Treace Announces Results of Three Clinical Studies Including the Milestone 5-Year ALIGN3D® Study Demonstrating Sustained, Positive Outcomes of the Lapiplasty® Procedure

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PONTE VEDRA, Fla., Sept. 17, 2026 (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 other foot & ankle conditions, today announced the presentation of the results from three clinical studies at the American Orthopaedic Foot & Ankle Society (“AOFAS”) Annual Meeting in Seattle, Washington. The presentations include data on the milestone 5-year ALIGN3D® Lapiplasty®, the MTA3D® Adductoplasty® and the SPRINT™ SpeedPlate® clinical studies.

"We are proud to present a robust body of clinical evidence at AOFAS 2026 that continues to reinforce the durability and clinical value of our flagship procedures and technologies," said John T. Treace, CEO, Founder and Chairman of Treace. "The 5-year ALIGN3D® data represents a first-in-industry milestone, demonstrating sustained, positive outcomes following the Lapiplasty® Procedure. Complementing this are our 2-year MTA3D® interim results and SPRINT™ study results that further validate our technologies. Together, these studies underscore our commitment to generating high-quality, prospective clinical evidence that differentiates our technologies and supports better outcomes for patients."

ALIGN3D® 5-Year Lapiplasty® Clinical Study Results

The ALIGN3D™ Lapiplasty® clinical study podium presentation, *“Five-Year Analysis of a Prospective Multicenter Study of Triplanar Tarsometatarsal Arthrodesis With Early Weightbearing: Radiographic, Clinical and Patient Reported Outcomes”*, to be presented by Daniel Farber, MD, Lehigh Valley Orthopedic Institute (Bethlehem, PA).

Featured data from the study included final analysis of 137 of 173 total patients treated with five 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 of 0.8% using HVA>20° and 5.3% using HVA>15° at 5 years; and
- Clinically significant reduction in patient-reported scores (MOxFQ and PROMIS) through 5 years.

MTA3D® Adductoplasty® Clinical Study Results

The MTA3D® Adductoplasty® clinical study podium presentation, *“Radiographic and Patient-Reported Outcomes Following Combined Metatarsus Adductus and Hallux Valgus Correction with Early Weightbearing – 2-year Interim Results of a Multicenter Prospective Study”*, presented by Mark Easley, MD, Duke University (Durham, NC).

The featured interim data from the study of patients undergoing both the Adductoplasty® and Lapiplasty® procedures included interim analysis of 59 of 66 and 35 of 66 patients treated with at least one- and two-year follow-up, respectively. The data showed:

- Early return to weight bearing in a walking boot at an average 7.6 days;
- Clinically significant improvement and maintenance of radiographic measures of both midfoot (metatarsus adductus) and 3D bunion correction through 24 months; and
- Clinically significant reduction in pain and patient-reported scores (VAS, MOxFQ, and PROMIS) through 24 months.

SPRINT™ SpeedPlate® Observational Study Results

The SPRINT™ SpeedPlate® observational clinical study audio poster presentation, *“Radiographic and Patient-Reported Outcomes Following Joint Arthrodesis in the Foot Using a Novel, Dynamic Compression Implant System”*, presented by Jody McAleer, DPM, Jefferson City Medical Group (Jefferson City, MO).

Featured data from the one-year, multicenter study included final analysis of 89 of 91 total patients following MTP and/or TMT joint arthrodesis using SpeedPlate® Rapid Compression Implants. The data showed:

- Early return to weight bearing in a walking boot at an average 9.0 days;
- High union rates with clinical and radiographic healing in 96.6% of patients at 12 months; and
- Clinically significant improvements in radiographic correction (HVA, IMA, TSP, Osseous Foot Width) at 6 weeks and

maintained through 12 months in patients with hallux valgus.

All 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 https://www.treace.com/resources/journal-publications/ following their presentations at ACFAS. More information on Treace's products can be found at www.treace.com.

About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market clinical study designed to evaluate outcomes of the Lapiplasty® 3D Bunion Correction® procedure in the surgical management of symptomatic hallux valgus. The study evaluates consistency and reliability of 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, and study completion with 5-year data was completed in 2026.

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 a boot and shoes; pain; quality of life; and range of motion of the big toe joint. The study treated up to 66 patients, aged 14 years and up, at 7 clinical sites in the United States. Patients will be followed for 2 years following the procedures.

About the SPRINT™ Observational Study

The SPRINT™ clinical study is an ambirectional, multicenter, post-market study designed to evaluate the healing/union rates following joint fixation using the SpeedPlate® Rapid Compression Implants and whether early weight-bearing following joint fixation affects the healing/union rates. The primary effectiveness endpoint is clinical/radiographic healing rates at 12 months. Key secondary endpoints include change in three-dimensional radiographic alignment; time to start of weight-bearing in a boot and in shoes; pain; and patient satisfaction. The study included 91 treated patients, aged 14 years and up, at 5 clinical sites in the United States. Patients were followed for 1 year following the procedure.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of being the recognized leader in the surgical treatment of bunions and other foot & ankle conditions. 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 surgeons and bunion patients, Treace offers its Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of midfoot deformities, two systems for minimally invasive osteotomy procedures, namely the Nanoplasty® 3D Minimally Invasive Bunion Correction System and the Percuplasty® Percutaneous 3D Bunion Correction System, and the SpeedMTP® 1st MTP Fusion System for bunions treated through great toe fusions. Treace continues to expand its footprint in the marketplace by extending its SpeedPlate® rapid compression implant platform to new applications, providing surgeons with advanced digital solutions with its IntelliGuide® patient specific, pre-op planning and cut guide technology, and offering SuperBite™ Fully-Threaded Compression Screws for use in fusions throughout the foot. For more information, please visit www.treace.com.

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

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