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# Amarantus Submits Orphan Drug Designation Application to US FDA for Treatment of Retinal Artery Occlusion With Product Candidate MANF

SAN FRANCISCO and GENEVA, Dec. 19, 2014 (GLOBE NEWSWIRE) --Amarantus BioScience Holdings, Inc. (OTCQB:AMBS), a biotechnology company focused on the development of diagnostics in Alzheimer's disease and therapeutic products in the areas of neurology, psychiatry, ophthalmology and regenerative medicine, announced that it has applied to the U.S. Food & Drug Administration (FDA) for Orphan Drug Designation for its investigational drug MANF (mesencephalic-astrocyte-derived neurotrophic factor) as a treatment for retinal artery occlusion (RAO). RAO is a blockage of the blood supply to the retina which causes severe and sudden loss of vision.

MANF, a naturally-occurring protein that reduces and prevents apoptosis (programmed cell death) in response to injury or disease, was discovered utilizing Amarantus' proprietary PhenoGuard™ Protein Discovery Engine. Pre-clinical data showed that MANF provided protective functional effects in an animal model of RAO. Moreover, toxicology studies have demonstrated that MANF was well-tolerated following a single intravitreal administration of a therapeutically relevant dose.

"Filing our second Orphan Drug Designation for MANF is an important component of our regulatory strategy for the program," said Gerald E. Commissiong, President & CEO of Amarantus. "We believe that our pre-clinical efficacy data with MANF supports its use in ophthalmologic disorders such as RAO and retinitis pigmentosa (orphan status applied for in October 2014) where there are currently limited or no treatment options available. We are extremely encouraged by our data and believe MANF has the potential to provide meaningful changes to the quality of life of patients and their families."

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 Retinal Artery Occlusion**

Retinal artery occlusion (RAO) is a rare eye condition caused by a loss of blood supply to the inner layer of the retina resulting in acute and often severe vision loss. RAO is further classified as central or branch retinal artery occlusion, respectively, depending on the location of the occlusion. The currently-available treatments are aimed at opening the

occluded artery before irreversible damage occurs and most often do not improve visual acuity above natural history. There are no effective neuroprotective agents for the treatment of acute retinal ischemia available. The prevalence for RAO is approximately 10,450 patients in the United States.

**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 injury or disease, via the unfolded protein response. 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 (IP) around MANF, and is initially focusing on the development of MANF-based protein therapeutics.

MANF's lead indication is retinitis pigmentosa, and additional indications including Parkinson's disease, diabetes and Wolfram's syndrome are currently pursued. Further applications for MANF may include Alzheimer's disease, traumatic brain injury (TBI), myocardial infarction, antibiotic-induced ototoxicity and certain other rare orphan diseases currently under evaluation.

**About Amarantus 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 disease Levodopa induced dyskinesia and Adult ADHD. AMBS has an exclusive worldwide license to the Lymphocyte Proliferation test ("LymPro Test®"), which was developed by Prof. Thomas Arendt, Ph.D., from the University of Leipzig, 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 and ophthalmic disorders. AMBS also owns intellectual property for the diagnosis of Parkinson's disease ("NuroPro") and the discovery of neurotrophic factors ("PhenoGuard™"). In November 2014, AMBS entered into an exclusive option agreement with Lonza Walkersville, Inc., a subsidiary of Lonza Group Ltd., to acquire Cutanogen Corporation, a subsidiary of Lonza Walkersville, to develop Engineered Skin Substitute (ESS-W), an autologous skin replacement product for the treatment of Stage 3 and Stage 4 intractable severe burns. For further information please visit www.Amarantus.com, or connect with the Company onFacebook, 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.

CONTACT: Investor and Media Contact:
Jenene Thomas
Jenene Thomas Communications, LLC
Investor Relations and Corporate Communications Advisor
T: (US) 908.938.1475
E: jenene@jenenethomascommunications.com

Shareholder Contact:
Aimee Boutcher, Investor Relations
T: (US) 408.737.2734 x 101
E: ir@amarantus.com

Media Contact:
Planet Communications
Deanne Eagle, Media Contact
T: (US) 917.837.5866

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