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CC-CHOC Pediatric Point Person Project (P4)
Protocol Information Form

Follow this link to indicate your interest in Protocol **# 5.10 Psych** https://redcap.ctsacentral.org/surveys/?s=7Gifps

Submitted May 7, 2012

Participant ID 5.10

Sponsor CRO

Study Title A Phase 1 Open-Label, Multicenter, Single and Multiple Ascending Dose Study to Evaluate Pharmacokinetics, Safety, and Tolerability in Subjects 6 to 17 Years Old with Schizophrenia Spectrum, Bipolar Spectrum, Autistic Spectrum Disorder, or Other Psychiatric Disorders

Target Population 6 to 17 years old with schizophrenia spectrum, bipolar spectrum, autistic spectrum disorder, or other psychiatric disorders

Study Objectives The purpose of this study is to characterize study drug PK following single and multiple oral doses of 20, 40, or 80 mg/day in the targeted pediatric population. Data from this study will be used to recommend pediatric doses that result in comparable exposures to those seen in adults given labeled doses of the study drug in subsequent efficacy and safety studies. To characterize the pharmacokinetics (PK) and assess safety and tolerability of single and multiple oral doses of 20, 40, or 80 mg/day study drug in subjects 6 to 17 years old with schizophrenia spectrum, bipolar spectrum, autistic spectrum disorder, or other psychiatric disorders.

Key Inclusion/Exclusion Criteria

Inclusion:

- Male or female subjects 6 to 17 years of age, inclusive.
- Subject is judged by the investigator to be clinically stable but symptomatic
- Subjects with the following diagnoses will be eligible for participation: primary schizophrenia spectrum diagnosis; bipolar spectrum disorder, pervasive developmental disorder (PDD) including autistic spectrum disorder, or Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS), attention-deficit hyperactivity (ADHD) with aggressive behavior, or Tourette's syndrome,
- Willing and able to remain off any antipsychotic medication other than study drug for the duration of the study,

Exclusion:

- Known history or presence of clinically significant intolerance to any antipsychotic medications

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Short Overview of Study Design

- Subjects from four age groups (6-9, 10-12, 13-15, and 16-17 years) will receive sequential escalating doses of study drug (20, 40, or 80 mg/day).
- This study will consist of a screening period (Day -28 to Day -2), followed by a study period (Day -1 to Day 11), and a follow-up period (14 +/- 3] days after the last dose of study medication). During the study period, subjects will have 2 in-patient visits (Day -1 to Day 2, and Day 9 to Day 11) for dosing and study assessments, and a telephone contact (Day 6) for assessment of safety and study medication compliance.
- Dosing of subsequent dose cohorts in each age group will not occur until a review of safety data from the prior dose level for each age group has been completed.

Study Synopsis

Total Number of Patients to be Enrolled 48 patients -6 sites required

Enrollment Period 10 months

Miscellaneous Details/Requirements

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Any question? Email ctsa_childhealth@ctsaC4.org