Tactile Medical Announces Enrollment of First Patient in Randomized, Controlled Clinical Trial Evaluating the Effectiveness of Flexitouch® Plus for the Treatment of Head and Neck Lymphedema

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MINNEAPOLIS, Sept. 30, 2021 (GLOBE NEWSWIRE) -- Tactile Systems Technology, Inc. (“Tactile Medical”) (Nasdaq: TCMD), a medical technology company focused on developing medical devices for the treatment of chronic diseases at home, today announced the enrollment of the first patient in a randomized, controlled clinical trial evaluating the effectiveness of its Flexitouch® Plus system for the treatment of head and neck lymphedema.

“With the enrollment of our first patient, we are pleased to initiate the largest randomized, controlled clinical trial ever conducted for the treatment of head and neck cancer-related lymphedema,” said Sheila Ridner, PhD, RN, FAAN, Professor of Nursing, Emerita, Vanderbilt University School of Nursing, a principal investigator of the trial. “In conducting this rigorous clinical trial, we hope to build on the initial body of evidence by evaluating the effectiveness of Flexitouch Plus in comparison to usual care, using a variety of measures to assess the benefits of this at-home treatment for patient health and quality of life.”

The trial will compare the short- and long-term effectiveness of Tactile Medical’s Flexitouch Plus system to usual care, such as complete decongestive therapy (“CDT”), for the management of lymphedema and fibrosis in head and neck cancer survivors. It will consist of approximately 250 subjects enrolled at six clinical sites: Vanderbilt University Medical Center, University of Michigan, Johns Hopkins University, University of Kentucky, Rush University and University of Alabama. Co-Primary Investigators for the study are Ridner and Barbara Murphy, MD, professor of Medicine, Vanderbilt University School of Medicine.

Subjects enrolled in the trial will be randomized to one of two arms, where they will either self-administer once daily treatment with Flexitouch Plus or receive usual care as would typically be directed at their site, which may include CDT by a lymphedema therapist or other conservative management measures as directed by the therapist. The trial’s primary outcome measures will include the assessment of swelling/inflammation, symptom burden and functional impairment, including swallowing; quality of life; work productivity; and activity impairment and body image via various measures. Short-term effectiveness will be evaluated at two months and long-term effectiveness will be evaluated at four and six months.

“More than 90% of patients treated for head and neck cancer develop lymphedema [1] – resulting in swelling, fibrosis, difficulty swallowing, pain and other symptoms impacting quality of life – with few viable options for long-term treatment,” said Dr. Thomas F. O’Donnell, Jr., Tactile Medical’s Chief Medical Officer. “For these patients, Flexitouch Plus for head and neck lymphedema is the first and only pneumatic compression device cleared and commercially available to treat this condition at home. The initiation of this clinical trial underscores Tactile Medical’s commitment to supporting the development of quality clinical evidence and expanding access to effective lymphedema treatment for this underserved patient population.”

For additional information about the trial, please visit: https://tactilemedical.com/head-and-neck-lymphedema-clinical-trial/

About Lymphedema

Lymphedema is a chronic disease in which excess fluid accumulates in areas of the body when lymphatic vessels do not work efficiently or have been damaged. An estimated 1.4 million U.S. patients are diagnosed with lymphedema annually. While there is no cure, lymphedema can be effectively managed to relieve symptoms, prevent worsening, and lower the risk of skin damage and infection. For more information, https://tactilemedical.com/information-for-patients/what-is-lymphedema/

About Flexitouch® Plus

The Flexitouch Plus system has been clinically proven to stimulate the lymphatic system. It delivers a noninvasive therapy that patients can administer themselves at home. Tens of thousands of patients with lymphedema in the limbs and trunk areas have benefited from the Flexitouch system since its introduction in 2002. In 2017, Tactile Medical launched a Flexitouch system designed for the treatment of lymphedema of the head and neck at home. For more information, https://tactilemedical.com/our-lymphedema-solutions/for-head-and-neck/flexitouch-plus/

About Tactile Medical

Tactile Medical is a leader in developing and marketing at-home therapy devices that treat chronic swelling conditions such as lymphedema and chronic venous insufficiency. Tactile Medical’s Mission is to help people suffering from chronic diseases live better and care for themselves at home. The Company’s unique offering includes advanced, clinically proven pneumatic compression devices, as well as continuity of care services provided by a national network of product specialists and trainers, reimbursement experts, patient advocates and clinicians. This combination of products and services ensures that tens of thousands of patients annually receive the at-home treatment necessary to better manage their chronic conditions. Tactile Medical takes pride in the fact that our solutions help increase clinical efficacy, reduce overall healthcare costs and improve the quality of life for patients with chronic conditions. For more information, https://tactilemedical.com/about-us/

Legal Notice Regarding Forward-Looking Statements:

This release contains forward-looking statements. Forward-looking statements are generally identifiable by the use of words like “may,” “will,” “should,” “could,” “expect,” “anticipate,” “estimate,” “believe,” “intend,” “continue,” “confident,” “outlook,” “guidance,” “project,” “goals,” “look forward,” “poised,” “designed,” “plan,” “return,” “focused,” “prospects” or “remain” or the negative of these words or other variations on these words or comparable terminology. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous factors and uncertainties outside of the Company’s control that can make such statements untrue, including, but not limited to, the impacts of the COVID-19 pandemic on the Company’s business, financial condition and results of operations; the course of the COVID-19 pandemic and its impact on general economic, business and market conditions; the Company’s inability to execute on its plans to respond to the COVID-19 pandemic; the

adequacy of the Company's liquidity to pursue its business objectives; the Company's ability to obtain reimbursement from third party payers for its products; loss or retirement of key executives, including prior to identifying a successor; adverse economic conditions or intense competition; loss of a key supplier; entry of new competitors and products; adverse federal, state and local government regulation; technological obsolescence of the Company's products; technical problems with the Company's research and products; the Company's ability to expand its business through strategic acquisitions; the Company's ability to integrate acquisitions and related businesses; price increases for supplies and components; the effects of current and future U.S. and foreign trade policy and tariff actions; or the inability to carry out research, development and commercialization plans. In addition, other factors that could cause actual results to differ materially are discussed in the Company's filings with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. The Company undertakes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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[1] Control group patients experienced a statistically significant increase in pain while Flexitouch group remained stable. Ridner SH, Dietrich MS, Niermann K, Cmelak A, Mannion K, Murphy B. A Prospective Study of the Lymphedema and Fibrosis Continuum in Patients with Head and Neck Cancer. Lymphat Res Biol. 2016;14(4):198–205.

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