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Integra LifeSciences Announces FOUNDER Study Results Which Show Increased Rate of Complete Wound Closure and Decreased Time to Complete Wound Closure With Integra(R) Dermal Regeneration Template (IDRT) for Treatment of Chronic Diabetic Foot Ulcers (DFU)

Results Accepted for Publication in Wound Repair and Regeneration

PLAINSBORO, N.J., Aug. 25, 2015 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (NASDAQ:IART) today announced the online publication of its pivotal clinical trial evaluating Integra Dermal Regeneration Template (IDRT) for the treatment of non-healing diabetic foot ulcers (DFUs) in the peer-reviewed journal, *Wound Repair & Regeneration*.

The publication, "A Clinical Trial of Integra® Template for Diabetic Foot Ulcer Treatment" evaluated the safety and efficacy of IDRT for the treatment of non-healing DFUs compared to standard of care. In the trial, IDRT outperformed standard of care treatment with respect to DFU closure during the treatment phase (51% vs 32% p=0.001) at sixteen weeks. Additionally, IDRT outperformed standard of care when comparing median time to complete DFU closure (43 days vs 78 days), and rate of wound size reduction per week (7.2% vs 4.8% p=0.012). The median number of applications per patient, including the initial application, for the active group was one.

"Integra is committed to providing the diabetic community and wound care specialists with a solution that greatly enhances the treatment of non-healing DFUs, backed by robust clinical data support," said Peter Arduini, President and Chief Executive Officer of Integra. "This is another important milestone, and we remain on track for DFU market commercialization in mid-2016. We would like to recognize the hard work and commitment of the investigators, institutions, and patients who participated in this trial and thank them for their contribution to this successful study."

As previously announced, Integra has completed the submission of a Premarket Approval (PMA) Supplement application to the United States Food and Drug Administration (the "FDA") for a new indication for the use of its Integra® Dermal Regeneration Template for the treatment of diabetic foot ulcers. The submission is still under review.

The article's authors include: Vickie R. Driver, MS of Brown University School of Medicine, Lawrence A. Lavery, MPH of University of Texas Southwestern, Alexander M. Reyzelman of UCSF Center for Limb Preservation, California School of Podiatric Medicine at Samuel Merritt University, Timothy G. Dutra, MS of California School of Podiatric Medicine at Samuel Merritt University, Cyaandi R. Dove of the Advanced Foot & Ankle Center, Las Vegas, NV, Sandra V. Kotsis, MPH of The University of Michigan Medical School, H. Myra Kim, ScD of the Center for Statistical Consultation and Research, The University of Michigan, and Kevin C. Chung MD, MS of The University of Michigan Medical School.

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 all patients were followed for up to 28 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, incidence of adverse events, and quality of life.

About Wound Repair and Regeneration

Wound Repair and Regeneration: The International Journal of Tissue Repair and Regeneration is the official publication of the Wound Healing Society, the European Tissue Repair Society, the Japanese Society for Wound Healing, and the Australian Wound Management Association. The Journal provides extensive international coverage of cellular and molecular biology, connective tissue, and biological mediator studies in the field of tissue repair and regeneration and serves a diverse audience of surgeons, plastic surgeons, dermatologists, biochemists, cell biologists, and others.

About the Diabetic Foot Ulcer Market

The prevalence of diabetes continues to rise, currently affecting an estimated 29 million people in the United States. Of those diagnosed, as many as 25% 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 \$500 million is in cellular and tissue based products (CTPs).

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 add 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 system, 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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