Clinical trial results:
A MULTICENTRE, SINGLE-ARM, OPEN-LABEL STUDY TO CHARACTERISE THE RELATIONSHIP BETWEEN PRE-TRANSPLANT PHARMACOKINETICS OF ADVAGRAF® AND THE DOSE REQUIRED POST-TRANSPLANT TO ACHIEVE TARGET TROUGH LEVELS IN DE NOVO KIDNEY TRANSPLANT RECIPIENTS

Summary

EudraCT number	2013-000985-13
Trial protocol	ES
Global end of trial date	31 October 2013

Results information

Result version number	v1 (current)
This version publication date	29 December 2019
First version publication date	29 December 2019
Summary attachment (see zip file)	Cancelled Before Active Statement (Cancelled Before Active Statement PMR-EC-1214.pdf)

Trial information

Trial identification

Sponsor protocol code	PMR-EC-1214

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Astellas Pharma Europe Ltd.
Sponsor organisation address	Sylviusweg 62, Leiden, Netherlands,
Public contact	Service Desk, Astellas Pharma Europe B.V., 0031 (0)715455878, contact@nl.astellas.com
Scientific contact	Service Desk, Astellas Pharma Europe B.V., 0031 (0)715455878, contact@nl.astellas.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	31 October 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to assess if Advagraf® pharmacokinetic parameters measured prior to transplantation can predict the dose required after transplantation to achieve target trough levels of 10 ng/mL in individual patients.

Protection of trial subjects:

This clinical study was written, conducted and reported in accordance with the protocol, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines, and applicable local regulations, including the European Directive 2001/20/EC, on the protection of human rights, and with the ethical principles that have their origin in the Declaration of Helsinki. Astellas ensures that the use and disclosure of protected health information (PHI) obtained during a research study complies with the federal, national and/or regional legislation related to the privacy and protection of personal information.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 October 2013
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the trial.

Pre-assignment

Screening details:

N/A

Period 1

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

Blinding implementation details:

N/A

Arms

Arm title	Advagraf

Arm description:

Advagraf oral capsules

Arm type	Experimental
Investigational medicinal product name	Advagraf
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

This trial was discontinued with no participants enrolled or dosed in the trial.

Number of subjects in period 1	Advagraf
Started	99999
Completed	99999

Baseline characteristics

End points

End points reporting groups

Reporting group title	Advagraf
Reporting group description:	
Advagraf oral capsules	

Primary: Dose of tacrolimus required to achieve a trough level of 10 ng/mL on Day 3 after transplantation.

End point title	Dose of tacrolimus required to achieve a trough level of 10 ng/mL on Day 3 after transplantation.[1]
End point description:	
99999 is "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe:	
Day 3 after transplantation	

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 analyses were performed. This trial was discontinued with no participants enrolled in the trial.

End point values	Advagraf			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: Number	99999			

Notes:

[2] - This trial was discontinued with no participants enrolled in the trial.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Not applicable. This trial was discontinued with no participants enrolled in the trial.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

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: 99999 is "Not applicable" value or 0 participants. This trial was discontinued with no participants enrolled in the 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