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FDA Advisory Committee Recommends Accelerated Approval of Pfizer's Maraviroc for Treatment-Experienced Patients Infected with CCR5-tropic HIV-1

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(BUSINESS WIRE)--Pfizer Inc announced today that the U.S. Food and Drug Administration's (FDA) Antiviral Drugs Advisory Committee voted unanimously (12-0) to recommend the approval of maraviroc, a CCR5 antagonist, for use along with other antiretroviral agents for treatment-experienced patients infected with CCR5-tropic HIV-1.

If approved, maraviroc would be the first member of a new class of oral HIV medicines in more than a decade.

Discovered by Pfizer scientists in 1997, maraviroc works by blocking viral entry to human cells. Rather than fighting HIV inside white blood cells, it prevents the virus from entering uninfected cells by blocking its predominant entry route, the CCR5 co-receptor.

In the pivotal MOTIVATE trials, nearly twice as many treatment-experienced CCR5-tropic HIV-1 infected patients treated with maraviroc plus optimized background therapy (OBT) achieved undetectable viral loads at 24 weeks compared to those receiving placebo plus OBT.

There were no significant increases in hepatotoxicity, malignancy or mortality in maraviroc's treatment arms, while there were slight increases in upper respiratory and herpes simplex virus infections as well as with ischemic events, consistent with the rate observed in treatment experienced HIV/AIDs patients.

Pfizer will carefully consider today's discussion and is committed to a robust risk management plan for maraviroc through long-term follow up of ongoing clinical trials, pediatric studies and pharmacovigilance, including a database study and a patient registry. Preliminary safety data beyond 24 weeks from the ongoing MOTIVATE trials were shared with the advisory panel today and the 48-week study outcomes will be submitted for presentation at a scientific forum later this year.

Maraviroc is currently undergoing expedited regulatory review. While the FDA is not bound by the Advisory Committee recommendations, in most cases, the FDA does follow the recommendations.

DISCLOSURE NOTICE: The information contained in this release is as of April 24, 2007. Pfizer assumes no obligation to update 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 a product candidate, including its potential benefits, that is under review by the FDA. Such risks and uncertainties

include, among other things, whether and when the FDA will approve the product candidate, the FDA's decisions regarding labeling and other matters that could affect its availability or commercial potential, as well as 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, 2006 and in its reports on Form 10-Q and Form 8-K.

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