Grafix Demonstrates Superior Clinical Outcomes Compared with EpiFix in “Real World” Study

Osiris completes comparative retrospective single center study of clinical outcomes achieved with Grafix® and EpiFix®

COLUMBIA, Md. – May 2, 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, announces the results of A Retrospective, Single-Center, Non-Randomized, Cross-Sectional Comparative Effectiveness Study Evaluating Surface Area Reduction, Volume Reduction and Closure Rates in Acute and Chronic Wounds Managed with Grafix® versus EpiFix®.

The primary objective of this investigator initiated study was to compare the efficacy of Grafix to EpiFix in a real world clinical setting. Per a protocol, all patients over the age of 18 that received at least one application of either Grafix or EpiFix for the management of any head-to-toe acute or chronic wound between February 2014 and March 2016 were included in the study. The primary analysis was the proportion of index wounds that achieved complete closure during the retrospective treatment period. Blinded statistical analyses for both Grafix and EpiFix treatment groups were performed by an independent third party clinical research organization.

A total of 79 patients with 101 wounds were identified for study analysis: 39 patients with 55 wounds received EpiFix and 40 patients with 46 wounds received Grafix. There were no patients or wound types excluded. Researchers used a pre-defined protocol to collect de-identified electronic health records from the wound care management software. The mean wound surface area at presentation was 7.7 cm² in the Grafix group and 7.0 cm² in the EpiFix group. The mean wound volume at presentation was 8.3 cm³ in the Grafix group and 2.7 cm³ in the EpiFix group. There were no statistical differences in the basic demographics between the two groups.

Study Highlights:

- The proportion of complete wound closure was 63.0% (29/46) for the Grafix group and 18.2% (10/55) for the EpiFix group (p< 0.0001). 90% of wounds, 26/29 in the Grafix group and 9/10 in the EpiFix group, achieved closure by week 12.

- The mean baseline surface area for closed wounds was 9.4 cm² in the Grafix group and 2.1 cm² in the EpiFix group.

- The mean baseline volume for closed wounds was 10.3 cm³ in the Grafix group and 0.55 cm³ in the EpiFix group.

- For wounds that did not reach complete closure during the study period, a mean 43% surface area reduction and a mean 40% reduction in volume was recorded for Grafix-treated wounds versus a mean 73% increase in surface area and a 136% increase in volume for EpiFix-treated wounds.

When compared to EpiFix, researchers determined that Grafix closed more wounds with surface areas that were over 4x greater in size and 19x greater in volume. The Grafix-treated wounds that did not achieve...
closure during the study period demonstrated clinically effective improvement with an average surface area and volume reduction of greater than 40%. By comparison, the unclosed EpiFix-treated wounds demonstrated a deterioration in clinical condition as evidenced by an average increase in surface area and volume of greater than 104%.

The results demonstrated by Grafix in this real world study are consistent with the previously published RCT data in which Laverty reported a 62% complete wound closure rate by 12 weeks in a large, blinded, multicenter DFU trial (Lavery et al., 2014).

“The clinical outcomes for patients seen and treated with advanced skin substitutes at our clinic in Bozeman have shown that Grafix has demonstrated superior outcomes to EpiFix,” said Dr. Eric Johnson, M.D., Bozeman Health Deaconess Hospital, Wound and Hyperbaric Center.

“We are very pleased to see that clinical outcomes for Grafix are consistent across all studies,” said Dwayne Montgomery, President and Chief Executive Officer of Osiris. “It is important to study real world patient cohorts, with no inclusion or exclusion criteria, to confirm the results obtained in the Randomised Controlled Clinical Trial. Osiris is proud of our proprietary technology, and pleased that Grafix is proving beneficial to patients.”

About the Study

The patient population consisted of all male and female patients (n=79) over the age of 18 years, who received at least one application of either Grafix or EpiFix between February 2014 and March 2016 at Bozeman Health Deaconess Hospital, Wound and Hyperbaric Center. 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 patients receiving either Grafix or EpiFix. The primary analysis was pre-specified in a retrospective clinical efficacy study protocol as the proportion of index wounds achieving complete closure. Osiris Therapeutics partnered with a statistical data management organization that performed the blinded independent analysis of the data.

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 stem cell research, bioengineering and viable tissue based products. Osiris has achieved commercial success with products in orthopaedics, sports medicine and
wound care, including BIO®, 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. BIO® is a registered trademark of Stryker Corporation (NYSE: SYK). More information can be found on the company's website, www.Osiris.com. (OSIR-G)

EpiFix is a registered trademark of MiMedx Tissue Services, LLC.


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, BIO® 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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