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Orthofix Announces Initiation of Enrollment in Rotator Cuff Repair Study

Clinical trial will evaluate the Company's proprietary PEMF technology for reducing tendon retears

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ:OFIX), a global medical device company focused on musculoskeletal healing products and value-added services, today announced that enrollment has begun in a study that will evaluate the use of pulsed electromagnetic field (PEMF) technology for rotator cuff repair. This study will assess the efficacy and safety of the Company's RCStim™ device as an adjunctive treatment to surgical repair of full thickness rotator cuff tears.

The study will evaluate if PEMF technology that is currently used to promote bone growth can reduce the rate of repaired tendons being subsequently torn again and improve overall patient outcomes. The study will also gather data to see if there is a correlation between patients treated with PEMF and improvements in muscle strength and range of motion and a decrease in pain scores.

"Arthroscopic repair of rotator cuff tears can improve pain and functional use of the shoulder but a continuing challenge is the high retear rates after repair," said Dr. Andrew Kuntz, an orthopedic shoulder surgeon at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia and an investigator in the clinical study. "If PEMF therapy can prove effective in improving the patient's ability to heal after repair surgery, this could provide us with a way to lower the number of revision surgeries and improve overall outcomes."

The PEMF study for rotator cuff repair is a prospective, randomized, double-blind, placebo-controlled trial that will enroll approximately 538 patients who are between 21 and 80 years of age at up to 30 sites in the U.S. Study participants will be randomized in a two-to-one ratio to either an active or placebo control (inactive) device and followed for 24 months after initiation of treatment.

"PEMF technology has been used for many years to promote bone growth and the healing of nonunion fractures," said James Ryaby, Ph.D., Chief Scientific Officer for Orthofix. "The rotator cuff clinical trial is based on our compelling pre-clinical research and it is our second ongoing study evaluating PEMF therapy for a soft tissue application. As we previously announced, we also have a study for Osteoarthritis of the Knee for providing symptomatic relief of OA pain, reducing cartilage breakdown and stimulating new cartilage formation. Ultimately, if results of these studies are positive, it could open the door to important new applications of this technology."

The Orthofix RCStim device is an investigational device and use in the study is being conducted under an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA). More information about the study is available at ClinicalTrials.gov.

Orthofix PEMF technology devices are currently approved by the FDA for the treatment of nonunion fractures that have not healed or have difficulty healing and as an adjunct to cervical and lumbar spinal fusions. To learn more please visit bonegrowththerapy.com.

About Rotator Cuff Tears

According to the American Academy of Orthopaedic Surgeons, rotator cuff tears send as many as two million Americans to their physicians' offices every year, many with a full-thickness or complete tear. A full-thickness tear means the tendon has separated from the bone. This common musculoskeletal injury often requires surgical intervention. An estimated 250,000 patients get rotator cuff surgery in the U.S. annually.

About Orthofix

Orthofix International N.V. is a global medical device company focused on musculoskeletal healing products and value-added services. The Company's mission is to improve patients' lives by providing superior reconstruction and regenerative orthopedic and spine solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has four strategic business units: BioStim, Extremity Fixation, Spine Fixation, and Biologics. Orthofix products are widely distributed via the

Company's sales representatives and distributors. 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 described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, 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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