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Amarantus Requests Rare Pediatric Disease Designation from US FDA for MANF in the Treatment of Retinitis Pigmentosa

SAN FRANCISCO, February 5, 2016 /PRNewswire/ --

Amarantus BioScience Holdings, Inc. (OTCQB: AMBS), a biotechnology company focused on developing products for Regenerative Medicine, Neurology and Orphan Diseases, announced that it has requested Rare Pediatric Disease Designation (RPDD) from the US Food and Drug Administration (FDA) for treating retinitis pigmentosa (RP) with MANF. MANF was previously granted orphan drug designation (ODD) by the US FDA in December 2014.

The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily aged from birth to 18 years. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application (NDA) or biologics license application (BLA) for a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain expedited FDA review for any subsequent marketing application. Vouchers may be sold or transferred by the recipient; in the last 6 months, 2 priority review vouchers have been sold for a combined $595M in cash.

In December 2015, Amarantus submitted ODD and RPDD applications to the US FDA for engineered skin substitute in the treatment of Giant Congenital Hairy Nevus (GCMN), in addition to its ODD application to the US FDA for eltoprazine in the treatment of Parkinson's disease levodopa-induced dyskinesia (PD-LID) submitted in October 2015. The Company expects to receive responses regarding these designation applications in the first quarter of 2016.

About Retinitis Pigmentosa

Retinitis pigmentosa (RP) refers to a group of inherited diseases causing retinal degeneration often leading to blindness. The retina lines the back inside wall of the eye and is responsible for capturing images from the visual field. People with RP experience a gradual decline in their vision because the retinal cells responsible for black-white and color perception die in response to stress. As a result, the telltale presenting symptoms often include night blindness and a loss of peripheral vision. RP is typically diagnosed in adolescents and young adults. The rate of progression and degree of visual loss varies from person to person. Most people with RP are legally blind by age 40; there is no approved therapeutic for this indication It is estimated that the market opportunity for Retinitis Pigmentosa exceeds $2B annually.

About Mesencephalic-Astrocyte-derived Neurotrophic Factor (MANF)

MANF (mesencephalic-astrocyte-derived neurotrophic factor) is believed to have broad potential because it is a naturally-occurring protein produced by the body for the purpose of reducing and preventing apoptosis (cell death) in response to stress from injury or disease, making it an attractive potential candidate for treating RP. By manufacturing MANF and administering it to the body, Amarantus is seeking to use a regenerative medicine approach to assist the body with higher quantities of MANF when needed. Amarantus is the front-runner and primary holder of intellectual property around MANF, and is initially focusing on the development of MANF-based protein therapeutics.

MANF's lead indication is RP, and additional indications including central retinal artery occlusion, Parkinson's disease, diabetes and Wolfram's syndrome are currently being evaluated. Further applications for MANF may include Alzheimer's disease, traumatic brain injury, myocardial infarction, antibiotic-induced ototoxicity and certain other rare orphan diseases currently being considered.

About Amarantus BioScience Holdings, Inc.

Amarantus 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.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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