Osiris Announces New Peer-Reviewed Publication Summarizing Clinical Outcomes of Viable Cryopreserved Placental Membranes for Management of Chronic Diabetic Foot Ulcers in Real World Setting

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COLUMBIA, Md., April 25, 2018 (GLOBE NEWSWIRE) -- Osiris Therapeutics, Inc. (OTC Pink:OSIR), a regenerative medicine company focused on developing and marketing products for wound care, orthopedics, and sports medicine, announced today that a new peer-reviewed manuscript entitled "Effectiveness of viable cryopreserved placental membranes for management of diabetic foot ulcers in a real world setting" has been published in the Wound Repair and Regeneration and is available online, https://onlinelibrary.wiley.com/doi/pdf/10.1111/wrr.12635.

In a prior multicenter, randomized, controlled clinical trial (RCT), application of our viable cryopreserved placental membrane product, Grafix®, to chronic diabetic foot ulcers (DFUs) resulted in a significantly higher proportion of wound closure by 12 weeks compared to control (62% vs. 21%)[1]. Although RCTs remain the gold standard to determine treatment efficacy, RCT results may not accurately reflect the effectiveness of therapies in real-world practice. Results in effectiveness studies may differ from results observed in tightly controlled experimental conditions of an efficacy study, as broader populations of patients and clinicians have access to products. Nonrandomized studies using secondary databases and registries offer an alternative approach to assess the effectiveness of therapies relevant to daily physician practice.

In this published retrospective study, the effectiveness of Grafix for the management of DFUs was evaluated using certain participating customer data from Net Health's WoundExpert ® electronic health records (EHR) database (Net Health, Pittsburgh, PA). De-identified consistent with the terms and conditions outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), EHR data for 360 patients with 441 wounds treated with Grafix from July 1, 2012 through June 30, 2016 were extracted from the database. The primary endpoint was the proportion of DFUs that achieved complete closure. Other endpoints included time and number of grafts to closure, probability of wound closure by week 12, and the number of wound-related infections and amputations.

The majority of patients were men (75%), the mean age was 63.7 years old, and 50% of patients by age (> 65 years old) were Medicare patients. The mean wound size was 5.1 cm^2 with 3.9 mm depth, and the mean wound duration was 102 days prior to treatment. Thirty percent of wounds were larger than 3 cm^2, and 15% were complex wounds with exposed bone or tendon.

Key clinical outcomes include:

- Closure at the end of treatment was achieved in 59.4% of wounds with a median treatment duration of 42.0 days and four applications of Grafix. This is consistent with 62% DFU closure with median of 42 days and six applications of Grafix reported in the RCT[1].
- The probability of wound closure at week 12 as calculated by Kaplan-Meier method was 71%, which is similar to the 67.8% probability of wound closure previously reported in the RCT[1].

We believe that analysis of Grafix clinical outcomes in the real world setting supports Grafix benefits for DFU management and supplements the RCT data. This information may aid policy and treatment decisions regarding advanced wound care modalities in the management of diabetic patients with chronic foot ulcers.

"We are very pleased to see consistent closure rates when Grafix is used for chronic DFU management in the real world setting, as compared to our RCT data," said Jason Keefer, Interim Chief Executive Officer. "This study was a joint effort of wound care and statistical science experts from leading academic institutions including University of Texas Southwestern, Dallas, TX, Johns Hopkins University, Baltimore, MD, University of Miami Miller School of Medicine, Miami, FL and MedStar Georgetown University Hospital, Washington, DC. On behalf of Osiris, I would like to congratulate and thank authors Drs. Katherine Raspovic, Dane Wukich, Daniel Naiman, Lawrence Lavery, Robert Kirsner, Paul Kim, John Steinberg and Christopher Attinger, for their significant scientific contributions."

About Grafix
Grafix is a cryopreserved placental membrane that retains the extracellular matrix, growth factors, endogenous cells, including neonatal mesenchymal stem cells, and fibroblasts of the native tissue, all of which are beneficial in supporting natural wound repair. It is a flexible and conforming wound cover designed for direct application to hard-to-treat acute and chronic wounds, including but not limited to diabetic foot ulcers, venous leg ulcers and thermal burns.

About Osiris Therapeutics
Osiris Therapeutics, Inc., based in Columbia, Maryland, researches, develops, manufactures and commercializes regenerative medicine products intended to improve the health and lives of patients and lower overall healthcare costs. We have achieved commercial success with products in orthopedics, sports medicine and wound care, including the Grafix product line, Stravix, BIO[4] (available exclusively through Stryker Corporation) and Cartiform (available exclusively through Arthrex, Inc.). We continue to advance our research and development by focusing on innovation in regenerative medicine, including the development of bioengineered stem cell and tissue-based products. Osiris®, Grafix®, Grafix CORE®, Grafix PRIME®, Grafix XC®, Stravix®, Cartiform®, and Prestige™ are our trademarks. BIO4® is a trademark of Howmedica Osteonics Corp., a subsidiary of Stryker Corporation. More information can be found on the Company's website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements
Statements herein relating to the future of Osiris Therapeutics, Inc. and the ongoing research and development of our products are forward-looking statements. Osiris Therapeutics, Inc. cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading “Risk Factors” in the Osiris Therapeutics Inc. Annual Report on Form 10-K for the years ended December 31, 2017, 2016 and 2015 as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Examples of forward-looking statements may include, without limitation, statements regarding the anticipated efficiencies and advantages of products and the likelihood of customer clinical adoption of any new products. Although well characterized in scientific literature and studies, preservation of tissue integrity including cells may not be indicative of clinical outcome. Accordingly, you should not unduly rely on these forward-looking statements. You are encouraged to read our filings with the SEC, available at sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

1-Lavery et al., Int Wound J, 2014, 11(5): 554-560

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