



Treace Announces New ALIGN3D™ Data at the 2021 AOFAS Annual Meeting

September 23, 2021

PONTE VEDRA, Fla., Sept. 23, 2021 (GLOBE NEWSWIRE) -- Treace Medical Concepts, Inc. ("Treace") (Nasdaq: TMCI), a commercial-stage orthopaedic medical device company driving a paradigm shift in the surgical treatment of hallux valgus (commonly known as bunions) through its Lapiplasty® 3D Bunion Correction™ procedure, today announced the presentation of new data at the ongoing 2021 American Orthopaedic Foot & Ankle Society (AOFAS) Annual Meeting in Charlotte, North Carolina. Updated interim analysis from the ALIGN3D™ clinical study demonstrated positive radiographic and patient-reported outcomes starting at 6 weeks and maintained at 24 months following the Lapiplasty® procedure.

"Results of an Interim Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing" was highlighted during the poster presentations. Data on 151 study participants showed:

- Early return to weight bearing in a walking boot at an average 8.3 days;
- Significant improvement in radiographic measures of 3-dimensional bunion correction and patient reported pain reduction and quality of life measurements at 12 months (n=104) and through 24 months (n=28) following the Lapiplasty® procedure;
- Return to work within 4 weeks and to full, unrestricted activity within 4.1 months of procedure; and
- Low recurrence rate maintained; 0.9% recurrence rate observed (1 out of 104 patients) at 12 months post-surgery.

John T. Treace, CEO of Treace commented, "New data continues to demonstrate sustained successful procedural and patient outcomes from our proprietary Lapiplasty® System, specifically designed to address the unmet needs of bunion patients. We are pleased with our growing body of clinical evidence that support our differentiated solution, as we advance the standard of care for bunion surgery with our proprietary Lapiplasty® procedure."

A poster summarizing the data and conclusions can be accessed by meeting attendees through the AOFAS mobile app.

About the ALIGN3D™ Clinical Study

The ALIGN3D™ clinical study is a prospective, multicenter, post-market study designed to evaluate outcomes of Lapiplasty® 3D Bunion Correction™ 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 is anticipated in the first half of 2023.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a commercial-stage orthopaedic medical device company with the goal of advancing the standard of care for the surgical management of bunion deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot. Treace has pioneered and patented the Lapiplasty® 3D Bunion Correction™ system - a combination of instruments, implants, and surgical methods designed to correct all 3 planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and getting patients back to their active lives quickly.

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.

Contacts:

Treace Medical Concepts

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

Investors:

Gilmartin Group

Lynn Lewis or Vivian Cervantes
LR@treace.net