

December 6, 2018



# Viveve Announces Positive 12-Month Data from Stress Urinary Incontinence Feasibility Study

— 72% of women treated experienced an improvement in the one-hour pad weight with an overall mean improvement of 56%

— Clinically meaningful benefit achieved at one year across all patient-reported outcome measures

— Complete results to be presented during live webcast of SUI symposium with physician key opinion leaders on December 11, 2018

ENGLEWOOD, Colo., Dec. 06, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ: VIVE) ("Viveve"), a medical technology company focused on women's intimate health, today announced positive 12-month data from an investigator-initiated, single-arm, 12-month feasibility study using its cryogen-cooled, monopolar radiofrequency (CMRF) technology platform for the treatment of mild-to-moderate stress urinary incontinence (SUI) in women. The study was conducted by Bruce Allan, PhD, MD, FRCS(C), founder and medical director of the Allan Centre in Calgary, Alberta.

"These positive results build upon the demonstrated effectiveness and durability of our single-session CMRF treatment for women experiencing SUI symptoms, as previously reported in the six-month interim data from this feasibility study, as well as the 12-month data in the separate SUI pilot study," said Scott Durbin, chief executive officer and director of Viveve. "We look forward to reporting the full data from this feasibility study at our upcoming SUI physician key opinion leader symposium and are continuing to advance our two SUI clinical registration trials, LIBERATE-International, currently underway, and the planned LIBERATE-U.S. study, pending U.S. Food and Drug Administration approval of an Investigational Device Exemption."

## Summary Results

This single-arm feasibility study initially included 35 subjects with mild-to-moderate SUI, based on the objective 1-hour Pad Weight Test, who underwent treatment with Viveve's CMRF technology under a proprietary treatment protocol. Twenty-five subjects successfully completed the 12-month study. Clinical results included the objective one-hour pad weight assessment and seven-day bladder voiding diary, as well as composite scores from multiple validated patient-reported outcomes, including: UDI-6 (Urogenital Distress Inventory-Short Form), IIQ-7 (Incontinence Impact Questionnaire) and ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form):

	1-Hr Pad Weight Test	Daily Incontinence Episodes	UDI-6	IIQ-7	ICIQ- UI-SF
MEAN Baseline Scores (n=35)	7.3	2.2	47	39	11.3
Scores at 12 months (n=25)	3.2	0.8	29	20	7.8
% reduction from baseline at 12 months (n=25)	56.1%	63.5%	37.4%	48.7%	30.7%
Responder rate at 12 months (improvement from baseline) (n=25)	72.0%	64.0%	68.0%	72.0%	76.0%

- 72% of patients treated experienced an improvement from baseline in the 1-hour Pad Weight Test at 12 months;
- A greater than 50% reduction in the 1-hour Pad Weight Test was achieved by 52% of patients at 12 months;
- 60% of patients experienced significant benefit as they had  $\leq$  one gram of urine leakage in the 1-hour Pad Weight Test at 12 months;
- A clinically meaningful benefit was achieved across all patient-reported outcome measures (SUI symptoms and quality of life) at 12 months (n=25); and
- No device-related safety issues were reported for any of the patients.

### **Live Webcast of SUI Physician Key Opinion Leader Symposium and Feasibility Study Results**

Viveve will host a live webcast of its Key Opinion Leader Symposium focused on SUI on December 11, 2018 beginning at 10:00 am ET. The symposium will address the use of Viveve's proprietary, cryogen-cooled monopolar radiofrequency technology to treat the prevalent condition of SUI in women and will include presentation of the 12-month data from the SUI feasibility study conducted by Dr. Bruce Allan.

The live webcast of this event can be accessed through Viveve's investor relations website at <http://ir.viveve.com>. A webcast replay of the presentation will be posted on the Viveve website approximately two hours after the event and will be available for 90 days.

### **About Viveve**

Viveve Medical, Inc. is a women's intimate health company committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve<sup>®</sup> System, that delivers the Viveve treatment, 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. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled clinical trial to assess improvement of sexual function in women following vaginal childbirth after receiving approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018. If successful, this trial 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.

Viveve has initiated LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of SUI in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S., after conducting certain safety testing in the third quarter of 2019. The results of these two trials, if successful, could support marketing applications in the U.S. and additional countries around the world for this new commercial indication.

For more information visit Viveve's website at [viveve.com](http://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, 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](http://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.

*Viveve is a registered trademark of Viveve, Inc.*

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