EU Clinical Trials Register

Clinical trial results:
An Open-label, Multi-Center, Rollover Study in Patients with Advanced Melanoma After Completing an IMCgp100 Clinical Study

Summary

EudraCT number	2016-002236-32
Trial protocol	GB
Global end of trial date	22 April 2019

Results information

Result version number	v1 (current)
This version publication date	07 May 2020
First version publication date	07 May 2020

Trial information

Trial identification

Sponsor protocol code	IMCgp100-401

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02889861
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Immunocore
Sponsor organisation address	181 Washington Street, Conshohocken, United States,
Public contact	Shaad E. Abdullah, MD FACP, Immunocore, Ltd. , +1 267-422-4532, clinicaltrials@immunocore.com
Scientific contact	Shaad E. Abdullah, MD FACP, Immunocore, Ltd. , +1 267-422-4532, clinicaltrials@immunocore.com

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	22 April 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 April 2019
Global end of trial reached?	Yes
Global end of trial date	22 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to determine the number of participants with adverse events associated with IMCgp100 treatment.

Protection of trial subjects:

Eligible participants were included in the study after providing written (witnessed, where required by law or regulation), IRB/IEC/REB-approved informed consent or, if incapable of doing so, after such consent had been provided by a legally acceptable representative of the participant. In cases where the participant's representative gave consent, the participant was informed about the study to the extent possible given his/her understanding. If the participant was capable of doing so, he or she indicated assent by personally signing and dating the written informed consent document or a separate assent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 November 2016
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: 3
Worldwide total number of subjects	3
EEA total number of subjects	3

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	2

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Eligible participants have tolerated IMCgp100 (77 kDa bi-specific protein) for a minimum of 4 weeks of dosing without significant toxicities that would preclude further dosing in the opinion of the principal investigator or Sponsor.

Pre-assignment

Screening details:

Participants were eligible for enrollment in this study from parent studies that have completed and satisfied its primary endpoints or have been terminated by the Sponsor for reasons other than safety.

Period 1

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

Arms

Arm title	IMCgp100 weekly dosing regimen (QW)

Arm description: -

Arm type	Experimental
Investigational medicinal product name	IMCgp100
Investigational medicinal product code	
Other name	Bispecific soluble HLA-A2 restricted gp100-specific TCR fused to anti-CD3
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

IMCgp100 dose as determined from previous regimen in parent IMCgp100 clinical study administered as an intravenous infusion over 15 minutes every week.

Number of subjects in period 1	IMCgp100 weekly dosing regimen (QW)
Started	3
Completed	1
Not completed	2
Survival Follow-up	2

Baseline characteristics

Reporting groups

Reporting group title	Regimen 1

Reporting group description: -

Reporting group values	Regimen 1	Total	
Number of subjects	3	3	
Age categorical Units: Subjects			
Between 18 and 65 years	1	1	
>=65 years	2	2	
Gender categorical Units: Subjects			
Female	1	1	
Male	2	2	

End points

End points reporting groups

Reporting group title	IMCgp100 weekly dosing regimen (QW)

Reporting group description: -

Primary: Incidence of Adverse Events: Number of Participants With Treatment-Emergent Adverse Events

End point title	Incidence of Adverse Events: Number of Participants With Treatment-Emergent Adverse Events[1]

End point description:

Incidence of adverse events was presented as the number of participants with treatment-emergent adverse events (TEAEs). TEAEs were defined as adverse events (AEs) that started or worsened in severity from the date of first
dose of the rollover study (regardless of time) up until 90 days after the last dose of study drug of this rollover study. Participants with multiple events in the same category were counted only once in that category. Participants with events in more than 1 category were counted once in each of those categories. TEAEs indicated considered related to IMCgp100 were determined by the investigator to be possibly related or related to study drug.

End point type	Primary

End point timeframe:

4 years

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: No statistical analysis was performed for this outcome as the outcome measure was a count of subjects by predefined category of TEAE.

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: number of participants				
Any TEAE	3			
Any TEAE of CTCAE Grade ≥3	2			
Any TEAE related to IMCgp100 by Investigator	2			
Any TEAE of CTCAE Grade ≥3 and related to IMCgp10	1			
Any serious TEAE	0			
Any serious TEAE related to IMCgp100	0			
Any TEAE leading to death	0			
Any TEAE leading to discontinuation of study drug	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability: Dose Interruptions and Reductions of IMCgp100 by

Participant (Participant 4001001)

End point title	Tolerability: Dose Interruptions and Reductions of IMCgp100 by Participant (Participant 4001001)

End point description:

Tolerability of study treatment was assessed by summarizing the number of treatment dose interruptions and dose reductions. Reasons for dose interruptions and dose reductions were listed by participant and summarized.

End point type	Secondary

End point timeframe:

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: characteristic/study drug				
Number of cycles started (rollover)	2			
Number of cycles completed (rollover)	1			
Duration of IMCgp100 treatment on rollover study	43			
Duration of interruption on rollover study (days)	0			
Duration of IMCgp100 treatment from first parent	423			
Total actual dose received (µg) (rollover)	350			

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability: Dose Interruptions and Reductions of IMCgp100 by Participant (Participant 4002001)

End point title	Tolerability: Dose Interruptions and Reductions of IMCgp100 by Participant (Participant 4002001)

End point description:

Tolerability of study treatment was assessed by summarizing the number of treatment dose interruptions and dose reductions. Reasons for dose interruptions and dose reductions were listed by participant and summarized.

End point type	Secondary

End point timeframe:

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: characteristic/study drug				
Number of cycles started (rollover)	26			
Number of cycles completed (rollover)	25			
Duration of IMCgp100 treatment on rollover study	728			
Duration of interruption on rollover study (days)	0			
Duration of IMCgp100 treatment from first parent	1156			
Total actual dose received (µg) (rollover)	5100			

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability: Dose Interruptions and Reductions of IMCgp100 by Participant (Participant 4003001)

End point title	Tolerability: Dose Interruptions and Reductions of IMCgp100 by Participant (Participant 4003001)

End point description:

Tolerability of study treatment was assessed by summarizing the number of treatment dose interruptions and dose reductions. Reasons for dose interruptions and dose reductions were listed by participant and summarized.

End point type	Secondary

End point timeframe:

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: characteristic/study drug				
Number of cycles started (rollover)	18			
Number of cycles completed (rollover)	17			
Duration of IMCgp100 treatment on rollover study	505			
Duration of interruption on rollover study (days)	0			
Duration of IMCgp100 treatment from first parent	960			
Total actual dose received (µg) (rollover)	3500			

Statistical analyses

No statistical analyses for this end point

Secondary: Assessments of Anti-IMCgp100 Antibody Formation: Number of Participants With Anti-IMCgp100 Antibody Formation

End point title	Assessments of Anti-IMCgp100 Antibody Formation: Number of Participants With Anti-IMCgp100 Antibody Formation
End point description:	

The concentration/AE — immunogenicity relationship was explored graphically, and tabulated to characterize a relationship between the changes from screening immunogenicity presence and serum concentration of IMCgp100.

End point type	Secondary
End point timeframe:	

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: participants				
Assessments of Anti-IMCgp100 Antibody Formation:	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival Status of All Participants Treated With IMCgp100: Number of Participants

End point title	Overall Survival Status of All Participants Treated With IMCgp100: Number of Participants
End point description:	

This endpoint was used to estimate the overall survival (OS) in participants treated with IMCgp100. OS is defined as the time from the date of first dose of study drug in the parent study until death due to any cause. Any participant not known to have died at the time of analysis was right-censored based on the last recorded date on which the participant was known to be alive, i.e. the latest of (i) the "Date of death or Last contact" (for those participants still alive) on the End of Study electronic case report form page and (ii) "Date patient last known to be alive" on the Survival Follow Up eCRF page. Number of days was then converted to months.

End point type	Secondary
End point timeframe:	

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
number (not applicable)				
Dead	27.0			
Study Terminated by Sponsor	41.0			
Alive	41.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Intensity of IMCgp100 by Participant (Participant 4001001)

End point title	Dose Intensity of IMCgp100 by Participant (Participant 4001001)
End point description:	

End point type	Secondary
End point timeframe:	
4 years	

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: number				
number (not applicable)				
Dose intensity (μg/week) (rollover)	57.0			
Relative dose intensity (%) (rollover)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Intensity of IMCgp100 by Participant (Participant 4002001)

End point title	Dose Intensity of IMCgp100 by Participant (Participant 4002001)

End point description:

End point type	Secondary

End point timeframe:

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: number				
number (not applicable)				
Dose intensity (µg/week) (rollover)	49.0			
Relative dose intensity (%) (rollover)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose Intensity of IMCgp100 by Participant (Participant 4003001)

End point title	Dose Intensity of IMCgp100 by Participant (Participant 4003001)

End point description:

End point type	Secondary

End point timeframe:

4 years

End point values	IMCgp100 weekly dosing regimen (QW)			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: number				
number (not applicable)				
Dose intensity (µg/week) (rollover)	48.5			
Relative dose intensity (%) (rollover)	100			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All participants who received any treatment with IMCgp100 were considered evaluable for safety. All AEs, regardless of study drug relationship, were collected through the 30-day Safety Follow up Period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	IMCgp100 weekly dosing regimen (QW)

Reporting group description: -

Serious adverse events	IMCgp100 weekly dosing regimen (QW)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	IMCgp100 weekly dosing regimen (QW)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
Investigations			
ALT increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
AST increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Lipase increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	5		
White blood cell count decreased			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	6		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Hypomagnesaemia			

subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 November 2016	Amendment 2 changes: -Added criteria for treatment beyond progression (Protocol Section 6.6.1) and rationale (Protocol Section 2.4) and treatment discontinuation in the setting of treatment beyond progression -Clarified that the dose and regimen of IMCgp100 was to be determined based upon the dose and schedule utilized in the parent study -Extended the Follow-up Period from 30 days to 90 days

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported