

May 14, 2015



Amarantus
BioScience

Amarantus Enters Into cGMP Manufacturing Agreement With Catalent Biologics for Production of MANF for Human Clinical Studies

- Catalent to Utilize Proprietary GPEX[®] Platform for Production of High Performance MANF Expressing Cell Line -

- cGMP Production of MANF to Enable Program Advancement Into Human Clinical Studies in Retinitis Pigmentosa, Retinal Artery Occlusion, Glaucoma and Parkinson's Disease -

SAN FRANCISCO and GENEVA, May 14, 2015 (GLOBE NEWSWIRE) -- [Amarantus BioScience Holdings, Inc.](#) (OTCQB:AMBS), a biotechnology company focused on developing therapeutic and diagnostic products for neurological disorders and orphan indications, today announced that it has entered into a manufacturing agreement with [Catalent Pharma Solutions](#) (NYSE:CTLT), the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, for clinical-grade production of [MANF](#) (mesencephalic-astrocyte-derived neurotrophic factor). Under the agreement, Catalent will provide all cell line engineering, process development and clinical Good Manufacturing Practices (cGMP) biomanufacturing activities necessary for the rapid development of a high performance cell line expressing MANF protein that will thereafter be advanced into scale up for cGMP production.

"We selected Catalent as our development and manufacturing partner because they have the cGMP capabilities, expertise and proprietary technologies required to efficiently synthesize and scale up MANF production for human clinical use," said Gerald E. Commissiong, President & CEO of Amarantus. "Advancing MANF, our first internally-discovered therapeutic product candidate, into human clinical studies will be a major advancement for the Company. Rapid production of MANF in collaboration with Catalent will enable us to achieve this objective as quickly and in the most cost-effective manner possible. The Company is currently targeting the orphan ocular indication retinitis pigmentosa (RP) for first-in-man studies, expected to start in 2016."

The project will utilize Catalent's proprietary GPEX[®] technology, which creates high-expression, extremely stable cell lines with speed and efficiency, typically capable of getting drug development projects to clinic in one-third the time of traditional approaches. The advantages of applying GPEX[®] technology span from early feasibility studies, to clinical manufacturing and commercial scale production.

MANF is a naturally-occurring protein that reduces and prevents apoptosis (programmed cell death) in response to injury or disease. Amarantus is developing MANF for the treatment of

orphan ocular indications, including retinitis pigmentosa (RP), and recently received orphan drug designation for MANF for the treatment of RP in the United States and in Europe. In addition, MANF proteins have demonstrated proof-of-concept in animal pre-clinical models to treat a wide range of conditions including retinal artery occlusion, glaucoma, Parkinson's disease (PD), diabetes and ischemic heart disease, among others.

With this announcement, Amaranthus is initiating Investigational New Drug enabling (IND-enabling) studies to support a first-in-man clinical study with MANF. The Company has retained regulatory expertise to identify the fastest path to human proof-of-concept data by evaluating well-respected regulatory pathways available worldwide, and will be working judiciously towards this objective. Amaranthus is targeting the initiation of first-in-man clinical studies for MANF in 2016.

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 around MANF, and is initially focusing on the development of MANF-based protein therapeutics. [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.

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, myocardial infarction, antibiotic-induced ototoxicity and certain other rare orphan diseases currently under evaluation.

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 8,000 people, including over 1,000 scientists, at 30 facilities across 5 continents, and in fiscal 2014 generated more than \$1.8 billion in annual revenue. Catalent is headquartered in Somerset, N.J. For more information, visit www.catalent.com.

About Amaranthus BioScience Holdings, Inc.

Amaranthus BioScience Holdings (AMBS) is a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology, psychiatry, ophthalmology and regenerative medicine. 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. 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 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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Source: Amarantus BioScience Holdings, Inc.