PART A: Efficacy and Safety of AEVI-001 in Children and Adolescents with ADHD and with mGluR Mutations

This study is not yet open for participant recruitment.

Verified August 2017 by Aevi Genomic Medicine

Sponsor:
Aevi Genomic Medicine

Information provided by (Responsible Party):
Aevi Genomic Medicine

ClinicalTrials.gov Identifier:
NCT03265119

First received: August 24, 2017
Last updated: August 25, 2017
Last verified: August 2017

History of Changes

- Full Text View
- Tabular View
- No Study Results Posted
- Disclaimer
- How to Read a Study Record

Purpose

This is PART A of a 3-part, 6-week, double-blind, dose-optimization, parallel-group study in children and adolescents (ages 6-17 years) with ADHD with and without CNVs in specific genes implicated in glutamatergic signaling and neuronal activity. Parts A will include subjects determined to have a specific gene mutation(s) implicated in glutamatergic signaling and neuronal activity.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Drug: AEVI-001 Drug: Placebo</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
- Intervention Model: Parallel Assignment
- Masking: Double (Participant, Investigator)
- Primary Purpose: Treatment

Official Title: A Multicenter, 3-Part, 6-Week, Double-blind, Randomized, Placebo-controlled, Parallel-design Study to Assess the Efficacy and Safety of AEVI-001 in Children and Adolescents (Ages 6-17
Years) With Attention Deficit Hyperactivity Disorder and With or Without Copy Number Variants in Specific Genes Implicated in Glutamatergic Signaling and Neuronal Activity

**Resource links provided by NLM:**

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

**Further study details as provided by Aevi Genomic Medicine:**

Primary Outcome Measures:
- Change from baseline in the ADHD-RS-5 Total Score [Time Frame: Baseline to Visit 8 (Week 6)]

Secondary Outcome Measures:
- Percentage of subjects with a dichotomized CGI-I assessment of improved [Time Frame: Visit 8 (Week 6)]
- Percentages of subjects considered responders as defined by protocol [Time Frame: Visit 8/ET (Week 6/ET)]
- Percentage of subjects considered in remission as defined by protocol [Time Frame: Visit 8/ET (Week 6/ET)]

Other Outcome Measures:
- Change from baseline in Conners 3-P(S) total score and subscale scores [Time Frame: Visit 8/ET (Week 6/ET)]

**Estimated Enrollment:** 64

Anticipated Study Start Date: September 2017

Estimated Study Completion Date: February 2018

Estimated Primary Completion Date: February 2018 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: AEVI-001</td>
<td>Drug: AEVI-001</td>
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<tr>
<td></td>
<td>Oral doses of 100 mg, 200 mg or 400 mg of AEVI-001 will be administered twice daily during the treatment period.</td>
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<tr>
<td></td>
<td>Other Names:</td>
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<tr>
<td></td>
<td>MDGN-001</td>
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<tr>
<td></td>
<td>NFC-1</td>
</tr>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Drug: Placebo</td>
</tr>
<tr>
<td></td>
<td>Oral doses of 100 mg, 200 mg or 400 mg of Placebo will be administered twice daily during the treatment period.</td>
</tr>
</tbody>
</table>
Eligibility

Ages Eligible for Study: 6 Years to 17 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Subject and parent/legally authorized representative (LAR) can speak English fluently and have provided written informed consent, and assent (as applicable) for this study.
2. Subject is 6 to 17 years of age (inclusive) at the time of consent/assent. The date of signature of the informed consent/assent is defined as the beginning of the Screening Period. This inclusion criterion will only be assessed at the Screening Visit (Visit 1).
3. Subject is male or non-pregnant, non-lactating female, who if of childbearing potential agrees to comply with any applicable contraceptive requirements prior to administration of investigational product (IP).
4. Subject meets Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for a primary diagnosis of ADHD based upon DSM 5 criteria.
5. Subject has a minimum score of ≥28 on the ADHD-RS-5 at the Baseline Visit (Visit 2).
6. Subject has been genotyped previously and has their identity confirmed.

Exclusion Criteria:

1. Subject or parent/LAR is, in the opinion of the investigator, mentally or legally incapacitated, has significant emotional problems at the time of the Screening Visit (Visit 1) which could interfere with the conduct of study evaluations.
2. Subject has a current, controlled or uncontrolled, co-morbid major psychiatric diagnosis (aside from ADHD), including an anxiety disorder, major depression, bipolar disease, schizophrenia (or any psychotic disorder), and moderate or severe intellectual disability. Mild anxiety and/or depressive symptoms that do not meet diagnostic criteria for an anxiety disorder or major depression and/or do not require treatment are not exclusionary.
3. Subject has autism spectrum disorder to include a DSM-IV diagnosis of autistic disorder, Asperger's disorder, or pervasive developmental disorder.
4. Subject is currently taking any medication that might confound the results of safety assessments conducted in the study.
5. Subject has a known history of cardiovascular disease, advanced arteriosclerosis, structural cardiac abnormality, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, cardiac conduction problems, exercise-related cardiac events including syncope and pre-syncope, or other serious cardiac problems.
6. Subject has any clinically significant abnormality on 12-lead ECG performed at the Screening Visit (Visit 1) and/or the Baseline Visit (Visit 2) such as serious arrhythmia, cardiac conduction problems, or other abnormalities deemed to be a potential safety issue.
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: NCT03265119

Contacts
Contact: Aevi Genomic Medicine  1-877-271-9623   AEVI-001-ADHD-202@aevigenomics.com

Locations
United States, Pennsylvania
Aevi Genomic Medicine  Not yet recruiting
Wayne, Pennsylvania, United States, 19087
Contact: Aevi Genomic Medicine

Sponsors and Collaborators
Aevi Genomic Medicine

More Information

Responsible Party: Aevi Genomic Medicine
ClinicalTrials.gov Identifier: NCT03265119   History of Changes
Other Study ID Numbers: AEVI-001-ADHD-202
Study First Received: August 24, 2017
Last Updated: August 25, 2017

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

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   Dyskinesias
Hyperkinesis   Neurologic Manifestations
Attention Deficit and Disruptive Behavior Disorders   Nervous System Diseases
Neurodevelopmental Disorders   Signs and Symptoms
Mental Disorders

ClinicalTrials.gov processed this record on August 29, 2017