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# Pfizer Inc.

## Pfizer Announces Plans to Establish Expanded Access Program for Maraviroc, Investigational HIV CCR5 Antagonist

01.12.2006 - 06:04 Uhr, Pfizer Inc.

New York (ots/PRNewswire) -

- Broad Access Program for Patients with Limited Available Treatment Options

Pfizer announced today that it plans to establish a multi-national Expanded Access Program (EAP) to make the investigational CCR5 antagonist maraviroc, currently in ongoing phase 3 clinical trials, available to HIV/AIDS patients with CCR5-tropic HIV-1 who have limited or no approved treatment options due to resistance or intolerance. Pending regulatory review and approvals of the EAP study protocol, the program will begin enrolling patients in the next few months, with a target to enroll patients from over 30 countries.

Maraviroc is in a new class of investigational HIV drugs known as CCR5 antagonists, designed to work differently from currently available HIV/AIDS antiretroviral medicines. Rather than fighting HIV inside white blood cells, CCR5 antagonists prevent the virus from entering cells by blocking its predominant entry route, the CCR5 co-receptor.

The EAP is designed to provide access to maraviroc for patients who, in the opinion of the program investigators, need it to create a viable regimen. "People living with HIV whose virus is resistant to available therapies have an urgent need for novel medicines," said John LaMattina, president, Pfizer Global Research and Development. "It is our hope that maraviroc, now in final stages of clinical development, may help those patients who have exhausted treatment options and are not already participating in our clinical studies."

Pfizer confirmed plans to submit applications for marketing approval in both the U.S. and EU following review of the data from the two Phase 3 maraviroc registrational trials. These are 24-week studies of Optimized Background Therapy (OBT), with or without maraviroc, in highly treatment experienced patients with CCR5-tropic HIV-1. Pfizer will submit these results expeditiously for presentation at an upcoming HIV conference.

To broaden the program's reach, Pfizer is recruiting many investigators with previous EAP experience as well as HIV clinical experts at centers which have not previously engaged in expanded access initiatives. Study patients will receive open-label maraviroc twice daily in addition to OBT. In some circumstances, the study allows the use of OBT that may contain other investigational antiretroviral agents in Phase 3 clinical development.

Health care professionals interested in enrollment should contact their local Pfizer office.

### Maraviroc Expanded Access Study Design

Investigators will follow patients in the EAP according to their local standard of care. The study will continue in each country until marketing approval and reimbursement is obtained in that country and the patient can obtain drug through local commercial distribution channels.

Pending regulatory review, preliminary program eligibility criteria include patients who are, clinically stable with documented CCR5-tropic HIV-1 infection; at least 16 years of age (or minimum adult age as determined by local regulatory authorities or as legal requirements dictate); have limited or no treatment options available to them due to resistance or treatment intolerance; and they must be failing to achieve adequate virologic suppression on their current

regimen. The study cannot include patients who have failed prior treatment with any CCR5 antagonist in a clinical trial; have evidence of dual/mixed-tropic or X4-tropic HIV; require any medications prohibited by the EAP protocol; have a condition which the study investigator deems will interfere with the patient's adherence and safety; or who are pregnant or lactating. Investigators will select the OBT based on the patient's prior treatment history and antiretroviral resistance testing conducted according to local practice. Pfizer will not provide OBT. Pfizer will monitor safety and tolerability of maraviroc throughout the course of the study.

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