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# Viveve Initiates LIBERATE-International Trial for Improvement of Stress Urinary Incontinence

*Company also receives regulatory clearance in Argentina for treatment of urinary incontinence*

*Confirms intent to submit IDE to FDA for LIBERATE-U.S. in the third quarter*

ENGLEWOOD, Colo., Aug. 14, 2018 (GLOBE NEWSWIRE) -- Viveve Medical, Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, announced today the initiation of LIBERATE-International, a multicenter, randomized, double-blinded, sham-controlled trial to evaluate the safety and efficacy of its proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women. The first-subject-first-visit has now been completed under an approved Investigational Testing Application with the Canadian Ministry of Health and central investigational review board (IRB) approval.

"Initiation of LIBERATE-International represents a significant advance in our pursuit of regulatory clearances for the treatment of SUI, a condition that affects an estimated 25-30 million women worldwide. Our single-session procedure offers women the potential for significant improvement in urine leakage and quality of life. The results of LIBERATE-International, if successful, could support multiple international clearances for use of our CMRF technology in the treatment of SUI around the world, including Health Canada and CE Mark clearances, among others," stated Scott Durbin, chief executive officer and director of Viveve.

In conjunction with initiation of the LIBERATE-International trial, Viveve also announced regulatory clearance in Argentina, for use of the Viveve® System, for the improvement of urinary incontinence.

"It is our belief that these clearances demonstrate continued regulatory confidence in the safety of our procedures and CMRF technology. As we continue our commitment towards rapid label expansion, we remain on track to complete the submission of our Investigational Device Exemption to the U.S. Food and Drug Administration (FDA) for LIBERATE-U.S., our second SUI registration trial, in the third quarter," continued Mr. Durbin.

## **About the LIBERATE International Study**

LIBERATE-International is a randomized, double-blinded, and sham-controlled trial with a planned enrollment of approximately 100 subjects at up to ten study sites in Canada. Subjects will be randomized in a 2:1 ratio for active and sham treatments.

The primary efficacy endpoint is the mean change from baseline in the standardized 1-hour Pad Weight Test at six months post-treatment. The objective 1-hour Pad Weight Test is an

FDA recommended endpoint. The study design also includes multiple exploratory endpoints, as well as, safety follow-up throughout the study. For more information, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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 in over 50 countries. In the second quarter of 2018, Viveve initiated VIVEVE II, a multicenter, randomized, double-blind, sham-controlled study to assess improvement of sexual function in women following childbirth following an Investigational Device Exemption (IDE) application approval 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 stress urinary incontinence in women and is preparing an IDE submission to the FDA for LIBERATE-U.S. The results of these two studies, 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 [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.

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

**Investor Relations contacts:**

Sarah McCabe  
Stern Investor Relations, Inc.  
(212) 362-1200  
[sarah@sternir.com](mailto:sarah@sternir.com)

Amato and Partners, LLC  
Investor Relations Counsel  
[admin@amatoandpartners.com](mailto:admin@amatoandpartners.com)

**Media contact:**

Kelly Wakelee  
Berry & Company Public Relations  
(212) 253-8881  
[kwakelee@berrypr.com](mailto:kwakelee@berrypr.com)

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