

# TherapeuticsMD®

FOR IMMEDIATE RELEASE

## **THERAPEUTICSMMD REPORTS POSITIVE RESULTS OF RABBIT IRRITATION STUDY FOR ITS ESTRADIOL VAGINAL CAPSULE VAGICAP™ (TX 004-HR) FOR TREATMENT OF VULVAR VAGINAL ATROPHY (VVA)**

**Boca Raton, FL – April 7, 2014** – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company ("TherapeuticsMD" or the "Company"), announced today positive outcomes of a rabbit irritation study for TX 004-HR (formerly referred to as TX 12-004-HR), a rapidly acting estrogen vaginal preparation capsule (VagiCap).

This toxicity study involved vaginal administration of VagiCap in New Zealand white female rabbits. The study demonstrated that TX 004-HR was "non-irritant" following a 28-day repeated application to the vaginal mucosa.

This toxicity study was conducted to meet a specific FDA requirement for any new component of a novel delivery system, such as the VagiCap vaginal softgel capsule for estradiol. Because the components of the VagiCap had not been previously studied in vaginal delivery, the capsule was required to pass this local toxicity assessment at repeated doses.

Sebastian Mirkin, M.D., Chief Medical Officer of TherapeuticsMD, said, "We are pleased that our VVA drug candidate has passed this toxicity hurdle. These results will enable us to move forward to late phase clinical testing."

"The VVA market is growing substantially due to increasing demands by maturing women who are remaining sexually active longer and finding dissatisfaction with currently available VVA therapies. We are committed to developing this drug candidate to offer women a significant advancement in treatment options and to fill their unmet needs," concluded Robert Finizio, Chief Executive Officer and Co-Founder of TherapeuticsMD.

### **About TX 004-HR**

TX 004-HR estradiol VagiCap is an investigational drug enabling the vaginal administration of estradiol that is designed to treat moderate to severe VVA symptoms associated with menopause. TX 004-HR leverages the solubilized estradiol technology developed by TherapeuticsMD in a unique, tear-shaped softgel capsule designed for easy intravaginal insertion. It is the first softgel capsule for the treatment of VVA being developed for review by the FDA.

### **About VVA and Market Size**

The North American Menopause Society (NAMS) estimates that up to 50% of postmenopausal women are affected by VVA, which results from the decrease in estrogen that occurs with menopause. The U.S. Census estimates the number of postmenopausal women in the U.S. will exceed 50 million in 2015. Despite symptoms that can adversely affect quality of life, sexual function, and urogynecologic health and that include vaginal and vulvar pain, irritation, itching, burning, discharge, and painful intercourse, approximately 75% of women with symptoms do not seek treatment. Source Healthcare Analytics estimated the U.S. market for postmenopausal VVA was over \$1 billion in 2013, increasing more than 20% over the prior year. GlobalData currently projects the global market for postmenopausal VVA will reach \$3.1 billion by 2019.

**About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is a women's healthcare company focused on developing and commercializing products targeted exclusively for women. We are developing advanced hormone therapy pharmaceutical products based on novel technologies that enable delivery of bioidentical hormones through a variety of dosage forms and administration routes. We also manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under our 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).

*Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the results of the toxicity study of TX 004-HR and the effect of such results on the Company and the clinical development of TX 004-HR; the Company's belief that VVA market is growing substantially due to increasing demands by maturing women who are remaining sexually active longer and finding dissatisfaction with currently available VVA therapies; the Company's commitment to developing this drug candidate to offer women a significant advancement in treatment options and to fill their unmet needs; the design and attributes of TX 004-HR; estimates regarding the percentage of postmenopausal women affected by VVA and the percentage of postmenopausal women with VVA symptoms who do not seek treatment; projections regarding the number of postmenopausal women in the United States in 2015; the estimated size of the U.S. VVA market in 2013 and the projected size of the global VVA market by 2019 are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including but not limited to: timely and successful completion of clinical studies and the results thereof; risks and uncertainties associated with the Company's business and finances in general; and other risks detailed in the Company's filings with the U.S. Securities and Exchange Commission including its Annual report on Form 10-K filed March 5, 2014, reports on Form 10-Q and Form 8-K, and other such filings. These forward-looking statements are based on current information that may change. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.*

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