

FOR IMMEDIATE RELEASE



**U. S. FOOD AND DRUG ADMINISTRATION ACCEPTS SHIONOGI'S OSPEMIFENE
NEW DRUG APPLICATION IN VULVAR AND VAGINAL ATROPHY**

Potential First Oral Alternative to Vaginal Estrogen Treatments

FLORHAM PARK, NJ (June 27, 2012) – Shionogi Inc., the U.S.-based company of Shionogi & Co., Ltd., today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the ospemifene New Drug Application (NDA) for the treatment of vulvar and vaginal atrophy (VVA) due to menopause, including moderate to severe symptoms of dyspareunia (painful sexual intercourse) and/or vaginal dryness and physiological changes (parabasal cells, superficial cells and pH). The product is expected to launch in the U.S. in the second or third quarter of 2013.

Ospemifene is a selective estrogen receptor modulator (SERM) for VVA. It has the potential to become the first oral treatment alternative to vaginal estrogens. Ospemifene's tissue specific profile exhibits positive activity on vaginal epithelium (decreasing parabasal cells, increasing superficial cells and lowering vaginal pH), resulting in a reduction of symptoms associated with VVA, including dyspareunia and/or vaginal dryness.

“Women spend more than a third of their lives in menopause, yet VVA is an underdiagnosed and undertreated condition that significantly impacts the health and well-being of women,” said Dr. John Keller, President and CEO, Shionogi Inc. “Shionogi is committed to developing breakthrough medicines, like ospemifene, that help safeguard women's health around the world.”

The submission includes data demonstrating the efficacy and safety of ospemifene from three Phase III trials involving approximately 2,100 (ospemifene and placebo subjects) postmenopausal women with VVA¹.

The first pivotal Phase III trial for ospemifene met all co-primary endpoints at a 60 mg dosage. Ospemifene demonstrated significant improvement in the physiological signs of VVA with statistically significant improvements in dyspareunia and /or vaginal dryness.¹

The results from the second pivotal study showed statistically significant positive results in four co-primary endpoints ($p \leq 0.0001$). These included an increase in the percentage of superficial cells, a decrease in the percentage of parabasal cells and a decrease in vaginal pH. Ospemifene also demonstrated an improvement in the patient's most bothersome moderate to severe symptom of dyspareunia¹.

In clinical trials, ospemifene was generally well tolerated. The most commonly reported adverse reactions included: hot flush, vaginal discharge, muscle spasms, genital discharge and hyperhidrosis.

About Vulvar and Vaginal Atrophy (VVA)

Vaginal atrophy has a significant negative impact on the post-menopausal woman's health and well-being. VVA is a chronic and progressive condition characterized by symptoms including vaginal dryness, pain with sexual activity (dyspareunia) and irritation. Declining estrogen levels during menopause can

cause tissues of the vaginal lining to grow thinner and to lose elasticity, a condition known as atrophy. Dryness and irritation associated with reductions in vaginal secretions often cause pain or bleeding during sexual intercourse. More than 7.1 million women are diagnosed with VVA each year, and only 11 percent are treated with a prescription medication.² These prescription therapies may be required for symptomatic women who do not respond to over-the-counter moisturizers or lubricants³. Currently, the most common prescription treatments are vaginally inserted tablets, creams or rings, all of which can be inconvenient or messy.

About Shionogi

Shionogi Inc. is the U.S.-based subsidiary of Shionogi & Co., Ltd. Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company has provided such innovative medicines as Crestor and Doripenem, which have been successfully delivered to millions of patients. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp. For more information on Shionogi Inc., headquartered in Florham Park, NJ, please visit www.shionogi.com.

Forward Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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References

¹ Ospemifene NDA

² Shionogi VVA Market Assessment – HP Analysis March 20, 2012. Source: IMS health plan claims database

-Contains fully integrated patient, medical and pharmaceutical service claims information

-Database contains over 70 million unique patients across 88 health plans

-Nationally representative & projectable to the US insured population

³ NAMS 2007/pg. 360/Col 1/paragraph 2.