

Shionogi Files a New Drug Application for Ospemifene Oral Tablets 60mg for the Treatment of Vulvar and Vaginal Atrophy

Osaka, Japan, May 9, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that the U.S. subsidiary Shionogi Inc. submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for ospemifene oral tablets 60 mg for the treatment of vulvar and vaginal atrophy (VVA) due to menopause on April 26, 2012.

Ospemifene is a selective estrogen receptor modulator (SERM) designed to mimic the effects of estrogen on the vaginal epithelium. The results from Phase 3 studies showed statistically significant positive results in co-primary endpoints, including improvement in moderate to severe symptoms of dyspareunia and vaginal dryness, a decrease in percentage of parabasal cells, an increase in percentage of superficial cells from the vaginal smear and a decrease in vaginal pH in post-menopausal women.

Shionogi and QuatRx Pharmaceuticals Company (Head Office: Ann Arbor, MI, USA; hereafter “QuatRx”) entered into a worldwide license agreement to develop and market ospemifene in March 2010, and Shionogi has been preparing the NDA filing with the FDA. Once approved by the FDA, ospemifene will be the first non-estrogen treatment for VVA, providing a new option for post-menopausal women suffering from VVA. Shionogi anticipates that this new product will help to build the foundations for the future growth of our U.S. business.

About Post-menopausal Vulvar and Vaginal Atrophy

Post-menopausal vulvar and vaginal atrophy is a chronic and progressive condition characterized by symptoms including sexual pain (dyspareunia), vaginal dryness and irritation. Declining estrogen levels during menopause can cause tissues of the vaginal lining to become thinner and to lose elasticity, a condition known as atrophy. Dryness and irritation associated with reductions in vaginal secretions often result in pain or bleeding during sexual intercourse. Current prescription treatments approved for this condition all contain estrogen, administered either systemically or locally in the vagina. None of the SERMs currently marketed for osteoporosis and breast cancer in the U.S. are approved for use in treating vaginal atrophy symptoms.

About QuatRx Pharmaceuticals Company

QuatRx is focused on the discovery, development, commercialization and licensing of compounds in the endocrine and metabolic therapeutic areas. For the Company information, please visit www.quatrx.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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