



Clinical trial results:

An Optional Prospective Follow-on Study to Evaluate the Continued Efficacy and Safety of Cat-PAD in Cat Allergic Subjects up to Five Years after the Administration of Treatment

Summary

EudraCT number	2013-004669-15
Trial protocol	BE DE CZ
Global end of trial date	31 May 2017

Results information

Result version number	v1 (current)
This version publication date	14 April 2018
First version publication date	14 April 2018

Trial information

Trial identification

Sponsor protocol code	CP007A
-----------------------	--------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02040844
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Circassia Limited
Sponsor organisation address	Robert Robinson Avenue, Oxford, United Kingdom,
Public contact	CP007A-ClinicalTrialInformationDesk, Circassia Limited, +44 1865598078, CP007AClinicalTrialInformationDesk@circassia.co.uk
Scientific contact	CP007A-ClinicalTrialInformationDesk, Circassia Limited, +44 1865598078, CP007AClinicalTrialInformationDesk@circassia.co.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001054-PIP10-03
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	27 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2017
Global end of trial reached?	Yes
Global end of trial date	31 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the continued efficacy of Cat-PAD, the first in a new class of Synthetic Peptide Immuno-Regulatory Epitopes, for a total of up to five years after the administration of treatment, based on the reduction of symptoms and the use of allergy medication in subjects previously participating in CP007.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 April 2014
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	Poland: 115
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Czech Republic: 85
Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Canada: 101
Country: Number of subjects enrolled	United States: 104
Worldwide total number of subjects	430
EEA total number of subjects	225

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)	23

Adults (18-64 years)	405
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who successfully completed CP007 were eligible for CP007A

Period 1

Period 1 title	Randomisation (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
------------------------------	-----

Arm title	Treatment Group 1
------------------	-------------------

Arm description:

single course of Cat-PAD 4x6 nmol 4 weeks apart followed by 4 x placebo 4 weeks apart

Arm type	Experimental
Investigational medicinal product name	Cat-PAD
Investigational medicinal product code	Cat-PAD
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

A single course of Cat-PAD 4x6 nmol 4 weeks apart followed by 4x placebo 4 weeks apart

Investigational medicinal product name	Cat-PAD
Investigational medicinal product code	Cat-PAD
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Single course of Cat-PAD 4x6 nmol 4 weeks apart followed by a second course of Cat-PAD 4x6 nmol 4 weeks apart

Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Two courses of 4 x placebo 4 weeks apart

Investigational medicinal product name	Cat-PAD
Investigational medicinal product code	Cat-PAD
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

A single course of Cat-PAD 4x6 nmol 4 weeks apart followed by 4x placebo 4 weeks apart

Arm title	Treatment Group 2
------------------	-------------------

Arm description:

single course of Cat-PAD 4x6 nmol 4 weeks apart followed by a second course of Cat-PAD 4x6 nmol 4 weeks apart

Arm type	Experimental
Investigational medicinal product name	Cat-PAD
Investigational medicinal product code	Cat-PAD
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Single course of Cat-PAD 4x6 nmol 4 weeks apart followed by a second course of Cat-PAD 4x6 nmol 4 weeks apart

Arm title	Treatment Group 3
------------------	-------------------

Arm description:

Two courses of 4 x placebo 4 weeks apart

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Two courses of 4 x placebo 4 weeks apart

Number of subjects in period 1	Treatment Group 1	Treatment Group 2	Treatment Group 3
Started	138	148	144
Completed	88	109	97
Not completed	50	39	47
Consent withdrawn by subject	16	22	25
Adverse event, non-fatal	-	-	1
Not specified	8	2	5
Concomittant medication	1	3	1
Lost to follow-up	12	9	13
Missing	13	3	2

Baseline characteristics

Reporting groups

Reporting group title	Randomisation
-----------------------	---------------

Reporting group description: -

Reporting group values	Randomisation	Total	
Number of subjects	430	430	
Age categorical Units: Subjects			
Adolescents (12-17 years)	23	23	
Adults (18-64 years)	405	405	
From 65-84 years	2	2	
Gender categorical Units: Subjects			
Female	292	292	
Male	138	138	

End points

End points reporting groups

Reporting group title	Treatment Group 1
Reporting group description: single course of Cat-PAD 4x6 nmol 4 weeks apart followed by 4 x placebo 4 weeks apart	
Reporting group title	Treatment Group 2
Reporting group description: single course of Cat-PAD 4x6 nmol 4 weeks apart followed by a second course of Cat-PAD 4x6 nmol 4 weeks apart	
Reporting group title	Treatment Group 3
Reporting group description: Two courses of 4 x placebo 4 weeks apart	

Primary: Mean Combined Score (CS) consisting of (TRSS/8 + Allergy Medication Score [AMS])

End point title	Mean Combined Score (CS) consisting of (TRSS/8 + Allergy Medication Score [AMS]) ^[1]
End point description:	
End point type	Primary
End point timeframe: The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study.	
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: The primary reporting value was least squares mean	

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: CS				
least squares mean (standard error)	1.99 (± 0.16)	1.91 (± 0.15)	1.93 (± 0.15)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean TRSS

End point title	Mean TRSS
End point description:	
End point type	Secondary
End point timeframe: The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study	

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: TRSS				
least squares mean (standard error)	12.95 (\pm 0.69)	13.15 (\pm 0.66)	12.92 (\pm 0.67)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean component scores of the TRSS (nasal)

End point title	Mean component scores of the TRSS (nasal)
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study.

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: TNSS				
least squares mean (standard error)	7.06 (\pm 0.39)	7.17 (\pm 0.37)	6.96 (\pm 0.38)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean component scores of the TRSS (ocular)

End point title	Mean component scores of the TRSS (ocular)
-----------------	--

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: TOSS				
least squares mean (standard error)	5.90 (\pm 0.35)	5.97 (\pm 0.33)	6.00 (\pm 0.34)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Allergy Medication Score (AMS)

End point title	Mean Allergy Medication Score (AMS)
-----------------	-------------------------------------

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study.

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: RMS				
least squares mean (standard error)	0.37 (\pm 0.09)	0.27 (\pm 0.09)	0.31 (\pm 0.09)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean RQLQ Score

End point title	Mean RQLQ Score
-----------------	-----------------

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study.

End point values	Treatment Group 1	Treatment Group 2	Treatment Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	109	97	
Units: RQLQ				
least squares mean (standard error)	1.58 (± 0.22)	1.62 (± 0.21)	1.51 (± 0.22)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The first analysis of the data will be performed on the first year's data after all subjects have completed one year in this study.

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

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	19.0
--------------------	------

Reporting groups

Reporting group title	Treatment Group 1
-----------------------	-------------------

Reporting group description:

single course of Cat-PAD 4x6 nmol 4 weeks apart followed by 4 x placebo 4 weeks apart

Reporting group title	Treatment Group 2
-----------------------	-------------------

Reporting group description:

single course of Cat-PAD 4x6 nmol 4 weeks apart followed by a second course of Cat-PAD 4x6 nmol 4 weeks apart

Reporting group title	Treatment Group 3
-----------------------	-------------------

Reporting group description:

Two courses of 4 x placebo 4 weeks apart

Serious adverse events	Treatment Group 1	Treatment Group 2	Treatment Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 138 (2.17%)	4 / 148 (2.70%)	4 / 144 (2.78%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 138 (0.00%)	1 / 148 (0.68%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Radius fracture			

subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	1 / 144 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Gestational hypertension			
subjects affected / exposed	0 / 138 (0.00%)	1 / 148 (0.68%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Haemolytic uraemic syndrome			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	1 / 144 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colonic fistula			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Uterine polyp			
subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	1 / 144 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	0 / 138 (0.00%)	1 / 148 (0.68%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	1 / 144 (0.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Colonic abscess			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Escherichia coli			
subjects affected / exposed	1 / 138 (0.72%)	0 / 148 (0.00%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 138 (0.00%)	1 / 148 (0.68%)	0 / 144 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Treatment Group 1	Treatment Group 2	Treatment Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 138 (39.13%)	62 / 148 (41.89%)	56 / 144 (38.89%)
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 138 (3.62%)	6 / 148 (4.05%)	6 / 144 (4.17%)
occurrences (all)	21	6	7
Migraine			
subjects affected / exposed	1 / 138 (0.72%)	1 / 148 (0.68%)	6 / 144 (4.17%)
occurrences (all)	1	2	7
Gastrointestinal disorders			

Nausea subjects affected / exposed occurrences (all)	1 / 138 (0.72%) 1	4 / 148 (2.70%) 4	3 / 144 (2.08%) 5
Abdominal pain subjects affected / exposed occurrences (all)	1 / 138 (0.72%) 2	1 / 148 (0.68%) 1	3 / 144 (2.08%) 3
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	5 / 138 (3.62%) 6	2 / 148 (1.35%) 2	5 / 144 (3.47%) 5
Asthma subjects affected / exposed occurrences (all)	2 / 138 (1.45%) 2	3 / 148 (2.03%) 3	6 / 144 (4.17%) 6
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 138 (0.72%) 1	4 / 148 (2.70%) 4	3 / 144 (2.08%) 4
Nasal congestion subjects affected / exposed occurrences (all)	2 / 138 (1.45%) 2	0 / 148 (0.00%) 0	3 / 144 (2.08%) 4
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 138 (0.00%) 0	1 / 148 (0.68%) 1	3 / 144 (2.08%) 3
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	15 / 138 (10.87%) 19	20 / 148 (13.51%) 30	18 / 144 (12.50%) 36
Sinusitis subjects affected / exposed occurrences (all)	6 / 138 (4.35%) 6	6 / 148 (4.05%) 9	5 / 144 (3.47%) 7
Influenza subjects affected / exposed occurrences (all)	5 / 138 (3.62%) 8	4 / 148 (2.70%) 4	7 / 144 (4.86%) 11
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 138 (1.45%) 4	2 / 148 (1.35%) 2	8 / 144 (5.56%) 10

Bronchitis			
subjects affected / exposed	4 / 138 (2.90%)	4 / 148 (2.70%)	2 / 144 (1.39%)
occurrences (all)	4	4	2
Tonsillitis			
subjects affected / exposed	3 / 138 (2.17%)	3 / 148 (2.03%)	2 / 144 (1.39%)
occurrences (all)	3	4	2
Pharyngitis			
subjects affected / exposed	1 / 138 (0.72%)	4 / 148 (2.70%)	1 / 144 (0.69%)
occurrences (all)	1	5	1
Conjunctivitis			
subjects affected / exposed	3 / 138 (2.17%)	1 / 148 (0.68%)	1 / 144 (0.69%)
occurrences (all)	3	1	1
Gastroenteritis viral			
subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	3 / 144 (2.08%)
occurrences (all)	0	0	3
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 148 (0.00%)	3 / 144 (2.08%)
occurrences (all)	0	0	6

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 January 2015	Protocol version 5.0. Introduction of more frequent study visits

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported