



## Clinical trial results:

### A PHASE 2 MULTICENTER, OPEN-LABEL, UNCONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, EFFICACY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF RA101495 IN SUBJECTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2016-003522-16 |
| Trial protocol           | FI GB HU DK    |
| Global end of trial date | 28 March 2018  |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 05 July 2019 |
| First version publication date | 05 July 2019 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | RA101495-01.201 |
|-----------------------|-----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03078582 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Ra Pharmaceuticals, Inc.   |
| Sponsor organisation address | 87 Cambridge Park Drive, Cambridge, United States, MA 02140                            |
| Public contact               | Ra Pharmaceuticals, Inc., Ra Pharmaceuticals, Inc., +1 6174014060, trials@rapharma.com |
| Scientific contact           | Ra Pharmaceuticals, Inc., Ra Pharmaceuticals, Inc., +1 6174014060, trials@rapharma.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                       | 14 February 2019 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 28 March 2018    |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 28 March 2018    |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

- To assess the safety and tolerability of RA101495 in subjects with PNH
- To assess preliminary efficacy of RA101495 in subjects with PNH
- To assess PK and PD of RA101495 in subjects with PNH

Protection of trial subjects:

Patients were to give freely their written informed consent before entering the study.

Patients were provided with updated information and re-consented if substantial changes in the study occurred.

This study was performed in accordance with Good Clinical Practice standards.

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 24 April 2017 |
| 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 | United Kingdom: 5 |
| Country: Number of subjects enrolled | Denmark: 1        |
| Country: Number of subjects enrolled | Finland: 3        |
| Country: Number of subjects enrolled | Germany: 5        |
| Country: Number of subjects enrolled | Hungary: 2        |
| Country: Number of subjects enrolled | Australia: 5      |
| Country: Number of subjects enrolled | Canada: 1         |
| Country: Number of subjects enrolled | New Zealand: 4    |
| Worldwide total number of subjects   | 26                |
| EEA total number of subjects         | 16                |

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)                     | 18 |
| From 65 to 84 years                      | 8  |
| 85 years and over                        | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 29 subjects were screened for enrollment into the study. A total of 26 subjects were enrolled into the study.

### Period 1

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

### Arms

|                              |          |
|------------------------------|----------|
| Are arms mutually exclusive? | Yes      |
| <b>Arm title</b>             | Cohort A |

Arm description:

Eculizumab Naïve - included subjects who have not received eculizumab for treatment of PNH

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | RA101495               |
| Investigational medicinal product code | RA101495               |
| Other name                             |                        |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

RA101495 was provided as a solution for injection containing 40mg/mL of active ingredient in a daily prefilled syringe. Doses provided for the study included 0.1mg/kg and 0.3mg/kg.

|                  |          |
|------------------|----------|
| <b>Arm title</b> | Cohort B |
|------------------|----------|

Arm description:

Eculizumab Switch - included subjects who have received treatment with eculizumab for at least 6 months prior to Screening

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | RA101495               |
| Investigational medicinal product code | RA101495               |
| Other name                             |                        |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

RA101495 was provided as a solution for injection containing 40mg/mL of active ingredient in a daily prefilled syringe. Doses provided for the study included 0.1mg/kg and 0.3mg/kg.

| <b>Number of subjects in period 1</b> | Cohort A | Cohort B |
|---------------------------------------|----------|----------|
| Started                               | 10       | 16       |
| Completed                             | 10       | 8        |
| Not completed                         | 0        | 8        |
| Adverse event, non-fatal              | -        | 8        |

## Baseline characteristics

### Reporting groups

|  |          |
|--|----------|
| Reporting group title  | Cohort A |
| Reporting group description:   |          |
| Eculizumab Naïve - included subjects who have not received eculizumab for treatment of PNH                                 |          |
| Reporting group title  | Cohort B |
| Reporting group description:   |          |
| Eculizumab Switch - included subjects who have received treatment with eculizumab for at least 6 months prior to Screening |          |

| Reporting group values    | Cohort A       | Cohort B       | Total |
|---------------------------|----------------|----------------|-------|
| Number of subjects        | 10             | 16             | 26    |
| Age categorical           |                |                |       |
| Units: Subjects           |                |                |       |
| Adults (18-64 years)      | 7              | 11             | 18    |
| From 65-84 years          | 3              | 5              | 8     |
| Age continuous            |                |                |       |
| Units: years              |                |                |       |
| median                    | 56.0           | 53.0           |       |
| full range (min-max)      | 32 to 81       | 22 to 72       | -     |
| Gender categorical        |                |                |       |
| Units: Subjects           |                |                |       |
| Female                    | 6              | 7              | 13    |
| Male                      | 4              | 9              | 13    |
| Race                      |                |                |       |
| Units: Subjects           |                |                |       |
| White                     | 10             | 14             | 24    |
| Black or African American | 0              | 2              | 2     |
| Weight                    |                |                |       |
| Units: kg                 |                |                |       |
| median                    | 78.10          | 80.15          |       |
| full range (min-max)      | 46.0 to 100.8  | 54.9 to 109.7  | -     |
| Height                    |                |                |       |
| Units: cm                 |                |                |       |
| median                    | 165.00         | 169.00         |       |
| full range (min-max)      | 157.5 to 188.0 | 154.2 to 182.0 | -     |

## End points

### End points reporting groups

|  |          |
|--|----------|
| Reporting group title  | Cohort A |
| Reporting group description:<br>Eculizumab Naïve - included subjects who have not received eculizumab for treatment of PNH                                 |          |
| Reporting group title  | Cohort B |
| Reporting group description:<br>Eculizumab Switch - included subjects who have received treatment with eculizumab for at least 6 months prior to Screening |          |

### Primary: Primary Efficacy Endpoint: Change in serum LDH levels

|  |  |
|--|--|
| End point title  | Primary Efficacy Endpoint: Change in serum LDH levels <sup>[1]</sup> |
| End point description:<br>Primary Efficacy Endpoint: Change from baseline in serum LDH levels during the primary evaluation period, defined as the mean LDH values of Weeks 6, 8, 10, and 12 minus the baseline LDH value. Efficacy Evaluable Population analysis is presented. For Cohort A subjects' baseline LDH is the average of the study Day 1 and Screening Period values. In Cohort A a Wilcoxon signed rank test is applied to assess the change from Baseline in the Primary Evaluation Period (p=0.0020 in the Efficacy Evaluable Population). |  |
| End point type   | Primary  |
| End point timeframe:<br>Primary Evaluation Period value is the patient's mean value across the Week 6, 8, 10, and 12 visits.   |  |

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: The planned statistical test on the Primary Efficacy Endpoint is a comparison between the Baseline value and the Primary Evaluation Period within Cohort A only. Since statistical tests are expected to compare different groups, this statistical test cannot be entered without evoking validation error message.

| End point values                     | Cohort A          | Cohort B         |  |  |
|--------------------------------------|-------------------|------------------|--|--|
| Subject group type                   | Reporting group   | Reporting group  |  |  |
| Number of subjects analysed          | 10 <sup>[2]</sup> | 8 <sup>[3]</sup> |  |  |
| Units: U/L                           |                   |                  |  |  |
| arithmetic mean (standard deviation) | -695.2 (± 589.2)  | 216.7 (± 209.2)  |  |  |

Notes:

[2] - Efficacy Evaluable Population analysis is presented here.

[3] - Efficacy Evaluable Population analysis is presented here.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

For all subjects, the AE reporting period started with the first administration of study drug on Day 1 and ended with the final study visit, after which no new AEs were to be reported.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 19.1 |
|--------------------|------|

### Reporting groups

|                       |          |
|-----------------------|----------|
| Reporting group title | Cohort A |
|-----------------------|----------|

Reporting group description:

Eculizumab Naïve - included subjects who have not received eculizumab for treatment of PNH

|                       |          |
|-----------------------|----------|
| Reporting group title | Cohort B |
|-----------------------|----------|

Reporting group description:

Eculizumab Switch - included subjects who have received treatment with eculizumab for at least 6 months prior to Screening

| Serious adverse events                               | Cohort A        | Cohort B       |  |
|--|-----------------|----------------|--|
| Total subjects affected by serious adverse events    |                 |                |  |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 1 / 16 (6.25%) |  |
| number of deaths (all causes)                        | 0               | 0              |  |
| number of deaths resulting from adverse events       | 0               | 0              |  |
| Injury, poisoning and procedural complications       |                 |                |  |
| Febrile nonhaemolytic transfusion reaction           |                 |                |  |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 16 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1           | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0          |  |
| General disorders and administration site conditions |                 |                |  |
| Pyrexia  |                 |                |  |
| subjects affected / exposed                          | 1 / 10 (10.00%) | 0 / 16 (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                          |                 |                |  |
| Urinary tract infection                              |                 |                |  |



|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 10 (0.00%) | 1 / 16 (6.25%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                     | Cohort A          | Cohort B         |  |
|---|-------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                   |                  |  |
| subjects affected / exposed                           | 10 / 10 (100.00%) | 15 / 16 (93.75%) |  |
| Vascular disorders                                    |                   |                  |  |
| Lymphoedema   |                   |                  |  |
| subjects affected / exposed                           | 1 / 10 (10.00%)   | 0 / 16 (0.00%)   |  |
| occurrences (all)                                     | 1                 | 0                |  |
| General disorders and administration site conditions  |                   |                  |  |
| Fatigue   |                   |                  |  |
| subjects affected / exposed                           | 1 / 10 (10.00%)   | 3 / 16 (18.75%)  |  |
| occurrences (all)                                     | 1                 | 3                |  |
| Injection site bruising                               |                   |                  |  |
| subjects affected / exposed                           | 3 / 10 (30.00%)   | 1 / 16 (6.25%)   |  |
| occurrences (all)                                     | 3                 | 1                |  |
| Asthenia  |                   |                  |  |
| subjects affected / exposed                           | 1 / 10 (10.00%)   | 0 / 16 (0.00%)   |  |
| occurrences (all)                                     | 1                 | 0                |  |
| Chest pain  |                   |                  |  |
| subjects affected / exposed                           | 0 / 10 (0.00%)    | 1 / 16 (6.25%)   |  |
| occurrences (all)                                     | 0                 | 1                |  |
| Crepitations  |                   |                  |  |
| subjects affected / exposed                           | 1 / 10 (10.00%)   | 0 / 16 (0.00%)   |  |
| occurrences (all)                                     | 1                 | 0                |  |
| Feeling cold  |                   |                  |  |
| subjects affected / exposed                           | 1 / 10 (10.00%)   | 0 / 16 (0.00%)   |  |
| occurrences (all)                                     | 1                 | 0                |  |
| Influenza like illness                                |                   |                  |  |
| subjects affected / exposed                           | 0 / 10 (0.00%)    | 1 / 16 (6.25%)   |  |
| occurrences (all)                                     | 0                 | 1                |  |
| Vaccination site pain                                 |                   |                  |  |

|   |   |  |  |
|---|---|--|--|
| subjects affected / exposed<br>occurrences (all)  | 1 / 10 (10.00%)<br>1  | 0 / 16 (0.00%)<br>0  |  |
| Reproductive system and breast disorders<br>Vaginal discharge<br>subjects affected / exposed<br>occurrences (all)   | 0 / 10 (0.00%)<br>0   | 1 / 16 (6.25%)<br>1  |  |
| Respiratory, thoracic and mediastinal disorders<br>Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Dyspnoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Epistaxis<br>subjects affected / exposed<br>occurrences (all) | 2 / 10 (20.00%)<br>2<br><br>1 / 10 (10.00%)<br>1<br><br>1 / 10 (10.00%)<br>1<br><br>0 / 10 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0<br><br>0 / 16 (0.00%)<br>0<br><br>0 / 16 (0.00%)<br>0<br><br>1 / 16 (6.25%)<br>1 |  |
| Psychiatric disorders<br>Agitation<br>subjects affected / exposed<br>occurrences (all)<br><br>Anxiety<br>subjects affected / exposed<br>occurrences (all)<br><br>Insomnia<br>subjects affected / exposed<br>occurrences (all)<br><br>Sleep disorder<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 10 (0.00%)<br>0<br><br>1 / 10 (10.00%)<br>1<br><br>0 / 10 (0.00%)<br>0<br><br>1 / 10 (10.00%)<br>1  | 1 / 16 (6.25%)<br>1<br><br>0 / 16 (0.00%)<br>0<br><br>1 / 16 (6.25%)<br>1<br><br>0 / 16 (0.00%)<br>0 |  |
| Product issues<br>Device failure<br>subjects affected / exposed<br>occurrences (all)  | 0 / 10 (0.00%)<br>0   | 1 / 16 (6.25%)<br>1  |  |

|  |                 |                 |  |
|--|-----------------|-----------------|--|
| Investigations                                 |                 |                 |  |
| Blood glucose fluctuation                      |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                              | 1               | 0               |  |
| Blood lactate dehydrogenase increased          |                 |                 |  |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                              | 0               | 1               |  |
| Haemoglobin decreased                          |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                              | 1               | 0               |  |
| Liver function test increased                  |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                              | 1               | 0               |  |
| Injury, poisoning and procedural complications |                 |                 |  |
| Contusion                                      |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                              | 1               | 0               |  |
| Febrile nonhaemolytic transfusion reaction     |                 |                 |  |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                              | 0               | 1               |  |
| Tooth fracture                                 |                 |                 |  |
| subjects affected / exposed                    | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                              | 0               | 1               |  |
| Nervous system disorders                       |                 |                 |  |
| Headache                                       |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 7 / 16 (43.75%) |  |
| occurrences (all)                              | 1               | 7               |  |
| Dizziness                                      |                 |                 |  |
| subjects affected / exposed                    | 2 / 10 (20.00%) | 3 / 16 (18.75%) |  |
| occurrences (all)                              | 2               | 3               |  |
| Dysgeusia                                      |                 |                 |  |
| subjects affected / exposed                    | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                              | 1               | 0               |  |
| Presyncope                                     |                 |                 |  |

|                                      |                 |                 |  |
|--------------------------------------|-----------------|-----------------|--|
| subjects affected / exposed          | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Syncope                              |                 |                 |  |
| subjects affected / exposed          | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                    | 1               | 0               |  |
| Blood and lymphatic system disorders |                 |                 |  |
| Anaemia                              |                 |                 |  |
| subjects affected / exposed          | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Haemolysis                           |                 |                 |  |
| subjects affected / exposed          | 0 / 10 (0.00%)  | 7 / 16 (43.75%) |  |
| occurrences (all)                    | 0               | 7               |  |
| Gastrointestinal disorders           |                 |                 |  |
| Abdominal pain                       |                 |                 |  |
| subjects affected / exposed          | 2 / 10 (20.00%) | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 2               | 1               |  |
| Abdominal pain upper                 |                 |                 |  |
| subjects affected / exposed          | 0 / 10 (0.00%)  | 3 / 16 (18.75%) |  |
| occurrences (all)                    | 0               | 3               |  |
| Diarrhoea                            |                 |                 |  |
| subjects affected / exposed          | 1 / 10 (10.00%) | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 1               | 1               |  |
| Constipation                         |                 |                 |  |
| subjects affected / exposed          | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Enteritis                            |                 |                 |  |
| subjects affected / exposed          | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                    | 1               | 0               |  |
| Nausea                               |                 |                 |  |
| subjects affected / exposed          | 0 / 10 (0.00%)  | 1 / 16 (6.25%)  |  |
| occurrences (all)                    | 0               | 1               |  |
| Proctalgia                           |                 |                 |  |
| subjects affected / exposed          | 1 / 10 (10.00%) | 0 / 16 (0.00%)  |  |
| occurrences (all)                    | 1               | 0               |  |
| Vomiting                             |                 |                 |  |

|  |  |  |  |
|--|--|--|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 10 (0.00%)<br>0  | 1 / 16 (6.25%)<br>1  |  |
| Skin and subcutaneous tissue disorders<br>Actinic keratosis<br>subjects affected / exposed<br>occurrences (all)  | 1 / 10 (10.00%)<br>1   | 0 / 16 (0.00%)<br>0  |  |
| Renal and urinary disorders<br>Paroxysmal nocturnal<br>haemoglobinuria<br>subjects affected / exposed<br>occurrences (all)   | 1 / 10 (10.00%)<br>1   | 2 / 16 (12.50%)<br>2   |  |
| Musculoskeletal and connective tissue disorders<br>Back pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Arthralgia<br>subjects affected / exposed<br>occurrences (all)<br><br>Pain in extremity<br>subjects affected / exposed<br>occurrences (all)<br><br>Flank pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Musculoskeletal chest pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Myalgia<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1<br><br>0 / 10 (0.00%)<br>0<br><br>0 / 10 (0.00%)<br>0<br><br>1 / 10 (10.00%)<br>1<br><br>0 / 10 (0.00%)<br>0<br><br>1 / 10 (10.00%)<br>1<br><br>0 / 10 (0.00%)<br>0 | 3 / 16 (18.75%)<br>3<br><br>2 / 16 (12.50%)<br>2<br><br>2 / 16 (12.50%)<br>2<br><br>0 / 16 (0.00%)<br>0<br><br>1 / 16 (6.25%)<br>1<br><br>0 / 16 (0.00%)<br>0<br><br>1 / 16 (6.25%)<br>1 |  |
| Infections and infestations<br>Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)   | 3 / 10 (30.00%)<br>3   | 1 / 16 (6.25%)<br>1  |  |

|  |                      |                     |  |
|--|----------------------|---------------------|--|
| Localised infection<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 10 (0.00%)<br>0  | 1 / 16 (6.25%)<br>1 |  |
| Rhinitis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 10 (0.00%)<br>0  | 1 / 16 (6.25%)<br>1 |  |
| Urosepsis<br>subjects affected / exposed<br>occurrences (all)  | 1 / 10 (10.00%)<br>1 | 0 / 16 (0.00%)<br>0 |  |
| Vulvovaginal mycotic infection<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 10 (10.00%)<br>1 | 0 / 16 (0.00%)<br>0 |  |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | 0 / 16 (0.00%)<br>0 |  |

## 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