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Integra LifeSciences Receives FDA Approval of Integra® Dermal Regeneration Template (IDRT) for Treatment of Chronic Diabetic Foot Ulcers (DFU)

PLAINSBORO, N.J., Jan. 07, 2016 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ:IART) today announced that the United States Food and Drug Administration (FDA) has [approved the PMA Supplement](#) for Integra® Dermal Regeneration Template (IDRT) for the treatment of diabetic foot ulcers (DFU). The approval of this new indication is based on results from the FOUNDER (FOot Ulcer New DErmal Replacement) Study, a multi-center, randomized, controlled, parallel group clinical trial conducted under an Investigational Device Exemption (IDE). The FOUNDER Study showed that patients treated with IDRT demonstrated a 59% improvement in the incidence of complete wound closure compared to standard of care. IDRT, with its newly approved DFU indication, will be marketed under the name Integra® Omnigraft™ Dermal Regeneration Matrix.

"Integra is pleased to announce the approval of IDRT for the treatment of diabetic foot ulcers. This approval allows us to provide clinicians and their patients with a product backed by a robust clinical trial to treat the nearly 1 million non-healing DFUs that will occur this year. This significant milestone enables us to remain on track for DFU market commercialization in mid-2016," said Peter Arduini, Integra's President and Chief Executive Officer.

The prevalence of diabetes continues to rise, currently affecting an estimated 30 million people in the United States. Of those diagnosed, as many as 15% may experience a diabetic foot ulcer in their lifetime. The advanced active healing dressings market is approximately \$3.0 billion in the U.S., of which nearly \$600 million is in cellular and tissue-based products (CTPs).

"The new indication for IDRT, supported by clinical evidence, will benefit clinicians and their patients. This product has been used in the operating room to treat life-threatening third-degree burns since 1996, and can now be used in the clinic to treat patients who suffer from diabetic foot ulcers," said FOUNDER Study Principle Investigator Dr. Lawrence A. Lavery, DPM, MPH of University of Texas Southwestern Medical Center.

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 followed for up to 29 weeks. The primary endpoint of the study was the incidence of complete wound closure at 16 weeks. The secondary outcome measures included time to complete wound closure, incidence of recurrence, and quality of life. 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 caregivers, so they can concentrate on providing the best patient care. Integra offers innovative solutions, including leading regenerative technologies, in specialty surgical solutions, orthopedics and tissue technologies. For more information, please visit www.integralife.com.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and reflect Integra's judgment as of the date of this release. 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, including the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and market requirements. 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, 2014 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results. These forward-looking statements are made only as the date thereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

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