



## Clinical trial results:

### A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab in Subjects with Moderate-to-Severe Atopic Dermatitis with Inadequate Response to or for Whom Cyclosporine A is not Medically Advisable

#### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2021-002166-40    |
| Trial protocol           | CZ PL LV ES IT DE |
| Global end of trial date | 14 April 2023     |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 04 May 2024  |
| First version publication date | 04 May 2024  |

#### Trial information

##### Trial identification

|                       |                  |
|-----------------------|------------------|
| Sponsor protocol code | RD.06.SPR.201591 |
|-----------------------|------------------|

##### Additional study identifiers

|                                    |                    |
|------------------------------------|--------------------|
| ISRCTN number                      | -                  |
| ClinicalTrials.gov id (NCT number) | -                  |
| WHO universal trial number (UTN)   | -                  |
| Other trial identifiers            | IND number: 117122 |

Notes:

##### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Galderma S.A.   |
| Sponsor organisation address | Zählerweg 10, Zug, Switzerland, 6300  |
| Public contact               | Clinical Trial Information Desk, Galderma S.A.,<br>CTA.Coordinator@galderma.com |
| Scientific contact           | Clinical Trial Information Desk, Galderma S.A.,<br>CTA.Coordinator@galderma.com |

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                       | 08 January 2024 |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 14 April 2023   |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 14 April 2023   |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to investigate the efficacy of nemolizumab administered in combination with topical background therapy (topical corticosteroids [TCS] with or without topical calcineurin inhibitors [TCI]) in adult subjects with moderate-to-severe atopic dermatitis (AD) who are not adequately controlled with or are not advised to use oral cyclosporine A (CsA) for medical reasons.

Protection of trial subjects:

The study was conducted in accordance with the accepted version of the Declaration of Helsinki and/or all relevant regulations, in compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Good Clinical Practice (GCP) guidelines and according to the appropriate regulatory requirements in the countries where the study was conducted. Before initiation of the study at each study site, the protocol, the informed consent form (ICF), other written material given to the subjects, and any other relevant study documentation were to be reviewed and approved by a duly constituted Independent Ethics Committee (IEC).

All subjects were to be informed about the clinical study according to GCP guidelines, and in accordance with the EU legislation and the applicable local requirements. Informed consent was to be obtained from each subject before the subject was admitted to the study. The Investigator did not undertake any study-related examination or activity before the subject had given written informed consent to participate.

Background therapy:

Subjects applied a moisturizer at least once daily and a prescribed authorized background topical therapy for atopic dermatitis (AD), including a medium-potency topical corticosteroids (TCS) for the body and a low-potency TCS or topical calcineurin inhibitors (TCI) for sensitive areas such as the face, neck, and intertriginous areas.

Evidence for comparator:

Placebo

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 18 February 2022 |
| 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 | Poland: 132 |
| Country: Number of subjects enrolled | Spain: 13   |
| Country: Number of subjects enrolled | Czechia: 55 |
| Country: Number of subjects enrolled | Germany: 47 |
| Country: Number of subjects enrolled | Italy: 7    |
| Country: Number of subjects enrolled | Latvia: 22  |
| Worldwide total number of subjects   | 276         |
| EEA total number of subjects         | 276         |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|---|-----|
| 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)                      | 267 |
| From 65 to 84 years                       | 9   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were screened at 50 study sites in 6 European countries: Italy (5 sites), Spain (7 sites), Czech Republic (4 sites), Poland (17 sites), Latvia (4 sites), and Germany (13 sites). Overall 46 sites randomized the subjects from 18 February 2022 to 16 November 2022.

### Pre-assignment

Screening details:

A total of 326 subjects were screened at 50 study sites and 276 subjects were randomized 1:1 to receive either Nemolizumab or placebo.

### Period 1

|                              |   |
|------------------------------|---|
| Period 1 title               | Treatment period up to week 16 (overall period) |
| Is this the baseline period? | Yes   |
| Allocation method            | Randomised - controlled                         |
| Blinding used                | Double blind                                    |
| Roles blinded                | Subject, Investigator, Monitor, Data analyst    |

Blinding implementation details:

To avoid bias and to ensure the integrity of the blind, personnel directly involved with the conduct of the study from the Sponsor, contract research organization (CRO), or study sites did not have access to any information that may have led to unblinding. Randomization through the interactive response technology (IRT) guarded against selection bias.

### Arms

|                              |                 |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes             |
| <b>Arm title</b>             | Nemolizumab arm |

Arm description:

Subjects randomized to receive Nemolizumab. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement.

|  |  |
|--|--|
| Arm type                               | Experimental                                   |
| Investigational medicinal product name | Nemolizumab 30 mg                              |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Powder and solution for solution for injection |
| Routes of administration               | Subcutaneous use                               |

Dosage and administration details:

At the baseline visit, subjects received a loading dose of nemolizumab by 2 SC injections. During the Treatment Period, nemolizumab was administered via a single SC injection every 4 weeks (Q4W) at Weeks 4, 8, and 12.

|                  |             |
|------------------|-------------|
| <b>Arm title</b> | Placebo arm |
|------------------|-------------|

Arm description:

Subjects randomized to receive Placebo. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement.

|  |  |
|--|--|
| Arm type                               | Placebo  |
| Investigational medicinal product name | Placebo  |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Powder and solution for solution for injection |
| Routes of administration               | Subcutaneous use                               |

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**Dosage and administration details:**

At the baseline visit, subjects received 2 SC injections with placebo. During the Treatment Period, placebo was administered via a single SC injection every 4 weeks (Q4W) at Weeks 4, 8, and 12.

| <b>Number of subjects in period 1</b> | Nemolizumab arm | Placebo arm |
|---------------------------------------|-----------------|-------------|
| Started                               | 138             | 138         |
| Completed                             | 132             | 131         |
| Not completed                         | 6               | 7           |
| Consent withdrawn by subject          | 2               | 5           |
| Adverse event, non-fatal              | 1               | 2           |
| Lost to follow-up                     | 2               | -           |
| Protocol deviation                    | 1               | -           |

## Baseline characteristics

### Reporting groups

|   |                 |
|---|-----------------|
| Reporting group title   | Nemolizumab arm |
| Reporting group description:  |                 |
| Subjects randomized to receive Nemolizumab. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement. |                 |
| Reporting group title   | Placebo arm     |
| Reporting group description:  |                 |
| Subjects randomized to receive Placebo. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement.     |                 |

| Reporting group values                | Nemolizumab arm | Placebo arm | Total |
|---------------------------------------|-----------------|-------------|-------|
| Number of subjects                    | 138             | 138         | 276   |
| Age categorical<br>Units: Subjects    |                 |             |       |
| Adults (18-64 years)                  | 132             | 135         | 267   |
| From 65 to 84 years                   | 6               | 3           | 9     |
| Age continuous<br>Units: years        |                 |             |       |
| arithmetic mean                       | 38.3            | 36.1        | -     |
| standard deviation                    | ± 13.15         | ± 12.21     | -     |
| Gender categorical<br>Units: Subjects |                 |             |       |
| Female                                | 66              | 66          | 132   |
| Male                                  | 72              | 72          | 144   |
| Ethnicity<br>Units: Subjects          |                 |             |       |
| Hispanic or Latino                    | 5               | 6           | 11    |
| Not Hispanic or Latino                | 132             | 132         | 264   |
| Unknown                               | 1               | 0           | 1     |
| EASI score<br>Units: units on a scale |                 |             |       |
| arithmetic mean                       | 29.535          | 31.328      | -     |
| standard deviation                    | ± 8.5041        | ± 9.6653    | -     |
| Body surface area<br>Units: percent   |                 |             |       |
| arithmetic mean                       | 44.61           | 46.09       | -     |
| standard deviation                    | ± 17.532        | ± 17.966    | -     |
| PP NRS<br>Units: units on a scale     |                 |             |       |
| arithmetic mean                       | 7.405           | 7.475       | -     |
| standard deviation                    | ± 1.3811        | ± 1.4634    | -     |

## End points

### End points reporting groups

|   |                 |
|---|-----------------|
| Reporting group title   | Nemolizumab arm |
| Reporting group description:<br>Subjects randomized to receive Nemolizumab. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement. |                 |
| Reporting group title   | Placebo arm     |
| Reporting group description:<br>Subjects randomized to receive Placebo. Subjects continued using background topical therapy, which was to be adjusted according to disease activity and tolerability, including tapering when signs and symptoms improved, discontinuing when lesions cleared, and restarting if signs and symptoms recurred, based on Investigator's clinical judgement.     |                 |

### Primary: Percentage of Subjects with $\geq 75\%$ Improvement in Eczema Area and Severity Index (EASI-75) at Week 16

|   |  |
|---|--|
| End point title   | Percentage of Subjects with $\geq 75\%$ Improvement in Eczema Area and Severity Index (EASI-75) at Week 16 |
| End point description:<br>The EASI score is used to measure the severity and extent of atopic dermatitis (AD) and measured erythema, infiltration, excoriation and lichenification on 4 anatomic regions of the body: head, trunk, upper and lower extremities. The EASI score is a composite score ranging from 0 to 72. EASI-75 responders were the subjects who achieved $\geq 75\%$ overall improvement in EASI score from baseline to Week 16. |  |
| End point type  | Primary  |
| End point timeframe:<br>At Week 16 compared with the baseline   |  |

| End point values            | Nemolizumab arm | Placebo arm     |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 138             | 138             |  |  |
| Units: percent              |                 |                 |  |  |
| number (not applicable)     |                 |                 |  |  |
| EASI-75 improvement         | 47.1            | 34.8            |  |  |

### Statistical analyses

|   |                               |
|---|-------------------------------|
| Statistical analysis title  | Statistical analysis          |
| Statistical analysis description:<br>Treatment difference of nemolizumab and placebo (in combination with TCS with or without TCI) in response rate.<br>The Intent-to Treat (ITT) population consisted of all randomized subjects |                               |
| Comparison groups   | Nemolizumab arm v Placebo arm |

|   |  |
|---|--|
| Number of subjects included in analysis | 276                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.04                                   |
| Method                                  | Cochran-Mantel-Haenszel                  |
| Parameter estimate                      | Strata-adjusted difference in proportion |
| Point estimate                          | 12.2                                     |
| Confidence interval                     |  |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.7                                      |
| upper limit                             | 23.6                                     |

### Primary: Percentage of subjects with Peak Pruritus Numerical Rating Scale (PP NRS) Improvement of $\geq 4$ from baseline at week 16

|                 |  |
|-----------------|--|
| End point title | Percentage of subjects with Peak Pruritus Numerical Rating Scale (PP NRS) Improvement of $\geq 4$ from baseline at week 16 |
|-----------------|--|

End point description:

The PP-NRS is an assessment tool used by the subjects to report the intensity of their pruritus (itch) during the last 24 hours on a scale of 0 to 10, with 0 being "no itch" and 10 being "worst itch imaginable". We report here the percentage of subjects with a weekly average improvement of Peak Pruritus Numerical Rating Scale (PP NRS)  $\geq 4$  from baseline at Week 16. Subjects who completed the Treatment Period up to Week 16 with an improvement of PP NRS  $\geq 4$  from baseline at Week 16 were classified as a success. Subjects who did not satisfy this criterion, who discontinued from the study prior to Week 16, or who required rescue therapy were classified as failures.

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

End point timeframe:

At Week 16 compared with the baseline

| End point values                          | Nemolizumab arm | Placebo arm     |  |  |
|---|-----------------|-----------------|--|--|
| Subject group type                        | Reporting group | Reporting group |  |  |
| Number of subjects analysed               | 138             | 138             |  |  |
| Units: percent                            |                 |                 |  |  |
| number (not applicable)                   |                 |                 |  |  |
| PP NRS improvement $\geq 4$ from baseline | 39.1            | 17.4            |  |  |

### Statistical analyses

|   |                               |
|---|-------------------------------|
| Statistical analysis title  | Statistical analysis          |
| Statistical analysis description:   |                               |
| Treatment difference of nemolizumab and placebo (in combination with TCS with or without TCI) in response rate. The Intent-to Treat (ITT) population consisted of all randomized subjects |                               |
| Comparison groups   | Nemolizumab arm v Placebo arm |



|   |  |
|---|--|
| Number of subjects included in analysis | 276                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | < 0.001                                  |
| Method                                  | Cochran-Mantel-Haenszel                  |
| Parameter estimate                      | Strata-adjusted difference in proportion |
| Point estimate                          | 21.7                                     |
| Confidence interval                     |  |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 11.4                                     |
| upper limit                             | 32                                       |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the baseline through week 16.

Adverse event reporting additional description:

For non-serious adverse events (NSAE): only subjects and events from selected preferred terms are included in the counts. Selected preferred terms are preferred terms from which at least 2% of the subjects experienced a NSAE in either group. Subjects who experienced NSAE only in non-selected preferred terms are excluded from the counts.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 25.0 |
|--------------------|------|

### Reporting groups

|                       |                                       |
|-----------------------|---------------------------------------|
| Reporting group title | Safety Analysis Set - Nemolizumab arm |
|-----------------------|---------------------------------------|

Reporting group description:

All subjects randomized to Nemolizumab and received at least 1 dose of study drug.

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | Safety Analysis Set - Placebo arm |
|-----------------------|-----------------------------------|

Reporting group description:

All subjects randomized to placebo and received at least 1 dose of placebo.

| Serious adverse events                            | Safety Analysis Set - Nemolizumab arm | Safety Analysis Set - Placebo arm |  |
|---|---------------------------------------|-----------------------------------|--|
| Total subjects affected by serious adverse events |                                       |                                   |  |
| subjects affected / exposed                       | 3 / 137 (2.19%)                       | 2 / 137 (1.46%)                   |  |
| number of deaths (all causes)                     | 0                                     | 0                                 |  |
| number of deaths resulting from adverse events    | 0                                     | 0                                 |  |
| Injury, poisoning and procedural complications    |                                       |                                   |  |
| Jaw fracture                                      |                                       |                                   |  |
| subjects affected / exposed                       | 0 / 137 (0.00%)                       | 1 / 137 (0.73%)                   |  |
| occurrences causally related to treatment / all   | 0 / 0                                 | 0 / 1                             |  |
| deaths causally related to treatment / all        | 0 / 0                                 | 0 / 0                             |  |
| Skin wound  |                                       |                                   |  |
| subjects affected / exposed                       | 0 / 137 (0.00%)                       | 1 / 137 (0.73%)                   |  |
| occurrences causally related to treatment / all   | 0 / 0                                 | 0 / 1                             |  |
| deaths causally related to treatment / all        | 0 / 0                                 | 0 / 0                             |  |
| Skin and subcutaneous tissue disorders            |                                       |                                   |  |
| Dermatitis atopic                                 |                                       |                                   |  |

|   |                 |                 |  |
|---|-----------------|-----------------|--|
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Urticaria                                       |                 |                 |  |
| subjects affected / exposed                     | 0 / 137 (0.00%) | 1 / 137 (0.73%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Psychiatric disorders                           |                 |                 |  |
| Aggression                                      |                 |                 |  |
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Dependence                                      |                 |                 |  |
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Personality disorder                            |                 |                 |  |
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Suicide threat                                  |                 |                 |  |
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           |  |
| Infections and infestations                     |                 |                 |  |
| Localised infection                             |                 |                 |  |
| subjects affected / exposed                     | 1 / 137 (0.73%) | 0 / 137 (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 / 137 (0.73%) | 0 / 137 (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: 2 %

| <b>Non-serious adverse events</b>                     | Safety Analysis Set -<br>Nemolizumab arm | Safety Analysis Set -<br>Placebo arm |  |
|---|--|--------------------------------------|--|
| Total subjects affected by non-serious adverse events |  |                                      |  |
| subjects affected / exposed                           | 43 / 137 (31.39%)                        | 37 / 137 (27.01%)                    |  |
| Investigations  |  |                                      |  |
| Blood creatine phosphokinase increased                |  |                                      |  |
| subjects affected / exposed                           | 5 / 137 (3.65%)                          | 1 / 137 (0.73%)                      |  |
| occurrences (all)                                     | 5  | 1                                    |  |
| Peak expiratory flow rate decreased                   |  |                                      |  |
| subjects affected / exposed                           | 3 / 137 (2.19%)                          | 1 / 137 (0.73%)                      |  |
| occurrences (all)                                     | 3  | 2                                    |  |
| Respiratory, thoracic and mediastinal disorders       |  |                                      |  |
| Asthma  |  |                                      |  |
| subjects affected / exposed                           | 5 / 137 (3.65%)                          | 2 / 137 (1.46%)                      |  |
| occurrences (all)                                     | 6  | 2                                    |  |
| Skin and subcutaneous tissue disorders                |  |                                      |  |
| Dermatitis atopic                                     |  |                                      |  |
| subjects affected / exposed                           | 10 / 137 (7.30%)                         | 6 / 137 (4.38%)                      |  |
| occurrences (all)                                     | 10                                       | 7                                    |  |
| Musculoskeletal and connective tissue disorders       |  |                                      |  |
| Back pain   |  |                                      |  |
| subjects affected / exposed                           | 4 / 137 (2.92%)                          | 1 / 137 (0.73%)                      |  |
| occurrences (all)                                     | 4  | 1                                    |  |
| Infections and infestations                           |  |                                      |  |
| Bronchitis  |  |                                      |  |
| subjects affected / exposed                           | 0 / 137 (0.00%)                          | 3 / 137 (2.19%)                      |  |
| occurrences (all)                                     | 0  | 3                                    |  |
| COVID-19  |  |                                      |  |
| subjects affected / exposed                           | 7 / 137 (5.11%)                          | 4 / 137 (2.92%)                      |  |
| occurrences (all)                                     | 7  | 4                                    |  |
| Nasopharyngitis                                       |  |                                      |  |
| subjects affected / exposed                           | 13 / 137 (9.49%)                         | 14 / 137 (10.22%)                    |  |
| occurrences (all)                                     | 14                                       | 17                                   |  |
| Rhinitis  |  |                                      |  |

|                                   |                 |                 |  |
|-----------------------------------|-----------------|-----------------|--|
| subjects affected / exposed       | 4 / 137 (2.92%) | 1 / 137 (0.73%) |  |
| occurrences (all)                 | 4               | 1               |  |
| Tonsillitis                       |                 |                 |  |
| subjects affected / exposed       | 0 / 137 (0.00%) | 3 / 137 (2.19%) |  |
| occurrences (all)                 | 0               | 3               |  |
| Upper respiratory tract infection |                 |                 |  |
| subjects affected / exposed       | 5 / 137 (3.65%) | 1 / 137 (0.73%) |  |
| occurrences (all)                 | 6               | 1               |  |
| Urinary tract infection           |                 |                 |  |
| subjects affected / exposed       | 3 / 137 (2.19%) | 3 / 137 (2.19%) |  |
| occurrences (all)                 | 3               | 3               |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported