

Major Depressive Disorder Case Study

A Phase 1, Single-center, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, and Pharmacokinetics of Ascending Multiple Oral Doses of XXXXX as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder

St. Louis Clinical Trials

Indication: Major Depressive Disorder
of Subjects: 32 Randomized (2 cohorts of 16)
Inpatient Period: 18 days

OBJECTIVES

Primary

To determine the safety and tolerability of XXXXX when administered as adjunctive therapy to other antidepressant therapy (ADT) to MDD patients following multiple ascending oral doses.

Secondary

To determine the steady-state pharmacokinetics (PK) of XXXXX and its metabolites in MDD patients following multiple oral doses of XXXXX.

Ratings

Mini International Neuropsychiatric Interview (M.I.N.I.), Simpson Angus Scale (SAS), Abnormal Involuntary Movement Scale (AIMS), Barnes Akathisia Rating Scale (BARS), Columbia-Suicide Severity Rating Scale (C-SSRS)

Lab Assessmentss — 24 per subject:

Screening
Day -1
Days 1: pre-dose
Days 16: pre-dose Days 17: pre-dose
Day 18: pre-dose, 0.5, 1, 2, 3, 4, 6, 8, 12, 16, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

ECGs—42 per subject:

Screening
Day -1
Day 1: pre-dose, 2, 4, and 6 hours post-dose
Days 2 to 4: pre-dose
Days 5: pre-dose, 2, 4, 6, 8 and 12 hours post-dose
Days 6 to 17: pre-dose only
Days 18: pre-dose, 2, 4, 6, 8, 12, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

- Resting 12-lead ECG performed after the subject has been supine at rest for 10 minutes

Key Elements:

- 16 Patient Cohorts
- Complex Procedure Schedule

Vitals—42 per subject in triplicate = 126

Screening
Day -1
Day 1: pre-dose, 2, 4, and 6 hours post-dose
Days 2 to 4: pre-dose
Day 5: pre-dose, 2, 4, 6, 8 and 12 hours post-dose
Days 6 to 17 at pre-dose
Day 18: pre-dose, 2, 4, 6, 8, 12, 24, 48, 72, 96, 120, 144, 168, 192, and 216 hours post-dose

- Blood pressure and heart rate taken in the supine, sitting, and standing positions after remaining for 3 minutes in each position.
- Respiratory rate and oral body temperature taken with the subject in the supine position.