



Clinical trial results:

A Remote, Open-Label, Long-Term, Follow-up Study to Determine the Safety, Tolerability, and Efficacy of Rotigotine Transdermal System as Monotherapy in Adolescents With Restless Legs Syndrome

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2021-003403-18 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 07 April 2023 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 21 October 2023 |
| First version publication date | 21 October 2023 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | RL0007 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03992196 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | UCB Biopharma SRL |
| Sponsor organisation address | Allée de la Recherche 60, Brussels, Belgium, 1070 |
| Public contact | Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com |
| Scientific contact | Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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? | Yes |

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 26 April 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 01 September 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 April 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To assess the long-term safety and tolerability of rotigotine treatment in adolescents with idiopathic Restless Legs Syndrome (RLS)

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol

Evidence for comparator:

Not applicable

| | |
|---|-------------------|
| Actual start date of recruitment | 03 December 2019 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Regulatory reason |
| Long term follow-up duration | 13 Months |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | United States: 10 |
| Worldwide total number of subjects | 10 |
| 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) | 0 |
| Adolescents (12-17 years) | 10 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |

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

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in December 2019 and concluded prematurely in September 2022. Study participants entered this study from the parent rotigotine study in adolescents (SP1006) (NCT03728933).

Pre-assignment

Screening details:

10 participants were screened and considered enrolled, but only 9 participants were treated. The 10th participant was lost to follow-up prior dosing and no Adverse events were reported for this participant. Participant Flow refers to the Enrolled Set.

Period 1

| | |
|------------------------------|----------------|
| Period 1 title | Enrollment |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | No Treatment |

Arm description:

Participant signed the informed consent form but never received any study medication during the study.

| | |
|---|---------------------------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Rotigotine Final Dose 2 mg/24 h |

Arm description:

Participants in this arm were initiated on 1 milligram (mg)/24 hours (h) rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|---|---------------------------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Rotigotine Final Dose 3 mg/24 h |

Arm description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 1 | No Treatment | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h |
|---------------------------------------|--------------|---------------------------------|---------------------------------|
| Started | 1 | 2 | 7 |
| Completed | 0 | 2 | 7 |
| Not completed | 1 | 0 | 0 |
| lost to follow-up prior dosing | 1 | - | - |

Period 2

| | |
|------------------------------|--------------------|
| Period 2 title | Treatment |
| Is this the baseline period? | Yes ^[1] |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|---------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Rotigotine Final Dose 2 mg/24 h |

Arm description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rotigotine |
| Investigational medicinal product code | Neupro |
| Other name | |
| Pharmaceutical forms | Transdermal patch |
| Routes of administration | Transdermal use |

Dosage and administration details:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|------------------|---------------------------------|
| Arm title | Rotigotine Final Dose 3 mg/24 h |
|------------------|---------------------------------|

Arm description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|--|-------------------|
| Arm type | Experimental |
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| Pharmaceutical forms | Transdermal patch |
| Routes of administration | Transdermal use |

Dosage and administration details:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Data cannot be reported for a single participant due to data protection/data privacy.

| Number of subjects in period 2 ^[2] | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h |
|---|------------------------------------|------------------------------------|
| | | |
| Started | 2 | 7 |
| Completed | 2 | 1 |
| Not completed | 0 | 6 |
| Poor drug compliance withdrawn by team & sponsor | - | 1 |
| PI's decision due to IMP non- compliance | - | 1 |
| Withdrawal due to non-compliance | - | 1 |
| Withdrawal by parent/guardian | - | 2 |
| Protocol deviation | - | 1 |

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 10 study participants were screened and enrolled, but only 9 participants were treated.

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------------------------|
| Reporting group title | Rotigotine Final Dose 2 mg/24 h |
|-----------------------|---------------------------------|

Reporting group description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|-----------------------|---------------------------------|
| Reporting group title | Rotigotine Final Dose 3 mg/24 h |
|-----------------------|---------------------------------|

Reporting group description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| Reporting group values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | Total |
|---------------------------|---------------------------------|---------------------------------|-------|
| Number of subjects | 2 | 7 | 9 |
| Age Categorical | | | |
| Units: Participants | | | |
| Adolescents (12-17 years) | 2 | 7 | 9 |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 2 | 2 | 4 |
| Male | 0 | 5 | 5 |

End points

End points reporting groups

| | |
|--|---------------------------------|
| Reporting group title | No Treatment |
| Reporting group description: Participant signed the informed consent form but never received any study medication during the study. | |
| Reporting group title | Rotigotine Final Dose 2 mg/24 h |
| Reporting group description: Participants in this arm were initiated on 1 milligram (mg)/24 hours (h) rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated. | |
| Reporting group title | Rotigotine Final Dose 3 mg/24 h |
| Reporting group description: Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated. | |
| Reporting group title | Rotigotine Final Dose 2 mg/24 h |
| Reporting group description: Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated. | |
| Reporting group title | Rotigotine Final Dose 3 mg/24 h |
| Reporting group description: Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated. | |

Primary: Percentage of participants with treatment-emergent adverse events (TEAEs) leading to withdrawal of study medication

| | |
|---|--|
| End point title | Percentage of participants with treatment-emergent adverse events (TEAEs) leading to withdrawal of study medication ^[1] |
| End point description: An AE is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. TEAEs were defined as events that started during the Treatment Period or within 30 days following the end of the Treatment Period (ie, on or after the date of first patch application and within 30 days following the date of last patch removal + 1 day), or those events where the intensity worsened within this time frame. The Safety Set consisted of all participants who had at least one patch (rotigotine) applied. | |
| End point type | Primary |
| End point timeframe: From Baseline until the Safety Follow-Up Visit (up to 14 Months) | |
| 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: No formal statistical hypothesis testing was planned due to early stopping of this study. Results were summarized in tables as descriptive statistics only. | |

| End point values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | | |
|-----------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 | 7 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants with treatment-emergent adverse events (TEAEs)

| | |
|-----------------|--|
| End point title | Percentage of participants with treatment-emergent adverse events (TEAEs) ^[2] |
|-----------------|--|

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. TEAEs were defined as events that started during the Treatment Period or within 30 days following the end of the Treatment Period (ie, on or after the date of first patch application and within 30 days following the date of last patch removal + 1 day), or those events where the intensity worsened within this time frame. The Safety Set consisted of all participants who had at least one patch (rotigotine) applied.

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

End point timeframe:

From Baseline until the Safety Follow-Up Visit (up to 14 Months)

Notes:

[2] - 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: No formal statistical hypothesis testing was planned due to early stopping of this study. Results were summarized in tables as descriptive statistics only.

| End point values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | | |
|-----------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 | 7 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | 85.7 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in Clinical Global Impressions (CGI) Item 1 at Visit 9

| | |
|-----------------|--|
| End point title | Changes from Baseline in Clinical Global Impressions (CGI) Item 1 at Visit 9 |
|-----------------|--|

End point description:

The Clinical Global Impressions Item 1 (Severity of Illness) score ranges from 0 to 7 as follows: 0=not assessed, 1=normal, not ill at all, 2=borderline ill, 3=mildly ill, 4=moderately ill, 5=markedly ill,

6=severely ill, 7=among the most extremely ill. The CGI Item 1 was completed during an interview between the participant and the investigator or designee. A negative change from Baseline indicates improvement. The Safety Set consisted of all participants who had at least one patch (rotigotine) applied. Here, Number of Participants analyzed signifies those who were evaluable for this outcome measure. 99999 signifies that summary statistics are not reported for N<3 due to small sample size and participant identification issues.

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

End point timeframe:

Visit 9 (Month 12), compared to Baseline (in SP1006)

| End point values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | | |
|--------------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 | 2 | | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | 99999 (± 99999) | 99999 (± 99999) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in Restless Legs-6 Rating Scales (RLS-6) at Visit 9

| | |
|-----------------|---|
| End point title | Changes from Baseline in Restless Legs-6 Rating Scales (RLS-6) at Visit 9 |
|-----------------|---|

End point description:

The RLS-6 Rating Scales was designed to assess severity of RLS and consisted of 6 subscales. The subscales assessed severity of symptoms at the following times of the day/evening: falling asleep, during the night, during the day at rest, and during the day when engaged in daytime activities (not at rest). In addition, the subscales assessed satisfaction with sleep and severity of daytime tiredness/sleepiness. Scores for each of the 6 subscales ranged from 0 (completely satisfied) to 10 (completely dissatisfied). The change from baseline was derived for each of the subscales and reported in this outcome measure. A negative change from Baseline indicates improvement. The Safety Set consisted of all participants who had at least one patch (rotigotine) applied. Here, Number of Participants analyzed signifies those who were evaluable for this outcome measure. 99999 signifies that summary statistics are not reported for N<3 due to small sample size and participant identification issues.

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

End point timeframe:

Visit 9 (Month 12), compared to Baseline (in SP1006)

| End point values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | | |
|---|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 | 2 | | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Satisfaction with sleep | 99999 (± 99999) | 99999 (± 99999) | | |
| Severity: RLS symptoms at falling asleep | 99999 (± 99999) | 99999 (± 99999) | | |
| Severity: RLS symptoms during the night | 99999 (± 99999) | 99999 (± 99999) | | |
| Severity: RLS symptoms during the day - at rest | 99999 (± 99999) | 99999 (± 99999) | | |
| Severity: RLS symptoms during the day-not at rest | 99999 (± 99999) | 99999 (± 99999) | | |
| How tired or sleepy during the day | 99999 (± 99999) | 99999 (± 99999) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in International Restless Legs Rating Scale (IRLS) sum score at Visit 9

| | |
|-----------------|---|
| End point title | Changes from Baseline in International Restless Legs Rating Scale (IRLS) sum score at Visit 9 |
|-----------------|---|

End point description:

The IRLS consisted of 10 questions, each scored using a 5-point scale ranging from 0=not present to 4=very severe. The IRLS sum score was calculated by summing up the single scores of all applicable questions, i.e., the total sum score ranged from 0 (no RLS symptoms present) to 40 (maximum severity in all symptoms). A score between 31 and 40, indicates very severe RLS. A score between 21 and 30 indicates severe RLS. A score between 11 and 20 indicates moderate RLS. A score between 1 and 10 indicates mild RLS and a score of 0 means no RLS. A negative change from Baseline indicates improvement. The Safety Set consisted of all participants who had at least one patch (rotigotine) applied. Here, Number of Participants analyzed signifies those who were evaluable for this outcome measure. 99999 signifies that summary statistics are not reported for N<3 due to small sample size and participant identification issues.

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

End point timeframe:

Visit 9 (Month 12), compared to Baseline (in SP1006)

| End point values | Rotigotine Final Dose 2 mg/24 h | Rotigotine Final Dose 3 mg/24 h | | |
|--------------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2 | 2 | | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | 99999 (± 99999) | 99999 (± 99999) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline until the Safety Follow-Up Visit (up to 14 Months)

Adverse event reporting additional description:

TEAEs: Events started during Treatment Period (TP) or within 30 days following end of TP (i.e., on or after date of first patch application and within 30 days following date of last patch removal + 1 day), or events where intensity worsened within this time frame. AEs are presented for 9 treated participants in the Safety Set.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------------------|
| Reporting group title | Rotigotine Final Dose 3 mg/24 h |
|-----------------------|---------------------------------|

Reporting group description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 3 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| | |
|-----------------------|---------------------------------|
| Reporting group title | Rotigotine Final Dose 2 mg/24 h |
|-----------------------|---------------------------------|

Reporting group description:

Participants in this arm were initiated on 1 mg/24 h rotigotine and up-titrated to a maximum of 2 mg/24 h rotigotine and the same dose was continued throughout the 1 year Maintenance Period. Dose adjustment was allowed at any time during the Maintenance Period, based on the investigator's assessment. At the end of the Maintenance Period, participants were down-titrated.

| Serious adverse events | Rotigotine Final Dose 3 mg/24 h | Rotigotine Final Dose 2 mg/24 h | |
|---|---------------------------------|---------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 2 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

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

| Non-serious adverse events | Rotigotine Final Dose 3 mg/24 h | Rotigotine Final Dose 2 mg/24 h | |
|---|---------------------------------|---------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 7 (85.71%) | 2 / 2 (100.00%) | |
| Injury, poisoning and procedural complications | | | |
| Procedural dizziness | | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 2 (50.00%) 1 | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| General disorders and administration site conditions Application site rash subjects affected / exposed occurrences (all) Application site erythema subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 2 / 7 (28.57%) 2 | 0 / 2 (0.00%) 0 2 / 2 (100.00%) 2 | |
| Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) | 3 / 7 (42.86%) 5 | 0 / 2 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 0 / 7 (0.00%) 0 | 0 / 2 (0.00%) 0 1 / 2 (50.00%) 1 | |
| Skin and subcutaneous tissue disorders Skin irritation subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Dermatitis contact | 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 1 / 2 (50.00%) 1 | |

| | | | |
|--|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Eczema subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Rash papular subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 1 / 2 (50.00%) 1 | |
| COVID-19 subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Ear infection subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Gastroenteritis subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Pharyngitis streptococcal subjects affected / exposed occurrences (all) | 1 / 7 (14.29%) 1 | 0 / 2 (0.00%) 0 | |
| Suspected COVID-19 subjects affected / exposed occurrences (all) | 0 / 7 (0.00%) 0 | 1 / 2 (50.00%) 1 | |

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