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Viveve Announces FDA Approval to Conduct PURSUIT Trial for Improvement of Stress Urinary Incontinence

Initiation of pivotal PURSUIT trial is targeted for Q4 2020 following pending results from Company's SUI feasibility study, which is evaluating a new sham treatment tip

PURSUIT clearance and pending results from the SUI feasibility study are significant milestones in Company's pursuit of a stress urinary incontinence indication in the U.S.

ENGLEWOOD, CO / ACCESSWIRE / July 7, 2020 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that the Company has received approval of its Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA) to begin a stress urinary incontinence (SUI) multicenter, randomized, double-blinded, sham-controlled clinical trial entitled PURSUIT - **P**rospective **U**.S. **R**adiofrequency **SUI T**rial. The trial is designed to evaluate the safety and efficacy of Viveve's Cryogen-cooled Monopolar Radiofrequency (CMRF) treatment versus an inert sham tip for the improvement of SUI in women.

In April 2020 VIVEVE announced resubmission of the SUI IDE to the FDA to conduct the PURSUIT Trial. In May 2020, the FDA outlined several study considerations that were successfully addressed in an IDE Supplement that VIVEVE submitted to the FDA on June 1, 2020.

"FDA approval of the IDE to conduct the PURSUIT Trial represents a significant regulatory milestone and a major advance in our SUI clinical development program", said Scott Durbin, Viveve's chief executive officer. "As we proceed with plans to initiate the PURSUIT Trial, we are equally focused on progressing our short-term, three-arm, SUI feasibility study that is targeted for readout in late summer of this year. A positive readout from the SUI feasibility study followed by the initiation of the PURSUIT Trial continue the momentum for our CMRF technology and our goal to bring an effective treatment to the 25-30 million women worldwide who suffer from the SUI medical condition," Mr. Durbin concluded.

About the U.S. SUI Trial

PURSUIT is a randomized, double-blinded, sham-controlled 12-month trial with enrollment of approximately 240 subjects at up to 25 study sites in the United States. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm will receive the CMRF treatment of 90J/cm^2 RF and cryogen-cooling. Subjects in the control arm will receive a clinically inert sham treatment of ≤1J/cm^2 RF and <2 degrees tissue cooling cryogen (sub-clinical and sub-therapeutic levels).

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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