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Integra LifeSciences Receives FDA Approval for Integra® Omnigraft™ Dermal Regeneration Matrix, Clearing the Way for Commercial Release

Launches New Treatment for Hard-to-Heal Diabetic Foot Ulcers

PLAINSBORO, N.J., May 11, 2016 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ:IART), a leading global medical technology company, today announced that the Company has received approval from the U.S. Food and Drug Administration (FDA) for the packaging of its new product, Integra® Omnigraft™ Dermal Regeneration Matrix, which clears the way for its commercial release. The product's unique packaging is designed for ease of handling and application in the outpatient wound care setting.

"Over 30 million people in the United States are impacted by diabetes, and the numbers are growing. Of these, almost 1 million have hard-to-heal diabetic foot ulcers, which require treatment with advanced wound care solutions," said Peter Arduini, Integra's President and CEO. "We are extremely pleased that we can now offer clinicians a differentiated treatment solution for their patients' DFUs. We believe Omnigraft is a great fit for the evolving healthcare environment, and will help improve the quality of life for patients and their families."

"This is a very exciting opportunity for Integra," said Mark Augusti, President of Integra's Orthopedics & Tissue Technologies division. "We have a dedicated wound care sales team, and have already educated over 175 health care professionals on the use of Omnigraft. We have also created www.omnigraft.com, for clinicians, patients and payers to learn more about this new product. With Omnigraft, we hope to solve the needs of diabetics by closing their hard-to-heal DFUs."

Integra's FOot Ulcer New Dermal Replacement (FOUNDER) Study on Omnigraft is the largest published DFU study to date evaluating a cellular and/or tissue based product (CTP), and demonstrated significantly improved healing compared to conventional therapy, with a median of one application. Competitive substitutes can require multiple applications to achieve closure. With only one application, Omnigraft may reduce the financial burden for patients and the overall healthcare system. Over 124 million covered lives have access to Omnigraft, through both private insurance and Medicare. Currently, 93% of Medicare patients, in 47 states, have access.

About Omnigraft

Omnigraft is indicated for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers (DFUs) that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care.

The FDA [approved the PMA Supplement](#) for Integra® Dermal Regeneration Template (IDRT), also marketed as Integra Omnigraft Dermal Regeneration Matrix, for the treatment of DFUs on January 7, 2016, based on results from the FOUNDER study. The published study, one of the largest to support the treatment of DFUs, demonstrated that, compared to conventional therapy, Omnigraft increases the incidence of wound closure by 59%, increases the average rate of wound size closure by 50%, and reduces the median time to wound closure by five weeks. Compared to other DFU therapies, Omnigraft healed patients with fewer applications, with 92% of those who healed requiring two applications or fewer.

The FOUNDER study was a multi-center, randomized, controlled, parallel group clinical trial conducted under an Investigational Device Exemption (IDE). The pivotal clinical trial enrolled 307 patients at 32 sites, and patients were monitored for up to 29 weeks. The primary endpoint of the study was the incidence of complete wound closure at 16 weeks, as assessed by the investigator. The secondary outcome measures included time to complete wound closure, rate of wound closure, incidence of recurrence, and change in quality of life metrics. The median number of applications per patient, including the initial application, for the IDRT group was one. The results from the FOUNDER Study were printed in the November/December issue of *Wound Repair and Regeneration* in the publication, "A clinical trial of Integra Template for diabetic foot ulcer treatment."

About Integra

Integra LifeSciences, a world leader in medical technology, is dedicated to limiting uncertainty for clinicians, so they can concentrate on providing the best patient care. Integra offers innovative solutions, including leading plastic and regenerative technologies, in specialty surgical solutions, orthopedics and tissue technologies. For more information, please

visit www.integralife.com.

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements concerning the products and services provided by Integra. Such forward looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Among other things, the willingness of surgical professionals to use Integra products may affect the prospects for their use in surgical procedures. In addition, the economic, competitive, governmental, technological and other factors, identified under the heading "Risk Factors" included in Item IA of Integra's Annual Report on Form 10-K for the year ended December 31, 2015 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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