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