An open-label extension trial of the long term safety of oral BIBF 1120 in patients with Idiopathic Pulmonary Fibrosis (IPF)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37909

Source
ToetsingOnline

Brief title
BIBF 1120 in IPF

Condition

- Respiratory disorders NEC

Synonym
idiopathic pulmonary fibrosis - lungfibrosis of unknown origine

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: BIBF 1120, extension study, IPF, open label

Outcome measures

Primary outcome

long-term safety

Secondary outcome

Absolute and relative change from baseline in FVC and in % predicted FVC;

On trial survival (all data collected based on fatal adverse events);

Time to first acute IPF exacerbation

Study description

Background summary

Idiopathic lung fibrosis is a chronic disease of unknown aetiology that is characterized by progressive fibrotic desctruction of the lung, resulting in disabling dyspnea. Up to now there is noglobally accepted treatment for this fatal disease in NL, except lung transplantation. BIBF 1120
BIBF 1120 is currently being developed for treatment of idiopathic lungfibrosis and completed phase II with a positive risk/benefit profile. Phase III is currently ongoing. The most effective dose is 150 mg bid. Positive effects have been seen for the decrease in reduction of FVC, number of acute IPF exacerbations, and the quality of life . BIBF 1120 also being developed for treatment for cancer.

Study objective

The aim of this extension trial is to provide BIBF 1120 treatment for all patients who have completed the 52 weeks treatment period and the follow up period in the phase III placebo controlled parent trial 1199.34, who may have experienced benefit from the trial and wish to continue treatment with BIBF 1120.

The scientific goal is to determine the safety of BIBF 1120 when given for a long term period to patients with Idiopathic Pulmonary Fibrosis

Study design

open label extension study

Intervention

twice daily BIBF 1120 orally taken

Study burden and risks

lunfunction testing (FVC, standard measure) - each visit
Physical examination including weight, heartrate and bloodpressure - each visit
Blood sampling - each visit
Blood sampling for liver function tests- after visit 6 in between each clinic visit
ECG - 2 x
Pregnancy test (urine dipstick) each visit if applicable

Contacts

Public
Boehringer Ingelheim

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1817 MS Alkmaar
NL
Scientific
Boehringer Ingelheim

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1817 MS Alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Signed Informed Consent consistent with ICH-GCP and local laws prior to trial participation.
2. Patients from trial 1199.34 who completed the 52 weeks treatment period and performed the follow-up visit.

Exclusion criteria

1. AST, ALT > 1.5 fold ULN; Patients who completed the parent trial with transaminase values > 1.5 fold ULN but < 3 fold ULN are considered eligible.
2. Bilirubin >1.5 fold ULN
3. Bleeding risk.
4. Planned major surgery within the next 3 months, including lung transplantation, major abdominal or major intestinal surgery.
5. New major thrombo-embolic events developed after completion of the parent trial.
6.Time period > 12 weeks between Visit 9 of the parent trial and Visit 2 of this study.
7. Usage of any investigational drug after completion of the parent trial or planned usage of a specific investigational drug during the course of this trial.
8. A disease or condition which in the opinion of investigator may put the patient at risk because of participation in this trial or limit the patient*s ability to participate in this trial.
9. Alcohol or drug abuse which in the opinion of the investigator would interfere with trial participation.
10. Pregnant women or women who are breast feeding or of child bearing potential not using two effective methods of birth control (one barrier and one highly effective non-barrier) for at least 1 month prior to Visit 2 and/or not committing to using it until 3 months after end of treatment.
11. Sexually active men not committing to using condoms during participation in the study (except if their partner is not of childbearing potential) and 3 months after the last intake of BIBF 1120.

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):	26-09-2012
Enrollment:	19
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	geen
Generic name:	BIBF 1120

Ethics review

Approved WMO Date:	19-03-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	11-06-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	04-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	07-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-04-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-04-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-08-2016

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2011-002766-21-NL
CCMO	NL40094.100.12
Other	nog niet bekend