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Viveve Initiates Enrollment of its Short-Term Feasibility Study in Stress Urinary Incontinence

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

ENGLEWOOD, CO / ACCESSWIRE / January 14, 2020 / Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, announced today that it has initiated enrollment in its 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. Approval of the Investigational Testing Application from the Canadian Ministry of Health to conduct the study was reported in mid-December 2019.

"We are pleased that patient enrollment in our SUI feasibility study has begun and anticipate rapid enrollment towards completion of the study. We continue to believe that our innovative technology has the potential to provide women with an effective, non-invasive treatment option for mild to moderate SUI. Initiation of this study represents a significant milestone in our clinical development program and our effort to achieve label expansion of our CMRF technology for the improvement of SUI in women," said Scott Durbin, Viveve's chief executive officer and director.

"SUI remains a significant health issue for millions of women around the world and we look forward to presenting results from this study in the second quarter of this year. Pending the results of this trial, if successful, our goal is to resubmit our Investigational Device Exemption application to the U.S. Food and Drug Administration (FDA) for approval to conduct the LIBERATE-U.S. trial," added Mr. Durbin.

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.

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