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: NCT03460652

Recruitment Status: Not yet recruiting
First Posted: March 9, 2018
Last Update Posted: March 9, 2018
See Contacts and Locations

Sponsor:
KemPharm, Inc.

Information provided by (Responsible Party):
KemPharm, Inc.

Study Details

- Tabular View
- No Results Posted

Study Description

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Brief Summary:
This study is a multicenter, dose-optimized, open-label safety study with KP415 in children with Attention-Deficit/Hyperactivity Disorder (ADHD).

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Drug: KP415 oral capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td></td>
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</tbody>
</table>

Detailed Description:
The study will consist of a Screening Period, a Dose Optimization Phase, and a Treatment Phase and a Follow-Up Visit, as follows:

- Screening Period: Subjects will undergo a screening period up to 30 days prior to entering the Dose Optimization Phase.
- Dose Optimization Phase: During the Dose Optimization Phase, subjects will be titrated to doses of 20, 30 or 40 mg KP415 based on tolerability and best individual dose-response in the opinion of the Investigator.
- Treatment Phase: Eligible subjects will receive single daily doses of KP415 for up to approximately 360 days (up to approximately 12 months). The dose of KP415 given in the Treatment Phase will be the dose of KP415 at the end of the Dose Optimization Phase. During the Treatment Phase, the dose of KP415 may be changed based on individual tolerability and best dose response (to either 20, 30, or 40 mg KP415 capsules). Safety, efficacy and sleep behavior assessments will be performed.
- Follow-Up Visit: 3 ±2 days after administration of the last dose of the Treatment Phase, subjects will enter a Follow-Up Visit to evaluate safety parameters.

Study Design
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Study Type: Interventional (Clinical Trial)

Estimated Enrollment: 250 participants

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: A Multicenter, Dose-Optimized, Open-Label Safety Study With KP415 in Children With Attention-Deficit/Hyperactivity Disorder

Anticipated Study Start Date: March 2018

Estimated Primary Completion Date: March 2019

Estimated Study Completion Date: March 2019

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>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Active Treatment</td>
<td>KP415 oral capsule 20, 30 or 40 mg (total d-MPH from IR d-MPH and KP415 prodrug) Drug: KP415 oral capsule Daily dose Other Name: KP415 20, 30 or 40 mg</td>
</tr>
</tbody>
</table>

Outcome Measures

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Primary Outcome Measures:

1. Occurrence of Treatment-Emergent Adverse Events (TEAEs) [Time Frame: Up to 12 month treatment phase]
   Occurrence of TEAEs will be assessed starting following the first dose of study drug, and ending with the Follow-Up Visit or Early Termination Visit.

2. Clinically significant change in Total Hematology measurements [Time Frame: Up to 12 month treatment phase]
   Total hematology and Coagulation will be performed at the first visit (at Screening, before the first dose of study drug), after approximately 6 months of treatment, and at the end of the Treatment Phase or at Early Termination. Evaluation will include red blood cell count, white blood cell count with differential (neutrophils, lymphocytes, monocytes, eosinophils, basophils), hemoglobin, hematocrit and platelets, Prothrombin Time (PT) and Partial Thromboplastin Time (PTT).
3. Clinically significant change in Serum Chemistry measurements [Time Frame: Up to 12 month treatment phase]

Serum Chemistry will be performed at the first visit (at Screening, before the first dose of study drug), after approximately 6 months of treatment, and at the end of the Treatment Phase or at Early Termination. Evaluation will include aspartate aminotransferase (AST), alanine aminotransferase (ALT), albumin, alkaline phosphatase, bicarbonate, total bilirubin, blood urea nitrogen, phosphorus (inorganic) calcium, chloride, creatine phosphokinase, creatinine, gamma glutamyl transferase, glucose, lactate dehydrogenase, potassium, sodium, total protein, and uric acid.

4. Clinically significant change in Urinalysis measurements [Time Frame: Up to 12 month treatment phase]

Urinalysis will be performed at the first visit (at Screening, before the first dose of study drug), after approximately 6 months of treatment, and at the end of the Treatment Phase or at Early Termination. Evaluation will include microanalysis for specific gravity, pH, protein, glucose, ketones, blood, nitrites, leukocytes. If positive for blood, protein or nitrites, a microscopic examination will be performed.

5. Clinically significant change in Electrocardiogram (ECG) [Time Frame: Up to 12 month treatment phase]

A 12-lead ECG will be collected at the first visit (at Screening, before the first dose of study drug), after approximately 6 months of treatment, and at the end of the Treatment Phase or at Early Termination. ECG will be obtained after the subject has been in a supine position for a minimum of 3 minutes. The QT interval corrected for heart rate will be calculated with Fridericia's formula (QTcF). ECG recordings will be evaluated by skilled readers operating from a centralized ECG laboratory.


Vital sign measurements will be obtained after the subject has been seated for 3 minutes. Vital signs will include sitting blood pressure (systolic and diastolic measurements), pulse rate (beats per minute), respiratory rate (breaths per minute), and oral temperature. Vital signs will be collected once at each visit.

7. Measurement of Height [Time Frame: Up to 12 month treatment phase]

Height will be recorded in centimeters (cm) at each visit with the subject's shoes removed.

8. Measurement of Weight [Time Frame: Up to 12 month treatment phase]

Body weight will be measured in kilograms (kg) at each visit; subjects will remain in their normal clothing with shoes and jacket (and/or outer clothing) removed.

9. Calculation of Body Mass Index (BMI) [Time Frame: Up to 12 month treatment phase]

BMI will be calculated based on subject's weight and height at each study visit.
10. Columbia-Suicide Severity Rating Scale (C-SSRS) [ Time Frame: Up to 12 month treatment phase ]

C-SSRS is a semi-structured interview that captures the occurrence, severity, and frequency of suicide-related thoughts and behaviors at all visits during the assessment period.

Secondary Outcome Measures:

1. Changes in ADHD-RS-5 [ Time Frame: Up to 12 month treatment phase ]

The clinician-administered ADHD-RS-5 is an 18-item scale that rates ADHD symptoms on a 4-point scale. Each item is scored using a combination of severity and frequency ratings from a range of 0 (reflecting no symptoms or a frequency of never or rarely) to 3 (reflecting severe symptoms or a frequency of very often), so that the total ADHD-RS-5 scores range from 0 to 54. The 18 items can be divided into two 9-item subscales: One for hyperactivity/impulsivity and the other for inattentiveness.

2. Changes in CGI-S [ Time Frame: Up to 12 month treatment phase ]

The CGI-S is a clinician-rated scale that evaluates the severity of psychopathology (ADHD symptoms in the study) on a scale from 1 (not at all ill) to 7 (among the most severely ill).

3. Changes in CSHQ [ Time Frame: Up to 12 month treatment phase ]

The modified, abbreviated Children's Sleep Habits Questionnaire (CSHQ) will be used to assess the sleep behavior. The CSHQ is a retrospective, 33-item parent questionnaire to examine sleep behavior in small children. Items are rated on a 3-point scale of "Usually", "Sometimes" and "Rarely" for occurrences in a number of key sleep domains. Scores will be obtained during a clinician-directed interview with the parent/guardian/caregiver.

Eligibility Criteria

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

Criteria

Inclusion Criteria:

1. Subject must meet Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition (DSM-5) criteria for a primary diagnosis of ADHD (combined, inattentive, or hyperactive/impulsive
presentation) per clinical evaluation and confirmed by the Mini International Neuropsychiatric Interview for Children and Adolescents (MINI-KID).

2. Subject must have a score of at least 3 (mildly ill) on the clinician-administered Clinical Global Impressions-Severity (CGI-S) scale.

3. Subjects who completed the efficacy study with KP415 may be rolled over into the current study.

4. Subject, subject's parent/legal guardian and caregiver (if applicable) must understand and be willing and able to comply with all study procedures and visit schedule.

Exclusion Criteria:

1. Subject with any clinically significant chronic medical condition that may interfere with the participant's ability to participate in the study.

2. Subject has any diagnosis of bipolar I or II disorder, major depressive disorder, conduct disorder, obsessive-compulsive disorder, any history of psychosis, autism spectrum disorder, disruptive mood dysregulation disorder (DMDD), intellectual disability, Tourette's Syndrome, confirmed genetic disorder with cognitive and/or behavioral disturbances.

3. Subject has evidence of any chronic disease of the central nervous system (CNS) such as tumors, inflammation, seizure disorder, vascular disorder, potential CNS related disorders that might occur in childhood, or history of persistent neurological symptoms attributable to serious head injury.

4. Subject has a current (last month) psychiatric diagnosis other than specific phobia, motor skills disorders, oppositional defiant disorder, sleep disorders, elimination disorders, adjustment disorders, learning disorders, or communication disorders. Participants with school phobia or separation anxiety will not be eligible.

5. Subject has clinically significant suicidal ideation/behavior, based on a history of attempted suicide and the C-SSRS assessment at Screening or at any time before the last dose of study drug.

6. Subject has any clinically significant unstable medical abnormality, chronic disease, or a history of a clinically significant abnormality of the cardiovascular, gastrointestinal, respiratory, hepatic, or renal systems, or a disorder or history of a condition that may interfere with drug absorption, distribution, metabolism, or excretion of study drug.

7. Subject has a history or presence of abnormal ECGs.

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): NCT03460652

Contacts

Contact: Jenn Gargione 267-536-3561 jenn.gargione@premier-research.com

Sponsors and Collaborators

KemPharm, Inc.

More Information

Go to Responsible Party: KemPharm, Inc.

ClinicalTrials.gov Identifier: NCT03460652 History of Changes

Other Study ID Numbers: KP415.S01
Key Record Dates

First Posted: March 9, 2018
Last Update Posted: March 9, 2018
Last Verified: March 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
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders