



Treace Highlights New Product Innovations and Updated ALIGN3D™ Clinical Study Data at the American Orthopaedic Foot & Ankle Society Annual Meeting 2023

September 20, 2023

PONTE VEDRA, Fla., Sept. 20, 2023 (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 hallux valgus (commonly known as bunions) through its Lapiplasty® 3D Bunion Correction® Procedure, today announced it will highlight new product innovations and present new interim data for the ALIGN3D™ clinical study at the [American Orthopaedic Foot & Ankle Society \(AOFAS\) Annual Meeting 2023](#) in Louisville, Kentucky from September 20-23, 2023.

"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 excited to feature our latest R&D innovations to surgeons attending the 2023 AOFAS conference," stated John T. Treace, CEO, Founder and Board Member of Treace. "Our new SpeedPlate™ and Micro-Lapiplasty™ technologies demonstrate Treace's commitment to rapid innovation with a focus on continually iterating the Lapiplasty® System with options for increased procedural efficiency and reduced incision size associated with the Lapiplasty® Procedure."

Mr. Treace continued, "Interim data readouts from our ongoing ALIGN3D™ clinical study continue to demonstrate sustained, successful procedural and patient outcomes on additional patients followed through 36- and 48-months post-procedure. We are proud to continue our commitment to investing in clinical studies and expanding the differentiated body of clinical evidence to advance the Lapiplasty® Procedure as the standard of care for bunion surgery."

Several technologies will be highlighted at Treace's booth at the AOFAS conference, including:

- **SpeedPlate™ Implant Fixation Platform:** This new platform of Lapiplasty® fixation technology is designed for rapid insertion while providing dynamic compression of the joint surfaces. Since it can be implanted through a small 2cm incision, the SpeedPlate™ technology not only offers broad applicability with the Company's standard Lapiplasty® and Adductoplasty® systems, but also serves as the enabling fixation technology for our Micro-Lapiplasty™ system. Full commercial launch of the SpeedPlate™ technology is anticipated in the fourth quarter of this year.
- **Micro-Lapiplasty™ Minimally Invasive System:** This advanced instrumentation option is designed to further reduce the incision size and related tissue dissection with the Lapiplasty® procedure. The advanced instrument set, including the Micro-Lapiplasty™ 3-n-1™ Guide and other specialized surgical instruments, allows the deformity correction and joint preparation steps of the patented Lapiplasty® Procedure to be performed through a 2cm incision. The Micro-Lapiplasty™ System is currently in limited clinical release with full commercial launch expected in the fourth quarter of this year.
- **New Lapiplasty® Innovations:** Recently commercialized innovations, including the LapiTome™ and RazorTome™ Osteotomes and Hammertoe PEEK Fixation System, will also be featured at Treace's booth and in hands-on training workshops.

ALIGN3D™ Clinical Study Poster Presentation

The ALIGN3D™ clinical study poster presentation, "*Primary Endpoint Analysis for a Prospective Multicenter Study Assessing Radiographic Recurrence and Patient Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing*", will be presented by Robert Santrock, MD of Dovetail Orthopedics, Fernandina Beach, FL on September 21 from 10:00 am to 10:45 am ET.

The interim analysis includes 173 patients treated with the Lapiplasty® Procedure with an average follow-up of 33.4 months. The data showed:

- Early return to weight bearing in a walking boot at an average 8.4 days (n=173);
- Low recurrence rate, defined as loss of radiographic correction (HVA > 20°), was observed in 0.7% of patients (1 of 151 patients) at 24 months and 1.1% (1 of 95 patients) at 36 months; and
- 81% reduction in pain (Visual Analog Scale) reported at 24 months post-procedure (n=156).

The interim analysis also continued to report statistically significant improvement in patient-reported outcomes, including a 92% and 93% improvement in walking/standing as well as social interaction at 36 months post-procedure, respectively, using the Manchester-Oxford Foot Questionnaire (MOxFAQ) scoring system (n=100). Additionally, at 36 months post-procedure, less than 5% of patients were unsatisfied with the overall results of the procedure (n=96).

The poster, which includes additional details, can be accessed by AOFAS meeting attendees on a kiosk at the Annual Meeting or on the mobile app. The Company plans to submit its primary endpoint ALIGN3D™ manuscript for publication in a top-tier peer-reviewed foot and ankle journal later in 2023.

More information on Treace's products can be found at www.lapiplasty.com.

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 expectation that the full commercial launch of the SpeedPlate™ technology and Micro-Lapiplasty™ System is anticipated in the fourth quarter of this year; and the Company plans to submit its primary endpoint ALIGN3D™ manuscript for publication in a top-tier peer-reviewed foot and ankle journal later in 2023. 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, 2022, and any subsequent Quarterly Report on Form 10-Q or Current Report on Form 8-K. 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 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 at 24 months follow-up. 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 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 65 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 3 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. Treace expanded its offering with the Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of the midfoot to provide further support to hallux valgus patients. For more information, please visit www.treace.com.

To learn more about Treace, connect with us on [LinkedIn](#), [Twitter](#), [Facebook](#) and [Instagram](#).

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