



Clinical trial results:

Veliparib (ABT888) and Topotecan (Hycamtin®) for Patients with Platinum-Resistant or Partially Platinum-Sensitive Relapse of Epithelial Ovarian Cancer with Negative or Unknown BRCA Status

Summary

EudraCT number	2012-001661-32
Trial protocol	DK
Global end of trial date	01 February 2015

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	VeTo
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01690598
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Vejle Hospital
Sponsor organisation address	Beriderbakken 4, Vejle, Denmark,
Public contact	Clinical Trial Unit, Vejle Hospital, kfe.onko@rsyd.dk
Scientific contact	Clinical Trial Unit, Vejle Hospital, kfe.onko@rsyd.dk

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 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2015
Global end of trial reached?	Yes
Global end of trial date	01 February 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Phase I:

To determine:

Maximum-tolerated dose (MTD)

Dose-limiting toxicities (DLT)

Recommended phase II dose

Phase II:

To investigate response rates (based on either CA125 GCIG or RECIST criteria) of combination topotecan and veliparib (ABT888) in relapsed ovarian cancer with negative or unknown BRCA status.

Protection of trial subjects:

Reduction of topotecan dose to 2mg/m2

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2013
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	Denmark: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	15
From 65 to 84 years	11

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Phase 1 included from 1 February to 2 October 2013.

Phase 2 included from 8 November 2013 to 3 October 2014.

Pre-assignment

Screening details:

Patients with platinum-resistant or partially platinum-sensitive relapse of epithelial ovarian cancer were screened on an outpatient basis.

Pre-assignment period milestones

Number of subjects started	26
Number of subjects completed	26

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	Phase II
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Veliparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use
Dosage and administration details:	
30 mg x 2 daily on days 1-3, 8-10, and 15-17	
Investigational medicinal product name	Topotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Topotecan 2 mg/m² iv over 30 minutes, days 2, 9 and 16 in 28-day cycles.

Number of subjects in period 1	Phase II
Started	26
Completed	26

Baseline characteristics

Reporting groups

Reporting group title	Phase II
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Reporting group description: -

Reporting group values	Phase II	Total	
Number of subjects	26	26	
Age categorical			
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)	15	15	
From 65-84 years	11	11	
85 years and over	0	0	
Gender categorical			
Danish ovarian cancer patients			
Units: Subjects			
Female	26	26	
Male	0	0	

End points

End points reporting groups

Reporting group title	Phase II
Reporting group description: -	

Primary: Response rate

End point title	Response rate ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Every three treatment cycles	

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: There is only one group and thus statistical analysis is not applicable.

End point values	Phase II			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Fraction				
number (not applicable)	26			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Every 3 weeks

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4
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Reporting groups

Reporting group title	Toxicity
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Reporting group description: -

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 frequency threshold for reporting non-serious adverse events was not exceeded.

Serious adverse events	Toxicity		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 26 (46.15%)		
number of deaths (all causes)	26		
number of deaths resulting from adverse events	0		
Investigations			
Reduced general condition			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pain			

subjects affected / exposed	3 / 26 (11.54%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 26 (7.69%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	3 / 26 (11.54%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	3 / 26 (11.54%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 26 (7.69%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Fever			

subjects affected / exposed	2 / 26 (7.69%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 26 (3.85%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Toxicity		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 May 2013	The starting dose of topotecan was not tolerated well and therefore reduced to 2 mg/m ² .

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported