

Amarantus Announces Publication of Human Clinical Data for Engineered Skin Substitute in the Treatment of Life-Threatening Pediatric Severe Burns

ESS reduces mortality and repeated donor skin harvesting in children

SAN FRANCISCO, August 8, 2016 /PRNewswire/ --

[Amarantus BioScience Holdings, Inc.](#) (OTCQB: AMBS), a biotechnology company focused on developing products for Regenerative Medicine, Neurology and Orphan Diseases, today announced the publication of a 16-subject clinical study of Engineered Skin Substitute ("ESS," or "Permaderm™") in children with life-threatening severe burns. In this study, ESS was compared with the standard of care (split-thickness autograft "AG") for treating full-thickness (dermal and epidermal layers of skin) life-threatening pediatric severe burns covering a total body surface area (TBSA) of 50% or greater. Amarantus' wholly-owned subsidiary Cutanogen Corporation is pursuing the development of ESS towards regulatory approval for the treatment of life-threatening severe burns. ESS has received orphan drug designation from the U.S. FDA in the treatment of full-thickness burns covering over 50% TBSA.

The article entitled "*Randomized, Paired-Site Comparison of Autologous Engineered Skin Substitutes and Split-Thickness Skin Graft for Closure of Extensive, Full-Thickness Burns*" was published online in the July edition of the *Journal of Burn Care and Research* (Boyce, et al, 2016). A copy of the article can be purchased online at: http://journals.lww.com/burncareresearch/Abstract/publishahead/Randomized_Paired_Site_Comparison_of_Autologous.98555.aspx.

"The publication of the human clinical data from the compassionate use study of ESS in the treatment of pediatric severe burns provides important detail surrounding the unprecedented results generated in the study, where all patients who survived long enough to receive ESS treatment ultimately survived, whereas the standard of care for the comparable patient population has a mortality rate in excess of 30%," said Dr. David Ahrenholz, retired President of the American Burn Association. "ESS has the potential to establish a new standard of care in the treatment of pediatric and adult severe burns, and I look forward to assisting the team at Amarantus in turning this clinical potential into medical reality."

Summary of the data:

- ESSs were prepared from split-thickness skin biopsies that were harvested from 16 pediatric burn patients who were enrolled in the IRB-approved study protocol;
- ESSs and split-thickness autograft (AG) were applied to 15 subjects with full-thickness burns covering a mean of 76.9% TBSA;
- Data consisted of photographs, tracings of donor skin and healed wounds, comparison of mortality with the National Burn Repository, correlation of TBSA closed wounds with TBSA full-thickness burn, frequencies of re-grafting, and immunoreactivity to the biopolymer scaffold;
- One subject expired before ESS application, and 15 subjects received 2056 ESS grafts in total;
- Correlation of % TBSA closed with ESSs with % TBSA full-thickness burn generated an R2 value of 0.65 (P < .001);
- **All 15 patients who received ESS survived;**
- **Mortality in this ESS study was 6.25%, as compared to a 30.3% mortality rate for a comparable population from the National Burn Repository (P < .05), indicating that ESS may potentially reduce mortality by over 75% in this pediatric patient population;**
- **These results indicate that autologous ESSs reduce mortality and requirements for donor skin harvesting, for grafting of full-thickness burns of greater than 50% TBSA.**

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-dermal 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. A non-GMP version ESS has been used in investigator-initiated and compassionate-use clinical settings in over 150 human subjects, primarily pediatric patients, for the treatment of severe burns up to 95% of total body surface area. The non-GMP version has also been used in the treatment of two patients with Giant Congenital Melanocytic Nevi (GCMN). The Company is evaluating opportunities to launch a pivotal clinical study with ESS in the areas of GCMN and pediatric severe burns once experience is gained in the adult severe burn setting.

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 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 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. MANF was discovered from the Company's proprietary discovery engine PhenoGuard. AMBS also received 80 million shares of Avant Diagnostics, Inc. via the sale of its wholly-owned subsidiary Amarantus Diagnostics, Inc.

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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