



Clinical trial results:

A Multicenter, Open-Label Trial of Belinostat in Patients with Relapsed or Refractory Peripheral T-Cell Lymphoma

Summary

EudraCT number	2008-005843-40
Trial protocol	DK FR IT NL BE DE ES HU SK PL GB
Global end of trial date	27 October 2014

Results information

Result version number	v1
This version publication date	11 November 2016
First version publication date	11 November 2016
Summary attachment (see zip file)	PDX-CLN19 Study Report (cln19--study-report-body.pdf) PDX-CLN19 Investigator's Brochure version 13 (belino-ib-v13.pdf) Demographics (t-1-dm.pdf) Dispositions (t-2-disp.pdf) Adverse Events (t-3-ae.pdf) Serious Adverse Events (t-4-sae.pdf) Adverse Events By Preferred Term (t-5-ae-pref.pdf) Related Treatment-Emergent Adverse Events By System Organ Class (t-6-ae-rel.pdf) Serious Related Treatment-Emergent Adverse Events By System Organ Class (t-7-sae-rel.pdf)

Trial information

Trial identification

Sponsor protocol code	PXD101-CLN-19
-----------------------	---------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00865969
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Spectrum Pharmaceuticals
Sponsor organisation address	157 Technology Drive, Irvine, United States, 92618
Public contact	Clinical Operations, Topotarget A/S, 45 39 17 83 92, enquiries@topotarget.com
Scientific contact	Clinical Operations, Topotarget A/S, 45 39 17 83 92, enquiries@topotarget.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	13 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the objective response rate in patients with peripheral T cell lymphoma who are treated with belinostat monotherapy.

Protection of trial subjects:

Informed Consent Form was used to ensure all participation is voluntary and study subjects are aware of their right, including personal health information privacy. Clinical monitoring visits were conducted throughout the life of study to ensure study patient safety are continuously monitored and protected. The assigned medical monitor also reviewed the data on frequent basis to ensure that all safety data are adequately monitored and issues addressed timely.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 2008
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	Netherlands: 10
Country: Number of subjects enrolled	Israel: 4
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	United States: 37
Country: Number of subjects enrolled	Croatia: 4
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	Slovakia: 2
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	France: 4

Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Hungary: 11
Country: Number of subjects enrolled	Italy: 3
Worldwide total number of subjects	129
EEA total number of subjects	78

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)	67
From 65 to 84 years	62
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients with relapsed or refractory T-Cell lymphoma must sign consent and meet all Inclusion/Exclusion criteria

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belinostat
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Belinostat
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m² of Belinostat administered as a 30 minutes IV infusion on days 1-5 of every 3-week cycle

Number of subjects in period 1	Belinostat
Started	129
Completed	129

Period 2

Period 2 title	Overall trial
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Belinostat
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Belinostat
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg/m² of Belinostat administered as a 30 minutes IV infusion on days 1-5 of every 3-week cycle

Number of subjects in period 2	Belinostat
Started	129
Completed	129

Baseline characteristics

End points

End points reporting groups

Reporting group title	Belinostat
Reporting group description: -	
Reporting group title	Belinostat
Reporting group description: -	

Primary: Objective Response Rate

End point title	Objective Response Rate ^[1]
End point description:	
Overall study duration from first dose until 2 years after the first dose	
End point type	Primary
End point timeframe:	
24 months	

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: The statistical analysis shows a 26% ORR of the total evaluable population of 120 subjects

End point values	Belinostat			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: percentage	31			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Patients must be carefully monitored for all adverse events that occur from the time Informed Consent is obtained until 30 days after the last study drug administration.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

Frequency threshold for reporting non-serious adverse events: 0.05 %

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: 125 subjects out of 129 treated subjects had at least 1 non-serious adverse event.

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