Clinical trial results:
A phase II, open-label, single-arm decentralized home-based approach study to evaluate the efficacy and safety of alectinib in locally advanced or metastatic ALK-positive solid tumors

Summary

EudraCT number	2021-002352-36
Trial protocol	SE
Global end of trial date	16 May 2022

Results information

Result version number	v1 (current)
This version publication date	13 May 2023
First version publication date	13 May 2023

Trial information

Trial identification

Sponsor protocol code	BO41929

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04644315
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, 4070
Public contact	Medical Communications, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	Medical Communications, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com

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	16 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 May 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

This was a phase II, openlabel, singlearm decentralized homebased approach study to evaluate the efficacy and safety of alectinib in locally advanced or metastatic solid tumors (excluding lung cancer) that were determined to be ALKpositive.

Protection of trial subjects:

All participants were required to sign an Informed Consent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 January 2021
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	United States: 1
Worldwide total number of subjects	1
EEA total number of subjects	0

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants at least 18 years of age with ALK-positive locally advanced or metastatic solid tumor (excluding lung cancer) with previously untreated disease or disease progression on prior treatment.

Period 1

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

Arms

Arm title	ALK-positive Solid Tumors

Arm description:

Participants with locally advanced or metastatic ALK-positive tumors were to receive alectinib twice daily (BID) until disease progression, unacceptable toxicity, death, or withdrawal from the study for any reason.

Arm type	Experimental
Investigational medicinal product name	Alectinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

BID until disease progression, unacceptable toxicity, death, or withdrawal from study

Number of subjects in period 1	ALK-positive Solid Tumors
Started	1
Completed	0
Not completed	1
Subject withdrawal of consent	1

Baseline characteristics

Reporting groups	
Reporting group title	ALK-positive Solid Tumors
Reporting group description:	
Participants with locally advanced or metastatic ALK-positive tumors were to receive alectinib twice daily (BID) until disease progression, unacceptable toxicity, death, or withdrawal from the study for any reason.	

Reporting group values	ALK-positive Solid Tumors	Total	
Number of subjects	1	1	
Age categorical Units: Subjects			
Adults (18-64 years)	1	1	
Age Continuous			
The risk of participant re-identification is unacceptable for a population of n=1 and this value will therefore not be provided.			
Units: years arithmetic mean standard deviation	 0 ± 0	 -	
Sex/Gender, Customized			
The risk of participant re-identification is unacceptable for a population of n=1 and this value will therefore not be provided.			
Units: Participants			
Unreported	1	1	
Race/Ethnicity, Customized			
The risk of participant re-identification is unacceptable for a population of n=1 and this value will therefore not be provided.			
Units: Subjects			
Unreported	1	1	

End points

End points reporting groups

Reporting group title	ALK-positive Solid Tumors

Reporting group description:

Participants with locally advanced or metastatic ALK-positive tumors were to receive alectinib twice daily (BID) until disease progression, unacceptable toxicity, death, or withdrawal from the study for any reason.

Primary: Confirmed Objective Response Rate (ORR) as Determined by the Investigator per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)

End point title	Confirmed Objective Response Rate (ORR) as Determined by the Investigator per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)[1]

End point description:

End point type	Primary

End point timeframe:

From 28 days after initial response up to 5 years

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: Endpoints were not analyzed as analysis would not be meaningful for one participant.

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: Percentage				

Notes:

[2] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Confirmed ORR as Determined by Blinded Independent Center Review (BICR) per RECIST v1.1

End point title	Confirmed ORR as Determined by Blinded Independent Center Review (BICR) per RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

From 28 days after initial response up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[3]			
Units: Percentage				

Notes:

[3] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Determined by both the Investigator and by BICR per RECIST v1.1

End point title	Duration of Response (DOR) as Determined by both the Investigator and by BICR per RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

From first occurrence of a documented objective response to disease progression or death from any cause, whichever occurs first (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[4]			
Units: Time				

Notes:

[4] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) as Determined by both the Investigator and by BICR per RECIST v1.1

End point title	Progression-Free Survival (PFS) as Determined by both the Investigator and by BICR per RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

From first dose of alectinib to disease progression or death from any cause, whichever occurs first (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[5]			
Units: Percentage				

Notes:

[5] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Central Nervous System (CNS) ORR by BICR per RECIST v1.1

End point title	Central Nervous System (CNS) ORR by BICR per RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: Percentage				

Notes:

[6] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: CNS DOR by BICR per RECIST v1.1

End point title	CNS DOR by BICR per RECIST v1.1

End point description:

End point type	Secondary

End point timeframe:

From the first observation of CNS response to the first observation of CNS progression or death from any cause (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[7]			
Units: Time				

Notes:

[7] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

End point type	Secondary

End point timeframe:

From the first dose of study drug to death from any cause (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[8]			
Units: Percentage				

Notes:

[8] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Adverse Events (AEs)

End point title	Percentage of Participants with Adverse Events (AEs)

End point description:

End point type	Secondary

End point timeframe:

Up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: Percentage				

Notes:

[9] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Serious Adverse Events (SAEs)

End point title	Percentage of Participants with Serious Adverse Events (SAEs)

End point description:

End point type	Secondary

End point timeframe:

Up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[10]			
Units: Percentage				

Notes:

[10] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Concentration of Alectinib

End point title	Plasma Concentration of Alectinib

End point description:

End point type	Secondary

End point timeframe:

Baseline up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[11]			
Units: ug/mL				

Notes:

[11] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per Response Assessment in Neuro-Oncology (RANO) Criteria

End point title	ORR in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per Response Assessment in Neuro-Oncology (RANO) Criteria

End point description:

End point type	Secondary

End point timeframe:

Up to 5 years

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[12]			
Units: Percentage				

Notes:

[12] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: DOR in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per RANO Criteria

End point title	DOR in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per RANO Criteria

End point description:

End point type	Secondary

End point timeframe:

From first occurrence of a documented objective response to disease progression or death from any cause, whichever occurs first (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[13]			
Units: Time				

Notes:

[13] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: PFS in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per RANO Criteria

End point title	PFS in Participants with Primary CNS Tumors as Determined by both BICR and the Investigator per RANO Criteria

End point description:

End point type	Secondary

End point timeframe:

From first dose of alectinib to disease progression or death from any cause, whichever occurs first (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[14]			
Units: Percentage				

Notes:

[14] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Secondary: OS in Participants with Primary CNS Tumors

End point title	OS in Participants with Primary CNS Tumors

End point description:

End point type	Secondary

End point timeframe:

From the first dose of study drug to death from any cause (up to 5 years)

End point values	ALK-positive Solid Tumors			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Percentage				

Notes:

[15] - Endpoint analysis was not meaningful for one participant and was therefore not performed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 5 years	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	ALK-positive Solid Tumors

Reporting group description:

Participants with locally advanced or metastatic ALK-positive tumors were to receive alectinib twice daily (BID) until disease progression, unacceptable toxicity, death, or withdrawal from the study for any reason.

Serious adverse events	ALK-positive Solid Tumors		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ALK-positive Solid Tumors		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		

Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Nervous system disorders			
Hypoaesthesia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Weight decreased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 June 2021	Allowed enrollment of participants with non-Foundation Medicine next-gen sequencing results; allowed enrollment of participants with carcinoma of unknown primary (CUP) site; changed endpoint of overall response rate (ORR) to confirmed ORR.
17 August 2021	Incorporated the use of physical study sites; changed overall response rate to objective response rate.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported