## **Therapeutics MD®**

#### FOR IMMEDIATE RELEASE

# THERAPEUTICSMD REPORTS POSITIVE PK STUDY RESULTS FOR ITS ESTRADIOL VAGINAL CAPSULE VAGICAP<sup>TM</sup> (TX 12-004-HR) FOR TREATMENT OF VULVAR VAGINAL ATROPHY (VVA)

Boca Raton, FL - January 28, 2014 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company ("TherapeuticsMD" or the "Company"), announced today the final PK results from two studies of TX 12-004-HR, a vaginal preparation capsule versus Novo Nordisk's Vagifem® (estradiol vaginal tablet). ESTR-1K-499 was an open label, single dose crossover, relative bioavailability study comparing  $10\mu g$  of TX 12-004-HR to  $10\mu g$  of Vagifem. ESTR-1K-500 was the study with the same design, but compared  $25\mu g$  of TX 12-004-HR to  $25\mu g$  of Vagifem. Study results showed substantially lower systemic estradiol exposure of TX 12-004-HR when compared to Vagifem.

The maximal concentration of TX 12-004-HR estradiol was about half that observed with Vagifem and the overall exposure to estradiol was approximately one-third that observed with Vagifem. The 24-hour exposure to estradiol in the case of  $25\mu g$  dose of TX 12-004-HR was 3.3 fold lower than the same dose of Vagifem, and in the case of  $10\mu g$  dose of TX 12-004-HR was 2.6 fold lower than the same dose of Vagifem.

Robert G. Finizio, Chief Executive Officer and Co-founder of TherapeuticsMD, said, "We are pleased that our drug candidate appears to have a lower systemic estradiol exposure. Our goal is to create a fast-acting, rapidly dissolving VagiCap with less systemic estradiol exposure in a more elegant form." These results will be used to design a development plan and a clinical program to be submitted to the Food and Drug Administration ("FDA") for treatment of VVA in postmenopausal women. The VVA market is growing substantially due to increasing demands by maturing women who are remaining sexually active longer and seeking new treatments options.

#### **About TX 12-004-HR**

TX 12-004-HR estradiol VagiCap is an investigational drug matching the molecular structure of estradiol that is designed to treat moderate to severe VVA symptoms associated with menopause. TX 12-004-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**

According to the North American Menopause Society (NAMS), up to 50% of postmenopausal women are estimated to be affected by this condition resulting from the decrease in estrogen that occurs with menopause. The U.S. Census estimates this number will exceed 50 million women 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 estimated the global market for postmenopausal VVA is currently projected to 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: <a href="www.vitamedmd.com">www.vitamedmd.com</a>, <a href="www.vitamedmd.com">www.vitamedmd.com</a>, <a href="www.vitamedmd.com">www.vitamedmd.com</a>, <a href="www.vitamedmd.com">www.vitamedmd.com</a>, and <a href="www.vitamedmd.com">www.vitamedmd.com</a>, <a href="www.vitamedmd.com">www.vi

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the ultimate results of clinical development of the Company's proposed estradiol VagiCap drug; the Company's belief that the PK data suggests that TX 12-004-HR may provide therapeutic advantages over Vagifem; the Company's belief that the side effects associated with vaginal hormone therapy may be related to peak concentrations or overall exposure to the hormones; the Company's belief that TX 12-004-HR appears to have a lower systemic estradiol exposure while achieving statistically significant clinical efficacy; the Company's goal to create a faster-acting, rapidly dissolving VagiCap with less systemic estradiol exposure in a more elegant form; the Company's expectation to use these results to design a development plan and a clinical program to be submitted to the FDA for treatment of VVA in postmenopausal women; the Company's belief that the VVA market is growing substantially due to increasing demands by maturing women who are remaining sexually active longer and finding dissatisfaction with current treatments options; the Company's commitment to developing this drug candidate to offer women a significant advancement in treatment options and to meet their unmet needs; the Company's belief in the anticipated achievements, attributes, and benefits of TX 12-004-HR; estimates of the percentage and number of women to be affected by VVA; estimate of the percentage of women with VVA symptoms that do not seek treatment for their symptoms; and the projected size and growth potential of the global and U.S.-based VVA market 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, reports on Form 10-O 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.

Contacts: TherapeuticsMD, Inc. Dan Cartwright 561-961-1900 Chief Financial Officer Dan.Cartwright@TherapeuticsMD.com

Investor Relations: In-Site Communications, Inc. Lisa M. Wilson 917-543-9932 lwilson@insitecony.com

Public Relations: Red Fox Communications Judy Grossman 917-913-1690 judy@redfoxcomm.com