An extension study to QTI571A2301 to evaluate the longterm safety, tolerability and efficacy of oral QTI571 (imatinib) in the treatment of severe pulmonary arterial hypertension.

Published: 24-09-2010
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Primary: To evaluate the long-term safety and tolerability of QTI571.Secondary: * Continue to evaluate the long-term efficacy of QTI571 as measured by the change in6MWD from baseline.* Continue to assess time to clinical worsening (TTCW) endpoints...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Interventional

Summary

ID

NL-OMON34535

Source
ToetsingOnline

Brief title
IMPRES Extension

Condition

- Pulmonary vascular disorders

Synonym
Pulmonary arterial hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma

Intervention

Keyword: Imatinib, pulmonary arterial hypertension, QTI571

Outcome measures

Primary outcome

Adverse events.

Secondary outcome

6 minute walk test. Time to clinical deterioration. Medical resource

utilization.

Study description

Background summary

This study is designed to determine the long term safety, tolerability and efficacy and tolerability of QTI571 in the treatment of PAH in patients who have completed or discontinued the IMPRES study. Safety will be monitored by standard safety laboratories, ECG, echocardiogram, adverse event reporting. Measurement of weight and physical assessment will be used to monitor peripheral edema and detrimental fluid retention.
Efficacy will be monitored by 6MWT and TTCW.
Echocardiograms will monitor right and left ventricular function and ECG will monitor for any arrhythmias and conduction defects. These tests will determine any long term cardiac toxicity related to QTI571.

Study objective

Primary: To evaluate the long-term safety and tolerability of QTI571.
Secondary:
* Continue to evaluate the long-term efficacy of QTI571 as measured by the change in
6MWD from baseline.
* Continue to assess time to clinical worsening (TTCW) endpoints including all

cause
mortality, hospitalization for worsening PAH for at least overnight (established by
external adjudication committee), worsening of WHO functional class, or a drop in
6MWD by 15% both as a composite endpoint and by individual time to clinical worsening events.
* To assess the impact of QTI571 on medical resource utilization.

Study design

This is a multinational, multi center extension study in patients with PAH.
Informed Consent should be obtained at Visit 1 for all patients. Upon providing written informed consent, patients will be screened for participation in the extension study.
The following screening procedures must be performed within 2 weeks of extension study enrollment (first drug assignment):
* Screening safety laboratories, ECG and 6MWD will be performed at Visit 1 if not
performed in the previous 4 weeks.
* Echocardiogram will be performed at Visit 1 if not performed in the previous 8 weeks.
Patients may remain in the extension study at the maximum tolerated dose for up to three years. At this timepoint, further access to QTI571 will be reviewed and be dependent upon the outcome of the core Phase III study CQTI571A2301.

Intervention

Treatment with QTI571.

Study burden and risks

Risk: Adverse effects of study medication.
Burden: 12 visits in over 2 years. Blood tests (approx. 10 ml/visit, aprox. 120 ml in total) and ECG during every visit.
In addition: Phys. examination 5x, echocardiogram 33-4x, 6 minute walk test 5-6x, pregnancy test 4-5x.
Extra in comparison to regular treatment : more and longer lasting visits, more often blood tests, extra ECG and echocardiogram (differnces depending on the physical condition of the individual patient), 6 minute walk test 5-6x (for study purposes only).

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age18 years and above.
* IMPRES study fully completed or prematurely discontinued due to other reasons than related to QTI571 or safety.

Exclusion criteria

* Pregnant or lactating females.
* Males and females of childbearing potential not using safe contraception method.
* Pulm wedge pressure >15 mmHg.
* LVEF <45%.
* Platelets < 50 x109/L.

* BP >160 mmHg (syst.) of >90 mmHg (diast.).
* QTcF >450 msec (males), c.q. 470 msec (females).

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):	07-12-2010
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Glivec
Generic name:	Imatinib mesylaat
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-09-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2010

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
Other	clinicaltrials.gov. Registratienummer n.n.b.
EudraCT	EUCTR2009-018167-26-NL
CCMO	NL33672.029.10