



Clinical trial results:

An Open-Label, Multicenter Extension Study of Onartuzumab in Patients with Solid Tumors on Study Treatment Previously Enrolled in an F. Hoffmann-La Roche and/or Genentech Sponsored Study

Summary

EudraCT number	2014-005438-69
Trial protocol	ES LV IT
Global end of trial date	29 June 2018

Results information

Result version number	v1 (current)
This version publication date	10 July 2019
First version publication date	10 July 2019

Trial information

Trial identification

Sponsor protocol code	GO29646
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02488330
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, 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	29 June 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this trial were: To provide continued onartuzumab and/or parent trial (P-trial)-designated control treatments to subjects with cancer previously enrolled in a Roche/Genentech P-trial; and to collect safety data related to the administration of continued onartuzumab therapy.

Protection of trial subjects:

All subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 August 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	Japan: 1
Country: Number of subjects enrolled	Latvia: 2
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	South Africa: 2
Country: Number of subjects enrolled	Serbia: 1
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Russian Federation: 1
Worldwide total number of subjects	12
EEA total number of subjects	7

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)	8
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 10 centers in Japan, Latvia, Italy, South Africa, Serbia, Spain, France, and the Russian Federation.

Pre-assignment

Screening details:

Participants with solid tumors previously enrolled in an F. Hoffmann-La Roche and/or Genentech parent trial (P-trial) who received either the control treatment or onartuzumab-based study treatment, had not met the treatment discontinuation criteria for their P-trial, and were able to start treatment within 42 days of the last day of their P-trial.

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	Control and/or Onartuzumab treatment
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Arm description:

Participants received treatment with either the control treatment (erlotinib, bevacizumab) and/or ornartuzumab-based study treatment until disease progression, unacceptable treatment-related toxicity, withdrawal of consent, or death (whichever occurred first).

Arm type	Experimental
Investigational medicinal product name	Onartuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Onartuzumab was administered intravenously (IV) at a dose of either 10 mg/kg every 2 weeks, or 15 mg/kg every 3 weeks.

Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	Avastin
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received IV bevacizumab at a dose based on the manufacturer's prescribing information.

Investigational medicinal product name	Erlotinib
Investigational medicinal product code	
Other name	Tarceva
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received oral erlotinib at a dose based on the manufacturers prescribing information.

Number of subjects in period 1	Control and/or Onartuzumab treatment
Started	12
Completed	0
Not completed	12
Adverse event, serious fatal	2
Physician decision	2
Adverse event, non-fatal	1
Study Termination by Sponsor	4
Disease Progression	3

Baseline characteristics

Reporting groups

Reporting group title	Control and/or Onartuzumab treatment
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Reporting group description:

Participants received treatment with either the control treatment (erlotinib, bevacizumab) and/or ornartuzumab-based study treatment until disease progression, unacceptable treatment-related toxicity, withdrawal of consent, or death (whichever occurred first).

Reporting group values	Control and/or Onartuzumab treatment	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
Adults (18-64 years)	8	8	
From 65-84 years	4	4	
Age Continuous Units: Years			
arithmetic mean	59.67	-	
standard deviation	± 9.78		
Sex: Female, Male Units: Subjects			
Female	6	6	
Male	6	6	
Race (NIH/OMB) Units: Subjects			
Asian	1	1	
White	9	9	
Unknown or Not Reported	2	2	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	12	12	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Control and/or Onartuzumab treatment
Reporting group description: Participants received treatment with either the control treatment (erlotinib, bevacizumab) and/or onartuzumab-based study treatment until disease progression, unacceptable treatment-related toxicity, withdrawal of consent, or death (whichever occurred first).	

Primary: Percentage of Participants With Serious Adverse Events Considered Related to Onartuzumab

End point title	Percentage of Participants With Serious Adverse Events Considered Related to Onartuzumab ^[1]
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End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.

End point type	Primary
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End point timeframe:

Baseline through the end of trial (approximately 3 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 analysis was planned for this study.

End point values	Control and/or Onartuzumab treatment			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Percent				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Baseline through the end of trial (approximately 3 years)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Control and/or Onartuzumab treatment
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Reporting group description:

Participants received treatment with either the control treatment (erlotinib, bevacizumab) and/or ornartuzumab-based study treatment until disease progression, unacceptable treatment-related toxicity, withdrawal of consent, or death (whichever occurred first).

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: The protocol states that only serious adverse events will be collected.

Serious adverse events	Control and/or Onartuzumab treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 12 (41.67%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events			
Vascular disorders			
Cyanosis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Sudden cardiac death			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
Pneumonia			

subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory failure			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 12 (8.33%)		
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	Control and/or Onartuzumab treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2015	Clarification of study treatment dose calculation; update to I/E criteria
17 August 2017	Classification of bevacizumab and erlotinib as control treatment for the study

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported