December 18, 2019

Viveve Announces Authorization to Initiate Short-Term Feasibility Study in Stress Urinary Incontinence from Canadian Ministry of Health

Three-arm, three-month study will compare Viveve's cryogen-cooled monopolar radiofrequency (CMRF) treatment and cryogen-only sham to an inert sham treatment

ENGLEWOOD, CO / ACCESSWIRE / December 18, 2019 /Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that it has received approval of its Investigational Testing Application (ITA) from the Canadian Ministry of Health to conduct a three-arm, three-month feasibility study to compare Viveve's cryogen-cooled monopolar radiofrequency (CMRF) treatment and a cryogen-only sham to an inert sham treatment for the improvement of stress urinary incontinence (SUI) in women.

"Our prior clinical research indicates that our advanced CMRF technology could play an important role in the treatment of SUI for millions of women around the world. We are pleased to have received approval from Health Canada to initiate a short-term SUI feasibility study and our outstanding team of investigators and trial sites are positioned to move forward rapidly," said Scott Durbin, Viveve's chief executive officer and director. "This trial represents a significant advance in our strategy to pursue label expansions for Viveve's CMRF technology to maximize the commercial potential of our platform."

In August 2019, Viveve presented results from the LIBERATE-International SUI clinical trial comparing use of the Viveve Treatment (cryogen cooling and 90 Joules/cm2 RF energy) to use of cryogen-only treatment (cryogen cooling with only 1 Joule/cm2 RF energy, identified in the study as "sham treatment") for improvement of SUI in women. Results from this trial showed that both treatments had a clinically meaningful effect on objective and subjective outcomes in patients, although the treatment effects were not statistically different from each other.

"The results from our LIBERATE-International trial provided us with many essential insights indicating the potential efficacy benefits of Viveve's CMRF technology in the treatment of mild to moderate SUI in women and enabled us to determine the optimal path forward for this development program. We look forward to working with our team of investigators to complete this trial in the coming months," Mr. Durbin added.

Pending Investigational Review Board approvals of the ITA cleared SUI treatment protocol, the Company anticipates rapid study initiation and subject enrollment with a potential data readout in the second quarter of 2020. If the results are positive, showing a definitive difference between the study arms, the Company intends to resubmit its pending

Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration (FDA) for approval to conduct the LIBERATE-U.S. trial for improvement of mild to moderate SUI in women. SUI is a condition that affects an estimated 25-30 million women worldwide.

About the International SUI Feasibility Study

The international three-arm SUI feasibility study is a prospective, randomized, single-blind clinical trial comparing use of the Viveve cryogen-cooled monopolar radiofrequency (CMRF) treatment and a cryogen-only sham to an inert sham treatment in women with SUI. Three clinical trial sites in Canada will enroll a total of approximately 36 subjects (12 per treatment arm) randomized on a 1:1:1 ratio to each of the three study arms. The primary efficacy endpoint is the mean change from baseline in the standardized 1-hour Pad Weight Test at three months post-treatment. The treatment protocol will assess additional objective endpoints including the 24-hour Pad Weight Test and 3-day voiding diary at three months post-treatment. The study design also includes exploratory endpoints as well as safety follow-up 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. Viveve is conducting VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth. Completion of full 250 subject enrollment was announced in early March 2019. The top-line 12-month data readout of the VIVEVE II trial is expected in April 2020. If successful, VIVEVE II results could support a marketing application for a new U.S. 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 or pursue 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.

Investor Relations contacts:

Amato and Partners, LLC
Investor Relations Counsel
admin@amatoandpartners.com

Media contact:

Jenna Urban
Berry & Company Public Relations
(212) 253-8881
jurban@berrypr.com

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