

October 8, 2015



Amarantus Reports Preliminary 13-Year Longitudinal Follow-Up Human Patient Data for Engineered Skin Substitute Treatment of Congenital Giant Hairy Nevus

- Single ESS Treatment Provided Successful Skin Replacement on Infant Patient, Supporting Natural Skin Growth That Required no Additional Grafts or Reconstructive Surgery

- Data Provides Translational Support for Multiple Pediatric Skin Conditions

SAN FRANCISCO and GENEVA, Oct. 08, 2015 (GLOBE NEWSWIRE) -- [Amarantus Bioscience Holdings, Inc.](#) (OTCQX:AMBS), a biotechnology company developing therapeutic and diagnostic product candidates in orphan indications and neurology, reported on preliminary 13-year longitudinal follow-up data presented on Engineered Skin Substitute (ESS) for the treatment of pediatric severe burns and Congenital Giant Hair Nevus at the [Tissue Products for Emergency Preparedness Symposium at the National Archives in Washington, DC](#) in May 2015.

Amarantus completed the acquisition of ESS in July 2015, and has focused the Company's near-term execution strategy on the advancement of ESS in several therapeutic areas including Congenital Giant Hairy Nevus and pediatric severe burns, two rare pediatric diseases that the Company believes would be eligible for a Rare Pediatric Disease Designation (RPDD) by the US Food and Drug Administration (FDA). The Sponsor of a treatment approved under the RPDD pathway is eligible to receive a PRV that may be sold to other companies. Two PRVs have been sold in the last 6 months for an aggregate of \$595 million to major pharmaceutical companies. The proceeds from the sale of a PRV are in addition to any potential revenues that could be generated from product sales. The Company intends to apply to the FDA for both orphan drug designation (ODD) and RPDD for ESS treatment of Congenital Giant Hairy Nevus in the fourth quarter of 2015.

Congenital Giant Hairy Nevus is a rare pediatric disease defined by one or more, large, darkly pigmented and sometimes hairy patches with a projected adult diameter of over 40 cm with hypertrichosis. The condition is sometimes known as giant congenital melanocytic nevus. The estimated prevalence for the largest forms is 0.002% of births, affecting approximately 1 in 50,000 to 1 in 500,000 births annually. Melanocytic Nevi often grow proportionally to the body size as the child matures. As they mature, they often develop thickness, and become elevated, although these features can also be present from birth. Prominent terminal hairs often form, especially after puberty. With maturity, the nevus can have variation in color, and the surface might be textured with proliferative growths. Neurocutaneous melanosis is associated with the presence of either giant congenital

melanocytic nevi or non-giant nevi of the skin. It is estimated that neurocutaneous melanosis is present in 2% to 45% of patients with giant congenital melanocytic nevi. Neurocutaneous melanosis is characterized by the presence of congenital melanocytic nevi on the skin and melanocytic tumors in the leptomeninges of the central nervous system.¹

CONGENITAL GIANT HAIRY NEVUS PUBLISHED DATA FOR ESS

In the scientific publication [Plastic and Reconstructive Surgery. 2004;114\(6\):1523-1528](#) entitled "Autologous cultured skin substitutes conserve donor autograft in elective treatment of congenital giant melanocytic nevus," the authors reported on the treatment of two (2) cases of Congenital Giant Hairy Nevus. ESS was previously known as Cultured Skin Substitute (CSS) or Permaderm™, a trademark Amarantus continues to own for the product.

ABSTRACT

The above report presents two patients having giant congenital nevi (400 to 650 cm²) treated by excision and grafting with autologous cultured skin substitutes prepared from less than 20 cm² of donor skin autograft. Nevi were excised to fascia and grafted with cadaveric allograft for 1 week, followed by removal of the allograft and grafting with cultured skin substitutes. The mean ratio of closed to donor areas was 26. In comparison to sheet split-thickness skin grafting, cultured skin substitutes exhibited comparable cosmesis, pliability, and durability while reducing the donor-site area by approximately one order of magnitude.

PRELIMINARY 13-YEAR LONG-TERM FOLLOW-UP DATA

A copy of the public presentation made at the [Tissue Products for Emergency Preparedness Symposium at the National Archives in Washington, DC](#) in May 2015, was disclosed in a regulatory filing under form 8-K by Amarantus on October 8th, 2015. The presentation discloses pictures from an up-to 13-year follow-up evaluation from one of the patients originally reported on in the scientific publication noted above. The patient received no reconstructive surgery after the initial ESS treatment. A link to the presentation can be found at http://www.sec.gov/Archives/edgar/data/1424812/000114420415058546/v421839_ex99-1.htm.

"The preliminary long-term follow-up data on the engraftment of ESS for the treatment of Congenital Giant Hairy Nevus provide a compelling rationale for the further evaluation of ESS as potential revolutionary treatment across a broad swath of pediatric dermatologic indications," said Gerald E. Commissiong, President & CEO of Amarantus. "Congenital Giant Hairy Nevus can be a devastating condition affecting not only the physical, but also the psychosocial maturation of newborns as they grow into childhood. Any clinical benefit that could be provided in terms of cosmesis outcomes will be heralded both by children and their families. ESS represents a potential paradigm shift in this indication, as not only is there potential initial cosmesis benefit, but also a potential long-term cosmesis improvement, as well as the potential reduction or elimination in reconstructive procedures due to the unique properties of ESS growing with pediatric patients – which distinguishes ESS from all other available treatment options in the market or in development that we are aware of. This property makes ESS potentially especially beneficial for the pediatric dermatologic population which is in dire need of a permanent full thickness skin replacement options."

Amarantus is also preparing to initiate a multi-center, controlled clinical study of ESS for the treatment of severe burns in the adult population, and has recently executed a Collaborative Research And Development Agreement (CRADA) with the U.S. Army to support the advancement of ESS for the treatment of the military population that is being partially supported by a grant from the Armed Forces Institute of Regenerative Medicine (AFIRM). With the integration of the Cutanogen Corporation now complete, Amarantus intends to vigorously pursue additional non-dilutive funding from the Department of Health and Human Services (HHS) and Biomedical Advanced Research and Development Authority (BARDA) for disaster readiness for the further development of ESS primarily for the treatment of thermal burns for routine burn care and mass casualties.

The Company believes, the development of ESS for the treatment of adult severe burns will provide additional proof of concept for the commercial manufacture of ESS for the treatment of pediatric severe burns and Congenital Giant Hairy Nevus. The Company intends to achieve GMP manufacturing status for ESS late in the fourth quarter of 2015. The Company also expects to initiate the clinical study with the U.S. Army shortly thereafter in the first quarter of 2016.

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, self-to-self skin grafts for autologous skin tissue are 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 (OTCQX:AMBS) is a biotechnology company developing treatments and diagnostics for diseases in the areas of neurology and orphan diseases. 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 adult severe burns currently preparing to enter Phase 2 clinical studies. The Company is currently evaluating human clinical data from previously conducted studies in pediatric severe burns and Congenital Giant Hairy Nevus to support clinical development expansion into those areas. AMBS also 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. 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) and retinal artery occlusion (RAO). 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) 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).

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.

¹ https://en.wikipedia.org/wiki/Congenital_melanocytic_nevus

Investor and Media Contact:

Ascendant Partners, LLC
Fred Sommer
732- 410-9810
fred@ascendantpartnersllc.com



Source: Amarantus BioScience Holdings, Inc.