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Amarantus Announces Positive Phase 2a Data for Eltoprazine in Adult ADHD

SAN FRANCISCO, February 4, 2014 /PRNewswire/ --

- 36 out of 47 adult subjects (77%) completed the double-blind placebo controlled, multiple dose, crossover study
- Primary endpoint met as measured by change from baseline in ADHD-RS-IV score in 5mg (p=0.003) and 10mg (p=0.037) doses which were statistically significantly superior to placebo with approximately 25% greater efficacy compared to placebo
- Secondary endpoints were also met for 5mg dose in Inattention subscale (p=0.003), Hyperactivity subscale (p=0.008), CGI-I scores (p=0.023), POMS (p=0.006), anger hostility score (p<0.001), BAS reduction in restlessness (p=0.029) and BAS Awareness of Restlessness sub score (p=0.003)
- The Company has initiated a review of strategic options for the ADHD program

Amarantus Bioscience Holdings, Inc. (OTCQB: AMBS), a biotechnology company focused on the discovery and development of novel diagnostics and therapeutics related to endoplasmic reticulum stress, cell cycle dysregulation, neurodegeneration and apoptosis, today announced positive clinical data for Eltoprazine in a Phase 2a clinical study Adult Attention Deficit Hyperactivity Disorder. The results from the study demonstrated statistically significant improvements of both doses of 5mg and 10mg vs. placebo in a range of ADHD clinical measures. Adult ADHD represents a $5B market opportunity.

"Following a thorough statistical review of the data announced by Psychogenics in 2008 by an independent clinical CRO retained for due diligence purposes, an updated study report was submitted in the Investigator's Brochure in 2010 that was better than originally reported," said David A. Lowe, PhD member of the Amarantus Board of Directors. "There is a significant need for non-stimulant ADHD treatments in the marketplace, especially in light of recent regulatory oversight of abuse of currently approved treatments. We believe Eltoprazine may fill this market need."

Eltoprazine is a 5HT1a/1b partial agonist small molecule drug candidate has a well-established safety profile, having been dosed in over 700 patients to date. The study entitled "The Effects of Eltoprazine on Symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in Adults: A Double-Blind, Multiple Dose, Crossover, Safety and Preliminary Efficacy Trial" enrolled 47 patients (48 enrollees were planned), with 36 patients completing the study. The study was conducted at 4 centers in the United States, including Duke University Medical Center, Riley Hospital for Children, NeuroScience, Inc. and UCI Child Development Center.

The primary objective of the study was to compare the effects of two doses of eltoprazine

(5mg and 10mg) with placebo on symptoms of ADHD in adults. The primary efficacy parameter is ADHD-RS-IV. The secondary efficacy parameters were to compare two doses of eltoprazine (5mg and 10mg) versus the Conner's Continuous Performance Test (CPT), the Investigator's Clinical Global Impression-Improvement (CGI-I), the safety/tolerability of multiple doses of eltoprazine and to assess the safety after discontinuation.

SUMMARY OF THE DATA:

- The data produced demonstrated that at both 5mg and 10 mg, the study met its Primary endpoint as measured by change from baseline in ADHD-RS-IV score in 5mg ($p=0.003$) and 10mg ($p=0.037$) doses which were statistically significantly superior to placebo with approximately 25% greater efficacy compared to placebo. Total ADHD-RS-IV scores improved by 13.6, 17.9 and 17.4 points from baseline for placebo, 5mg and 10mg of Eltoprazine, respectively. Inattention, Hyperactivity, and Impulsivity ADHD-RS-IV subscales were also analyzed.
- For the Inattention subscale, both 5mg and 10mg groups showed a statistically significant benefit over placebo (0.003 and 0.039, respectively).
- For the Hyperactivity subscale, the 5mg dose showed a statistically significant benefit in favor of Eltorprazine treatment compared to placebo ($p=0.008$); the 10mg dose was superior to placebo, however the difference was not statistically significant ($p=0.130$).
- For the Impulsivity subscale, no significant benefit was observed for either drug dose compared to placebo.
- Both 5mg and 10mg demonstrated significantly greater improvement over placebo for CGI-I scores ($p=0.023$ and 0.004, respectively).
- The percentage of subjects who were considered improved by the investigator was 57.9% for placebo, 68.4% for 5mg, and 81.1% for 10mg. The percentage difference was significant between 10mg and placebo (0.029), but it was not between 5mg and placebo ($p=0.342$).

The results indicate the overall positive outcomes reported on the ADHD-RS-IV were largely driven by the Inattention and Hyperactivity subscales. This phenomenon was expected because most enrolled subjects had primary deficit in Inattention at baseline. Significant benefits of the active treatments were also observed for the following secondary efficacy variables:

Profile of Mood States (POMS):

- The 5mg dose was statistically significantly better than placebo for POMS total score ($p=0.006$)
- Both the 5mg and 10mg groups were statistically significantly better than placebo for anger-hostility score ($p<0.001$ and $p=0.036$, respectively)
- The 5mg group was also statistically significantly better than placebo for tension anxiety score ($p=0.046$)

Barnes Akathisia Scale (BAS)

- Both 5mg and 10mg groups showed a reduction in restlessness and were statistically significantly better than placebo for BAS ($p=0.029$ and $p=0.007$, respectively)
- Both 5mg and 10mg groups were statistically significantly better than placebo for Awareness of Restlessness subscore ($p=0.003$ and $p<0.001$, respectively).

- The 10mg group was also statistically significantly better than placebo for Distress Related Restlessness subscore (p=0.047)

Abnormal Involuntary Movement Scale (AIMS)

- 10mg showed a significantly greater reduction in abnormal movements than placebo (p<0.001)

There were no serious adverse events (SAEs). Most adverse events were mild of moderate in severity, with only 2 severe treatment-related adverse events with the 5mg/day (hypnagogic hallucination and constipation) and 1 severe treatment-related adverse event with the 10mg/day (fatigue).

"We are pleased to update the marketplace on the Eltoprazine ADHD program at this time, as we have initiated a review of strategic options for the further development of the program. We believe there is significant value to be unlocked with this program and intend to pursue business development-related transactions that we believe will bolster shareholder value as we prepare to up-list to a national stock exchange." said Gerald Commissiong, President & CEO of Amarantus Bioscience Holdings.

About Attention-Deficit Hyperactivity Disorder (ADHD)

ADHD is a neurobehavioral developmental disorder affecting about 3-5% of the world's population under the age of 19. It typically presents itself during childhood, and is characterized by a persistent pattern of inattention and/or hyperactivity, as well as forgetfulness, poor impulse control or impulsivity, and distractibility. There is a clear need for new non-stimulant therapies for ADHD, currently considered to be a persistent and chronic condition for which no medical cure is available. ADHD is one of the most common psychiatric disorders in children and adolescents with approximately 7.8 percent of all U.S. school-age children, or about 4.4 million children aged 4 to 17 years, having been diagnosed with ADHD at some point in their lives, according to the U.S. Centers for Disease Control and Prevention (CDC). Over 8 million adults in the US also exhibit the symptoms of ADHD, while only an estimated 600,000 are being treated. Adult ADHD is characterized by difficulty maintaining attention, as well as hyperactivity and impulsive behavior. Adult ADHD symptoms can lead to a number of problems, including unstable relationships, poor work or school performance, and low self-esteem. Treatment for adult ADHD is similar to treatment for childhood ADHD, and includes stimulant drugs or other medications, and psychological counseling.

The ADHD market is valued at over $3.5 billion dollars, with approximately 35 million prescriptions written annually.

About Amarantus

Amarantus is a biotechnology company developing treatments and diagnostics for diseases associated with neurodegeneration and protein misfolding-related apoptosis. The Company has licensed Eltoprazine a phase 2b ready indication for Parkinson's Levodopa induced dyskinesia. The Company has an exclusive worldwide license to the Lymphocyte Proliferation test ("LymPro Test®") for Alzheimer's disease and owns the intellectual property rights to a therapeutic protein known as Mesencephalic-Astrocyte-derived

Neurotrophic Factor ("MANF") and is developing MANF-based products as treatments for brain disorders. Amarantus is a Founding Member of the Coalition for Concussion Treatment (#C4CT), a movement initiated in collaboration with Brewer Sports International seeking to raise awareness of new treatments in development for concussions and nervous-system disorders. The Company also owns intellectual property for the diagnosis of Parkinson's disease ("NuroPro") and the discovery of neurotrophic factors ("PhenoGuard"). For further information please visit http://www.Amarantus.com, or connect with the Company on Facebook, LinkedIn, Twitter and Google+.

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are forward-looking statements." These forward-looking statements generally are identified by the words believes," project," expects," anticipates," estimates," intends," strategy," plan," may," will," would," will be," will continue," will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse effect on our operations and future prospects on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition, and generally accepted accounting principles. These risks and uncertainties should also be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

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