



Clinical trial results:

A Follow-Up Study of Long-Term Efficacy of Patients with HER2-Positive Early Breast Cancer Who Had Been Enrolled in Study CT-P6 3.2

Summary

EudraCT number	2019-003518-15
Trial protocol	PL RO
Global end of trial date	21 October 2021

Results information

Result version number	v1 (current)
This version publication date	11 June 2022
First version publication date	11 June 2022

Trial information

Trial identification

Sponsor protocol code	CT-P6 4.2
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Celltrion, Inc.
Sponsor organisation address	23, Academy-ro, Yeonsu-gu, Incheon, Korea, Republic of, 22014
Public contact	Celltrion, Inc., Celltrion, Inc., +82 8505000, contact@celltrion.com
Scientific contact	Celltrion, Inc., Celltrion, Inc., +82 8505000, contact@celltrion.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 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 October 2021
Global end of trial reached?	Yes
Global end of trial date	21 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To collect long-term efficacy data from patients who completed the last follow-up visit in main study.

Protection of trial subjects:

The study was conducted according to the principles of the International Council for Harmonisation (ICH) harmonised tripartite guideline E6(R1): Good Clinical Practice (GCP) (ICH 1996) and the ethical principles that have their origin in the World Medical Association Declaration of Helsinki.

Background therapy:

This is a 6-year post-treatment follow-up study extended from the main study, CT-P6 3.2 (EudraCT Number: 2013-004525-84). Therefore, study drug has not been administered in this extended follow-up study.

Evidence for comparator: -

Actual start date of recruitment	14 January 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	6 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belarus: 42
Country: Number of subjects enrolled	Georgia: 30
Country: Number of subjects enrolled	Poland: 12
Country: Number of subjects enrolled	Romania: 18
Country: Number of subjects enrolled	Russian Federation: 76
Country: Number of subjects enrolled	Ukraine: 38
Worldwide total number of subjects	216
EEA total number of subjects	30

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)	193
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The investigator/center personnel from each center contacted all their respective patients who were known to be alive at the last follow-up visit of the main study via telephone to inform them of the observational extended follow-up study and to invite them to an on-center enrollment visit.

Pre-assignment

Screening details:

Female patients age 18 years or older with a pathologically confirmed, newly diagnosed, operable early breast cancer (Stage I, II, or IIIa) who completed the last FU visit of main study around October 2018 (regardless of her study treatment completion status) were included. Patients who died during participation in main study were not eligible.

Period 1

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

Blinding implementation details:

This was open-label study.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P6

Arm description: -

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

Dosage and administration details:

8 mg/kg body weight on Day 1 of Neoadjuvant Period Cycle 1, followed by 6 mg/kg body weight repeated every 3 weeks for 8 cycles

Arm title	Herceptin
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Trastuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use

Dosage and administration details:

8 mg/kg body weight on Day 1 of Neoadjuvant Period Cycle 1, followed by 6 mg/kg body weight repeated every 3 weeks for 8 cycles

Number of subjects in period 1	CT-P6	Herceptin
Started	107	109
Completed	107	109

Baseline characteristics

Reporting groups

Reporting group title	CT-P6
Reporting group description: -	
Reporting group title	Herceptin
Reporting group description: -	

Reporting group values	CT-P6	Herceptin	Total
Number of subjects	107	109	216
Age categorical Units: Subjects			
Adults (18-64 years)	96	97	193
From 65-84 years	11	12	23
Age continuous Units: years			
median	54	51.0	
full range (min-max)	30 to 73	26 to 71	-
Gender categorical Units: Subjects			
Female	107	109	216

Subject analysis sets

Subject analysis set title	Intent-to-Treat Set
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patients in the ITT set for whom data were collected for the extension study.	

Reporting group values	Intent-to-Treat Set		
Number of subjects	216		
Age categorical Units: Subjects			
Adults (18-64 years)	193		
From 65-84 years	23		
Age continuous Units: years			
median			
full range (min-max)			
Gender categorical Units: Subjects			
Female			

End points

End points reporting groups

Reporting group title	CT-P6
Reporting group description: -	
Reporting group title	Herceptin
Reporting group description: -	
Subject analysis set title	Intent-to-Treat Set
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patients in the ITT set for whom data were collected for the extension study.	

Primary: Overall Survival

End point title	Overall Survival
End point description:	
The interval between the date of randomization in the main study and the date of death from any cause.	
End point type	Primary
End point timeframe:	
Up to approximately 6 years.	

End point values	CT-P6	Herceptin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	109		
Units: Months				
median (confidence interval 95%)				
Median	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Overall Survival
Statistical analysis description:	
All patients in the ITT set for whom data were collected for the extension study.	
Comparison groups	CT-P6 v Herceptin
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	other
Method	Adjusted stratified Cox Regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	2.02

Primary: Disease-Free Survival

End point title	Disease-Free Survival
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End point description:

The interval between the date of breast surgery to disease progression, recurrence or death from any cause, whichever occurs first. Patients who underwent breast surgery are included in the disease-free survival analysis.

End point type	Primary
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End point timeframe:

Up to approximately 6 years.

End point values	CT-P6	Herceptin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	107	109		
Units: Months				
median (confidence interval 95%)				
Median	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Disease-Free Survival
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Statistical analysis description:

All patients in the ITT set for whom data were collected for the extension study.

Comparison groups	Herceptin v CT-P6
Number of subjects included in analysis	216
Analysis specification	Pre-specified
Analysis type	other
Method	Adjusted stratified Cox Regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.32

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Up to approximately 6 years.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.1
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Frequency threshold for reporting non-serious adverse events: 0 %

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 study does not have a specific safety objective, nor protocol-mandated products were administered. It was planned to use existing data collected/medical records as data sources, hence, there was no requirement for AE to be recorded in the eCRF or equivalent. PI was advised to report any SAE/AE believed to be related to any medicinal product, according to the standard spontaneous reporting procedures for marketed products in their country. No specific AE were reported during the study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported