Evolution Research Group
430 Mountain Avenue, Suite 302
New Providence, NJ 07974
www.ergclinical.com
Office: 908.756.4411 | Fax: 908.756.1122
Email: info@ergclinical.com

Acute Schizophrenia PANSS Case Study

A Phase 2, Multicenter, Double-Blind, Randomized, Parallel Group, 4-Week Inpatient Study to Evaluate the Safety and Efficacy of Two Fixed Doses of XXXXX Compared to Placebo in the Treatment of Acute Exacerbation of Schizophrenia Using Risperidone as an Active Control

St. Louis Clinical Trials

Indication: Schizophrenia (Acute)
# of Subjects: 13 subjects screened; 5 subjects screen failed; 6 completed; 2 terminated early
Inpatient Period: 28-35 Days

Key Elements:
- Clintara Review
- Long Confinement
- Inpatient

OBJECTIVES

Primary
- Efficacy using the PANSS to measure change in symptoms
- Safety and tolerability of two fixed dose regimens of XXXXX
- Incidence rate of dystonia

Secondary
- Safety: Adverse events, weight and abdominal girth, vital signs, physical examination, neurological examination, electrocardiogram (ECG) and clinical laboratory findings
- Change from baseline to Week 4 on:

- PANSS
- CGI-Severity
- Brief Psychiatric Rating Scale (BPRS)
- CGI-Improvement
- Global Assessment of Functioning (GAF)
- Treatment Satisfaction Questionnaire for Medication (TSQM)

Ratings
Brief Psychiatric Rating Scale (BPRS)
Positive and Negative Syndrome Scale (PANSS)
Clinical Global Impression-Severity (CGI-S)
Clinical Global Impression-Improvement (CGI-I)
Abbreviated Extrapyramidal Symptom Rating Scale (ESRS-A)
Global Assessment of Functioning (GAF)
Treatment Satisfaction Questionnaire for Medication (TSMQ)
Columbia-Suicide Severity Rating Scale (C-SSRS)
Suicidal Behavior Questionnaire Revised (SBQ-R)

Lab Assessments—43 per subject
Screening, Days 1-28, Follow-up

ECGs (Triplicate)
Screening, Day 1, Day 14, Day 28, Follow-up

Vitals
Screening, Days 1-29, Follow-up

Clintara
- Appropriate subject selection confirmed by Clintara through C-Visa (Clinical Validation Inventory for Subject Admission)
  - Diagnostic verification, symptom severity confirmation, subject validity and reliability
- All 13 subjects screened by St. Louis Clinical Trials passed independent review by Clintara without disagreement (i.e., no tier 2 review necessary)