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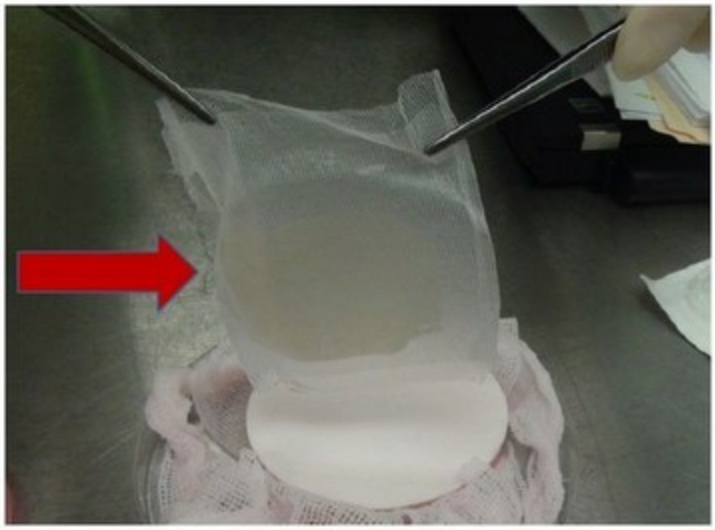
Amarantus Provides Update on cGMP Manufacturing Validation for the Engineered Skin Substitute (ESS) Program

SAN FRANCISCO, Dec. 22, 2015 /PRNewswire/ --Amarantus BioScience Holdings, Inc. (OTCQB: AMBS), a biotechnology company focused on developing products for Regenerative Medicine, Neurology and Orphan Diseases, today provided an update on the status of its current manufacturing process validation for producing ESS at Lonza Walkersville, a premier contract manufacturer providing cell- and tissue-based products for clinical development. Ongoing engineering run activities are progressing successfully, and Amarantus expects to complete the necessary steps to confirm the process in January. Upon completing the validation studies, Amarantus will be ready from the operational perspective to open the planned Phase 2 clinical study for the treatment of full thickness thermal burns covering over 50% of the body. The trial is being conducted under a Collaborative Research & Development Agreement (CRADA) with the U.S. Army at the Institute for Surgical Research at Fort Sam Houston in Texas.



Milestones towards validation are as follows:

1. Aseptic process simulation execution and qualification of the process and personnel used in manufacturing:
   Completed in November 2015
2. Initial engineering run whereby autologous full thickness skin from an adult human donor is produced:
   Completed in December 2015

3. Confirmatory engineering run whereby autologous full thickness skin from an adult human donor is produced:
   In progress - Expected completion in January 2016

"Validating the manufacturing process for ESS is the key operational milestone at this point on the program's path towards commercialization," said Gerald E. Commissiong, President & CEO of Amarantus. "Working with an established contract manufacturer, we will be operationally enabled to open up the 10 patient Phase 2 clinical study under our CRADA with the US Army's ISR, and we will also be in a position to initiate discussions with the FDA on trial designs for evaluating ESS in Giant Congenital Melanocytic Nevi (GCMN) and pediatric severe burn indications. We believe ESS may be eligible to achieve Rare Pediatric Disease Designation (RPDD) for both of these indications, and our regulatory team is now focused on submitting the request for RPDD for the treatment of GCMN to the U.S. FDA by the end of 2015, with a decision in the first quarter of 2016. Given that it is estimated GCMN affects a very small pediatric population, (between 8 and 80 newborns annually in the U.S), we anticipate a potentially rapid product approval pathway with the pivotal program anticipated to initiate in the second half of 2016."

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 Designation (RPDD) Priority Review Voucher (PRV) 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. The PRV may be sold or transferred by the recipient. The two most recent PRVs that were sold garnered a combined $595M in cash from Sanofi and Abbvie.

About Giant Congenital Melanocytic Nevus

Giant Congenital Melanocytic Nevus, a rare pediatric condition (also known as "Bathing trunk nevus," "Garment nevus," "Giant hairy nevus", and "Nevus pigmentosus et pilosus"), is defined by one or more large, darkly pigmented and sometimes hairy patches. The congenital (present at birth) melanocytic nevus appears as a circumscribed, light brown to black patch, potentially varying in consistency, covering any size surface area and any part of the body. As compared with melanocytic nevi that arise after birth, congenital melanocytic nevi are usually larger in diameter and may have excess hair, a condition called hypertrichosis. The estimated prevalence for the largest melanocytic nevi is 0.002% of births in the US. A serious risk factor for the largest CMN concerns the incidence of melanoma, which can be up to 10%. Generally, melanoma in patients with large to giant CMN occurs within the first decade of life with the greatest incidence rate before age 5 and has a high fatality rate. A second life-threatening complication of the larger forms of CMN is neurocutaneous melanocytosis (NCM), a neurological and dermatological disorder characterized by abnormal cellular aggregations within the central nervous system and the skin. The incidence of NCM ranges between 5 and 15 % in this CMN patient subset; death usually occurs within 2-3 years of diagnosis of symptomatic NCM.

About Engineered Skin Substitute (ESS)

Engineered Skin Substitute (ESS) is a tissue-engineered skin prepared from autologous (patient's own) skin cells. It is a combination of cultured epithelium with a collagen-fibroblast

implant that produces a skin substitute that contains both epidermal and dermal components. This model has been shown in preclinical studies to generate a functional skin barrier. Most importantly, because ESS is composed of a patient's own cells, it is less likely to be rejected by the immune system of the patient, unlike with porcine or cadaver grafts in which immune system rejection is a possibility. ESS has been used in an investigator initiated clinical setting in over 130 human subjects, primarily pediatric patients, for the treatment of severe burns up to 95% total body surface area.

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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/amarantus-provides-update-on-cgmp-manufacturing-validation-for-the-engineered-skin-substitute-ess-program-300196351.html

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