December 23, 2013

Integra LifeSciences Announces Completion of Patient Enrollment in Clinical Study of Integra(R) Dermal Regeneration Template for the Treatment of Diabetic Foot Ulcers

PLAINSBORO, N.J., Dec. 23, 2013 (GLOBE NEWSWIRE) -- Integra LifeSciences Holdings Corporation (Nasdaq:IART) announced today that it has completed patient enrollment in a multi-center, randomized, controlled clinical trial comparing the safety and effectiveness of Integra® Dermal Regeneration Template to the standard of care for the treatment of diabetic foot ulcers. Integra Dermal Regeneration Template is an advanced bilayer skin replacement system designed to provide immediate wound closure and permanent regeneration of the dermis.

The pivotal trial enrolled 307 patients at 32 sites, and all patients are followed for up to 28 weeks. Once patient follow-up is complete, which is expected to occur in mid-2014, this data will form the foundation for submission for Premarket Approval (PMA) from the United States Food and Drug Administration (FDA). The PMA, if approved, along with publication of the data in a peer-reviewed journal, will support reimbursement for the product.

"Integra Dermal Regeneration Template has a long clinical history of success in burns and scar contracture release, and has the potential to help many people who are suffering with diabetic foot ulcers," said Dr. Vickie Driver, lead clinical investigator in the trial. "I look forward to seeing the results from the study, and am hopeful that we will have a new therapy to treat patients with difficult-to-heal wounds."

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 currently nearly $500 million is in cellular and tissue based products (CTPs).

"Completion of patient enrollment in the Integra Dermal Regeneration Template diabetic foot ulcer clinical trial is a major milestone for Integra, and marks an important first step toward product commercialization," said Robert D. Paltridge, President, Extremity Reconstruction. "We hope to use the results from this study to receive the expanded indication, which will allow us to provide an additional treatment option to address the increasing prevalence of diabetic foot ulcers. We look forward to being able to better serve our customers and the diabetic population by providing clinically relevant, cost effective solutions."

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.

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, 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 IA of Integra's Annual Report on Form 10-K for the year ended December 31, 2012 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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