



Clinical trial results:

A phase IV, multicenter, single-arm and open-label study with omalizumab (Xolair®) in chronic spontaneous urticaria (CSU) patients who remain symptomatic despite antihistamine (H1) treatment

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2014-005424-97 |
| Trial protocol | FR |
| Global end of trial date | 11 January 2016 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 27 January 2017 |
| First version publication date | 27 January 2017 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | CIGE025EFR02 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02550106 |
| 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? | No |

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 11 January 2016 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 11 January 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 January 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the proportion of patients with a urticaria control test (UCT) score ≥ 12 (indicating a well-controlled urticaria) at Week 12 in adult patients with chronic spontaneous urticaria (CSU) with inadequate response to H1 antihistamine treatment and treated by omalizumab 300 mg S.C. every 4 weeks.

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 | 22 April 2015 |
| 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 | France: 136 |
| Worldwide total number of subjects | 136 |
| EEA total number of subjects | 136 |

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) | 0 |
| Adults (18-64 years) | 126 |
| From 65 to 84 years | 10 |

| | |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

Subject disposition

Recruitment

Recruitment details:

Full Analysis Set

Pre-assignment

Screening details:

The study consisted of a screening period (Day -7 to Day -1), a treatment period of 12 weeks (Day 1 to Day 85) and an extension period up to commercial availability of omalizumab in France. Omalizumab was launched on the French market on 03-Nov-2015.

Period 1

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

Blinding implementation details:

This was an open-label, non-blinded study.

Arms

| | |
|-----------|------------|
| Arm title | OMALIZUMAB |
|-----------|------------|

Arm description:

sub cutaneous injections of 300 mg every 4 weeks until Week 8

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Omalizumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Intravesical solution/solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg S.C. every 4 weeks

| Number of subjects in period 1 | OMALIZUMAB |
|--------------------------------|------------|
| Started | 136 |
| Completed | 124 |
| Not completed | 12 |
| Consent withdrawn by subject | 2 |
| Adverse event, non-fatal | 1 |
| Lack of efficacy | 3 |
| Protocol deviation | 6 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | OMALIZUMAB |
|-----------------------|------------|

Reporting group description:

sub cutaneous injections of 300 mg every 4 weeks until Week 8

| Reporting group values | OMALIZUMAB | Total | |
|--|------------|-------|--|
| Number of subjects | 136 | 136 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 126 | 126 | |
| From 65-84 years | 10 | 10 | |
| 85 years and over | 0 | 0 | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 44.4 | | |
| standard deviation | ± 12.67 | - | |
| Gender, Male/Female | | | |
| Units: Subjects | | | |
| Female | 106 | 106 | |
| Male | 30 | 30 | |

End points

End points reporting groups

| | |
|--|-------------------------------|
| Reporting group title | OMALIZUMAB |
| Reporting group description: sub cutaneous injections of 300 mg every 4 weeks until Week 8 | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB without angioedema |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until Week 8 | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until Week 8 | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until End Of Study (EOS) | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |

| | |
|--|-------------------------------|
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until EOS | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until Week 8 | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB with ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB without ANGIOEDEMA |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until W8 | |
| Subject analysis set title | OMALIZUMAB Without angioedema |
| Subject analysis set type | Full analysis |
| Subject analysis set description: sub cutaneous injections of 300 mg every 4 weeks until Week 8 | |

Primary: Percent of participants with an urticaria control test [UCT] score of greater than or equal to 12

| | |
|--|--|
| End point title | Percent of participants with an urticaria control test [UCT] score of greater than or equal to 12 ^[1] |
| End point description: UCT number and percentage of patients with disease control, UCT score at least 12 at Week 12 | |
| No statistical analysis was planned for this primary outcome in this single-arm study | |
| End point type | Primary |
| End point timeframe: WEEK 12 | |

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: This is a single-arm study

| End point values | OMALIZUMAB | | | |
|----------------------------------|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 136 | | | |
| Units: percent of participants | | | | |
| number (confidence interval 95%) | 75 (66.9 to 82) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with UAS7≤6 (patients achieving disease control), in adult patients with CSU, with or without the presence of angioedema

| | |
|---------------------------------|---|
| End point title | Proportion of participants with UAS7≤6 (patients achieving disease control), in adult patients with CSU, with or without the presence of angioedema |
| End point description: | |
| End point type | Secondary |
| End point timeframe: WEEK 12 | |

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without angioedema | | |
|----------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 83 | 51 | | |
| Units: percent of participants | | | | |
| number (confidence interval 95%) | 69.6 (58.2 to 79.5) | 63.8 (48.5 to 77.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: CSU disease activity using the urticaria activity score (UAS7), with or without the presence of angioedema

| | |
|---------------------------------|--|
| End point title | CSU disease activity using the urticaria activity score (UAS7), with or without the presence of angioedema |
| End point description: | |
| End point type | Secondary |
| End point timeframe: WEEK 12 | |

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 79 | 47 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 29.7 (± 7.32) | 29.2 (± 6.72) | | |
| at week 12 | 6.6 (± 10.08) | 6.5 (± 9.11) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: control of the CSU using the UCT score, with or without the presence of angioedema

| | |
|-----------------|--|
| End point title | control of the CSU using the UCT score, with or without the presence of angioedema |
|-----------------|--|

End point description:

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

End point timeframe:
WEEK 12

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 82 | 50 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 3 (± 2.06) | 3.6 (± 2.55) | | |
| at week 12 | 13.1 (± 3.95) | 12.9 (± 3.97) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: control of the CSU using the UCT score for patients in extension treatment period phase at week 16, with or without the presence of angioedema

| | |
|-----------------|---|
| End point title | control of the CSU using the UCT score for patients in extension treatment period phase at week 16, with or without |
|-----------------|---|

the presence of angioedema

End point description:

End point type Secondary

End point timeframe:
week 16

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 70 | 42 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | 14.2 (\pm 2.96) | 13.4 (\pm 3.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: control of the CSU using the UCT score for patients in extension treatment period phase at week 20, with or without the presence of angioedema

| | |
|-----------------|--|
| End point title | control of the CSU using the UCT score for patients in extension treatment period phase at week 20, with or without the presence of angioedema |
|-----------------|--|

End point description:

End point type Secondary

End point timeframe:
week 20

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 48 | 34 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | 14.4 (\pm 2.4) | 13.3 (\pm 4.11) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: control of the CSU using the UCT score for patients in extension

treatment period phase at week 24, with or without the presence of angioedema

| | |
|-----------------|--|
| End point title | control of the CSU using the UCT score for patients in extension treatment period phase at week 24, with or without the presence of angioedema |
|-----------------|--|

End point description:

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

End point timeframe:

week 24

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 14 | 12 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | 14.5 (\pm 2.14) | 13.4 (\pm 3.75) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: control of the CSU using the UCT score for patients in extension treatment period phase at week 28, with or without the presence of angioedema

| | |
|-----------------|--|
| End point title | control of the CSU using the UCT score for patients in extension treatment period phase at week 28, with or without the presence of angioedema |
|-----------------|--|

End point description:

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

End point timeframe:

week 28

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2 | 2 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | 13.5 (\pm 3.54) | 12 (\pm 5.66) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The quality of life using the chronic urticaria quality of life (CU-QoL) questionnaire

| | |
|-----------------|--|
| End point title | The quality of life using the chronic urticaria quality of life (CU-QoL) questionnaire |
|-----------------|--|

End point description:

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

End point timeframe:

WEEK 12

| End point values | OMALIZUMAB with ANGIOEDEMA | OMALIZUMAB without ANGIOEDEMA | | |
|--------------------------------------|----------------------------|-------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 80 | 49 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 68.9 (± 15.64) | 62.4 (± 17.76) | | |
| at 12 weeks | 32.5 (± 13.33) | 33.3 (± 13.32) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The angioedema quality of life (AE-QoL)

| | |
|-----------------|---|
| End point title | The angioedema quality of life (AE-QoL) |
|-----------------|---|

End point description:

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

End point timeframe:

WEEK 12

| End point values | OMALIZUMAB with ANGIOEDEMA | | | |
|--------------------------------------|----------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 78 | | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 57.88 (± 22.474) | | | |
| at week 12 | 16.4 (± 20.074) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The dermatology life quality index (DLQI)

| | |
|-----------------|---|
| End point title | The dermatology life quality index (DLQI) |
|-----------------|---|

End point description:

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

End point timeframe:

WEEK 12

| End point values | OMALIZUMAB without ANGIOEDEMA | OMALIZUMAB Without angioedema | | |
|--------------------------------------|-------------------------------------|-------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 79 | 49 | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 14.2 (± 5.39) | 13.2 (± 6.67) | | |
| at week 12 | 2.4 (± 3.95) | 2.7 (± 5.12) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: angioedema activity using the angioedema activity score (AAS)

| | |
|-----------------|---|
| End point title | angioedema activity using the angioedema activity score (AAS) |
|-----------------|---|

End point description:

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

End point timeframe:

WEEK 12

| | | | | |
|--------------------------------------|----------------------------------|--|--|--|
| End point values | OMALIZUMAB with ANGIOEDEMA | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 78 | | | |
| Units: absolute value | | | | |
| arithmetic mean (standard deviation) | | | | |
| baseline | 32.7 (\pm 27.21) | | | |
| at week 12 | 3.7 (\pm 10.4) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 18.1 |

Reporting groups

| | |
|-----------------------|-------------------|
| Reporting group title | Omalizumab 300 mg |
|-----------------------|-------------------|

Reporting group description:

Omalizumab 300 mg

| Serious adverse events | Omalizumab 300 mg | | |
|---|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 136 (6.62%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| CERVICAL VERTEBRAL FRACTURE | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| FRACTURED SACRUM | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| LIGAMENT SPRAIN | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| PHARYNGEAL OEDEMA | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| BLADDER DILATATION | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| URINARY INCONTINENCE | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| FOOT DEFORMITY | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| INTERVERTEBRAL DISC PROTRUSION | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| SACROILIITIS | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| PNEUMONIA | | | |
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| OBESITY | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 136 (0.74%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|---|-------------------|--|--|
| Non-serious adverse events | Omalizumab 300 mg | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 44 / 136 (32.35%) | | |
| Investigations | | | |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 7 / 136 (5.15%) | | |
| occurrences (all) | 7 | | |
| Nervous system disorders | | | |
| HEADACHE | | | |
| subjects affected / exposed | 22 / 136 (16.18%) | | |
| occurrences (all) | 33 | | |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 23 / 136 (16.91%) | | |
| occurrences (all) | 33 | | |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 12 / 136 (8.82%) | | |
| occurrences (all) | 14 | | |

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