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Viveve Announces Completion of VIVEVE II Pivotal FDA Clinical Trial for Improvement of Sexual Function

Unblinded top-line results of the 12-month U.S. study anticipated in April

If positive, results may support a 2020 marketing application for an expanded U.S. indication for improvement of sexual function in women

ENGLEWOOD, CO / ACCESSWIRE /March 12, 2020 / Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that all patients have now completed participation in the VIVEVE II pivotal FDA clinical trial. VIVEVE II is a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the Company's proprietary, Cryogen-cooled Monopolar Radiofrequency (CMRF) technology for the improvement of sexual function in women following vaginal childbirth.

"Completion of our VIVEVE II trial represents an important milestone for our Company. An estimated 12-14 million women worldwide suffer from diminished sexual function following vaginal childbirth who are candidates for our treatment. Through several prior clinical studies, our CMRF technology has shown the potential to provide women with a safe and effective, single session treatment for sexual dysfunction associated with vaginal childbirth. We anticipate reporting the top-line results from the VIVEVE II trial in April 2020. If the trial results are positive, we intend to apply for an expanded U.S. indication for the improvement of sexual function in women," said Scott Durbin, chief executive officer of Viveve.

"The burgeoning field of female sexual health and wellness is gaining tremendous attention on a global basis. Viveve continues its tradition of high-quality clinical research to provide safe and effective treatment options to millions of women experiencing intimate health conditions such as sexual dysfunction and its related symptoms," stated Michael Krychman, M.D., executive director, The Southern California Center for Sexual Health and Survivorship, and chief medical consultant for Viveve. "The Company has been at the forefront of providing clinically proven treatments with its CMRF technology as demonstrated by the success of the randomized, blinded and sham-controlled VIVEVE I clinical study and two earlier single-arm clinical studies conducted in the U.S. and Japan."

"Viveve II is a landmark trial in female sexual function," continued Dr. Krychman. "Completion of all patient visits in this large-scale, 12-month, randomized, prospective, double-blind trial is a significant milestone. The medical community, focused on women's health, looks forward to the upcoming trial results, and if positive, the impact it could have on the women we care for with sexual dysfunction conditions."

About the VIVEVE II Study

VIVEVE II is a randomized, double-blinded, and sham-controlled trial that is targeting enrollment of 250 subjects at up to 19 clinical sites in the United States and Canada. Subjects were randomized in a 1:1 ratio for active and sham treatments and have now all completed 12-month follow-up visits.

The primary efficacy endpoint is the mean change from baseline in the total FSFI (Female Sexual Function Index) at 12 months. Safety assessments will also be reported for the duration of the 12-month trial. The Investigational Device Exemption (IDE) protocol approved by the U.S. Food and Drug Administration (FDA) also includes a variety of secondary and exploratory endpoints that evaluate the efficacy of and improvement in FSFI domain scores for desire, lubrication, orgasm, arousal, satisfaction, and pain.

About Viveve

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

In the United States the Viveve System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis. International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in more than 50 countries.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI) and has initiated a short-term feasibility study under an investigational testing application approved by the Canadian Ministry of Health as reported in mid-December 2019. Following the positive yet inconclusive results of the LIBERATE-International trial, the feasibility study is a single-blind, three-arm, three-month study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment in order to capture short-term safety and effectiveness data on use of the Viveve System for the improvement of SUI in women. Subject enrollment in the study was completed in March 2020. Results of the three-month feasibility study are targeted for readout in the third quarter of 2020. If positive, the results could be used to support Viveve's re-submission of its IDE to the FDA for approval to conduct the LIBERATE-U.S. trial designed to evaluate the safety and effectiveness of the Viveve System for improvement of SUI in women. The results of these trials, if successful, could support marketing applications in the U.S. and over 30 countries around the world for this new commercial indication.

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, 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.

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