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## **Integra LifeSciences Announces Completion of Its Multicenter Clinical Trial for the Treatment of Diabetic Foot Ulcers**

PLAINSBORO, N.J., Aug. 5, 2014 (GLOBE NEWSWIRE) -- [Integra LifeSciences Holdings Corporation](#) (Nasdaq:IART) today announced that it has completed its multicenter clinical trial evaluating the safety and effectiveness of INTEGRA® Dermal Regeneration Template for the Treatment of Diabetic Foot Ulcers ("the DFU study"). Integra Dermal Regeneration Template is an advanced bilayer skin replacement system designed to provide immediate wound closure and permanent regeneration of the dermis. The clinical trial was conducted under an FDA Investigational Device Exemption.

"We closed out the DFU study and are in the process of evaluating all of our data. We believe that we achieved the key goals that we designed for the study," said Peter Arduini, Integra's President and Chief Executive Officer. "We are currently assessing and finalizing the data from the DFU study, and are preparing submissions in advance of our clinical publication, reimbursement and regulatory strategies."

Consistent with prior communications, Integra expects to submit the data from this clinical trial to the Food and Drug Administration (FDA) by the end of 2014. In parallel, Integra will pursue publishing the data in a peer-reviewed journal. An FDA approval, coupled with published data, is the key to securing reimbursement. The Company anticipates commercializing the resulting DFU product mid-2016.

### **About the Diabetic Foot Ulcer Market**

The prevalence of diabetes continues to rise, currently affecting an estimated 26 million people in the United States. Of those diagnosed, as many as 25% may experience a diabetic foot ulcer in their lifetime. The advanced wound care market is approximately \$2.5 billion in the U.S., of which nearly \$500 million is in cellular and tissue based products (CTPs).

### **About Integra's Wound Care Products**

The Company 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 victims 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.

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 the DFU Study**

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 is 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. Each of these was measured over 28 weeks.

The Company closed out the DFU study in July and is in the process of evaluating the data from the study. Based on the initial review of the data, the Company believes it achieved the key goals of the study.

### **About Integra**

Integra LifeSciences, a world leader in medical technology, is dedicated to limiting uncertainty for surgeons, so they can concentrate on providing the best patient care. Integra offers innovative solutions in orthopedic extremity surgery,

neurosurgery, spine surgery, and reconstructive and general surgery. 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 that involve risks, uncertainties and reflect the Company's judgment as of the date of this release. 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, the ability to achieve reimbursement and market requirements. In addition, market conditions, the economic, competitive, governmental, technological and other factors beyond the Company's control 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, 2013 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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