Trial record **1 of 1** for: 1050256
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# Lurasidone - A 24-week Extension Study of Patients With Bipolar I Depression

This study has been completed.

**Sponsor:**
Sunovion

**Information provided by (Responsible Party):**
Sunovion

**ClinicalTrials.gov Identifier:**
NCT00868959

First received: March 23, 2009
Last updated: March 15, 2016
Last verified: March 2016
History of Changes

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

Results First Received: February 17, 2014

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment |
| **Condition:** | Bipolar Depression |
| **Intervention:** | Drug: lurasidone |

## 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** |
|---|
| 817 represents the total number of subjects who provided informed consent and enrolled, which is different from the total number of subjects who were treated with study drug, which was 813. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Lurasidone** | lurasidone: Lurasidone 20-120 mg/d Flexibly Dosed - 24 weeks |

**Participant Flow: Overall Study**

| | **Lurasidone** |
|---|---|
| **STARTED** | **817** [1] |
| **COMPLETED** | **559** |
| **NOT COMPLETED** | **258** |

[1] 817 represents total number of subjects who provided informed consent.

## 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. |
|---|
| Safety population - received at least one dose of study medication |

**Reporting Groups**

| | Description |
|---|---|
| **Lurasidone** | lurasidone: Lurasidone 20-120 mg/d Flexibly Dosed - 24 weeks |

**Baseline Measures**

| | Lurasidone |
|---|---|
| **Number of Participants [units: participants]** | **813** |
| **Age [units: years] Mean (Standard Deviation)** | **42.7 (12.03)** |
| **Age [units: participants]** | |
| **<=18 years** | **6** |
| **Between 18 and 65 years** | **790** |
| **>=65 years** | **17** |
| **Gender [units: participants]** | |
| **Female** | **427** |
| **Male** | **386** |
| **Region of Enrollment [units: participants]** | |
| **United States** | **283** |
| **Slovakia** | **19** |
| **Ukraine** | **78** |
| **Lithuania** | **16** |
| **Russian Federation** | **31** |
| **Colombia** | **15** |
| **India** | **128** |
| **France** | **23** |
| **Czech Republic** | **108** |
| **Canada** | **14** |
| **Poland** | **12** |
| **Romania** | **9** |
| **Peru** | **12** |
| **South Africa** | **56** |
| | |

| | |
|---|---|
| Japan | 6 |
| Germany | 3 |

## Outcome Measures

Show All Outcome Measures

1. Primary: Number of Participants With Serious and Non-serious Treatment-emergent Adverse Events Who Have Completed 24 Weeks of Extension Study Treatment [ Time Frame: 24 weeks ]

**Show Outcome Measure 1**

2. Secondary: Change From Open-label Extension Baseline to Week 24 (Month 6/LOCF Endpoint) in Montgomery-Asberg Depression Rating Scale (MADRS) Total Score [ Time Frame: 24 weeks ]

**Show Outcome Measure 2**

3. Secondary: Change From Open-label Extension Baseline to Week 24 (Month 6/LOCF Endpoint) in Clinical Global Impressions Bipolar Version, Severity of Illness (CGI-BP-S) Score (Depression) [ Time Frame: 24 weeks ]

**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: | NCT00868959 History of Changes |
| Other Study ID Numbers: | D**1050256**<br>EUDRACT No. 2008-007483-42 |
| Study First Received: | March 23, 2009 |
| Results First Received: | February 17, 2014 |
| Last Updated: | March 15, 2016 |
| Health Authority: | United States: Food and Drug Administration<br>Czech Republic: State Institute for Drug Control<br>France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)<br>India: Drugs Controller General of India<br>Poland: Ministry of Health<br>Romania: National Medicines Agency<br>Russia: Ministry of Health of the Russian Federation<br>South Africa: Medicines Control Council<br>Ukraine: Ministry of Health<br>Canada: Health Canada<br>Colombia: National Institutes of Health<br>Peru: Ministry of Health<br>Lithuania: State Medicine Control Agency - Ministry of Health<br>Japan: Pharmaceuticals and Medical Devices Agency<br>Slovakia: State Institute for Drug Control<br>Germany: Ministry of Health |