A Trial to Evaluate the Efficacy, Safety, and Tolerability of Centanafadine Sustained-release Tablets in Adults With Attention-deficit/Hyperactivity Disorder

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: NCT03605836
Recruitment Status: Not yet recruiting
First Posted: July 30, 2018
Last Update Posted: July 30, 2018
See Contacts and Locations

Sponsor:
Otsuka Pharmaceutical Development & Commercialization, Inc.
Information provided by (Responsible Party):
Otsuka Pharmaceutical Development & Commercialization, Inc.

Study Description

Brief Summary:
This study evaluates the efficacy, safety, and tolerability of centanafadine sustained-release tablets in adults with ADHD. Patients will either receive a twice-daily dose of centanafadine sustained-release tablets, or twice-daily placebo.

Condition or disease

Attention Deficit Disorder
Attention Deficit Hyperactivity Disorder

Detailed Description:
Screening & Washout Period: up to 28 days
Investigational Treatment Period: 49 days
Follow-up Period: 7 days or 10 days

Study Design

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 450 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Triple (Participant, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Double-blind, Multicenter, Placebo-controlled, Parallel-group Trial Evaluating the Efficacy, Safety, and Tolerability of Centanafadine Sustained-release Tablets in Adults With Attention-deficit/Hyperactivity Disorder

Estimated Study Start Date: October 2018
Estimated Primary Completion Date: January 2020
Estimated Study Completion Date: January 2020

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

Arms and Interventions
Go to ▼

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<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Experimental: Centanafadine Treatment 1</td>
<td>Drug: Centanafadine SR</td>
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<tr>
<td>Total daily dose of 200 mg</td>
<td>100 mg, BID, oral tablets</td>
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<td>Other Name: EB-1020</td>
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<td>Other: Placebo</td>
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<tr>
<td></td>
<td>BID, oral tablet</td>
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Outcome Measures
Go to ▼

Primary Outcome Measures:

1. Adult ADHD Investigator Symptom Rating Scale (AISRS) [ Time Frame: Up to 49 days or early termination ]

   18-item scale with a total score range of 0 to 54 points. Composed of 2 subscales that can range from 0 to 27 points. A higher value represents a worse outcome. Change from baseline in AISRS total score to assess efficacy.

Secondary Outcome Measures:

1. Clinical Global Impression-Severity of Illness Scale (CGI-S) [ Time Frame: Up to 42 days or early termination ]

   An observer-rated scale with a total score range of 0 to 7. A higher score represents a worse outcome. Change from baseline to assess efficacy.
Other Outcome Measures:

1. Adverse Event Reporting [Time Frame: Up to 77 days or early termination]
   Frequency and severity of treatment-emergent adverse events (TEAEs) will be assessed to determine safety and tolerability of centanafadine SR tablets

2. ADHD Impact Module - Adult (AIM-A) [Time Frame: Up to 49 days or early termination]
   Scale composed of 3 subscales with a maximum score of 100. A lower score indicates a worse outcome. Exploratory endpoint; comparison of baseline score to other points throughout the study.

3. Adult ADHD Self Report Scale (ASRS) [Time Frame: Up to 77 days or early termination]
   An 18 question report, total score ranges from 0 to 124. A higher score denotes a worse outcome. Exploratory endpoint; comparison of baseline score to other points throughout the study.

4. AISRS [Time Frame: Up to 77 days or early termination]
   Change from baseline total score compared to every scheduled visit. Each subscale is composed of 9 items each. Scores can range from 0 to 27, with a higher score representing a worse outcome. Change from baseline scores are compared to every scheduled visit score.

Eligibility Criteria

Go to ▼

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: 18 Years to 55 Years (Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Subjects must meet the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) criteria for ADHD (including predominantly inattentive presentation, hyperactive presentation, or combined presentation) as confirmed by the Adult ADHD Clinical Diagnostic Scale (ACDS) Version 1.2. To confirm that ADHD is the primary diagnosis, the Mini International Neuropsychiatric Interview (MINI) will be used to identify and exclude other psychiatric conditions which would preclude enrollment.
Subjects who were not receiving any pharmacological treatment for ADHD must have an Adult ADHD Investigator Symptom Rating Scale (AISRS) score of ≥ 28 at screening and baseline. Subjects who were receiving pharmacological treatment for ADHD at screening must have a minimum AISRS score of ≥ 22 at screening, and a score of ≥ 28 at baseline.

All subjects must be willing to discontinue all prohibited psychotropic medications starting from the time of signing the informed consent through the 7-day follow-up period. Subjects that do not rollover into Trial 405-201-00015 must be willing to discontinue all prohibited psychotropic medications starting from the time of signing the informed consent until after the follow-up telephone call 10 days after the last dose of IMP.

Subjects must have a Clinical Global Impression-Severity of Illness Scale (CGI-S) score of ≥ 4 (≥ moderate impairment) at baseline.

Exclusion Criteria:

- Subject has a DSM-5 Diagnosis of Other Specified or Unspecified Attention Deficit/Hyperactivity Disorder.
- Subject has a current comorbid psychiatric disorder that either could be expected to require treatment with medications prohibited in this trial, or to confound efficacy or safety assessments. Examples include, but are not limited to, psychotic disorder, bipolar disorder, generalized anxiety disorder, obsessive-compulsive disorder, panic disorder, a current major depressive episode, or posttraumatic stress disorder, as established by the MINI.
- In the opinion of the investigator, subject has not derived significant therapeutic benefit from 2 or more ADHD therapies of 2 different classes (eg, amphetamine and methylphenidate) given with an acceptable dose and duration of adulthood (aged 18 or older). NOTE: If subject has not derived significant therapeutic benefit due to an inability to tolerate side effects, eligibility can be discussed on case-by-case basis with the medical monitor.
- Subjects that have a positive test (via breathalyzer or blood), a positive drug screen for cocaine, or other illicit drugs (excluding marijuana). Subjects with a positive drug screen for confirmed prescription or over-the-counter (OTC) use of ADHD medications at screening will be required to undergo a washout period. NOTE: Subjects that test positive for marijuana may be permitted to be enrolled if they have no evidence of a substance use disorder, and if they agree to refrain from use for the duration of the trial. Allowance for subjects testing positive for marijuana at screening require explicit approval from the medical monitor.
- In the opinion of the investigator, the subject is unable to adhere to the treatment regimen or other requirements outlined in the protocol.

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): NCT03605836

Contacts

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Sponsors and Collaborators

Otsuka Pharmaceutical Development & Commercialization, Inc.

More Information

Go to ▼

Responsible Party: Otsuka Pharmaceutical Development & Commercialization, Inc.

ClinicalTrials.gov Identifier: NCT03605836 History of Changes
Other Study ID Numbers: 405-201-00014
First Posted: July 30, 2018  Key Record Dates
Last Update Posted: July 30, 2018
Last Verified: July 2018

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Otsuka Pharmaceutical Development & Commercialization, Inc.:
Centanafadine
ADD
ADHD

Additional relevant MeSH terms:
Disease  Mental Disorders
Attention Deficit Disorder with Hyperactivity  Dyskinesias
Hyperkinesis  Neurologic Manifestations
Pathologic Processes  Nervous System Diseases
Attention Deficit and Disruptive Behavior Disorders  Signs and Symptoms
Neurodevelopmental Disorders