

# Stable Schizophrenia Phase 1b Complex Design Case Study

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

## St. Louis Clinical Trials

**Phase:** 1b

**Indication:** Schizophrenia (Stable)

**# of Subjects:** 32 randomized (2 cohorts of 16)

**Inpatient Period:** 30 Days

## OBJECTIVES

### Primary

- Tolerability and safety of XXXXX following single and multiple ascending oral dosing
- 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)

### 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.

### 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.

### Achievements

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

### Key Elements:

- Complex Design
- Long Confinement
- High Enrollment