Clinical trial results:
Oral Desensitization to Peanut in Peanut-Allergic Children and Adults Using Characterized Peanut Allergen (CPNA) Peanut Oral Immunotherapy (OIT) Safety Follow-On Study.

Summary

EudraCT number	2021-002533-42
Trial protocol	Outside EU/EEA
Global end of trial date	04 January 2018

Results information

Result version number	v1 (current)
This version publication date	19 February 2022
First version publication date	19 February 2022

Trial information

Trial identification

Sponsor protocol code	ARC002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02198664
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aimmune Therapeutics Inc.
Sponsor organisation address	8000 Marina Blvd, Suite 300, Brisbane, United States, 94005
Public contact	Director of Regulatory Affairs, Aimmune Therapeutics Inc., +1 650-409-5164, RegulatoryAffairs@aimmune.com
Scientific contact	Director of Regulatory Affairs, Aimmune Therapeutics Inc., +1 650-409-5164, RegulatoryAffairs@aimmune.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001734-PIP01-14
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	12 April 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 January 2018
Global end of trial reached?	Yes
Global end of trial date	04 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a multi-center, open-label, follow-on study to gather additional information on the safety and tolerability of oral desensitization with CPNA in the subjects who participated in ARC001 (2021-002087-47).

Protection of trial subjects:

Protocol and ICF were approved by IECs or IRBs and FDA in conformance with US code of Federal Regulations and ICH guidelines. Study was conducted per GCP and Declaration of Helsinki guidelines. Patients or parents /legal guardians of patients were educated on study and to notify sites of allergic symptoms occurring at home. Diary logs for completion at home by patients/families to measure IP compliance and alert sites of Adverse Events of Interest, including accidental exposure or Epi pen use.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 August 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Scientific research
Long term follow-up duration	23 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 47
Worldwide total number of subjects	47
EEA total number of subjects	0

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)	35
Adolescents (12-17 years)	11
Adults (18-64 years)	1

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 47 subjects between the ages of 4 and 26 years with peanut allergy screened and enrolled. The population comprised of 26 subjects on the ARC001 placebo group and 21 subjects in the ARC001 AR101 group.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ARC001 Placebo Group

Arm description:

A peanut-derived oral immunotherapy drug

Arm type	Experimental
Investigational medicinal product name	AR101
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral powder
Routes of administration	Oral use

Dosage and administration details:

Study product provided in peanut protein in pull-apart capsules at 5 dosage strengths (0.5, 1, 10, 100, and 475 mg) or sachets at 2 dosage strengths (300 and 1000 mg)

Arm title	ARC001 AR101 Group

Arm description:

A peanut-derived oral immunotherapy drug

Arm type	Experimental
Investigational medicinal product name	AR101
Investigational medicinal product code	
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Number of subjects in period 1	ARC001 Placebo Group	ARC001 AR101 Group
Started	26	21
Completed	10	13
Not completed	16	8
Consent withdrawn by subject	11	8
unknown	1	-
Adverse event, non-fatal	4	-

Baseline characteristics

Reporting groups	
Reporting group title	ARC001 Placebo Group
Reporting group description:	
A peanut-derived oral immunotherapy drug	
Reporting group title	ARC001 AR101 Group
Reporting group description:	
A peanut-derived oral immunotherapy drug	

Reporting group values	ARC001 Placebo Group	ARC001 AR101 Group	Total
Number of subjects	26	21	47
Age categorical Units: Subjects			
Children (2-11 years)	20	15	35
Adolescents (12-17 years)	6	5	11
Adults (18-64 years)	0	1	1
Age continuous Units: years			
median	8.5	8.0	
full range (min-max)	5 to 14	4 to 21	-
Gender categorical Units: Subjects			
Female	10	7	17
Male	16	14	30

Subject analysis sets	
Subject analysis set title	ARC001 Placebo Group safety population
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety population (subjects who received any amount of AR101)	
Subject analysis set title	ARC001 AR101 Group safety population
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety population (subjects who received any amount of AR101)	

Reporting group values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population	
Number of subjects	26	21	
Age categorical Units: Subjects			
Children (2-11 years)	20	15	
Adolescents (12-17 years)	6	5	
Adults (18-64 years)	0	1	
Age continuous Units: years			
median	8.5	8.0	

full range (min-max)	5 to 14	4 to 21	

Gender categorical Units: Subjects			
Female	10	7	
Male	16	14	

End points

End points reporting groups

Reporting group title	ARC001 Placebo Group
Reporting group description: A peanut-derived oral immunotherapy drug	
Reporting group title	ARC001 AR101 Group
Reporting group description: A peanut-derived oral immunotherapy drug	
Subject analysis set title	ARC001 Placebo Group safety population
Subject analysis set type	Safety analysis
Subject analysis set description: Safety population (subjects who received any amount of AR101)	
Subject analysis set title	ARC001 AR101 Group safety population
Subject analysis set type	Safety analysis
Subject analysis set description: Safety population (subjects who received any amount of AR101)	

Primary: Number of Participants With Treatment-Emergent Adverse Events and Dosing Symptoms Occurring With Peanut OIT Over a Protracted Treatment Period Comprising at Least 18 Months

End point title	Number of Participants With Treatment-Emergent Adverse Events and Dosing Symptoms Occurring With Peanut OIT Over a Protracted Treatment Period Comprising at Least 18 Months[1]
End point description:	
End point type	Primary
End point timeframe: 90 weeks	

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 formal statistical analysis was performed for this end point, because no formal sample size calculation or hypothesis testing was done as this study was an open-label, follow-on study of ARC001. The number of subjects enrolled in ARC002 depended on the number of subjects completed ARC001.

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: participants				
Any TEAE	26	21		
Any Grade 3 or Higher TEAE	1	1		
Any TEAE Related to Study Treatment	25	15		
Any TEAE Leading to Treatment Permanent Withdrawn	4	0		
Any TEAE Leading to Treatment TemporarilyWithdrawn	12	15		
Any Treatment-Related Hypersensitivity AE	5	4		
Any serious TEAE	0	1		

Any Serious TEAE leading to Death	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Proportion of Subjects Who Tolerated at Least 300 mg (443 mg) and 600 mg (1043 mg Cumulative) Peanut Protein With no More Than Mild Symptoms During the Up-dosing DBPCFC

End point title	The Proportion of Subjects Who Tolerated at Least 300 mg (443 mg) and 600 mg (1043 mg Cumulative) Peanut Protein With no More Than Mild Symptoms During the Up-dosing DBPCFC

End point description:

Only results for the "ARC001 AR101 Group" is reported as only subjects in this group underwent the Up-dosing Double Blind Placebo Controlled Food Challenge (DPPCFC) in the ARC002 study.

End point type	Secondary

End point timeframe:

Up to 36 weeks.

End point values	ARC001 Placebo Group safety population			
Subject group type	Subject analysis set			
Number of subjects analysed	26			
Units: participants				
Up-dosing DBPCFC: Responder at 300 mg	20			
Up-dosing DBPCFC: Responder at 600 mg	19			

Statistical analyses

No statistical analyses for this end point

Secondary: The Proportion of Subjects Who Tolerated at Least 300 mg (443 mg), 600 mg (1043 mg Cumulative), and 1000 mg Peanut Protein (2043 mg Cumulative) With no More Than Mild Symptoms During the Maintenance DBPCFC.

End point title	The Proportion of Subjects Who Tolerated at Least 300 mg (443 mg), 600 mg (1043 mg Cumulative), and 1000 mg Peanut Protein (2043 mg Cumulative) With no More Than Mild Symptoms During the Maintenance DBPCFC.

End point description:

Multiple food challenge dose levels were given at each DBPCFC, so results at 300 mg and 600 mg for Maintenance DBPCFC are not expected to match those for Up-dosing DBPCFC.

End point type	Secondary

End point timeframe:

Up to 60 weeks.

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26[2]	21[3]		
Units: participants				
Maintenance DBPCFC: Responder at 300 mg	20	20		
Maintenance DBPCC: Responder at 600 mg	20	18		
Maintenance DBPCC: Responder at 1000 mg	17	14		

Notes:

[2] - Subjects who received placebo in study ARC001

[3] - Subjects who received AR101 and tolerated up to 300 mg peanut protein in DBPCFC the at end of ARC001

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Single Highest Tolerated Dose of Peanut Protein

End point title	Change From Baseline in the Single Highest Tolerated Dose of Peanut Protein

End point description:

Only includes the food challenge completer population.
Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Up to 60 weeks (Up to 36 weeks for up-dosing; up to 24 weeks for maintenance).

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21[4]		
Units: milligram(s)				
geometric mean (standard deviation)				
AR101 baseline	38.90 (± 4.37)	0 (± 0)		
Up-dosing DBPCFC	501.2 (± 1.55)	524.8 (± 1.32)		
Maintenance DBPCFC	776.2 (± 1.41)	758.6 (± 1.55)		

Notes:

[4] - ARC001 AR101 group baseline values already summarized in ARC001 and were not resummarized for ARC002

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Who Tolerated Maximum Dose of Peanut Protein With no More Than Mild Symptoms Maximum Dose of Peanut Protein Tolerated

End point title	Number of Participants Who Tolerated Maximum Dose of Peanut Protein With no More Than Mild Symptoms Maximum Dose of Peanut Protein Tolerated

End point description:

The maximum dose of peanut protein tolerated with no more than mild symptoms during the up-dosing and maintenance DBPCFCs.
Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Up to 60 weeks (Up to 36 weeks for up-dosing; up to 24 weeks for maintenance).

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: participants				
Up-dosing DBPCFC: 100 mg	1	0		
Up-dosing DBPCFC: 300 mg	3	4		
Up-dosing DBPCFC: 600 mg	17	17		
Maintenance: 100 mg	0	0		
Maintenance: 300 mg	1	3		
Maintenance: 600 mg	8	4		
Maintenance: 1000 mg	11	13		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Peanut-specific IgE From Baseline and Up-dosing to Extended Maintenance

End point title	Change in Peanut-specific IgE From Baseline and Up-dosing to Extended Maintenance

End point description:

Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Baseline, Up-dosing (up to 36 weeks), Extended Maintenance (up to 90 weeks).

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: kU/L				
geometric mean (standard deviation)				
Baseline	56.826 (± 2.8864)	0 (± 0)		
Up-dosing	59.145 (± 2.9154)	29.964 (± 4.4817)		
Extended maintenance	14.880 (± 6.7531)	10.381 (± 4.0149)		
Change from baseline	0.387 (± 2.2479)	0 (± 0)		
Change from up-dosing	0.364 (± 2.8292)	0.228 (± 2.0544)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Peanut-specific IgG4 From Baseline and Up-dosing to Extended Maintenance

End point title	Change in Peanut-specific IgG4 From Baseline and Up-dosing to Extended Maintenance

End point description:

Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Baseline, Up-dosing (up to 36 weeks), Extended Maintenance (up to 90 weeks).

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: µg/mL				
geometric mean (standard deviation)				
Baseline	0.538 (± 2.4351)	0 (± 0)		
Up-dosing	3.004 (± 3.8962)	4.096 (± 3.9749)		
Extended maintenance	5.755 (± 3.6328)	12.429 (± 2.8292)		
Change from baseline	12.429 (± 2.2705)	0 (± 0)		
Change from up-dosing	1.682 (± 3.1268)	2.746 (± 3.4556)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Skin Prick Test (SPT) Mean Peanut Wheal Diameter and Peanut Erythema/Flare From Baseline and Up-dosing to Extended Maintenance

End point title	Change in Skin Prick Test (SPT) Mean Peanut Wheal Diameter and Peanut Erythema/Flare From Baseline and Up-dosing to Extended Maintenance

End point description:

Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Baseline, Up-dosing (up to 36 weeks), Extended Maintenance (up to 90 weeks)

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: millimeter(s)				
arithmetic mean (standard deviation)				
Peanut wheal diameter; baseline	11.8 (± 6.29)	0 (± 0)		
Peanut wheal diameter; up-dosing	8.6 (± 4.62)	6.6 (± 3.04)		
Peanut wheal diameter; extended maintenance	9.0 (± 5.77)	5.1 (± 3.40)		
Change from baseline: Peanut wheal diameter	-1.5 (± 6.52)	0 (± 0)		
Change from up-dosing: Peanut wheal diameter	-0.8 (± 4.72)	-0.7 (± 2.98)		

Peanut erythema/flare; baseline	37.6 (± 17.69)	0 (± 0)		
Peanut erythema/flare; up-dosing	26.8 (± 12.05)	21.8 (± 8.76)		
Peanut erythema/flare; extended maintenance	28.2 (± 19.73)	14.7 (± 11.62)		
Change from baseline: peanut erythema/flare	-8.7 (± 15.35)	0 (± 0)		
Change from up-dosing: peanut erythema/flare	-1.8 (± 11.55)	-5.4 (± 9.79)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Physician Global Assessment, Disease Activity as Measured on a 100 mm Visual Analogue Scale (VAS) From Baseline and Up-dosing to Extended Maintenance

End point title	Change in Physician Global Assessment, Disease Activity as Measured on a 100 mm Visual Analogue Scale (VAS) From Baseline and Up-dosing to Extended Maintenance

End point description:

A 100-mm Visual Analog Scale (VAS) was used by the investigators for the Physician Global Assessment of disease activity as a marker for safety. The investigator was to assign a single integrated overall disease activity score ranging from 0 to 100 mm. Zero indicated no disease activity and 100 indicated very severe disease activity.

Note: Baseline values for ARC001 AR101 group were already summarized in ARC001 and were not re-summarized in ARC002. Consequently, values are reported as "0".

End point type	Secondary

End point timeframe:

Baseline, Up-dosing (up to 36 weeks), Extended Maintenance (up to 90 weeks).

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	21		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline	36.4 (± 24.31)	0 (± 0)		
Up-dosing	34.9 (± 21.42)	25.6 (± 17.78)		
Extended maintenance	27.5 (± 25.03)	20.1 (± 12.61)		
Change from baseline	-26.30 (± 34.50)	0 (± 0)		
Change from up-dosing	-20.00 (± 38.87)	-15.5 (± 20.56)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Maximum Symptom Severity at Each Challenge Dose of Peanut Protein in All Subjects During Up-Dosing DBPCFC

End point title	Number of Participants With Maximum Symptom Severity at Each Challenge Dose of Peanut Protein in All Subjects During Up-Dosing DBPCFC

End point description:

Maximum severity of symptoms that occurred at each challenge dose of peanut protein for all subjects during up-dosing DBPCFC.

End point type	Secondary

End point timeframe:

Up to 36 weeks for up-dosing.

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	21	21		
Units: participants				
No symptoms at 3 mg	11	18		
Mild symptoms at 3 mg	0	3		
Moderate symptoms at 3 mg	0	0		
Severe symptoms at 3 mg	0	0		
Missing symptom at 3 mg	10	0		
No symptoms at 10 mg	10	21		
Mild symptoms at 10 mg	1	0		
Moderate symptoms at 10 mg	0	0		
Severe symptoms at 10 mg	0	0		
Missing symptom at 10 mg	10	0		
No symptoms at 30 mg	10	20		
Mild symptoms at 30 mg	2	1		
Moderate symptoms at 30 mg	0	0		
Severe symptoms at 30 mg	0	0		
Missing symptoms at 30 mg	9	0		
No symptoms at 100 mg	11	18		
Mild symptoms at 100 mg	1	3		
Moderate symptoms at 100 mg	0	0		
Severe symptoms at 100 mg	0	0		
Missing symptoms at 100 mg	9	0		
No symptoms at 300 mg	7	20		
Mild symptoms at 300 mg	4	1		
Moderate symptoms at 300 mg	0	0		
Severe symptoms at 300 mg	0	0		
Missing symptoms at 300 mg	10	0		
No symptoms at 600 mg	6	12		
Mild symptoms at 600 mg	6	5		
Moderate symptoms at 600 mg	0	4		
Severe symptoms at 600 mg	0	0		

Missing symptoms at 600 mg	9	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Maximum Symptom Severity at Each Challenge Dose of Peanut Protein in All Subjects During Maintenance DBPCFC

End point title	Number of Participants With Maximum Symptom Severity at Each Challenge Dose of Peanut Protein in All Subjects During Maintenance DBPCFC

End point description:

Maximum severity of symptoms that occurred at each challenge dose of peanut protein for all subjects during maintenance DBPCFC.

End point type	Secondary

End point timeframe:

Up to 60 weeks (Up to 36 weeks for up-dosing; up to 24 weeks for maintenance)

End point values	ARC001 Placebo Group safety population	ARC001 AR101 Group safety population		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: participants				
No symptoms at 3 mg	7	9		
Mild symptoms at 3 mg	0	1		
Moderate symptoms at 3 mg	0	0		
Severe symptoms at 3 mg	0	0		
Missing symptoms at 3 mg	13	10		
No symptoms at 10 mg	6	9		
Mild symptoms at 10 mg	0	0		
Moderate symptoms at 10 mg	0	0		
Severe symptoms at 10 mg	0	0		
Missing symptoms at 10 mg	14	11		
No symptoms at 30 mg	6	9		
Mild symptoms at 30 mg	0	1		
Moderate symptoms at 30 mg	0	0		
Severe symptoms at 30 mg	0	0		
Missing symptoms at 30 mg	14	10		
No symptoms at 100 mg	6	9		
Mild symptoms at 100 mg	1	0		
Moderate symptoms at 100 mg	0	0		
Severe symptoms at 100 mg	0	0		
Missing symptoms at 100 mg	13	11		
No symptoms at 300 mg	6	8		

Mild symptoms at 300 mg	0	1		
Moderate symptoms at 300 mg	0	0		
Severe symptoms at 300 mg	0	0		
Missing symptoms at 300 mg	14	11		
No symptoms at 600 mg	7	7		
Mild symptoms at 600 mg	2	3		
Moderate symptoms at 600 mg	0	1		
Severe symptoms at 600 mg	0	0		
Missing symptoms at 600 mg	11	9		
No symptoms at 1000 mg	5	7		
Mild symptoms at 1000 mg	7	4		
Moderate symptoms at 1000 mg	2	2		
Severe symptoms at 1000 mg	0	1		
Missing symptoms at 1000 mg	6	6		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 90 weeks	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0
Reporting groups	
Reporting group title	ARC001 Placebo Group
Reporting group description: A peanut-derived oral immunotherapy drug	
Reporting group title	ARC001 AR101 Group
Reporting group description: A peanut-derived oral immunotherapy drug	

Serious adverse events	ARC001 Placebo Group	ARC001 AR101 Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	1 / 21 (4.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 26 (0.00%)	1 / 21 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	ARC001 Placebo Group	ARC001 AR101 Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 26 (100.00%)	21 / 21 (100.00%)	
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	3 / 26 (11.54%)	1 / 21 (4.76%)	
occurrences (all)	3	1	
Joint injury			

subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	2	1	
Ligament sprain			
subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	3	2	
Vascular disorders			
Flushing			
subjects affected / exposed	3 / 26 (11.54%)	0 / 21 (0.00%)	
occurrences (all)	4	0	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 26 (23.08%)	8 / 21 (38.10%)	
occurrences (all)	8	47	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 26 (26.92%)	6 / 21 (28.57%)	
occurrences (all)	11	14	
Chest discomfort			
subjects affected / exposed	1 / 26 (3.85%)	2 / 21 (9.52%)	
occurrences (all)	1	4	
Malaise			
subjects affected / exposed	1 / 26 (3.85%)	2 / 21 (9.52%)	
occurrences (all)	2	4	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	6 / 26 (23.08%)	7 / 21 (33.33%)	
occurrences (all)	7	20	
Anaphylactic reaction			
subjects affected / exposed	4 / 26 (15.38%)	2 / 21 (9.52%)	
occurrences (all)	5	3	
Seasonal allergy			
subjects affected / exposed	1 / 26 (3.85%)	3 / 21 (14.29%)	
occurrences (all)	1	8	
Food allergy			
subjects affected / exposed	0 / 26 (0.00%)	3 / 21 (14.29%)	
occurrences (all)	0	4	

Ear and labyrinth disorders			
Ear pruritus			
subjects affected / exposed	3 / 26 (11.54%)	0 / 21 (0.00%)	
occurrences (all)	3	0	
Eye disorders			
Eye pruritus			
subjects affected / exposed	1 / 26 (3.85%)	2 / 21 (9.52%)	
occurrences (all)	3	6	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	15 / 26 (57.69%)	9 / 21 (42.86%)	
occurrences (all)	62	33	
Vomiting			
subjects affected / exposed	15 / 26 (57.69%)	8 / 21 (38.10%)	
occurrences (all)	20	27	
Abdominal pain upper			
subjects affected / exposed	7 / 26 (26.92%)	7 / 21 (33.33%)	
occurrences (all)	23	24	
Nausea			
subjects affected / exposed	7 / 26 (26.92%)	6 / 21 (28.57%)	
occurrences (all)	12	9	
Oral pruritus			
subjects affected / exposed	6 / 26 (23.08%)	2 / 21 (9.52%)	
occurrences (all)	33	9	
Abdominal discomfort			
subjects affected / exposed	3 / 26 (11.54%)	3 / 21 (14.29%)	
occurrences (all)	14	5	
Diarrhoea			
subjects affected / exposed	3 / 26 (11.54%)	3 / 21 (14.29%)	
occurrences (all)	3	3	
Lip swelling			
subjects affected / exposed	4 / 26 (15.38%)	2 / 21 (9.52%)	
occurrences (all)	8	12	
Dyspepsia			
subjects affected / exposed	3 / 26 (11.54%)	1 / 21 (4.76%)	
occurrences (all)	4	2	
Constipation			

subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	2	1	
Gastritis			
subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	2	1	
Lip pruritus			
subjects affected / exposed	1 / 26 (3.85%)	2 / 21 (9.52%)	
occurrences (all)	1	30	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 26 (42.31%)	6 / 21 (28.57%)	
occurrences (all)	21	20	
Nasal congestion			
subjects affected / exposed	9 / 26 (34.62%)	7 / 21 (33.33%)	
occurrences (all)	16	10	
Oropharyngeal pain			
subjects affected / exposed	7 / 26 (26.92%)	4 / 21 (19.05%)	
occurrences (all)	12	25	
Rhinorrhoea			
subjects affected / exposed	6 / 26 (23.08%)	5 / 21 (23.81%)	
occurrences (all)	8	7	
Sneezing			
subjects affected / exposed	8 / 26 (30.77%)	3 / 21 (14.29%)	
occurrences (all)	14	10	
Throat irritation			
subjects affected / exposed	6 / 26 (23.08%)	5 / 21 (23.81%)	
occurrences (all)	30	16	
Rhinitis allergic			
subjects affected / exposed	6 / 26 (23.08%)	3 / 21 (14.29%)	
occurrences (all)	8	4	
Wheezing			
subjects affected / exposed	7 / 26 (26.92%)	2 / 21 (9.52%)	
occurrences (all)	14	15	
Nasal turbinate hypertrophy			

subjects affected / exposed	3 / 26 (11.54%)	1 / 21 (4.76%)	
occurrences (all)	3	1	
Asthma			
subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	2	3	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	7 / 26 (26.92%)	5 / 21 (23.81%)	
occurrences (all)	36	20	
Rash			
subjects affected / exposed	5 / 26 (19.23%)	5 / 21 (23.81%)	
occurrences (all)	7	7	
Pruritus			
subjects affected / exposed	5 / 26 (19.23%)	4 / 21 (19.05%)	
occurrences (all)	19	6	
Eczema			
subjects affected / exposed	1 / 26 (3.85%)	3 / 21 (14.29%)	
occurrences (all)	5	3	
Erythema			
subjects affected / exposed	2 / 26 (7.69%)	1 / 21 (4.76%)	
occurrences (all)	3	1	
Musculoskeletal and connective tissue disorders			
Musculoskeletal discomfort			
subjects affected / exposed	3 / 26 (11.54%)	0 / 21 (0.00%)	
occurrences (all)	4	0	
Infections and infestations			
Pharyngitis streptococcal			
subjects affected / exposed	10 / 26 (38.46%)	5 / 21 (23.81%)	
occurrences (all)	13	8	
Upper respiratory tract infection			
subjects affected / exposed	7 / 26 (26.92%)	8 / 21 (38.10%)	
occurrences (all)	13	10	
Gastroenteritis viral			
subjects affected / exposed	4 / 26 (15.38%)	5 / 21 (23.81%)	
occurrences (all)	8	5	
Viral infection			

subjects affected / exposed	5 / 26 (19.23%)	4 / 21 (19.05%)	
occurrences (all)	7	6	
Gastroenteritis			
subjects affected / exposed	3 / 26 (11.54%)	5 / 21 (23.81%)	
occurrences (all)	6	6	
Nasopharyngitis			
subjects affected / exposed	4 / 26 (15.38%)	4 / 21 (19.05%)	
occurrences (all)	8	4	
Otitis media			
subjects affected / exposed	3 / 26 (11.54%)	2 / 21 (9.52%)	
occurrences (all)	4	3	
Ear infection			
subjects affected / exposed	2 / 26 (7.69%)	2 / 21 (9.52%)	
occurrences (all)	2	2	
Influenza			
subjects affected / exposed	2 / 26 (7.69%)	2 / 21 (9.52%)	
occurrences (all)	2	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 March 2015	Changes in study design, selection and withdrawal of subjects, study medication, study procedures and safety monitoring.
23 November 2015	Modified the formulation, packaging, and labeling. Changes in study procedures including treatment instructions, missed doses and anaphylaxis as well as pregnancy reporting requirements.
15 August 2017	Addition of optional OFC. To assess an exploratory objective or the maximum amount of desensitization based on an open-label food challenge up to a cumulative dose of 4043 mg of total peanut protein. To specify the procedures for termination of the study for all subjects remaining and provide continued treatment in a rollover trial ARC008

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported