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Viveve Announces Topline Results from Pivotal U.S. VIVEVE II Trial for Improvement of Sexual Function in Women

ENGLEWOOD, CO / ACCESSWIRE / April 9, 2020/ Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced topline results from the VIVEVE II clinical trial. VIVEVE II is a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the company's proprietary, Cryogen-cooled Monopolar Radiofrequency (CMRF) technology for the improvement of sexual function in women following vaginal childbirth.

The VIVEVE II study did not meet its primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline in total Female Sexual Function Index (FSFI) score at 12 months. The study included 220 subjects that successfully completed 12-month follow-up. Subjects were randomized in a 1:1 ratio for the active (N=114) and the sham (N=106) treatments at 17 clinical sites in the United States. Adjusted mean change for the active group was 9.8 and the adjusted mean change for the sham group was 9.0, a difference of 0.8 (p=0.3942). There were no serious device-related adverse events reported. The treatment groups were well balanced, and the number of subjects lost to follow-up was as expected.

"We are extremely disappointed that the VIVEVE II trial did not achieve its primary endpoint. Although there was substantial improvement in the total FSFI score from baseline to the final 12-month follow-up in the active group, indicating a significant treatment effect, there was not sufficient separation from the sham group to achieve statistical significance," said Scott Durbin, chief executive officer of Viveve. "We intend to thoroughly analyze the complete data set, including all secondary and exploratory endpoints to better understand this outcome. We want to thank our investigators, clinical sites, and patients for their dedicated efforts and participation in this study."

In light of the VIVEVE II trial outcome and the current COVID-19 pandemic, the company is currently evaluating strategic alternatives, as well as actively assessing its current organization and cost structure.

Study Design

VIVEVE II is a randomized, double-blinded, and sham-controlled trial with a targeted enrollment of approximately 250 subjects at up to 25 clinical sites in the United States and Canada. The target population for this study was pre-menopausal females 18 years of age or older who experienced at least one full-term vaginal delivery (>37 completed weeks gestation) and had a total score of ≤26.5 on the FSFI indicating sexual dysfunction at the

screening visit. Subjects were randomized in a 1:1 ratio for active (cryogen cooling and 90 Joules/cm^2 RF) and sham (cryogen cooling with only 1 Joule/cm^2 RF) treatments. Subjects were followed up with at 10 days and 1, 3, 6, 9, and 12-months post-treatment per the protocol.

The primary efficacy endpoint is the mean change from baseline in the total FSFI score at 12 months. A variety of secondary and exploratory endpoints that evaluate the efficacy of and improvement in FSFI domain scores for arousal, orgasm, desire, lubrication, satisfaction, and pain are also included throughout the trial.

Safety assessments were performed and will be reported for the duration of the 12-month trial.

Initiated in May of 2018, the study advanced through the FDA's required staged approach that included multiple submissions to and Agency review of patient safety data at 30- and 90-day post treatment time periods for a defined number of subjects enrolled in the trial. The staged or gated approach to patient enrollment and the Agency's review of safety data at the specified time intervals was completed in December of 2018. The FDA had determined that the company had provided sufficient data to support continuation of the trial and that there were no safety concerns that precluded continuation of the study to full enrollment.

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 continues to advance its clinical development program in stress urinary incontinence (SUI) and has initiated a short-term feasibility study under an investigational testing application approved by the Canadian Ministry of Health as reported in mid-December 2019. The feasibility study is a single-blind, three-arm, three-month study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment in order to capture short-term safety and effectiveness data on use of the Viveve System for the improvement of SUI in women. Subject enrollment in the study was completed in March 2020. Results of the three-month feasibility study are targeted for readout in the third quarter of 2020. If positive, the results could be used to support Viveve's re-submission of its IDE to the FDA for approval to conduct a U.S. trial designed to evaluate the safety and effectiveness of the Viveve System for improvement of SUI in women. The results of these trials, if successful, could support marketing applications in the U.S. and over 30 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 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, 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.

Investor Relations Contacts:

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

Media Contact:

Bill Berry
Berry & Company Public Relations
(212) 253-8881
bberry@berrypr.com

SOURCE: Viveve Medical, Inc.