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# Viveve Announces CE Mark Clearance for its Next Generation 2.0 Platform in the European Union

***Viveve 2.0 system and its consumable treatment tips can now be sold in over 30 countries in addition to the United States***

**ENGLEWOOD, CO / ACCESSWIRE / April 11, 2019** Viveve Medical Inc. (NASDAQ: VIVE), a medical technology company focused on women's intimate health, today announced that the company received CE Mark clearance for its next generation Viveve 2.0 cryogen-cooled monopolar radiofrequency (CMRF) system and tips in the European Union.

"As part of our ongoing regulatory strategy to expand the commercial launch of our Viveve 2.0 platform globally, we're extremely pleased that our next generation system and its consumable treatment tips are now available in over 30 countries in Europe. Our 2.0 platform has significantly reduced manufacturing costs for both the next generation system and for the consumable tips since becoming available in the U.S. and it should have a positive impact on our overall gross margins going forward," said Scott Durbin, Viveve's chief executive officer and director.

The company is also providing an update on its core activities: Revenue for the recently completed first quarter will be reported in early May and is anticipated to be in-line with expectations. Final clinical data from LIBERATE-International in stress urinary incontinence is expected in late July 2019. The VIVEVE II trial for improved sexual function in women is fully enrolled and results are expected in April 2020. These trials represent major clinical milestones for Viveve and if successful can expand the company's commercial opportunities significantly.

## **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.

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.

Viveve has fully enrolled LIBERATE-International, one of two planned independent, multicenter, randomized registration trials for the improvement of stress urinary incontinence in women and plans to re-submit an IDE to the FDA for LIBERATE-U.S. after conducting certain safety testing. The results of these two trials, if successful, could support marketing applications in the U.S. and in over 35 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, 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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