

Survey shows postmenopausal women with VVA reported improved satisfaction and quality of life with VagiCap[™] investigational local estrogen treatment

*Patient experience data to be presented at
International Society for the Study of Women's Sexual Health Annual Meeting*

Austin, Texas, Feb. 20, 2015 – Newly released patient satisfaction survey results from a study of a novel investigational vaginal estrogen treatment show promise for improving quality of life and satisfaction for postmenopausal women who experience pain during sex and other symptoms associated with vulvar and vaginal atrophy (VVA).

University Hospitals Case Medical Center and TherapeuticsMD, Inc. (NYSE MKT: TXMD) announced that Sheryl A. Kingsberg, PhD, will present results today from a patient experience survey of investigational compound TX-004HR (VagiCap[™]) at the International Society of Women's Sexual Health (ISSWSH) 2015 Annual Meeting, February 19-22 at the Sheraton Hotel in Austin, Texas.

Dr. Kingsberg, Chief of the Division of Behavioral Medicine Department of OB/GYN at UH Case Medical Center in Cleveland, will present the findings of a survey evaluating use and satisfaction of a vaginal softgel capsule utilized in a pilot phase 2, 14-day study on VVA. The presentation, "Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap[™])" is scheduled for today at 11:40 a.m. CST. The ISSWSH Annual Meeting brings together scholars, researchers and practitioners to further their knowledge and commitment to the field of women's sexual health.

"Menopause is typically associated with hot flashes, but there are other common and distressing symptoms such as pain and discomfort during sex due to lack of estrogen. Approximately 30 million women in the United States experience this condition, which can really impact their quality of life," said Dr. Kingsberg. "It's important that women have options when it comes to their sexual health, and TX-004HR VagiCap may, if approved by the FDA, represent a novel treatment for VVA that women may find to be convenient and easy to use."

Between 25 and 45 percent of postmenopausal women find sex painful, a condition called dyspareunia. While there are many causes, the most common in women over 50 is VVA. Symptomatic VVA can significantly impair the quality of life in postmenopausal women and impact their sexual function and health. Although more than 50 percent of postmenopausal women will experience VVA symptoms, the condition remains underdiagnosed and undertreated – only 7 percent are on prescription therapy.[†]

VVA is a chronic condition resulting from the decrease in naturally occurring estrogen during menopause, resulting in thinning of the vaginal lining and an increase in vaginal pH levels. Women with VVA may suffer mild to severe symptoms that include vaginal and vulvar pain and discomfort, irritation, itching, burning, discharge, pain with urination (dysuria) and painful intercourse (dyspareunia).

The pilot phase 2 randomized study involved women between the ages of 40-75. The research team found based on a qualitative survey that 63 percent of women on TX-004HR VagiCap reported an improved "[change] in quality of life after treatment in this study" with only two weeks of therapy treatment, compared to 48 percent on the placebo.

"For many women, symptoms such as these have a major impact on frequency and spontaneity of their sexual activity. It is essential that health care attendants routinely engage in open and sensitive discussions with postmenopausal women to ensure that symptomatic atrophy is detected early and appropriately managed," said Dr. Kingsberg, who is also a professor at Case Western Reserve University School of Medicine. "New treatment options — such as this VagiCap, if approved by the FDA — have the potential to improve satisfaction for these women. There is medical consensus that estrogen administered locally is the preferred mode of treatment for both symptom reduction and restoring and maintaining healthy vaginal tissue and sexual function."

VVA and dyspareunia fall under the umbrella of “genitourinary syndrome of menopause” (GSM) that refers to the collection of symptoms associated with decreased estrogen levels that can involve the genital system or the lower urinary tract.

About TX-004HR

TX-004HR is a solubilized vaginal estrogen capsule under development for the treatment of moderate to severe postmenopausal dyspareunia, a symptom of VVA. TherapeuticsMD began its phase 3 Rejoice Trial for TX-004HR in September 2014 and is investigating 4 mcg, 10 mcg and 25 mcg estradiol doses — potentially enabling multiple dosing options to meet women’s treatment needs.

About University Hospitals

University Hospitals, the second largest employer in Northeast Ohio with 25,000 employees, serves the needs of patients through an integrated network of 15 hospitals, 28 outpatient health centers and primary care physician offices in 15 counties. At the core of this \$3.5 billion health system is University Hospitals Case Medical Center, ranked among America’s 50 best hospitals by U.S. News & World Report in all 12 methodology-ranked specialties. The primary affiliate of Case Western Reserve University School of Medicine, UH Case Medical Center is home to some of the most prestigious clinical and research centers of excellence in the nation, including cancer, pediatrics, women's health, orthopaedics, radiology, neuroscience, cardiology and cardiovascular surgery, digestive health, transplantation and genetics. Its main campus includes UH Rainbow Babies & Children's Hospital, ranked among the top children’s hospitals in the nation; UH MacDonald Women's Hospital, Ohio's only hospital for women; and UH Seidman Cancer Center, part of the NCI-designated Case Comprehensive Cancer Center at Case Western Reserve University. For more information, go to www.uhhospitals.org

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 and cosmetics under the 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.

Reference

† Kingsberg, Sheryl A., et. al. "Vulvar and Vaginal Atrophy in Postmenopausal Women: Findings from the REVIVE (REal Women's VIEWS of Treatment Options for Menopausal Vaginal ChangEs) Survey." *Journal of Sexual Medicine* 2013, no. 10, 1790-1799.

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