Medtronic News

First-of-Its-Kind Independent Review of INFUSE® Bone Graft Coordinated by Yale University is Complete

Thomson Reuters ONE via COMTEX) --INFUSE Bone Graft Remains Important Treatment Option

MINNEAPOLIS - June 17, 2013 - Medtronic, Inc. [NYSE: MDT] acknowledged today the publication of the findings from Yale University's third-party, independent review of INFUSE® Bone Graft, a proprietary formulation of recombinant human bone morphogenetic protein-2 (rhBMP-2) that was approved by the U.S. Food and Drug Administration (FDA) in 2002 for use in anterior lumbar interbody spine fusion to stimulate natural bone growth. Since it was approved, Medtronic has worked with the FDA to communicate the benefits and risks of the product in its FDA-approved labeling. The findings published in the June 18 issue of the Annals of Internal Medicine add to a growing body of evidence regarding INFUSE Bone Graft as a safe and effective treatment option for patients in approved indications for use.

Medtronic commissioned Yale to lead the review in 2011 as part of its commitment to patient safety and transparency and as a result of questions raised about data included in peer-reviewed medical journals about INFUSE Bone Graft. The findings from two systematic reviews released today highlight known and studied benefits and risks associated with INFUSE Bone Graft and rhBMP-2. The findings reiterate, as with all therapies and surgical procedures, INFUSE Bone Graft poses certain risks that must be evaluated carefully by patients and physicians before use. Medtronic reported complete adverse event information to the FDA during the IDE clinical trials, and that information appears in the product labeling for approved indications.

"Through this open access process coordinated by Yale, we provided an unprecedented level of data access in order to test new approaches to data sharing of industry research," said Omar Ishrak, chairman and CEO of Medtronic. "We recognize that our products and therapies must have the public and medical community's trust, so we will continue to create, test and explore new ways to make our clinical research available as part of our commitment to transparency and to providing information that informs the medical decisions that physicians make based on each patient's needs."

"The complex analyses laid out in the systematic reviews add to a better understanding of the benefits and risks outlined in our labeling for INFUSE Bone Graft, which guides the safe and effective use of the product for patients in FDA-approved indications," said Rick Kuntz, M.D., senior vice president and chief scientific, clinical and regulatory officer at Medtronic. "We are grateful to the participants of the reviews, which have taken patient-level data from multiple individual rhBMP-2 studies and literature reports, each with different areas of focus, and combined these into two systematic reviews of the safety and effectiveness of rhBMP-2. We will continue to conduct research on rhBMP-2 to further add to an increased understanding of the benefits and risks of this important treatment option."

As part of the independent review, Medtronic provided Yale with patient-level data from 17 completed spine clinical trials conducted by Medtronic on INFUSE Bone Graft and investigational products with varying carriers, surgical approaches and concentrations of rhBMP-2 involving more than 2,000 patients. The analyses also included post-market adverse event (safety) reports that were submitted to FDA and data from published literature. Yale independently assembled a panel of experts and commissioned Oregon Health & Sciences University and University of York in the United Kingdom to conduct the analyses of the data.

Both analyses concluded that there are equivalent clinical success outcomes with INFUSE Bone Graft compared to iliac crest (hip) bone graft procedures. These findings are consistent with those in the original clinical studies of the INFUSE Bone Graft, which were designed to demonstrate the product is as effective as graft material harvested from a hip without the potential pain and complications associated with an iliac crest bone harvest procedure.

Furthermore, one of the adverse events addressed in the two analyses was cancer. The analyses concluded that the rates of

cancer were low, the types of cancer were heterogenous and the strength of the evidence to draw specific conclusions was low. Given Medtronic's extensive pre-clinical studies of rhBMP-2, the totality of clinical trial evidence and retrospective analyses by other researchers on the occurrence of cancer in real-world use, the company believes the data do not support a causal relation between INFUSE Bone Graft and the development of cancer. Looking forward, Medtronic has funded a retrospective analysis of a large, national payer database to investigate the incidence of cancer in real-world use of INFUSE Bone Graft. This analysis has been accepted for presentation in the Fall of 2013.

Medtronic also remains committed to ongoing monitoring of the long-term safety of INFUSE Bone Graft. The company uses post-market surveillance to monitor the long-term outcomes of the product and is planning a post-market registry to collect data from real-world use of the product. In addition, the company is in ongoing discussions with the FDA to determine pathways for new indications for INFUSE Bone Graft and for new rhBMP-2 products, including alternate formulations and carriers.

"We are pleased to have reached a milestone in completing this review as we move forward with this important treatment option," said Chris O'Connell, executive vice president and president of Medtronic's Restorative Therapies Group, including the Spine business. "We remain committed to INFUSE Bone Graft, which has a decade of clinical use and has been cited as one of the most important innovations in orthopedic medicine."

About INFUSE Bone Graft

INFUSE Bone Graft is recombinant human bone morphogenetic protein-2 (rhBMP-2) applied to an absorbable collagen sponge (ACS) carrier. One of the functions of the protein is to stimulate natural bone formation. Overall, BMP technology has a lengthy history of extensive research and study dating back more than fifty years. INFUSE Bone Graft was approved by the FDA in 2002 for use in Anterior Lumbar Interbody Fusion (ALIF) spine surgical procedures. Additional approvals were received in 2004 and 2007 for trauma and oral-maxillofacial (OMF) indications, respectively. The FDA-approved indications are:

- In combination with Medtronic's LT-CAGE® Lumbar Tapered Fusion Device, INTER FIX(TM) Threaded Fusion Device, or INTER FIX(TM) RP Threaded Fusion Device, in anterior lumbar interbody spinal fusion procedures to treat skeletally mature patients with degenerative disc disease (DDD) at a single level from L2-S1;

- In treating acute, open tibial shaft fractures in skeletally mature patients that have been stabilized with IM nail fixation after appropriate wound management (within 14 days after the initial fracture); and

- In OMF procedures as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

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 worldwide.

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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