July 3, 2018

Viveve Submits VIVEVE II Clinical Study 30-Day Patient Safety Data to FDA

No serious adverse events reported in the submission

Final study results could support a marketing application for expanded U.S. indication for the improvement of sexual function in women

ENGLEWOOD, Colo., July 03, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced that it has submitted 30-day patient safety data to the U.S. Food and Drug Administration (FDA) for 38 subjects completing the 1-month assessment in the company's multicenter randomized **Vi**veve Treatment of the **V**aginal Introitus to **EV**aluate Safety and **E**fficacy (VIVEVE II) clinical study.

"Submission of this safety data addresses the FDA's request to review the 30-day safety data from at least 25 patients in the VIVEVE II study and represents a major step forward in the progression of the VIVEVE II trial," said Scott Durbin, chief executive officer of Viveve. "As planned, enrollment will continue up to 50 patients. Following FDA review of the safety data, and approval of an IDE supplement to expand the study, Viveve plans to continue enrollment up to 250 patients. The VIVEVE II trial has the opportunity to 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."

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 on March 19, 2018. In the first stage, enrollment is limited to 50 subjects and requires safety review by the FDA of a minimum of 25 subjects at one-month post-treatment.

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 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 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.

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