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# Viveve Reports Positive Six-Month Data from Stress Urinary Incontinence Feasibility Study

***83% of women treated experienced an improvement in one-hour pad weight with an overall mean improvement of 73%***

***Clinically meaningful benefit achieved across all quality of life outcome measures***

***Company to host conference call on Tuesday, June 19<sup>th</sup> at 8:00 am ET***

ENGLEWOOD, Colo., June 18, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ:VIVE), a medical technology company focused on women's intimate health, today reported positive and sustained six-month data from an ongoing single-arm 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 ongoing study is being conducted by Bruce Allan, PhD, MD, FRCS(C), founder and medical director of the Allan Centre in Calgary, Alberta.

“These new data are extremely encouraging for women suffering from stress urinary incontinence, further validating the positive 12-month SUI pilot study data that we reported in February. The objective one-hour pad weight test, used as the primary endpoint in this study, showed that at six months post-treatment women experienced a 73% reduction in stress urinary incontinence on this standardized assessment, which is a U.S. Food and Drug Administration guided endpoint and planned primary endpoint of our two upcoming LIBERATE trials,” said Scott Durbin, chief executive officer and director of Viveve. “We look forward to advancing our two clinical registration trials, LIBERATE-International and LIBERATE-U.S., and our effort to position this promising technology for regulatory review and potential approval in markets around the world for the treatment of stress urinary incontinence and drastically improve the quality of life for women with this treatment.”

## **Feasibility Study Six-Month Results**

This single-arm feasibility study included 36 subjects with mild to moderate SUI (based on the one-hour pad weight test) who underwent treatment with Viveve’s CMRF technology under a proprietary treatment protocol. Currently, 29 subjects have successfully completed the six-month follow-up. 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-HOUR PAD WEIGHT	DAILY INCONTINENCE EPISODE FREQUENCY	UDI-6	IIQ-7	ICIQ- UI-SF
BASELINE SCORES (N=29)	6.2 g	2.0 (N=28)	44	36	10.9
SCORES AT 6 MONTHS (N=29)	1.7 g	1.0 (N=28)	21	18	6.8
% REDUCTION FROM BASELINE AT 6 MONTHS (N=29)	72.6%	50.0% (N=28)	53.6%	49.2%	38.0%
RESPONDER RATE AT 6 MONTHS (IMPROVEMENT FROM BASELINE) (N=29)	82.8%	78.6% (N=28)	82.8%	69.0%	86.2%

No device-related safety issues were reported in any of the patients. This ongoing study received both ethics committee and Health Canada approval. Subjects will be followed for a total of 12 months.

Dr. Bruce Allan commented, “The results of this study at six months are extremely encouraging scientifically and even more impactful from a patient outcomes perspective. The fact that 84% of women treated showed a reduction in pad weight and 66% experienced one gram or less of urine leakage post-treatment is unprecedented from a medical standpoint and is life-changing for women suffering from stress urinary incontinence. On all validated SUI symptom and quality of life outcome measures, these subjects experienced a clinically meaningful benefit. For women suffering from this condition, this can mean reduced need for external pads to absorb urine leakage, the ability to resume many normal activities of daily life, reduced worry of embarrassment and improved self-confidence. In my experience a non-invasive, single-session, in-office, procedure using Viveve’s cryogen-cooled deep penetrating RF technology is of great benefit in addressing the prevalent condition of stress urinary incontinence in women and could change the way it is treated by physicians around the world.”

### Live Conference Call

Viveve will host a live presentation at 8:00 am ET, Tuesday, June 19, 2018 with Scott Durbin and Dr. Bruce Allan. The conference call may be accessed by dialing 1-866-777-2509 (domestic) or 1-412-317-5413 (international) or via live webcast at <https://services.choruscall.com/links/vive180614.html>. Participants may also pre-register for the conference at <http://dprejister.com/10121239>. Registered participants will receive their dial in number upon registration.

A recording of the webcast will be posted on the company’s website following the call at <http://ir.viveve.com> and will be available online for 90 days.

### About Stress Urinary Incontinence

Stress urinary incontinence is a medical condition affecting an estimated 25-30 million women worldwide. It is a major challenge for women, particularly those who have experienced childbirth or are menopausal. About 55% of women who had a previous vaginal delivery may exhibit symptoms of SUI. Management of SUI often involves use of external pads to absorb urine leakage associated with even normal activities such as coughing or laughing which is unsatisfactory, inconvenient, often embarrassing and negatively impacts a woman's quality of life. Currently available and effective treatment options are extremely limited. Pelvic floor exercises (Kegels) and muscle strengthening products have been shown to offer some benefit but can present challenges with compliance and sustained benefit can be an issue. More aggressive approaches to manage SUI include pelvic surgery including implantation of slings and mesh. These options involve risk, recovery time and are a last resort for many patients. The ability to offer a minimally invasive, safe and effective treatment option for SUI using Viveve's CMRF technology would address an enormous unmet healthcare need for women.

### **About Viveve**

Viveve Medical, Inc. is a women's intimate health company passionately committed to advancing new solutions to improve women's overall well-being and quality of life. The internationally patented Viveve® System, that delivers the Viveve treatment, incorporates clinically-proven cryogen-cooled, monopolar radiofrequency (CMRF) technology to uniformly deliver volumetric heating while gently cooling surface tissue to generate robust 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 from over 55 countries. Viveve received approval of an Investigational Device Exemption (IDE) application from the U.S. Food and Drug Administration (FDA) in March of 2018 to proceed with VIVEVE II, a multicenter, randomized, double-blind, sham-controlled study to assess improvement of sexual function in women following childbirth. Initiation of the trial began in the second quarter of 2018 and if successful, 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 submitted an Investigational Trial Application to the Canadian Ministry of Health and plans to submit an IDE to the FDA to conduct two independent multicenter randomized registration trials (LIBERATE-International and LIBERATE-U.S. respectively) for use of the CMRF device in stress urinary incontinence treatment.

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

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