



Clinical trial results:

An open label multicentric phase II study of Panitumumab (Vectibix®) in cutaneous squamous cell carcinoma (SCC)

Summary

EudraCT number	2009-015237-76
Trial protocol	BE
Global end of trial date	17 January 2017

Results information

Result version number	v1 (current)
This version publication date	17 March 2021
First version publication date	17 March 2021

Trial information

Trial identification

Sponsor protocol code	LUC 09-002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01129154
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cliniques universitaires Saint-Luc
Sponsor organisation address	Avenue Hippocrate, 10, Brussels, Belgium, 1200
Public contact	Jean-François Baurain, Cliniques universitaires Saint-Luc, +32 2 7645471, jean-francois.baurain@uclouvain.be
Scientific contact	Jean-François Baurain, Cliniques universitaires Saint-Luc, +32 2 7645471, jean-francois.baurain@uclouvain.be

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	01 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2012
Global end of trial reached?	Yes
Global end of trial date	17 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Overall Response Rate (ORR)

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines, and country-specific national and local laws.
Description AE management in the protocol.

Background therapy:

PANITUMUMAB (Vectibix®)

Evidence for comparator:

No active RI in this disease at this stage.

Actual start date of recruitment	10 September 2010
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	Belgium: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	3
From 65 to 84 years	7

85 years and over	8
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Subject disposition

Recruitment

Recruitment details:

Dermatology consultation from September 2010 till May2016.

Pre-assignment

Screening details:

NA

Period 1

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

Arms

Arm title	PANITUMUMAB – Vectibix ARM
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Arm description:

Experimental treatment

Arm type	Experimental
Investigational medicinal product name	PANITUMUMAB
Investigational medicinal product code	
Other name	Vectibix
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 mg/kg p 2 weeks

Number of subjects in period 1	PANITUMUMAB – Vectibix ARM
Started	18
Completed	15
Not completed	3
Adverse event, non-fatal	3

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	18	18	
Age categorical			
Ages Eligible for Study: 18 years and older (Adult)			
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)	3	3	
From 65-84 years	7	7	
85 years and over	8	8	
Age continuous			
Units: years			
arithmetic mean	79.4		
standard deviation	± 13.6	-	
Gender categorical			
Sexes Eligible for Study: All			
Units: Subjects			
Female	7	7	
Male	11	11	

End points

End points reporting groups

Reporting group title	PANITUMUMAB – Vectibix ARM
Reporting group description:	
Experimental treatment	

Primary: Overall Response Rate (ORR)

End point title	Overall Response Rate (ORR) ^[1]
End point description:	To measure the efficacy of Panitumumab for SCC in terms of Overall Response Rate (ORR). Overall Response Rate (ORR) is defined as the sum of complete and partial tumour responses seen, divided by the total number of evaluable patients. Imaging evaluation will be done via photography and CT-scan, MRI or PET-scan every 6 weeks on 2 occasions, then every 12 weeks. Response evaluation will be assessed according Modified RECIST version 1.1. Patient will be declared progressive at that time if their clinical situation requires an immediate alternative treatment. Response evaluation will be assessed at week 12. Best observed response will also be recorded.
End point type	Primary
End point timeframe:	
Via imaging every 12 weeks	

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: Only descriptive statistical analysis has been performed.

ORR and duration of response measured according to modified RECIST version 1.1. Responders and non-responders subjects compared for their demographic parameters, by Fisher exact and Student T tests, according to the type of variables.

The Kaplan-Meier technique used to obtain the TTF and the TTP. Subjects without evidence of progression at the end of follow up considered as censored.

Proportion of all adverse events are reported.

End point values	PANITUMUMAB – Vectibix ARM			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percent				
number (not applicable)	36.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression free survival (PFS)

End point title	Progression free survival (PFS)
End point description:	PFS is defined as the time from date of first dose of study medication to first occurrence of any following event: documentation of objective tumor progression, toxicities requiring prematurely stop of treatment or death.
End point type	Secondary

End point timeframe:
Via imaging, every 12 weeks.

End point values	PANITUMUMAB – Vectibix ARM			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: months				
median (full range (min-max))	4.4 (1.2 to 15.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: overall survival (OS)

End point title	overall survival (OS)
End point description: Duration of overall response measured according RECIST guidelines version 1.1. Duration of response is measured from the time measurement criteria are first met for CR/PR (whichever is first recorded) until the first date that recurrent or progressive disease is objectively documented.	
End point type	Secondary
End point timeframe: Via imaging, every 12 weeks.	

End point values	PANITUMUMAB – Vectibix ARM			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: months				
median (full range (min-max))	12.6 (1.2 to 70.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Serious AE occurring at any time after the patient has signed the informed consent, the screening visit, and within 30 days of the last day on which the investigational agent was administered must be reported within 24 hours of awareness of the event.

Adverse event reporting additional description:

Adverse Events attributes assigned by the investigator: AE diagnosis or syndrome(s); event description; dates of onset and resolution; severity; assessment of relatedness to study treatment; and action taken.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	3.0
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Reporting groups

Reporting group title	PANITUMUMAB - Vectibix ARM
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Reporting group description:

6 SAE occurred in study, all due to a patient hospitalization. The 6 were not related to the study drug, and 3 resolved without sequelae.

Serious adverse events	PANITUMUMAB - Vectibix ARM		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 15 (40.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Cerebellous infarction			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac infarction			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fatigue	Additional description: Due to an underlying gastroenteritis		
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

General condition impairment subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Fever with shivers and Testicle pus collection			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Deshydration	Additional description: Due to an esophageal dysphagia		
subjects affected / exposed	1 / 15 (6.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	PANITUMUMAB - Vectibix ARM		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 15 (86.67%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	9 / 15 (60.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Anemia			
subjects affected / exposed	1 / 15 (6.67%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	5 / 15 (33.33%)		
occurrences (all)	1		

Gastrointestinal disorders Diarrhea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 1 1 / 15 (6.67%) 1 1 / 15 (6.67%) 1		
Respiratory, thoracic and mediastinal disorders Epistaxis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Skin and subcutaneous tissue disorders Skin rash acne/acneiform (Pustulosis) subjects affected / exposed occurrences (all) Skin rash acne/acneiform subjects affected / exposed occurrences (all) Skin Erythema subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Skin dryness subjects affected / exposed occurrences (all) Nail changes subjects affected / exposed occurrences (all) Xerosis, skin dryness subjects affected / exposed occurrences (all)	3 / 15 (20.00%) 1 7 / 15 (46.67%) 1 5 / 15 (33.33%) 1 1 / 15 (6.67%) 1 5 / 15 (33.33%) 1 3 / 15 (20.00%) 1 1 / 15 (6.67%) 1		

Infections and infestations Paronychia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		
Metabolism and nutrition disorders Hypomagnesia subjects affected / exposed occurrences (all)	5 / 15 (33.33%) 1		
Hypokalemia subjects affected / exposed occurrences (all)	3 / 15 (20.00%) 1		
Hypocalcemia subjects affected / exposed occurrences (all)	4 / 15 (26.67%) 1		
Hyperkalemia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 November 2009	1.1 Protocol classification
29 December 2009	1.2 Protocol classification

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.

None

Notes: