Medtronic News

Medtronic Engages Yale University to Oversee Independent, Systematic Reviews of Recombinant Bone Morphogenic Protein-2

First of its Kind Post-Review Website to Provide Scientific Access to Full Clinical Data

MINNEAPOLIS, Aug 03, 2011 (BUSINESS WIRE) --

Medtronic, Inc. [NYSE: MDT] announced today that it has provided a grant to Yale University to conduct two fully independent, third-party systematic reviews of the safety and effectiveness of its recombinant bone morphogenic protein-2 (rhBMP-2) product, which stimulates bone formation.

Medtronic will provide Yale with all available patient-level data on rhBMP-2 from Medtronic-sponsored clinical trials, both published and unpublished, as well as all FDA-filed adverse event reports, for the purpose of executing an independent and comprehensive review of the entire body of evidence. Yale will assemble a panel of experts and will commission two academically recognized, publicly trusted clinical research organizations specializing in systematic reviews to conduct the analyses and ensure the findings are reproducible and of the highest integrity.

In addition, Medtronic will voluntarily make all of its clinical-trial results information on the product available publicly on ClinicalTrials.gov, the clinical-trial registry managed by the National Library of Medicine. Besides the clinical studies on rhBMP-2 already available on the site, Medtronic will retroactively register all pre-market-approval and post-market clinical trials on the product that were completed before the September 2007 requirement for registering such trials on the site was established.

Finally, Medtronic has agreed with Yale to develop a novel program to provide researchers access to all data on rhBMP-2 by means of a defined registration process and website. This planned program is unprecedented in the medical industry, and will differ from clinical trial publications or other data sources in that it will provide access to the full patient-level data sets possessed by Medtronic, including independent de-identified patient level data, not just the data summaries that are commonly used in meta-analysis and systematic reviews.

"We understand questions have been recently raised about rhBMP-2 and look forward to sharing our conclusions publicly on the safety and effectiveness of this product at the end of our reviews of a full set of patient-level product data," said Harlan Krumholz, Harold H. Hines Jr. Professor of Internal Medicine, Epidemiology and Public Health at Yale School of Medicine. "This project, including making the data accessible to all researchers, is intended to establish a landmark model for data transparency - a breakthrough in balancing the needs of industry with the public's desire for an independent review of the complete set of data. If successful, this new approach can become standard practice. Medtronic is taking an important leadership position that we hope others will follow."

Rick Kuntz, M.D., Medtronic's chief scientific officer, said, "Our pledge to support full access to the clinical data, in the form of independent patient-level data for the systematic reviews, retroactive registration of all trials with the National Library of Medicine, and the provision for broad investigator access of all patient-level data from Medtronic-sponsored studies, represents a novel and significant commitment to transparency and open-access scientific research."

Dr. Krumholz will assemble a steering committee of 12 to 15 advisors including those with expertise in clinical issues, clinical reviews, clinical trial conduct, systematic reviews, statistical analysis of clinical trial program data and ethical standards related to conflicts of interest, as well as a consumer representative. Two leading organizations with significant expertise in conducting large systematic reviews will evaluate the data independently. These efforts will be funded by a sponsored research grant of approximately $2.5 million provided by Medtronic to Yale to cover the costs of the analysis, oversight and operations of the systematic reviews and data management program. While Medtronic will provide the grant, it will not participate in any manner

in the selection of the research organizations or the steering committee, the reviews, or the manner of the data release. Yale will expedite the reviews and seek to complete them within six months, and plans to make the data available within 18 months.

Omar Ishrak, chairman and CEO of Medtronic said, "Integrity and patient safety are Medtronic's highest priorities, so it is important that a respected academic institution provide a publicly trusted source of information by way of these systematic reviews and the novel data access program for researchers."

"In recent years Medtronic has put in place several voluntary, industry-leading policies on conflicts of interest and appropriate research practices. Our continued leadership in the area of business ethics is one of my top personal priorities, and I'm committed to continuous improvement and the consideration of new and improved policies as warranted," he added.

INFUSE(R) Bone Graft is recombinant human Bone Morphogenic Protein-2 (rhBMP-2) applied to an absorbable collagen sponge carrier. The purpose of the protein, which occurs naturally in the body, is to stimulate bone formation. The first FDA approval was received in 2002 and the product has been approved by the FDA for three indications.

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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