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Viveve Resubmits U.S. Investigational Device Exemption to FDA to Conduct New PURSUIT Trial for Improvement of Stress Urinary Incontinence

Proposed pivotal trial reinforces the company's strategic pursuit of label expansion for Cryogen-cooled, Monopolar Radiofrequency (CMRF) technology in SUI indication

ENGLEWOOD, CO / ACCESSWIRE / April 15, 2020 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that the company has resubmitted its Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for approval to begin a stress urinary incontinence (SUI) multicenter, randomized, double-blinded, sham-controlled trial now entitled, PURSUIT - **P**rospective **U**.S. **R**adiofrequency **SUI T**rial. The trial is designed to evaluate the safety and efficacy of Viveve's CMRF treatment versus an inert sham tip for the improvement of SUI in women.

Following the original IDE submission to conduct a U.S. SUI trial, Viveve completed multiple rounds of discussions with the FDA. Based on these discussons, the resubmitted IDE addresses specific protocol requests and provides positive results from additional in vivo animal safety testing requested by the FDA.

The results of the LIBERATE-International SUI study, reported in August of 2019, demonstrated significant and durable improvement across all study endpoints, including nearly an 80% reduction in leakage as measured by one-hour Pad Weight Test at six months. As reported however, patients in the sham arm of the study (who received less than 1 joule/cm2 of RF and cryogen cooling) also demonstrated significant improvement. Based on a significant indiction of efficacy in the treatment arm, Viveve rapidly launched a short-term 3-arm SUI feasibility trial, utilizing a completely inert sham tip, under an approved Investigational Testing Application by the Canadian Ministry of Health. Initiated in January of 2020, the SUI feasibility trial completed enrollment in March, and is targeted for readout in late summer of this year. If positive, the results of the SUI feasibility trial could support the launch of the pivotal PURSUIT trial in the U.S. for the improvement of SUI in women.

"We are enthusiastic about the progress we have achieved in our SUI clinical development program. It is our steadfast belief that availability of a non-invasive single session Viveve CMRF treatment could benefit the estimated 25-30 million women worldwide who suffer from the SUI medical condition," said Scott Durbin, chief executive officer of Viveve.

"With the expected readout from our SUI feasibility trial and the potential for FDA clearance to conduct the U.S. PURSUIT trial, Viveve has several important events pending for late summer 2020. Positive trial results, and achievement of FDA IDE approval, will enable us to

continue our course to potentially obtain global label expansion of our CMRF technology for the treatment of SUI in women," Mr. Durbin concluded.

About the U.S. SUI Trial

PURSUIT is intended to be a randomized, double-blinded, and sham-controlled trial with enrollment of approximately 240 subjects at up to 25 study sites in the United States. Subjects will be randomized in a 2:1 ratio for active and sham treatments.

The primary efficacy endpoint is intended to be the 1-hour Pad Weight Test at 12 months post-treatment. The study design includes secondary endpoints assessed by the 3-day bladder voiding diary and Quality of Life and SUI benefits as measured by the Urogenital Distress Inventory-6 (UDI-6), Incontinence Quality of Life (I-QOL), and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF). Subject safety will be monitored throughout the study.

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.

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 impact of the novel coronavirus termed COVID-19 on our clinical development and regulatory review and clearances and on the manufacturing, placements and patient utilization of our Viveve Systems, the performance of management and our employees, the outcome of our assessment of our organization and cost structure, our ability to obtain financing, our evaluation of strategic alternatives, 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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