Treatment of Impulsive Aggression (IA) in Adolescent With ADHD in Conjunction With Standard ADHD Treatment

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03597503

Recruitment Status: Not yet recruiting
First Posted: July 24, 2018
Last Update Posted: July 24, 2018
See Contacts and Locations

Sponsor:
Supernus Pharmaceuticals, Inc.

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

Study Description

Brief Summary:
The purpose of this study is to evaluate the effect of SPN-810 for the treatment of impulsive aggression (IA) in adolescents diagnosed with ADHD when taken in conjunction with standard ADHD treatment.

Condition or disease

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Drug</th>
</tr>
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<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
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Detailed Description:

This study is an addition to the ongoing pediatric studies (CHIME 1 and CHIME 2) to assess the efficacy and safety of SPN-810 in the improvement of impulsive aggression (IA) behaviors in adolescents with ADHD.

SPN-810 will be administered in patients diagnosed with ADHD and comorbid IA, who are currently being treated with an FDA-approved standard ADHD treatment and with persistent IA behaviors. The frequency of impulsive aggressive behaviors will be assessed as a primary outcome.

Study Design

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 186 participants
Allocation: Randomized
Intervention Model: Parallel Assignment

Intervention Model Description: Double-blind, randomized, parallel group, two-arm, placebo-controlled study with flexible dosing

Masking: Triple (Participant, Care Provider, Investigator)

Primary Purpose: Treatment

Official Title: Assessment of Efficacy and Safety of SPN-810 for the Treatment of Impulsive Aggression (IA) in Adolescent Subjects With Attention Deficit/Hyperactivity Disorder (ADHD) in Conjunction With Standard ADHD Treatment

Estimated Study Start Date: July 31, 2018
Estimated Primary Completion Date: July 29, 2019
Estimated Study Completion Date: December 20, 2019

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Flexible dose of SPN-810</td>
<td>Drug: SPN-810</td>
</tr>
<tr>
<td>Subjects will be treated with flexible dose of SPN-810</td>
<td>Flexible dose</td>
</tr>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo</td>
</tr>
<tr>
<td>Subjects will be treated with Placebo</td>
<td>Placebo</td>
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</tbody>
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Outcome Measures

Primary Outcome Measures:

1. Frequency of impulsive aggression behaviors per 7 days over a period of 7 weeks [Time Frame: 7 weeks]

   The frequency of impulsive aggression behaviors will be measured using an impulsive aggression (IA) diary, developed by the sponsor as an electronic observer-reported outcome (eObsRO) instrument.

Eligibility Criteria

Information from the National Library of Medicine
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, Learn About Clinical Studies.

Ages Eligible for Study: 12 Years to 17 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Otherwise, healthy non-smoking, male and females adolescents (12-17 years of age at the time of screening) with a primary diagnosis of ADHD and currently taking an optimized FDA-approved ADHD medication.
- IA will be confirmed at screening using R-MOAS scale and Vitiello Aggression Questionnaire.

Exclusion Criteria:

- History or current diagnosis of epilepsy, major depressive disorder, bipolar disorder, schizophrenia and other psychotic disorders, personality disorder, Tourette's syndrome or dissociative disorder, autism spectrum disorder, pervasive developmental disorder, obsessive compulsive disorder, post-traumatic stress disorder, or intermittent explosive disorder.
- Currently meeting DSM-5 criteria for pervasive developmental disorder, obsessive compulsive disorder, post-traumatic stress disorder or intermittent explosive disorder.
- Known or suspected intelligence quotient (IQ) <70, active suicidal plan/intent or active suicidal thought, criminal arrest, alcohol or drug use or pregnancy.

Contacts and Locations
Go to Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03597503

Contacts
Contact: Ronald Marcus, MD 301-838-2569 rmarcus@supernus.com

Sponsors and Collaborators
Supernus Pharmaceuticals, Inc.

More Information
Go to

Responsible Party: Supernus Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier: NCT03597503 History of Changes
Other Study ID Numbers: 810P503
First Posted: July 24, 2018 Key Record Dates
Last Update Posted: July 24, 2018
Last Verified: July 2018

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No
Additional relevant MeSH terms:
- Attention Deficit Disorder with Hyperactivity
- Hyperkinesis
- Aggression
- Attention Deficit and Disruptive Behavior Disorders
- Neurodevelopmental Disorders
- Mental Disorders

- Dyskinesias
- Neurologic Manifestations
- Nervous System Diseases
- Signs and Symptoms
- Behavioral Symptoms