Medtronic News

Medtronic's AMPLIFY(TM) rhBMP-2 Matrix Receives Positive Votes from FDA Advisory Panel on All Three Key Questions: Safety, Effectiveness and Benefit/Risk

New biologic bone graft product demonstrated superior fusion rates compared to current standard of care for complex fusion procedures of the lower spine in the pivotal clinical trial

MINNEAPOLIS, Jul 27, 2010 (BUSINESS WIRE) --

The U.S. Food and Drug Administration (FDA) Orthopaedic and Rehabilitation Devices Panel today voted 9 for and 4 against (1 abstention) on safety and 10 for and 3 against (1 abstention) on effectiveness, that data including results from a large, prospective randomized clinical trial demonstrated the safety and effectiveness of AMPLIFY(TM) rhBMP-2 Matrix for fusions of the lower spine in patients with degenerative disc disease. The benefits of this new bone graft option, which is specifically designed for single-level, posterolateral spinal fusion procedures, were also found by a majority of those voting to outweigh any risks associated with this product by a vote of 6 for and 5 against (3 abstention).

AMPLIFY(TM) rhBMP-2 Matrix was found in the clinical trial to produce statistically higher rates of bone fusion at the designated 24-month endpoint compared to the control group, which used the patient's own bone harvested from the hip. Harvested hip bone, long considered the standard of care bone graft, presents challenges for patients and surgeons, including the need for a second surgery to harvest the bone.

"AMPLIFY(TM) rhBMP-2 Matrix represents a monumental advancement in the arsenal of bone grafting options available for posterolateral spine fusions. This is the first recombinant bone graft that has been proven to yield statistically higher fusion rates than the current standard of care," said James Hardacker, MD, an orthopedic surgeon from Indianapolis, and a researcher in the AMPLIFY(TM) rhBMP-2 Matrix clinical trial. "With this important new product, a second operation to harvest bone from the hip, which can increase pain and other complications for the patient, can be avoided."

AMPLIFY(TM) rhBMP-2 Matrix is a combination product that includes the following:

- Recombinant human bone morphogenetic protein-2 (rhBMP-2) solution, a synthetically produced version of a naturally occurring protein in the body, which is used to stimulate bone formation
- A unique porous carrier system called a compression-resistant matrix (CRM) comprised of collagen and resorbable ceramic to carry the rhBMP-2 solution and maintain the rhBMP-2 at the site of implantation. The CRM also serves as a scaffold on which new bone may form.

AMPLIFY(TM) rhBMP-2 Matrix must be used in conjunction with a metallic posterior supplemental fixation device that is indicated for temporary stabilization of the spine.

Medtronic vice president Tom McGuinness, who serves as the General Manager of the firm's Biologics business, noted that the Advisory Panel's affirmative votes on all three questions represent an important first step of bringing this product to market to meet the needs of degenerative disc disease patients. "We will continue to collaborate closely with the FDA to develop the path forward. The potential approval of AMPLIFY(TM) rhBMP-2 Matrix will further strengthen our position as the market-leading provider of a comprehensive portfolio of bone grafting options."

Clinical Effectiveness, Safety and Positive Benefit/Risk Ratio of AMPLIFY(TM) rhBMP-2 Matrix

The panel reviewed data from a large, prospective clinical trial that enrolled 463 patients who were randomized to receive AMPLIFY(TM) rhBMP-2 Matrix or undergo surgical treatment with autogenous bone harvested from their hip bone, referred to as autograft.

AMPLIFY(TM) rhBMP-2 Matrix was shown to be statistically non-inferior to autograft for the primary study endpoint, Overall Success, which was a combination of both safety and effectiveness measures. Amplify(TM) rhBMP-2 Matrix also achieved statistically superior fusion results at 24 months, with sustained high fusion rates and patient satisfaction through 60 months. The safety profile also compared favorably to autograft with reduced surgery blood loss and shorter mean operative times. AMPLIFY(TM) rhBMP-2 Matrix provides a solution for patients that lack sufficient high quality hip bone to harvest, and also eliminates the complications and pain of the bone harvest surgery in all patients.

About Posterolateral Spine Fusions

Posterolateral spine fusions stabilize two adjoining vertebrae by inducing bone formation to form across a space, sometimes as much as 4 cm in length, where bone previously never existed. To induce bone formation, bone grafting material is required. Currently, local bone, allograft or ceramic substitutes may be used, but the standard of care is bone taken from patients' hip bone, which can cause significant postoperative pain, blood loss and morbidity.

About Degenerative Disc Disease

Degenerative disc disease is pain caused by deterioration of the disc confirmed by patient history and radiographic studies. Degeneration makes the disc more susceptible to herniation that can lead to sciatica, severe pain caused by irritation of the spinal nerves. Degenerative disc disease can result in significant, chronic pain and greatly affect patient's productivity and quality of life. When pain from degenerative disc disease is significant, non-surgical treatment options may be ineffective.

About the Biologics Business at Medtronic

Medtronic Biologics, based in Memphis, Tenn., is the global leader in biologics therapies for regeneration and pain across a variety of musculoskeletal and other applications. The business markets breakthrough innovations such as INFUSE(TM), which received the prestigious Prix Galien USA Award for Best Biotechnology Product in 2008. Medtronic Biologics also has a robust pipeline of other products, including sciatica and post-op pain therapies. Today, the business participates across three key markets including spine, orthopedic trauma, and dental and collaborates with world-renowned surgeons, researchers, and innovative partners to offer state-of-the-art products and technologies.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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