Clinical trial results:
A 104-Week, Flexible-Dose, Open-Label, Multicenter, Extension Study to Evaluate the Long-Term Safety and Effectiveness of Lurasidone in Pediatric Subjects

Summary

EudraCT number	2013-001694-24
Trial protocol	ES IT BG Outside EU/EEA HU GB DE PL BE FR
Global end of trial date	17 October 2018

Results information

Result version number	v1
This version publication date	21 April 2019
First version publication date	21 April 2019

Trial information

Trial identification

Sponsor protocol code	D1050302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01914393
WHO universal trial number (UTN)	-

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., 1 866-503-6351, ClinicalTrialDisclosure@sunovion.com
Scientific contact	CNS Medical Director, Sunovion Pharmaceuticals Inc., 1 866--503-6351, ClinicalTrialDisclosure@sunovion.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001230-PIP01-11
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	17 October 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 October 2018
Global end of trial reached?	Yes
Global end of trial date	17 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety, tolerability, and effectiveness of lurasidone (20, 40, 60 or 80 mg/day, flexibly dosed) in pediatric subjects who have completed a prior lurasidone study.

Protection of trial subjects:

The study was conducted according to the protocol, International Council for 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	18 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Russian Federation: 77
Country: Number of subjects enrolled	Mexico: 38
Country: Number of subjects enrolled	Poland: 12
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	United States: 332
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 10
Country: Number of subjects enrolled	Philippines: 6
Country: Number of subjects enrolled	Ukraine: 131
Country: Number of subjects enrolled	Romania: 15
Country: Number of subjects enrolled	Malaysia: 4
Country: Number of subjects enrolled	Colombia: 23
Country: Number of subjects enrolled	Bulgaria: 37
Country: Number of subjects enrolled	Hungary: 12
Worldwide total number of subjects	701
EEA total number of subjects	80

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)	111
Adolescents (12-17 years)	565
Adults (18-64 years)	25
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who completed participation in the preceding double-blind efficacy and safety studies (D1050301, D1050325, or D1050326) were eligible for enrollment in this study.
Treatment groups in study D1050301: Placebo, Lurasidone 40 mg/day, Lurasidone 80 mg/day.
Treatment groups in study D1050325: Placebo, Lurasidone 20 mg/day, Lurasidone 60 mg/d

Period 1

Period 1 title	lurasidone (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	lurasidone

Arm description:

Lurasidone 20, 40, 60, 80 mg, flexibly dosed

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

Dosage and administration details:

Lurasidone 20, 40, 60, 80 mg, flexibly dosed once daily

Number of subjects in period 1	lurasidone
Started	701
Completed	378
Not completed	323
Consent withdrawn by subject	105
no reason given	38
Adverse event, non-fatal	78
Lost to follow-up	37
Lack of efficacy	32
Protocol deviation	33

Baseline characteristics

Reporting groups	
Reporting group title	lurasidone

Reporting group description: -

Reporting group values	lurasidone	Total	
Number of subjects	701	701	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	111	111	
Adolescents (12-17 years)	565	565	
Adults (18-64 years)	25	25	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	14.3		
standard deviation	± 2.66	-	
Gender categorical Units: Subjects			
Female	276	276	
Male	425	425	
Country Units: Subjects			
Bulgaria	37	37	
Colombia	23	23	
Spain	1	1	
France	3	3	
Hungary	12	12	
South Korea	10	10	
Mexico	38	38	
Malaysia	4	4	
Philippines	6	6	
Poland	12	12	
Romania	15	15	
Russia	77	77	
Ukraine	131	131	
United States	332	332	

Subject analysis sets	
Subject analysis set title	Rollover from D1050301
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from D1050301	
Subject analysis set title	Rollover from study D1050325
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from study D1050325	
Subject analysis set title	Rollover from study D1050326
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from study D1050326	

Reporting group values	Rollover from D1050301	Rollover from study D1050325	Rollover from study D1050326
Number of subjects	271	125	306
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	75	36
Adolescents (12-17 years)	257	50	258
Adults (18-64 years)	14	0	11
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	15.5	11.1	14.4
standard deviation	± 1.44	± 3.12	± 2.18
Gender categorical Units: Subjects			
Female	101	23	152
Male	170	102	153
Country Units: Subjects			
Bulgaria	21	0	16
Colombia	11	0	12
Spain	1	0	0
France	2	0	1
Hungary	2	0	10
South Korea	3	0	7
Mexico	10	0	28
Malaysia	4	0	0
Philippines	4	0	2
Poland	7	0	5
Romania	15	0	0
Russia	41	0	36

Ukraine	68	0	63
United States	82	125	125

End points

End points reporting groups

Reporting group title	lurasidone
Reporting group description: Lurasidone 20, 40, 60, 80 mg, flexibly dosed	
Subject analysis set title	Rollover from D1050301
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from D1050301	
Subject analysis set title	Rollover from study D1050325
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from study D1050325	
Subject analysis set title	Rollover from study D1050326
Subject analysis set type	Sub-group analysis
Subject analysis set description: Rollover from study D1050326	

Primary: Number of subjects with adverse events (AEs), discontinuations due to AEs and serious AEs (SAEs)

End point title	Number of subjects with adverse events (AEs), discontinuations due to AEs and serious AEs (SAEs)[1]
End point description: The Safety population consists of all subjects who received at least one dose of study drug in this study.	
End point type	Primary
End point timeframe: During 104 Weeks (2-years) treatment period	

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 was an open label study

End point values	Rollover from D1050301	Rollover from study D1050325	Rollover from study D1050326	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	271	125	305	
Units: subjects				
Subjects with at least one treatment emergent AE	214	106	272	
Sujbects with at least one treatment emergent SAE	28	13	37	
Subjects with AEs leading to discontinuation	28	18	31	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Positive and Negative Syndrome Scale (PANSS) Total Score

End point title	Change from Baseline in the Positive and Negative Syndrome Scale (PANSS) Total Score

End point description:

Change from Baseline in the Positive and Negative Syndrome Scale (PANSS) Total Score for subjects continued from study D1050301.

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open Label Baseline	76.0 (± 17.72)			
Week 28	-11.9 (± 13.74)			
Week 52	-15.6 (± 14.97)			
Week 104	-18.4 (± 16.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PANSS Positive Subscale Score

End point title	Change from Baseline in PANSS Positive Subscale Score

End point description:

Change from Baseline in PANSS Positive Subscale Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open Label baseline	17.9 (± 5.51)			
Week 28	-3.9 (± 4.68)			
Week 52	-5.1 (± 5.13)			

Week 104	-5.4 (± 5.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PANSS Negative Subscale Score

End point title	Change from Baseline in PANSS Negative Subscale Score

End point description:

Change from Baseline in PANSS Negative Subscale Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open Label baseline	20.5 (± 4.91)			
Week 28	-2.6 (± 4.16)			
Week 52	-3.4 (± 4.34)			
Week 104	-4.3 (± 4.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PANSS General Psychopathology Subscale Score

End point title	Change from Baseline in PANSS General Psychopathology Subscale Score

End point description:

Change from Baseline in PANSS General Psychopathology Subscale Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	37.5 (± 9.38)			
Week 28	-5.4 (± 7.65)			
Week 52	-7.2 (± 7.65)			
Week 104	-8.7 (± 8.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in PANSS Excitability Subscale Score

End point title	Change from Baseline in PANSS Excitability Subscale Score

End point description:

Change from Baseline in PANSS Excitability Subscale Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	9.0 (± 3.73)			
Week 28	-1.3 (± 3.09)			
Week 52	-1.7 (± 3.31)			
week 104	-2.1 (± 3.63)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Clinical Global Impression -Severity Score

End point title	Change from Baseline in the Clinical Global Impression -Severity Score

End point description:

Change from Baseline in the Clinical Global Impression -Severity Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	4.0 (± 0.97)			
Week 28	-0.87 (± 0.941)			
Week 52	-1.10 (± 1.084)			
Week 104	-1.31 (± 1.196)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinician-Rated Children's Global Assessment Score (CGAS) Score

End point title	Change from Baseline in Clinician-Rated Children's Global Assessment Score (CGAS) Score

End point description:

Change from Baseline in Clinician-Rated Children's Global Assessment Score (CGAS) Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	55.0 (± 11.96)			
Week 28	10.94 (± 11.943)			
Week 52	14.28 (± 12.814)			
Week 104	17.85 (± 15.155)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score

End point title	Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score

End point description:

Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score for subjects continued from study D1050301

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from D1050301			
Subject group type	Subject analysis set			
Number of subjects analysed	271			
Units: percent of score				
arithmetic mean (standard deviation)				
Open label baseline	57.14 (± 14.850)			
Week 28	7.48 (± 13.336)			
Week 52	9.98 (± 13.541)			
Week 104	11.74 (± 15.783)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Aberrant Behavior Checklist (ABC) Irritability Subscale Score

End point title	Change from Baseline in Aberrant Behavior Checklist (ABC) Irritability Subscale Score

End point description:

Change from Baseline in Aberrant Behavior Checklist (ABC) Irritability Subscale Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	19.0 (± 10.63)			
Week 28	-2.1 (± 9.16)			
Week 52	-2.9 (± 9.85)			
Week 104	-4.2 (± 11.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Aberrant Behavior Checklist (ABC) Lethargy and Social Withdrawal Subscale Score

End point title	Change from Baseline in Aberrant Behavior Checklist (ABC) Lethargy and Social Withdrawal Subscale Score

End point description:

Change from Baseline in Aberrant Behavior Checklist (ABC) Lethargy and Social Withdrawal Subscale Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
median (standard deviation)				
Open label baseline	10.3 (± 9.48)			
Week 28	-0.7 (± 7.01)			
Week 52	-1.1 (± 6.94)			
Week 104	-1.1 (± 6.57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Aberrant Behavior Checklist (ABC) Stereotypic Behavior Subscale Score

End point title	Change from Baseline in Aberrant Behavior Checklist (ABC) Stereotypic Behavior Subscale Score

End point description:

Change from Baseline in Aberrant Behavior Checklist (ABC) Stereotypic Behavior Subscale Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	6.1 (± 5.87)			
Week 28	-0.9 (± 3.55)			
Week 52	-0.9 (± 4.53)			
Week 104	-1.1 (± 4.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Aberrant Behavior Checklist (ABC) Hyperactivity and Noncompliance Subscale Score

End point title	Change from Baseline in Aberrant Behavior Checklist (ABC) Hyperactivity and Noncompliance Subscale Score

End point description:

Change from Baseline in Aberrant Behavior Checklist (ABC) Hyperactivity and Noncompliance Subscale Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	24.1 (± 12.19)			
Week 28	-3.8 (± 10.16)			
Week 52	-4.3 (± 11.24)			
Week 104	-5.6 (± 12.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Aberrant Behavior Checklist (ABC) Inappropriate Speech Subscale Score

End point title	Change from Baseline in Aberrant Behavior Checklist (ABC) Inappropriate Speech Subscale Score

End point description:

Change from Baseline in Aberrant Behavior Checklist (ABC) Inappropriate Speech Subscale Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	5.2 (± 3.61)			
Week 28	-0.7 (± 2.75)			
Week 52	-0.7 (± 2.88)			
Week 104	-0.5 (± 3.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Global Impression (CGI) – Severity Score

End point title	Change from Baseline in Clinical Global Impression (CGI) –

	Severity Score

End point description:

Change from Baseline in Clinical Global Impression (CGI) – Severity Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	3.9 (± 1.25)			
Week 28	-0.43 (± 0.984)			
Week 52	-0.71 (± 1.078)			
Week 104	-0.78 (± 1.313)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Children's Yale-Brown Obsessive Compulsive Score (CY-BOCS)

End point title	Change from Baseline in Children's Yale-Brown Obsessive Compulsive Score (CY-BOCS)

End point description:

Change from Baseline in Children's Yale-Brown Obsessive Compulsive Score (CY-BOCS) for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	10.2 (± 5.43)			
Week 28	-2.2 (± 3.39)			

Week 52	-2.3 (± 4.32)			
Week 104	-3.2 (± 4.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Caregiver Strain Questionnaire (CGSQ) Global Strain Score

End point title	Change from Baseline in Caregiver Strain Questionnaire (CGSQ) Global Strain Score

End point description:

Change from Baseline in Caregiver Strain Questionnaire (CGSQ) Global Strain Score for subjects continued from study D1050325

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050325			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	7.95 (± 2.213)			
Week 28	-0.48 (± 1.887)			
Week 52	-0.60 (± 2.032)			
Week 104	-0.63 (± 2.123)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Children's Depression Rating Scale, Revised (CDRS-R) Total Score

End point title	Change from Baseline in Children's Depression Rating Scale, Revised (CDRS-R) Total Score

End point description:

Change from Baseline in CDRS-R Total Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	39.2 (± 13.38)			
Week 28	-9.9 (± 13.48)			
Week 52	-13.4 (± 13.01)			
Week 104	-16.4 (± 13.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Global Impression Bipolar Version (CGI-BP-S) Depression Score

End point title	Change from Baseline in Clinical Global Impression Bipolar Version (CGI-BP-S) Depression Score

End point description:

Change from Baseline in Clinical Global Impression Bipolar Version (CGI-BP-S) Depression Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	3.2 (± 1.09)			
Week 28	-1.10 (± 1.140)			
Week 52	-1.39 (± 1.184)			
Week 104	-1.61 (± 1.153)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinician-rated Children's Global Assessment Scale (CGAS) Score

End point title	Change from Baseline in Clinician-rated Children's Global Assessment Scale (CGAS) Score

End point description:

Change from Baseline in Clinician-rated Children's Global Assessment Scale (CGAS) Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	61.1 (± 12.54)			
Week 28	11.17 (± 13.893)			
Week 52	14.67 (± 14.347)			
Week 104	18.96 (± 14.898)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score

End point title	Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score

End point description:

Change from Baseline in Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) Percentage Maximum Possible Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: score				
arithmetic mean (standard deviation)				
Open label baseline	59.52 (± 15.569)			
Week 28	8.16 (± 16.345)			
Week 52	11.37 (± 16.343)			
Week 104	14.75 (± 16.744)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pediatric Anxiety Rating Scale (PAR) Total Score

End point title	Change from Baseline in Pediatric Anxiety Rating Scale (PAR) Total Score

End point description:

Change from Baseline in Pediatric Anxiety Rating Scale (PAR) Total Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	8.0 (± 6.94)			
Week 28	-2.7 (± 5.41)			
Week 52	-3.2 (± 5.97)			
Week 104	-4.9 (± 6.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Attention-Deficity/Hyperactivity Disorder Rating Scale (ADHD-RS) Total Score

End point title	Change from Baseline in Attention-Deficity/Hyperactivity Disorder Rating Scale (ADHD-RS) Total Score

End point description:

Change from Baseline in Attention-Deficity/Hyperactivity Disorder Rating Scale (ADHD-RS) Total Score for subjects continued from study D1050326

End point type	Secondary

End point timeframe:

Open-Label Baseline, Week 28, Week 52, and Week 104

End point values	Rollover from study D1050326			
Subject group type	Subject analysis set			
Number of subjects analysed	305			
Units: units on a scale				
arithmetic mean (standard deviation)				
Open label baseline	9.4 (± 10.58)			
Week 28	-2.2 (± 6.29)			
Week 52	-2.4 (± 5.83)			
Week 104	-3.3 (± 6.24)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

An AE onset on or after the start of the open-label treatment period (treatment duration: 104 weeks) through 7 days after study drug discontinuation (14 days for serious adverse events and deaths)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	lurasidone

Reporting group description:

Lurasidone 20, 40, 60, 80 mg, flexibly dosed- (All indications)

Reporting group title	Rollover from D1050301

Reporting group description:

Lurasidone flexibly dosed (20, 40, 60 or 80 mg/day) for subjects continued from study D1050301

Reporting group title	Rollover from D1050325

Reporting group description:

Lurasidone flexibly dosed (20, 40, 60 or 80 mg/day) for subjects continued from study D1050325 (Lurasidone (autistic disorder))

Reporting group title	Rollover from D1050326

Reporting group description:

Lurasidone flexibly dosed (20, 40, 60 or 80 mg/day) for subjects continued from study D1050326 (Lurasidone (bipolar depression))

Serious adverse events	lurasidone	Rollover from D1050301	Rollover from D1050325
Total subjects affected by serious adverse events			
subjects affected / exposed	78 / 701 (11.13%)	28 / 271 (10.33%)	13 / 125 (10.40%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign ovarian tumour			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	3 / 701 (0.43%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intentional overdose			
subjects affected / exposed	3 / 701 (0.43%)	2 / 271 (0.74%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	2 / 701 (0.29%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clavical fracture			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			

subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Frostbite			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve injury			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
convulsion			
subjects affected / exposed	2 / 701 (0.29%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Akathisia			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bezoar			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	14 / 701 (2.00%)	8 / 271 (2.95%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 16	1 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	11 / 701 (1.57%)	11 / 271 (4.06%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	1 / 12	1 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	8 / 701 (1.14%)	1 / 271 (0.37%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	2 / 9	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	6 / 701 (0.86%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	5 / 701 (0.71%)	5 / 271 (1.85%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	3 / 5	3 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aggression			
subjects affected / exposed	4 / 701 (0.57%)	1 / 271 (0.37%)	3 / 125 (2.40%)
occurrences causally related to treatment / all	2 / 4	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	4 / 701 (0.57%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
subjects affected / exposed	4 / 701 (0.57%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	2 / 701 (0.29%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal behaviour			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
confusional state			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressive symptom			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emotional disorder			

subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional drug misuse			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Violence-related symptom			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematinuria			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	3 / 701 (0.43%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 701 (0.14%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 701 (0.14%)	1 / 271 (0.37%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Rollover from D1050326		
Total subjects affected by serious adverse events			
subjects affected / exposed	37 / 305 (12.13%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign ovarian tumour			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	2 / 305 (0.66%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
clavical fracture			

subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured coccyx				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Frostbite				
subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral nerve injury				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue injury				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				

subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
convulsion			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Akathisia			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bezoar			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicidal ideation			

subjects affected / exposed	5 / 305 (1.64%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Schizophrenia				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	6 / 305 (1.97%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Bipolar I disorder				
subjects affected / exposed	6 / 305 (1.97%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	0 / 0			
Psychotic disorder				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aggression				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	4 / 305 (1.31%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
depression				
subjects affected / exposed	3 / 305 (0.98%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Suicidal behaviour				

subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abnormal behaviour				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Agitation				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
confusional state				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depressive symptom				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Emotional disorder				
subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
intentional drug misuse				
subjects affected / exposed	1 / 305 (0.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Violence-related symptom				
subjects affected / exposed	0 / 305 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Haematinuria				

subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	2 / 305 (0.66%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 305 (0.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	lurasidone	Rollover from D1050301	Rollover from D1050325
Total subjects affected by non-serious adverse events			
subjects affected / exposed	560 / 701 (79.89%)	208 / 271 (76.75%)	104 / 125 (83.20%)
Investigations			
Weight increased			
subjects affected / exposed	70 / 701 (9.99%)	21 / 271 (7.75%)	20 / 125 (16.00%)
occurrences (all)	73	22	21
Nervous system disorders			
Headache			
subjects affected / exposed	156 / 701 (22.25%)	65 / 271 (23.99%)	18 / 125 (14.40%)
occurrences (all)	281	126	31

Somnolence			
subjects affected / exposed	68 / 701 (9.70%)	24 / 271 (8.86%)	14 / 125 (11.20%)
occurrences (all)	73	26	17
Akathisia			
subjects affected / exposed	49 / 701 (6.99%)	22 / 271 (8.12%)	8 / 125 (6.40%)
occurrences (all)	72	33	12
Dizziness			
subjects affected / exposed	0 / 701 (0.00%)	17 / 271 (6.27%)	0 / 125 (0.00%)
occurrences (all)	0	23	0
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	36 / 701 (5.14%)	0 / 271 (0.00%)	12 / 125 (9.60%)
occurrences (all)	48	0	17
Fatigue			
subjects affected / exposed	0 / 701 (0.00%)	0 / 271 (0.00%)	10 / 125 (8.00%)
occurrences (all)	0	0	14
Pyrexia			
subjects affected / exposed	0 / 701 (0.00%)	0 / 271 (0.00%)	7 / 125 (5.60%)
occurrences (all)	0	0	9
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 701 (0.00%)	0 / 271 (0.00%)	8 / 125 (6.40%)
occurrences (all)	0	0	9
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	93 / 701 (13.27%)	34 / 271 (12.55%)	9 / 125 (7.20%)
occurrences (all)	156	59	16
Vomiting			
subjects affected / exposed	68 / 701 (9.70%)	16 / 271 (5.90%)	27 / 125 (21.60%)
occurrences (all)	108	21	41
Diarrhoea			
subjects affected / exposed	38 / 701 (5.42%)	0 / 271 (0.00%)	7 / 125 (5.60%)
occurrences (all)	49	0	8
Toothache			
subjects affected / exposed	0 / 701 (0.00%)	19 / 271 (7.01%)	0 / 125 (0.00%)
occurrences (all)	0	26	0

Constipation			
subjects affected / exposed	0 / 701 (0.00%)	14 / 271 (5.17%)	0 / 125 (0.00%)
occurrences (all)	0	18	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	39 / 701 (5.56%)	0 / 271 (0.00%)	14 / 125 (11.20%)
occurrences (all)	44	0	16
Psychiatric disorders			
Anxiety			
subjects affected / exposed	75 / 701 (10.70%)	35 / 271 (12.92%)	14 / 125 (11.20%)
occurrences (all)	111	53	23
Insomnia			
subjects affected / exposed	58 / 701 (8.27%)	23 / 271 (8.49%)	13 / 125 (10.40%)
occurrences (all)	76	32	18
Agitation			
subjects affected / exposed	45 / 701 (6.42%)	20 / 271 (7.38%)	14 / 125 (11.20%)
occurrences (all)	69	30	24
Depression			
subjects affected / exposed	38 / 701 (5.42%)	18 / 271 (6.64%)	7 / 125 (5.60%)
occurrences (all)	46	23	8
Schizophrenia			
subjects affected / exposed	0 / 701 (0.00%)	24 / 271 (8.86%)	0 / 125 (0.00%)
occurrences (all)	0	42	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	78 / 701 (11.13%)	24 / 271 (8.86%)	28 / 125 (22.40%)
occurrences (all)	106	30	42
Upper respiratory tract infection			
subjects affected / exposed	36 / 701 (5.14%)	0 / 271 (0.00%)	14 / 125 (11.20%)
occurrences (all)	43	0	18
Viral infection			
subjects affected / exposed	0 / 701 (0.00%)	17 / 271 (6.27%)	0 / 125 (0.00%)
occurrences (all)	0	33	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 701 (0.00%)	0 / 271 (0.00%)	8 / 125 (6.40%)
occurrences (all)	0	0	8

Rhinitis			
subjects affected / exposed	0 / 701 (0.00%)	0 / 271 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Rollover from D1050326		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	248 / 305 (81.31%)		
Investigations			
Weight increased			
subjects affected / exposed	29 / 305 (9.51%)		
occurrences (all)	30		
Nervous system disorders			
Headache			
subjects affected / exposed	73 / 305 (23.93%)		
occurrences (all)	124		
Somnolence			
subjects affected / exposed	30 / 305 (9.84%)		
occurrences (all)	30		
Akathisia			
subjects affected / exposed	19 / 305 (6.23%)		
occurrences (all)	27		
Dizziness			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Irritability			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	18 / 305 (5.90%)		
occurrences (all)	20		
Pyrexia			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal allergy			

subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	50 / 305 (16.39%)		
occurrences (all)	81		
Vomiting			
subjects affected / exposed	25 / 305 (8.20%)		
occurrences (all)	46		
Diarrhoea			
subjects affected / exposed	18 / 305 (5.90%)		
occurrences (all)	24		
Toothache			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	26 / 305 (8.52%)		
occurrences (all)	35		
Insomnia			
subjects affected / exposed	22 / 305 (7.21%)		
occurrences (all)	26		
Agitation			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Schizophrenia			

subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	26 / 305 (8.52%)		
occurrences (all)	34		
Upper respiratory tract infection			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 305 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	19 / 305 (6.23%)		
occurrences (all)	24		

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