FDA Panel Recommends rhBMP-2 Product Including Integra LifeSciences Absorbable Collagen Sponge

PLAINSBORO, N.J.--(BUSINESS WIRE)--Jan. 11, 2002--Integra LifeSciences Holdings Corporation (Nasdaq:IART) today announced that the Orthopedic and Rehabilitation Devices Panel of the United States Food and Drug Administration (FDA) has unanimously recommended for approval, with conditions, the InFUSE™ Bone Graft used with the LT-CAGE™ Lumbar Tapered Fusion Device for use in spinal fusion procedures.

The InFUSE Bone Graft, a product of Medtronic Sofamor Danek (NYSE:MDT), includes the Absorbable Collagen Sponge developed and manufactured by Integra LifeSciences. When used with the LT-CAGE Lumbar Tapered Fusion Device, the InFUSE Bone Graft will be indicated to treat certain types of spinal degenerative disc disease, a common cause of low back pain.

The FDA panel conditions for approval included three additional post-approval studies in the areas of antibody response during pregnancy, dosing and tumorogenicity. In addition, the panel recommended the product only be used with tapered cages.

InFUSE Bone Graft replaces the use of autograft bone because it contains a recombinant human bone morphogenetic protein, or rhBMP-2, which induces the body to grow its own bone where needed.

rhBMP-2 was discovered and developed by Wyeth-Ayerst Laboratories, the pharmaceutical division of American Home Products Corporation (NYSE:AHP), and is manufactured in its Andover, Mass., biopharmaceutical facility. When surgeons use InFUSE Bone Graft, rhBMP-2 powder is reconstituted with sterile water and then applied to an Absorbable Collagen Sponge (ACS).

The ACS is used inside two LT-CAGE Lumbar Tapered Fusion Devices implanted between the vertebrae.

"We are very excited to contribute to this important new medical technology," said Stuart M. Essig, Integra's Chief Executive Officer. "Yesterday's panel recommendation is another important step toward the commercialization of this product, and further validation of Integra LifeSciences major presence in the field of tissue regeneration and repair."

If approved by the FDA, Integra's Absorbable Collagen Sponge for the InFUSE product will join Integra's other leading tissue regeneration and repair products.

They include the INTEGRA® Dermal Regeneration Template for regeneration of the dermis, the DuraGen® Dural Graft Matrix for repair of the dura mater, the NeuraGen™ Nerve Guide for repair of peripheral nerves, and the Biomend® products for guided repair of the periodontal ligament in dental surgery.

The INTEGRA Dermal Regeneration Template is sold through Johnson & Johnson's Ethicon division, the Biomend line of products is sold through the Sulzer Dental division of Sulzer Medica, and the DuraGen and NeuraGen products are sold through Integra NeuroSciences, the neurosurgical devices division of Integra LifeSciences Holdings Corporation.

Integra LifeSciences Holdings Corporation, headquartered in Plainsboro, New Jersey, has approximately 600 permanent employees. Please visit the Company's website at http://www.Integra-LS.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 relating to the anticipated regulatory approval of the InFUSE product and the ultimate prospects for commercial success of the product.

Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results.

In addition, the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in the Business section of Integra's Annual Report on Form 10-K/A for the year ended December 31, 2000 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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