Treace Announces Clinical Study Data Demonstrating Positive Lapiplasty® and Adductoplasty® Outcomes at the 2025 ACFAS Annual Scientific Conference

March 28, 2025

PONTE VEDRA, Fla., March 28, 2025 (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 the presentation of updated interim data for the ALIGN3D™ and Mini3D™ Lapiplasty® clinical studies, as well as the first presentation of the MTA3D™ Adductoplasty® clinical study, at the 2025 American College of Foot and Ankle Surgeons (ACFAS) Annual Meeting in Phoenix, Arizona.

"We are excited to feature our growing body of clinical data to surgeons attending the 2025 ACFAS conference," stated John T. Treace, CEO, Founder and Board Member of Treace. "This builds on our commitment to support our flagship Lapiplasty® and Adductoplasty® procedures with clinical evidence and notably marks the first meeting where all three of our prospective, multicenter studies are presented, including our ALIGN3D™, Mini3D™, and MTA3D™ studies, demonstrating positive clinical outcomes and further differentiating these procedures with surgeons and patients."

ALIGN3D™ Lapiplasty® Clinical Study Presentation

ALIGN3D™ clinical study results presented by Daniel Hatch, DPM (Foot & Ankle Center of the Rockies, Greeley, CO) on Friday, March 28 as a podium presentation entitled, *"Four-Year Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic Recurrence and Patient Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing."* The featured interim data from the prospective, five-year, multicenter ALIGN3D™ clinical study of the Lapiplasty® Procedure included interim analysis of 135 of 173 patients treated with at least four years of follow-up. The data showed:

- Early return to protected weight bearing at an average 8.4 days;
- Low radiographic recurrence rates of 0.8% using HVA>20° and 7.7% using HVA>15° at 48 months; and
- Continued significant improvement in pain and patient-reported outcome scores (MOxFQ and PROMIS) at 48 months.

Mini3D™ Lapiplasty Mini-Incision™ Clinical Study Presentation

Mini3D™ clinical study results presented by Jody McAleer, DPM (Jefferson City Medical Group, Jefferson City, MO) on Friday, March 28 as a podium presentation entitled, *"Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following an Instrumented Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing."* The featured results of this prospective, multicenter Mini3D™ clinical study of the Lapiplasty® Mini-Incision™ Procedure (median incision length: 3.5cm) included interim analysis of 75 of 105 patients treated with at least one year follow-up. The data showed:

- Early return to protected weightbearing at an average 7.9 days;
- Low radiographic recurrence rates of 0.0% using HVA>20° and 5.5% using HVA>15° at 12 months; and
- Significant improvements in pain and patient-reported scores (MOxFQ and PROMIS) at 12 months.

MTA3D™ Adductoplasty® Clinical Study Presentation

MTA3D™ clinical study results presented by Paul Dayton, DPM (Foot and Ankle Center of Iowa, Ankeny, IA) on Friday, March 28 as a poster presentation, entitled *"Interim 1-Year Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient-Reported Outcomes Following Combined Metatarsus Adductus and Hallux Valgus Correction through 3rd, 2nd, and 1st Tarsometatarsal Arthrodesis with Early Weightbearing."* The featured interim data from the prospective, five-year, multicenter MTA3D™ clinical study of the patients undergoing both the Adductoplasty® and Lapiplasty® procedures included interim analysis of 18 of 38 patients treated with at least one year follow-up. The data showed:

- Early return to protected weightbearing at an average 7.5 days;
- Clinically significant improvement relative to baseline in radiographic measures of both midfoot (metatarsus adductus) and 3D bunion deformity correction at 12 months; and
- Clinically significant reduction in pain and patient-reported scores (MOxFQ and PROMIS) at 12 months.

Additionally, results from a retrospective study on the Adductoplasty® Procedure were presented by Jody McAleer, DPM (Jefferson City Medical Group, Jefferson City, MO) on Friday, March 28 as a podium presentation, entitled "*Instrumented Correction of Metatarsus Adductus with Hallux Valgus – A Multicenter Radiographic Assessment."* The data from this retrospective clinical study of patients undergoing both the Adductoplasty® and Lapiplasty® procedures included an analysis of 43 patients treated with a mean follow up of 17.7 months, demonstrating positive clinical results and radiographic correction of both the midfoot (metatarsus adductus) and 3D bunion deformities.

All ACFAS 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 ACFAS. 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.

About the MTA3D™ Clinical Study

The MTA3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate the combined Adductoplasty® and Lapiplasty® Procedures for patients in need of metatarsus adductus and hallux valgus corrective surgery. The study will evaluate for consistent, maintained radiographic correction and patient reported outcome scores following combined Adductoplasty® and Lapiplasty® procedures. The primary effectiveness endpoint is maintenance of radiographic correction of the hallux valgus and metatarsus adductus deformities. Key secondary endpoints include clinical radiographic healing, time to start weight-bearing in boot and shoes, pain, quality of life, and range of motion of the big toe joint. The study will treat up to 80 patients, aged 14 years and up, at up to 13 clinical sites in the United States. Patients will be followed for 5 years following the procedures.

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 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 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 surgeons and address the four classes of bunions, Treace introduced its Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of midfoot deformities, the SpeedMTP™ Rapid Compression Implant for addressing bunions through big toe joint fusions, and two systems for minimally invasive osteotomy surgeries: the Nanoplasty™ 3D Minimally Invasive Bunion Correction System and the Percuplasty™ Percutaneous 3D Bunion Correction System. 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 across Lapiplasty®, Adductoplasty® and SpeedMTP™ procedures, as well as other common bone fusion procedures of the foot. For more information, please visit www.treace.com.

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

Contacts:

Treace Medical Concepts
Mark L. Hair
Chief Financial Officer
mhair@treace.net
(904) 373-5940

Investors:
Gilmartin Group
Vivian Cervantes
IR@treace.net