Osiris Announces Enrollment of Patients in a Clinical Trial Evaluating GrafixPL PRIME™ in the Treatment of Chronic Venous Leg Ulcers

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COLUMBIA, Md., July 11, 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 the initiation of its "Multicenter, Prospective, Randomized, Open-Label Study with a Crossover Extension Option to Evaluate the Safety and Efficacy of GrafixPL PRIME™ in the Treatment of Chronic Venous Leg Ulcers."

This study is expected to enroll up to 200 patients in approximately 30 clinical sites. Patients will be randomized 1:1 to receive GrafixPL PRIME plus standard compression therapy (SOC) versus SOC alone in patients with chronic venous leg ulcers (VLUs). The study objective is to evaluate the safety and efficacy of weekly applications of GrafixPL PRIME plus SOC versus SOC alone for chronic VLUs with a size between 1 cm^2 and 25 cm^2. Patients in the SOC alone group whose ulcers do not close will be offered GrafixPL PRIME adjunct to SOC in a crossover extension treatment phase of up to 12 treatments.

Osiris Therapeutics is partnering with CPC Clinical Research, an Academic Clinical Research Organization (ARO), who will be responsible for clinical site monitoring, all data management, and pharmacovigilance and biostatistical services.

The study protocol has been designed using the FDA guidelines for Industry clinical trials for products used to treat burns and cutaneous ulcers (Guidance for Industry, 2006). The primary efficacy endpoint of the study is complete ulcer closure by week 12. The primary endpoint will undergo confirmation by blinded evaluators at the Wound Core Lab at CPC Clinical Research.

About Venous Leg Ulcers

Venous Leg Ulcers (VLUs) constitute more than half of lower leg ulcerations, with an overall prevalence that ranges from 0.06% to 2%.[1] The prognosis of these ulcers is very poor, with only 50% of ulcers reportedly achieving closure after four months of treatment.[2] In many cases VLUs can remain open even after years of treatment; for example 20% of ulcers remained open after two years and 8% of ulcers after eight years.[2] Treatment of those chronic VLUs remains a challenging problem for wound care providers. Chronic VLUs have a major negative impact on a patient's quality of life and are associated with more than $18B annual cost of care.[3]

About Prestige Lyotechnology℠ (PL) and GrafixPL PRIME

GrafixPL PRIME is processed using Prestige Lyotechnology, which is Osiris' novel proprietary preservation technique for ambient storage of living tissues. It is flexible and conforming and designed as a wound cover/barrier 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. The structural matrix, growth factors, and cell viability of GrafixPL PRIME are equivalent to that of Grafix PRIME, a cryopreserved placental membrane, but without the constraints of ultra-low temperature storage.

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®, BIO4® 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®, GrafixPL®, GrafixPL PRIME ™Cartiform®, Prestige℠ and Prestige Lyotechnology℠ 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)

About CPC Clinical Research

CPC Clinical Research is an academically led clinical research organization who has responded to the demands of a fast-paced clinical research industry and competitive market for over 25 years. CPC offers full service clinical trial design, oversight, and management with rapid access to Key Opinion Leaders in a variety of therapeutic areas. Many of CPC's leadership team have chaired and/or served on FDA advisory committees including the Cardiovascular and Renal, Endocrine and Metabolism, and Reproductive Health committees. www.cpcmed.org

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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Primary Logo

Source: Osiris Therapeutics, Inc.