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Viveve Reports Additional Clinical Results of LIBERATE-International Trial for Stress Urinary Incontinence

ENGLEWOOD, CO / ACCESSWIRE / August 7, 2019 / Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today reported additional clinical results from the LIBERATE-International Trial, a multicentered, randomized, double-blinded, sham-controlled trial to evaluate the safety and efficacy of Viveve's proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women. Initial results related to the primary endpoint of this trial were previously reported on July 22, 2019.

About the LIBERATE-International Study

LIBERATE-International included 99 subjects with mild-to-moderate SUI based on the standardized 1-hour Pad Weight Test. Subjects were randomized in a 2:1 ratio for active and sham treatments at nine study sites in Canada. Eighty-five subjects successfully completed the six-month study and no serious device-related events were reported. Treatment groups were well balanced and early termination from the study was as expected (~ 14%).

The primary efficacy endpoint in this trial was the change from baseline in the standardized 1-hour Pad Weight Test at six months post-treatment. In addition to safety follow up throughout, the trial included multiple exploratory endpoints including: 24-hour pad weight test, three-day bladder voiding diary and composite scores from multiple validated patient-reported outcomes, including: UDI-6 (Urogenital Distress Inventory-Short Form), I-QOL (Incontinence Quality of Life Questionnaire), ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form), and Female Sexual Function Index (FSFI) scores.

As previously reported, in this trial both the active and control groups demonstrated substantial improvement on the primary endpoint, the 1-hour Pad Weight test at six months post-treatment, and the comparison therefore did not achieve statistical significance when comparing the active group with the control group. Evaluation of the trial's exploratory endpoints demonstrated consistent improvements in the active group and control group across all six endpoints at six months post-treatment. Patient demographics were similar in both treatment groups and there were no device-related safety issues reported.

	1-Hr Pad Weight Test	24-Hr Pad Weight Test	3 Day Diary Incontinence Episodes	UDI-6	I-QOL	ICIQ-UI-SF
MEDIAN BASELINE SCORES						
ACTIVE (N=66)	12.8g	19.8g	8	55.6	52.8	14
SHAM (N=33)	12.9g	21.8g	8	55.6	56.8	13
MEDIAN PERCENTAGE CHANGE FROM BASELINE						
AT 6 MONTHS*						
ACTIVE	-77.2%	-71.0%	-83.3%	-44.4%	35.6%	-46.2%
SHAM	-81.0%	-61.3%	-72.7%	-37.5%	27.1%	-33.3%

*Percentage change results based upon observed case data.

UDI-6: Range of 0 (no problem at all) to 100 (maximum problem)

IQOL: Range of 0 (maximum problem) to 100 (no problem at all)

ICIQ-UI-SF: Range of 0 (no problem at all) to 21 (maximum problem)

“While the study did not meet its primary endpoint, review of the full clinical data demonstrates a consistency of benefit at six months post-treatment across all endpoints in the majority of patients within both groups,” said Scott Durbin, Viveve’s chief executive officer.

“Our analysis of the results is ongoing. However, we remain optimistic that there may be a path forward for our SUI clinical development program, with physicians around the world consistently reporting positive and durable SUI patient outcomes in their practices. We are further analyzing the data and evaluating potential options to move forward in SUI,” concluded Mr. Durbin.

Conference Call Information

The company will host a live conference call and webcast to provide second quarter 2019 results and corporate update on Thursday, August 8th at 4:30 PM ET. The conference call

may be accessed by dialing 1-833-255-2833 (domestic) or 1-412-902-6728 (international) or via live webcast at https://services.choruscall.com/links/vive190808.html. Participants may also pre-register for the conference call at http://dpregister.com/10133641.

A recording of the webcast will be posted on the company's investor relations website following the call at ir.viveve.com and will be available online for 90 days.

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 cryogen-cooled monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate neocollagenesis in a single in-office session.

International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in over 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. If successful, VIVEVE II results could support a marketing application for a new U.S. commercial indication. Currently, in the United States, the Viveve® System is cleared by the FDA for use in general surgical procedures for electrocoagulation and hemostasis.

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:

Sarah McCabe
Stern Investor Relations, Inc.
(212) 362-1200
sarah.mccabe@sternir.com

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

Media contact:

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

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