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Amarantus Receives Orphan Drug Designation for MANF From U.S. Food and Drug Administration for Treatment of Retinitis Pigmentosa

SAN FRANCISCO and GENEVA, Dec. 23, 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 the U.S. Food and Drug Administration (FDA) has granted the company's investigational drug MANF (mesencephalic-astrocyte-derived neurotrophic factor) orphan drug designation for the treatment of Retinitis Pigmentosa (RP). RP refers to a group of inherited diseases causing retinal degeneration often leading to blindness.

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

"We are very pleased to receive orphan drug designation for MANF in RP. This represents an important milestone for the company as well as a significant step forward for our clinical and regulatory strategy," said Gerald E. Commissiong, President & CEO of Amaranthus. "Our goal is to continue to identify ways to build value into our MANF program and advance this promising product candidate in multiple therapeutic areas with significant unmet need."

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 Retinitis Pigmentosa

Retinitis pigmentosa (RP) refers to a group of inherited diseases causing retinal degeneration often leading to blindness. The cell-rich retina lines the inside back 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 photoreceptor cells (rods and cones)

die. Symptoms include a progressive degeneration of peripheral and night vision, as well as the degeneration in color perception and central vision. Night blindness is one of the earliest and most frequent symptoms of RP.

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. It is estimated that the market opportunity for Retinitis Pigmentosa exceeds \$10B 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 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.

Amaranthus 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.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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