# **Therapeutics MD**\*

#### FOR IMMEDIATE RELEASE

## THERAPEUTICSMD INITIATES PHASE 3 CLINICAL TRIAL OF ITS PROGESTERONE CANDIDATE (TX 12-002-HR) FOR TREATMENT OF SECONDARY AMENORRHEA

**Boca Raton, FL - January 24, 2014 –** TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company ("TherapeuticsMD" or the "Company"), announced today that it has initiated the SPRY Trial, a randomized, placebo-controlled phase 3 clinical trial designed to evaluate the safety and efficacy of TX 12-002-HR, its oral progesterone candidate for secondary amenorrhea, a condition treated to maintain fertility in young premenopausal women. Clinical endpoints of the SPRY Trial include withdrawal bleeding and complete secretory change in three consecutive cycles. The trial is designed to enroll approximately 180 patients in the United States and is expected to be completed in late 2014.

TX 12-002-HR is a natural progesterone formulation without the potentially allergenic component of peanut oil, which is contained in currently available oral progesterone formulations. This investigational product is chemically identical to the hormone that naturally occurs in a woman's body.

Robert G. Finizio, Chief Executive Officer and Co-founder, said, "Based on its increased bioavailability, we believe that our oral progesterone candidate may provide a safe and effective treatment for secondary amenorrhea at a lower dose than oral therapies that are currently approved by the Food and Drug Administration. If approved, we believe our lower-dose bioidentical progesterone, with its non-allergenic formulation, would have a significant competitive advantage. We look forward to completing enrollment and reporting the results of the SPRY Trial after the 12-week treatment phase."

Secondary amenorrhea is defined as the absence of menses for three months in a woman with previously normal menstruation. Causes include hormonal disturbances from the hypothalamus and the pituitary gland, polycystic ovarian syndrome, premature menopause, and intrauterine scar formation.

### **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. In a recent study commissioned by the Company, inThought<sup>TM</sup>, a Symphony Health Solutions company, estimated the current market to be over \$3.7 billion per year.

### 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, www.vitamedmd.com, www.vitamedmdrx.com, and www.bocagreenmd.com.

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding the Company's expectations with respect to the design, the timing, and the size of enrollment in the SPRY Trial, as well as the ultimate results of the SPRY Trial; the Company's

belief that TX 12-002-HR may provide a safe and effective treatment for secondary amenorrhea at a lower dose versus currently approved oral therapies; the Company's belief that if approved by the FDA, the Company's oral progesterone candidate would have a significant competitive advantage; and the size of the hormone therapy 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 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 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 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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