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Schizophrenia Case Study 1

A Phase 2 Six Week, Multicenter, Randomized Double-Blind Placebo Controlled Study to Evaluate Efficacy Safety and Tolerability Of Oral XXXXX Once Daily and Aripirizole Once Daily for Treatment of Hospitalized Adult Patients with Acute Schizophrenia

Rick Mofsen, DO

Key Elements:
- Inpatient
- Long Confinement

Phase: 2
Indication: Schizophrenia (Acute)
# of Subjects: 10
In-patient Period: 6 weeks

Objectives
Primary
Change in PANSS Total Score

Secondary
Comparison of treatment group vs. placebo
- CGI-S and CGI-I scores
- PANSS positive subscale score
- PANSS negative subscale score
- Response rate
- PSP score

Ratings
Positive and Negative Syndrome Scale (PANSS)
Clinical Global Impression-Severity (CGI-S)
Clinical Global Impression-Improvement (CGI-I)
Personal and Social Performance Scale (PSP)
Simpson-Angus Scale (SAS)
Abnormal Involuntary Movement Scale (AIMS)
Barnes Akathisia Rating Scale (BARS)
Columbia-Suicide Severity Rating Scale (C-SSRS)

Lab Assessments
Screening
Day 1: 0.5, 3, 10, and 20 hr post-dose
Week 3: 0.5, 3, 10, and 20 hr post-dose

ECGs
Weekly
Standard 12-lead ECGs performed supine and at rest for ≥ 5 minutes prior to the ECG.

Vitals
Weekly
Blood pressure and heart rate measured in the supine, sitting, and standing positions after the subject has been in each position for at least 3 minutes.