Tactile Medical Receives FDA 510(k) Clearance for New Indication of At-Home Lymphedema Treatment

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With new indication, the Flexitouch System® becomes the first and only pneumatic compression device cleared for the treatment of head and neck lymphedema

MINNEAPOLIS, Sept. 22, 2016 (GLOBE NEWSWIRE) -- Tactile Systems Technology, Inc. ("Tactile Medical") (Nasdaq:TCMD), a medical technology company that develops and provides innovative medical devices for the treatment of chronic diseases at home, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Flexitouch System in treating lymphedema of the head and neck, a common consequence of head and neck cancer.

"This is a major milestone for our company and a first for the lymphedema treatment market," said Gerald R. Mattys, Chief Executive Officer of Tactile Medical. "More importantly, this new FDA clearance for our Flexitouch System represents a significant advancement in the treatment of head and neck lymphedema, as it enables patients to manage their condition at home." Mr. Mattys continued, "We look forward to the commercialization of our Flexitouch System for the treatment of head and neck lymphedema in the first half of 2017."

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. This chronic disease affects between three million and five million people in the United States. While there is no cure, lymphedema can be effectively managed to relieve symptoms, prevent worsening, and lower the risk of skin damage and infection.

The Flexitouch 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. The new FDA clearance expands the addressable patient population for the Flexitouch System to those that are suffering from lymphedema of the head and neck. The Flexitouch System is the first and only pneumatic compression device cleared for the treatment of lymphedema of the head and neck in the United States.

"It is widely known that lymphedema of the arms, legs or trunk causes immense suffering; utilizes health resources; and, as a result, is costly to the patient, community and society," explained Alan T. Hirsch, M.D., Tactile Medical's Chief Medical Officer and Director of the Vascular Medicine Program at the University of Minnesota Medical School. "Increasingly, we recognize head and neck lymphedema as being particularly challenging. This new at-home treatment of head and neck lymphedema will fill an important healthcare gap."

About Tactile Systems Technology, Inc.

Tactile Systems Technology, Inc. ("Tactile Medical") is a medical technology company that develops and provides innovative medical devices for the treatment of chronic diseases at home. The Company is the sole manufacturer and distributor of the Flexitouch and Entré ™ Systems, medical devices to help control symptoms of lymphedema, a chronic and progressive medical condition that is often an unintended consequence of cancer treatment, and the ACTitouch® System, a medical device to treat venous leg ulcers and chronic venous insufficiency. The Company provides products for use both in the home and in health care institutions, including hospitals and vascular, wound and lymphedema clinics throughout the United States. For additional information, please visit http://www.tactilemedical.com. To receive future press releases via email, please visit Investors.tactilemedical.com.

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," or "project" 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 adequacy of the Company's liquidity to pursue its complete business objectives; the Company's ability to obtain reimbursement from third party payers for its products; loss or retirement of key executives; 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; and 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, including the final prospectus for the Company's initial public offering. Investors and security holders are urged to read these documents free of charge on the SEC's web site 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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