Medtronic News

Medtronic Launches Long Term Clinical Study Program of INFUSE Bone Graft in Two Common Spine Procedures: PLF and TLIF

First Patient Enrolled in Initial Posterolateral Fusion Study

DUBLIN - September 5, 2017 - Medtronic plc (NYSE: MDT) today announced the launch of a long term clinical study program to collect prospective data on INFUSE® Bone Graft in Posterolateral Fusion (PLF) and Transforaminal Lumbar Interbody Fusion (TLIF) spine procedures. The first patient has been enrolled in the PLF study at Fort Wayne Orthopedics in Fort Wayne, Ind. The Spine team led by Dr. Kevin Rahn and Dr. Robert Shugart performed the procedure. The use of INFUSE Bone Graft in PLF and TLIF procedures is investigational only.

"Failed back surgery is a real concern with long-term implications, and successful outcomes in PLF and TLIF procedures require solid fusion," said Dr. Brian Subach, president at The Virginia Spine Institute. "We believe there is significant data on the safety and efficacy profile of INFUSE in approved ALIF and OLIF procedures, and we are hopeful this clinical study program can generate evidence about the potential to use this important technology to help a broader group of patients."

INFUSE Bone Graft is used with certain Medtronic interbody fusion devices to treat lumbar degenerative disc disease, and eliminates the need to harvest bone from the patient's body in a secondary surgical procedure.

The global clinical program, called B.O.N.E (BMP Outcomes and New Evidence in PLF and TLIF Procedures), is designed to expand the clinical understanding of INFUSE and to evaluate efficacy, safety and health-economic outcomes for use in PLF and TLIF spine procedures. The current plan for the prospective, multi-center, ten-year program will include approximately 40-50 sites and 550-700 patients between the Pilot and Pivotal studies of both procedures. The PLF Pilot dosing study, which will include approximately 125 patients, will be followed by a TLIF Pilot dosing study in 2018. If successful, the Pilot studies would be followed by a larger Pivotal study. The results may also potentially be used to support peer-reviewed publications and regulatory filings.

"INFUSE is one of the most extensively-researched biologic agents commercially available today and Medtronic continues to invest in research of INFUSE to deepen the understanding of the benefits and risks of this novel treatment," said Doug King, senior vice president and president of Medtronic's Spine division, which is part of the Restorative Therapies Group. "We're hopeful that if successful, the trials will generate additional data to expand indications and provide surgeons with additional options to help alleviate pain and restore health for more patients."

About Degenerative Disc Disease

Back pain, including degenerative disc disease (DDD), is a significant issue that is increasing as the population ages. One in four adults suffer from chronic low back pain and it causes 52 million health care visits annually. DDD is typically a result of an aging disc or repeated physical stresses over extended periods of time. In the United States, more than 300,000 individuals with a variety of spinal conditions, like DDD, undergo spinal fusions annually to treat degenerative changes in the lumbar spine.

About INFUSE BONE GRAFT

INFUSE Bone Graft is FDA-approved for certain spine, oral-maxillofacial and orthopedic trauma surgeries. The active ingredient in INFUSE Bone Graft (rhBMP-2) is a manufactured version of a protein already present in the body that promotes new bone growth. During surgery, INFUSE is applied to an absorbable collagen sponge (ACS). The ACS is a carrier to deliver the rhBMP-2 to the implant site and acts as a scaffold for the formation of new bone, and it will resorb, or disappear, over time. INFUSE has been on the market since 2002 and more than one million patients have used INFUSE.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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