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## **SHIONOGI ENTERS INTO EXCLUSIVE LICENSE AGREEMENT WITH QUATRx PHARMACEUTICALS TO MARKET OSPEMIFENE**

**Osaka, Japan, Atlanta, GA and Ann Arbor, MI (March 2, 2010)** — Shionogi & Co., Ltd. and QuatRx Pharmaceuticals Company, a privately-held pharmaceutical company, today announced that they have entered into a worldwide license agreement to develop and market ospemifene, a selective estrogen receptor modulator ("SERM").

Under the terms of this agreement, Shionogi will have worldwide marketing rights to ospemifene. QuatRx will receive an up-front payment of \$25 million and is eligible to receive in excess of \$100 million in development and regulatory milestone payments. QuatRx will also be eligible to receive additional payments for approval of ospemifene outside the US as well as sales milestones and royalties on product sales. A New Drug Application ("NDA") with the FDA is planned to be filed in 2010 for ospemifene for the treatment of post-menopausal vulvovaginal atrophy ("VVA"), utilizing the Phase 3 clinical trials that were conducted by QuatRx.

Patrick Fourteau, President and CEO of Shionogi Pharma, Inc., a US-based group company of Shionogi, said, "All of us at Shionogi are excited about the potential of ospemifene and, upon FDA approval, we look forward to bringing the first non-estrogen treatment option to millions of women in the US who are living with post-menopausal vulvovaginal atrophy. Our efforts to market ospemifene represent an important step in our strategy to further diversify Shionogi Pharma's Women's Health portfolio and broaden the Company's R&D pipeline."

Ospemifene is a SERM designed to mimic the positive effects of estrogen on the vaginal epithelium while avoiding estrogen stimulation of breast and other tissues. In September 2009, QuatRx announced the results of a second pivotal Phase 3 study for ospemifene. The results showed highly statistically significant positive results in four co-primary endpoints ( $p \leq 0.0001$ ), including a decrease in percentage of parabasal cells and an increase in percentage of superficial cells from the vaginal smear, decrease in vaginal pH and improvement in the patient's most bothersome moderate to severe symptom of dyspareunia. The first Phase 3 trial for ospemifene met all the co-primary endpoints at a 60 mg dosage, with statistically significant improvements in vaginal dryness and dyspareunia, as well as statistically significant improvement in the proportion of parabasal and superficial cells in the epithelium of vaginal walls and a decline in vaginal pH levels. Data from the long term safety studies demonstrated that daily doses of 60 mg of ospemifene are well-tolerated.

Robert L. Zerbe M.D., CEO and Co-Founder of QuatRx, said, "QuatRx is very pleased to have completed the comprehensive development program for ospemifene. Pending regulatory approval, the results of our clinical research for ospemifene indicate that this promising non-estrogen therapy could play a significant role in the treatment of vulvovaginal atrophy in the years ahead. Shionogi is the ideal company to successfully support the effort to commercialize ospemifene in the U.S. and around the world."

### **About Post-menopausal Vaginal Atrophy**

Post-menopausal vulvovaginal atrophy is a chronic and progressive condition characterized by symptoms including vaginal dryness, sexual pain (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. It is estimated that 45-75 percent of postmenopausal women experience chronic symptoms of vaginal atrophy, and in most cases these symptoms are highly bothersome to patients. Current prescription treatments approved for this condition all contain estrogen, administered either systemically or locally in the vagina. SERMs that are currently approved and marketed in the United States have not been shown to have beneficial effects on vaginal tissue and none are approved for use in treating vaginal atrophy symptoms.

### **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](http://www.shionogi.co.jp). For more information on Shionogi Pharma, Inc. based in Atlanta, Georgia, please visit [www.shionogipharma.com](http://www.shionogipharma.com).

### **About QuatRx Pharmaceuticals Company**

QuatRx Pharmaceuticals is focused on the discovery, licensing, development and commercialization of compounds in the endocrine, metabolic and cardiovascular therapeutic areas. In addition to ospemifene, QuatRx has three other product candidates in clinical development and a preclinical program. Fispemifene is a new selective estrogen receptor antagonist that is in Phase 2 studies as an oral treatment for the symptoms of secondary hypogonadism in men. Sobetirome, a novel, selective thyroid receptor beta agonist, is in Phase 1 as a potential treatment for dyslipidemia. Becocaldiol, a novel Vitamin D analogue, is in Phase 2 clinical studies for the treatment of psoriasis through QuatRx's partner, Galderma. QuatRx's preclinical program is designed to address sex steroid dependent diseases through inhibition of 17beta-HSD enzymes. In Europe, QuatRx operates through its Finnish subsidiary, Hormos Medical Ltd, located in Turku, Finland. For press releases and other Company information, please visit [www.quatrx.com](http://www.quatrx.com).