

FOR IMMEDIATE RELEASE

## **TherapeuticsMD Completes Enrollment in The Rejoice Trial, a Phase 3 Clinical Trial of TX-004HR (estradiol in VagiCap<sup>™</sup>)**

*– Topline Results Expected in Fourth Quarter of 2015 –*

**BOCA RATON, Fla., June 9, 2015** – TherapeuticsMD Inc. (NYSE MKT: TXMD), an innovative women’s healthcare company, today announced that the Company has completed patient enrollment in The Rejoice Trial, a phase 3 clinical trial of TX-004HR (estradiol in VagiCap<sup>™</sup>) to evaluate multiple doses of an investigational, applicator-free vaginal estradiol for the treatment of pain during sexual intercourse (dyspareunia), a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

TX-004HR is an investigational bio-identical estradiol softgel capsule administered vaginally without the need for an applicator. The Rejoice Trial is also collecting efficacy data on vaginal dryness, and vaginal and/or vulvar itching or burning.

“Recent studies have shown that current therapies used to treat VVA generate some concerns from women with respect to their efficacy, convenience and safety,” stated Sebastian Mirkin, MD., Chief Medical Officer of TherapeuticsMD. “TX-004HR was designed to try to address these unmet needs. Completion of patient recruitment in the Rejoice Trial marks an important milestone in our development efforts and we look forward to disclosing topline results from the Rejoice Trial later this year.”

### **Trial Design**

A pivotal safety and efficacy study, the Rejoice Trial is a randomized, multicenter, double-blind, placebo-controlled study evaluating three strengths of TX-004HR – 4 mcg, 10 mcg and 25 mcg. The 4 mcg strength represents a new low-dose option. The 12-week trial enrolled over 700 participants in approximately 100 sites across the United States and Canada.

### **About Vulvar and Vaginal Atrophy (VVA)**

VVA is a chronic 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. Approximately half of postmenopausal women report having symptoms of VVA.<sup>1</sup> In total, an estimated 32 million women in the United States are currently suffering from symptoms of VVA<sup>2</sup>, and only 2.3 million (7%) are currently being treated with prescription therapy.<sup>1,3</sup> The burden of VVA in the United States is likely to increase due to aging of the population.<sup>4</sup> Furthermore, due to increasing longevity, women may now suffer from VVA or other conditions related to decreased reproductive hormone levels for over one-third of their lives.<sup>4</sup>

### **About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. With its patented SYMBODA<sup>™</sup> technology, TherapeuticsMD is developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of

---

<sup>1</sup> Mac Bride MB, Rhodes DJ, Shuster LT. Vulvovaginal atrophy. *Mayo Clin Proc* 2010;85:87–94

<sup>2</sup> Kingsberg SA, Wysocki S, Magnus L, and Krychman ML. Vulvar and vaginal atrophy in postmenopausal women: Findings from the REVIVE (REal Women’s Views of Treatment Options for Menopausal Vaginal ChangEs) survey. *J Sex Med* 2013;10:1790–1799.

<sup>3</sup> North American Menopause Society. The role of local vaginal estrogen for treatment of vaginal atrophy in postmenopausal women: 2007 position statement of The North American Menopause Society. *Menopause* 2007;14(3 Pt 1):355–69.

<sup>4</sup> US Census Bureau. Age and Sex Composition: 2010. 2011 May. Report No.: C2010BR-03.

dosage forms and administration routes. The company's clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® 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).

## **Forward Looking Statements**

*This press release by TherapeuticsMD, Inc. may contain forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to TherapeuticsMD's objectives, plans and strategies as well as statements, other than historical facts, that address activities, events or developments that the company intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes 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 the company's 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 the company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as reports on Form 8-K, and include the following: the company's ability to maintain or increase sales of its products; the company's ability to develop and commercialize its hormone therapy drug candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of the company's clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of the company's hormone therapy drug candidates; the company's reliance on third parties to conduct its clinical trials, research and development and manufacturing; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; the influence of extensive and costly government regulation; the volatility of the trading price of the company's common stock and the concentration of power in its stock ownership. PDF copies of the company's historical press releases and financial tables can be viewed and downloaded at its website: [www.therapeuticsmd.com/pressreleases.aspx](http://www.therapeuticsmd.com/pressreleases.aspx).*

###

Contact:

Dan Cartwright

Chief Financial Officer

561-961-1900

[Dan.Cartwright@TherapeuticsMD.com](mailto:Dan.Cartwright@TherapeuticsMD.com)

FTI Consulting

Robert D. Stanislaro

212-850-5657

[Robert.Stanislaro@fticonsulting.com](mailto:Robert.Stanislaro@fticonsulting.com)