

February 10, 2016



Amarantus
BioScience

Amarantus Receives Orphan Drug Designation From the US FDA for Eltoprazine in the Treatment of Parkinson's Disease Levodopa-Induced Dyskinesia

SAN FRANCISCO, February 10, 2016 /PRNewswire/ --

[Amarantus BioScience Holdings, Inc. \(OTCQB: AMBS\)](#), a biotechnology company focused on developing products for Regenerative Medicine, Neurology and Orphan Diseases, today announced that it has received orphan drug designation from the US FDA for Eltoprazine in the treatment of Parkinson's disease levodopa-induced dyskinesia (PD-LID). Amarantus published positive results from a Phase 2 initial proof-of-concept clinical study in [February of 2015 in the journal Brain](#), and highlighted the publication of two independent peer-reviewed scientific publications describing the mechanism of action of eltoprazine for the treatment of PD LID in [August of 2015](#) and [December 2016](#).

"The grant of this orphan drug designation for eltoprazine in PD-LID squarely positions Amarantus as an orphan drug company, as each of our pipeline candidates in our therapeutics division has received such designations from the FDA for one or more indications," said Gerald E. Commissiong, President & CEO of Amarantus. "PD-LID is a tremendously debilitating disorder, and we will now begin evaluating expedited pathways to market for eltoprazine that may now be afforded by the orphan drug designation."

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 Amaranthus following successful proof-of-concept trials in PD-LID and adult ADHD.

About Amaranthus BioScience Holdings, Inc.

Amaranthus BioScience Holdings (AMBS) is a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology, regenerative medicine and orphan diseases. AMBS' Therapeutics division has development rights to eltoprazine, a Phase 2b-ready small molecule indicated for Parkinson's disease levodopa-induced dyskinesia, adult ADHD and Alzheimer's aggression, 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 and ophthalmic disorders. More recently, AMBS acquired the rights to the Engineered Skin Substitute program (ESS), a regenerative medicine-based approach for treating severe burns with full thickness autologous skin grown in tissue culture. ESS is entering Phase 2 clinical studies under a CRADA agreement with the US Army. 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). AMBS also owns the discovery of neurotrophic factors (PhenoGuard[™]) that led to MANF's discovery.

For further information please visit <http://www.Amaranthus.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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