

**An Open-Label, Parallel-Arm, Two-Period, Single-Dose Pilot Study to Assess the Pharmacokinetics and the Effect of Food on the Pharmacokinetics of Five Once Weekly Oral Formulations of XXXXX in Adult Subjects with Schizophrenia**

Rick Mofsen, DO

**Key Elements:**

- Inpatient
- Long Confinement
- High Enrollment

**Phase: 1b**

Indication: Schizophrenia (Staple)  
Start Date: September, 2009  
# of Subjects: 30 Randomized  
In-patient Period: 28 days

**Objectives**

**Primary**

Pharmacokinetics of XXXXX and its metabolite in plasma following administration of once weekly XXXXX tablets in the fasted state and after a high fat meal.

**Secondary**

Safety and tolerability of XXXXX following administration of once weekly XXXXX

**Ratings**

Abnormal Involuntary Movement Scale (AIMS)  
Simpson-Angus Neurologic Rating Scale (SAS)  
Barnes-Akathisia Rating Scale (BARS)  
Clinical Global Impression Severity Scale (CGI-S)  
Clinical Global Impression for Severity of Suicidality (CGI-SS)  
Columbia Suicide Scale  
Epworth Sleepiness Scale (ESS)

**Lab Assessments—43 per subject**

Screening

Day -3: Pre-dose, 12, 24, 36, 48 and 60 hours

Day 1: Pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, 14, 24, 36, 48, 72, 96, 120, 144, 168 hours

Day 8: Pre-dose, 1, 2, 3, 4, 6, 8, 10, 12, 14, 24, 36, 48, 72, 96, 120, 144, 168 hours

**ECGs**

Screening

Day 1: Pre-dose, 3, 5, 8 and 24 hr

Day 8: Pre-dose, 3, 5, 8 and 24 hr

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

**Vitals**

Screening

Day 1: Pre-dose, 3, 5, 8 and 24 hr

Day 8: Pre-dose, 3, 5, 8 and 24 hr

- 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.