Osiris Therapeutics, Inc. Announces Peer-Reviewed Publication Comparing the Efficacy of Viable Cryopreserved Placental Membranes to Human Fibroblast-Derived Dermal Substitute in the Treatment of Chronic Diabetic Foot Ulcers (DFUs) in a Multicenter Randomi

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COLUMBIA, Md., Aug. 27, 2018 (GLOBE NEWSWIRE) -- Osiris Therapeutics, Inc. (NASDAQ: 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 "A multicenter, randomized, single-blind trial comparing the efficacy of viable cryopreserved placental membrane to human fibroblast-derived dermal substitute in the treatment of chronic diabetic foot ulcers" has been published in the Wound Repair and Regeneration and is available online https://onlinelibrary.wiley.com/doi/10.1111/wrr.12645

Dermagraft® [1] is a bioengineered human fibroblast-derived dermal substitute product that has been on the U.S. market for more than 15 years [2, 3]. Grafix® is a cryopreserved placental tissue allograft that has been developed using a proprietary cryopreservation method. This method allows the retention of intact matrix, growth factors and cells native to placental tissue. Prior clinical studies have shown the safety and efficacy of both Grafix and Dermagraft when used in the treatment for chronic DFUs in their respective trials [4, 5]. The study's objective was to compare clinical outcomes and product cost between Grafix and Dermagraft as an adjunct to standard of care (SOC) in the treatment of chronic DFUs in a prospective, multicenter, single-blind study.

The study's objective was to compare clinical outcomes and product cost between Grafix and Dermagraft as an adjunct to standard of care (SOC) in the treatment of chronic DFUs in a non-inferiority prospective, multicenter, single-blind study. Sixty two patients were evaluable in the per protocol (PP) population: 31 Grafix patients and 31 Dermagraft patients. There were no significant differences between treatment cohorts with an exception of longer wound duration and more plantar wound locations for the Grafix group. The average wound size was 7.12 cm^2 in the Grafix group and 5.70 cm^2 (p=0.732) in the Dermagraft group. Both patient cohorts had noteworthy comorbidities, such as heart disease (92.1% of Grafix patients and 94.6% of Dermagraft patients) and prior amputations (55.5% of Grafix patients and 54.1% of Dermagraft patients).

Key clinical outcomes include:

- The study met its primary endpoint: Grafix was not inferior to Dermagraft for the proportion of patients achieving complete wound closure (48.4% of Grafix patients and 38.7% of Dermagraft patients, a non-inferiority criterion of the lower limit of 90% confidential interval greater than -15% was met) when the established-for-Dermagraft-treatment- regimen of up to 8 weekly application was used for both skin substitutes.

- For a subset of patients with typical DFUs (≤ 5 cm^2), closure at the end of treatment was achieved in 81.3% (13/16) of Grafix patients, compared to 37.5% (6/16) of Dermagraft patients (p=0.0118).

- For DFUs of less or equal to 5 cm^2, mean per-patient product cost for Grafix patients was $3,846 compared to $7,968 for Dermagraft patients ($p < 0.0001$).

"With growing number of wound care products and development of new technologies, comparative research in prospective randomized studies has tremendous value," said Dr. Charles Ananian, DPM, who is the lead study investigator. "Wound-care providers like myself and my colleagues may utilize results of this study when selecting what we believe is the best treatment option for the patient."

1. Dermagraft® is a registered trademark of Organogenesis, Inc. (Canton, MA).
2. Naughton G, Mansbridge J, Gentzkow G. A metabolically active human dermal replacement for the treatment of diabetic foot ulcers. Arti Organs 1997;21:1203-10.
3. Hart CE, Loewen-Rodriguez A, Lessem J. Dermagraft: use in the treatment of chronic wounds. Adv Wound Care (New Rochelle) 2012;1:138-41.
4. Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix ® for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J. 2014;11:554-60.
5. Marston WA, Hanft J, Norwood P, Pollak R; Dermagraft Diabetic Foot Ulcer Study Group. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of a prospective randomized trial. Diabetes Care 2003;26:1701-05.

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. The membrane 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$^{4®}$ and Cartiform®. 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 Prime®, and Cartiform® are our trademarks. BIO^{4}® 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, 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.

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