January 3, 2019

Viveve Completes Enrollment in LIBERATE-International Trial for Improvement of Stress Urinary Incontinence

ENGLEWOOD, Colo., Jan. 03, 2019 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, announced today that it has completed enrollment in its LIBERATE-International trial, a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of its proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women. This study is being conducted under an Investigational Testing Application which was approved by the Canadian Ministry of Health and by a central investigational review board (IRB).

"As we seek to achieve regulatory clearances for our CMRF technology for the treatment of SUI, a condition that affects an estimated 25-30 million women worldwide, completion of enrollment in the LIBERATE-International trial is an important milestone," stated Scott Durbin, chief executive officer and director of Viveve. "Our single-session procedure offers women the potential for significant improvement in urine leakage and the ability to engage in their daily lives with greater comfort and control. We are hopeful that the results from this study will support regulatory clearances in Canada, the EU and other international markets."

About the LIBERATE-International Study
LIBERATE-International is a multicenter, randomized, double-blinded, and sham-controlled trial with an enrollment of approximately 100 subjects at up to ten study sites in Canada. Subjects are randomized in a 2:1 ratio for active and sham treatments.

The primary efficacy endpoint is the mean change from baseline in the standardized 1-hour Pad Weight Test at six months post-treatment. The objective 1-hour Pad Weight Test is an FDA recommended endpoint for SUI clinical trials. The study design also includes multiple exploratory endpoints as well as safety follow-up throughout the study. For more information, please visit www.clinicaltrials.gov.

About Viveve
Viveve Medical, Inc. is a women's intimate health company committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System incorporates cryogen-cooled, monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session.

International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in over 50 countries. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth after receiving approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018. If successful, this trial could support a marketing application for a new U.S. commercial indication. Currently, in the United States, the Viveve System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis.

Viveve has fully enrolled LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of SUI in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S., after conducting certain safety testing. The results of these two trials, if successful, could support marketing applications in the U.S. and additional countries around the world for this new commercial indication. For more information visit Viveve's website at www.viveve.com.

Safe Harbor Statement

All statements in this press release that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. While management has based any forward-looking statements included in this press release on its current expectations, the information on which such expectations were based may change. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties and other factors, many of which are outside of our control, which could cause actual results to materially differ from such statements. Such risks, uncertainties and other factors include, but are not limited to, the fluctuation of global economic conditions, the performance of management and our employees, our ability to obtain financing, our ability to obtain approval or clearance for sale of our medical device for all indications sought, competition, general economic conditions and other factors that are detailed in our periodic and current reports available for review at www.sec.gov. Furthermore, we operate in a highly competitive and rapidly changing environment where new and unanticipated risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. We disclaim any intention to, and undertake no obligation to, update or revise forward-looking statements to reflect events or circumstances that subsequently occur or of which we hereafter become aware, unless required by law.

Investor Relations Contacts:
Sarah McCabe
Stern Investor Relations, Inc.
(212) 362-1200
sarah@sternir.com

Amato and Partners, LLC
Investor Relations Counsel

admin@amatoandpartners.com

Media Contact:
Kelly Wakelee
Berry & Company Public Relations
(212) 253-8881
kwakelee@berrypr.com

Source: Viveve Medical, Inc.