

# SND111 STUDY

CLINICAL RESEARCH STUDY ON ADOLESCENT SCHIZOPHRENIA

## Investigational Product (NaBen<sup>®</sup>)/Study Background:

Hypofunction of the N-methyl-D-Aspartate receptor (NMDAR) plays an important role in the pathophysiology of schizophrenia. Enhancing NMDAR-mediated neurotransmission is considered a novel treatment approach in improving schizophrenia associated symptoms. One method to enhance NMDA function is to raise the levels of D-amino acid (DAA) by reducing their metabolism via DAA oxidase (DAAO) inhibitors.

NaBen<sup>®</sup> (sodium benzoate) is a readily available DAAO inhibitor with a well-developed safety profile, and has received the FDA orphan product designation for the indication of schizophrenia in the pediatric population, as well as breakthrough therapy designation in adult schizophrenia. Previous studies have shown excellent efficacy and safety for NaBen<sup>®</sup> in improving schizophrenia symptoms.

This multi-center, randomized, placebo-controlled, parallel-group study is to further assess the safety and efficacy of NaBen<sup>®</sup> in improving symptoms of schizophrenia in

NaBen<sup>®</sup> will be an “add-on” medication for this study. Subjects will NOT be taken off their current antipsychotics.

12-17 year old subjects with an established diagnosis of Schizophrenia.

## Study Visits:

There will be a total of 7 visits during 10 weeks including screening, double-blind treatment and follow-up phases.

## Eligibility Criteria for SND111 study:

### Major Inclusion criteria:

- 1) Teens between 12 and 17 years of age
- 2) Confirmed diagnosis of schizophrenia
- 3) Clinically stable with residual symptoms (PANSS  $\geq$  60 and SANS  $\geq$  40)
- 4) On an unchanged antipsychotic medication regimen for at least eight weeks prior to randomization into the study and expected to remain unchanged during the study

### Major Exclusion criteria:

- 1) Meeting the DSM criteria for major mental illness other than schizophrenia at Screening
- 2) Schizophrenia resistant to antipsychotics
- 3) Current substance abuse or positive urine illicit drug screening or history of substance dependence
- 4) Use of depot antipsychotics in the past six months
- 5) Body Mass Index  $>$  35

Study Website: [www.syneurxtrials.com](http://www.syneurxtrials.com)

Toll-free: **1-866-971-0917**

For further information please contact:

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