Clinical trial results:
Phase II trial of Pembrolizumab in combination with Doxorubicin in Advanced, Recurrent or Metastatic Endometrial Cancer (TOPIC)

Summary

EudraCT number	2017-002824-26
Trial protocol	ES
Global end of trial date	31 October 2019

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022
Summary attachment (see zip file)	Justification_no_results_available (TOPIC_Clinical_Trial.pdf) Abstract (A118.2.full.pdf)

Trial information

Trial identification

Sponsor protocol code	VHIO17001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03276013
WHO universal trial number (UTN)	-
Other trial identifiers	TOPIC: VHIO17001

Notes:

Sponsors

Sponsor organisation name	Vall d'Hebron Institute of Oncology (VHIO)
Sponsor organisation address	Carrer de Natzaret, 117, Barcelona, Spain, 08035
Public contact	Sponsor, Clinical Research Support Unit, Vall d' Hebron Institute of Oncology (VHIO), 34 9325434508614, mcarboneras@vhio.net
Scientific contact	Sponsor, Vall d' Hebron Institute of Oncology (VHIO), 686187838 9325434508614, mcarboneras@vhio.net

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	Interim
Date of interim/final analysis	10 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the efficacy of anti-PD1 blockade with pembrolizumab in combination with immunogenic chemotherapy with doxorubicin in patients with recurrent endometrial cancer in terms of patients who survived progression free (PFS) at least 6 months. Therefore the primary efficacy objective in this triail is PFS rate at 6 months according to RECIST 1.1 criteria.

Protection of trial subjects:

This clinical study was designed and implemented and reported in accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations (including European Directive 2001/20/EC and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2018
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	Spain: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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)	22
From 65 to 84 years	26

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects with recurrent/metastatic endometrial cancer and progressive disease after platinum-containing cytotoxic
chemotherapy. Subjects with advanced epithelial endometrial tumor histologies, including endometriod, serous, clear cell, and squamous carcinoma were enrolled.

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	Complete Set

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab in combination with Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Doxorubicin 60 mg/kg IV over 30 minutes on day 1 every 3 weeks up to 9 cycles in combination with Pembrolizumab (MK-3475) 200 mg IV Q3W

Number of subjects in period 1	Complete Set
Started	48
Completed	48

Baseline characteristics

End points

End points reporting groups

Reporting group title	Complete Set
Reporting group description: -	
Subject analysis set title	Complete Set
Subject analysis set type	Full analysis
Subject analysis set description:	
All patients receiving treatment	

Primary: PFS rate at 6 months

End point title	PFS rate at 6 months[1]
End point description:	
End point type	Primary
End point timeframe:	
6 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: We are currently finalizing the final statistical analysis on all pre-specified outcome measures. Consequently, no results are available for this trial.

End point values	Complete Set			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: %	48			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From the time of treatment allocation through 30 days following cessation of treatment, all adverse events were reported by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24

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

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: We are currently finalizing the final statistical analysis on all pre-specified outcome measures. Consequently, no results are available for this trial

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