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PHASE 1 DATA PRESENTED ON FIRST ORAL COMBINATION 17β -ESTRADIOL AND PROGESTERONE CAPSULE TO TREAT MENOPAUSAL SYMPTOMS BEING DEVELOPED FOR FDA REVIEW

Phase 3 REPLENISH Trial Now Under Way
Investigational hormone therapy also avoids use of peanut oil, a known allergen

Boca Raton, FL, October 9, 2013 – TherapeuticsMD, Inc. (NYSE MKT:TXMD) - Pharmacokinetic study being presented tomorrow evening in a poster session at The North American Menopause Society 2013 Annual Meeting in Dallas suggests that the first combination 17β-estradiol and progesterone capsule in clinical development may have overcome the well-recognized difficulties of achieving good bioavailability with oral administration of these hormones in combination.

In a study of 66 healthy postmenopausal women, bioavailability of TX 12-001-HR, a capsule containing both 17β-estradiol and progesterone for oral use being developed by TherapeuticsMD, Inc., was found to be similar to that of the standard reference products for the human hormones estradiol (Estrace®) and progesterone (Prometrium®), when taken concurrently. Hormone therapy is widely used to alleviate the symptoms of menopause and to reduce the health risks resulting from hormone deficiencies associated with menopause.

"It has been notoriously difficult to combine these two body-identical hormones and obtain consistently good bioavailability. And, when compounding pharmacies create specialized blends of these hormones, there is a great deal of variability in what is produced," according to James H. Pickar, M.D., Adjunct Associate Professor of Obstetrics and Gynecology, Columbia University College of Physicians & Surgeons in New York, who presented the study findings. In two FDA surveys of compounding pharmacies, the amount of hormone found in the compounded products was not the amount claimed in approximately 34% of compounded products sampled and in 29% of hormone samples, versus the <2% variability found for commercially manufactured products.[1,2]

In this study, bioequivalence criteria were met for all analytes, except C_{max} for total estrone. The extent of absorption of the estradiol and progesterone in the Test capsule was similar to that for Estrace and Prometrium, while the rate of estradiol absorption for the Test capsule appeared to be slightly faster than for the Estrace reference.

"The similarity in bioavailability of progesterone and estradiol in the test product to that of the two reference products suggests that the safety profile also should be similar," Dr. Pickar said. Studies suggest that products more closely resembling the human hormones progesterone and estradiol may have a more favorable safety profile than synthetic hormones.[3, 4] Dr. Pickar also noted that this investigational therapy offers the additional advantage of avoiding use of the known allergen, peanut oil, which is used in Prometrium and its generic equivalents.

The need to ensure adequate bioavailability is critical for progesterone, which protects the endometrium from estrogen stimulation. "When progesterone levels are inadequate, women taking estrogen are put at unnecessary risk for uterine cancer," added Dr. Pickar.

About the Study

The study, which was sponsored by TherapeuticsMD, Inc., was designed to determine the pharmacokinetics and bioavailability of the company's combination capsule of 17β-estradiol and progesterone (test drug: TX12-001-HR).

Participants included 66 healthy, postmenopausal women, age 40-65 years. Each participant was randomly assigned to begin one of three dosing sequences, each including three periods. During one period participants received a single dose of the Test drug, and during two periods they received single doses of both the estradiol and progesterone Reference drugs, which were taken concurrently. Blood samples were collected at multiple intervals, beginning one hour prior to start of dosing and continuing to 48 hours after dosing. Bioavailability was determined by measuring the rate and extent of absorption of the drugs.

About Hormone Therapy

Menopausal hormone therapy (HT) 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 bioidentical products. A body-identical combination product, which exactly matches the molecular structure of the human hormones estradiol and progesterone, is being developed by TherapeuticsMD and is currently in phase 3 clinical trials. 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 a body-identical investigational drug designed to treat menopausal symptoms by replacing the 17ß-estradiol and progesterone hormones the body has stopped producing as the result of menopause. Enrollment is currently under way in the REPLENISH Trial, a Phase 3, investigational research 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.

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® 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 continuation and ultimate results of clinical development of the Company's proposed combination17β-estradiol and progesterone drug, the use of hormone therapy to alleviate the symptoms of menopause and to reduce the health risks resulting from hormone deficiencies associated with menopause, the critical need to ensure adequate bioavailability for progesterone, the Company's belief in the attributes and the expected benefits of TX 12-001HR, what the TX 12-001HR clinical trial is designed to measure, and the 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; 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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