Clinical trial results:
A phase II Investigation of Pembrolizumab (Keytruda) in combination with radiation and an immune modulatory cocktail in patients with cervical and uterine cancer.

Summary

EudraCT number	2016-001569-97
Trial protocol	BE
Global end of trial date	08 December 2021

Results information

Result version number	v1 (current)
This version publication date	06 June 2024
First version publication date	06 June 2024
Summary attachment (see zip file)	Results of the phase II Primmo study - original article (s00262-022-03253-x.pdf) Results of the phase II PRIMMO study - Supplementary Material (262_2022_3253_MOESM1_ESM.docx) Final Study Report (2016-001569-97_PRIMMO_Final study report_2022-10-13_signature.pdf)

Trial information

Trial identification

Sponsor protocol code	AGO/2016/004

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Joke Tommelein, Bimetra Clinics, 32 93320500, hiruz.cut@uzgent.be
Scientific contact	Joke Tommelein, Bimetra Clinics, 32 93320500, hiruz.ctu@uzgent.be

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	08 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy (objective response rate) at week 26 according irRC criteria

Protection of trial subjects:

see attachement

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 January 2017
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	Belgium: 44
Worldwide total number of subjects	44
EEA total number of subjects	44

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)	44
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachement final study report

Pre-assignment

Screening details:

See attachement final study report

Period 1

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

Blinding implementation details:

See attachement final study report

Arms

Arm title	Arm title

Arm description:

See attachement final study report

Arm type	Active comparator
Investigational medicinal product name	See attachement final study report
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Other use

Dosage and administration details:

See attachement final study report

Number of subjects in period 1	Arm title
Started	44
Completed	44

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm title

Reporting group description:

See attachement final study report

Primary: End Point

End point title	End Point[1]

End point description:

End point type	Primary

End point timeframe:

See attachement final study report

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: See attachement final study report

End point values	Arm title			
Subject group type	Reporting group			
Number of subjects analysed	44[2]			
Units: 44	44			

Notes:

[2] - See attachement final study report

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: See attachement final study report	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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

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: See attachement final study report

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