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Schizophrenia Case Study 5

A Phase 2a, Multicenter, Randomized, Double-Blind, Active-Controlled Pilot Polysomnography Study of the Effects of XXXXX on Sleep in Adult Subjects with Stable Schizophrenia

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Key Elements:

- Complex Design
- PK, ECG, PSG, Actigraphy

Phase: 2a

Indication: Schizophrenia (Stable)

of Subjects: 10

In-patient Period: 35 days

Objectives

Primary

Examine the XXXXX sleep profile compared to aripiprazole as measured by polysomnography

Secondary

Compare the XXXXX efficacy via:

- Positive and Negative Syndrome Scale
- Clinical Global Impression - Severity of Illness scale (CGI-S) and Clinical Global Impression – Improvement scale (CGI-I)

Ratings

Positive and Negative Syndrome Scale (PANSS)

Clinical Global Impression Severity Scale (CGI-S)

Clinical Global Impression Improvement Scale (CGI-I)

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 Assessments – 16 per subject

Screening

Day 1, Day 14, Day 15, Day 21: Pre-dose, 1, 2, 3, 4, 5, 6, 8, 12 and 24 hours, Day 28, Day 29

ECGs – 5 per subject

Day -7

Day 1

Day 14

Day 28

- Standard 12-lead ECGs performed after the subject has been supine and at rest for ≥ 5 minutes

Vitals – 29 per subject

Daily

- Blood pressure and heart rate measured in supine, sitting, and standing positions after rest in each position for 3 mins

Computerized Cognition Testing

Day -1, Day -2, Day 1, Day 27, Day 28

Polysomnography

Day -8, Days -2 & -1, Days 6 & 7, Days 13 & 14, Days 27 & 28

Actigraphy

Continuous measurements from Day -2 thru Day 29