Clinical trial results:
A Single Arm Phase II trial of BMN 673 for inoperable, advanced endometrial cancer with retrospective PTEN, MSI and MRE11 analysis.

Summary

EudraCT number	2013-003469-32
Trial protocol	GB
Global end of trial date	09 December 2015

Results information

Result version number	v1 (current)
This version publication date	31 October 2019
First version publication date	31 October 2019
Summary attachment (see zip file)	Statement (PANDA - EudraCT - Statement on discontinuation of the study.pdf)

Trial information

Trial identification

Sponsor protocol code	UCL/13/0045

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02127151
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University College London
Sponsor organisation address	Gower Street, London, United Kingdom,
Public contact	Cancer Research UK & UCL Cancer Trials Centre, University College London, ctc.enquiries@ucl.ac.uk
Scientific contact	Cancer Research UK & UCL Cancer Trials Centre, University College London, ctc.enquiries@ucl.ac.uk

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	09 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 December 2015
Global end of trial reached?	Yes
Global end of trial date	09 December 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main aim of this trial is to show whether or not BMN 673 has therapeutic benefit in the treatment of inoperable, advanced, recurrent or metastatic endometrial cancer; specifically whether the drug extends the progression free survival of patients i.e. the length of time during and after the treatment that the patient lives with the cancer but it does not get significantly worse. This will be measured by looking at how many patients of the recruited patients are alive and progression free 6 months after their first dose of BMN 673.

Protection of trial subjects:

No specific measure in place.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2014
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	United Kingdom: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Trial abandoned during set-up by the sponsor (University College London) due to withdrawal of industry support. No sites activated and no patients entered the study, therefore no data/results are available. PLEASE NOTE: THE RESULTS SYSTEM DOES NOT ALLOW NUMBER OF PATIENTS TO BE ZERO, INSTEAD '1' WAS ADDED IN PATIENT SECTION TO ALLOW RESULT POSTING

Period 1

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

Arms

Arm title	Treatment Phase
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	BMN 673
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

250ug

Number of subjects in period 1	Treatment Phase
Started	1
Completed	0
Not completed	1
No patients actually enrolled on study	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment Phase

Reporting group description: -

Primary: Progression free survival (PFS) rate at 6 months measured by RECIST v1.1.

End point title	Progression free survival (PFS) rate at 6 months measured by RECIST v1.1.[1]

End point description:

End point type	Primary

End point timeframe:

6 months from first BMN 673 dose.

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: Trial abandoned during set-up by the sponsor (University College London) due to withdrawal of industry support. No sites activated and no patients entered the study, therefore no data/results are available.
PLEASE NOTE: THE RESULTS POSTING SYSTEM DOES NOT ALLOW NUMBER OF PATIENTS TO BE ZERO, INSTEAD NUMBER OF PATIENTS WAS ADDED AS 1 IN ORDER TO ALLOW POSTING OF THE DATASET.

End point values	Treatment Phase			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: Patients	0			

Notes:

[2] - No patients were actually enrolled in trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Dosing period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	Treatment Phase

Reporting group description: -

Serious adverse events	Treatment Phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Treatment Phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

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: Trial abandoned during set-up by the sponsor (University College London) due to withdrawal of industry support. No sites activated and no patients entered the study, therefore no data/results are available.
PLEASE NOTE: THE RESULTS POSTING SYSTEM DOES NOT ALLOW NUMBER OF PATIENTS TO BE ZERO, INSTEAD NUMBER OF PATIENTS WAS ADDED AS 1 IN ORDER TO ALLOW POSTING OF THE DATASET.

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