



A Pilot, Multi-Center, Randomized, Double-Blind, Comparator-Controlled Study to Assess the Tolerability, Safety, Efficacy and Pharmacokinetics of Ascending Multiple Oral Doses of XXXXX in Adult Subjects with a Diagnosis of Schizophrenia

Rick Mofsen, DO

Key Elements:

- Complex Design
- Long Confinement
- High Enrollment

Phase: Ib

Indication: Schizophrenia (Stable)

of Subjects: 32 randomized (2 cohorts of 16)

In-patient Period: 30 Days

Primary Objectives

- Tolerability and safety of XXXXX following single and multiple ascending oral dosing Secondary
- Pharmacokinetic (PK) profile of XXXXX and its metabolites in plasma following single and multiple ascending oral dosing of XXXXX
- Evaluate the ability of XXXXX to maintain a stable symptom profile in subjects with schizophrenia

Ratings

Positive and Negative Syndrome Scale (PANSS)

Abnormal Involuntary Movement Scale (AIMS)

Simpson-Angus Neurologic Rating Scale (SAS)

Barnes-Akathisia Rating Scale (BARS)

Clinical Global Impression Severity Scale (CGI-S)

Lab Assessments—33 per subject

Screening

Day 1: Pre-dose, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72 and 96 hours

Days 16-18: Pre-dose

Day 18: Pre-dose, 1, 2, 4, 6, 8, 12, 16, 24, 36, 48, 72, 96, 120, 144, and 168 hours

ECGs—21 per subject

Screening

Day 1: Pre-dose, 1, 2, 4, 8, 12, 24, 36, 48, 72 and 96 hours

Days 16-18: Pre-dose, 4 and 8 hours

Day 25: Pre-dose

- Standard 12-lead ECGs
- Subjects need to be supine and at rest for ≥ 10 minutes prior to the ECG.

Vitals—19 per subject

Screening

Day 1: Pre-dose, 1, 2, 4, 8, 12, 24, 36, 48, 72 and 96 hours

Days 16-18: Pre-dose, 4 and 8 hours

Day 25: Pre-dose

- Orthostatic (supine, sitting and standing) blood pressure and heart rate, body temperature and respiration rate.
- Orthostatic assessments are to be made after subjects have been in the supine position for at least 5 minutes and again after subjects have been standing for 2 minutes.

Achievements

- Met enrollment roles 3 weeks early
- All queries resolved and database locked within 3 weeks of last patient last visit (LPLV)