Treace Announces Interim 3-Year ALIGN3D™ Clinical Study Data at the 2024 ACFAS Scientific Conference Demonstrating Sustained, Positive Outcomes of the Lapiplasty® Procedure

February 2, 2024

PONTE VEDRA, Fla., Feb. 02, 2024 (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 three-year interim clinical data from its ALIGN3D™ post-market study supporting the use of the Lapiplasty® procedure for treating bunions were presented in a podium presentation at the 2024 American College of Foot and Ankle Surgeons ("ACFAS") Annual Scientific Conference.

"This interim data from the ALIGN3D™ study showed consistent, positive radiographic and patient-reported outcomes maintained at three years," stated Daniel Hatch, DPM, of the Foot and Ankle Center of the Rockies in Greeley, Colorado and presenting surgeon.[1] "Importantly, by providing a comprehensive, 3D correction of the bunion deformity, study participants were able to quickly return to protected weightbearing in approximately eight days and get back to their active lifestyle with a low rate of clinical complications and recurrence."

"We are pleased that this three-year data from our prospective, multicenter ALIGN3D™ study continues to demonstrate sustained, successful patient outcomes from our proprietary Lapiplasty® Procedure," said John T. Treace, CEO, Founder and Board Member of Treace. "We believe these three-year clinical study results set a high standard for a commercial bunion technology and one that further differentiates Lapiplasty® in the marketplace with our surgeons and their patients. We look forward to continuing to expand our market-leading body of clinical evidence, as we advance the standard of care for bunion surgery."

ALIGN3D™ Clinical Study

The scientific presentation, titled *"Three-Year Analyses of a Five-Year Prospective Multicenter Study Assessing Radiographic and Patient Reported Outcomes Following Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing,"* featured interim data from the prospective, five-year, multicenter ALIGN3D™ clinical study with 173 enrolled patients and demonstrated positive results following the Lapiplasty® Procedure, which included:

- Early return to weight bearing in a walking boot at an average 8.4 days;
- Low radiographic recurrence rates at latest visit of 0.9% using HVA>20° (1 out of 115) and 5.2% using HVA>15° (6 out of 115);
- 81% reduction in pain measured using the Visual Analog Scale ("VAS") at 24 months (n=156);
- 86% and 85% improvement in walking/standing and social interaction patient-reported quality of life measures, respectively, using the Manchester-Oxford Foot Questionnaire ("MOxFQ") through latest subject visit [mean 40.5 months (n=118)];
- Significant improvement in patient reported outcomes across all Patient-Reported Outcomes Measurement Information System ("PROMIS") domains over time through latest subject visit [mean 40.5 months (n=113)]; and
- Low symptomatic non-union rate of 1.8% (3 out of 173).

The ALIGN3D™ study is ongoing, and patients are expected to be followed for five years. The Company has submitted its primary endpoint ALIGN3D™ manuscript to a top-tier, peer-reviewed foot and ankle journal at the end of 2023 and expects publication in 2024.

Mini3D™ Clinical Study

In addition to the ALIGN3D™ data, interim data from the Company's Mini3D™ prospective, multicenter study was presented in a poster presentation at ACFAS titled *"Interim Analysis of a Prospective Multicenter Study Assessing Radiographic and Patient Outcomes Following a Mini-Open Triplanar Tarsometatarsal Arthrodesis with Early Weightbearing."* This poster presentation included data from 103 enrolled patients and demonstrated favorable clinical and patient-reported outcomes with a mini-incision approach (median incision length: 3.5cm) at an average follow-up time of 7.4 months post-procedure, including:

- Early return to weight-bearing in a walking boot at an average 7.8 days;
- Maintenance of radiographic correction (IMA, HVA, TSP) through 12 months;
- Significant reduction in pain (VAS) and significant improvement in patient reported outcomes (MOxFQ) through 12 months; and
- Favorable scores for scar quality using the Patient and Observer Scar Assessment Scale ("POSAS").

Both ACFAS presentations, which include additional details such as patient demographics, inclusion/exclusion criteria, and complications reported in the studies, are available on Treace's website at www.lapiplasty.com/surgeons/journal-publications/. 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 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; patient-reported quality of life measures; 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; change, if any, in the initial incision length and scar quality; change in radiographic foot length and width as well as swelling; and any correlation between the amount of time an external positioner is actively used during the procedure with necrosis, blistering, bruising, and tissue ulceration. The study is scheduled to enroll 105 patients, aged 14 to 58 years, at 9 clinical sites in the United States with 9 participating surgeons.

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 expectations for publication of the primary endpoint ALIGN3D™ manuscript in 2024. 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 its subsequent SEC filings. 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 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 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 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. To further support the needs of bunion patients, Treace has introduced its Adductoplasty® Midfoot Correction System, designed for reproducible surgical correction of the midfoot as well as its Hammertoe PEEK Fixation System designed to address hammertoe, claw toe and mallet toe deformities. 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® and Adductoplasty® 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, Twitter, Facebook and Instagram.

[1] Daniel Hatch, DPM is a member of Treace's Surgeon Advisory Board and a paid consultant for Treace.

Contacts:

Treace Medical Concepts, Inc.
Julie Dewey, IRC
Chief Communications & Investor Relations Officer
jddewey@treace.com | 209-613-6945