THIEVON-WRIGHT
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Schizophrenia Case Study 7

A phase II randomized, double-blind, placebo-controlled, and active-controlled trial was conducted at eight sites in the United States with randomization of 335 acutely psychotic adults with schizophrenia. XXX-XXX (60 mg and 120 mg), placebo, and risperidone, included for assay sensitivity, were evaluated as monotherapy for 4 weeks

Key Elements:

- Long Confinement Period
- High Enrolling Sites
- High Retention Rate
- Novel Compound

Phase: 2
Indication: Schizophrenia (Acute)
End Date: November 2013
# of Subjects: 335
In-patient Period: 40 days

Objectives:
Primary
Change in total Positive and Negative Syndrome Scale (PANSS) score from baseline to day 28

Secondary:
Change in total Positive and Negative Syndrome Scale (PANSS) score from baseline to day 8, 15 and 22

Ratings:
Positive and Negative Syndrome Scale (PANSS)
Calgary Depression Scale for Schizophrenia (CDSS)
Brief Psychiatric Rating Scale (BPRS)

Safety End Point Assessments:
Simpson-Angus Scale
Barnes Akathisia Ratings Scale
Abnormal Involuntary Movement Scale
Columbia Suicide Severity Rating Scale
Clinical Laboratory Assessments
Vital Signs
ECGS

Achievements:
Of the 8 participating sites, 5 were TWCG network members
Enrolled 236 patients or 70% of the 335 study total
81% of subjects completed study treatment, providing a study completion rate of 74%