



Clinical trial results:

A Long-term, Multicenter, Open-Label, Flexible Dose Continuation Study in Subjects Who Have Completed a Prior Lurasidone Study

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2011-000682-12 |
| Trial protocol | SK LT CZ |
| Global end of trial date | 01 February 2014 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 15 October 2016 |
| First version publication date | 15 October 2016 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | D1050298 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01485640 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Sunovion Pharmaceuticals Inc. |
| Sponsor organisation address | One Bridge Plaza North, Suite 510, Fort Lee, United States, 07024 |
| Public contact | Medical Director, Sunovion Pharmaceuticals Inc., 001 1-866-503-6351 , clinicaltrialdisclosure@sunovion.com |
| Scientific contact | Medical Director, Sunovion Pharmaceuticals Inc., 001 1-866-503-6351 , 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 | 01 February 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 01 February 2014 |
| Global end of trial reached? | Yes |
| Global end of trial date | 01 February 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

This is an open-label continuation study designed to monitor the safety, tolerability and effectiveness of lurasidone in subjects who have completed participation in a lurasidone extension study (NCT00868959 and NCT01566162) and who may benefit from continued treatment with lurasidone.

Protection of trial subjects:

The study was conducted according to the protocol, International Conference on Harmonisation (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 | 01 June 2011 |
| 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 | Serbia: 6 |
| Country: Number of subjects enrolled | France: 6 |
| Country: Number of subjects enrolled | Czech Republic: 25 |
| Country: Number of subjects enrolled | Slovakia: 17 |
| Country: Number of subjects enrolled | Canada: 3 |
| Country: Number of subjects enrolled | Ukraine: 11 |
| Country: Number of subjects enrolled | Romania: 2 |
| Country: Number of subjects enrolled | Lithuania: 8 |
| Country: Number of subjects enrolled | Russian Federation: 20 |
| Country: Number of subjects enrolled | South Africa: 26 |
| Country: Number of subjects enrolled | Colombia: 6 |
| Country: Number of subjects enrolled | India: 32 |
| Worldwide total number of subjects | 162 |
| EEA total number of subjects | 58 |

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) | 1 |
| Adults (18-64 years) | 159 |
| From 65 to 84 years | 2 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Continuation study designed to monitor safety, tolerability and effectiveness of lurasidone in subjects who completed participation in a lurasidone extension study and who may benefit from continued treatment with lurasidone. Eligible subjects could enroll into this continuation study directly (or within 14 days) after completing the extension study

Period 1

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

Arms

| | |
|-----------|------------|
| Arm title | Lurasidone |
|-----------|------------|

Arm description:

Lurasidone flexibly dosed

Lurasidone: Lurasidone flexibly dosed; doses of 20, 40, 60 or 80 mg/day will be taken orally with food

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

Dosage and administration details:

once daily

| Number of subjects in period 1 | Lurasidone |
|--------------------------------|------------|
| Started | 162 |
| Completed | 40 |
| Not completed | 122 |
| Terminated by Sponsor | 95 |
| Consent withdrawn by subject | 14 |
| Adverse event, non-fatal | 10 |
| Lack of efficacy | 2 |
| Protocol deviation | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Lurasidone |
|-----------------------|------------|

Reporting group description:

Lurasidone flexibly dosed

Lurasidone: Lurasidone flexibly dosed; doses of 20, 40, 60 or 80 mg/day will be taken orally with food

| Reporting group values | Lurasidone | Total | |
|---|------------|-------|--|
| Number of subjects | 162 | 162 | |
| Age Categorical | | | |
| Units: participants | | | |
| <=18 years | 1 | 1 | |
| Between 18 and 65 years | 159 | 159 | |
| >=65 years | 2 | 2 | |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 41.3 | | |
| standard deviation | ± 12.08 | - | |
| Gender, Male/Female | | | |
| Units: participants | | | |
| Female | 77 | 77 | |
| Male | 85 | 85 | |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 32 | 32 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 5 | 5 | |
| White | 105 | 105 | |
| More than one race | 0 | 0 | |
| Unknown or Not Reported | 20 | 20 | |
| Region of Enrollment | | | |
| Units: Subjects | | | |
| Serbia | 6 | 6 | |
| France | 6 | 6 | |
| Czech Republic | 25 | 25 | |
| Slovakia | 17 | 17 | |
| Canada | 3 | 3 | |
| Ukraine | 11 | 11 | |
| Romania | 2 | 2 | |
| Lithuania | 8 | 8 | |
| Russian Federation | 20 | 20 | |
| South Africa | 26 | 26 | |
| Colombia | 6 | 6 | |
| India | 32 | 32 | |

End points

End points reporting groups

| | |
|--|------------|
| Reporting group title | Lurasidone |
| Reporting group description: Lurasidone flexibly dosed | |
| Lurasidone: Lurasidone flexibly dosed; doses of 20, 40, 60 or 80 mg/day will be taken orally with food | |

Primary: Number of subjects with treatment emergent AEs, SAEs or who discontinued due to AEs

| | |
|-----------------------------------|--|
| End point title | Number of subjects with treatment emergent AEs, SAEs or who discontinued due to AEs ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: 18 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: this is an extended use study, and every subject took lurasidone during the study, and thus only one treatment group is reported and no statistical analyses can be performed.

| End point values | Lurasidone | | | |
|--|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 162 | | | |
| Units: number of participants | | | | |
| Subject with at least one treatment emergent AE | 63 | | | |
| Subject with at least one treatment emergent SAE | 7 | | | |
| Subjects discontinued due to TEAE | 1 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to Month 18 (LOCF) in the Clinical Global Impression Severity score (CGI-S)

| | |
|--|--|
| End point title | Change from baseline to Month 18 (LOCF) in the Clinical Global Impression Severity score (CGI-S) |
| End point description: The CGI-S score is a single value, clinician-rated assessment of illness severity and ranges from 1= 'Normal, not at all ill' to 7= 'Among the most extremely ill patients'. A higher score is associated with greater illness severity. | |
| End point type | Secondary |
| End point timeframe: 18 months | |

| | | | | |
|--------------------------------------|-----------------|--|--|--|
| End point values | Lurasidone | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 153 | | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | -0.18 (± 0.877) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

18 Months

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 14.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Lurasidone |
|-----------------------|------------|

Reporting group description:

Lurasidone flexibly dosed

Lurasidone: Lurasidone flexibly dosed; doses of 20, 40, 60 or 80 mg/day will be taken orally with food

| Serious adverse events | Lurasidone | | |
|---|-----------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 162 (4.32%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 1 / 162 (0.62%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 1 / 162 (0.62%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Depression suicidal | | | |
| subjects affected / exposed | 1 / 162 (0.62%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mania | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 2 / 162 (1.23%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Schizophrenia, paranoid type | | | |
| subjects affected / exposed | 1 / 162 (0.62%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Pilonidal cyst | | | |
| subjects affected / exposed | 1 / 162 (0.62%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| | | | |
|---|-------------------|--|--|
| Non-serious adverse events | Lurasidone | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 40 / 162 (24.69%) | | |
| Investigations | | | |
| Hepatic enzyme increase | | | |
| subjects affected / exposed | 4 / 162 (2.47%) | | |
| occurrences (all) | 4 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 9 / 162 (5.56%) | | |
| occurrences (all) | 12 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 162 (3.70%) | | |
| occurrences (all) | 8 | | |
| Vomiting | | | |
| subjects affected / exposed | 5 / 162 (3.09%) | | |
| occurrences (all) | 11 | | |
| Nausea | | | |
| subjects affected / exposed | 4 / 162 (2.47%) | | |
| occurrences (all) | 4 | | |

| | | | |
|--|---|--|--|
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) | 5 / 162 (3.09%) 11 5 / 162 (3.09%) 6 4 / 162 (2.47%) 4 | | |
| Infections and infestations Influenza subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 6 / 162 (3.70%) 6 6 / 162 (3.70%) 9 4 / 162 (2.47%) 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|------|
| none |
|------|

Notes: