Integra LifeSciences Announces FDA Clearance for the NeuraGen Nerve Guide for Repair of Severed Peripheral Nerves

PLAINSBORO, N.J., Jul 5, 2001 (BUSINESS WIRE) --

Product Launch to Begin in Fourth Quarter

Integra LifeSciences Holdings Corporation (Nasdaq: IART) today announced that it has received 510(k) clearance from the FDA to market the NeuraGen™ Nerve Guide, an absorbable implant for the repair of severed peripheral nerves in the extremities.

Peripheral nerves may become severed through traumatic accidents or surgical injuries, often resulting in the permanent loss of motor and sensory function. The NeuraGen™ Nerve Guide is an absorbable collagen tube designed to provide a protective environment for the regenerating nerve and to provide a conduit through which regenerating axons can bridge the injury.

"Although the axons of severed peripheral nerves regenerate spontaneously, they will not establish functional connections unless the nerve stumps are surgically reconnected," said Simon Archibald, Ph.D., Integra NeuroSciences' Vice President of Research and Development. "The NeuraGen™ Nerve Guide offers a rapid method for rejoining severed peripheral nerves, in contrast to conventional microsurgical techniques. The technology behind the NeuraGen™ Nerve Guide is based on a semi-permeable collagen tube that isolates and defines an environment for the extension of axons and growth of Schwann cells that are the elements responsible for functional recovery following nerve injury."

Integra NeuroSciences, the neurosurgical division of Integra LifeSciences Holdings Corporation, will launch the NeuraGen™ Nerve Guide in the United States in the fourth quarter through its 50 person direct sales force. The launch will coincide with the meetings for the Congress of Neurological Surgeons and the American Society for Surgery of the Hand in October.

The Company plans a submission for CE Mark Certification to market the NeuraGen™ product in the European Community and is working with its strategic partner, Century Medical, Inc., to obtain market approval in Japan. Integra NeuroSciences expects to use its worldwide network of distributors to reach other major markets. The Company estimates that the annual worldwide market potential for the repair of peripheral nerve injuries approximates $40 million.

The NeuraGen™ Nerve Guide is the fifth of a series of absorbable medical devices developed by Integra LifeSciences and has been in development for over 15 years. The Company's other absorbable medical devices include the following:

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--  DuraGen&reg; Dural Graft Matrix for the sutureless repair of the
    dura mater;
--  INTEGRA&reg; Dermal Regeneration Template for regeneration of
    the dermis; and
--  BioMend&reg; and BioMend&reg; Extend Absorbable Collagen Membrane
    for guided tissue repair of the gingiva.
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Integra NeuroSciences designs, manufactures and sells implants, devices and monitors used in neurosurgery, neurotrauma, and related critical care. Together with its seven-person clinical development team, Integra NeuroSciences' direct selling effort exceeds 60 field personnel in the United States and Europe. Integra NeuroSciences also sells its products in approximately 80 countries worldwide through a network of international distributors.

Integra LifeSciences Holdings Corporation, headquartered in Plainsboro, New Jersey, has approximately 550 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 market launch of the NeuraGen™ products, the potential market size for these products and their use in approved therapeutic applications, and product development programs and regulatory approval. 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 Company's ability to manufacture the NeuraGen™ products may affect product launch activities, the willingness of physicians to adopt new products may affect their use in approved therapeutic applications and the potential market size, and the willingness of strategic partners to continue development programs may affect product development and regulatory approval activities. 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. Integra disclaims any obligation to update any of the forward-looking statements contained herein to reflect future events or developments.

Source: Integra LifeSciences Holdings Corporation

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