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Amarantus Receives Orphan Drug Designation From the U.S. Food and Drug Administration for MANF for the Treatment of Retinal Artery Occlusion

SAN FRANCISCO and GENEVA, Sept. 14, 2015 (GLOBE NEWSWIRE) --[Amarantus BioScience Holdings, Inc.](#) (OTCQX:AMBS), a biotechnology company developing therapeutic and diagnostic product candidates in orphan indications and neurology, announced that the U.S. Food and Drug Administration (FDA) has granted the company's investigational drug mesencephalic-astrocyte-derived neurotrophic factor (MANF) orphan drug designation for the treatment of 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 demonstrated 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.

"We are extremely pleased to have received the second orphan drug designation for MANF for use in ophthalmologic disorders. At the end of 2014 we received orphan drug designation for MANF to treat retinitis pigmentosa (RP), and this additional designation for treatment of RAO is an important step in our regulatory strategy for what we believe has the potential to become a broad ophthalmic therapeutic franchise," said Gerald E. Commissiong, President & CEO of Amarantus BioSciences Holdings, Inc. "RAO is an acute condition that can potentially lead to blindness and the toxicology data generated thus far directly supports the translational potential for MANF in this indication. We believe MANF has promise as a safe and effective therapeutic option to treat RAO and RP."

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. 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, Amaranthus is seeking to use a regenerative medicine approach to assist the body with higher quantities of MANF when needed. Amaranthus 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 Amaranthus 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. AMBS' Therapeutics division 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. 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 severe burns currently preparing to enter Phase 2 clinical studies. 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). 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), and 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 further 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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