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Amarantus Submits Orphan Drug Designation Application to US FDA for Eltoprazine in the Treatment of Levodopa-Induced Dyskinesia

SAN FRANCISCO, Oct. 22, 2015 (GLOBE NEWSWIRE) -- Amarantus Bioscience Holdings, Inc. (OTCQX:AMBS), a biotechnology company developing therapeutic and diagnostic product candidates in orphan indications and neurology, today announced that it has submitted a request to the US FDA for orphan drug designation (ODD) for eltoprazine in the treatment of levodopa-induced dyskinesia (PD-LID).

“A successful application to the US FDA for ODD for eltoprazine in PD LID would complete the transition of our therapeutics portfolio into the orphan drug arena, thereby squarely positioning Amarantus as an orphan drug company,” said Gerald E. Commissiong, President & CEO of Amarantus.

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent so-called orphan diseases and disorders that affect fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition, as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees.

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 Eltoprazine

Eltoprazine is a small molecule 5HT1A/1B partial agonist in clinical development for the treatment of Parkinson's disease levodopa-induced dyskinesia (PD-LID), adult attention deficit hyperactivity disorder (ADHD) and Alzheimer’s aggression. Eltoprazine has been evaluated in over 680 human subjects to date, and has a 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 Amarantus BioScience Holdings, Inc.

Amarantus BioScience Holdings (OTCQX:AMBS) is a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology and orphan diseases. The Company has an exclusive worldwide license to intellectual property rights associated to Engineered Skin Substitute (ESS), an orphan drug designated autologous full thickness skin replacement product in development for the treatment of adult severe burns currently preparing to enter Phase 2 clinical studies. The Company is currently evaluating human clinical data from previously conducted studies in pediatric severe burns and Congenital Giant Hairy Nevus to support clinical development expansion into those areas. AMBS also has development rights to eltoprazine, a small molecule currently in a Phase 2b clinical program for Parkinson's disease levodopa-induced dyskinesia with the potential to expand into adult ADHD and Alzheimer's aggression. AMBS owns the intellectual property rights to a therapeutic protein known as mesencephalic-astrocyte-derived neurotrophic factor (MANF) and is developing MANF as a treatment for orphan ophthalmic disorders, initially in retinitis pigmentosa (RP) and retinal artery occlusion (RAO). AMBS also owns the discovery of neurotrophic factors (PhenoGuard™) that led to MANF's discovery.

AMBS' Diagnostics division owns the rights to MSPrecise®, a proprietary next-generation DNA sequencing (NGS) assay for the identification of patients with relapsing-remitting multiple sclerosis (RRMS) at first clinical presentation, has an exclusive worldwide license to the Lymphocyte Proliferation test (LymPro Test®) for Alzheimer's disease, which was developed by Prof. Thomas Arendt, Ph.D., from the University of Leipzig, and owns intellectual property for the diagnosis of Parkinson's disease (NuroPro).

For further information please visit www.Amarantus.com, or connect with the Company on Facebook, LinkedIn, Twitter and Google+.

Forward-Looking Statements

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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