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# Viveve Announces Clearance of Next Generation 2.0 System in Taiwan

***Viveve 2.0 cryogen-cool monopolar radiofrequency technology and consumable treatment tips are now available in the U.S., China, Hong Kong, South Korea, Taiwan and more than 30 European countries***

**ENGLEWOOD, CO / ACCESSWIRE / March 26, 2020** Viveve Medical, Inc.

(NASDAQ:VIVE), a medical technology company focused on women's intimate health, today announced registration clearance from the Taiwanese Food and Drug Administration for the Company's next-generation Viveve 2.0 Cryogen-cooled Monopolar Radiofrequency (CMRF) system and consumable treatment tips for use in general surgical procedures for electrocoagulation and hemostasis.

"We are pleased to have received regulatory clearance for our Viveve 2.0 technology platform in Taiwan, which represents one of the largest markets in Asia for advanced medical technologies. Regulatory clearance in this market represents an important milestone in our ongoing strategy to expand the global commercial availability of our next generation CMRF technology and consumable treatment tips," said Scott Durbin, chief executive officer of Viveve. "We are also pleased to continue our support of Dynamic Medical Technologies, Inc., our exclusive distribution partner in Taiwan, and their efforts to advance clinician adoption and utilization of Viveve's innovative technology platform for the treatment of women's intimate health conditions."

## **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. In the United States, the Viveve System is cleared by the Food and Drug Administration (FDA) for use in general surgical procedures for electrocoagulation and hemostasis. International regulatory approvals and clearances have been received for vaginal laxity and/or improvement in sexual function indications in more than 50 countries.

Viveve is conducting VIVEVE II, a multicenter, randomized, double-blind, sham-controlled U.S. clinical trial to assess improvement of sexual function in women following vaginal childbirth. Completion of the trial was announced on March 12, 2020. The topline 12-month data readout of the VIVEVE II trial is expected in April 2020. If successful, VIVEVE II results could support a 2020 marketing application for a new U.S. commercial indication.

Viveve continues to advance its clinical development program in stress urinary incontinence (SUI) and is conducting a short-term feasibility study under an Investigational Testing

Application (ITA) approved by the Canadian Ministry of Health as reported in December 2019. The feasibility study is a single-blind, three-arm, three-month study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment in order to capture short-term safety and effectiveness data on use of the Viveve System for the improvement of SUI in women. Subject enrollment in the study was completed in March 2020. Results of the three-month feasibility study are targeted for readout in the third quarter of 2020. If positive, Viveve intends to re-submit its Investigational Device Exemption (IDE) application to the FDA to conduct a U.S. trial designed to evaluate the safety and effectiveness of the Viveve System for improvement of SUI in women. The results of these trials, if successful, could support marketing applications in the U.S. and more than 30 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 impact of the novel coronavirus termed COVID-19 on our clinical development and regulatory review and clearances and on the manufacturing, placements and patient utilization of our Viveve Systems, 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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