Trial record 1 of 1 for: 1050292
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Lurasidone HCl - A 6-week Phase 3 Study of Patients With Bipolar I Depression (PREVAIL3)

This study has been completed.

Sponsor:
Sunovion

Information provided by (Responsible Party):
Sunovion

ClinicalTrials.gov Identifier:
NCT01284517

First received: January 25, 2011
Last updated: October 31, 2013
Last verified: October 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: August 7, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Bipolar Depression
Interventions:	Drug: Lurasidone Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Lurasidone 20-120 mg Flexible Dose+Li/VPA	Lurasidone 20-120 mg/day (PO) flexibly dosed+Lithium/divalproex
Placebo + Li/VPA	Placebo + Lithium/divalproex

Participant Flow: Overall Study

	Lurasidone 20-120 mg Flexible Dose+Li/VPA	Placebo + Li/VPA
STARTED	**180**	**176**
COMPLETED	**148**	**140**

NOT COMPLETED	32	36

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This is the full analysis set (intent-to-treat population)

Reporting Groups

	Description
Lurasidone 20-120 mg Flexible Dose+Li/VPA	No text entered.
Placebo + Li/VPA	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Lurasidone 20-120 mg Flexible Dose+Li/VPA	Placebo + Li/VPA	Total
Number of Participants [units: participants]	**176**	**166**	**342**
Age [units: participants]			
<=18 years	**3**	**0**	**3**
Between 18 and 65 years	**166**	**161**	**327**
>=65 years	**7**	**5**	**12**
Age [units: years] Mean (Standard Deviation)	**43.1 (11.90)**	**44.1 (11.99)**	**43.6 (11.94)**
Gender [units: participants]			
Female	**91**	**93**	**184**
Male	**85**	**73**	**158**
Region of Enrollment [units: participants]			
United States	**71**	**63**	**134**
Czech Republic	**9**	**8**	**17**
Slovakia	**17**	**21**	**38**
Canada	**9**	**8**	**17**
Ukraine	**17**	**14**	**31**
Lithuania	**10**	**9**	**19**
Peru	**6**	**7**	**13**
Colombia	**12**	**10**	**22**
Japan	**5**	**4**	**9**
India	**20**	**22**	**42**

Outcome Measures

Show All Outcome Measures

1. Primary: Mean Change From Baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score at Endpoint (Week 6) [Time Frame: Baseline to week 6]

Show Outcome Measure 1

2. Secondary: Mean Change From Baseline to Endpoint (Week 6) in: Clinical Global Impression Bipolar Version, Severity of Illness (CGI-BP-S) Score (Depression) [Time Frame: Baseline to week 6]

Show Outcome Measure 2

3. Secondary: Mean Change From Baseline to Endpoint (Week 6) in: Sheehan Disability Scale (SDS) Total Score [Time Frame: Baseline to week 6]

Show Outcome Measure 3

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** In addition to the <60-180 day restriction above, since this is a multicenter study, 1st publication of study results shall be made with other participating study sites as a multicenter publication; provided, if a multicenter publication is not forthcoming within 24 months following completion of study at all sites, the PI shall be free to publish.

Results Point of Contact:

Name/Title: Medical Director, CNS
Organization: Sunovion
phone: 1-866-503-6351

Responsible Party:	Sunovion
ClinicalTrials.gov Identifier:	NCT01284517 History of Changes
Other Study ID Numbers:	D**1050292** 2010-019778-34 (EudraCT Number)
Study First Received:	January 25, 2011
Results First Received:	August 7, 2013
Last Updated:	October 31, 2013
Health Authority:	United States: Food and Drug Administration United States: Institutional Review Board Canada: Health Canada China: Ministry of Health Colombia: National Institutes of Health Czech Republic: State Institute for Drug Control India: Drugs Controller General of India Japan: Pharmaceuticals and Medical Devices Agency Peru: Ministry of Health Slovakia: State Institute for Drug Control Ukraine: Ministry of Health