

FOR IMMEDIATE RELEASE

## **TherapeuticsMD begins phase 3 clinical trial of TX-004HR (VagiCap™) for the treatment of painful intercourse, a symptom of VVA, due to menopause**

*The Rejoice Trial is a pivotal research study of TX-004HR, an investigational treatment for a condition affecting up to half<sup>1</sup> of the 43 million women of postmenopausal age in the United States.<sup>2</sup>*

**BOCA RATON, Fla., September 29, 2014** – TherapeuticsMD Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, announced today that enrollment opened for its Rejoice Trial, a phase 3 clinical trial of TX-004HR (VagiCap™) to evaluate multiple doses of an investigational, applicator-free estradiol for treatment of painful intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

Created with TherapeuticsMD’s patented SYMBODA™ technology, TX-004HR is an investigational bio-identical estradiol softgel capsule administered vaginally without the need for an applicator. The Rejoice Trial will also collect data on vaginal dryness, itching and irritation for future evaluation.

“I am pleased we have met our goal to initiate the pivotal, phase 3 study this quarter, evaluating a new, potentially lower dose estradiol treatment option for women who suffer from dyspareunia associated with VVA,” said TherapeuticsMD CEO Robert G. Finizio. “We are committed to leveraging our proprietary technology and developing alternatives that further our mission to bring improved hormone therapies to women.”

VVA is a condition resulting from the decrease in naturally occurring estrogen during menopause, resulting in thinning of the vaginal lining and an increase in vaginal pH levels. The condition is diagnosed in approximately 50 percent of postmenopausal women.

“VVA is a serious condition that is significantly underdiagnosed in millions of postmenopausal women,” said Dr. David J. Portman, director of the Columbus (Ohio) Center for Women's Health Research, clinical instructor at Ohio State University and a primary investigator in the trial. “There is a medical need for lower-dose alternative treatments and more convenient delivery options to help women who suffer pain and discomfort from VVA.”

The North American Menopause Society (NAMS) reaffirmed in a 2013 position statement the benefits of estrogen therapy for treatment of VVA and concluded, “Estrogen delivery locally is now the preferred mode of delivery when vaginal symptoms are the only complaint.”<sup>3</sup>

### **Trial Design**

A pivotal safety and efficacy study, the Rejoice Trial is a randomized, double-blind, placebo-controlled study evaluating three doses of TX-004HR in dosing levels of 25 mcg, 10 mcg and 4 mcg, a potentially new low-dose option. The 12-week trial is designed to enroll 700 participants in approximately 100 sites across the United States.

### **Enrollment Information**

Patients interested in enrolling in the Rejoice Trial should speak with their physicians and may visit [www.rejoicetrial.com](http://www.rejoicetrial.com) or call toll-free 1-800-70-REJOICE (1-800-707-3564).

## **About TherapeuticsMD Inc.**

TherapeuticsMD Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. TherapeuticsMD is developing advanced hormone therapy pharmaceutical products based on novel technologies that enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. The company's clinical development pipeline includes three phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under the vitaMedMD<sup>®</sup> and BocaGreenMD<sup>®</sup> brands. More information is available at the following websites: [www.therapeuticsmd.com](http://www.therapeuticsmd.com), [www.vitamedmd.com](http://www.vitamedmd.com), [www.vitamedmdrx.com](http://www.vitamedmdrx.com) and [www.bocagreenmd.com](http://www.bocagreenmd.com).

*This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future. These statements are often characterized by terminology such as "believe," "hope," "may," "anticipate," "should," "intend," "plan," "will," "expect," "estimate," "project," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of our management's experience and perception of historical trends, current conditions, expected future developments, and other factors we believe to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of our control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as our reports on Form 8-K and include the following: our ability to develop and commercialize our hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost, and uncertain results of our clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of our hormone therapy drug candidates; our reliance on third parties to conduct our clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for our products; the impact of product liability lawsuits and the influence of extensive and costly government regulation.*

PDF copies of TherapeuticsMD's historical press releases and financial tables can be viewed and downloaded at the company's website: [www.therapeuticsmd.com/pressreleases.aspx](http://www.therapeuticsmd.com/pressreleases.aspx).

## References

<sup>1</sup> Nappi, R. E., and M. Kokot-Kierepa. "Vaginal Health: Insights, Views & Attitudes (VIVA) – results from an international survey." *Climacteric* 15.1 (2012): 36-44.

<sup>2</sup> United States Census Bureau, <http://www.census.gov/population/age/data/2012comp.html>

<sup>3</sup> "Management of symptomatic vulvovaginal atrophy." *Menopause: The Journal of The North American Menopause Society* 20.9 (2013): 886-887.

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