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Viveve Announces Initiation of VIVEVE II Clinical Study

Results could support a marketing application for an expanded U.S. indication for the improvement of sexual function in women

ENGLEWOOD, Colo., May 16, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced that patient enrollment is underway in the multicenter randomized **VI**veve Treatment of the **V**aginal Introitus to **EV**aluate Safety and **E**fficacy (VIVEVE II) clinical study to assess the safety and effectiveness of the Viveve® System for the improvement of sexual function in women following vaginal childbirth.

“We are extremely excited about the recent initiation of the VIVEVE II study and we are already seeing rapid patient enrollment and a high level of enthusiasm from our clinical investigators. As a result, we anticipate submitting the 30-day safety data from the first 25 treated patients to the FDA for review by the end of the second quarter,” said Scott Durbin, chief executive officer of Viveve. “We believe that VIVEVE II, if successful, will clinically demonstrate that a single treatment with the Viveve System provides significant benefits to women suffering from diminished sexual function following vaginal childbirth and may support a marketing application for an expanded U.S. indication for the improvement of sexual function.”

Mr. Durbin continued, “Currently 58 countries around the world have regulatory approvals and clearances for the treatment of vaginal laxity and/or improvement of sexual function using our technology and these marketed indications are based on the positive results obtained from previously completed studies including, VIVEVE I – a multicenter, randomized, blinded and sham-controlled trial.”

About the VIVEVE II Study

The VIVEVE II clinical study is a randomized, double-blinded, and sham-controlled trial with a planned enrollment of approximately 250 patients 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, or roll-in, for clinical enrollment was required by the U.S. Food and Drug Administration (FDA) in its Investigational Device Exemption (IDE) approval letter to the company on March 19, 2018. In the first stage, enrollment is limited to 50 subjects. The roll-in will require safety review by the FDA of a minimum of 25 subjects, one-month post-treatment. Following the roll-in, an IDE Supplement will be submitted to the agency to expand the study up to its intended 250 patients. While the safety data from the initial 25 patients are being reviewed by the FDA, Viveve will continue to enroll up to an additional 25 patients (total of 50 patients enrolled).

The primary efficacy endpoint is intended to be the mean change from baseline in the total FSFI (Female Sexual Function Index) at 12 months, following the submission of an IDE supplement. Patients 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 55 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 has submitted an Investigational Trial Application to the Canadian Ministry of Health and plans to submit an IDE to the FDA to conduct two independent multicenter randomized registration trials (LIBERATE-International and LIBERATE-U.S. respectively) for use of the CMRF device in stress urinary incontinence treatment.

InControl Products by Viveve are FDA-cleared medical devices that treat stress, urge, and mixed incontinence conditions and that improve pelvic floor strength. Viveve exclusively distributes InControl Medical's products to healthcare providers in the United States.

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.

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