



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of SEP-4199 for the Treatment of Major Depressive Episode Associated with Bipolar I Disorder (Bipolar I Depression)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-000103-16 |
| Trial protocol | BG SK PL |
| Global end of trial date | 23 April 2020 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v2 (current) |
| This version publication date | 04 June 2023 |
| First version publication date | 23 April 2021 |
| Version creation reason | |
| Summary attachment (see zip file) | null (PharmaCM_ Print Preview-updated.pdf) |

Trial information

Trial identification

| | |
|-----------------------|------------|
| Sponsor protocol code | SEP380-201 |
|-----------------------|------------|

Additional study identifiers

| | |
|------------------------------------|-----------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03543410 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Japan: jRCT2031220302 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Sunovion Pharmaceuticals Inc. |
| Sponsor organisation address | 84 Waterford Drive, Marlboro, United States, 01752 |
| Public contact | CNS Medical Director, Sunovion Pharmaceuticals Inc., 01 18665036351, ClinicalTrialDisclosure@sunovion.com |
| Scientific contact | CNS Medical Director, Sunovion Pharmaceuticals Inc., 01 18665036351, ClinicalTrialDisclosure@sunovion.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 | 23 April 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 23 April 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 23 April 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of SEP-4199 200 mg/day and 400 mg/day compared with placebo for major depressive episode associated with bipolar I disorder (diagnosed by DSM-5 criteria) as measured by Montgomery-Asberg Depression Rating Scale (MADRS) total score

Protection of trial subjects:

The study was conducted according to the protocol, ICH Good Clinical Practice (GCP), ICH guidelines, and the ethical principles that have their origin in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 26 June 2018 |
| 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 | Bulgaria: 43 |
| Country: Number of subjects enrolled | Japan: 49 |
| Country: Number of subjects enrolled | Poland: 11 |
| Country: Number of subjects enrolled | Russian Federation: 46 |
| Country: Number of subjects enrolled | Serbia: 63 |
| Country: Number of subjects enrolled | Slovakia: 19 |
| Country: Number of subjects enrolled | Ukraine: 67 |
| Country: Number of subjects enrolled | United States: 43 |
| Worldwide total number of subjects | 341 |
| EEA total number of subjects | 73 |

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 | 0 |

| | |
|---------------------------|-----|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 339 |
| From 65 to 84 years | 2 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total 344 subjects were randomized in this study. Three subjects, who were randomized but never received any dose of study medication, were not included in the reporting.

Period 1

| | |
|------------------------------|---|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Arms

| | |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | SEP-4199 200 mg |

Arm description:

SEP-4199 200 mg/day (supplied in two 100mg tablets)

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | SEP-4199 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

200 mg/day (supplied in two 100mg tablets)

| | |
|------------------|-----------------|
| Arm title | SEP-4199 400 mg |
|------------------|-----------------|

Arm description:

SEP-4199 400 mg/day (supplied in two 200mg tablets)

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | SEP-4199 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

400 mg /day (supplied in two tablets)

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Placebo (supplied in two tablets/day)

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:
supplied in two tablets

| Number of subjects in period 1 | SEP-4199 200 mg | SEP-4199 400 mg | Placebo |
|---------------------------------------|-----------------|-----------------|---------|
| Started | 113 | 114 | 114 |
| Completed | 92 | 101 | 99 |
| Not completed | 21 | 13 | 15 |
| Consent withdrawn by subject | 5 | 2 | 8 |
| NON-COMPLIANCE WITH STUDY DRUG | - | - | 2 |
| Adverse event, non-fatal | 10 | 8 | 2 |
| Not Due to COVID-19 | 2 | - | 1 |
| Lost to follow-up | - | 1 | - |
| Due to COVID-19 | 4 | - | 2 |
| Lack of efficacy | - | 1 | - |
| Protocol deviation | - | 1 | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------------|
| Reporting group title | SEP-4199 200 mg |
|-----------------------|-----------------|

Reporting group description:

SEP-4199 200 mg/day (supplied in two 100mg tablets)

| | |
|-----------------------|-----------------|
| Reporting group title | SEP-4199 400 mg |
|-----------------------|-----------------|

Reporting group description:

SEP-4199 400 mg/day (supplied in two 200mg tablets)

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo (supplied in two tablets/day)

| Reporting group values | SEP-4199 200 mg | SEP-4199 400 mg | Placebo |
|---|-----------------|-----------------|---------|
| Number of subjects | 113 | 114 | 114 |
| Age Categorical | | | |
| Units: Participants | | | |
| <=18 years | 1 | 1 | 1 |
| Between 18 and 65 years | 112 | 111 | 113 |
| >=65 years | 0 | 2 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 42 | 44.4 | 43.3 |
| standard deviation | ± 11.65 | ± 12.72 | ± 12.10 |
| Gender, Male/Female | | | |
| Units: Participants | | | |
| Female | 69 | 76 | 64 |
| Male | 44 | 38 | 50 |
| Age, Customized | | | |
| Units: Subjects | | | |
| 18-64 years | 113 | 112 | 114 |
| >=65 years | 0 | 2 | 0 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 1 | 0 |
| Asian | 16 | 16 | 17 |
| Black or African American | 6 | 8 | 8 |
| More than one race | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 1 | 2 | 1 |
| Unknown or Not Reported | 0 | 0 | 0 |
| White | 89 | 87 | 88 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 3 | 3 | 2 |
| Not Hispanic or Latino | 110 | 109 | 112 |
| Unknown or Not Reported | 0 | 2 | 0 |
| Country Name | | | |
| Units: Subjects | | | |

| | | | |
|---|---------|---------|---------|
| Bulgaria | 11 | 10 | 22 |
| Japan | 16 | 16 | 17 |
| Poland | 5 | 1 | 5 |
| Russia | 18 | 20 | 8 |
| Serbia | 19 | 26 | 18 |
| Slovakia | 8 | 5 | 6 |
| Ukraine | 22 | 20 | 25 |
| United States | 14 | 16 | 13 |
| Region of Enrollment | | | |
| Units: Subjects | | | |
| Europe | 83 | 82 | 84 |
| Japan | 16 | 16 | 17 |
| United States | 14 | 16 | 13 |
| Baseline BMI Category | | | |
| Units: Subjects | | | |
| < 18.5 kg/m2 | 0 | 3 | 0 |
| 18.5 - <25.0 kg/m2 | 51 | 50 | 45 |
| 25.0 - <30.0 kg/m2 | 42 | 33 | 40 |
| >=30.0 kg/m2 | 20 | 28 | 29 |
| Baseline Weight (kg) | | | |
| Units: kg | | | |
| arithmetic mean | 75.3 | 74.8 | 77.5 |
| standard deviation | ± 14.47 | ± 16.19 | ± 16.59 |
| Baseline CGI-BP-S Depression Score | | | |
| Measure Description: Clinical Global Impressions - Severity: Bipolar Version (CGI-BP-S) score (depression) is a single value, clinician-rated assessment of illness severity, and 7-point scale with range from 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill subjects. A higher score is associated with greater illness severity. | | | |
| Units: units on a scale | | | |
| arithmetic mean | 4.8 | 4.8 | 4.9 |
| standard deviation | ± 0.66 | ± 0.65 | ± 0.70 |
| Baseline MADRS Total Score | | | |
| Measure Description: MADRS is a clinician-rated assessment of the subject's level of depression. The measure contains 10 items that measure apparent and reported sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lassitude, inability to feel, and pessimistic and suicidal thoughts, each ranging from 0 to 6. The MADRS total score ranges from 0 to 60, with higher scores indicating increased depressive symptoms | | | |
| Units: units on a scale | | | |
| arithmetic mean | 33.5 | 33.8 | 34.1 |
| standard deviation | ± 5.77 | ± 5.63 | ± 5.35 |
| Baseline BMI (kg/m^2) | | | |
| Units: kg/m^2 | | | |
| arithmetic mean | 26.2 | 26.6 | 27 |
| standard deviation | ± 4.53 | ± 4.91 | ± 4.94 |
| Reporting group values | Total | | |
| Number of subjects | 341 | | |
| Age Categorical | | | |
| Units: Participants | | | |
| <=18 years | 3 | | |
| Between 18 and 65 years | 336 | | |
| >=65 years | 2 | | |

| | | | |
|--|-----|--|--|
| Age Continuous Units: Years arithmetic mean standard deviation | - | | |
| Gender, Male/Female Units: Participants | | | |
| Female | 209 | | |
| Male | 132 | | |
| Age, Customized Units: Subjects | | | |
| 18-64 years | 339 | | |
| >=65 years | 2 | | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 2 | | |
| Asian | 49 | | |
| Black or African American | 22 | | |
| More than one race | 0 | | |
| Native Hawaiian or Other Pacific Islander | 4 | | |
| Unknown or Not Reported | 0 | | |
| White | 264 | | |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 8 | | |
| Not Hispanic or Latino | 331 | | |
| Unknown or Not Reported | 2 | | |
| Country Name Units: Subjects | | | |
| Bulgaria | 43 | | |
| Japan | 49 | | |
| Poland | 11 | | |
| Russia | 46 | | |
| Serbia | 63 | | |
| Slovakia | 19 | | |
| Ukraine | 67 | | |
| United States | 43 | | |
| Region of Enrollment Units: Subjects | | | |
| Europe | 249 | | |
| Japan | 49 | | |
| United States | 43 | | |
| Baseline BMI Category Units: Subjects | | | |
| < 18.5 kg/m2 | 3 | | |
| 18.5 - <25.0 kg/m2 | 146 | | |
| 25.0 - <30.0 kg/m2 | 115 | | |
| >=30.0 kg/m2 | 77 | | |
| Baseline Weight (kg) Units: kg arithmetic mean standard deviation | - | | |

| | | | |
|---|--|--|--|
| Baseline CGI-BP-S Depression Score | | | |
| Measure Description: Clinical Global Impressions - Severity: Bipolar Version (CGI-BP-S) score (depression) is a single value, clinician-rated assessment of illness severity, and 7-point scale with range from 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill subjects. A higher score is associated with greater illness severity. | | | |
| Units: units on a scale arithmetic mean standard deviation | | | |
| Baseline MADRS Total Score | | | |
| Measure Description: MADRS is a clinician-rated assessment of the subject's level of depression. The measure contains 10 items that measure apparent and reported sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lassitude, inability to feel, and pessimistic and suicidal thoughts, each ranging from 0 to 6. The MADRS total score ranges from 0 to 60, with higher scores indicating increased depressive symptoms | | | |
| Units: units on a scale arithmetic mean standard deviation | | | |
| Baseline BMI (kg/m ²) Units: kg/m ² arithmetic mean standard deviation | | | |

End points

End points reporting groups

| | |
|---|-----------------|
| Reporting group title | SEP-4199 200 mg |
| Reporting group description: SEP-4199 200 mg/day (supplied in two 100mg tablets) | |
| Reporting group title | SEP-4199 400 mg |
| Reporting group description: SEP-4199 400 mg/day (supplied in two 200mg tablets) | |
| Reporting group title | Placebo |
| Reporting group description: Placebo (supplied in two tablets/day) | |

Primary: Change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6

| | |
|--|---|
| End point title | Change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6 |
| End point description: MADRS is a clinician-rated assessment of the subject's level of depression. The measure contains 10 items that measure apparent and reported sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lassitude, inability to feel, and pessimistic and suicidal thoughts, each ranging from 0 to 6. The MADRS total score ranges from 0 to 60, with higher scores indicating increased depressive symptoms | |
| End point type | Primary |
| End point timeframe: 6 Weeks | |

| End point values | SEP-4199 200 mg | SEP-4199 400 mg | Placebo | |
|-------------------------------------|-------------------|-------------------|-------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 96 ^[1] | 97 ^[2] | 96 ^[3] | |
| Units: units on a scale | | | | |
| least squares mean (standard error) | -19.485 (± 1.226) | -19.324 (± 1.182) | -16.196 (± 1.231) | |

Notes:

[1] - The analysis population was the ITT population, excluding subjects from Japan Region

[2] - The analysis population was the ITT population, excluding subjects from Japan Region

[3] - The analysis population was the ITT population, excluding subjects from Japan Region

Statistical analyses

| | |
|----------------------------|----------------------------|
| Statistical analysis title | SEP-4199 400mg and Placebo |
| Comparison groups | SEP-4199 400 mg v Placebo |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 193 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.051 ^[4] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -3.128 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.273 |
| upper limit | 0.017 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.597 |

Notes:

[4] - nominal p-value

| | |
|---|--------------------------------|
| Statistical analysis title | SEP-4199 200mg and Placebo |
| Comparison groups | Placebo v SEP-4199 200 mg |
| Number of subjects included in analysis | 192 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.044 ^[5] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -3.29 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.489 |
| upper limit | -0.09 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 1.625 |

Notes:

[5] - nominal p-value

Secondary: Change from baseline in global severity assessed by the Clinical Global Impressions – Severity: Bipolar Version (CGI-BP-S) score (depression) at Week 6

| | |
|-----------------|---|
| End point title | Change from baseline in global severity assessed by the Clinical Global Impressions – Severity: Bipolar Version (CGI-BP-S) score (depression) at Week 6 |
|-----------------|---|

End point description:

Clinical Global Impressions – Severity: Bipolar Version (CGI-BP-S) score (depression) is a single value, clinician-rated assessment of illness severity, and 7-point scale with range from 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill subjects. A higher score is associated with greater illness severity.

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

End point timeframe:

6 Weeks

| End point values | SEP-4199 200 mg | SEP-4199 400 mg | Placebo | |
|-------------------------------------|-----------------------|-----------------------|-----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 96 ^[6] | 97 ^[7] | 96 ^[8] | |
| Units: units on a scale | | | | |
| least squares mean (standard error) | -2.020 (\pm 0.144) | -1.958 (\pm 0.138) | -1.739 (\pm 0.144) | |

Notes:

[6] - The analysis population was the ITT population, excluding subjects from Japan Region

[7] - The analysis population was the ITT population, excluding subjects from Japan Region

[8] - The analysis population was the ITT population, excluding subjects from Japan Region

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | SEP-4199 400mg and Placebo |
| Comparison groups | SEP-4199 400 mg v Placebo |
| Number of subjects included in analysis | 193 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.243 ^[9] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.219 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.588 |
| upper limit | 0.15 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.187 |

Notes:

[9] - nominal p-value

| | |
|---|--------------------------------|
| Statistical analysis title | SEP-4199 200mg and Placebo |
| Comparison groups | SEP-4199 200 mg v Placebo |
| Number of subjects included in analysis | 192 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.143 ^[10] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.281 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.658 |
| upper limit | 0.095 |

| | |
|----------------------|----------------------------|
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.191 |

Notes:

[10] - nominal p-value

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were untoward medical occurrences that occurred on or after the first dose of study medication.

Up to 7 weeks

Adverse event reporting additional description:

Adverse events were untoward medical occurrences that occurred on or after the first dose of study medication.

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

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|-----------------|
| Reporting group title | SEP-4199 200 mg |
|-----------------------|-----------------|

Reporting group description:

SEP-4199 200 mg/day (supplied in two 100mg tablets)

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo (supplied in two tablets/day)

| | |
|-----------------------|-----------------|
| Reporting group title | SEP-4199 400 mg |
|-----------------------|-----------------|

Reporting group description:

SEP-4199 400 mg/day (supplied in two 200mg tablets)

| Serious adverse events | SEP-4199 200 mg | Placebo | SEP-4199 400 mg |
|---|-----------------|-----------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 113 (0.88%) | 1 / 114 (0.88%) | 0 / 114 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 113 (0.00%) | 1 / 114 (0.88%) | 0 / 114 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 1 / 113 (0.88%) | 0 / 114 (0.00%) | 0 / 114 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | SEP-4199 200 mg | Placebo | SEP-4199 400 mg |
|---|-------------------|-------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 21 / 113 (18.58%) | 29 / 114 (25.44%) | 23 / 114 (20.18%) |
| Investigations | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 113 (0.00%) | 0 / 114 (0.00%) | 9 / 114 (7.89%) |
| occurrences (all) | 0 | 0 | 9 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 11 / 113 (9.73%) | 13 / 114 (11.40%) | 3 / 114 (2.63%) |
| occurrences (all) | 12 | 16 | 3 |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 5 / 113 (4.42%) | 7 / 114 (6.14%) | 5 / 114 (4.39%) |
| occurrences (all) | 6 | 9 | 6 |
| Anxiety | | | |
| subjects affected / exposed | 1 / 113 (0.88%) | 7 / 114 (6.14%) | 2 / 114 (1.75%) |
| occurrences (all) | 2 | 7 | 5 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 4 / 113 (3.54%) | 6 / 114 (5.26%) | 4 / 114 (3.51%) |
| occurrences (all) | 4 | 6 | 4 |

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