NEWS RELEASE

Orthofix Announces First Presentation of Seven-Year Outcome Data for the M6-C Artificial Cervical Disc With Other Clinical and Scientific Abstracts at the ISASS Annual Meeting

2023-06-01

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc**. (NASDAQ:OFIX), a leading global spine and orthopedics company, today announced the presentation of multiple clinical and scientific abstracts during the International Society for the Advancement of Spine Surgery (ISASS) annual meeting in San Francisco June 1-3, 2023.

Illustration of the Orthofix M6-C artificial cervical disc. (Graphic: Business Wire)

"We are pleased to support a wide range of abstracts and clinical data during the annual ISASS meeting, including the first presentation of the seven-year data from the M6-C artificial cervical disc U.S. IDE study," said Kevin Kenny, President of Global Spine. "ISASS is an important opportunity for attendees to learn from a distinguished surgeon panel that will provide their insights about cervical disc replacement and long-term outcomes of this therapy. Additionally, we are proud to support presentation of data for our Bone Growth Therapy and Biologic solutions."

At the ISASS annual meeting, Orthofix is presenting a variety of industry abstracts and posters focused on the company's **M6-C™ artificial cervical disc**, **CervicalStim™ bone growth stimulator** and **Trinity Elite™ Allograft** with viable cells.

Motion Preservation

"M6-C Artificial Cervical Disc: Seven-Year Outcomes for Single-Level Total Disc Replacement with a Novel Viscoelastic Artificial Cervical Disc" – abstract presentation by Dr. Todd Lanman.

This abstract is the first public presentation of specific seven-year clinical results associated with the use of the M6-C artificial cervical disc for the treatment of single-level symptomatic cervical radiculopathy. The presentation will be

on Saturday, June 3 at 10:00 a.m. in Salons 10-12 by Dr. Todd Lanman. Highlighted results include:

- Decreases in disability as measured by NDI and decreases in Neck and Arm Pain Scores that were observed at prior follow-up periods and were retained through seven-years post-op
- Eleven Secondary Surgical Interventions (SSI) were observed among the M6-C disc cohort (6.9%). This rate is comparable to seven-year SSI rates reported for other commercially available artificial cervical discs
- Annual follow-up of this cohort will continue through 10-years post-op

"Cervical Disc Arthroplasty Expert Panel: Osteolysis and Periprosthetic Bone Changes in Cervical Disc Replacement" – academic programsession with moderator Dr. Gunnar Andersson and speakers Dr. Josh Jacobs, Dr. Armen Khachatryan, Dr. Todd Lanman, Dr. Steven Kurtz and Dr. Sophia Sangiorgio.

This multidisciplinary panel of clinicians and researchers will discuss the assessment of bone changes around artificial cervical disc implants, leveraging prior research in hip and knee arthroplasty. Panel will be conducted on Friday, June 2 at 1:20 p.m. in Salons 10-12. Topics covered include:

- Categorization and classification of radiographic observations
- Clinical management of observed bone changes post-cervical disc replacement

"Proposed Classification System of Radiographic Bony Changes after Cervical Disc Replacement" – poster by Dr. Armen Khachatryan.

Poster will be located in the Exhibit Hall. Content highlights include:

- Introduction of classification system for post-cervical disc replacement radiographic observations
- Analysis of system reliability

Bone Growth Therapy

"CervicalStim Bone Growth Therapy: Electrical Stimulation Used as an Adjunct to Cervical Spine Fusion in Patients at Risk for Pseudarthrosis" – podium presentation with Dr. Ilyas Aleem.

This presentation will cover the results of a prospective multicenter study that evaluated the adjunct effect of PEMF in subjects undergoing cervical spinal surgery who presented with risk factors for pseudarthrosis (multilevel fusion, prior failed cervical spine fusion, diabetes, osteoporosis, or nicotine use). Presentation will be conducted on Saturday June 3, at 10:32 a.m. in Salons 13-15. Highlights include:

- Out of 160 subjects, 144 (90.0%) were graded as fused (all levels) at the 12-month visit
- Fusion success was 91.7% (n=55/60) for subjects with a single risk factor, 89.0% (n=89/100) for subjects with

two or more risk factors, and 90.9% (n=20/22) for subjects with three or more risk factors
- Significant improvements in NDI, VAS (arm and neck), SF-36, and EQ-5D were observed compared to baseline scores ($p<0.001$)

"CervicalStim Bone Growth Therapy: Adjunctive Use of Bone Growth Stimulation in Cervical Spine Fusion in Patients at Risk for Pseudarthrosis" – poster by Dr. Ilyas Aleem.

Poster highlights results of a study that evaluated cervical spine fusion rates for subjects with one or more risk factors for pseudarthrosis; subjects that received PEMF treatment were compared to matched subjects that did not receive PEMF treatment. Poster will be located in the Exhibit Hall. Results include:

- At 12 months post-op, subjects in the PEMF treated group (n=161) had a 90.1% fusion rate, compared to a 65.4% fusion rate for the control group (n=26) ($p<0.001$)
- Subjects in the PEMF treated group had a significantly higher number of risk factors for nonunion (1.8 for treated group vs. 1.1 for control, $p<0.001$), and significantly higher number of surgical levels (2.8 for treated group vs. 2.0 for control, $p<0.005$)
- When compared to control subjects that did not use PEMF stimulation, treated subjects had improved fusion outcomes despite being older, having more risk factors for pseudarthrosis, and undergoing more complex surgeries

Biologics

"Trinity Elite Allograft: Radiographic and Clinical Outcomes in Subjects that Underwent Single-Level or Multilevel Anterior, Posterior or Lateral Lumbar Interbody Fusion with a Cellular Bone Allograft" – podium presentation by Dr. Pierce Nunley on behalf of Dr. Todd Lansford.

This study investigates the effectiveness of cellular bone allograft in lumbar spinal fusion by surgical approach (e.g., anterior, lateral, and posterior). Presentation of data will be on Saturday, June 3 at 10:30 a.m. in Salons 13-15. Highlights include:

- Analysis of 252 subjects treated via anterior, lateral, or posterior approaches reported fusion success by bridging bone assessment, as well as bridging bone and Quantitative Motion Analysis (QMA) assessment, at time of study closure.
- At 12 months, the overall fusion success rate for bridging bone was 98.5%; fusion success was 98.1%, 100.0%, and 97.9% for anterior, lateral, and posterior approaches, respectively. Fusion success for bridging bone and QMA assessment was 83%, 94.6%, and 93.8% for anterior, lateral, and posterior approaches, respectively.
- At 24 months, the overall fusion success rate for bridging bone was 98.9%; fusion success was 97.9%, 100.0%, and 98.8% for anterior, lateral, and posterior approaches, respectively. Fusion success for bridging bone and

QMA assessment was 85.4%, 96.1%, and 92.9% for anterior, lateral, and posterior approaches, respectively.
- Significant improvements in quality-of-life, pain, and disability scores were also noted, irrespective of the surgical approach.

"Trinity Elite Allograft: Twenty-Four-Month Interim Results from a Prospective Clinical Trial Evaluating the Performance and Safety of Cellular Bone Allograft in Patients Undergoing Lumbar Spinal Fusion" – podium presentation by Dr. Daniel Park.

This abstract reports on the outcome measures from a prospective, multicenter center clinical study that assessed the efficacy and safety of cellular bone allograft when used as an adjunct to lumbar arthrodesis out to 24-months follow-up. This data will be presented on Friday, June 2 at 11:02 a.m. in Salons 10-12. Highlights include:

- At the time of interim analysis, 86 subjects reported data necessary to evaluate both fusion and disability through 24-months postoperative
- Fusion rate, based on bridging bone assessment and QMA, was reported to be 95.3% (N=86)
- ODI and VAS Leg and VAS Back Pain scores all reported significant improvements from baseline ($p<0.001$)

To learn more about the full portfolio of **Orthofix** solutions, please visit us at booth #100 at the ISASS meeting.

About Orthofix

The newly merged Orthofix-SeaSpine organization is a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions and a leading surgical navigation system. Its products are distributed in approximately 68 countries worldwide.

The Company is headquartered in Lewisville, Texas and has primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. The combined company's global R&D, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France and São Paulo, Brazil.

Media Relations

Denise Landry
DeniseLandry@orthofix.com
214.937.2529

Investor Relations

Louisa Smith, Gilmartin Group
IR@orthofix.com

Source: Orthofix Medical Inc