



Neurovance's EB-1020 SR for Adult ADHD Shows Stimulant-Like Efficacy and Good Tolerability in Phase 2a Trial

—Data Presented at Society of Biological Psychiatry 69th Annual Scientific Meeting—

—Lays the Groundwork for EB-1020 SR as a Potential New Treatment Option for Adult Attention Deficit Hyperactivity Disorder (ADHD)—

Cambridge, MA – May 8, 2014 – Neurovance, Inc. today announced complete results from its phase 2a pilot study of EB-1020 SR, a non-stimulant, in adult male patients with all subtypes of ADHD (attention deficit hyperactivity disorder). EB-1020 SR is a norepinephrine- and dopamine-preferring triple reuptake inhibitor. The data showed a statistically significant improvement in ADHD symptoms on the ADHD-Rating Scale-IV (ADHD-RS-IV), the primary outcome measure, in a range similar to that reported in previously published trials with stimulants. EB-1020 SR appears to be well tolerated at the doses studied. If these results are replicated in larger trials, EB-1020 SR could be among the first non-stimulants to challenge stimulants for broad use in ADHD. Results were presented at the Society of Biological Psychiatry 69th Annual Scientific Meeting in New York.

“These data indicate that EB-1020 SR has the potential to be the first non-stimulant with efficacy similar to stimulants,” said Anthony A. McKinney, President and CEO of Neurovance. “This is important because stimulants are the most effective medications used to treat ADHD today, yet they carry a risk of abuse and diversion. Evidence in validated animal models suggests that EB-1020 SR carries less risk of reward. We are now moving ahead with a human abuse liability study to evaluate whether EB-1020 demonstrates less risk of abuse or diversion than the standard dose of d-amphetamine in known stimulant users, and expect results by the fourth quarter of this year.”

Adult ADHD is a very serious medical condition. A recent study showed drivers with ADHD are nearly 50% more likely to be in a serious car crash. The inattention and impulsivity associated with ADHD contribute to higher rates of incarceration, unemployment and unwanted pregnancies. Adult ADHD is often associated with serious psychiatric comorbidities, including depression, anxiety and substance abuse, which may have negative long-term consequences in patients' lives.

Timothy E. Wilens, MD, of Massachusetts General Hospital, leading ADHD expert, senior advisor for the clinical trial and lead presentation author, said, “As many as 10 million American adults are diagnosed with ADHD, an important condition that results in disabling levels of inattention, distraction and impulsive actions, yet only one patient in ten is receiving treatment. This is clear evidence of the need for safe and effective therapeutics without the inconvenience and restrictions of controlled substances.”

The final phase 2a data were presented in a poster, “A Pilot Study of a Novel Monoamine Triple Reuptake Inhibitor EB-1020 SR in the Treatment of ADHD in Adults,” at the Society of Biological Psychiatry 69th Annual Scientific Meeting in New York.

STUDY ABSTRACT

Background: This pilot study was designed to evaluate EB-1020 SR as a novel non-stimulant treatment option for adult attention deficit hyperactivity disorder (ADHD). EB-1020 SR is a norepinephrine-

preferring triple reuptake inhibitor with IC₅₀ values for human transporter reuptake inhibition of 6 nM, 38 nM and 83 nM, for norepinephrine (NE), dopamine (DA) and serotonin (5HT), respectively.

Methods: A total of 41 adult males with well-characterized ADHD enrolled in this 4-week, single-blind study with a 1-week placebo run-in. EB-1020 SR was given twice daily and titrated over one week to a target dose of 500 mg as a total daily dose. Outcomes assessed included ADHD symptoms, executive functioning and tolerability.

Results: 37 subjects completed the trial. EB-1020 SR produced a 21-point reduction on the ADHD-Rating Scale-IV (endpoint mean score=17, p<0.0001), including significant reductions in inattentive (p<0.0001) and hyperactive/ impulsive symptoms (p < 0.0001). Overall, 68% of subjects were considered responders using the Clinical Global Impression-Improvement (much/very much improved). Clinically and statistically significant improvements in overall and specific domains of executive function using the Behavioral Inventory of Executive Functioning (BRIEF-A) were observed (overall p<0.0001). No clinically meaningful trends in adverse events, laboratory values, vital signs or ECG parameters were noted.

Conclusions: EB-1020 SR appears effective in treating ADHD and executive functioning deficits in adult males. The maximum dose studied was well tolerated. Based on these results, randomized, controlled studies of EB-1020 SR appear warranted.

ADHD

According to the most recent data from IMS Health, the US ADHD prescription market for adults is now larger than that for children, with 30 million and 29 million total prescriptions, respectively. Although Neurovance is initially focused on adults because of the paucity of products available for adults and the rapid growth rate among the adult segment (prescriptions growing at a CAGR of 16% per year), Neurovance plans to expand its development to include adolescents and children once EB-1020 SR has been demonstrated safe and effective in adults.

About Neurovance

Neurovance is a clinical stage neuroscience-focused company developing EB-1020 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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