

FOR IMMEDIATE RELEASE

THERAPEUTICSM^{MD} PHASE 1 PILOT STUDY SHOWS TX-12-004-HR ESTRADIOL VAGICAP IMPROVES CONDITIONS OF VULVAR AND VAGINAL ATROPHY (VVA)

-VVA Estimated to Affect up to 50% of Postmenopausal Women-

-2013 North American Menopause Society Position Statement Re-affirms Estrogen as Therapeutic Standard
for Moderate to Severe VVA-

Boca Raton, FL, October 22, 2013 – TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company ("TherapeuticsMD" or the "Company"), announced today that its investigational drug, TX 12-004-HR estradiol VagiCap[™], improved objective measures of VVA in a phase 1 clinical study. The study evaluated the efficacy and safety of a 10µg dose of TX 12-004-HR vs. placebo over a two-week period in 48 postmenopausal women with symptoms of VVA. Statistically significant differences were found between the treatment and placebo groups, with the treatment group showing changes in Maturation index (cell composition) and pH more closely resembling that found in premenopausal women with healthy, non-atrophied vaginal tissue.

Up to 50% of postmenopausal women are estimated to be affected by this condition which results from the decrease in estrogen that occurs with menopause. Despite symptoms that can adversely affect quality of life, sexual function, and urogynecologic health and include vaginal and vulvar pain, irritation, itching, burning, discharge, and painful intercourse, approximately 75% of women with symptoms do not seek treatment. The global market for postmenopausal VVA is currently estimated at over \$1.6 billion and is projected to reach \$3.1 billion by 2019.

TherapeuticsMD is developing TX 12-004-HR, its investigational drug for the treatment of VVA, for review by the U.S. Food and Drug Administration (FDA). TX 12-004-HR leverages the Company's solubilized estradiol technology in a unique, tear-shaped softgel capsule designed for easy intravaginal insertion.

"VVA has a deleterious effect on a woman's emotional and physical intimacy. As a company dedicated to meeting women's health needs at every life stage, we are pleased that this phase 1 study suggests our investigational softgel capsule may offer a benefit. We are encouraged by the statistically significant improvements demonstrated here with our lowest dose and look forward to initiating a 12-week, phase 3 clinical trial to evaluate the efficacy of both 10µg and 25µg doses on the exact same measures evaluated in this trial," said Julia Amadio, Chief Product Officer of TherapeuticsMD.

"Current estrogen therapies are antiquated. We are looking to leverage new technology to remove common and frustrating application and compliance issues related to legacy products. We believe the market is ripe for innovation and will grow significantly," said Robert G. Finizio, Co-Founder and Chief Executive Officer of TherapeuticsMD.

The value of vaginally-administered estrogen therapy for women with moderate to severe VVA was recently re-affirmed in a 2013 Position Statement of The North American Menopause Society.

About the Study

This phase 1 pilot study sponsored by TherapeuticsMD was designed to evaluate the efficacy and safety of TX 12-004-HR in treating moderate to severe symptoms of VVA associated with menopause after 14 days of treatment, and to estimate the effect size and variability of VVA endpoints. Participants included 48 postmenopausal women (mean age 62.3 years) with at least one self-assessed symptom of vulvar and/or

vaginal atrophy and meeting all other entry criteria were randomized in a 1:1 ratio to receive either TX 12-004-HR or a placebo VagiCap. Clinical evaluations were performed during the screening period at baseline (day 1 of the study) and on days 8 and 15. Serial blood samples for estradiol levels were collected on day 1 at 0, 1.0, 3.0 and 6.0 hours relative to administration of the first dose. Participants self-administered their assigned treatment intra-vaginally once daily at approximately the same time each morning. The primary efficacy analyses included all 48 women who completed the study.

Key findings of the study were evaluated by standard statistical methods and concluded that, as compared to the placebo group, women treated with TX 12-004-HR showed:

- Statistically significant improvements in the Maturation index which included significant decreases in parabasal cells ($p < 0.0001$);
- Significant increases in superficial cells ($p = 0.0002$) and in intermediate cells ($p = 0.0017$);
- Statistically significant decreases in vaginal pH ($p = 0.0002$); and,
- A significant reduction in the atrophic effects on epithelial integrity and vaginal secretions.

Although this study was not powered to demonstrate significant improvement in subjective symptoms such as vaginal dryness, irritation and pain during sexual activity, the treatment group demonstrated marginal improvement in the severity of these subjective symptoms.

“Subjective measures were included in this study to understand which symptoms occur most frequently so that our phase 3 trial could be appropriately designed and adequately powered to capture differences between the Treatment and Placebo groups,” explained Ms. Amadio. “Given the small size of this study and the short duration of treatment, we did not expect to see any discernible differences between the two groups.”

About Hormone Therapy

Menopausal hormone therapy (HT, previously known as HRT) is the administration of hormones to treat menopausal symptoms resulting from a lack of naturally occurring hormones. Current HT options include FDA-approved combination products, FDA-approved estrogen-only and progestogen-only products, and non-FDA approved compounded bio-identical products. TherapeuticsMD is developing several products that match the molecular structure of the human hormones estradiol and progesterone alone or in combination, in addition to the TX 12-004-HR estradiol vaginal softgel capsule. A combination product (TX 12-001-HR) for the treatment of menopausal symptoms is currently being evaluated in a phase 3 clinical trial (www.ReplenishTrial.com). Additionally, a phase 3 trial will soon commence for a progesterone product for the treatment of amenorrhea (TX 12-002-HR). HT is projected to be the largest growth segment in the overall women’s health market. The potential market for pharmacy-compounded, bio-identical HT products is estimated to be approximately \$1.5 billion per year.

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 TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is a women’s healthcare company focused on developing and commercializing products targeted exclusively for women. We manufacture and distribute branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under our vitaMedMD[®] and BocaGreenMD[™] brands. We are developing advanced hormone therapy pharmaceutical products that fill the critical and long-ignored need for better treatments in the hormone and women’s health market. Our advanced hormone therapies are based on a novel technology that enables delivery of bio-identical hormones through a variety of dosage forms and administration routes. These bio-identical hormone therapies match the molecular structure of the estradiol and/or progesterone produced in the body. Current programs include the REPLENISH trial, a phase 3

clinical trial evaluating the safety and efficacy of our TX 12-001-HR 17 β -estradiol and progesterone combination product candidate in reducing the symptoms of menopause. We are also evaluating various other potential indications for our hormone technology, including oral contraception, preterm birth, VVA, and premature ovarian failure. More information is available at the following websites: www.therapeuticsmd.com, www.ReplenishTrial.com, www.vitamedmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com.

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Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the continuation and ultimate results of clinical development of the Company's proposed estradiol VagiCap[™] drug and the combination 17 β -estradiol and progesterone drug, estimates of the percentage of women to be affected by VVA and the percentage of women with VVA symptoms that do not seek treatment for their symptoms, statements regarding the effect of VVA on a woman's emotional and physical intimacy, the Company's belief in the anticipated achievements, attributes, and benefits of TX 12-004-HR, the Company's dedication to meeting women's health needs at every life stage, the effects of the phase 1 clinical study of TX 12-004-HR on further clinical development of TX 12-004-HR, the commencement and design of the phase 3 trial for TX 12-004-HR and the phase 3 trial for TX 12-002-HR, the value of vaginally administered estrogen therapy and the status of current estrogen therapies, the current estimates and Company's beliefs regarding the VVA market, what the REPLENISH clinical trial for TX 12-001-HR is designed to evaluate, current HT options and projections of the HT market, the Company's focus, the Company's commitment to the development of advanced hormone therapy pharmaceutical products that fill a critical and long-ignored need in the hormone and women's health market, and statements regarding other hormone technology that the Company is currently evaluating 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-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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