



## 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)<br>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 trial 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 endometrioid, 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

|                                       |              |
|---------------------------------------|--------------|
| <b>Number of subjects in period 1</b> | 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 <sup>[1]</sup> |
| 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.

|                             |                      |  |  |  |
|-----------------------------|----------------------|--|--|--|
| <b>End point values</b>     | 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

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### Adverse events information<sup>[1]</sup>

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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.

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

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### Dictionary used

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|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 24     |

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

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#### 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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported