



Treace Announces Interim Results from ALIGN3D™ Clinical Study at ACFAS 2021

May 19, 2021

PONTE VEDRA, Fla., May 19, 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 positive interim results from the ALIGN3D™ clinical study in a podium presentation at the ongoing American College of Foot and Ankle Surgeons (ACFAS) Annual Scientific Conference.

Dr. George T. Liu, Associate Professor of Orthopaedic Surgery at UT Southwestern Medical Center, and ALIGN3D™ participating surgeon presented the *Interim Analysis of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient Reported Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing*. Data on the 128 study participants included in the interim analysis demonstrated:

- Early return to weightbearing in a walking boot at an average of 8.3 days;
- Significant improvements in radiographic measurements of 3-dimensional bunion correction (hallux valgus angle, intermetatarsal angle, and tibial sesamoid position);
- 1.4% recurrence rate observed (1 out of 72 patients) at 12 months post-surgery; and
- Significant improvements in patient-reported pain reduction and quality of life measurements at 6 months, which were maintained at 12 months post procedure.

"This interim data showed consistent, positive radiographic and patient-reported outcomes starting at 6 weeks and maintained at 12 months. Time to weightbearing of approximately 8 days in a walking boot compares favorably with up to 6-8 weeks, often in a cast, associated with traditional Lapidus fusion.¹ With enrollment in the ALIGN3D™ study now completed, we look forward to reporting on longer-term results in the future," stated Dane Wukich, MD, Professor and Chairman, Department of Orthopaedic Surgery at the UT Southwestern Medical Center and the study's lead principal investigator.

John T. Treace, CEO of Treace commented, "The Lapiplasty® 3D Bunion Correction™ system was developed to provide surgeons the tools and surgical methods to reliably correct all 3 dimensions of the bunion deformity and address its root cause. ALIGN3D™ is a unique and comprehensive 5-year study, and we are pleased to report these positive interim results. We look forward to continuing to build our robust portfolio of clinical evidence, as we advance the standard of care for bunion surgery with our proprietary Lapiplasty® procedure."

¹Catanzariti AR, et al. **J Foot Ankle Surgery**, 38:325-32 and Park CH, Ahn JY, Kim YM, Lee WC. **Int Orthop**. 2013 Jun;37(6):1085-92.

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 ACFAS Scientific Conference

The American College of Foot and Ankle Surgeons (ACFAS) is a professional society of more than 7,800 foot and ankle surgeons. The annual ACFAS Scientific Conference is an educational event gathering foot and ankle surgeons worldwide.

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 feet quickly in a walking boot.

To learn more about the benefits and risks of Lapiplasty® 3D Bunion Correction™, or find a Lapiplasty® surgeon in your area, please visit: www.AlignMyToe.com or www.treace.com/patients.

Contacts:

Treace Medical Concepts

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

Investors:

Gilmartin Group

Lynn Lewis or Vivian Cervantes
IR@treace.net