



Clinical trial results:

A Multicenter, International, Rollover Study of Alectinib in Patients with Anaplastic Lymphoma Kinase (ALK)-positive or Rearranged During Transfection (RET)-positive Cancer

Summary

EudraCT number	2017-000207-24
Trial protocol	ES FR PL IT
Global end of trial date	18 September 2025

Results information

Result version number	v1 (current)
This version publication date	02 October 2026
First version publication date	02 October 2026

Trial information

Trial identification

Sponsor protocol code	BO39694
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03194893
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse, 124, Basel, Switzerland, CH-4058
Public contact	Hoffmann-La Roche, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com
Scientific contact	Hoffmann-La Roche, Hoffmann-La Roche, +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	18 September 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	18 September 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of the study is to assess safety and provide continued treatment with alectinib to participants with ALK- or RET-positive cancer who were previously enrolled in any Roche-sponsored alectinib study and who are deriving continued clinical benefit from alectinib in the parent trial at the time of parent trial closure.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 2017
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	France: 13
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Türkiye: 6
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	Russian Federation: 3
Country: Number of subjects enrolled	United States: 10
Country: Number of subjects enrolled	Hong Kong: 2
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Poland: 2
Worldwide total number of subjects	50
EEA total number of subjects	26

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)	35
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 50 participants with anaplastic lymphoma kinase (ALK)-positive or rearranged during transfection (RET)-positive cancer took part in the rollover study at 30 investigative sites across 9 countries from 5 July 2017 to 18 September 2025.

Pre-assignment

Screening details:

Participants continued alectinib treatment at the same dose received at the time of parent study closure without treatment interruption. No participants were enrolled in the crizotinib arm.

Period 1

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

Arms

Arm title	Alectinib
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Arm description:

Participants with ALK-positive or RET-positive cancer who were deriving clinical benefit from alectinib treatment in a Roche-sponsored parent trial continued to receive alectinib at the same dose they received at the time of parent study closure (registered dose: 600 milligrams [mg]) taken orally twice daily (BID) until no further clinical benefit was expected, unacceptable toxicity, availability of commercial supply, withdrawal of consent, or death.

Arm type	Experimental
Investigational medicinal product name	Alectinib
Investigational medicinal product code	
Other name	RO5424802
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Registered dose of alectinib is 600 mg BID, until no further clinical benefit was expected, unacceptable toxicity, availability of commercial supply, withdrawal of consent, or death.

Number of subjects in period 1	Alectinib
Started	50
Completed	35
Not completed	15
Consent withdrawn by subject	1
Death	1
Progressive disease	1
Reason not Specified	12

Baseline characteristics

Reporting groups

Reporting group title	Alectinib
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Reporting group description:

Participants with ALK-positive or RET-positive cancer who were deriving clinical benefit from alectinib treatment in a Roche-sponsored parent trial continued to receive alectinib at the same dose they received at the time of parent study closure (registered dose: 600 milligrams [mg]) taken orally twice daily (BID) until no further clinical benefit was expected, unacceptable toxicity, availability of commercial supply, withdrawal of consent, or death.

Reporting group values	Alectinib	Total	
Number of subjects	50	50	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	56.6		
standard deviation	± 11.8	-	
Sex: Female, Male			
Units: participants			
Female	30	30	
Male	20	20	
Race (NIH/OMB)			
Units: Subjects			
White	37	37	
American Indian or Alaska Native	0	0	
Asian	6	6	
Black or African American	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
More than one race	0	0	
Unknown or Not Reported	6	6	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	1	
Not Hispanic or Latino	44	44	
Unknown or Not Reported	5	5	

End points

End points reporting groups

Reporting group title	Alectinib
Reporting group description:	
Participants with ALK-positive or RET-positive cancer who were deriving clinical benefit from alectinib treatment in a Roche-sponsored parent trial continued to receive alectinib at the same dose they received at the time of parent study closure (registered dose: 600 milligrams [mg]) taken orally twice daily (BID) until no further clinical benefit was expected, unacceptable toxicity, availability of commercial supply, withdrawal of consent, or death.	

Primary: Number of Participants with Adverse Events (AEs), Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESI)

End point title	Number of Participants with Adverse Events (AEs), Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESI) ^[1]
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End point description:

An AE is any untoward medical occurrence in a participant administered a study drug, regardless of causal relationship. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is a medically important event. AESI included drug induced liver injury that include an elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) in combination with either an elevated bilirubin or clinical jaundice and suspected transmission of infectious agent via study drug. Safety Population included all enrolled participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

From study initiation until 4 weeks after the last dose (up to approximately 8.19 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: No formal statistical analyses were planned for this endpoint.

End point values	Alectinib			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: participants				
AEs	36			
SAEs	6			
AESI	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Causes of Death on Study

End point title	Number and Causes of Death on Study
End point description:	
Safety Population included all enrolled participants who received at least one dose of study drug.	
End point type	Secondary

End point timeframe:

Up to approximately 8.19 years

End point values	Alectinib			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: participants				
Progressive Disease	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From study initiation until 4 weeks after the last dose (up to approximately 8.19 years)

Adverse event reporting additional description:

Safety Population included all enrolled participants who received at least one dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	Alectinib 600mg BID
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Reporting group description: -

Serious adverse events	Alectinib 600mg BID		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 50 (12.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Haemoptysis			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Salmonellosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Alectinib 600mg BID		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 50 (46.00%)		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	5		
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 50 (12.00%)		
occurrences (all)	6		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Oedema peripheral			

subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3		
Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Nausea			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Vomiting			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Productive cough			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 November 2019	Changes to the protocol are summarized: 1) Language had been modified to accommodate changes in local product information without requiring a protocol amendment by directing questions regarding dose reduction or discontinuation for hematologic and non-hematologic toxicities to the U.S. Package Insert or Crizotinib summary of product characteristics (SmPC) or local prescribing information. 2) The Medical Monitor name and contact information was updated.
18 January 2022	Changes to the protocol are summarized: 1) The table providing guidelines for the management of risks, adverse events, and laboratory abnormalities had been updated overall. 2) Hematologic findings from alectinib toxicity studies in animals had been provided to the section describing the risks associated with alectinib. 3) Benefit-risk assessment and guidance on concomitant administration of severe acute respiratory syndrome coronavirus 2 vaccines with alectinib had been added. 4) The Medical Monitor contact information had been updated. 5) The name of a Roche policy on data sharing had been corrected.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported