



QUATRx Pharmaceuticals Company
777 East Eisenhower Parkway, Suite 100
Ann Arbor, MI 48108
(734) 913-9900 • fax (734) 913-0743
www.quatrx.com

QUATRx ANNOUNCES POSITIVE RESULTS OF SECOND PIVOTAL PHASE 3 CLINICAL STUDY FOR *OPHENA*[™] (OSPEMIFENE TABLETS) IN TREATMENT OF POSTMENOPAUSAL VAGINAL ATROPHY

Results show positive efficacy in all four co-primary endpoints among patients with dyspareunia (sexual pain); study completes QuatRx's Phase 3 program

ANN ARBOR, MI— QuatRx Pharmaceuticals Company, a privately-held biopharmaceutical company, today announced positive efficacy results from the second of two patient cohorts in the second pivotal Phase 3 study for *Ophena*[™] (ospemifene tablets), the company's investigational compound in development for the treatment of postmenopausal vulvovaginal atrophy (VVA). This study, together with the recent completion of a long-term safety study for *Ophena*[™], marks the end of the company's comprehensive Phase 3 efficacy and safety program for *Ophena*[™] and positions QuatRx to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in early 2010.

This second phase 3 study of *Ophena*[™] was a randomized, double-blind, placebo-controlled study with 919 women with vulvovaginal atrophy. The study was conducted at 116 sites in the United States. Among the cohort of 605 women in the study who identified dyspareunia as their most bothersome symptom, positive efficacy results were achieved in all four co-primary endpoints, including decrease in parabasal and superficial cells from vaginal smear, decrease in vaginal pH and improvement in the patient's most bothersome moderate to severe symptom of dyspareunia. The results showed highly statistically significant changes from baseline to week 12 compared to placebo in all four co-primary endpoints ($p < 0.0001$). All women were supplied with a non-hormonal vaginal lubricant to be used as needed during the treatment period and the study results demonstrated efficacy above and beyond this lubricant usage, as also observed in the first Phase 3 study.

"These findings provide substantial additional evidence indicating the potential of *Ophena*[™] to be a first-in-class non-estrogen drug for the treatment of vaginal atrophy," said Robert L. Zerbe, M.D., Chief Executive Officer of QuatRx. "With the completion of our second pivotal Phase 3 study, we believe we have now fully confirmed the efficacy of *Ophena* according to the criteria established by FDA under the applicable guidance for this indication. Based on this, we are working aggressively to move forward with our NDA submission and to bring this promising new treatment option to the millions of women affected by vaginal atrophy who want an alternative to estrogen therapy."

The company's planned NDA for 2010 will seek regulatory approval for *Ophena*[™], a new SERM (selective estrogen receptor modulator), for the treatment of the symptoms of postmenopausal vulvovaginal atrophy. *Ophena*[™] is the only non-estrogen therapy currently in late-stage development for the treatment of vaginal symptoms associated with menopause.

In January 2008, QuatRx announced results from the first Phase 3 study for *Ophena*[™]. These results confirmed that women treated with *Ophena*[™] at the 60 mg dose showed statistically significant improvements in vaginal dryness and dyspareunia (painful intercourse), 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. In July 2009, QuatRx announced results from the first patient cohort involved in the second Phase 3 study. Among 314 patients identifying vaginal dryness as their most bothersome symptom, the study showed efficacy in all four co-primary endpoints, confirming the results seen in the first pivotal Phase 3 study of *Ophena*[™]. The results also demonstrated that *Ophena*[™] was well-tolerated.

Phase 3 Long-Term Safety Update

QuatRx has also recently completed its long term safety program for *Ophena*[™]. This included two safety extensions from the first pivotal Phase 3 study, together with a placebo controlled, one year study involving 426 women with an intact uterus, randomized 6:1 to Ophena designed to evaluate long term endometrial safety. Data from the long term safety studies show that daily doses of 60mg of *Ophena*[™] are well-tolerated with most treatment-emergent adverse events being mild or moderate in severity. There were no deaths in any of the studies and no confirmed cases of endometrial hyperplasia or carcinoma. Overall, the safety profile of *Ophena*[™] compares favorably to estrogen treatment, which remains the only class of drugs available for this condition.

About Postmenopausal Vaginal Atrophy

Postmenopausal 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 orally 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 QuatRx

QuatRx Pharmaceuticals is focused on the discovery, licensing, development and commercialization of compounds in the endocrine, metabolic and cardiovascular therapeutic areas. In addition to *Ophena*[™], QuatRx has three other product candidates in clinical development and 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.