Neurovance Announces Top-Line Study Results Suggest Lower Abuse Potential for Centanafadine Compared to Stimulants Used for Adult ADHD

—Recent Trials Provide Evidence of Both Efficacy and Reduced Abuse Liability—

—Full Results of the Human Abuse Liability Study Presented at the American College of Neuropsychopharmacology Meeting in Phoenix—

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Neurovance, Inc. today announced top-line results from a human abuse liability (HAL) study in recreational stimulant users. Centanafadine (CTN) sustained-release (SR) is a novel triple reuptake inhibitor being developed for the treatment of adults with ADHD and has shown favorable efficacy with good tolerability in a phase 2a patient study. Centanafadine works by modulating the activity of norepinephrine, dopamine and serotonin, three neurotransmitters known to be relevant in patients with ADHD. The results of the HAL study suggest that CTN has reduced abuse potential compared to the Schedule II stimulants which are commonly used for ADHD, though restricted due to risk of abuse and diversion.

In the HAL study, treatment with CTN immediate release (IR) at high doses resulted in a markedly different profile than comparators (vs. Vyvanse or d-amphetamine or placebo) with acute onset of aversive effects in the majority of subjects including nausea, vomiting and dysphoria. Almost two hours after administration of CTN, test subjects reported liking at about two-thirds of the magnitude of amphetamines, a finding likely indicative of dopamine activity. However, unlike amphetamines that provided an immediate positive experience, subjects receiving CTN experienced negative effects before reaching this point. This early aversive profile of CTN is unique, inherent to the norepinephrine and serotonin pharmacology of the molecule, and is believed likely to deter abuse if the SR is misused. Full results of the HAL study were presented at the 53rd Annual Meeting of the American College of Neuropsychopharmacology in Phoenix on December 10th.

“The results of the HAL study suggest that the abuse potential for CTN appears lower than that of stimulants,” said Anthony A. McKinney, President and CEO of Neurovance. “Currently, doctors must choose either treatments that are effective but come with tight restrictions on writing and filling prescriptions, or they can use treatments that are unscheduled but also less effective. This HAL study and the earlier ADHD efficacy study combined suggest that CTN SR has the potential to bridge that gap.”

The HAL study was a five-arm crossover study designed to evaluate the abuse liability potential for CTN IR among subjects known to use recreational stimulants. Single doses
of 400 or 800 mg IR were tested alongside Schedule II comparators d-amphetamine or lisdexamfetamine (Vyvanse), or placebo. The findings showed that CTN IR, at a dose sufficient to elicit a measurable reward, would also result in negative effects. For example, subjects said they would significantly prefer to take d-amphetamine as compared to CTN 800 mg.

“The results of the HAL study confirm CTN effects on dopamine and provide confidence in the high level of ADHD efficacy observed in the phase 2a ADHD data reported in May,” said Brigitte A. Robertson, MD, Chief Medical Officer of Neurovance. She added, “Most importantly, when the dose is increased beyond the therapeutic range, subjects experienced an acute onset of aversion and disliking, a distinct profile, which may serve to limit abuse and diversion.”

Edward M. Sellers, MD, PhD, FRCPC, noted expert in the evaluation of medications for abuse liability, commented on the HAL results: “These data show that centanafadine has a different profile than the comparator agents d-amphetamine and lisdexamfetamine, consistent with a lower abuse potential. If this profile is confirmed through development then CTN could qualify for less restrictive scheduling than C-II of the Controlled Substances Act.”

The HAL study was designed in conjunction with a team of abuse liability testing experts at Altreos, Inc. of Toronto and was conducted by Vince & Associates Clinical Research of Overland Park, Kansas, a CRO with expertise in conducting complex clinical pharmacology studies.

About ADHD

Adult ADHD is a very serious medical condition that results in disabling levels of inattention, distraction and impulsive actions. Approximately 10 million American adults are diagnosed with ADHD, but only one in ten receives diagnosis and treatment. Adult ADHD is often associated with serious psychiatric comorbidities, including depression, anxiety and substance abuse. According to the most recent data from IMS Health, the 2013 US ADHD prescription market for adults is now larger than that for children, with 30 million and 29 million total prescriptions written, respectively.

About Neurovance

Neurovance is a clinical stage neuroscience-focused company developing centanafadine SR for adult attention deficit hyperactivity disorder (ADHD). Neurovance is led by co-founder Anthony McKinney and other seasoned drug developers who have been involved in the development of several successful neuroscience medications. Neurovance is a privately held company with headquarters in Cambridge, Massachusetts. Additional information can be found on the Neurovance website at www.neurovance.com.
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