August 7, 2018

Viveve Announces FDA Approval to Continue VIVEVE II Clinical Study

Agency determines one-month safety data sufficient in first-stage and grants continued enrollment of up to 100 subjects in second stage of sexual function trial

ENGLEWOOD, Colo., Aug. 07, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to continue enrollment in the company's multicenter randomized **Vi**veve Treatment of the **V**aginal Introitus to **EV**aluate Safety and **E**fficacy (VIVEVE II) clinical trial to assess the safety and effectiveness of the Viveve® System for the improvement of sexual function in women following vaginal childbirth. The Agency's approval was based on a determination that the company provided sufficient data to support continued subject enrollment in the trial and that there are no subject protection concerns that preclude continuation of the study.

"This clearance to continue enrollment represents a major step forward in the progression of the VIVEVE II trial and for women seeking an improvement in sexual function following child birth. Following FDA review of the second stage of safety data, and approval of an IDE supplement to expand the study, Viveve plans to continue enrollment up to 250 patients," stated Scott Durbin, chief executive officer and director of Viveve.

About the VIVEVE II Study
VIVEVE II is a randomized, double-blinded, and sham-controlled trial with a planned enrollment of approximately 250 subjects at up to 25 study sites in the United States and Canada. Subjects will be randomized in a 1:1 ratio for active and sham treatments.

A staged approach for clinical enrollment was required by the FDA in its Investigational Device Exemption (IDE) approval letter to the company. The first requested safety review was completed based on one-month follow-up data for the initial 25 subjects in the trial. A second safety review will now occur after safety data are collected from an additional 25 subjects out to one-month follow-up, and from the first 50 subjects at three-month follow-up. While safety data are being reviewed from the second stage, enrollment in the trial will continue up to 100 subjects.

The primary efficacy endpoint is intended to be the mean change from baseline in the total FSFI (Female Sexual Function Index) at 12 months. Subjects will also be assessed for safety over the 12 months. The approved protocol also includes a variety of secondary and exploratory endpoints measured at six months post-treatment that address the efficacy of and improvement in FSFI domain scores for Desire, Lubrication, Orgasm, Arousal, Satisfaction, and Pain.

About Viveve
Viveve Medical, Inc. is a women's intimate health company passionately committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System incorporates clinically-proven cryogen-cooled, monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate robust 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 from over 50 countries. Viveve received approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018 to proceed with VIVEVE II, a multicenter, randomized, double-blind, sham-controlled study to assess improvement of sexual function in women following childbirth. Initiation of the trial began in the second quarter of 2018 and if successful, the results 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 is awaiting approval to conduct two independent, multicenter, randomized, registration trials (LIBERATE-International and LIBERATE-U.S.). The results of these studies, if successful, could support marketing applications in the U.S, and around the world, for the improvement of stress urinary incontinence in women.

For more information visit Viveve's website atwww.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, 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.

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.