

# TherapeuticsMD®

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## FOR IMMEDIATE RELEASE

### **THERAPEUTICSMDBEGINS PATIENT ENROLLMENT IN PIVOTAL PHASE 3 CLINICAL TRIAL OF TX 12-001-HR TO TREAT SYMPTOMS OF MENOPAUSE AND PROVIDE ENDOMETRIAL PROTECTION**

**Boca Raton, FL, September 5, 2013** – TherapeuticsMD, Inc. (NYSE MKT: TXMD) announced today the enrollment and dosing of the first patient in the REPLENISH Trial, a Phase 3 clinical trial designed to measure the safety and effectiveness of TX 12-001-HR, the Company’s bioidentical combination 17 $\beta$ -estradiol and progesterone drug candidate, in treating the symptoms of menopause. Clinical endpoints of the REPLENISH Trial ([www.ReplenishTrial.com](http://www.ReplenishTrial.com)) include measuring the reduction in frequency and severity of hot flashes over a 90-day period while ensuring endometrial protection for one year, in accordance with FDA Guidance for Estrogen/Progestins.

Robert G. Finizio, Co-Founder and Chief Executive Officer, said, “We are pleased to enroll our first patient in the pivotal Phase 3 clinical trial of TX 12-001-HR. We believe this novel combination of 17 $\beta$ -estradiol and progesterone may provide a safer and effective alternative as compared to current hormone therapies, and we look forward to achieving full enrollment of patients in the trial for this promising drug candidate.”

#### **About Hormone Therapy**

Hormone therapy (HT) is the administration of hormones to supplement a lack of naturally occurring hormones. HT options include natural, bioidentical, and non-bioidentical (conjugated) hormones. HT is projected to be the largest growth segment in the overall women’s health market. The potential market for pharmacy-compounded, bioidentical HT products is estimated to be approximately \$1.5 billion per year.

#### **About TX 12-001-HR**

TX 12-001-HR is an investigational drug designed to replace the 17 $\beta$ -estradiol and progesterone hormones the body has stopped producing as the result of menopause, and to reduce the symptoms of menopause due to the reduction of those hormones. Enrollment is currently underway in the REPLENISH Trial, a Phase 3 clinical study made up of 1,550 patients to evaluate the safety and efficacy of TX 12-001-HR in reducing the symptoms of menopause. For more information, please visit: [www.ReplenishTrial.com](http://www.ReplenishTrial.com).

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

TherapeuticsMD, Inc. is a women’s healthcare company focused on developing and commercializing products targeted exclusively for women. We are currently developing advanced hormone therapy pharmaceutical products designed to alleviate the symptoms of and reduce the health risks resulting from menopause-related hormone deficiencies. We are also evaluating various other potential indications for

our hormone technology, including oral contraception, preterm birth, vulvar and vaginal atrophy, and premature ovarian failure. Additionally, our business includes the manufacture and distribution of branded and generic prescription prenatal vitamins, as well as over-the-counter vitamins and cosmetics, under our 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).

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*Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the Company's goals for the REPLENISH Trial, the Company's belief in the attributes and the expected benefits of TX 12-001-HR, the Company's expectation with respect to enrollment of patients in the REPLENISH Trial, the size of the REPLENISH Trial and the projected growth and potential size of the HT 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; challenges and costs inherent in product marketing; the risks and uncertainties associated with economic and market conditions; risks and uncertainties associated with TherapeuticsMD's business and finances in general; and other risks detailed in TherapeuticsMD's filings with the U.S. Securities and Exchange Commission including its annual report on Form 10-K filed on March 12, 2013, 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 TherapeuticsMD 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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