# 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:<br>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:<br>2 injections of 1.0 mL ligelizumab from Week 16 through Week 52 | |
| **Arm title** | Placebo 16 weeks and ligelizumab 120 mg |
| Arm description:<br>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:<br>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:<br>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:<br>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<br>Units: Participants | | | |
| 12 - 17 years | 27 | 29 | 25 |
| 18 - 55 years | 20 | 22 | 21 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 19.5 | 18.8 | 18.7 |
| standard deviation | ± 7.50 | ± 6.27 | ± 6.95 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 25 | 25 | 19 |
| Male | 22 | 26 | 27 |
| Race (NIH/OMB)<br>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<br>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 (%)<br>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<br>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<br>Units: Years | | | |
| arithmetic mean | 16.287 | 16.381 | 15.556 |
| standard deviation | ± 7.9393 | ± 6.9248 | ± 7.5799 |
| Peanut specific Immunoglobulin E (IgE)<br>Units: IU/mL | | | |
| arithmetic mean | 109.021 | 80.644 | 131.948 |
| standard deviation | ± 147.9877 | ± 117.6312 | ± 189.7757 |
| Total Immunoglobulin E (IgE)<br>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<br>Units: Participants | | | |
| 12 - 17 years | 24 | 6 | 8 |
| 18 - 55 years | 20 | 5 | 4 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 20.0 | 17.4 | 16.1 |
| standard deviation | ± 7.75 | ± 4.57 | ± 3.58 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 20 | 3 | 6 |
| Male | 24 | 8 | 6 |
| Race (NIH/OMB)<br>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<br>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 (%)<br>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<br>Units: Years<br>arithmetic mean<br>standard deviation | -<br> | | |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 98 | | |
| Male | 113 | | |
| Race (NIH/OMB)<br>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<br>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 (%)<br>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<br>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 | |
| 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 | |

| **Reporting group values** | Placebo | Placebo | Placebo |
|---|---|---|---|
| Number of subjects | 23 | 20 | 19 |
| Age Categorical<br>Units: Participants | | | |
| 12 - 17 years | | | |
| 18 - 55 years | | | |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | | | |
| standard deviation | ± | ± | ± |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | | | |
| Male | | | |
| Race (NIH/OMB)<br>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<br>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 (%)<br>Units: Subjects | | | |
| < 1 mg | | | |

| | | | |
|---|---|---|---|
| 1 mg<br>3 mg<br>10 mg<br>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<br>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<br>Poly-allergic to food = No | | | |
| History of anaphylactic reaction to food<br>Units: Subjects | | | |
| History of anaphylactic reaction to food = Yes<br>History of anaphylactic reaction to food = No<br>History of anaphylactic reaction to food = Unknown | | | |
| Time to diagnosis of peanut allergy<br>Units: Years<br>arithmetic mean<br>standard deviation | <br><br>1<br>± | <br><br><br>± | <br><br><br>± |
| Peanut specific Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>standard deviation | <br><br>1<br>± | <br><br><br>± | <br><br><br>± |
| Total Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>standard deviation | <br><br>1<br>± | <br><br><br>± | <br><br><br>± |
| 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<br>arithmetic mean<br>standard deviation | <br>1<br>± | <br><br>± | <br><br>± |
| 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<br>arithmetic mean<br>standard deviation | <br>1<br>± | <br><br>± | <br><br>± |

| **Reporting group values** | Placebo | Placebo | Placebo |
|---|---|---|---|
| Number of subjects | 16 | 9 | 8 |

| | | | |
|---|---|---|---|
| Age Categorical<br>Units: Participants | | | |
| 12 - 17 years | | | |
| 18 - 55 years | | | |
| Age Continuous<br>Units: Years<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | | | |
| Male | | | |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native<br>Asian<br>Native Hawaiian or Other Pacific Islander<br>Black or African American<br>White<br>More than one race<br>Unknown or Not Reported | | | |
| Number of participants with at least one food allergy<br>Units: Subjects | | | |
| 1 food allergy<br>2 food allergies<br>3 food allergies<br>4 food allergies<br>5 food allergies<br>> 5 food allergies | | | |
| MTD (maximum tolerated dose) of peanut protein (mg) - n (%)<br>Units: Subjects | | | |
| < 1 mg<br>1 mg<br>3 mg<br>10 mg<br>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<br>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<br>Poly-allergic to food = No | | | |
| History of anaphylactic reaction to food<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| History of anaphylactic reaction to food = Yes<br>History of anaphylactic reaction to food = No<br>History of anaphylactic reaction to food = Unknown | | | |
| Time to diagnosis of peanut allergy<br>Units: Years<br>arithmetic mean<br>standard deviation | <br><br>-2.38<br>± 3.788 | <br><br>± | <br><br>± |
| Peanut specific Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>standard deviation | <br><br>-2.38<br>± 3.788 | <br><br>± | <br><br>± |
| Total Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>standard deviation | <br><br>-2.38<br>± 3.788 | <br><br>± | <br><br>± |
| 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<br>arithmetic mean<br>standard deviation | <br>-2.38<br>± 3.788 | <br>± | <br>± |
| 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<br>arithmetic mean<br>standard deviation | <br>-2.38<br>± 3.788 | <br>± | <br>± |

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

| | | | |
|---|---|---|---|
| Native Hawaiian or Other Pacific Islander<br>Black or African American<br>White<br>More than one race<br>Unknown or Not Reported | | | |
| Number of participants with at least one food allergy<br>Units: Subjects | | | |
| 1 food allergy<br>2 food allergies<br>3 food allergies<br>4 food allergies<br>5 food allergies<br>> 5 food allergies | | | |
| MTD (maximum tolerated dose) of peanut protein (mg) - n (%)<br>Units: Subjects | | | |
| < 1 mg<br>1 mg<br>3 mg<br>10 mg<br>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<br>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<br>Poly-allergic to food = No | | | |
| History of anaphylactic reaction to food<br>Units: Subjects | | | |
| History of anaphylactic reaction to food = Yes<br>History of anaphylactic reaction to food = No<br>History of anaphylactic reaction to food = Unknown | | | |
| Time to diagnosis of peanut allergy<br>Units: Years<br>arithmetic mean<br>standard deviation | ± | | |
| Peanut specific Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>standard deviation | ± | | |
| Total Immunoglobulin E (IgE)<br>Units: IU/mL<br>arithmetic mean<br>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<br>arithmetic mean<br>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<br>arithmetic mean<br>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<br>Mental Component Score | 3.15 (± 5.342)<br>-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: