Evaluation of SPN-812 (Viloxazine Extended-release Capsule) in Preschool-age Children With ADHD

Status: RECRUITING

Eligibility Criteria

Age: 48 months to 69 months old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Is male or female 4 years 0 months of age to less than or equal to 5 years 9 months of age at Visit 1 (Screening) and considered medically healthy. 2. Subject's parent(s) or legal guardian(s)/representative(s) is (are) willing and able to provide written informed consent before completing any study related procedures. 3. Has a primary diagnosis of ADHD according to DSM-IV-TR criteria and confirmed with the Kiddie Schedule for Affective Disorders and Schizophrenia

•Present and Lifetime Version (K-SADS-PL). 4. Has an ADHD-RS-IV-P Total Score of ≥ 28 (males) or ≥ 24 (females) at Visit 1 (Screening) and at Visit 2 (Baseline). 5. Has a CGI-S score of ≥ 4 (moderate or worse) at Visit 1 (Screening) and at Visit 2 (Baseline). 6. Has undergone an adequate course of non-pharmacologic treatment or is having symptoms severe enough to warrant pharmacologic treatment without prior non-pharmacologic treatment. 7. Is participating in a structured group activity (e.g., preschool, kindergarten, sports, Sunday school, summer camp or childcare program) at least 2 days a week during study so as to assess symptoms and impairment in a setting outside the home. 8. Has not initiated any behavioral intervention/therapy within 30 days of Visit 1 (Screening) and does not plan to initiate any new or discontinue any ongoing behavioral intervention/therapy during the study (e.g., subject is eligible if behavioral intervention/therapy is initiated 30 or more days prior to Visit 1 \[Screening\] and continues with a similar duration/frequency throughout their study). 9. Subjects who are on ADHD medication at Visit 1 (Screening), but whose ADHD symptoms are not well controlled on current ADHD medication (e.g., meets Inclusion Criterion #4), meet all other inclusion/exclusion criteria, and discontinues ADHD medication at least 7 days prior to the day of Visit 2 (Baseline) are eligible to participate. 10. Has no current condition in the opinion of the Investigator that could confound efficacy assessments, safety assessments or increase participant risk. 11. Has lived with the same parent(s) or legal guardian(s) or has lived under a shared living arrangement (e.g., joint legal custody) for greater than or equal to 6 months prior to Visit 1 (Screening). 12. Has a body weight ≥5th percentile for age and sex at Visit 1 (Screening) and Visit 2 (Baseline).

Exclusion Criteria:

1. Has a diagnosis at Screening (per K-SADS-PL) of another psychiatric disorder that is considered to be the primary diagnosis rather than ADHD or has a comorbid psychiatric disorder secondary to ADHD that, in the opinion of the investigator (after consulting medical monitor), will likely interfere with study treatment adherence and/or impact study results. 2. Has a current diagnosis of a major neurological disorder. The eligibility of those who have seizures, a history of seizure-like events (e.g., syncope, myoclonus, severe muscle spasms), a family history of seizure disorder (immediate family, i.e., sibling, parent), and/or febrile seizures will be assessed on a case-by-case basis after consulting the medical monitor. 3. History of Bipolar Disorder diagnosed in a first degree relative. 4. Has global development delay or intellectual disability by medical history. 5. Has a current diagnosis of a significant (per Investigator's evaluation and/or judgement) systemic disease. 6. Has body mass index \> 95th percentile for the subject's age and sex at Visit 1 (Screening) or Visit 2 (Baseline). 7. Has a mean resting systolic and diastolic blood pressure* that are both \>95th percentile for age sex, and height and has a mean resting pulse rate* that is \>95th percentile for age and sex (males: \>117 bpm; females: \>122 bpm) at Visit 1 (Screening) or Visit 2 (Baseline). * Note: The mean of three measurements while seated. 8. Has a clinically significant electrocardiogram finding(s) at Visit 1 (Screening). 9. Is currently taking SPN-812 for ADHD, has previously taken SPN-812 for ADHD, but discontinued due to a lack of efficacy or adverse reactions, or has history of allergic reaction, hypersensitivity or intolerance to viloxazine. 10. Has an allergy to or cannot swallow pudding and applesauce and cannot swallow intact capsule whole. 11. Has any food allergy, intolerance, restriction or special diet that, in the opinion of the Investigator, could contraindicate the subject's participation in the study. 12. Has received any investigational drug within the longer of 30 days or 5 half-lives prior to Visit 2 (e.g., first dose of study medication). 13. Has a positive urine drug test at Visit 1 (Screening). A positive test for amphetamines is allowed for subjects receiving a stimulant ADHD medication at Screening. The subject will be required to discontinue the stimulant for the duration of the study, beginning at least 7 days prior to Visit 2 (Baseline). 14. Is using of prohibited concomitant medications including known CYP1A2 substrates (e.g., theophylline, melatonin) during the Screening Period or (anticipated) for the duration of the study. 15. Any reason that, in the opinion of the Investigator, would prevent the subject from participating in the study. 16. Has suicidal ideation ("Yes" indicated on C-SSRS question 4 or 5) or suicidal behavior ("Yes" indicated on C-SSRS for any suicidal behavior) within 6 months prior to or the day of Visit 1 (Screening) or has attempted suicide ("Yes" indicated on C-SSRS for lifetime).

Conditions & Interventions

Interventions:
DRUG: 100mg SPN-812, DRUG: Placebo
Conditions:
Attention-Deficit/Hyperactivity Disorder
Keywords:
ADHD

More Information

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