Integra LifeSciences Announces FDA Clearance for New Indication for Accell Evo3(R) Demineralized Bone Matrix

PLAINSBORO, N.J., April 12, 2011 (GLOBE NEWSWIRE) -- Integra LifeSciences Holdings Corporation (Nasdaq:IART) today announced that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) to market Accell Evo3® Demineralized Bone Matrix as a bone void filler product for use in the posterolateral spine.

In a pivotal animal study, Accell Evo3® Demineralized Bone Matrix demonstrated effective bone formation and achieved bilateral fusion at 12 weeks, when tested in the posterolateral rabbit spine model. Radiographic, histologic and biomechanical analyses showed that Accell Evo3® Demineralized Bone Matrix performed as well as autograft, which served as the basis for the Pre-Market Notification decision.

Accell Evo3® Demineralized Bone Matrix is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use as a bone graft extender in the spine, extremities and pelvis. Accell Evo3® Demineralized Bone Matrix may also be used as a bone void filler in the posterolateral spine, extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

"Integra is very pleased that the FDA cleared this new indication for Accell Evo3® Demineralized Bone Matrix," said Bill Weber, Vice President and General Manager of Integra Orthobiologics. "Surgeons must frequently obtain healthy bone graft material from the patient's own body. Accell Evo3® Demineralized Bone Matrix now offers them an alternative to harvesting the patient's own bone, which may spare the patient additional surgeries and post-operative pain."

Integra currently provides a complete range of bone graft substitutes to orthopedic surgeons and neurosurgeons, which includes Accell TBM®, Accell Evo3®, Accell Evo3®c, Accell Connexus®, DynaGraft®, and OrthoBlast® demineralized bone matrices, as well as the Integra Mozaik™ line of products.

Integra LifeSciences, a world leader in medical devices, is dedicated to limiting uncertainty for surgeons, so they can concentrate on providing the best patient care. Integra offers innovative solutions in orthopedics, neurosurgery, spine, 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. 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, 2010 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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