A MULTI-CENTER, OPEN LABEL, EXPANDED ACCESS TRIAL OF MARAVIROC

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Primary Objective:The primary objective of the maraviroc expanded access program is to facilitate access to maraviroc for subjects, who have limited therapeutic options and to collect safety data in a larger and more diverse patient population than...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31084

Source
ToetsingOnline

Brief title
Early access Program (EAP)

Condition

- Viral infectious disorders

Synonym
AIDS, CCR5 HIV

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer Inc.

Intervention

Keyword: HIV, Maraviroc

Outcome measures

Primary outcome

Safety data will be categorically summarized: Proportion of subjects with Grade 3 and 4 AEs, SAEs, and laboratory abnormalities (overall and according to investigator assigned causality). Possible AIDS-related infections and diseases will be summarized. Possible AIDS-related infections/events will also be summarized in their entirety, by baseline viral load, by baseline/nadir CD4 cell counts and by time on therapy. Safety by gender, race, age and baseline HBV and/or HCV serology will also be summarized.

Secondary outcome

Secondary Endpoints include the following and will be descriptive in nature.

•Viral response

•The change in CD4 count

•The emergence/unmasking of CXCR4 using virus between screening (baseline) and time of virologic failure will be assessed.

Study description

Background summary

Maraviroc is a member of a new class of antiretroviral compounds known as small molecule CCR5 antagonists that block R5 HIV entry into CD4 cells. Maraviroc has demonstrated selective and reversible binding to CCR5, as well as potent antiviral activity in vitro against a wide range of laboratory adapted strains of R5 HIV from Clades A, B, C, D, E, F, G, J and O. Maraviroc also retains in vitro antiviral activity against clinical isolates resistant to the existing

drug classes, but has no activity against viruses that enter CD4+ cells using CXCR4. 18 In vitro studies with approved antiretroviral medications indicate that there is no evidence of antagonism with any members of the other four classes of antiretroviral medications; nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non- nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs) or fusion inhibitors (FIs). In vitro synergy with enfuvirtide (T-20) has been reported.

Study objective

Primary Objective:
The primary objective of the maraviroc expanded access program is to facilitate access to maraviroc for subjects, who have limited therapeutic options and to collect safety data in a larger and more diverse patient population than that which participated in the phase 2/3 clinical trials.
Secondary Objectives:
The secondary objective of the maraviroc expanded access program is to evaluate the effectiveness of maraviroc in treatment-experienced patients who are followed according to local medical practice.

Study design

This is an open label, non-comparative, international, phase 3b safety study of maraviroc in HIV positive, treatment-experienced patients with R5 HIV who have limited or no therapeutic options with approved therapy. It will be conducted with approximately 600 investigators in more than 30 countries. Based on available epidemiologic data including screening data from the A4001027 and A4001028 studies, it is anticipated that approximately 12,000 to 18,000 treatment experienced patients will be screened for the study to identify up to 6,000 subjects with R5 HIV-1 as identified by the Monogram Biosciences (San Francisco, California) TrofileTM assay. The tropism assay requires an HIV-1 RNA (viral load) >1000 copies/mL, and is able to detect minority X4 HIV-1 in 100% and 83% of samples when X4 HIV-1 represents >10% and >5% of the viral population, respectively. Subjects who meet all of the inclusion criteria and none of the exclusion criteria will receive investigator selected OBT plus maraviroc twice daily to be initiated simultaneously. Total maraviroc dosage in the twice daily regimen will be adjusted according to OBT and concomitant medications (See Table 3). Ideally, subjects will be treated with at least one additional antiretroviral agent to which their virus is susceptible and/or with which they have not been treated. This may require that physicians and subjects have access to more than one investigational antiretroviral agent. Therefore, subjects receiving other investigational antiretroviral agents that meet inclusion criteria number nine (Section 4.1 Inclusion Criteria) will be permitted to screen for the maraviroc EAP.
Study enrollment will begin at each site following local regulatory and institutional review board (IRB) or ethics committee (EC) approval, collection

of all required documents and site initiation. Enrollment and provision of study drug will continue until approval and drug reimbursement is available in the country where the subject resides or Pfizer, Inc discontinues the program.

Intervention

Maraviroc therapy

Study burden and risks

To take part in this study, patients will get study drug (maraviroc) and a number of lab tests , at no costs. The patient may or may not have a good response to the study drug and the other drugs they receive to treat HIV infection. The information from this study may help to treat future patients with HIV better. There is no guarantee that every subject will benefit from taking part in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- subjects must be failing on adequate virologic suppression: HIV-1 RNA > 1000 copies/ml
- R5 HIV-1 at screening as verified by Monogram Biosciences Trofile assay

Exclusion criteria

- potentially life threatening lab abnormalities or medical condition still under investigation felt not to affect risk/benefit assessment of safety results.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2007
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Celsentri
Generic name:	Maraviroc

Ethics review

Approved WMO Date:	02-04-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-10-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-10-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-10-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-05-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-004306-50-NL
CCMO	NL16808.041.07