An open-label trial with TMC278 25 mg q.d. in combination with a background regimen containing 2 nucleoside/nucleotide reverse transcriptase inhibitors in HIV-1 infected subjects, who participated in TMC278 clinical trials.

Published: 01-02-2011
Last updated: 04-05-2024

Primary ObjectiveThe primary objective of the trial is to provide continued access to TMC278 for subjects who were randomized andtreated with TMC278 in the Phase IIb (e.g., TMC278-C204 [C204]) or Phase III trials (e.g., TMC278-TiDP6-C209[ECHO] and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON36498

Source
ToetsingOnline

Brief title
Open trial with TMC278 25mg in HIV-infected subjects until reimbursement

Condition

- Immunodeficiency syndromes
- Viral infectious disorders

Synonym

HIV-1 infection - AIDS

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen-Cilag

Intervention

Keyword: HIV-1, safety, TMC278, tolerability

Outcome measures

Primary outcome

confer supra

Secondary outcome

confer supra

Study description

Background summary

This is a Phase III, open-label, multicenter, roll-over trial to provide continued access to TMC278 to HIV-1 infected subjects who were randomized and treated with TMC278 in the Phase IIb (e.g., C204) or Phase III trials (e.g., ECHO [C209] or THRIVE [C215]) and who continue to benefit from their antiretroviral treatment, according to the investigator. In addition, information on the long-term safety and tolerability of oral doses of TMC278 25 mg q.d. in combination with a background regimen containing 2 N(t)RTIs will be collected. Available efficacy data will also be collected.
The Final/Withdrawal visit of the Phase IIb or Phase III trial will be the first visit of this trial. From this visit onwards, all enrolled subjects will continue to receive TMC278 25 mg q.d. in combination with a background regimen of 2 N(t)RTIs until TMC278 is available to subjects in their country outside of a clinical trial setting, the

subject meets at least one of the withdrawal criteria, or the subject no longer has clinical benefit from treatment in the
opinion of the investigator, whichever comes first.

Study objective

Primary Objective
The primary objective of the trial is to provide continued access to TMC278 for subjects who were randomized and
treated with TMC278 in the Phase IIb (e.g., TMC278-C204 [C204]) or Phase III trials (e.g., TMC278-TiDP6-C209
[ECHO] and TMC278-TiDP6-C215 [THRIVE]).

Secondary Objectives
The secondary objective is to evaluate the long-term safety and tolerability of TMC278 25 mg q.d. in combination
with a background regimen containing 2 N(t)RTIs. Available efficacy data will also be collected.

Study design

confer supra

Intervention

Oral tablets of TMC278 25 mg q.d. should be administered together with a meal.

Study burden and risks

For more details, confer informed consent form;

TMC278 has the following adverse events reported: headache, somnolence, nausea, upper respiratory tract infection, tiredness and sinusbradycardia, dizziness, constipation, vomiting, nose- and throatinfection, anemia, cough, arthralgia, back pain, diarrhea and dyspepsia , immune reconstitution syndrome, alanine-aminotransferase (ALAT) and aspartateaminotransferase (ASAT) increased. Rash also been reported for TMC278, as for other hiv-medication.

Other ARV-medication as part of the OBR, each have their known adverse events.

Calculated risk for normal blood draw procedure.

Contacts

Public
Janssen-Cilag

Antwerpseweg 15-17
B-2340 Beerse
BE
Scientific
Janssen-Cilag

Antwerpseweg 15-17
B-2340 Beerse
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male or female subjects, aged 18 years or older.
2. Subjects must have signed an informed consent form (ICF) indicating that they are willing to
participate in the trial and understand the purpose and procedures required for the trial.
3. Subjects are HIV-1 infected and were previously randomized to receive TMC278 in a TMC278 clinical trial and completed the protocol defined treatment period.
4. Subjects continue to benefit from treatment with TMC278 in the opinion of the investigator.
5. Subjects can comply with the current protocol requirements.
6. The subject's general medical condition, in the investigator's opinion, does not interfere with
participation in the trial.

Exclusion criteria

1. Use of disallowed concomitant therapy (see Section 8).
2. Females of childbearing potential* who are pregnant, or without the use of effective birth control methods, or not willing to continue practicing these birth control methods during the trial and for at least 1 month after the end of the trial (or after last intake of TMC278).
Effective birth control methods:
(1) male condom in combination with diaphragm or cervical cap or male condom with spermicide**,
(2) intrauterine device or hormonal contraceptive,
(3) be non-heterosexually active, practice sexual abstinence or have a vasectomized partner, vasectomy should have been performed more than 6 months prior to trial initiation.
* Women who are postmenopausal for at least 2 years, women with total hysterectomy and women who have a bilateral tubal ligation are considered of non-childbearing potential.
** a male and female condom should not be used together due to risk of breakage or damage caused by latex friction.

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):	12-09-2011
Enrollment:	3
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Edurant

Generic name:	Rilpivirine

Ethics review

Approved WMO Date:	01-02-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-08-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2010-021209-18-NL
CCMO	NL35065.078.10