NEWS RELEASE

Orthofix Announces Publication of Data Demonstrating the Clinical Benefits of Trinity Elite Cellular Bone Allograft in Lumbar Fusion Procedures

12/22/2022

LEWISVILLE, TEXAS--(BUSINESS WIRE)-- **Orthofix Medical Inc**. (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced results from a prospective, multicenter clinical study evaluating the safety and efficacy of the Trinity Elite™ cellular bone allograft (CBA) in lumbar spinal fusion procedures. Published in **Neurology International**, patients treated with the Trinity Elite CBA demonstrated fusion rates of 98.6 percent, measured by bridging bone at 12 months follow-up.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20221222005119/en/

Image of the Trinity Elite cellular bone allograft. (Photo: Business Wire)

"The 12-month data show that patients treated with the Trinity Elite allograft achieved a high rate of successful fusion and significant improvements in ODI and VAS scores," said Dr. Joshua Wind, neurosurgeon at Sibley Memorial Hospital and lead author of the journal article. "Additionally, these high fusion rates were observed in subjects reporting single and multiple risk factors for pseudoarthrosis. The findings from this study provide further evidence for the use of cellular bone allografts as effective bone graft substitutes in lumbar spinal fusion."

In this prospective, multicenter, open-label clinical study, the Trinity Elite allograft was evaluated in subjects undergoing posterolateral fusion (1-4 levels) or interbody fusion (1-2 levels) with CBA. Subject risk factors included smoking, diabetes, obesity, and osteoporosis. A total of 274 subjects were enrolled in the study, with available data from 201 subjects who completed the 12-month follow-up. Radiographic fusion status was assessed by an independent review of dynamic radiographs and CT scans. Clinical outcome measures included the Oswestry Disability Index (ODI) and visual analogue scale (VAS) for back and leg pain. At 12 months, 98.6 percent fusion was assessed by the presence of bridging bone on thin-cut CT scans.

“We are pleased to continue to invest in clinical research and provide physicians the information they need to make the best decisions for their patients,” said Orthofix President of Global Spine Kevin Kenny. “The results of this publication support Trinity Elite as a safe and efficacious alternative to autograft for patients undergoing lumbar fusion procedures and demonstrate the compelling benefits of this cellular bone allograft. Trinity Elite is a key example of our commitment to deliver evidence-based, quality-driven solutions that can improve patients’ lives.”

Trinity Elite is a cryopreserved CBA from allograft donor bone that facilitates bone formation by providing an osteoconductive scaffold, inherent osteoinductive growth factors and osteogenic cells. Trinity Elite eliminates the need for harvesting autograft from patients, which reduces operating time and expense as well as discomfort and potential complications. Processed by **MTF Biologics**, a nonprofit organization dedicated to providing quality tissue, Trinity Elite is a moldable bone graft material that enables physicians to easily control the placement of tissue during procedures.

About Orthofix

Orthofix Medical Inc. is a global medical device company with a spine and orthopedics focus. The Company’s mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix’s spine and orthopedics products are distributed in more than 60 countries via the Company's sales representatives and distributors. For more information, please visit **www.Orthofix.com**.

About MTF Biologics

MTF Biologics is a global nonprofit organization that saves and heals lives by honoring donated gifts, serving patients and advancing science. They provide unmatched service, resources, and expertise to donors and their loved ones who give the gift of donation, people who depend on tissue and organ transplants, healthcare providers, and clinicians and scientists.

The International Institute for the Advancement of Medicine (IIAM), a Division of MTF Biologics, honors donors of non-transplantable organs by providing their gifts to the medical research community to combat and cure diseases. Statline, also a Division of MTF Biologics, provides specialized communications and technology expertise to organ, tissue, and eye procurement organizations, as well as the hospitals and patients that they serve. Its sister organization, Deutsches Institute for Zell-und Gewebeersatz – DIZG (The German Institute for Cell and Tissue Transplantation), expands its reach to patients across the globe. For more information, visit **www.mtfbiologics.org**.

Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our

business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "2021 Form 10-K"). In addition to the risks described there, factors that could cause or contribute to such differences may include, but are not limited to: the risk that surgeons may be slow to adopt the Trinity Elite cellular bone allograft; the risk that future patient studies or clinical experience and data may indicate that treatment with the Trinity Elite cellular bone allograft does not improve patient outcomes as much as previously believed, or otherwise call into question the benefits of the use of these products to patients, hospitals and surgeons; the risk that the products may not perform as intended and may therefore not continue or achieve commercial success; the risk that competitors may develop superior products or may have a greater market position enabling more successful commercialization; the risk that insurance payers may decline to reimburse healthcare providers for the use of our products.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in reports we file from time-to-time with the SEC, which are available to read at **www.sec.gov**. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20221222005119/en/**

Alexa Huerta
Investor Relations
Tel 214 937 3190
alexahuerta@orthofix.com

Denise Landry
Media Relations
Tel 214 937 2529
deniselandry@orthofix.com

Source: Orthofix Medical Inc.