Finger Lakes Clinical Research

Professional Resource: Pediatric Trials

FLCR pediatric trial information for health professionals

Following is summary information on our currently-enrolling pediatric trials. Pease contact Dr. Atkinson at 585.241.9670 or sda@flclinical.com if you have a patient who might be a candidate for one of these studies.

ADHD With Aggression (Supernus)

Protocol(s): 810P301, 810P304

(NOTE: 810P304 is an open label extension)

Age range: 6-12 (810P301), Open label extension (810P304)

Study summary: 810P301 evaluates the efficacy, safety and tolerability of SPN-810 in the treatment of impulsive aggression in subjects with Attention Deficit/Hyperactivity Disorder (ADHD) in conjunction with standard ADHD treatment.

810P304: Children between the ages of 6-12 years who are diagnosed with impulsive aggression comorbid with ADHD and have participated in the 810P301 or 810P302 study are invited to participate in this study. This is a Phase 3 open label extension (OLE) study with the objective of collecting long-term safety data on the use of SPN-810 in treating impulsive aggression in pediatric subjects with ADHD, when taken in conjunction with standard ADHD treatment. After confirmation of eligibility, all subjects will be treated with SPN-810.Subjects will be given a choice to extend participation in this study every 6 months for up to 36 months.

Bipolar I Disorder (Pfizer)

Protocol(s): A1281198

(NOTE: After-care is provided with this study)

Age range: 10-17

Study summary: The purpose of this study is to determine if ziprasidone is safe and effective for the treatment of children and adolescents (ages 10-17) with bipolar I disorder (manic or mixed).

Depression, OCD, GAD (Pfizer)

Protocol(s): A0501093

Age range: 6-16

Study summary: To evaluate the long-term impact of treatment with sertraline on aspects of cognitive, emotional and physical development and pubertal maturation in pediatric subjects ages 6 to 16 years (inclusive) with a diagnosis of anxiety disorder, depressive disorder or obsessive compulsive disorder.

Major Depressive Disorder (Forest)

Protocol(s): VLZ-MD-22

(NOTE: This study has an open label extension)

Age range: 7-17

Study summary: The purpose of this study is to evaluate the efficacy, safety, and tolerability of vilazodone compared with placebo in pediatric outpatients (7-17 years of age) with major depressive disorder.

Major Depressive Disorder (Lundbeck)

Protocol(s): 12709A, 12170A

(NOTE: After-care is provided with this study)

Age range: 7-11 (12709A), 12-17 (12710A)

Study summary: 12709A Investigates the efficacy and safety of a fixed-dose of vortioxetine in Pediatric Patients Aged 7 to 11 with Major Depressive Disorder (MDD).

12710A Evaluates the efficacy of vortioxetine 10 mg/day and 20 mg/day versus placebo on depressive symptoms in adolescents (age ≥12 and ≤17 years) with a DSM-5 diagnosis of Major depressive disorder (MDD).

Schizophrenia (Amarex)

Protocol(s): SNR01-NaBen

Age range: 12-17

Study summary: The purpose of this study is to evaluate the efficacy and safety of Naben (Sodium Benzoate), a D-amino acid oxidase inhibitor, as an add-on treatment for schizophrenia in adolescents.