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Pfizer's Celsentri(R) Approved in the European Union, Providing a Novel Treatment Option for Treatment-Experienced HIV Patients

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First in a New Oral Class of HIV Medicines in 10 Years

(BUSINESS WIRE)--Pfizer Inc announced today that the European Commission (EC) has approved Celsentri® (maraviroc). Treatment-experienced HIV patients in the EU can soon benefit from the first CCR5 antagonist and only oral entry inhibitor. Maraviroc, in combination with other antiretroviral medicinal products, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 virus detectable.

Maraviroc is the first member of a new class of oral HIV medicines in more than a decade (CCR5-antagonists). Discovered and developed by Pfizer scientists in Sandwich, UK, since 1997, maraviroc works by blocking viral entry into human cells. Rather than fighting HIV inside white blood cells, maraviroc prevents the virus from entering white blood cells by blocking its predominant entry route, the CCR5 co-receptor.

“HIV is a significant health concern in Europe and infection rates are still increasing. Without new medicines, resistance to current treatments is one of the biggest challenges facing HIV care today,” said Filippo von Schloesser, president of Italian HIV patient organization, Fondazione Nadir Onlus. “The approval of maraviroc will offer a new option to many people living with HIV in Europe.”

The EC approval of maraviroc is based on 48-week data from the two ongoing double-blind, placebo-controlled MOTIVATE clinical trials. The data of the MOTIVATE trials show that:

- Maraviroc and optimized background therapy (OBT) provided substantially greater viral load reduction compared to patients receiving OBT alone.
- More than twice as many patients receiving maraviroc plus optimized background therapy (OBT) achieved undetectable viral load at 48 weeks compared with those receiving OBT alone.
- The group receiving maraviroc and OBT in the MOTIVATE trials demonstrated significantly greater increases in CD4 white cells compared to the group receiving OBT alone.
- The rates of most frequently reported adverse reactions (diarrhoea, nausea and headache) were similar in patients receiving maraviroc and OBT compared with those receiving OBT alone.
- Patients treated with maraviroc and OBT had low discontinuation rates (3.8%) similar to the group receiving OBT alone (3.8%).

“Maraviroc is an important additional treatment option for R5 tropic treatment-experienced patients in Europe,” noted Gerd Faetkenheuer, MD, Department of Internal Medicine, University of Cologne, Germany. “Although other treatments are currently available, maraviroc targets the fight against the HIV virus in a new way.”

Further details and product information will be available in the European Public Assessment Report on the web site of the European Medicines Agency at www.emea.europa.eu.

Pfizer's Ongoing Commitment to HIV/AIDS

Pfizer scientists discovered maraviroc in 1997. Maraviroc's clinical program initiated the first combined phase 2b/3 trial design in HIV to efficiently characterize its clinical profile and submit data to regulatory authorities as quickly as possible. Maraviroc, known as Selzentry™ in the United States, was approved by the U.S. Food and Drug Administration (FDA) on August 6, 2007 and is currently available in the U.S.

In December 2006, Pfizer announced plans to establish a multi-national Expanded Access Program, a clinical study that provides maraviroc to patients who have limited or no approved treatment options due to resistance or intolerance to existing drug classes. The program is open for enrollment with a target to enroll patients from over 30 countries.

Pfizer is committed to bringing meaningful improvement to the lives of people living with HIV/AIDS and those at risk around the world. This commitment is embodied in significant philanthropic activities that provide access to life-saving medicines, resources and skills to help improve patient care for people throughout the world living with HIV/AIDS.

Current initiatives include the building of the Infectious Disease Institute in Kampala, Uganda, the Pfizer Global Health Fellows Program, the Diflucan Partnership Program and ConnectHIV, an HIV prevention program in the U.S.

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