Treatment of Impulsive Aggression in Subjects With ADHD in Conjunction With Standard ADHD Treatment (CHIME 1)

This study is not yet open for participant recruitment. (see Contacts and Locations)

Verified November 2015 by Supernus Pharmaceuticals, Inc.

Sponsor:
Supernus Pharmaceuticals, Inc.

Information provided by (Responsible Party):
Supernus Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT02618408

First received: November 20, 2015
Last updated: November 25, 2015
Last verified: November 2015

Purpose

The purpose of this study is to demonstrate 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. Approximately 291 subjects aged 6 to 12 years with ADHD and comorbid impulsive aggression will be recruited in this study. The frequency of impulsive aggression behaviors will be assessed as a primary outcome. Additionally, the severity and improvement in impulsive aggression, and quality of life measures for the subject and caregiver will be assessed using validated scales.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder (ADHD)</td>
<td>Drug: SPN-810 Drug: Placebo</td>
<td>Phase 3</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment
Further study details as provided by Supernus Pharmaceuticals, Inc.:

Primary Outcome Measures:

- Frequency of impulsive aggression behaviors per 7 days over a period of 7 weeks. [Time Frame: 7 weeks] [Designated as safety issue: No]
  
The frequency of impulsive aggression behaviors will be assessed using an impulsive aggression diary, a newly developed and validated electronic observer reported outcome measurement tool.

Estimated Enrollment: 291

Study Start Date: December 2015

Estimated Primary Completion Date: February 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: Low dose SPN-810  
Subjects will be treated with low dose SPN-810 | Drug: SPN-810 |
| Experimental: High dose SPN-810  
Subjects will be treated with high dose SPN-810 | Drug: SPN-810 |
| Placebo Comparator: Placebo  
Subjects will be treated with a Placebo | Drug: Placebo |

Eligibility

Ages Eligible for Study: 6 Years to 12 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Otherwise healthy male or female subjects, age 6 to 12 years at the time of screening with a primary diagnosis of ADHD and currently receiving monotherapy treatment with an optimized FDA-approved ADHD medication.
- Impulsive aggression will be confirmed at screening using R-MOAS and Vitiello Aggression Scale.

Exclusion Criteria:

- Current or lifetime diagnosis of epilepsy, major depressive disorder, bipolar disorder, schizophrenia or related disorder, personality disorder, Tourette's disorder, or psychosis not otherwise specified.
- Currently meeting DSM criteria for autism spectrum disorder, pervasive developmental disorder, obsessive compulsive disorder, post-traumatic stress disorder, or any other anxiety disorder as primary diagnosis.
- Known or suspected intelligence quotient (IQ) < 70, suicidality, pregnancy, or substance or alcohol abuse.

Contacts and Locations
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02618408

Contacts
Contact: Stefan Schwabe, MD, PhD  301-838-2527  sschwabe@supernus.com

Sponsors and Collaborators
Supernus Pharmaceuticals, Inc.

No publications provided

Responsible Party: Supernus Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier: NCT02618408  History of Changes
Other Study ID Numbers: 810P301
Study First Received: November 20, 2015
Last Updated: November 25, 2015
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Mental Disorders
Mental Disorders Diagnosed in Childhood

ClinicalTrials.gov processed this record on December 01, 2015