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Orthofix Receives FDA and CE Mark Approvals for New Bone Growth Stimulators

New first-to-market feature aims to facilitate patient compliance and improve spinal fusion outcomes

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ:OFIX), a diversified, global medical device company, today announced U.S. Food and Drug Administration (FDA) and European CE Mark approvals for its next-generation CervicalStim™ and SpinalStim™ bone growth stimulators. These Class III medical devices use a low-level pulsed electromagnetic field (PEMF) designed to activate and augment the body's natural healing process, providing patients with a safe, noninvasive treatment option for promoting post-operative spinal fusion.

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Next-generation SpinalStim and CervicalStim bone growth stimulators developed by Orthofix. (Photo: Business Wire)

The CervicalStim and SpinalStim systems available in the U.S. will be accompanied by a new application for mobile devices called Stim onTrack™. Designed for use with smartphones and other mobile devices, Stim onTrack provides tools to help patients follow their prescription, including daily treatment reminders and a device usage calendar. The mobile app also includes a first-to-market feature that enables physicians to receive real-time data on how their patients are adhering to their prescribed treatment protocol. Stim onTrack is free and available through the iTunes App Store. In addition to the app, the next-generation bone growth stimulators include patient enhancements aimed at improving fit, comfort and ease of use.

"With the launch of these new devices, our goal is to redefine the recovery experience of patients using bone growth stimulation devices post-operatively for lumbar and cervical fusion surgical procedures," said Brad Niemann, President of the Orthofix BioStim strategic business unit. "We are proud to offer the addition of Stim onTrack to our CervicalStim and SpinalStim devices as we continue to find ways to partner with physicians in achieving improved clinical outcomes."

"Patient recovery is often dependent on how well they follow the prescription for the device," said James Ryaby, Ph.D., Chief Scientific Officer at Orthofix. "Equipping patients with a mobile app to help them adhere to their prescription is an excellent addition to this system while simultaneously enhancing post-surgical care by giving physicians additional data to help personalize follow-up protocols."

These next-generation devices are the latest in a line of bone growth stimulator systems that Orthofix first introduced into the market in 1990 (SpinalStim) and 2004 (CervicalStim). With a 92 percent clinical success rate when used adjunctively to spinal fusion surgery, the SpinalStim device is the only bone growth therapy device approved by the FDA as both a lumbar spinal fusion adjunct and as a non-surgical treatment for spinal pseudarthrosis. The CervicalStim device has an over-all clinical success rate of 84 percent and is the only bone growth therapy device approved by the FDA as a noninvasive, adjunctive treatment option for cervical fusion in high risk patients. Together, these devices are the number one prescribed bone growth stimulators for spinal fusion.

Recently the North American Spine Society (NASS) issued first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of PEMF stimulation devices

as an adjunct to spinal fusion surgery.

A leader in the bone growth stimulation market, Orthofix is dedicated to expanding indications for the use of PEMF devices. The Company is currently conducting two investigational device exemption (IDE) clinical trials to collect safety and effectiveness data of the CervicalStim system for treating odontoid fractures and the Physio-Stim system for osteoarthritis of the knee.

About Orthofix

Orthofix International N.V. is a diversified, global medical device company focused on improving patients' lives by providing superior reconstructive and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, TX, the company has four strategic business units that include BioStim, Biologics, Extremity Fixation and Spine Fixation. Orthofix products are widely distributed via the company's sales representatives, distributors and subsidiaries. In addition, Orthofix is collaborating on research and development activities with leading clinical organizations such as Brown University, Sinai Hospital of Baltimore, Cleveland Clinic, Texas Scottish Rite Hospital for Children and the Musculoskeletal Transplant Foundation. For more information, please visit www.orthofix.com.

Forward-Looking Statements

This communication contains certain forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, but are not limited to, statements concerning the projections, financial condition, results of operations and businesses of Orthofix and its subsidiaries, are based on management's current expectations and estimates and involve risks and uncertainties that could cause actual results or outcomes to differ materially from those contemplated by the forward-looking statements. The forward-looking statements in this release do not constitute guarantees or promises of future performance. Factors that could cause or contribute to such differences may include, but are not limited to, risks relating to: practices of health insurance companies and other third-party payors with respect to reimbursement for our PEMF devices; any future changes to the coverage determinations of NASS for electrical bone growth stimulators; and other risks described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as well as in other reports that we file in the future. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this press release.

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