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Viveve Announces FDA Clearance to Advance VIVEVE II Clinical Study to Full Enrollment

- Sites to continue enrollment up to 250 patients in sexual function trial -

ENGLEWOOD, Colo., Dec. 20, 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 determined that the company provided sufficient data to support continued subject enrollment in the trial and that there are no safety concerns that preclude the continuation of the study.

"The positive outcome of the safety review by FDA and clearance to advance the VIVEVE II trial to full enrollment represents a significant clinical milestone for Viveve. The VIVEVE II trial has the opportunity to clinically demonstrate that a single treatment with the Viveve System can provide meaningful benefits to women suffering from diminished sexual function following vaginal childbirth. The results of this study, if successful, may support a marketing application for an expanded U.S. indication for the Viveve System for improvement of sexual function," said 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.

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 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 initiated 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 in the third quarter of 2019. 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 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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