FUTURE 3 extension study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27501

Source
NTR

Brief title
FUTURE 3 EXT

Health condition

Pulmonary arterial hypertension in children

Sponsors and support

Primary sponsor: Actelion Pharmaceuticals
Gewerbestrasse 16
CH-4123 Allschwil
Switzerland
Source(s) of monetary or material Support: Actelion Pharmaceuticals
Gewerbestrasse 16
CH-4123 Allschwil
Switzerland

Intervention

Outcome measures

Primary outcome

No primary endpoint was defined in this study.

Secondary outcome

Exploratory efficacy endpoints:

1. Change from baseline to end of study in WHO functional class;

2. Time to death, lung transplantation or hospitalization for PAH-Progression;

3. Time to death, lung transplantation, hospitalization for PAH-progression or initiation of new therapy for PAH or new/worsening right heart failure;

4. Changes from baseline to 3, 6, 9, 12, 15 and 18 months of treatment over AC 052 373 and AC-052-374 in Global Clinical Impression scale assessed by the physician and parents.

Safety and tolerability endpoints:

1. Treatment-emergent AEs and serious adverse events (SAEs) up to 7 days after permanent discontinuation of study drug;

2. Adverse events leading to premature discontinuation of study drug;

3. Serious adverse events from 7 up to 60 days after permanent discontinuation of study drug;

4. Changes from baseline to end of study in vital signs, body weight, and height/length;

5. Treatment-emergent marked laboratory abnormalities up to end of study.

Study description

Background summary

This is a prospective, multicenter, multinational, open-label, double-arm exploratory Phase 3 extension study enrolling those patients who completed the FUTURE 3 core study (AC 052-373). It is designed to evaluate the long-term tolerability and safety of bosentan using the pediatric formulation in children with idiopathic or heritable PAH or PAH persisting after complete repair of a congenital heart defect.

Patients will receive the bosentan pediatric formulation. The bosentan dosage will be adjusted to the patient’s body weight during the study to achieve a maintenance dose of 2 mg/kg either b.i.d. or t.i.d.

The maximum number of participants corresponds to the number of patients treated in the FUTURE 3 core study (AC-052-373).

The study will be conducted at expert pediatric PAH centers in Europe, US, Latin America, Australia and Asia.

The study will consist of a treatment period and a post-treatment follow-up period of 60 days. Patients will receive the maintenance dose (2 mg/kg either b.i.d. or t.i.d.) of bosentan using the pediatric formulation for the entire duration of the study.

The treatment period in FUTURE 3 Study Extension will last for 12 months or until:

1. The investigator or the patient decides to discontinue the study treatment permanently;

2. The sponsor decides not to pursue the development of the pediatric formulation of bosentan.

Study objective

Evaluate the long-term safety, tolerability and efficacy of the pediatric formulation of bosentan two versus three times a day in children with pulmonary arterial hypertension (PAH).

Study design

The study will consist of a treatment period and a post-treatment follow-up period of 60 days. Patients will receive the maintenance dose (2 mg/kg either b.i.d. or t.i.d.) of bosentan using the pediatric formulation for the entire duration of the study. The treatment period in FUTURE 3 Study Extension will last for 12 months or until:

1. The investigator or the patient decides to discontinue the study treatment permanently;

2. The sponsor decides not to pursue the development of the pediatric formulation of bosentan.

Intervention

Bosentan dispersible tablet (32 mg) in the dosage of 2 mg/kg b.i.d. or 2 mg/kg t.i.d.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients who completed the FUTURE 3 core study (AC-052-373) or prematurely discontinued due to PAH progression, if bosentan was not permanently discontinued;

2. Patients who tolerated bosentan pediatric formulation and for whom bosentan is considered beneficial by the investigator at the end of FUTURE 3 core study (AC-052-373);

3. Signed informed consent by the parents or the legal representatives prior to any study-mandated procedure.

Exclusion criteria

1. Known intolerance or hypersensitivity to bosentan or any of the excipients of the dispersible bosentan tablet;

2. Any clinically significant laboratory abnormality that precludes continuation of bosentan therapy;

3. Pregnancy;

4. AST and/or ALT values > 3 times the upper limit of normal range (ULN);

5. Moderate to severe hepatic impairment, i.e., Child-Pugh Class B or C;

6. Premature and permanent study drug discontinuation during the FUTURE 3 core study (AC-052-373);

7. Any major violation of the FUTURE 3 core study (AC 052 373) protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	64
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2538
NTR-old	NTR2656
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A