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Pfizer Receives Positive Opinion from CHMP for Celsentri(R) (maraviroc) for Treatment-Experienced Patients Infected with CCR5-Tropic HIV-1

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(BUSINESS WIRE)--Pfizer Inc announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) issued a positive opinion recommending marketing authorization for Celsentri® (maraviroc), the first CCR5 antagonist for use in combination with other antiretroviral agents for treatment-experienced adult patients where only CCR5-tropic virus is detectable.

The CHMP's positive opinion will be reviewed by the European Commission, which has authority to approve medicines for the European Union. Pfizer anticipates a final decision from the Commission in the coming months.

"New, effective and well-tolerated treatments are urgently needed for the thousands of people living with HIV whose virus has become resistant to one or more currently available options. Recognizing the needs of these patients, Pfizer moved with urgency in the research and development for maraviroc," said Dr. Joseph Feczko, Pfizer's Chief Medical Officer.

Subject to the necessary regulatory approvals, Pfizer will make this novel medicine available to patients as Celsentri outside the US. Pfizer has recently received an approvable letter for maraviroc from the US Food and Drug Administration (FDA).

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, England, since 1997, maraviroc works extracellularly by blocking viral entry to 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.

In the treatment of HIV two parameters are considered main markers of treatment success: viral load reduction and increase of CD4 white cells. The maraviroc MOTIVATE pivotal trials compared the safety and efficacy of the addition of maraviroc to an optimized combination drug regimen (referred to as optimized background therapy-OBT) to the addition of placebo to OBT.

Twenty-four week data from the two maraviroc MOTIVATE trials presented at CROI (Conference on Retroviruses and Opportunistic Infections – February 2007) showed that:

- Maraviroc and optimized background therapy provided substantially greater viral load reduction compared to patients receiving OBT alone.

- Nearly twice as many patients treated with maraviroc (two times per day) plus optimized background therapy (OBT) achieved undetectable viral loads (< 50 copies/ml HIV RNA) compared to those receiving placebo plus OBT (MOTIVATE-1, 48.5% versus 24.6%; MOTIVATE-2, 40.8% versus 20.9%)
- The group receiving maraviroc in the MOTIVATE trials demonstrated significantly greater increases in CD4 white cells compared to the group receiving OBT alone.
- The rate of most common adverse events (diarrhea, nausea and headache) as well as rates of discontinuation due to adverse events were similar in patients receiving maraviroc and OBT compared with those receiving placebo and OBT.
- Forty-eight week data have further confirmed these findings and led to the positive opinion from the CHMP

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 engaged 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. These include the US Southern HIV/AIDS Prevention Initiative (2004-2007); US ConnectHIV prevention initiative (2007-2010); the establishment of the Infectious Disease Institute in Kampala, Uganda; Pfizer's Global Health Fellows Program and Diflucan Partnership Program.

DISCLOSURE NOTICE: The information contained in this release is as of July 20, 2007. The Company assumes no obligation to update any forward-looking statements contained in this release as a result of new information or future events or developments.

This release contains forward-looking information about Celsentri, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, whether and when regulatory authorities will approve Celsentri, their decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as competitive developments.

A further description of these risks and uncertainties can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 and in its reports on Forms 10-Q and 8-K.

Pfizer IncJoel Morris, +44 7966 338652Shreya Prudlow, 917-743-4349