FDA Advisory Committee Recommends Approval of Pfizer's Selzentry for Use in Patients Starting HIV Therapy for the First Time

Thursday, October 08, 2009 - 02:31am

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration's (FDA) Antiviral Drugs Advisory Committee voted (10 to 4) to recommend the approval of Selzentry® (maraviroc) tablets for use in treatment-naïve adult patients with CCR5-tropic HIV-1 virus as part of combination therapy.

"Pfizer is pleased that the Committee has recognized the effectiveness and safety profile of maraviroc in patients who are starting HIV therapy," said Dr. Howard Mayer, Pfizer's executive director and disease area leader, antivirals. "Today's discussion marks an important step in expanding available treatment options for patients with HIV infection and we look forward to working with the FDA to further address the points raised by the panel."

Selzentry was granted accelerated approval in August 2007 and full approval in November 2008 by the FDA for use in treatment-experienced adult patients with only CCR5-tropic HIV-1 virus in combination with other antiretroviral therapies. 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.

In making its decision, the Advisory Committee reviewed 48- and 96-week efficacy and safety data from the ongoing Phase 3 MERIT (Maraviroc versus Efavirenz Regimens as I nitial Therapy) trial and MERIT ES (analysis of the MERIT study with the enhanced sensitivity Trofile™ assay).

Results of MERIT at 48-weeks showed that Selzentry plus Combivir® (zidovudine/lamivudine) was as effective as Sustiva® (efavirenz) plus zidovudine/lamivudine at reducing viral load for the co-primary endpoint of <400 copies/mL, but did not show non-inferiority for the co-primary endpoint of <50 copies/mL at 48-weeks. Safety results at 96-weeks showed that among those patients who remained on therapy, less than half the number of malignancies were observed in patients taking Selzentry compared to those taking efavirenz. Additionally, no new safety signals were identified in association with Selzentry at 96-weeks. The most frequently reported adverse events were nausea, headache, dizziness, diarrhea, fatigue, upper respiratory tract infection, and vomiting. Patients were screened into the study using the original Trofile™ assay which is no longer available.

MERIT ES is a retrospective analysis, which utilized the enhanced sensitivity Trofile™ assay in screening samples from the MERIT trial. Results of MERIT ES at 48-weeks showed that treatment-naïve patients with CCR5-tropic HIV-1 taking Selzentry plus zidovudine/lamivudine experienced comparable virologic suppression to undetectable levels (<50 copies/mL) to those taking efavirenz plus zidovudine/lamivudine. The enhanced sensitivity Trofile™ assay used in the MERIT ES analysis has been the only available version of the Trofile™ assay since June 2008.

The FDA often seeks the advice of its Advisory Committees when evaluating potential treatments, but is not required to follow its recommendation. Through the joint venture with GlaxoSmithKline, which is expected to close in the fourth quarter of 2009, Pfizer remains committed to the expansion of Selzentry/Celsentri’s current indications to include appropriate treatment-naïve populations throughout the world.

At the end of 2006, an estimated 1.1 million people in the U.S. were living with HIV infection. The Centers for Disease Control and Prevention (CDC) estimates that in 2006 approximately 56,300 people were newly infected with HIV in the U.S. (the most recent year that data are available).

About Selzentry

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

Maraviroc is marketed under the trade name Selzentry® in the U.S. and Celsentri® in all other countries in which it is approved.

Pfizer Inc: Working together for a healthier world™

Founded in 1849, Pfizer is the world's premier biopharmaceutical 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, 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 8, 2009. 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 that involves substantial risks and uncertainties about (i) a potential additional indication for Selzentry/Celsentri, including its potential benefits, that is under review by the United States Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMEA), and (ii) the closing of an agreement with GlaxoSmithKline to create a joint venture company. 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; competitive developments; and the ability to satisfy the conditions to closing the agreement with GlaxoSmithKline.

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.

Pfizer IncMedia:Kristen E. Neese, 646-299-2526Kristen.E.Neese@pfizer.comorInvestors:Jennifer Davis, 212-733-0717Jennifer.M.Davis@pfizer.com