NEUROVANCE ANNOUNCES SERIES OF THREE CLINICAL TRIALS TO SUPPORT ADVANCED DEVELOPMENT OF CENTANAFADINE (CTN) IN ADULT ADHD

--The Trio of Studies Sets the stage for phase 2b/3a trials in 2016--

--Previous Studies Indicate CTN for Adult Attention Deficit Hyperactivity Disorder (ADHD) Has the Potential Efficacy Profile of a Stimulant but with Reduced Abuse Liability--

CAMBRIDGE, MA – Jan 7, 2016 – Neurovance, Inc. today announced a series of three clinical trials to advance the development of centanafadine (CTN), a triple reuptake inhibitor for the treatment of adults with ADHD and related co-morbidities. The series of three trials include a phase 1 imaging study, a phase 2 efficacy trial in adult ADHD and a phase 1 pharmacokinetics (PK) study evaluating several once-daily formulations. Together these three studies will measure brain transporter occupancy, clinical efficacy in ADHD, onset and duration of action, guidance on optimal dosing and formulation selection. These trials will lay the groundwork for phase 2b/3a trials as well as other trials using a once-daily formulation beginning in 2016.

CTN is a triple reuptake inhibitor that modulates the activity of norepinephrine (NE), dopamine (DA) and serotonin (5-HT) for the treatment of ADHD. Previous studies have demonstrated CTN has efficacy in ADHD approaching that of stimulants but with reduced potential for abuse compared to two currently available stimulants.

“These three studies are powerful because they work together to establish a path to demonstrate safety and efficacy for CTN in adult ADHD,” said Anthony A. McKinney, President and CEO of Neurovance. “We previously demonstrated that CTN has the potential efficacy to bridge the gap between stimulants that are effective for ADHD but have abuse liability, or non-stimulants that are non-scheduled but have modest efficacy. These studies will help confirm previous findings and help us determine optimal once-daily dosing for the clinical trials to follow.”

The principal study in this trio, intended to establish the efficacy and safety of twice-daily CTN in ADHD patients, is a phase 2 double-blind, randomized. placebo-controlled three-week crossover trial. The primary endpoint is the change from baseline on the ADHD-Rating Scale, one of the standard instruments used in ADHD registration trials. A phase 2a pilot study has previously demonstrated the onset of action may be within one week with CTN and there may be sustained activity following discontinuation. This finding suggests that treatment with CTN may be less sensitive to missed doses with the potential of maintenance of response after discontinuation. The study is taking place at several US centers of excellence for ADHD studies.

The results of the phase 2 ADHD efficacy trial will be assessed alongside an ongoing NE, DA and 5-HT transporter occupancy study with SPECT imaging and using active comparators versus CTN SR. Top-line data for both trials are expected in the first quarter 2016.

These results in turn will provide the baseline for a third study, a phase 1 pharmacokinetics study designed to help select the preferred, among three extended-release (XR) formulation candidates for advanced development. This trial is expected to start in the first quarter of 2016.

Adult ADHD is among the most rapidly growing diagnoses affecting Americans. According to a recent report, the use of ADHD medications in the US rose 36% in the five years ending 2012. This growth has resulted in the number of privately-insured individuals treated with ADHD medications to approach 5 million in 2012. US government data estimates 10.5 million adults have ADHD (Kessler et al., 2006).

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