

FOR IMMEDIATE RELEASE

THERAPEUTICSM^D TO PRESENT THE DESIGN OF ITS REPLENISH TRIAL AT THE INTERNATIONAL MENOPAUSE SOCIETY'S 14TH WORLD CONGRESS

Boca Raton, FL -- May 1, 2014 -- TherapeuticsMD, Inc. (NYSE MKT: TXMD), a women's healthcare company ("TherapeuticsMD" or the "Company"), will detail the design of its REPLENISH Trial, a large-scale pivotal phase 3 clinical trial to evaluate TX-001HR, the first oral combination for FDA approval of 17 β -estradiol and progesterone in a single capsule for the treatment of menopausal symptoms, at the session on May 2 of the International Menopause Society's 14th World Congress.

The investigational combination product being studied in the phase 3 REPLENISH Trial uses SYMBODA[™], an advanced technology developed and patented by the Company for solubilizing bio-identical hormones estradiol and progesterone.

TherapeuticsMD will present the study plan for its proprietary formulation at this year's gathering of the International Menopause Society, the leading global, nonprofit association dedicated to promoting women's health education and research.

"The combination of the bio-identical hormones 17 β -estradiol and natural progesterone in a single oral dose represents a novel alternative for treating menopausal vasomotor symptoms in women with a uterus," said Sebastian Mirkin, M.D., Chief Medical Officer of TherapeuticsMD, who will present the study design for TX-001HR, the Company's investigational combination drug candidate.

Hormone therapy (HT) combining estrogen with a progestogen is considered to be the most consistently effective treatment for menopause symptoms for non-hysterectomized women. Currently there is no single FDA-approved product combining these two natural hormones. While compounding pharmacies produce unapproved combinations, the variable purity and potency have led many medical societies to choose not to recommend them. TX-001HR is an oral agent that, if approved, will be the first FDA approval of an oral combination of 17 β -estradiol and progesterone in a gelatin capsule, representing a significant advancement in treatment options.

"We are encouraged by the potential of our SYMBODA technology to deliver an exciting first for HT dosing. If approved, our lowest combination dose containing 0.25 mg 17 β -estradiol and 50 mg natural progesterone could prove to be the lowest available dose of both hormones administered orally," Dr. Mirkin said.

About The REPLENISH Trial

The phase 3 REPLENISH Trial is a prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter trial evaluating the safety and efficacy of TX-001HR, a gelatin capsule containing both 17 β -estradiol and progesterone for oral use being developed for FDA review by TherapeuticsMD. A total of 1,750 healthy postmenopausal women (age 40 to 65 years old) will be enrolled and randomly assigned to 1 of 4 oral doses of TX-001HR or placebo for a treatment period of 12 months.

The primary efficacy endpoint is mean change from baseline in the frequency and severity of moderate to severe vasomotor symptoms at weeks 4 and 12. The primary safety endpoint is rate of endometrial hyperplasia at 12 months, as determined by endometrial biopsy.

About Hormone Therapy (also referred to as Hormone Replacement Therapy)

Menopausal HT is the administration of hormones to treat menopausal symptoms which result from a lack of naturally occurring hormones. Current HT options include FDA-approved combination products using non-bio-identical hormones, FDA-approved estrogen-only and progestogen-only products, and non-FDA approved compounded bio-identical products. The market for pharmacy-compounded, bio-identical HT products is estimated to be approximately \$1.5 billion per year.

About TX-001HR

TX-001HR is a proprietary solubilized bio-identical investigational drug designed to treat menopausal symptoms. Combining 17 β -estradiol and natural progesterone in a single oral capsule, it is the first combination bio-identical hormone therapy being developed under FDA guidance to replace the hormones the body has stopped producing in menopause. TX-001HR uses hormones that are chemically and biologically identical to the estradiol and progesterone naturally produced in a woman's body.

About SYMBODA Technology

SYMBODA is a proprietary technology that solubilizes active pharmaceutical ingredients to create bio-identical hormone formulations that meet FDA uniformity and stability requirements. This technology is designed to deliver these hormones in new combinations, routes of administration, and lower dosages.

About TherapeuticsMD, Inc.

TherapeuticsMD, Inc. is a women's health care 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 bio-identical 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 participation in and presentation at the 14th World Congress on Menopause of the Company's design of the REPLENISH Trial; the Company's belief that the REPLENISH Trial represents a large-scale pivotal phase 3 clinical study; the Company's belief that the combination of the bio-identical hormones 17 β -estradiol and progesterone in a single oral dose represents a novel alternative for treating menopausal vasomotor symptoms in women with a uterus; the benefits of HT combining estrogen with progestogen for menopause symptoms for non-hysterectomized women; the current lack of FDA-approved products that combine estrogen and progestogen; the lack of approval among the medical societies of the production by compounding pharmacies of unapproved combinations of estrogen and progestogen; the Company's belief that TX-001HR, if approved, will be the first FDA approval for an oral combination of 17 β -estradiol and progesterone in a gelatin capsule, representing a significant advancement in treatment options; the Company's belief in the ability of its proprietary technology to deliver an exciting first for HT dosing; the design of the phase 3 REPLENISH Trial and its safety and efficacy endpoints; current HT options, estimates of the market for pharmacy-compounded, bio-identical HT products, and the projected growth of HT; the design of TX-001HR and its attributes and benefits; and the Company's evaluation of various potential indications for its hormone technology 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 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.

References:

⁽¹⁾Pickar JH, Bon C, Amadio JM, Bernick B. Pharmacokinetics of the first combination 17 β -estradiol/progesterone capsule in clinical development for hormone therapy. Paper presented at: 24th Annual Meeting of the North American Menopause Society; October 9-12, 2013; Dallas, TX.

⁽²⁾Smith NL, Blondon M, Wiggins KL, et al. Lower risk of cardiovascular events in postmenopausal women taking oral estradiol compared with oral conjugated equine estrogens. *JAMA Intern Med.* 2014;174:25-31.

⁽³⁾Cordina-Duverger E, Truong T, Anger A, et al. Risk of breast cancer by type of menopausal hormone therapy: a case-control study among postmenopausal women in France. *PLoS One.* 2013;8:e78016.

⁽⁴⁾Fournier A, Berrino F, Cleavel-Chapelon F. Unequal risks for breast cancer associated with different hormone replacement therapies: results from E3N cohort study. *Breast Cancer Res Treat* 2008;107:103-111.

⁽⁵⁾National Institutes of Health. State-of-the-Science Conference Statement on Management of Menopause-Related Symptoms. Bethesda, MD: US Department of Health and Human Services; 2005.

⁽⁶⁾Food and Drug Administration. Report: Limited FDA survey of compounded drug products. Available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm>. Accessed on September 19, 2013.

⁽⁷⁾Food and Drug Administration. Report: 2006 limited FDA survey of compounded drug products. Available at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm/>. Accessed on July 19, 2013.

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