



Clinical trial results:

Traitement des carcinomes à cellules de Merkel inopérables et/ou métastatiques par analogue de la somatostatine – Etude nationale multicentrique mono-bras de phase II.

Summary

EudraCT number	2014-001273-13
Trial protocol	FR
Global end of trial date	15 May 2017

Results information

Result version number	v1 (current)
This version publication date	17 July 2022
First version publication date	17 July 2022
Summary attachment (see zip file)	document justifying the missing/partial results _ PHRC MERKEL (PHRC-MERKEL_Note to file EudraCT_2022 05 27 signed MTLecchia.pdf)

Trial information

Trial identification

Sponsor protocol code	38RC14.040
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02351128
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Grenoble Alpes University Hospital
Sponsor organisation address	CS 10217, Grenoble , France, 38043
Public contact	CIC Cancérologie, University Hospital of Grenoble , 33 476769481, ChMendoza@chu-chu-grenoble.fr
Scientific contact	Cancérologie, University Hospital of Grenoble , 33 4 76 76 70 81, SMouret@chu-chu-grenoble.fr

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 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of lanreotide at 3 months in patients with inoperable and/or metastatic Merkel cell carcinoma (MCC).

Protection of trial subjects:

Treatment of localized forms of MCC is currently based on surgery and radiotherapy, but when patients are in the metastatic stage no survival benefit has been demonstrated using chemotherapy, unlike other neuroendocrine tumors. The prognosis for patients with stage IV disease is severe with a 1-year survival of about 44%.

Chemotherapy is therefore currently considered a palliative treatment in case of disseminated disease. In this context we can offer this treatment to these patients. The clinical benefits of this treatment have been observed in some patients without side effects. This treatment already has MA in other indications and is well tolerated.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	24 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 35
Worldwide total number of subjects	35
EEA total number of subjects	35

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)	2
From 65 to 84 years	23
85 years and over	10

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Inoperable or histologically confirmed merkel cell carcinoma stage III B or IV (according to AJCC 2010 classification)

First line of treatment or more

At least one measurable target of more than 20 mm with a conventional scanner or more than 10 mm with a spiral scanner or evaluable clinical targets

Period 1

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

Arms

Arm title	intervention
Arm description: lanretotide	
Arm type	Experimental
Investigational medicinal product name	lanréotide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

120 mg each 28 days

Number of subjects in period 1	intervention
Started	35
Completed	35

Baseline characteristics

Reporting groups

Reporting group title	lanreotide
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Reporting group description: -

Reporting group values	lanreotide	Total	
Number of subjects	35	35	
Age categorical			
Units: Subjects			
Adults (18-64 years)	2	2	
From 65-84 years	23	23	
85 years and over	10	10	
Gender categorical			
Units: Subjects			
Female	23	23	
Male	12	12	

End points

End points reporting groups

Reporting group title	intervention
Reporting group description:	
lanretotide	
Subject analysis set title	One Arm
Subject analysis set type	Full analysis
Subject analysis set description:	
One Arm analysis	

Primary: efficacy of lanreotide

End point title	efficacy of lanreotide
End point description:	
Treatment will be considered effective if 40% of patients have a positive response. The positive response is defined by all patients with either a complete response, a partial response, or a stable response according to RECIST 1.1 criteria.	
End point type	Primary
End point timeframe:	
evaluation at 3 months of treatment	

End point values	intervention	One Arm		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	35	35		
Units: RECIST 1.1 criteria.				
number (not applicable)	35	35		

Statistical analyses

Statistical analysis title	Primary endpoint
Comparison groups	intervention v One Arm
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	≤ 0.05
Method	Shapiro-Wilks

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During all the study periods

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	intervention
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Reporting group description:

lanretoride

Serious adverse events	intervention		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 35 (2.86%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Metabolism and nutrition disorders			
Hyponatraemia			
alternative dictionary used: MedDRA 20.1			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	intervention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 35 (11.43%)		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 June 2015	Updating of the centres and associated investigators. The investigators' table is removed from the protocol and appended separately. Somatuline SPC update, minor version update.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported