Clinical trial results:
A 52 week, multi-center, randomized, double-blind placebo-controlled study to assess the clinical efficacy and safety of ligelizumab (QGE031) in decreasing the sensitivity to peanuts in patients with peanut allergy

Summary

EudraCT number	2020-005339-56
Trial protocol	FR ES DE IT DK NL
Global end of trial date	27 November 2023

Results information

Result version number	v1 (current)
This version publication date	07 June 2024
First version publication date	07 June 2024

Trial information

Trial identification

Sponsor protocol code	CQGE031G12301

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001811-PIP03-20
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 November 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the efficacy of ligelizumab 240 mg and 120 mg (subcutaneous injection once every 4 weeks (SC q4w)) compared to placebo, as measured by the proportion of participants who can tolerate a single dose of >= 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled food challenge (DBPCFC) at Week 12

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 December 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	Canada: 35
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Japan: 7
Country: Number of subjects enrolled	Netherlands: 4
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	United States: 109
Worldwide total number of subjects	211
EEA total number of subjects	51

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)	119
Adults (18-64 years)	92
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study was conducted in 56 centers in 10 countries worldwide

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ligelizumab 240 mg

Arm description:

ligelizumab 240 mg subcutaneous injection for 52 weeks

Arm type	Experimental
Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

2 injections of 1.0 mL ligelizumab from Day 1 through Week 52

Arm title	ligelizumab 120 mg

Arm description:

ligelizumab 120 mg subcutaneous injection for 52 weeks

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

1 injection of 1.0 mL placebo from Day 1 through Week 52

Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

1 injection of 1.0 mL ligelizumab from Day 1 through Week 52

Arm title	Placebo 8 weeks and ligelizumab 240 mg

Arm description:

Placebo subcutaneous injection for first 8 weeks and ligelizumab 240 mg subcutaneous injection for 44 weeks

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

2 injections of 1.0 mL placebo at Day 1 and Week 4

Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

2 injections of 1.0 mL ligelizumab from Week 8 through Week 52

Arm title	Placebo 8 weeks and ligelizumab 120 mg

Arm description:

Placebo subcutaneous injection for first 8 weeks and ligelizumab 120 mg subcutaneous injection for 44 weeks

Arm type	Experimental
Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

1 injection of 1.0 mL ligelizumab from Week 8 through Week 52

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

1 injection of 1.0 mL placebo from Week 8 through Week 52

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

2 injections of 1.0 mL placebo at Day 1 and Week 4

Arm title	Placebo 16 weeks and ligelizumab 240 mg

Arm description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 240 mg subcutaneous injection for 36 weeks

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details: 2 injections of 1.0 mL placebo at Day 1 and Week 12	
Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 2 injections of 1.0 mL ligelizumab from Week 16 through Week 52	
Arm title	Placebo 16 weeks and ligelizumab 120 mg
Arm description: Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg subcutaneous injection for 36 weeks	
Arm type	Experimental
Investigational medicinal product name	ligelizumab
Investigational medicinal product code	
Other name	QGE031
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 1 injection of 1.0 mL ligelizumab from Week 16 through Week 52	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 1 injection of 1.0 mL placebo from Week 16 through Week 52	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 2 injections of 1.0 mL placebo at Day 1 and Week 12	

Number of subjects in period 1	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg
Started	47	51	46
Randomized Analysis Set (RAS)	47	51	46
Full Analysis Set (FAS)	47	51	46
Safety Set (SAF)	47	51	46
Completed	44	40	41
Not completed	3	11	5
Physician decision	1	-	-
Subject decision	2	10	3
Adverse event, non-fatal	-	-	1

Lost to follow-up	-	-	1
Guardian decision	-	1	-

Number of subjects in period 1	Placebo 8 weeks and ligelizumab 120 mg	Placebo 16 weeks and ligelizumab 240 mg	Placebo 16 weeks and ligelizumab 120 mg
Started	44	11	12
Randomized Analysis Set (RAS)	44	11	12
Full Analysis Set (FAS)	44	11	12
Safety Set (SAF)	44	11	12
Completed	37	8	11
Not completed	7	3	1
Physician decision	1	-	-
Subject decision	3	3	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	1	-	-
Guardian decision	2	-	1

Baseline characteristics

Reporting groups	
Reporting group title	ligelizumab 240 mg
Reporting group description:	
ligelizumab 240 mg subcutaneous injection for 52 weeks	
Reporting group title	ligelizumab 120 mg
Reporting group description:	
ligelizumab 120 mg subcutaneous injection for 52 weeks	
Reporting group title	Placebo 8 weeks and ligelizumab 240 mg
Reporting group description:	
Placebo subcutaneous injection for first 8 weeks and ligelizumab 240 mg subcutaneous injection for 44 weeks	
Reporting group title	Placebo 8 weeks and ligelizumab 120 mg
Reporting group description:	
Placebo subcutaneous injection for first 8 weeks and ligelizumab 120 mg subcutaneous injection for 44 weeks	
Reporting group title	Placebo 16 weeks and ligelizumab 240 mg
Reporting group description:	
Placebo subcutaneous injection for first 16 weeks and ligelizumab 240 mg subcutaneous injection for 36 weeks	
Reporting group title	Placebo 16 weeks and ligelizumab 120 mg
Reporting group description:	
Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg subcutaneous injection for 36 weeks	

Reporting group values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg
Number of subjects	47	51	46
Age Categorical Units: Participants			
12 - 17 years	27	29	25
18 - 55 years	20	22	21
Age Continuous Units: Years			
arithmetic mean	19.5	18.8	18.7
standard deviation	± 7.50	± 6.27	± 6.95
Sex: Female, Male Units: Participants			
Female	25	25	19
Male	22	26	27
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	10	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	3	1
White	31	36	42
More than one race	1	1	0
Unknown or Not Reported	1	1	1

Number of participants with at least one food allergy Units: Subjects			
1 food allergy	12	15	13
2 food allergies	10	5	8
3 food allergies	5	5	2
4 food allergies	8	7	6
5 food allergies	0	4	4
> 5 food allergies	12	15	13
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg	2	5	2
1 mg	4	4	6
3 mg	14	14	11
10 mg	9	14	7
30 mg	18	14	20
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes	29	27	22
Poly-sensitized to food = No	18	24	24
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes	35	36	33
Poly-allergic to food = No	12	15	13
History of anaphylactic reaction to food Units: Subjects			
History of anaphylactic reaction to food = Yes	32	36	29
History of anaphylactic reaction to food = No	14	15	16
History of anaphylactic reaction to food = Unknown	1	0	1
Time to diagnosis of peanut allergy Units: Years			
arithmetic mean	16.287	16.381	15.556
standard deviation	± 7.9393	± 6.9248	± 7.5799
Peanut specific Immunoglobulin E (IgE) Units: IU/mL			
arithmetic mean	109.021	80.644	131.948
standard deviation	± 147.9877	± 117.6312	± 189.7757
Total Immunoglobulin E (IgE) Units: IU/mL			
arithmetic mean	524.35	482.25	455.38
standard deviation	± 444.009	± 478.047	± 397.960
Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm			

arithmetic mean	13.83	14.61	13.23
standard deviation	± 5.720	± 6.007	± 6.414
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm			
arithmetic mean	7.232	7.273	7.508
standard deviation	± 2.8339	± 2.7253	± 2.7624

Reporting group values	Placebo 8 weeks and ligelizumab 120 mg	Placebo 16 weeks and ligelizumab 240 mg	Placebo 16 weeks and ligelizumab 120 mg
Number of subjects	44	11	12
Age Categorical Units: Participants			
12 - 17 years	24	6	8
18 - 55 years	20	5	4
Age Continuous Units: Years			
arithmetic mean	20.0	17.4	16.1
standard deviation	± 7.75	± 4.57	± 3.58
Sex: Female, Male Units: Participants			
Female	20	3	6
Male	24	8	6
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	2	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0
White	39	7	10
More than one race	2	1	0
Unknown or Not Reported	0	1	0
Number of participants with at least one food allergy Units: Subjects			
1 food allergy	11	5	3
2 food allergies	4	1	1
3 food allergies	5	3	1
4 food allergies	4	0	1
5 food allergies	3	1	2
> 5 food allergies	17	1	4
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg	2	1	0
1 mg	9	1	2
3 mg	11	1	1
10 mg	11	4	5

30 mg	11	4	4
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes	27	8	8
Poly-sensitized to food = No	17	3	4
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes	33	6	9
Poly-allergic to food = No	11	5	3
History of anaphylactic reaction to food			
Units: Subjects			
History of anaphylactic reaction to food = Yes	32	9	8
History of anaphylactic reaction to food = No	12	2	4
History of anaphylactic reaction to food = Unknown	0	0	0
Time to diagnosis of peanut allergy			
Units: Years			
arithmetic mean	17.748	15.598	14.971
standard deviation	± 7.8969	± 5.3525	± 3.5291
Peanut specific Immunoglobulin E (IgE)			
Units: IU/mL			
arithmetic mean	116.198	51.606	262.136
standard deviation	± 128.9151	± 48.6951	± 543.7764
Total Immunoglobulin E (IgE)			
Units: IU/mL			
arithmetic mean	436.31	325.15	635.42
standard deviation	± 335.113	± 208.482	± 535.099
Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm			
arithmetic mean	16.82	14.45	12.17
standard deviation	± 8.262	± 4.845	± 3.664
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm			
arithmetic mean	7.907	6.575	7.743
standard deviation	± 2.8866	± 2.3809	± 2.3547

Reporting group values	Total		
Number of subjects	211		
Age Categorical			
Units: Participants			
12 - 17 years	119		

18 - 55 years	92		

Age Continuous Units: Years arithmetic mean standard deviation	- 		
Sex: Female, Male Units: Participants			
Female	98		
Male	113		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	25		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	12		
White	165		
More than one race	5		
Unknown or Not Reported	4		
Number of participants with at least one food allergy Units: Subjects			
1 food allergy	59		
2 food allergies	29		
3 food allergies	21		
4 food allergies	26		
5 food allergies	14		
> 5 food allergies	62		
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg	12		
1 mg	26		
3 mg	52		
10 mg	50		
30 mg	71		
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes	121		
Poly-sensitized to food = No	90		
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes	152		
Poly-allergic to food = No	59		
History of anaphylactic reaction to food Units: Subjects			
History of anaphylactic reaction to food = Yes	146		

History of anaphylactic reaction to food = No	63		
History of anaphylactic reaction to food = Unknown	2		
Time to diagnosis of peanut allergy Units: Years			
arithmetic mean			
standard deviation	-		
Peanut specific Immunoglobulin E (IgE) Units: IU/mL			
arithmetic mean			
standard deviation	-		
Total Immunoglobulin E (IgE) Units: IU/mL			
arithmetic mean			
standard deviation	-		
Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm			
arithmetic mean			
standard deviation	-		
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm			
arithmetic mean			
standard deviation	-		

Subject analysis sets

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

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Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Reporting group values	Placebo	Placebo	Placebo
Number of subjects	23	20	19
Age Categorical Units: Participants			
12 - 17 years			
18 - 55 years			
Age Continuous Units: Years			
arithmetic mean			
standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female			
Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
More than one race			
Unknown or Not Reported			
Number of participants with at least one food allergy Units: Subjects			
1 food allergy			
2 food allergies			
3 food allergies			
4 food allergies			
5 food allergies			
> 5 food allergies			
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg			

1 mg 3 mg 10 mg 30 mg			
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes Poly-sensitized to food = No			
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes Poly-allergic to food = No			
History of anaphylactic reaction to food Units: Subjects			
History of anaphylactic reaction to food = Yes History of anaphylactic reaction to food = No History of anaphylactic reaction to food = Unknown			
Time to diagnosis of peanut allergy Units: Years arithmetic mean standard deviation	 1 ±	 ±	 ±
Peanut specific Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	 1 ±	 ±	 ±
Total Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	 1 ±	 ±	 ±
Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm arithmetic mean standard deviation	 1 ±	 ±	 ±
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm arithmetic mean standard deviation	 1 ±	 ±	 ±

Reporting group values	Placebo	Placebo	Placebo
Number of subjects	16	9	8

Age Categorical Units: Participants			
12 - 17 years			
18 - 55 years			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female			
Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Number of participants with at least one food allergy Units: Subjects			
1 food allergy 2 food allergies 3 food allergies 4 food allergies 5 food allergies > 5 food allergies			
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg 1 mg 3 mg 10 mg 30 mg			
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes Poly-sensitized to food = No			
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes Poly-allergic to food = No			
History of anaphylactic reaction to food Units: Subjects			

History of anaphylactic reaction to food = Yes History of anaphylactic reaction to food = No History of anaphylactic reaction to food = Unknown			
Time to diagnosis of peanut allergy Units: Years arithmetic mean standard deviation	 -2.38 ± 3.788	 ±	 ±
Peanut specific Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	 -2.38 ± 3.788	 ±	 ±
Total Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	 -2.38 ± 3.788	 ±	 ±
Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm arithmetic mean standard deviation	 -2.38 ± 3.788	 ±	 ±
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm arithmetic mean standard deviation	 -2.38 ± 3.788	 ±	 ±

Reporting group values	Placebo		
Number of subjects	5		
Age Categorical Units: Participants			
12 - 17 years 18 - 55 years			
Age Continuous Units: Years arithmetic mean standard deviation	 ±	 	
Sex: Female, Male Units: Participants			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian			

Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Number of participants with at least one food allergy Units: Subjects			
1 food allergy 2 food allergies 3 food allergies 4 food allergies 5 food allergies > 5 food allergies			
MTD (maximum tolerated dose) of peanut protein (mg) - n (%) Units: Subjects			
< 1 mg 1 mg 3 mg 10 mg 30 mg			
Poly-sensitized to food			
Poly-sensitization is defined as specific Immunoglobulin E (sIgE) >=0.35kUA/L for a food allergen in the panel other than peanut.			
Units: Subjects			
Poly-sensitized to food = Yes Poly-sensitized to food = No			
Poly-allergic to food			
Poly-allergic: Participants experiencing more than one food allergies in medical history.			
Units: Subjects			
Poly-allergic to food = Yes Poly-allergic to food = No			
History of anaphylactic reaction to food Units: Subjects			
History of anaphylactic reaction to food = Yes History of anaphylactic reaction to food = No History of anaphylactic reaction to food = Unknown			
Time to diagnosis of peanut allergy Units: Years arithmetic mean standard deviation	±		
Peanut specific Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	±		
Total Immunoglobulin E (IgE) Units: IU/mL arithmetic mean standard deviation	±		

Peanut Skin Prick Test (SPT) (undiluted): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters			
Units: mm arithmetic mean standard deviation	±		
Peanut Skin Prick Test (SPT) (average across dilutions): Size of mean wheal diameter			
Size of Mean wheal diameter (mm) = [(Mean of peanut wheal longest diameter + Mean of peanut wheal orthogonal diameter)/2]- average of the non-missing negative control diameters. Range of dilutions (1:10 to 1:100,000).			
Units: mm arithmetic mean standard deviation	±		

End points

End points reporting groups

Reporting group title	ligelizumab 240 mg

Reporting group description:

ligelizumab 240 mg subcutaneous injection for 52 weeks

Reporting group title	ligelizumab 120 mg

Reporting group description:

ligelizumab 120 mg subcutaneous injection for 52 weeks

Reporting group title	Placebo 8 weeks and ligelizumab 240 mg

Reporting group description:

Placebo subcutaneous injection for first 8 weeks and ligelizumab 240 mg subcutaneous injection for 44 weeks

Reporting group title	Placebo 8 weeks and ligelizumab 120 mg

Reporting group description:

Placebo subcutaneous injection for first 8 weeks and ligelizumab 120 mg subcutaneous injection for 44 weeks

Reporting group title	Placebo 16 weeks and ligelizumab 240 mg

Reporting group description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 240 mg subcutaneous injection for 36 weeks

Reporting group title	Placebo 16 weeks and ligelizumab 120 mg

Reporting group description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Subject analysis set title	Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Placebo subcutaneous injection for first 16 weeks and ligelizumab 120 mg OR 240 mg subcutaneous injection for 36 weeks

Primary: Percentage of participants who tolerated a single dose of >= 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12

End point title	Percentage of participants who tolerated a single dose of >= 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12[1]

End point description:

Responder rate was defined as the percentage of participants tolerating a single dose of >= 600 mg (1044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) conducted at Week 12. The cumulative tolerated dose is the sum of the tolerated doses, not including the reactive dose. Dose-limiting symptoms indicate a true allergic reaction occurring during administration of a single dose of peanut protein at the DBPCFC that should preclude the administration of any further doses in the view of the investigator. Symptoms that require administration of any rescue medication were considered dose-limiting symptoms. Participants with treatment discontinuation or missing more than 1 doses of study drug prior to Week 12 due to reasons other than operational complications caused by public health emergency were considered non-responders.

End point type	Primary

End point timeframe:

Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	47	51	23	
Units: Participants	21	8	1	

Statistical analyses

Statistical analysis title	Single dose of >= 600 mg without DLT at Week 12
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.073
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	100.98

Statistical analysis title	Single dose of >= 600 mg without DLT at Week 12
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	25.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.34
upper limit	506.78

Secondary: Percentage of participants who tolerated a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12

End point title	Percentage of participants who tolerated a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12[2]

End point description:

Responder rate was defined as the percentage of participants tolerating a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) conducted at Week 12. The cumulative tolerated dose is the sum of the tolerated doses, not including the reactive dose. Dose-limiting symptoms indicate a true allergic reaction occurring during administration of a single dose of peanut protein at the DBPCFC that should preclude the administration of any further doses in the view of the investigator. Symptoms that require administration of any rescue medication were considered dose-limiting symptoms. Participants with treatment discontinuation or missing more than 1 doses of study drug prior to Week 12 due to reasons other than operational complications caused by public health emergency were considered non-responders.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	47	51	23	
Units: Participants	14	6	1	

Statistical analyses

Statistical analysis title	Single dose of >= 1000 mg without DLT at Week 12
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.164
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.45
upper limit	59.93

Statistical analysis title	Single dose of >= 1000 mg without DLT at Week 12
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.018
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	9.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.69
upper limit	188.85

Secondary: Percentage of maximum severity of symptoms occurring at any challenge dose of peanut protein up to and including 1000 mg at Week 12

End point title	Percentage of maximum severity of symptoms occurring at any challenge dose of peanut protein up to and including 1000 mg at Week 12[3]

End point description:

Symptom severity occurring at any challenge dose of peanut protein up to and including 1000 mg during

the DBPCFC conducted at Week 12 was categorized as 4 levels: None, Mild, Moderate, Severe. The CoFAR grading system was used to categorize the symptom severity as mild, moderate and severe. Symptom severity for participants who completed DBPCFC without any symptom were categorized as none.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	47	51	23	
Units: Participants				
None	5	2	0	
Mild	15	10	2	
Moderate	24	37	13	
Severe	3	2	8	

Statistical analyses

Statistical analysis title	Max. severity of symptoms at any dose at Week 12
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	proportional odds model
Parameter estimate	Odds ratio (OR)
Point estimate	5.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	14.36

Statistical analysis title	Max. severity of symptoms at any dose at Week 12
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	proportional odds model
Parameter estimate	Odds ratio (OR)
Point estimate	10.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	3.63
upper limit	31.56

Secondary: Percentage of participants who tolerated a single dose of 3000 mg (5044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12

End point title	Percentage of participants who tolerated a single dose of 3000 mg (5044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12[4]

End point description:

Responder rate was defined as the percentage of participants tolerating a single dose of 3000 mg (5044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) conducted at Week 12. The cumulative tolerated dose is the sum of the tolerated doses, not including the reactive dose. Dose-limiting symptoms indicate a true allergic reaction occurring during administration of a single dose of peanut protein at the DBPCFC that should preclude the administration of any further doses in the view of the investigator. Symptoms that require administration of any rescue medication were considered dose-limiting symptoms. Participants with treatment discontinuation or missing more than 1 doses of study drug prior to Week 12 due to reasons other than operational complications caused by public health emergency were considered non-responders.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	47	51	23	
Units: Participants	7	5	1	

Statistical analyses

Statistical analysis title	Single dose of >= 3000 mg without DLT at Week 12
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.247
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	45.56

Statistical analysis title	Single dose of >= 3000 mg without DLT at Week 12
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.138
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	70.08

Secondary: Percentage of participants who tolerated a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12 after 4 weeks of Treatment

End point title	Percentage of participants who tolerated a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms at Week 12 after 4 weeks of Treatment[5]

End point description:

Responder rate was defined as the percentage of participants tolerating a single dose of >= 1000 mg (2044 mg cumulative tolerated dose) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) conducted at Week 12 after 4 weeks of treatment (8 weeks of placebo + 4 weeks of ligelizumab treatment versus 12 weeks of placebo). The cumulative tolerated dose is the sum of the tolerated doses, not including the reactive dose. Participants with treatment discontinuation or missing more than 1 doses of study drug prior to Week 12 due to reasons other than operational complications caused by public health emergency were considered non-responders.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	46	44	23	
Units: Participants	8	1	1	

Statistical analyses

Statistical analysis title	>= 1000 mg without DLT at Week 12 after 4 wks Tx
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.082
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	93.16

Statistical analysis title	>= 1000 mg without DLT at Week 12 after 4 wks Tx
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	67
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.632
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	16.43

Secondary: Percentage of participants who tolerated the specified peanut protein dose without dose-limiting symptoms at Week 52

End point title	Percentage of participants who tolerated the specified peanut protein dose without dose-limiting symptoms at Week 52[6]

End point description:

Responder rate was defined as the percentage of participants tolerating the specified peanut protein doses (>= 600 mg (1044 mg cumulative tolerated dose), >= 1000 mg (2044 mg cumulative tolerated dose) or 3000 mg (5044 mg cumulative tolerated dose)) of peanut protein without dose-limiting symptoms during the double blind placebo controlled food challenge (DBPCFC) conducted at Week 52. The cumulative tolerated dose is the sum of the tolerated doses, not including the reactive dose. Dose-limiting symptoms indicate a true allergic reaction occurring during administration of a single dose of peanut protein at the DBPCFC that should preclude the administration of any further doses in the view of the investigator. Symptoms that require administration of any rescue medication were considered dose-limiting symptoms.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	2	4
Units: Participants				
MTD >= 600 mg	2	1	0	1
MTD >= 1000 mg	1	1	0	0
MTD = 3000 mg	1	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in maximum tolerated dose (MTD) of peanut protein without dose-limiting symptoms during the DBPCFC at Week 12 and Week 52

End point title	Change from baseline in maximum tolerated dose (MTD) of peanut protein without dose-limiting symptoms during the DBPCFC at Week 12 and Week 52[7]

End point description:

Change from baseline in maximum tolerated dose (MTD) of peanut protein without dose-limiting symptoms during the DBPCFC at Week 12 and Week 52. Dose-limiting symptoms indicate a true allergic reaction occurring during administration of a single dose of peanut protein at the DBPCFC that should preclude the administration of any further doses in the view of the investigator.

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 52

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	48	46	40
Units: mg				
geometric mean (geometric coefficient of variation)				
Week 12	274.05 (± 501.051)	104.31 (± 794.248)	148.98 (± 754.171)	44.29 (± 768.803)
Week 52	800.41 (± 178.687)	164.23 (± 459916.375)	89.55 (± 408.957)	146.48 (± 113.009)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: mg				
geometric mean (geometric coefficient of variation)				
Week 12	46.62 (± 555.207)			
Week 52	999 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in peanut-specific immunoglobulin E (IgE) at Week 12 and Week 52

End point title	Change from baseline in peanut-specific immunoglobulin E (IgE) at Week 12 and Week 52[8]

End point description:

Change from baseline of serum levels of peanut-specific immunoglobulin E (IgE)

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 52

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	46	45	39
Units: kilounits per liter (kU/L)				

arithmetic mean (standard deviation)				
Week 12	258.28 (± 282.477)	295.60 (± 321.451)	302.22 (± 323.846)	400.03 (± 611.676)
Week 52	362.36 (± 436.857)	297.94 (± 285.827)	338.63 (± 435.532)	361.44 (± 587.852)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: kilounits per liter (kU/L)				
arithmetic mean (standard deviation)				
Week 12	-35.52 (± 179.040)			
Week 52	174.75 (± 433.889)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in peanut-specific immunoglobulin G4 (IgG4) at Week 12 and Week 52

End point title	Change from baseline in peanut-specific immunoglobulin G4 (IgG4) at Week 12 and Week 52[9]

End point description:

Change from baseline of serum levels of peanut-specific immunoglobulin G4 (IgG4)

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 52

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	46	45	40
Units: mg/L				
arithmetic mean (standard deviation)				
Week 12	-0.09 (± 0.65)	0.35 (± 3.178)	0.12 (± 0.903)	0.11 (± 0.789)
Week 52	-0.01 (± 0.608)	0.73 (± 3.103)	0.21 (± 0.909)	0.01 (± 0.768)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: mg/L				
arithmetic mean (standard deviation)				
Week 12	0.03 (± 0.469)			
Week 52	-0.09 (± 1.126)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in total and domain scores in the Food Allergy Quality of Life Questionnaire (FAQLQ) Teenager Form (FAQLQ-TF)

End point title	Change from baseline in total and domain scores in the Food Allergy Quality of Life Questionnaire (FAQLQ) Teenager Form (FAQLQ-TF)[10]

End point description:

The Food Allergy Quality of Life Questionnaire (FAQLQ) Teenager Form (FAQLQ-TF) completed by adolescents aged 13-17 is a self-reported instrument intended to assess the effect of food allergy on the participant's health-related quality of life (HRQoL). Each question is scored on a 7-point scale (coded as 1-7 in analysis, with a higher level indicating greater impairment in HRQoL). The total score and the domain scores are the arithmetic average of all completed items: Emotional impact (EI) (item no. 5, 12, 19-23), Allergen avoidance and dietary restrictions (AADR) (item no. 1-4, 6-10, 16), Risk of accidental exposure (RAE) (item no. 11, 13-15, 17, 18). If more than one item in any domain is missing, a domain score should not be calculated for that case. A total score could still be calculated if 20% or fewer of the items are missing.

End point type	Secondary

End point timeframe:

Baseline, Week 12 Part 1 (10 Days Before Day 1 Oral Food Challenge (OFC)), Week 12 Part 2 (3 Days After Day 2 Oral Food Challenge (OFC))

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	20	15	16
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	-0.09 (± 0.833)	-0.01 (± 0.779)	-0.30 (± 0.647)	-0.07 (± 0.972)
Week 12 Part 2 - Total Score	-0.49 (± 0.839)	-0.13 (± 0.869)	-0.08 (± 0.879)	0.04 (± 1.255)
Week 12 Part 1 - EI	-0.03 (± 0.896)	-0.12 (± 0.846)	-0.40 (± 0.745)	-0.11 (± 1.062)
Week 12 Part 2 - EI	-0.51 (± 1.057)	-0.19 (± 0.875)	-0.23 (± 0.737)	-0.05 (± 1.348)

Week 12 Part 1 - AADR	-0.15 (± 0.873)	0.02 (± 0.977)	-0.35 (± 0.988)	-0.11 (± 1.130)
Week 12 Part 2 - AADR	-0.61 (± 0.946)	-0.14 (± 1.004)	-0.08 (± 1.291)	0.12 (± 1.235)
Week 12 Part 1 - RAE	-0.07 (± 1.085)	0.08 (± 0.868)	-0.10 (± 0.796)	0.02 (± 1.016)
Week 12 Part 2 - RAE	-0.28 (± 0.718)	-0.04 (± 1.028)	0.08 (± 0.733)	0.03 (± 1.366)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	0.27 (± 0.835)			
Week 12 Part 2 - Total Score	0.09 (± 0.954)			
Week 12 Part 1 - EI	0.27 (± 1.034)			
Week 12 Part 2 - EI	-0.04 (± 1.486)			
Week 12 Part 1 - AADR	0.11 (± 0.599)			
Week 12 Part 2 - AADR	0.25 (± 0.628)			
Week 12 Part 1 - RAE	0.54 (± 1.204)			
Week 12 Part 2 - RAE	-0.04 (± 1.253)			

Statistical analyses

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.173
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	0.36

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo

Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.202
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	0.39

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.123
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.16
upper limit	0.3

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.258
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	0.47

Statistical analysis title	Week 12 Part 2 - Total Score

Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.324
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.92
upper limit	0.58

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.473
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.78
upper limit	0.73

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.151
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.09
upper limit	0.34

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.264
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	0.49

Secondary: Change from Baseline in Skin Prick Test (SPT) mean wheal diameters at Week 16/Week 56

End point title	Change from Baseline in Skin Prick Test (SPT) mean wheal diameters at Week 16/Week 56[11]

End point description:

An allergen specific SPT is a commonly used diagnostic tool. In this study a titration SPT using peanut allergen provided additional information on the impact of Immunoglobulin E (IgE) suppression on skin mast cells. The size of the wheal and flare (the longest diameter and the midpoint orthogonal diameter) at each site was evaluated. Considering the study termination, SPT originally scheduled at Week 56 was performed 4 weeks after Week 12 assessment in some patients.

End point type	Secondary

End point timeframe:

Baseline, Week 16/Week 56

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	40	37	36
Units: undiluted peanut protein (mm)				
arithmetic mean (standard deviation)	-10.85 (± 6.423)	-8.40 (± 5.805)	-5.28 (± 5.237)	-7.25 (± 7.354)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: undiluted peanut protein (mm)				

arithmetic mean (standard deviation)	-2.38 (± 3.788)			

Statistical analyses

Statistical analysis title	Skin Prick Test (SPT) at Week 16/Week 56
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-3.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.15
upper limit	-2.4

Statistical analysis title	Skin Prick Test (SPT) at Week 16/Week 56
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.13
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.62
upper limit	1.25

Statistical analysis title	Skin Prick Test (SPT) at Week 16/Week 56
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo

Number of subjects included in analysis	53
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.015
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.08
upper limit	-0.32

Statistical analysis title	Skin Prick Test (SPT) at Week 16/Week 56
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-4.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.77
upper limit	-2.09

Secondary: Change from baseline in total and domain scores in the Food Allergy Quality of Life Questionnaire (FAQLQ) Adult Form (FAQLQ-AF)

End point title	Change from baseline in total and domain scores in the Food Allergy Quality of Life Questionnaire (FAQLQ) Adult Form (FAQLQ-AF)[12]

End point description:

The Food Allergy Quality of Life Questionnaire (FAQLQ) Adult Form (FAQLQ-AF) completed by adults aged 18-55 is a self-reported instrument intended to assess the effect of food allergy on the participant's health-related quality of life (HRQoL). Each question is scored on a 7-point scale (coded as 1-7 in analysis, with a higher level indicating greater impairment in HRQoL). The total score and domain scores are the arithmetic average of all completed items: Emotional impact (EI) (item no. 5, 24-29), Allergen avoidance and dietary restrictions (AADR) (item no. 1-4, 6, 8-12, 20), Risk of Accidental Exposure (RAE) (item no. 7, 13-18, 21), Food allergy related health (FAH) (item no. 19, 22, 23). If more than one item in any domain is missing, a domain score should not be calculated for that case. A total score could still be calculated if 20% or fewer of the items are missing.

End point type	Secondary

End point timeframe:

Baseline, Week 12 Part 1 (10 Days Before Day 1 Oral Food Challenge (OFC)), Week 12 Part 2 (3 Days After Day 2 Oral Food Challenge (OFC))

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	19	17
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	-0.01 (± 0.560)	-0.40 (± 0.439)	-0.20 (± 0.601)	0.00 (± 0.656)
Week 12 Part 2 - Total Score	-0.16 (± 0.742)	-0.55 (± 0.671)	-0.60 (± 0.783)	-0.22 (± 0.727)
Week 12 Part 1 - EI	0.07 (± 0.747)	-0.31 (± 0.838)	-0.35 (± 0.601)	-0.04 (± 0.857)
Week 12 Part 2 - EI	-0.11 (± 0.980)	-0.47 (± 1.006)	-0.90 (± 1.027)	-0.26 (± 0.828)
Week 12 Part 1 - AADR	-0.07 (± 0.609)	-0.41 (± 0.526)	-0.31 (± 0.805)	-0.12 (± 0.731)
Week 12 Part 2 - AADR	-0.10 (± 0.788)	-0.74 (± 0.585)	-0.70 (± 1.106)	-0.20 (± 0.749)
Week 12 Part 1 - RAE	0.06 (± 0.647)	-0.40 (± 0.427)	0.02 (± 0.834)	0.18 (± 0.794)
Week 12 Part 2 - RAE	-0.15 (± 0.750)	-0.31 (± 0.917)	-0.34 (± 0.468)	-0.26 (± 0.821)
Week 12 Part 1 - FAH	-0.17 (± 1.082)	-0.53 (± 0.717)	-0.05 (± 0.788)	0.06 (± 1.056)
Week 12 Part 2 - FAH	-0.47 (± 0.864)	-0.73 (± 0.854)	-0.22 (± 0.770)	-0.06 (± 1.153)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	0.00 (± 0.330)			
Week 12 Part 2 - Total Score	-0.14 (± 0.542)			
Week 12 Part 1 - EI	-0.06 (± 0.358)			
Week 12 Part 2 - EI	0.00 (± 0.553)			
Week 12 Part 1 - AADR	-0.05 (± 0.508)			
Week 12 Part 2 - AADR	-0.15 (± 0.532)			
Week 12 Part 1 - RAE	0.10 (± 0.471)			
Week 12 Part 2 - RAE	-0.33 (± 0.549)			
Week 12 Part 1 - FAH	0.04 (± 1.073)			

Week 12 Part 2 - FAH	0.07 (± 1.140)			

Statistical analyses

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.597
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	0.57

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.064
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.89
upper limit	0.11

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.191
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	0.28

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.368
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	0.48

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.537
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	0.62

Statistical analysis title	Week 12 Part 2 - Total Score

Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.141
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.91
upper limit	0.27

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.063
Method	ANCOVA
Parameter estimate	LS Meand difference
Point estimate	-0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	0.13

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.472
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	0.48

Secondary: Change from baseline in total scores in the Food Allergy Independent Measure (FAIM) – Teenager Form (FAIM-TF)

End point title	Change from baseline in total scores in the Food Allergy Independent Measure (FAIM) – Teenager Form (FAIM-TF)[13]

End point description:

The Food Allergy Independent Measure (FAIM) – Teenager Form (FAIM-TF) completed by adolescents aged 13-17 reflects the participant's perceived food allergy severity and food allergy-related risk. It consists of six questions (the first four of them assess participant's food allergy expectation outcomes, and the other two reflect aspects of the perceived severity of food allergy). Each question is scored on a 7-point scale (coded as 1-7 in analysis, with a greater score indicating a higher level of perceived risk or chance of adverse events occurring). The total score is the arithmetic average of all completed items. If less than 80% of the items within the score are complete, it was not calculated.

End point type	Secondary

End point timeframe:

Baseline, Week 12 Part 1 (10 Days Before Day 1 Oral Food Challenge (OFC)), Week 12 Part 2 (3 Days After Day 2 Oral Food Challenge (OFC))

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	19	15	14
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	-0.03 (± 0.751)	-0.11 (± 0.760)	-0.04 (± 0.529)	0.31 (± 0.989)
Week 12 Part 2 - Total Score	-0.31 (± 0.952)	0.31 (± 0.784)	-0.07 (± 0.524)	0.39 (± 1.133)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	0.19 (± 0.930)			
Week 12 Part 2 - Total Score	0.25 (± 1.306)			

Statistical analyses

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo

Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.225
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.87
upper limit	0.39

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.179
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.95
upper limit	0.34

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.514
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	0.72

Statistical analysis title	Week 12 Part 2 - Total Score

Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.06
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	0.14

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.404
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	0.56

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.135
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	0.3

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.153
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.3

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.631
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	0.77

Secondary: Change from baseline in total scores in the Food Allergy Independent Measure (FAIM) – Adult Form (FAIM-AF)

End point title	Change from baseline in total scores in the Food Allergy Independent Measure (FAIM) – Adult Form (FAIM-AF)[14]

End point description:

The Food Allergy Independent Measure (FAIM) – Adult Form (FAIM-AF) completed by adults aged 18-55 reflects the participant's perceived food allergy severity and food allergy-related risk. It consists of six questions (the first four of them assess participant's food allergy expectation outcomes, and the other two reflect aspects of the perceived severity of food allergy). Each question is scored on a 7-point scale (coded as 1-7 in analysis, with a greater score indicating a higher level of perceived risk or chance of adverse events occurring). The total score is the arithmetic average of all completed items. If less than 80% of the items within the score are complete, it was calculated.

End point type	Secondary

End point timeframe:

Baseline, Week 12 Part 1 (10 Days Before Day 1 Oral Food Challenge (OFC)), Week 12 Part 2 (3 Days After Day 2 Oral Food Challenge (OFC))

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	16	17
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	0.17 (± 0.574)	-0.23 (± 0.496)	-0.09 (± 0.694)	0.00 (± 0.489)
Week 12 Part 2 - Total Score	-0.23 (± 0.681)	-0.36 (± 0.562)	-0.27 (± 0.492)	-0.24 (± 0.479)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Week 12 Part 1 - Total Score	0.17 (± 0.309)			
Week 12 Part 2 - Total Score	0.07 (± 0.703)			

Statistical analyses

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.574
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	0.51

Statistical analysis title	Week 12 Part 1 - Total Score

Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.069
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	0.12

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.056
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	0.09

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.048
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	0.09

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.071
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	0.14

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	ligelizumab 240 mg v Placebo
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.248
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	0.37

Statistical analysis title	Week 12 Part 2 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.142
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.85
upper limit	0.25

Statistical analysis title	Week 12 Part 1 - Total Score
Comparison groups	Placebo 8 weeks and ligelizumab 120 mg v Placebo
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.205
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.65
upper limit	0.27

Secondary: Change from baseline in the SF-36v2 Physical Component Score (PCS) and Mental Component Score (MCS)

End point title	Change from baseline in the SF-36v2 Physical Component Score (PCS) and Mental Component Score (MCS)[15]

End point description:

The SF-36v2 Health Survey is a 36-item instrument that measures generic health-related quality of life. It is designed for use in surveys of general and specific populations, health policy evaluations and clinical practice and research. It contains 8 scales and 2 component summary indices evaluating physical, social and emotional functioning in addition to general health perceptions and mental health. Responses to items allow for direct calculation of scale scores, while the physical component summary (PCS) and mental component summary (MCS) scores are computed from weighted scale scores. For all scales and summary measures, higher scores indicate better health outcomes (PCS and MCS scores range 0 to 100).

End point type	Secondary

End point timeframe:

Baseline, Week 12 Part 2 (3 Days After Day 2 Oral Food Challenge (OFC))

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This outcome measure applies to ligelizumab 120 mg arm, ligelizumab 240 mg arm, Placebo 8 weeks and ligelizumab 240 mg, Placebo 8 weeks and ligelizumab 120 mg and placebo 16-week to ligelizumab 120/240 mg arm (labelled as placebo for efficacy estimands).

End point values	ligelizumab 240 mg	ligelizumab 120 mg	Placebo 8 weeks and ligelizumab 240 mg	Placebo 8 weeks and ligelizumab 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	10	12
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Physical Component Score	0.51 (± 8.022)	0.38 (± 2.912)	2.13 (± 3.909)	-2.19 (± 5.090)
Mental Component Score	-0.15 (± 9.950)	-0.12 (± 8.175)	-1.78 (± 8.458)	-3.26 (± 8.256)

End point values	Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: Unit on a scale				
arithmetic mean (standard deviation)				
Physical Component Score Mental Component Score	3.15 (± 5.342) -9.43 (± 14.662)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose of study treatment to 30 days after last dose of study medication, up to approximately 22 months.

Adverse event reporting additional description:

Any sign or symptom that occurred during the conduct of the trial and safety follow-up.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Placebo controlled period (Up to Week 8) QGE031 240 mg SCq4w

Reporting group description:

Placebo controlled period (Up to Week 8) QGE031 240 mg SCq4w

Reporting group title	Placebo controlled period (Up to Week 8) QGE031 120 mg SCq4w

Reporting group description:

Placebo controlled period (Up to Week 8) QGE031 120 mg SCq4w

Reporting group title	Placebo controlled period (Up to Week 8) Placebo

Reporting group description:

Placebo controlled period (Up to Week 8) Placebo

Reporting group title	Entire study period (Up to Week 68) QGE031 120 mg SCq4w

Reporting group description:

Entire study period (Up to Week 68) QGE031 120 mg SCq4w

Reporting group title	Placebo controlled period (Up to Week 16) QGE031 120 mg SCq4w

Reporting group description:

Placebo controlled period (Up to Week 16) QGE031 120 mg SCq4w

Reporting group title	Placebo controlled period (Up to Week 16) Placebo

Reporting group description:

Placebo controlled period (Up to Week 16) Placebo

Reporting group title	Entire study period (Up to Week 68) QGE031 240 mg SCq4w

Reporting group description:

Entire study period (Up to Week 68) QGE031 240 mg SCq4w

Reporting group title	Placebo controlled period (Up to Week 16) QGE031 240 mg SCq4w

Reporting group description:

Placebo controlled period (Up to Week 16) QGE031 240 mg SCq4w

Serious adverse events	Placebo controlled period (Up to Week 8) QGE031 240 mg SCq4w	Placebo controlled period (Up to Week 8) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 8) Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	0 / 113 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural complication			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Entire study period (Up to Week 68) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 16) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 16) Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Post procedural complication			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	0 / 23 (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

Serious adverse events	Entire study period (Up to Week 68) QGE031 240 mg SCq4w	Placebo controlled period (Up to Week 16) QGE031 240 mg SCq4w	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99 (0.00%)	0 / 47 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Post procedural complication			
subjects affected / exposed	0 / 99 (0.00%)	0 / 47 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo controlled period (Up to Week 8) QGE031 240 mg SCq4w	Placebo controlled period (Up to Week 8) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 8) Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 47 (44.68%)	17 / 51 (33.33%)	27 / 113 (23.89%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 47 (4.26%)	0 / 51 (0.00%)	1 / 113 (0.88%)
occurrences (all)	2	0	1
Headache			
subjects affected / exposed	2 / 47 (4.26%)	3 / 51 (5.88%)	5 / 113 (4.42%)
occurrences (all)	2	3	7
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	3 / 47 (6.38%)	0 / 51 (0.00%)	2 / 113 (1.77%)
occurrences (all)	4	0	2
Injection site erythema			
subjects affected / exposed	5 / 47 (10.64%)	7 / 51 (13.73%)	0 / 113 (0.00%)
occurrences (all)	6	8	0
Injection site swelling			
subjects affected / exposed	2 / 47 (4.26%)	4 / 51 (7.84%)	0 / 113 (0.00%)
occurrences (all)	3	4	0
Pyrexia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 51 (0.00%)	0 / 113 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	3 / 47 (6.38%)	0 / 51 (0.00%)	0 / 113 (0.00%)
occurrences (all)	3	0	0
Injection site pain			
subjects affected / exposed	2 / 47 (4.26%)	3 / 51 (5.88%)	4 / 113 (3.54%)
occurrences (all)	2	4	4
Injection site oedema			
subjects affected / exposed	3 / 47 (6.38%)	1 / 51 (1.96%)	0 / 113 (0.00%)
occurrences (all)	6	1	0
Gastrointestinal disorders			
Vomiting			

subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	3 / 113 (2.65%)
occurrences (all)	0	0	3
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 47 (2.13%)	1 / 51 (1.96%)	1 / 113 (0.88%)
occurrences (all)	1	1	1
Cough			
subjects affected / exposed	1 / 47 (2.13%)	0 / 51 (0.00%)	3 / 113 (2.65%)
occurrences (all)	1	0	3
Asthma			
subjects affected / exposed	2 / 47 (4.26%)	0 / 51 (0.00%)	1 / 113 (0.88%)
occurrences (all)	2	0	1
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	5 / 47 (10.64%)	1 / 51 (1.96%)	1 / 113 (0.88%)
occurrences (all)	8	1	1
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 47 (2.13%)	2 / 51 (3.92%)	2 / 113 (1.77%)
occurrences (all)	1	2	2
Influenza			
subjects affected / exposed	1 / 47 (2.13%)	1 / 51 (1.96%)	0 / 113 (0.00%)
occurrences (all)	1	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	2 / 113 (1.77%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	1 / 47 (2.13%)	3 / 51 (5.88%)	7 / 113 (6.19%)
occurrences (all)	1	4	8
Nasopharyngitis			
subjects affected / exposed	4 / 47 (8.51%)	2 / 51 (3.92%)	5 / 113 (4.42%)
occurrences (all)	4	2	6

Non-serious adverse events	Entire study period (Up to Week 68) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 16) QGE031 120 mg SCq4w	Placebo controlled period (Up to Week 16) Placebo
Total subjects affected by non-serious adverse events			

subjects affected / exposed	53 / 101 (52.48%)	20 / 51 (39.22%)	9 / 23 (39.13%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 101 (1.98%)	0 / 51 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	12 / 101 (11.88%)	4 / 51 (7.84%)	1 / 23 (4.35%)
occurrences (all)	22	6	1
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	2 / 101 (1.98%)	1 / 51 (1.96%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Injection site erythema			
subjects affected / exposed	13 / 101 (12.87%)	8 / 51 (15.69%)	0 / 23 (0.00%)
occurrences (all)	28	13	0
Injection site swelling			
subjects affected / exposed	4 / 101 (3.96%)	4 / 51 (7.84%)	0 / 23 (0.00%)
occurrences (all)	7	5	0
Pyrexia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Injection site pain			
subjects affected / exposed	4 / 101 (3.96%)	3 / 51 (5.88%)	0 / 23 (0.00%)
occurrences (all)	10	4	0
Injection site oedema			
subjects affected / exposed	3 / 101 (2.97%)	2 / 51 (3.92%)	0 / 23 (0.00%)
occurrences (all)	7	2	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	3
Respiratory, thoracic and mediastinal disorders			

Nasal congestion			
subjects affected / exposed	4 / 101 (3.96%)	1 / 51 (1.96%)	0 / 23 (0.00%)
occurrences (all)	4	1	0
Cough			
subjects affected / exposed	2 / 101 (1.98%)	0 / 51 (0.00%)	2 / 23 (8.70%)
occurrences (all)	3	0	2
Asthma			
subjects affected / exposed	3 / 101 (2.97%)	0 / 51 (0.00%)	0 / 23 (0.00%)
occurrences (all)	4	0	0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	6 / 101 (5.94%)	1 / 51 (1.96%)	0 / 23 (0.00%)
occurrences (all)	8	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	14 / 101 (13.86%)	5 / 51 (9.80%)	0 / 23 (0.00%)
occurrences (all)	14	5	0
Influenza			
subjects affected / exposed	6 / 101 (5.94%)	3 / 51 (5.88%)	0 / 23 (0.00%)
occurrences (all)	6	3	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 101 (0.99%)	0 / 51 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2
Upper respiratory tract infection			
subjects affected / exposed	9 / 101 (8.91%)	4 / 51 (7.84%)	2 / 23 (8.70%)
occurrences (all)	15	8	3
Nasopharyngitis			
subjects affected / exposed	14 / 101 (13.86%)	3 / 51 (5.88%)	3 / 23 (13.04%)
occurrences (all)	17	3	4

Non-serious adverse events	Entire study period (Up to Week 68) QGE031 240 mg SCq4w	Placebo controlled period (Up to Week 16) QGE031 240 mg SCq4w	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 99 (57.58%)	26 / 47 (55.32%)	
Nervous system disorders			
Dizziness			

subjects affected / exposed	3 / 99 (3.03%)	3 / 47 (6.38%)	
occurrences (all)	3	3	
Headache			
subjects affected / exposed	10 / 99 (10.10%)	4 / 47 (8.51%)	
occurrences (all)	14	4	
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	9 / 99 (9.09%)	3 / 47 (6.38%)	
occurrences (all)	15	4	
Injection site erythema			
subjects affected / exposed	15 / 99 (15.15%)	6 / 47 (12.77%)	
occurrences (all)	27	8	
Injection site swelling			
subjects affected / exposed	6 / 99 (6.06%)	2 / 47 (4.26%)	
occurrences (all)	8	3	
Pyrexia			
subjects affected / exposed	5 / 99 (5.05%)	1 / 47 (2.13%)	
occurrences (all)	5	1	
Injection site pruritus			
subjects affected / exposed	4 / 99 (4.04%)	3 / 47 (6.38%)	
occurrences (all)	4	3	
Injection site pain			
subjects affected / exposed	6 / 99 (6.06%)	3 / 47 (6.38%)	
occurrences (all)	12	3	
Injection site oedema			
subjects affected / exposed	7 / 99 (7.07%)	4 / 47 (8.51%)	
occurrences (all)	14	9	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 99 (1.01%)	0 / 47 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	5 / 99 (5.05%)	2 / 47 (4.26%)	
occurrences (all)	6	2	
Cough			

subjects affected / exposed	7 / 99 (7.07%)	4 / 47 (8.51%)	
occurrences (all)	7	4	
Asthma			
subjects affected / exposed	7 / 99 (7.07%)	2 / 47 (4.26%)	
occurrences (all)	11	4	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	11 / 99 (11.11%)	7 / 47 (14.89%)	
occurrences (all)	14	10	
Infections and infestations			
COVID-19			
subjects affected / exposed	7 / 99 (7.07%)	5 / 47 (10.64%)	
occurrences (all)	7	5	
Influenza			
subjects affected / exposed	5 / 99 (5.05%)	2 / 47 (4.26%)	
occurrences (all)	5	2	
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 99 (2.02%)	0 / 47 (0.00%)	
occurrences (all)	2	0	
Upper respiratory tract infection			
subjects affected / exposed	8 / 99 (8.08%)	3 / 47 (6.38%)	
occurrences (all)	12	6	
Nasopharyngitis			
subjects affected / exposed	19 / 99 (19.19%)	8 / 47 (17.02%)	
occurrences (all)	23	10	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 April 2022	The main purpose of Protocol Amendment 1 was to: • Change the data review mode for the DMC from semi-blinded to unblinded as per request of the DMC from 12-Oct-2021; • Adjust inclusion criterion number 4: The amended cutoff for positive peanut-specific IgE (peanut sIgE) was set at ≥ 0.35 kUA/L at Screening Visit 1 to avoid excluding participants with otherwise strong evidence supporting the diagnosis of peanut allergy (based on medical history and SPT); • Clarify and harmonize usage of prohibited medication and medication allowed under certain conditions; • Add serum tryptase as biomarker; • Reduce the number of stool samples required to determine participant eligibility at screening from three to one in asymptomatic participants; • Define two entry timepoints for participants who wish to enter the Extension study: at Week 68 (end of follow-up) for the first one third of participants or Week 52 (end of treatment) for the remaining participants. It also included other clarifications, minor updates, and corrections of typographical errors across the document.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results.
Please use https://www.novctrd.com/#/ for complete trial results.

Notes: