

A phase III randomised, double-blind, active comparator-controlled clinical trial to study the safety and efficacy of lurasidone in subjects with schizophrenia (PEARL 3 extension study)

Submission date 14/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/05/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
D1050234

Study information

Scientific Title

Acronym

PEARL 3 Extension Study

Study objectives

Lurasidone HCl is a compound being developed for the treatment of schizophrenia. This clinical study is designed to test the hypothesis that lurasidone is effective, tolerable, and safe as compared with quetiapine XR long-term among schizophrenic outpatients with chronic schizophrenia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

USA: Copernicus Group IRB, approved on 05/09/2008.

All other centres will seek ethics approval before recruitment of the first participant.

Study design

Randomised double-blind active comparator-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Subjects who meet entry criteria will continue treatment with either flexibly dosed lurasidone or quetiapine XR based on their treatment assignment in Study D1050233 in a double-blinded fashion. Subjects treated with placebo in Study D1050233 will be treated with lurasidone.

Arm 1: Lurasidone HCl 40-160 mg/day orally for 12 months

Arm 2: Quetiapine XR 200-800 mg/day orally for 12 months

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Lurasidone HCl, quetiapine XR

Primary outcome(s)

1. Primary efficacy endpoint:

1.1. Time to relapse of psychotic symptoms in subjects to measure the long-term maintenance of antipsychotic efficacy of lurasidone compared with quetiapine XR.

2. Primary safety endpoints:

The proportion of subjects with:

2.1. Adverse Events (AEs)

2.2. Discontinuations due to AEs

2.3. Serious Adverse Events (SAEs)

AEs will be monitored throughout the study until Month 12.

Key secondary outcome(s)

Efficacy endpoints of interest:

Time to relapse of psychotic symptoms. Mean change from D1050233 baseline in the Positive and Negative Syndrome Scale (PANSS): positive score, negative score, and excitability score. PANSS will be carried out at Month 3, 6, 9, 12 in this extension study.

Completion date

01/12/2010

Eligibility

Key inclusion criteria

Screening for the present study will take place after subjects' participation in Study D1050233 has been completed, and after providing informed consent.

Principal inclusion criteria:

1. Males and females 18-75 years of age inclusive
2. Provide written informed consent
3. Completed all required assessments on the final study visit in Study D1050233
4. Suitable for treatment in an outpatient setting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

1. Any chronic organic disease of the central nervous system (CNS) (other than schizophrenia)
2. Considered by the investigator to be at imminent risk of suicide or injury to self, others, or property

Date of first enrolment

01/12/2008

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Colombia

Germany

India

Philippines

Romania

Russian Federation

Ukraine

United States of America

Study participating centre

Dainippon Sumitomo Pharma America Inc.

New Jersey

United States of America

07024

Sponsor information

Organisation

Dainippon Sumitomo Pharma America Inc. (USA)

ROR

<https://ror.org/04vwbmb32>

Funder(s)

Funder type

Industry

Funder Name

Dainippon Sumitomo Pharma Co. Ltd. (Japan)

Alternative Name(s)

Dainippon Sumitomo Pharma Co., Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Japan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration