Neurocrine Biosciences Presents Elagolix Data

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SAN DIEGO, June 16 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that data from Phase I and Phase II elagolix trials and preclinical work was presented at the 91st Annual Meeting of the Endocrine Society (ENDO 09) in Washington DC, June 10-13, 2009.

The first clinical abstract presentation at ENDO 09 reviews the results of a Phase I study in which elagolix was evaluated over six weeks (42 days) in 60 healthy premenopausal women. The study was a double-blind, placebo-controlled study in parallel groups in which 88% of the participants completed the treatment period. The purpose of this study was to evaluate the safety, tolerability, pharmacokinetics and endocrine effects of elagolix. The results of this study showed that daily administration of elagolix induced partial suppression of gonadotropins for 12-18 hours per day with a return to baseline each morning for 42 days. The effect on gonadotropins translated in a dose related fashion to maintenance of low estradiol levels over the six week period without inducing severe hot flashes or excessive bone resorption as determined by n-telopeptide. Consistent pharmacokinetic profiles were maintained throughout the 42 days of treatment, and adverse events were comparable among the placebo and elagolix groups.

The second clinical abstract at ENDO 09 reports results from a Phase II study where the safety of elagolix was evaluated in 252 women with a confirmed diagnosis of endometriosis. The study was a randomized, double-blind study of elagolix and depo-subQ provera 104 (used as an active control) administered over six months followed by six months of additional assessments. The primary endpoint of the study was to assess the impact of elagolix on bone mineral density using dual energy x-ray absorptiometry (DXA) scanning at months six and twelve. The results showed that elagolix had no long-term bone risk during or after treatment.

"We are pleased to share this body of work with the scientific community," said Chris O'Brien, Chief Medical Officer, Neurocrine Biosciences. "An orally active gonadotropin releasing hormone antagonist with no long-term bone risk would be a significant step forward in the treatment of endometriosis and other hormone dependent diseases. These safety results support selection of the appropriate elagolix dose and regimen for the Phase III trials."

Neurocrine Biosciences also presented a preclinical study which was designed to examine the impact of a gonadotropin releasing hormone (GnRH) antagonist on prostate tissue. The animal model provided detailed information on changes in prostate size, weight, hormone levels and cell immunohistochemistry. The data reveal that transient inhibition of plasma testosterone and intra-prostatic androgens results in the reduction of prostate weight, a reduction in epithelial proliferation and suppression of prostate growth. If these preclinical results are replicated in men, daily transient inhibition of androgens with a GnRH antagonist may constitute a new paradigm for the treatment of benign prostatic hyperplasia.

About Endometriosis

Endometriosis is a painful gynecological disease that affects approximately 7.5 million women of reproductive age in the United States alone. The pain caused by endometriosis can be related to menstruation (dysmenorrhea), sexual intercourse (dyspareunia) as well as chronic pelvic pain throughout the menstrual cycle. Infertility and abnormally heavy and prolonged bleeding (menorrhagia) are also common of which, in combination with pain, contribute to more than 100,000 hysterectomies performed annually. The annual direct and indirect costs of endometriosis are estimated to exceed $20 billion in the Unites States.

Treatment options for endometriosis suffer from both efficacy and safety shortcomings. The current standards of care such as contraceptives and analgesics (non-steroidal anti-inflammatory drugs) are often ineffective in controlling the symptoms of endometriosis. Likewise, while peptide gonadotropin-releasing hormone (GnRH) agonists such as Lupron(R) (leuprolide acetate) and Zoladex(R) (goserelin acetate) are highly effective in controlling symptoms of endometriosis, these products cause an initial, transient heightening in symptom severity, as well as hot flashes throughout the course of therapy. Most importantly, because all GnRH agonists suppress estrogen to very low levels, long-term treatment is not possible due to the severe bone loss that occurs in patients.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine related diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including endometriosis, irritable bowel syndrome (IBS), anxiety, depression, pain, diabetes, benign prostatic hyperplasia (BPH) and other neurological and endocrine related diseases and disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's GnRH program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include, but are not limited to, risk that the Company's elagolix Phase II clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to later stage clinical trials; risk associated with the Company's dependence on corporate collaborators for development, commercial manufacturing and marketing and sales activities. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2008 and report on Form 10-Q for the quarter ended March 31, 2009. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE:
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