Treace Highlights New Product Innovations and Updated Clinical Study Data at the American Orthopaedic Foot & Ankle Society Annual Meeting 2024

September 11, 2024

PONTE VEDRA, Fla., Sept. 11, 2024 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. (“Treace” or the “Company”) (NasdaqGS: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of bunions and related midfoot deformities through its flagship Lapiplasty® and Adductoplasty® Procedures, today announced it will highlight new product innovations and present new interim data for the ALIGN3D™ and Mini3D™ Lapiplasty® clinical studies at the American Orthopaedic Foot & Ankle Society (AOFAS) Annual Meeting 2024 ir Vancouver, British Columbia, Canada from September 11-14, 2024.

“We are excited to feature our latest R&D innovations and growing body of clinical data to surgeons attending the 2024 AOFAS conference,” stated John T. Treace, CEO, Founder and Board Member of Treace. “The results from our ongoing ALIGN3D™ clinical study continue to demonstrate sustained, successful procedural and patient outcomes at 3 and 4 years post-procedure. In addition, interim results from our Mini3D™ Lapiplasty® Mini-Incision™ clinical study also demonstrated meaningful procedural and patient outcomes at 1 and 2 years post-procedure.”

Speaking about new innovations that will be presented at the AOFAS conference, Mr. Treace continued, “As the industry’s only company solely focused on advancing the standard of care in the surgical correction of bunion and related midfoot deformities, we are committed to developing a comprehensive suite of advanced instrumented solutions to meet the evolving preferences of surgeons and their patients.”

Several current and next-generation technologies will be highlighted at Treace’s booth and in surgeon training events at the AOFAS conference, including:

- **Nanoplasty™ MIS 3D Osteotomy System:** Nanoplasty™ offers surgeons an elegantly instrumented, reproducible 3D correction performed through a discreet 1.5cm incision on the side of the foot, making it a cosmetically attractive therapy for bunion patients. Consistent with minimally invasive surgical approaches, the Nanoplasty™ Procedure is designed to minimize post-op pain and swelling as well as visible scars. The Nanoplasty™ Procedure represents Treace’s first entry into the osteotomy segment, which the Company estimates to represent approximately 70% of the bunion surgical procedure mix. The Company expects to initiate a limited market release of its Nanoplasty™ System in the fourth quarter.
- **IntelliGuide™ PSI Cut Guides for Lapiplasty® and Adductoplasty® Procedures** A first and only in the market, IntelliGuide™ PSI incorporates RedPoint™ technology offering surgeons a pre-op plan and 3D-printed cutting guide derived from the patient’s CT-scan for a streamlined and personalized correction of their bunion and/or midfoot deformity. The Company plans to expand surgeon access to its IntelliGuide™ PSI technology in the fourth quarter.
- **Mini-Adductoplasty™ Guides:** Innovative less-invasive instrumentation allows surgeons to perform the Adductoplasty® midfoot correction procedure through a 50% smaller incision, thus minimizing soft tissue dissection. Full commercial rollout of Mini-Adductoplasty™ is underway and will continue through the fourth quarter.
- **New SpeedPlate™ Innovations:** Recently-commercialized SpeedPlate™ designs addressing fusion of larger bones of the midfoot and rearfoot will be featured. Additionally, Treace will preview the SpeedPlate™ Micro-Quad™, a next-generatior SpeedPlate™ implant designed for high-stability and anatomic fit in small incision surgical approaches such as the Micro-Lapiplasty™ and Mini-Adductoplasty™ procedures
- **Micro-Lapiplasty ™ Minimally Invasive System:** Advanced instrumentation designed to allow the patented Lapiplasty® Procedure to be performed through a small 2cm incision.

ALIGN3D™ Lapiplasty® Clinical Study Presentation

The ALIGN3D™ clinical study ePodium presentation, *“Four-Year Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic Recurrence and Patient Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing”*, will be presented by Robert Santrock, MD, Duke University (Durham, NC).

The featured interim data from the prospective, five-year, multicenter ALIGN3D™ clinical study included interim analysis of 102 of 173 total patients treated with at least four years of follow-up following the Lapiplasty® Procedure. The data showed:

- Early return to weight bearing in a walking boot at an average 8.4 days;
- Low radiographic recurrence rates at 48 months of 0.0% using HVA>20° and 8.1% using HVA>15° with low symptomatic non-union rate of 1.7%; and
- Continued significant improvement in pain and patient-reported scores at 48 months.

Mini3D™ Lapiplasty Mini-Incision™ Clinical Study Presentation

Interim data from the Mini3D™ prospective, multicenter study will also be presented at AOFAS in a Podium presentation titled "*Interim Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following a Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing*", by Justin Daigre, MD of DOC Orthopaedics and Sports Medicine, Decatur, AL on Thursday, September 12.

This presentation includes favorable clinical and patient-reported outcomes with the Lapiplasty® Mini-Incision™ System (median incision length: 3.5cm) at 1 and 2 years.

Both AOFAS presentations, which include additional details such as patient demographics, inclusion/exclusion criteria, and complications reported in the studies, will be available on Treace's website at www.lapiplasty.com/surgeons/journal-publications/ following their presentations at AOFAS. More information on Treace's products can be found at www.lapiplasty.com.

About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate outcomes of the Lapiplasty® 3D Bunion Correction® procedure in the surgical management of symptomatic hallux valgus. The study will evaluate for consistent and reliable correction of all three dimensions of the bunion deformity with the Lapiplasty® Procedure, as well as maintenance of such correction following accelerated return to weight-bearing, initially in a walking boot. The primary effectiveness endpoint is radiographic recurrence of the hallux valgus deformity. Key secondary endpoints include change in three-dimensional radiographic alignment; clinical radiographic healing; time to start of weight-bearing in a boot and in shoes; pain; quality of life; and range of motion of the big toe joint. The study enrolled 173 patients, aged 14 to 58 years, at 7 clinical sites in the United States with 13 participating surgeons. Final patient follow-up for the primary endpoint was completed in the first half of 2023.

About the Mini3D™ Clinical Study

The Mini3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate the ability of the Lapiplasty® Mini-Incision™ Procedure to consistently and reliably correct all three dimensions of the bunion deformity and maintain the correction following accelerated return to weight-bearing. The study's primary endpoint is radiographic recurrence of the bunion deformity at 24 months follow up. Secondary endpoints include changes in three-dimensional radiographic alignment; clinical radiographic healing; time to start of weight-bearing in a boot and in shoes; pain; quality of life; range of motion of the big toe joint; scar quality; change in radiographic foot length and width as well as swelling. The study enrolled 105 patients, aged 14 to 58 years, at 9 clinical sites in the United States with 9 participating surgeons.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements, including, but not limited to, the Company's plans for the limited market release of its Nanoplasty™ System in the fourth quarter, expansion of surgeon access to its IntelliGuide™ PSI technology in the fourth quarter, and continued full commercial rollout of Mini-Adductoplasty™ through the fourth quarter Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of Treace's public filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 27, 2024, and its subsequent SEC filings. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

Internet Posting of Information

Treace routinely posts information that may be important to investors in the "Investor Relations" section of its website at www.treace.com. The Company encourages investors and potential investors to consult the Treace website regularly for important information about Treace.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 67 million Americans, of which Treace estimates 1.1 million are annual surgical candidates. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction® System – a combination of instruments, implants, and surgical methods designed to surgically correct all three planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. To further support the needs of bunion patients, Treace has introduced its Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of midfoot deformities. The Company continues to expand its footprint in the foot and ankle market with the introduction of its SpeedPlate™ Rapid Compression Implants, an innovative fixation platform with broad versatility. For more information, please visit www.treace.com.

To learn more about Treace, connect with us on LinkedIn, X, Facebook and Instagram.

About AOFAS Annual Meeting

The American Orthopaedic Foot & Ankle Society® (AOFAS) mobilizes its global community of foot and ankle orthopaedic specialists to improve patient care through education, research, and advocacy. The AOFAS Annual Meeting is the premier event for foot and ankle education, offering presentations from renowned speakers, special interest forums, social events, and the latest products and technology.

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