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Orthofix Initiates First US Clinical Study of Osteogenesis Stimulation for Odontoid Fractures

Study will evaluate Cervical-Stim as an aid to current treatments

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V., (NASDAQ:OFIX), today announced the Company's first large-scale clinical study to evaluate the use of pulsed electromagnetic fields (PEMF) technology to see if the therapy can improve osteogenesis (bone growth) in Type II odontoid fractures. The study will examine the safety and effectiveness of PEMF treatment with the Orthofix Cervical-Stim® device as an adjunct to standard immobilization with a rigid collar.

"Typically we see Type II odontoid fractures in patients as the result of a bad fall or a car accident," said Dr. Richard Guyer, orthopedic spine surgeon and President of Texas Back Institute in Dallas, TX and an investigator in the study. "Despite immobilization or in some cases surgical fixation, often the bones do not heal correctly. Cervical PEMF stimulation may provide us with an additional treatment approach that can enhance odontoid fracture healing."

A prospective, double-blind, randomized, placebo-controlled, multicenter clinical trial, the Odontoid Fracture Study will investigate the safety and effectiveness of PEMF therapy with the Orthofix Cervical-Stim device in patients with Type II fractures of the odontoid process. The study will enroll approximately 360 patients who are 50 years of age or older at up to 50 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 12 months after initiation of treatment. The odontoid study is a direct result of Orthofix's previously announced strategy for conducting clinical trials to expand the Company's PEMF indications.

"Initiation of the Odontoid Fracture Study represents an important step in obtaining clinical evidence to support new indications and reimbursement for our PEMF technology," said James Ryaby, Ph.D., Chief Scientific Officer for Orthofix. "We are hopeful that the results of this study will support the use of Cervical-Stim as an adjunct therapy for managing patients with these difficult to treat injuries."

The Orthofix Cervical-Stim device is currently approved by the U.S. Food and Drug Administration (FDA) as a noninvasive, adjunctive treatment option for improving cervical fusion outcomes. The device uses a low-level electromagnetic field (PEMF) that helps activate and augment the body's natural healing process to enhance vertebral bone fusion. In the study, the Cervical-Stim device will be worn directly over a rigid collar. Use in the Odontoid Fracture Study is investigational and is being conducted under an Investigational Device Exemption (IDE) from the FDA. More information is available at ClinicalTrials.gov.

About Odontoid Fractures

The odontoid process is a small finger-like projection from the second cervical vertebra (C2) around which the first cervical vertebra (C1) rotates. The most common mechanisms of injury producing an odontoid fracture are motor vehicle accidents or severe falls. For the elderly, a fall from a standing position may cause such a fracture. When the bone does not heal correctly as a result of an odontoid fracture, the base of the skull may be unstable thereby placing the patient at risk for neurological impairment and even death. Studies show that odontoid fractures account for approximately 15 percent of all cervical spine fractures. According to a 2010 report published by the Agency for Healthcare Research and Quality, there are approximately 21,476 odontoid fractures annually in the U.S. The most common classification is Type II which accounts for 65 percent of all odontoid fractures or approximately 13,960 yearly. Currently there are no therapies that accelerate healing and improve long-term outcomes in these patients.

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 the Musculoskeletal Transplant Foundation and the Texas Scottish Rite Hospital for Children. 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 and 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 those described in our annual report on Form 10-K for the fiscal year ended December 31, 2013 and other subsequent periodic reports filed by the Company with the SEC. 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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