PART B: Efficacy and Safety of AEVI-001 in Children and Adolescents With ADHD and Without mGluR Mutations

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: NCT03609619

Recruitment Status: Not yet recruiting
First Posted: August 1, 2018
Last Update Posted: August 1, 2018
See Contacts and Locations

Sponsor:
Aevi Genomic Medicine

Information provided by (Responsible Party):
Aevi Genomic Medicine

Study Description

Go to Brief Summary:
This is PART B of a 2-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. PART B will assess subjects who do not have CNVs in any of the specific gene mutation(s) implicated in glutamatergic signaling and neuronal connectivity.

Condition or disease

| Attention Deficit Hyperactivity Disorder |

Drug:

Study Design

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Study Type: Interventional (Clinical Trial)

Estimated Enrollment: 82 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment
Official Title: A Multicenter, 2-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 Connectivity

Estimated Study Start Date: August 2018
Estimated Primary Completion Date: December 2018
Estimated Study Completion Date: December 2018

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

Arms and Interventions
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<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tbody>
<tr>
<td>Experimental: AEVI-001</td>
<td>Drug: AEVI-001</td>
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<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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<td>Other Names:</td>
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<tr>
<td></td>
<td>• MDGN-001</td>
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<td></td>
<td>• NFC-1</td>
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<tr>
<td>Placebo Comparator:</td>
<td>Drug: Placebo</td>
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<tr>
<td>Placebo</td>
<td>Oral doses of Placebo will be administered twice daily, during the treatment period.</td>
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Outcome Measures
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Primary Outcome Measures:
1. Change from baseline in the ADHD-RS-5 Total Score [Time Frame: Baseline to Visit 8 (Week 6)]

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

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

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:** 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 (if required).

**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.
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): NCT03609619

Contacts

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

Locations

United States, Pennsylvania

Aevi Genomic Medicine
Wayne, Pennsylvania, United States, 19087

Sponsors and Collaborators
Aevi Genomic Medicine

More Information

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Responsible Party: Aevi Genomic Medicine
ClinicalTrials.gov Identifier: NCT03609619  History of Changes
Other Study ID Numbers: AEVI-001-ADHD-202B
First Posted: August 1, 2018  Key Record Dates
Last Update Posted: August 1, 2018
Last Verified: July 2018

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