Clinical trial results:
Nintedanib (BIBF 1120) plus docetaxel in NSCLC patients progressing after first-line CTX: angiogenic biomarker identification, phase II trial

Summary

EudraCT number	2014-003891-22
Trial protocol	AT
Global end of trial date	18 May 2018

Results information

Result version number	v1 (current)
This version publication date	17 October 2020
First version publication date	17 October 2020

Trial information

Trial identification

Sponsor protocol code	BIO_LUME_1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020
Public contact	Priv.Doz. Dr. Andreas Pircher, Medical University Innsbruck Department of Internal Medicine V Anichstrasse 35 6020 Innsbruck, 43 (0)512/504-24003, andreas.pircher@i-med.ac.at
Scientific contact	Priv.Doz. Dr. Andreas Pircher, Medical University Innsbruck Department of Internal Medicine V Anichstrasse 35 6020 Innsbruck, 43 (0)512/504-24003, andreas.pircher@i-med.ac.at

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 May 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 May 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to explore novel biomarkers and to evaluate biomarker combinations measured in different biosamples (plasma, whole blood, DNA, tumor tissue) when combined with clinical parameters.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	30 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Docetaxel/ Nintedanib

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Nintedanib
Investigational medicinal product code	
Other name	Vargatef, BIBF 1120
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

Subjects would have recived 200mg Nintedanib twice a day.

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects would have been treated using the following scheme: All patients should be premedicated with oral corticosteroids such as dexamethasone 16 mg per day (e.g. 8 mg twice daily) for three days starting one day prior to docetaxel administration. Four cycles of docetaxel application should be given. Docetaxel will be administered as a one hour infusion on day one of each treatment cycle.

Number of subjects in period 1	Docetaxel/ Nintedanib
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Treatment period

Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Docetaxel/ Nintedanib

Reporting group description: -

Primary: Progression free survival

End point title	Progression free survival[1]

End point description:

End point type	Primary

End point timeframe:

N/A

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No subjects were included in this trial, therefore no statistical analysis was done.

End point values	Docetaxel/ Nintedanib			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A				
number (not applicable)	99999			

Notes:

[2] - "99999" is a value for 0 participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
30.10.2015- 18.05.2018	
Adverse event reporting additional description:	
No patients were included in this trial, therefore no AEs and SAEs were reported.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No subjects were included in this trial, therefore no AEs or SAEs were observed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 September 2016	Meldung Protokolländerung

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants, as it was not possible to fill in "0" for the number of included patients.

Notes: