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## **Integra LifeSciences Provides Update for Omnigraft™ Commercialization Plans, Including Expectations for an Earlier Launch**

PLAINSBORO, N.J., April 27, 2016 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ:IART), a leading global medical technology company, today announced that the Company is prepared to launch Omnigraft™ Dermal Regeneration Matrix in June 2016, pending receipt of final U.S. Food and Drug Administration (FDA) packaging approval.

The FDA [approved the PMA Supplement](#) for Integra® Dermal Regeneration Template (IDRT) for the treatment of diabetic foot ulcers (DFUs) on January 7, 2016, based on results from the FOot Ulcer New DErmal Replacement (FOUNDER) Study. The published study, one of the largest to support the treatment of DFUs, demonstrated that Omnigraft increases wound closure by 59%, increases the rate of wound size reduction by 50%, reduces the median time to wound closure by five weeks, over standard of care, and treats patients with fewer applications than other DFU therapies. Omnigraft is indicated for use in the treatment of partial and full-thickness neuropathic 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.

Integra has held medical education events at several leading industry conferences and conducted hands-on training over the last two months.

"We have already trained more than 175 healthcare professionals on the use of Omnigraft, and are dedicated to providing best-in-class hands-on and didactic training throughout the year," said John Mahoney, Integra's Vice President of Professional Affairs and Medical Education.

The FOUNDER Study provides the strong clinical evidence necessary to drive payer access for Omnigraft. Over 112 million covered lives have access to Omnigraft, through both private insurance and Medicare. Currently, 93% of Medicare patients, in 47 states, have access. Omnigraft may help to lower total cost of treatment, based on the clinical data, which demonstrated that of those patients who healed, 72% did so with one application and 92% with two applications or fewer.

Dr. Carl Van Gils, Medical Director of the Wound Clinic at Intermountain Healthcare's Dixie Regional Medical Center, St. George, Utah, and a FOUNDER study participant said, "The results of the study were remarkable, and I see Omnigraft as a game changer in terms of not only quality of care, but also the economics of healthcare. I'm looking forward to the availability of Omnigraft as another treatment option for my patients' hard-to-heal DFUs."

"Integra currently markets PriMatrix® Dermal Repair Scaffold, an acellular dermal matrix, in both the hospital and out-patient wound clinic setting for the treatment of DFUs," said Bill Weber, Integra's Vice President and General Manager, Tissue Technologies. "In addition, we recently announced an agreement to market and sell VoITAC™ antimicrobial wound dressings, an advanced wound care technology that can be used to manage chronic and acute wounds. Once Omnigraft is launched, we will be in the unique position to offer clinicians a broad portfolio of wound care solutions."

### **About the FOUNDER Study**

The FOot Ulcer New DErmal Replacement (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's Wound Care Products**

Integra was founded on a technology platform to repair and regenerate tissue with engineered collagen devices. In 1996, the FDA approved the Company's first product, Integra® Dermal Regeneration Template, a collagen matrix designed as a skin replacement system for the treatment of third-degree burns. Integra Dermal Regeneration Template was the first product approved with a claim of regeneration of dermal tissue. Integra's skin and wound products also include Integra® Meshed Bilayer Wound Matrix, which can be used with Negative Pressure Wound Therapy; and Integra® Flowable Wound

Matrix, designed for easy application to tunneled and/or undermined wounds. Together, these products represent over 30 years of science and innovation in the development of collagen technology. Integra's Ultra Pure Collagen™ is the base material of implants used successfully in over 12 million procedures.

In July 2015, Integra acquired TEI Biosciences and TEI Medical, which added the SurgiMend® and PriMatrix® product lines to address a number of indications in wound care and tissue repair.

**Integra® Dermal Regeneration Template** is an advanced skin replacement matrix, designed to provide immediate wound closure and permanent regeneration of the dermis. The product is placed in direct contact with the excised wound and consists of a complex three-dimensional porous matrix that acts as a scaffold for cell migration and allows for regeneration of the dermal layer of the patient's skin.

#### **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](http://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 1A 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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