: 17, 65]).

Safety results from the full MERIT population show that, among those patients who remained on therapy (total patient years of exposure of 506 years for Celsentri/Selzentry and 507.9 years for efavirenz), less than half the number of malignancies were observed in patients taking Celsentri/Selzentry compared to those taking efavirenz (1.1 percent and 2.8 percent, respectively). There were also fewer cases of tuberculosis with Celsentri/Selzentry compared to efavirenz (0.3 percent and 2.2 percent, respectively).

At 96-weeks, similar to 48-weeks, the most common adverse events reported by patients taking Celsentri/Selzentry were nausea, headache, fatigue and dizziness. For patients taking efavirenz, nausea, headache, diarrhea, dizziness, vomiting and abnormal dreams were the most commonly reported adverse events.

Among those patients taking Celsentri/Selzentry in MERIT at 96-weeks, 1.5 percent had elevated LDL-cholesterol levels that exceeded established thresholds to consider lipid-lowering drug initiation (defined by the NCEP guidelines)2, compared to 9.9 percent for patients taking efavirenz.

About MERIT and MERIT ES

MERIT is an ongoing randomized, blinded, non-inferiority trial in treatment-naïve patients with CCR5-tropic HIV-1. The Phase 3 trial compares the safety and efficacy of Celsentri/Selzentry 300 mg twice daily versus efavirenz 600 mg once daily, administered with the fixed-dose combination Combivir (a standard of care at the time of trial enrollment). Results of MERIT at 48-weeks were presented in July 2007 at the IAS Conference on HIV Pathogenesis, Treatment and Prevention in Sydney, Australia.

Overall for the MERIT ES analysis, 106 patients (15 percent) originally classified as having CCR5-tropic virus were reclassified as having dual or mixed tropic virus. Results of MERIT ES at 48-weeks were presented in October 2008 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.

* A patient classified as a TLOVR non-responder required two consecutive viral load measurements of >50 copies/mL. A patient classified as a primary efficacy non-responder required one viral load measurement of >50 copies/mL.

About Celsentri/Selzentry

Celsentri/Selzentry is an oral medicine that blocks viral entry to human cells. Rather than fighting HIV inside white blood cells, Celsentri/Selzentry prevents the virus from entering uninfected cells by blocking its predominant entry route, the CCR5 co-receptor.

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

In South Africa, maraviroc is not available commercially and is currently under review by the Medicine Control Council. Maraviroc is marketed under the trade name Selzentry® in the United States and Celsentri® in all other countries in which it is approved.

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countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

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This release contains forward-looking information that involves substantial risks and uncertainties about a potential additional indication for Celsentri/Selzentry, including its potential benefits, that is under review by the United States Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMEA). Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by the FDA, the EMEA and other regulatory authorities regarding whether and when to approve supplemental drug applications that have been or 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, 2008 and in its reports on Form 10-Q and Form 8-K.

1 Pfizer Abstract: The MERIT study of maraviroc in antiretroviral-naïve patients with R5 HIV-1: 96-week results.

2 Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation. 2002;106:3143–3421.

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