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Osiris Therapeutics announced a Comparative Effectiveness Study on the Use of Two Human Placental Membranes in Wound Management is Available Electronically in a Peer-Reviewed Journal

COLUMBIA, Md., Jan. 19, 2017 (GLOBE NEWSWIRE) -- [Osiris Therapeutics, Inc.](http://www.osiris-therapeutics.com) (NASDAQ:OSIR) announced today that the study "A Comparative Outcomes Analysis Evaluating Clinical Effectiveness in Two Different Human Placental Membrane Products for Wound Management" has been published in the peer-reviewed journal *Wound Repair and Regeneration* and is available [online \(http://bit.ly/comparativeoutcomes\)](http://bit.ly/comparativeoutcomes). This is the first comparative effectiveness study to report on the clinical outcomes associated with the use of different placental wound care products once broadly implemented in the clinical setting.

The a priori specification of the research question focused on the clinical outcomes in two nonrandomized past patient cohorts receiving wound treatment with either a viable intact cryopreserved human placental membrane (vCPM) (Grafix®; Osiris Therapeutics, Inc., Columbia, MD), or a dehydrated human amnion/chorion membrane (dHACM) (EpiFix®; MiMedx Group Inc., Marietta, GA) as an adjunct to standard of care, as evidenced through a single-center electronic database. A total of 79 patients with 101 wounds were analyzed: 40 patients with 46 wounds received vCPM and 39 patients with 55 wounds received dHACM. Both subject groups represent consecutive sets of patients treated by either graft. Treatment cohorts were equal, as there were no statistical differences in the baseline patient characteristics, wound characteristics or etiological distribution of wound types between the two groups.

Highlights of the Study Results:

- | The proportion of complete wound closure was 63.0% (29/46) for vCPM and 18.2% (10/55) for dHACM ($p < 0.0001$) for all treated wound types
- | Mean size for closed wounds was 9.4 cm² for vCPM versus 2.1 cm² for dHACM group ($p=0.0201$)
- | For all non-closed wounds in the vCPM group ($n = 17$), reductions in both surface area and volume indicate clinical improvement. In contrast, there was no clinical improvement observed in the non-closed dHACM population ($n = 45$) based on an overall increase in wound dimensions after treatment with dHACM
- | Kaplan-Meier probability of complete wound closure by week 12 was 74.3% for vCPM and 19.0% for dHACM

Physician and principal investigator of the study, Eric Johnson, M.D., of Bozeman Health Deaconess Hospital, Wound and Hyperbaric Center stated, "The importance of analyzing the clinical outcomes associated with a center's advanced wound care product utilization cannot be overstated. In order to promote evidence-based medicine in wound care, we must validate the recommendations provided by randomized clinical trials through real-world practice. This is how we will best measure and understand benefits to patient care while making cost-effective decisions that ultimately impact our delivery of that care. I believe that the publication of this study speaks for itself."

About the Study

The study population ($N = 79$) was comprised of two subject groups, dHACM ($n = 39$) and vCPM ($n = 40$), and represent distinct and consecutive sets of patients that were managed at Bozeman Health Deaconess Hospital- Wound and Hyperbaric Center with either graft for the purposes of wound closure and do not reflect a subset of either population. All male and female patients over the age of 18 years of age, receiving at least one application of either dHACM or vCPM between February 2014 and March 2016 with at least one follow up measurement were eligible for analysis. Consistent with the terms and conditions dictated by the Health Insurance Portability Act of 1996 (HIPPA), de-identified information was obtained from the electronic health record database for the purposes of a retrospective comparative effectiveness analysis between the two human placental products. Osiris Therapeutics, Inc. partnered with a biostatistics research organization as well as a consultant from the Department of Applied Mathematics and Statistics at The Johns Hopkins University to perform the blinded independent data analysis.

About Grafix

Grafix is a cryopreserved placental membrane comprised of an extracellular matrix (ECM) rich in collagen, growth factors, and viable cells native to the tissue. Grafix is processed using Osiris' proprietary technology; it is flexible and conforming

and designed for application directly to hard-to-treat acute and chronic wounds, including but not limited to diabetic foot ulcers, venous leg ulcers and thermal burns. Grafix is a Human Cells, Tissues, and Cellular Tissue Based Product (HCT/P) as defined in 21 CFR part 1271 and Section 361 of the Public Health Service Act.

About Osiris Therapeutics

Osiris Therapeutics, Inc., based in Columbia, Maryland, is a world leader in researching, developing, and marketing regenerative medicine products that improve health and lives of patients and lower overall healthcare costs. Having developed the world's first approved stem cell drug, the company continues to advance its research and development in biotechnology by focusing on innovation in regenerative medicine - including bioengineering, stem cell research and viable tissue based products. Osiris has achieved commercial success with products in orthopaedics, sports medicine and wound care, including BIO⁴®, Cartiform®, Grafix®, and Stravix™. Osiris, Grafix, Cartiform, and Stravix are trademarks of Osiris Therapeutics, Inc. BIO⁴ is a trademark of Howmedica Osteonics Corp. More information can be found on the company's website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements

This press release may contain forward-looking statements. These forward-looking statements may generally be identified by the use of the words "may," "will," "expects," "anticipates," "believes," "estimates," and similar expressions, and involve a number of risks and uncertainties. For a variety of reasons, actual results may differ materially from those described in or contemplated by any such forward-looking statement. Examples of forward-looking statements may include, without limitation, statements regarding the anticipated efficiencies and advantages of products or services. Consequently, the reader is cautioned to consider all forward-looking statements in light of the risks to which they are subject.

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