

## **EMA Accepts MAA Submission of Shionogi's Ospemifene for the Treatment of VVA**

**London, 27<sup>th</sup> March 2013** – Shionogi Limited, the London-based European subsidiary of Shionogi & Co., Ltd announced today that on 26<sup>th</sup> March 2013 the European Medicines Agency (EMA) accepted its Marketing Authorisation Application (MAA) submission for ospemifene for the treatment of vulvar and vaginal atrophy (VVA) in post-menopausal women.

“We are pleased to announce the MAA submission for ospemifene to the EMA following the US Food and Drug Administration (FDA) approval last month. The acceptance of the MAA submission for ospemifene not only represents an important step forward in expanding the treatment options for women living in Europe with this condition, but it is also an important milestone for Shionogi as it continues to build its business in Europe” said Takashi Takenoshita, CEO of Shionogi Limited.

### **About Shionogi**

Shionogi Limited is the London-based, European 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. 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](http://www.shionogi.co.jp). For more information on Shionogi Limited, headquartered in London, United Kingdom, please contact +44 203 609 8660.

### **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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