



SHIONOGI FILES A NEW DRUG APPLICATION FOR OSPEMIFENE ORAL TABLETS 60MG FOR THE TREATMENT OF VULVAR AND VAGINAL ATROPHY

FLORHAM PARK, NJ (April 26, 2012) –Shionogi Inc. (Shionogi) has filed a New Drug Application for Ospemifene oral tablets 60 mg for the treatment of vulvar and vaginal atrophy (VVA) due to menopause, including moderate to severe symptoms of dyspareunia and/or vaginal dryness and physiological changes (parabasal cells, superficial cells and pH) in post-menopausal women.

About 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.

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日本語要約

経口用閉経後膣萎縮症治療薬「Ospemifene 60 mg 錠」の 米国における新薬承認申請について

塩野義製薬株式会社（本社：大阪市中央区）の米国子会社 Shionogi Inc.（本社：米国ニュージャージー州）は、このたび、経口用閉経後膣萎縮症治療薬「Ospemifene（一般名）60 mg 錠」の新薬承認申請を米国食品医薬品局（FDA）に提出しましたので、お知らせいたします。

本剤は、閉経後女性における中等度から重度の性交疼痛や膣乾燥感、膣上皮の生理学的変化（旁基底細胞や表層細胞、膣内 pH）など、膣萎縮症の治療に役立つことが期待できる薬剤です。

以 上