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Amarantus Provides Program Update on Phase 2b Eltoprazine for Parkinson's Disease and Adult ADHD

SAN FRANCISCO and GENEVA, Sept. 17, 2014 (GLOBE NEWSWIRE) --[Amarantus Bioscience Holdings, Inc.](#) (OTCQB:AMBS), a biotechnology company focused on the development of diagnostics and therapeutics for Alzheimer's disease, Parkinson's disease and orphan ophthalmological disorders, today provided a program update on its Phase 2b-ready Eltoprazine program for Parkinson's disease levodopa-induced dyskinesia patients ("PD LID") and adult attention deficit and hyperactivity disorder ("Adult ADHD"). The company expects to initiate its Phase 2b PD LID clinical trial in the fourth quarter of 2014 or early in 2015.

Eltoprazine for Parkinson's disease levodopa-induced dyskinesia patients ("PD LID")

"We have spent the last six months evaluating the historical Eltoprazine data and laying out the clinical program going forward," said Dr. Charlotte Keywood, Chief Medical Officer of Amarantus' therapeutics division. "We have designed a robust Phase 2b study based upon a thorough evaluation of state of the art trial designs for drugs in the PD LID indication. We will be engaging with the FDA in the coming weeks to commence the regulatory process for the initiation of the PD LID clinical program in the US."

Since the [in-license of Eltoprazine](#) in the first quarter of 2014, Amarantus has accomplished the following milestones:

1. Undertaken a comprehensive review of the existing Eltoprazine data package, to determine the development strategy for Phase 2b to registration in PD-LID, including pharmacokinetic modelling and dose definition
2. Conducted additional manufacturing work to support the qualification of the existing Eltoprazine stockpile for use in the proposed Phase 2b PD LID trial
3. Designed the Phase 2b trial in consultation with Key Opinion Leaders in PD LID
4. Identified the principle investigator and key sites for PD LID Phase 2b clinical trial
5. Commenced supporting work for initiation of the trial by the end of 2014
6. Finalized the clinical trial synopsis for submission to the FDA

In preparation for the trial initiation, the Company has identified the following important steps on the path to Phase 2b initiation:

1. Request pre-IND meeting with the FDA
2. Submit IND to the FDA
3. Obtain IND approval
4. Start enrolment for the Phase 2b PD LID clinical trial in the USA
5. Submit Phase 2b design to EMEA
6. Obtain agreement on Phase 2b trial design with EMEA
7. Start enrolment for the Phase 2b PD LID clinical trial in Europe

"We are very pleased that our Eltoprazine program has progressed so rapidly under the direction of Dr. Keywood and Dr. Lowe," said Gerald E. Commissiong. "The initiation of the Phase 2b trial in PD LID will mark a major milestone for Amarantus. We expect to be in the clinic for this important indication by early 2015. PD LID represents a significant unmet medical need for Parkinson's disease patients."

Eltoprazine for adult attention deficit and hyperactivity disorder ("Adult ADHD")

Commissiong added, "concurrently the Company is taking the first steps in a second important indication for this compound -- Adult ADHD. Adult ADHD represents another massive market opportunity, where non-stimulant drugs are highly sought after to replace current marketed drugs that are highly prone to addiction."

"The non-stimulant Adult ADHD competitive landscape is now maturing to the point where there is greater definition on approvable endpoints, making the planning of a Phase 2b trial in Adult ADHD feasible," said David A. Lowe, PhD, member of the Amarantus Board of Directors. "Regulatory bodies in the United States and in Europe have identified Adult ADHD as a significant unmet medical need, thereby increasing the importance of Eltoprazine's positive Adult ADHD Phase 2a clinical trial data to Amarantus' pipeline."

Amarantus will evaluate the initiation of a Phase 2b clinical development program for Eltoprazine in Adult ADHD after the PD LID program is underway.

About Eltoprazine

Eltoprazine is a small molecule 5HT_{1a/1b} partial agonist in clinical development for the treatment of PD LID and Adult ADHD. Eltoprazine has been evaluated in over 600 human subjects to date, with a very strong and well-established safety profile. Eltoprazine was originally developed by Solvay Pharmaceuticals for the treatment of aggression. Upon Solvay's merger with Abbott Pharmaceuticals, the Eltoprazine program was out-licensed to PsychoGenics. PsychoGenics licensed Eltoprazine to Amarantus following successful proof-of-concept trials in PD LID and adult ADHD.

About Parkinson's disease Levodopa-induced dyskinesia (PD LID)

Parkinson's disease is a chronic, progressive motor disorder that causes tremors, rigidity, slowed movements and postural instability. The Parkinson's Disease Foundation estimates

that there were approximately one million people living with Parkinson's disease in the United States in 2011. The most commonly-prescribed treatments for Parkinson's disease are levodopa-based therapies. In the body, levodopa is converted to dopamine to replace the dopamine loss caused by the disease. The therapeutic efficacy of levodopa is gradually lost over time, and abnormal involuntary movements, dyskinesias, gradually emerge as a prominent side-effect in response to previously beneficial doses of the drug. Levodopa-induced dyskinesia can be severely disabling, rendering patients unable to perform routine daily tasks.

About adult attention deficit and hyperactivity disorder (Adult ADHD)

Attention-deficit/hyperactivity disorder (ADHD) is a common and impairing neuropsychiatric condition, with a total worldwide market size exceeding \$8 billion, growing at an annual rate of 10%. Once believed to only affect children, ADHD is now known to persist into adolescence and adulthood in a sizeable number of cases. Approximately 4-5% of adults worldwide are affected with ADHD. Most adults with ADHD remain undiagnosed and untreated. While approved stimulant medications have been shown to be effective and safe for the treatment of ADHD, up to 30% to 50% of those who are prescribed stimulants for ADHD either do not respond to or do not tolerate these treatments; the utility of stimulants is further hindered by potential risk for abuse (stimulants are controlled substances regulated by the DEA and other international government agencies). Consequently, it is important to develop safe and effective non-stimulant treatment alternatives. [Eltoprazine positive phase 2a data for Adult ADHD](#).

About Amaranthus Bioscience Holdings, Inc.

Amarantus BioScience Holdings (AMBS) is a biotechnology company developing treatments and diagnostics for diseases associated with neurodegeneration and protein misfolding-related apoptosis. AMBS has licensed Eltoprazine ("Eltoprazine"), a phase 2b ready small molecule indicated for Parkinson's Levodopa induced dyskinesia and Adult ADHD. AMBS 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 orphan ophthalmological disorders and other indications. AMBS also owns intellectual property for the diagnosis of Parkinson's disease ("NuroPro") and the discovery of neurotrophic factors ("PhenoGuard"). Amaranthus operations are located in offices and labs at Janssen Labs @QB3. For further information please visit 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.

CONTACT: Amarantus Bioscience Holdings, Inc.
Aimee Boutcher, Investor Relations
408.737.2734 x 101
ir@amarantus.com

Planet Communications
Deanne Eagle, Media Contact
(917) 837-5866

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