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Orthofix Announces Publication of Data Demonstrating Benefits of Trinity Evolution Cellular Bone Allograft in Patients Undergoing Anterior Cervical Discectomy

LEWISVILLE, Texas--(BUSINESS WIRE)-- Orthofix International N.V. (NASDAQ: OFIX), a diversified, global medical device company, today announced the print publication of a 12-month study of patients that have undergone single-level anterior cervical discectomy and fusion (ACDF) with Trinity Evolution® in combination with a PEEK interbody spacer and supplemental anterior fixation. Published in the *European Spine Journal*, the data demonstrates the effectiveness of the bone graft with patient fusion rates of 78.6 percent at 6 months and 93.5 percent at 12 months. Seventy-five percent of the study participants were current or former smokers, diabetic, overweight, obese or extremely obese and considered to be at high risk for bone growth failure.

"To alleviate pain and neurological deficits resulting from nerve compression caused by degenerative disc disease, the most common recourse is surgical decompression through an anterior approach followed by the insertion of a structural interbody spacer filled with bone graft material," said Dr. Timothy A. Peppers, at Scripps Hospital and a co-author of the journal article. "This study demonstrated the effectiveness of Trinity Evolution in achieving a solid fusion when used in this manner, indicating that it is a viable option for patients needing anterior cervical discectomy and fusion."

This prospective, multi-center, clinical study was designed to evaluate the effectiveness of Trinity Evolution, a viable cellular bone allograft in patients undergoing a single level fusion at the vertebral locations between C3/C4 and C6/C7. Trinity Evolution was placed within and around each Orthofix PEEK interbody spacer to promote bone growth.

"We are committed to investing in meaningful clinical research to aid physicians in their treatment decisions," said Orthofix Chief Scientific Officer James Ryaby, Ph.D. "These results are important as they further substantiate that Trinity Evolution is effective even in challenging patient populations who might not respond well to traditional allograft and autograft materials."

The primary endpoint was radiographic fusion status based on independent review of CT scans and radiographic review of angular motion. The criteria for fusion was the presence of bridging bone across the adjacent endplates as seen on thin cut CT scans in addition to angular motion from flexion/extension X-rays.

In addition, secondary endpoints were measured including function as assessed by the Neck Disability Index and neck and arm pain as assessed by individual Visual Analog Scales (VAS). Neck function and neck/arm pain were found to significantly improve at both 6 and 12 months. There were no serious adverse events attributable to Trinity Evolution as determined by an independent consultant.

Processed by the Musculoskeletal Transplant Foundation (MTF), a nonprofit organization dedicated to providing quality tissue, Trinity Evolution is a cryopreserved allograft that consists of cancellous bone with viable cells retained within that matrix and a demineralized cortical bone component. It possesses all three of the key properties for successful bone grafting, which makes it an ideal autograft substitute.

"MTF is committed to research to ensure innovative clinical options exist for all patients," said Bruce Stroever, President and Chief Executive Officer of MTF. "We are pleased these results support the use of a high quality MTF allograft like Trinity Evolution to augment the patients' recovery."

Trinity Evolution is the predecessor of Trinity ELITE®, a moldable bone graft material that enables physicians to easily control the placement of tissue during procedures. To date there have been more than 150,000 procedures using Trinity Evolution and Trinity ELITE.

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, Texas, 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 its 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.

About MTF

The Musculoskeletal Transplant Foundation, a non-profit organization based in Edison, NJ, is a national consortium comprised of leading organ procurement organizations, tissue recovery organizations and academic medical institutions. Since its inception in 1987, MTF has received tissue from more than 100,000 donors and distributed more than six million grafts for transplantation. For more information, visit www.mtf.org

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 the risks described in the "Risk Factors" section of our 2015 Annual Report on Form 10-K, 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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