

FOR IMMEDIATE RELEASE

## **Physicians' visual assessments correlate with objective measurements of postmenopausal VVA patients treated with TX-004HR VagiCap™**

*New data from 14-day phase 2 pilot study featured at ENDO 2015 show visual assessments may be appropriate to establish patient need and treatment response*

**BOCA RATON, Fla., March 9, 2015** — TherapeuticsMD, Inc. (NYSE MKT: TXMD), an innovative women's healthcare company, presented at the Endocrine Society's 97<sup>th</sup> annual meeting new data showing healthcare providers' visual assessments of vulvar and vaginal atrophy (VVA) before and after treatment with the investigational drug TX-004HR in the VagiCap dosage form correlated with significant changes in vaginal cellular response and pH in postmenopausal women with VVA.

Dr. Ginger Constantine, president of EndoRheum Consultants LLC and a TherapeuticsMD clinical consultant, presented the poster titled, "Vaginal Physical Examination Correlates with Vaginal Epithelial Cells and pH and Can be Used to Assess Treatment Efficacy" Friday in San Diego.

"Although it has long been believed that vaginal physical examinations are useful for the diagnosis of VVA and response to treatment, we now have data showing a correlation of the physical examination of the vagina with objective measures, such as cells and pH," said Constantine, who coauthored the poster. "Interestingly, following just two weeks of treatment with TX-004HR, improvements in vaginal assessments on physical exam correlated with the objective findings, supporting the use of vaginal examination to follow treatment response."

Healthcare providers (HCPs) often utilize physical examination of the vagina to assess and diagnose VVA and to determine appropriate treatment options. Consistent with FDA guidelines, TherapeuticsMD is evaluating its investigational solubilized vaginal estradiol softgel, TX-004HR, based on change from baseline to week 12 in both objective (vaginal cells and vaginal pH) and subjective patient assessment measures of the most bothersome symptom.

The pilot phase 2 study — previously announced at the 25<sup>th</sup> Annual Meeting of The North American Menopause Society in October 2014 — involved 50 healthy postmenopausal women between ages 40 to 75 and experiencing moderate to severe VVA symptoms. The patients, whose superficial cells were less than or equal to 5 percent and vaginal pH of greater than 5, participated in the randomized study comparing a placebo with the 10 mcg TX-004HR once-a-day for two weeks. The data presented Friday show visual assessments of vaginal atrophy correlated with objective measures, including parabasal and intermediate cells at baseline and at day 15 as well as vaginal pH at day 15. Visual assessments of the vagina by HCPs appear to be valid and reliable measures to diagnose VVA and assess response to treatment.

TherapeuticsMD's phase 3 Rejoice Trial for this drug candidate is investigating 4 mcg, 10 mcg and 25 mcg estradiol doses. The investigational 4 mcg dose represents a potentially new low dose local estrogen treatment.

Patients interested in enrolling in the Rejoice Trial should speak with their physicians and may visit [www.rejoicetrial.com](http://www.rejoicetrial.com) or call toll-free 1-800-70-REJOICE (1-800-707-3564).

Vulvar and vaginal atrophy (VVA), a common chronic condition and part of the genitourinary syndrome associated with menopause, is caused by the decrease in naturally occurring estrogen and results in thinning of the vaginal lining and an increase in vaginal pH levels.<sup>1,2</sup> An estimated 32 million women in the United States currently are suffering from symptoms of VVA, and fully 93 percent of this population currently receive no prescription therapy for the condition.<sup>1</sup>

Dedicated to research on hormones and the clinical practice of endocrinology, the Endocrine Society is the world's oldest, largest and most active organization of its kind. The Society's yearly gathering of scientific and clinical experts is internationally renowned as a source of cutting-edge research and the advancement of clinical practices in endocrinology and metabolism.

## **About TherapeuticsMD, Inc.**

TherapeuticsMD, Inc. is an innovative healthcare company focused on developing and commercializing products exclusively for women. With its patented SYMBODA™ technology platform, TherapeuticsMD is developing advanced hormone therapy pharmaceutical products to enable delivery of bio-identical hormones through a variety of dosage forms and administration routes. The company's clinical development pipeline includes two phase 3 products. The company also manufactures and distributes branded and generic prescription prenatal vitamins as well as over-the-counter vitamins under the vitaMedMD® and BocaGreenMD® 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).

## References

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2. Portman DJ, Gass MLS, on behalf of the Vulvovaginal Atrophy Terminology Consensus Conference Panel. Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and The North American Menopause Society. *Menopause: The Journal of The North American Menopause Society* 2014, no. 21.10, 1-8.

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