Grafix Demonstrates Positive Clinical Outcomes in Chronic Complex Wounds with Exposed Tendon and Bone

Osiris completes first prospective post-market study using Grafix® in the management of chronic complex diabetic foot ulcers: demonstrates positive outcomes in patients typically excluded from clinical research due to the severity of their wounds and co-morbid health conditions.

COLUMBIA, Md. – March 4, 2016 - Osiris Therapeutics, Inc. (NASDAQ: OSIR), a leading cellular and regenerative medicine company focused on developing and marketing products to treat conditions in wound care, orthopaedics and sports medicine, announced today the results of its prospective, multi-center, single-arm clinical trial evaluating the clinical outcomes of Grafix® in patients with complex chronic diabetic foot ulcers with exposed tendon and bone.

Grafix is a cryopreserved placental membrane intended to be used as a wound cover for patients suffering from chronic wounds. It is a flexible, conforming membrane that is applied directly to acute and chronic wounds.

A total of 31 patients were enrolled, 27 of whom completed the protocol (4 early withdrawals). The patient group had significant co-morbidity, with over 80% having hypertension, over 60% being current or former smokers, 55% having heart disease and 45% having had a previous partial amputation. The mean wound area at baseline was 14.6 cm², all wounds were present for at least 4 weeks with a mean wound duration of 7.5 months. Per protocol (PP n=27) and Intention to Treat (ITT n=31) analyses were performed.

- The proportion of patients meeting the primary end-point of complete (100%) granulation at 16 weeks was 96.3% (83.9 % ITT).
- The mean time to 100% granulation was 6.8 weeks with a mean of 6.8 applications of Grafix.
- The proportion of patients meeting the secondary endpoint of complete (100%) wound closure at 16 weeks was 59.3% (51.6% ITT).
- The mean percentage area reduction of all wounds at 16 weeks was 92.3%.
- There were no Grafix-related adverse events recorded.
- Of the 4 (13%) patients who withdrew early, 2 (6.5%) were unwilling or unable to comply with the treatment protocol, and 2 (6.5%) required a mid-foot amputation.

It has been reported that 18.3% of patients with a diabetic foot ulcer that can be probed to bone will need a mid-foot or higher level amputation in the next 6 months: 11 times more likely than non-complex wounds¹. “Complex diabetic foot wounds present a significant challenge to patients and to the health care system in terms of mortality, morbidity and cost,” said Robert Frykberg, DPM, MPH at Carl T. Hayden Medical Center in Phoenix, AZ. “This study was deliberately designed to include the most difficult patients we see in our clinic. It demonstrates the benefits of using Grafix to close these very difficult wounds effectively and potentially prevent initial or further amputation.”

“Complex wounds and patients with other significant illness are normally excluded from prospective clinical studies because they are so difficult to treat, and yet they are frequently encountered by wound care professionals in their clinics,” said Dwayne Montgomery, President and Chief Executive Officer. “This study demonstrates that Grafix can be effective in this patient group and considered in the management of such serious wounds.”

“The first question a clinician asks when encountering a complex wound with exposed deep structures is, ‘Can I prevent an amputation?’ and the second is, ‘Can I get the wound to granulate?’” said Jon Hopper, FRCSEd., Chief Medical Officer. “This is the first prospective study demonstrating the positive impact that Grafix has on real world, difficult to manage complex wounds. It shows that structurally intact cryopreserved placental membranes that preserve matrix, growth factors and viable cells will support granulation in the vast majority of complex wounds and do so in a reasonable timeframe.”

Osiris Therapeutics partnered with CPC Clinical Research, an Academic Clinical Research Organization (CRO), who was responsible for all data management and pharmacovigilance services.

Osiris intends to submit the full trial results for peer review and publication in due course.

About the Trial (Protocol 310)

Protocol 310 is a multi-center, open-label, single-arm trial evaluating the clinical outcomes of weekly applications of Grafix for the treatment of complex chronic diabetic foot ulcers with exposed tendon or bone. A total of 31 patients were enrolled at four leading wound care centers across the United States. Patients between 18 and 85 years of age with confirmed type 1 or type 2 diabetes and with chronic complex diabetic foot wounds that extended through the dermis and into the subcutaneous tissue with evidence of exposed muscle, tendon, bone, and/or joint capsule were considered for this study. Ulcers had to be able to accommodate up to three 5 cm x 5 cm pieces of Grafix. Patients were excluded from the trial if the ulcer had any evidence of active infection at screening. Patients received treatment with Grafix weekly for up to 16 weeks. The primary endpoint measured 100% granulation of wound by 16 weeks as determined by the investigator. Secondary endpoints included complete wound closure rates, time to 100% granulation, number of applications, and percent wound area reduction at 4 weeks, 8 weeks, 12 weeks, and 16 weeks. The protocol was submitted to clinicaltrials.gov (Reference # NCT02260609).

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 BioSmart™ 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.

About Osiris Therapeutics

Osiris Therapeutics, Inc., based in Columbia, Maryland, is a leader in researching, developing and marketing cellular regenerative medicine products that improve the health and lives of patients and lower overall healthcare costs. Having developed the world’s first approved stem cell drug, Osiris works to further advance the medical field. Osiris’ research and development in biotechnology focuses 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®, a viable bone matrix, Cartiform®, a viable osteochondral allograft, Grafix, a cryopreserved placental membrane, TruSkin™, a viable human skin allograft and Stravix™, a durable placental allograft.

Osiris, Grafix and Cartiform are registered trademarks of Osiris Therapeutics, Inc.; TruSkin and Stravix are trademarks of Osiris Therapeutics, Inc. BIO4® is a registered trademark of Stryker Corporation (NYSE: SYK). More information can be found on the company’s website, www.Osiris.com. (OSIR-G)

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "ongoing," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project" or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements may include, without limitation, statements regarding any of the following: our product development efforts; our clinical trials and anticipated regulatory requirements, and our ability to successfully navigate these requirements; the success of our product candidates in development; status of the regulatory process for our biologic drug candidates; implementation of our corporate strategy; our financial performance; our product research and development activities and projected expenditures, including our anticipated timeline and clinical strategy biologic drug candidates and marketed Biosurgery products (including Grafix, BIO4® and Cartiform); our cash needs; patents, trademarks and other proprietary rights; the safety and ability of our products and potential products to treat disease; our ability to supply a sufficient amount of our marketed products or product candidates and, if approved or otherwise commercially available, products to meet demand; our costs to comply with governmental regulations; our plans for sales and marketing; our plans regarding facilities; types of regulatory frameworks we expect will be applicable to our products and potential products; and results of our scientific research. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K and other Periodic Reports filed on Form 10-Q, with the United States Securities and Exchange Commission. Accordingly, you should not unduly rely on these forward-looking statements. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this press release or to reflect the occurrence of unanticipated events.

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