Open-label Study to Evaluate Long-term Safety and Efficacy of SPN-812 ER

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

Verified April 2016 by Supernus Pharmaceuticals, Inc.

Sponsor:
Supernus Pharmaceuticals, Inc.

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

ClinicalTrials.gov Identifier:
NCT02736656

First received: April 4, 2016
Last updated: April 7, 2016
Last verified: April 2016
History of Changes

Purpose
This is a multicenter, open-label extension study aimed to assess long-term safety and efficacy of SPN-812 ER when administered alone or in conjunction with an FDA-approved ADHD medication in the treatment of ADHD in pediatric subjects who have participated in a previous blinded study of SPN 812 ER. All pediatric subjects who complete a blinded study of SPN 812 ER will have the option to participate in this study in which all subjects receive SPN 812 ER. After an initial dose, subjects will enter an dose optimization phase for three to nine weeks. Following optimization, subjects will return to the clinic every 3 months or until the subject discontinues or the study ends at 36 months.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Drug: SPN-812 ER</td>
<td>Phase 3</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Further study details as provided by Supernus Pharmaceuticals, Inc.:
Primary Outcome Measures:

- Incidence of adverse events [Time Frame: 36 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Trends in Attention Deficit/Hyperactivity Disorder Rating Scale (ADHD-RS-IV) Score [Time Frame: ADHD-RS-IV will be administered at baseline and every 3 months for up to 36 months] [Designated as safety issue: No]
- Trends in Clinical Global Impression-Improvement (CGI-I) and Clinical Global Impression-Severity (CGI-S) score [Time Frame: CGI-S will be assessed at baseline and every 3 months for up to 36 months and CGI-I will be assessed every 3 months for up to 36 months.] [Designated as safety issue: No]

Estimated Enrollment: 200

Study Start Date: April 2016

Estimated Study Completion Date: April 2019

Estimated Primary Completion Date: April 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Open-Label Treatment</td>
<td>Drug: SPN-812 ER</td>
</tr>
<tr>
<td>Subjects aged 6-12 years will be treated with SPN-812 ER followed by dose optimization. The subject will be given a choice to extend their participation in the study every 6-months for up to 36 months.</td>
<td></td>
</tr>
</tbody>
</table>

Eligibility

Ages Eligible for Study: 6 Years to 12 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Completion of a previous blinded study of SPN-812 ER for the treatment of ADHD.
2. Continues to be medically healthy and with clinically normal laboratory profiles, vital signs, and electrocardiograms (ECGs).
3. Weight of at least 20 kg.
4. Written Informed Consent obtained from the subject's parent or legally authorized representative (LAR); written Informed Assent obtained from the subject if appropriate.

Exclusion Criteria:
1. Diagnosis of major depressive disorder, bipolar disorder, personality disorder, Tourette's disorder, or psychosis not otherwise specified.
2. Currently meeting DSM-V criteria for an anxiety disorder as primary diagnosis.
3. Current evidence of suicidality (suicidal thoughts or behaviors).
4. Body Mass Index greater than 95th percentile for the appropriate age and gender.
5. Pregnancy, or refusal to practice contraception during the study (for female subjects of childbearing potential).
6. Current substance or alcohol use.
7. Any reason which, in the opinion of the Investigator, would prevent the subject from participating in the study.

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: NCT02736656

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

Sponsors and Collaborators
Supernus Pharmaceuticals, Inc.

More Information
Responsible Party: Supernus Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier: NCT02736656  History of Changes
Other Study ID Numbers: 812P310
Study First Received: April 4, 2016
Last Updated: April 7, 2016
Health Authority: United States: Food and Drug Administration

ClinicalTrials.gov processed this record on April 12, 2016