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Schizophrenia Case Study 8

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of XXX-XXXX (90 mg and 120 mg) as a Treatment in Subjects with Acute Schizophrenia Over 8 Weeks (2 Subcutaneous Doses)

Bernadette D'Souza, MD

Key Elements:
- Long Confinement

Phase: 3
Indication: Schizophrenia
# of Subjects: 15
In-patient Period: 60 days

Objectives
Primary
To assess the efficacy of XXX-XXXX (90 mg and 120 mg) compared with placebo on the symptoms of schizophrenia over an 8-week treatment period using the change from baseline to end of treatment in the total Positive and Negative Syndrome Scale (PANSS) score, which is the sum of all 30 PANSS items.

Secondary
- To assess the efficacy of XXX-XXXX (90 mg and 120 mg doses) compared with placebo over an 8-week treatment period using the change from baseline to end of treatment in the Clinical Global Impression – Severity of Illness (CGI-S) Scale.
- To establish a pharmacokinetic (PK)/pharmacodynamic(PD) model using non-linear mixed effect modeling approach.

Ratings
Positive and Negative Syndrome Scale (PANSS)
Clinical Global Impression Severity Scale (CGI-S)
Abnormal Involuntary Movement Scale (AIMS)
Barnes Akathisia Rating Scale (BARS)
Columbia-Suicide Severity Rating Scale (C-SSRS)

Lab Assessments—4 per subject
Screening, Day 1, Day 29, Day 57

ECGs—4 per subject
Prescreening
Day 1
Day 29
Day 57
- Standard 12-lead ECGs performed after the subject has been supine and at rest for ≥ 5 minutes

Vitals—9 per subject
Prescreening, Day -1, Day 1, Day 2, Day 15, Day 29, Day 30, Day 43, Day 57
- Includes blood pressure, pulse, respiratory rate, and oral temperature after 5 minutes in the supine position.