



Clinical trial results: Peanut Oral Immunotherapy Study of Early Intervention for Desensitization (POSEIDON)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-001749-15 |
| Trial protocol | GB IE FR DE |
| Global end of trial date | 05 July 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 26 February 2023 |
| First version publication date | 26 February 2023 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | ARC005 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03736447 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001734-PIP01-14 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 14 December 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 05 July 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 July 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the efficacy and safety of Characterized Peanut Allergen (AR101) through reduction in clinical reactivity to limited amounts of peanut allergen in peanut allergic children aged 1 to < 4 years.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 01 November 2018 |
| 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 | United States: 84 |
| Country: Number of subjects enrolled | United Kingdom: 41 |
| Country: Number of subjects enrolled | Germany: 14 |
| Country: Number of subjects enrolled | France: 7 |
| Worldwide total number of subjects | 146 |
| EEA total number of subjects | 21 |

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) | 49 |
| Children (2-11 years) | 97 |

| | |
|---------------------------|---|
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

289 subjects were screened and 146 were initially randomized and enrolled in the study. The randomized population consisted of 98 subjects in the AR101 group and 48 subjects in the placebo group. The final intent-to-treat (ITT) population had 146 subjects.

Period 1

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

Arms

| | |
|------------------------------|-------|
| Are arms mutually exclusive? | Yes |
| Arm title | AR101 |

Arm description:

A peanut-derived oral immunotherapy drug

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

Dosage and administration details:

Pull-apart capsules containing 0.5, 1, 10 or 100 mg peanut protein

Sachets containing 300 mg peanut protein

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Matching placebo

| | |
|--|-------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral powder |
| Routes of administration | Oral use |

Dosage and administration details:

Equivalent amount of placebo powder containing inactive ingredients in pull-apart capsules and sachets.

| Number of subjects in period 1 | AR101 | Placebo |
|---|-------|---------|
| Started | 98 | 48 |
| Completed | 83 | 45 |
| Not completed | 15 | 3 |
| Continued commitment to study treatment | 3 | - |
| Physician decision | 1 | - |
| Consent withdrawn by subject | 5 | 1 |
| Adverse event, non-fatal | 5 | 1 |
| Taste aversion to study product | - | 1 |
| Lost to follow-up | 1 | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------|
| Reporting group title | AR101 |
|-----------------------|-------|

| |
|------------------------------|
| Reporting group description: |
|------------------------------|

| |
|--|
| A peanut-derived oral immunotherapy drug |
|--|

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

| |
|------------------------------|
| Reporting group description: |
|------------------------------|

| |
|------------------|
| Matching placebo |
|------------------|

| Reporting group values | AR101 | Placebo | Total |
|------------------------|-------|---------|-------|
| Number of subjects | 98 | 48 | 146 |
| Age categorical | | | |
| Units: Subjects | | | |
| 1-<2 years | 33 | 16 | 49 |
| 2-<3 years | 35 | 15 | 50 |
| 3-<4 years | 30 | 17 | 47 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 41 | 20 | 61 |
| Male | 57 | 28 | 85 |

End points

End points reporting groups

| | |
|--|---------|
| Reporting group title | AR101 |
| Reporting group description: | |
| A peanut-derived oral immunotherapy drug | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Matching placebo | |

Primary: Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 1000 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC)

| | |
|---|---|
| End point title | Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 1000 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC) |
| End point description: | |
| The percentage of subjects in the ITT population who achieve desensitization as determined by tolerating specified challenge doses of peanut protein with no more than mild allergy symptoms during the exit double-blind placebo-controlled food challenge (DBPCFC). | |
| End point type | Primary |
| End point timeframe: | |
| 12 months | |

| End point values | AR101 | Placebo | | |
|----------------------------------|---------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 48 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | 68.4 (58.2 to 77.4) | 4.2 (0.5 to 14.3) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | % of subjects who tolerated 1000 mg in DBPCFC |
| Comparison groups | AR101 v Placebo |
| Number of subjects included in analysis | 146 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Farrington-Manning test |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 64.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 47 |
| upper limit | 81.4 |

Secondary: Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 600 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC)

| | |
|-----------------|--|
| End point title | Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 600 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC) |
|-----------------|--|

End point description:

The percentage of subjects in the ITT population who achieve desensitization as determined by tolerating specified challenge doses of peanut protein with no more than mild allergy symptoms during the exit double-blind placebo-controlled food challenge (DBPCFC).

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

End point timeframe:

12 months

| End point values | AR101 | Placebo | | |
|----------------------------------|---------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 48 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | 73.5 (63.6 to 81.9) | 6.3 (1.3 to 17.2) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | % of subjects who tolerated 600 mg in DBPCFC |
| Comparison groups | AR101 v Placebo |
| Number of subjects included in analysis | 146 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Farrington-Manning test |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 67.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 50 |
| upper limit | 84.5 |

Secondary: Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 300 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC)

| | |
|-----------------|--|
| End point title | Percentage of Subjects Who Tolerated a Single Highest Dose of at Least 300 mg in the Exit Double-Blind, Placebo-Controlled Food Challenge (DBPCFC) |
|-----------------|--|

End point description:

The percentage of subjects in the ITT population who achieve desensitization as determined by tolerating specified challenge doses of peanut protein with no more than mild allergy symptoms during the exit double-blind placebo-controlled food challenge (DBPCFC).

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

End point timeframe:

12 months

| End point values | AR101 | Placebo | | |
|----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 48 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | 79.6 (70.3 to 87.1) | 22.9 (12.0 to 37.3) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | % of subjects who tolerated 300 mg in DBPCFC |
| Comparison groups | AR101 v Placebo |
| Number of subjects included in analysis | 146 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Farrington-Manning test |
| Parameter estimate | Risk difference (RD) |
| Point estimate | 56.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 39.8 |
| upper limit | 73.5 |

Secondary: Maximum Severity of Symptoms in Participants at Any Challenge Dose During the Exit Double-blind Placebo Controlled Food Challenge (DBPCFC)

| | |
|-----------------|--|
| End point title | Maximum Severity of Symptoms in Participants at Any Challenge Dose During the Exit Double-blind Placebo Controlled Food Challenge (DBPCFC) |
|-----------------|--|

End point description:

The maximum severity of symptoms that occurred at any challenge dose of peanut protein during the exit DBPCFC.

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

End point timeframe:

12 months

| End point values | AR101 | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 48 | | |
| Units: Participants | | | | |
| None | 50 | 2 | | |
| Mild | 29 | 23 | | |
| Moderate | 17 | 21 | | |
| Severe | 2 | 2 | | |
| Life-threatening or fatal | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

12 months

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 21.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------|
| Reporting group title | AR101 |
|-----------------------|-------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description: -

| Serious adverse events | AR101 | Placebo | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 98 (7.14%) | 2 / 48 (4.17%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Carbon monoxide poisoning | | | |
| subjects affected / exposed | 0 / 98 (0.00%) | 1 / 48 (2.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 98 (0.00%) | 1 / 48 (2.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Enterovirus infection | | | |
| subjects affected / exposed | 1 / 98 (1.02%) | 0 / 48 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 1 / 98 (1.02%) | 0 / 48 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 1 / 98 (1.02%) | 0 / 48 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status asthmaticus | | | |
| subjects affected / exposed | 1 / 98 (1.02%) | 0 / 48 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 98 (1.02%) | 0 / 48 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 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 | AR101 | Placebo | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 96 / 98 (97.96%) | 47 / 48 (97.92%) | |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | | | |
| subjects affected / exposed | 7 / 98 (7.14%) | 2 / 48 (4.17%) | |
| occurrences (all) | 7 | 2 | |
| Contusion | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Head injury | | | |
| subjects affected / exposed | 6 / 98 (6.12%) | 1 / 48 (2.08%) | |
| occurrences (all) | 6 | 1 | |
| Nervous system disorders | | | |
| Headache | | | |

| | | | |
|--|---|--|--|
| subjects affected / exposed occurrences (all) | 10 / 98 (10.20%) 10 | 1 / 48 (2.08%) 1 | |
| General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) | 50 / 98 (51.02%) 50 | 20 / 48 (41.67%) 20 | |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) | 5 / 98 (5.10%) 5 | 3 / 48 (6.25%) 3 | |
| Immune system disorders Anaphylactic reaction subjects affected / exposed occurrences (all) Seasonal allergy subjects affected / exposed occurrences (all) | 8 / 98 (8.16%) 8 4 / 98 (4.08%) 4 | 4 / 48 (8.33%) 4 4 / 48 (8.33%) 4 | |
| Eye disorders Eye pruritus subjects affected / exposed occurrences (all) Eye swelling subjects affected / exposed occurrences (all) Ocular hyperaemia subjects affected / exposed occurrences (all) | 9 / 98 (9.18%) 9 9 / 98 (9.18%) 9 6 / 98 (6.12%) 6 | 5 / 48 (10.42%) 5 3 / 48 (6.25%) 3 2 / 48 (4.17%) 2 | |
| Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Constipation | 23 / 98 (23.47%) 23 14 / 98 (14.29%) 14 | 6 / 48 (12.50%) 6 4 / 48 (8.33%) 4 | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 11 / 98 (11.22%) | 5 / 48 (10.42%) | |
| occurrences (all) | 11 | 5 | |
| Diarrhoea | | | |
| subjects affected / exposed | 34 / 98 (34.69%) | 13 / 48 (27.08%) | |
| occurrences (all) | 34 | 13 | |
| Flatulence | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Lip swelling | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Nausea | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 2 / 48 (4.17%) | |
| occurrences (all) | 5 | 2 | |
| Oral pruritus | | | |
| subjects affected / exposed | 10 / 98 (10.20%) | 2 / 48 (4.17%) | |
| occurrences (all) | 10 | 2 | |
| Teething | | | |
| subjects affected / exposed | 10 / 98 (10.20%) | 7 / 48 (14.58%) | |
| occurrences (all) | 10 | 7 | |
| Vomiting | | | |
| subjects affected / exposed | 52 / 98 (53.06%) | 15 / 48 (31.25%) | |
| occurrences (all) | 52 | 15 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 11 / 98 (11.22%) | 7 / 48 (14.58%) | |
| occurrences (all) | 11 | 7 | |
| Cough | | | |
| subjects affected / exposed | 52 / 98 (53.06%) | 21 / 48 (43.75%) | |
| occurrences (all) | 52 | 21 | |
| Dysphonia | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 1 / 48 (2.08%) | |
| occurrences (all) | 5 | 1 | |
| Nasal congestion | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 14 / 98 (14.29%) | 5 / 48 (10.42%) | |
| occurrences (all) | 14 | 5 | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 1 / 48 (2.08%) | |
| occurrences (all) | 5 | 1 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 42 / 98 (42.86%) | 15 / 48 (31.25%) | |
| occurrences (all) | 42 | 15 | |
| Sneezing | | | |
| subjects affected / exposed | 23 / 98 (23.47%) | 9 / 48 (18.75%) | |
| occurrences (all) | 23 | 9 | |
| Throat irritation | | | |
| subjects affected / exposed | 8 / 98 (8.16%) | 2 / 48 (4.17%) | |
| occurrences (all) | 8 | 2 | |
| Wheezing | | | |
| subjects affected / exposed | 14 / 98 (14.29%) | 4 / 48 (8.33%) | |
| occurrences (all) | 14 | 4 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 6 / 98 (6.12%) | 5 / 48 (10.42%) | |
| occurrences (all) | 6 | 5 | |
| Dry skin | | | |
| subjects affected / exposed | 8 / 98 (8.16%) | 2 / 48 (4.17%) | |
| occurrences (all) | 8 | 2 | |
| Eczema | | | |
| subjects affected / exposed | 24 / 98 (24.49%) | 12 / 48 (25.00%) | |
| occurrences (all) | 24 | 12 | |
| Erythema | | | |
| subjects affected / exposed | 34 / 98 (34.69%) | 17 / 48 (35.42%) | |
| occurrences (all) | 34 | 17 | |
| Perioral dermatitis | | | |
| subjects affected / exposed | 17 / 98 (17.35%) | 4 / 48 (8.33%) | |
| occurrences (all) | 17 | 4 | |
| Pruritus | | | |
| subjects affected / exposed | 27 / 98 (27.55%) | 15 / 48 (31.25%) | |
| occurrences (all) | 27 | 15 | |

| | | | |
|-----------------------------|------------------|------------------|--|
| Rash | | | |
| subjects affected / exposed | 23 / 98 (23.47%) | 11 / 48 (22.92%) | |
| occurrences (all) | 23 | 11 | |
| Rash erythematous | | | |
| subjects affected / exposed | 8 / 98 (8.16%) | 3 / 48 (6.25%) | |
| occurrences (all) | 8 | 3 | |
| Swelling face | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 1 / 48 (2.08%) | |
| occurrences (all) | 5 | 1 | |
| Urticaria | | | |
| subjects affected / exposed | 51 / 98 (52.04%) | 24 / 48 (50.00%) | |
| occurrences (all) | 51 | 24 | |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 6 / 98 (6.12%) | 1 / 48 (2.08%) | |
| occurrences (all) | 6 | 1 | |
| Infections and infestations | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 6 / 98 (6.12%) | 5 / 48 (10.42%) | |
| occurrences (all) | 6 | 5 | |
| Coronavirus infection | | | |
| subjects affected / exposed | 6 / 98 (6.12%) | 6 / 48 (12.50%) | |
| occurrences (all) | 6 | 6 | |
| Ear infection | | | |
| subjects affected / exposed | 11 / 98 (11.22%) | 2 / 48 (4.17%) | |
| occurrences (all) | 11 | 2 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 10 / 98 (10.20%) | 6 / 48 (12.50%) | |
| occurrences (all) | 10 | 6 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 8 / 98 (8.16%) | 1 / 48 (2.08%) | |
| occurrences (all) | 8 | 1 | |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 2 / 48 (4.17%) | |
| occurrences (all) | 5 | 2 | |
| Influenza | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 28 / 98 (28.57%) | 13 / 48 (27.08%) | |
| occurrences (all) | 28 | 13 | |
| Rhinitis | | | |
| subjects affected / exposed | 20 / 98 (20.41%) | 8 / 48 (16.67%) | |
| occurrences (all) | 20 | 8 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 35 / 98 (35.71%) | 13 / 48 (27.08%) | |
| occurrences (all) | 35 | 13 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Viral infection | | | |
| subjects affected / exposed | 9 / 98 (9.18%) | 5 / 48 (10.42%) | |
| occurrences (all) | 9 | 5 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 9 / 98 (9.18%) | 5 / 48 (10.42%) | |
| occurrences (all) | 9 | 5 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 5 / 98 (5.10%) | 0 / 48 (0.00%) | |
| occurrences (all) | 5 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---------------|
| 27 June 2019 | Amendment 1.0 |
| 02 March 2020 | Amendment 2.0 |
| 29 May 2020 | Amendment 3.0 |
| 17 March 2021 | Amendment 4.0 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|---------------|--|------------------|
| 18 March 2020 | <p>On the 11 March 2020 the World Health Organization (WHO) declared COVID-19 a global pandemic. On the 18 March 2020, Aimmune notified the sites globally of a halt to screening, enrolment and exit visits. A protocol amendment was submitted on the 29 March 2020 to include an emergency situations appendix. Temporary halt notifications were sent to some countries.</p> <p>It was agreed that prior to sites restarting these specified study procedures, and following the lifting of emergency restrictions, several points needed to be considered to ensure sites are ready to recommence these procedures again onsite:</p> <ol style="list-style-type: none">1. Required Aimmune resources, clinical supplies and related vendor processes are in place and fully functional to restart specified procedures as per protocol.2. Site can restart inclinic visit procedures/assessments (e.g., screening, updosing, maintenance) as per protocol for all subjects.3. Site can accommodate and recommence CRA onsite monitoring visits.4. Site has adequate resources and clinical supplies in place to conduct the required procedures per protocol, including data entry and query resolution. <p>Upon completion of Study Procedure Restart Checklist forms, sites were then able to recommence their study activities. The last site restarted activities on the 13 February 2021.</p> | 13 February 2021 |

Notes:

Limitations and caveats

None reported

