



Clinical trial results:

An Extension Study to CIGE025B1301 to Evaluate the Long-term Safety, Tolerability and Efficacy of Omalizumab in Japanese Children (6 - 15 Years) With Inadequately Controlled Allergic Asthma Despite Current Recommended Treatment

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2015-003536-12 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 26 December 2013 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 04 January 2017 |
| First version publication date | 04 January 2017 |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | CIGE025B1301E1 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01328886 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Novartis Pharma AG |
| Sponsor organisation address | CH 4002, Basel, Switzerland, |
| Public contact | Clinical Disclosure Office, Novartis Pharma AG, +41 613241111, |
| Scientific contact | Clinical Disclosure Office, Novartis Pharma AG, +41 613241111, |

Notes:

Paediatric regulatory details

| | |
|--|-----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| 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 | 26 December 2013 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 26 December 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to assess the long-term safety and tolerability of omalizumab as add-on therapy in Japanese pediatric subjects with inadequately controlled allergic asthma despite current recommended treatment.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 18 March 2011 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | Japan: 38 |
| Worldwide total number of subjects | 38 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 21 |
| Adolescents (12-17 years) | 17 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 15 centers in Japan.

Pre-assignment

Screening details:

This study was the extension study of the core study CIGE025B1301 (EudraCT Number: 2015-003534-27).

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | Overall period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

The study was open label study, hence no blinding was performed.

Arms

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|-----------|------------|
| Arm title | Omalizumab |
|-----------|------------|

Arm description:

Omalizumab 75 to 375 mg was administered subcutaneously (sc) every 2 or 4 weeks depending on the dose. Omalizumab dose was individualized for each subject, based on their body weight and total serum immunoglobulin E (IgE) level at screening visit.

| | |
|--|------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Omalizumab |
| Investigational medicinal product code | IGE025B |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects were administered with Omalizumab 75 to 375 mg subcutaneously every 2 or 4 weeks.

| Number of subjects in period 1 | Omalizumab |
|--------------------------------|------------|
| Started | 38 |
| Completed | 35 |
| Not completed | 3 |
| Consent withdrawn by subject | 2 |
| Lack of efficacy | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | Overall period |
|-----------------------|----------------|

Reporting group description: -

| Reporting group values | Overall period | Total | |
|---------------------------|----------------|-------|--|
| Number of subjects | 38 | 38 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Children (2-11 years) | 21 | 21 | |
| Adolescents (12-17 years) | 17 | 17 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 11.5 | | |
| standard deviation | ± 2.52 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 15 | 15 | |
| Male | 23 | 23 | |

End points

End points reporting groups

| | |
|---|------------|
| Reporting group title | Omalizumab |
| Reporting group description: Omalizumab 75 to 375 mg was administered subcutaneously (sc) every 2 or 4 weeks depending on the dose. Omalizumab dose was individualized for each subject, based on their body weight and total serum immunoglobulin E (IgE) level at screening visit. | |

Primary: Number of subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), AE leading to discontinuation and who died

| | |
|-----------------|--|
| End point title | Number of subjects with Adverse Events (AEs), Serious Adverse Events (SAEs), AE leading to discontinuation and who died ^[1] |
|-----------------|--|

End point description:

AEs are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. Serious adverse events are any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgment of investigators represent significant hazards. The analysis was performed on safety set population, defined subjects with at least one dose of study medication during the study..

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From day 1 to 30 days post last study treatment

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive summary statistics was planned for this outcome measure.

| End point values | Omalizumab | | | |
|-------------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 38 | | | |
| Units: Subjects | | | | |
| AEs | 38 | | | |
| SAEs | 10 | | | |
| SAEs other than asthma exacerbation | 4 | | | |
| Asthma exacerbation | 7 | | | |
| Death | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events are monitored from date of First Subject First Visit (FSFV) until Last Subject Last Visit (LSLV). All other adverse events are monitored from First Subject First Treatment until LSLV

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Omalizumab |
|-----------------------|------------|

Reporting group description:

Omalizumab 75 to 375 mg was administered sc every 2 or 4 weeks depending on the dose. Omalizumab dose was individualized for each subject, based on their body weight and total serum IgE level at screening visit.

| Serious adverse events | Omalizumab | | |
|---|------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 10 / 38 (26.32%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Lymphadenitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 7 / 38 (18.42%) | | |
| occurrences causally related to treatment / all | 0 / 10 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |

| | | | |
|---|----------------|--|--|
| Appendicitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peritonsillar abscess | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tonsillitis bacterial | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Viral pharyngitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|---|-------------------|--|--|
| Non-serious adverse events | Omalizumab | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 38 / 38 (100.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Skin papilloma | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Vascular disorders | | | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| General disorders and administration | | | |

| | | | |
|-----------------------------|-----------------|--|--|
| site conditions | | | |
| Administration site pain | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Application site erythema | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Application site swelling | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Discomfort | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Injection site eczema | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Injection site erythema | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Injection site swelling | | | |
| subjects affected / exposed | 4 / 38 (10.53%) | | |
| occurrences (all) | 4 | | |
| Malaise | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Pyrexia | | | |
| subjects affected / exposed | 9 / 38 (23.68%) | | |
| occurrences (all) | 14 | | |
| Swelling | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Food allergy | | | |

| | | | |
|--|--|--|--|
| subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | | |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | | |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal discomfort subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Upper respiratory tract inflammation subjects affected / exposed occurrences (all) | 6 / 38 (15.79%) 10 1 / 38 (2.63%) 1 2 / 38 (5.26%) 2 1 / 38 (2.63%) 1 1 / 38 (2.63%) 1 1 / 38 (2.63%) 2 4 / 38 (10.53%) 5 5 / 38 (13.16%) 9 | | |
| Psychiatric disorders Conversion disorder subjects affected / exposed occurrences (all) Dysphoria | 1 / 38 (2.63%) 1 | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Psychosomatic disease | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Investigations | | | |
| Blood pressure diastolic increased | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Urine output decreased | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Injury, poisoning and procedural complications | | | |
| Arthropod sting | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Contusion | | | |
| subjects affected / exposed | 8 / 38 (21.05%) | | |
| occurrences (all) | 10 | | |
| Epicondylitis | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Epiphyseal injury | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Foot fracture | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Hand fracture | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |
| Heat illness | | | |

| | | | |
|-----------------------------|------------------|--|--|
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Injury | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Ligament sprain | | | |
| subjects affected / exposed | 6 / 38 (15.79%) | | |
| occurrences (all) | 7 | | |
| Scratch | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Wound | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 11 / 38 (28.95%) | | |
| occurrences (all) | 16 | | |
| Migraine | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |
| Orthostatic intolerance | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Tremor | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Ear and labyrinth disorders | | | |
| Auricular perichondritis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Eye disorders | | | |
| Chalazion | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Conjunctivitis allergic | | | |

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|-----------------------------|-----------------|--|--|
| subjects affected / exposed | 5 / 38 (13.16%) | | |
| occurrences (all) | 6 | | |
| Eczema eyelids | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Eye swelling | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Myopia | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Visual acuity reduced | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 6 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Cheilitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Constipation | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 4 | | |
| Dental caries | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |

| | | | |
|--|-----------------|--|--|
| Gastritis | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Enterocolitis | | | |
| subjects affected / exposed | 7 / 38 (18.42%) | | |
| occurrences (all) | 9 | | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Periodontal disease | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Nausea | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Radicular cyst | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Stomatitis | | | |
| subjects affected / exposed | 7 / 38 (18.42%) | | |
| occurrences (all) | 8 | | |
| Toothache | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Vomiting | | | |
| subjects affected / exposed | 6 / 38 (15.79%) | | |
| occurrences (all) | 6 | | |
| Hepatobiliary disorders | | | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 4 / 38 (10.53%) | | |
| occurrences (all) | 4 | | |
| Asteatosis | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Dry skin | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Eczema | | | |
| subjects affected / exposed | 10 / 38 (26.32%) | | |
| occurrences (all) | 11 | | |
| Eczema nummular | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Rash | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Urticaria | | | |
| subjects affected / exposed | 5 / 38 (13.16%) | | |
| occurrences (all) | 6 | | |
| Renal and urinary disorders | | | |
| Enuresis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Arthropathy | | | |

| | | | |
|------------------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Back pain | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 4 | | |
| Growing pains | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |
| Infrapatellar fat pad inflammation | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Myalgia | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 3 | | |
| Myofascial pain syndrome | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Upper extremity mass | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Body tinea | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Acute tonsillitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 38 (7.89%) | | |
| occurrences (all) | 5 | | |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---------------------------------|------------------|--|--|
| Chronic sinusitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Folliculitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Fungal skin infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 6 / 38 (15.79%) | | |
| occurrences (all) | 8 | | |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Herpangina | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 2 | | |
| Impetigo | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Influenza | | | |
| subjects affected / exposed | 15 / 38 (39.47%) | | |
| occurrences (all) | 17 | | |
| Injection site infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Laryngitis | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Kaposi's varicelliform eruption | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |

| | | | |
|-----------------------------------|------------------|--|--|
| Mumps | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 20 / 38 (52.63%) | | |
| occurrences (all) | 52 | | |
| Oral herpes | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Otitis externa | | | |
| subjects affected / exposed | 4 / 38 (10.53%) | | |
| occurrences (all) | 4 | | |
| Otitis media | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Parotitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 7 / 38 (18.42%) | | |
| occurrences (all) | 10 | | |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Sinobronchitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 3 | | |

| | | | |
|-----------------------------------|------------------|--|--|
| Streptococcal infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 1 | | |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences (all) | 3 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 14 / 38 (36.84%) | | |
| occurrences (all) | 34 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported