Neurocrine Biosciences Announces Successful Completion of Daisy PETAL Study

November 22, 2010

UPDATE TO TIMING OF END OF PHASE II MEETING

SAN DIEGO, Nov. 22, 2010 /PRNewswire via COMTEX/ --

Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced results from the open-label portion of the six month Phase II Daisy PETAL study (901 study) using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis.

"The previously announced improvements across all endometriosis-associated pain domains, during the eight week placebo controlled portion of this Daisy PETAL study, continued to show sustained effect through the open-label, single-arm portion of the 901 Study up to twenty-four weeks of treatment," said Chris O'Brien, M.D., Chief Medical Officer at Neurocrine. "We are pleased with the persistence of effect and the safety profile that elagolix continues to display. It is encouraging to see further improvement in dysmenorrhea, non-menstrual pelvic pain and dyspareunia with continued treatment."

Non-Menstrual Pelvic Pain

The previously reported eight week top-line data demonstrated that elagolix is associated with a statistically significant reduction in Non-Menstrual Pelvic Pain daily scores when compared to placebo (ITT population, ANCOVA). This latest week twenty-four data show a further decrease in non-menstrual pelvic pain scores for those subjects who were initially randomized to the 150mg elagolix arm. Additionally, for those subjects who received elagolix 150mg after spending the initial eight weeks in the placebo group, the non-menstrual pelvic pain scores were reduced at Week 24.

Dysmenorrhea

The previously reported eight week top-line data demonstrated that elagolix is associated with a statistically significant reduction in dysmenorrhea daily pain scores when compared to placebo (ITT population, ANCOVA). The new week twenty-four data show a further decrease in dysmenorrhea pain scores for those subjects who were initially randomized to the 150mg elagolix arm. Additionally, for those subjects who received elagolix 150mg after spending the initial eight weeks in the placebo group, the dysmenorrhea pain scores were reduced at Week 24.

Dyspareunia

The previously reported eight week top-line data demonstrated that elagolix is associated with a statistically significant reduction in dyspareunia daily pain scores when compared to placebo (ITT population, ANCOVA). This week twenty-four data show a further decrease in dyspareunia pain scores for those subjects who were initially randomized to the 150mg elagolix arm. Additionally, for subjects who received elagolix 150mg after spending the initial eight weeks in the placebo group, the dyspareunia pain scores were reduced at Week 24.

Additional Endpoints

Utilizing the Patient Global Impression of Change (PGIC); a 1-7 scale where a score of 4 is "no change," 3 is "minimally improved," 2 is "much improved," and 1 is "very much improved;" elagolix showed improvement. At Week 24 the PGIC percentage of subjects scoring "much improved" or "very much improved" was 86% for those subjects on 150mg elagolix for all 24 weeks, and 74% for those subjects who received elagolix 150mg after spending eight weeks in the placebo group.

The Endometriosis Health Profile 5 (EHP-5) assesses the impact of endometriosis symptoms on five domains utilizing a 0-100 scale. The baseline mean score, for the EHP-5 core pain domain, across all subjects was 54. The EHP-5 core pain domain score showed improvement for subjects randomized to elagolix. At Week 24, the EHP-5 pain score decreased by 36 for those subjects on 150mg of elagolix for the entire 24 weeks of treatment, and by 30 for those subjects who received elagolix 150mg after spending eight weeks in the placebo group.

The Composite Pelvic Signs and Symptoms Scale (CPSSS), a 0-15 scale, was assessed at screening, Week 8, and Week 24 (Baseline score of 9.5). At Week 24 the reduction in the overall CPSSS score was a mean reduction of -5.5. During the placebo controlled portion of the study, the reduction from the Baseline score in the CPSSS showed a statistically significant improvement with 150mg of elagolix, -4.5; vs. placebo, -2.2; ($p < 0.0001$, ITT population, ANCOVA), as previously reported.

Safety Profile

In this clinical trial, the elagolix safety profile was consistent with previous trials. The discontinuation rate from the clinical trial due to adverse events was 5.1%. The most common adverse events during the 6 months of treatment were generally mild and transient: headache, nausea or hot flushes were reported by 9.9% of subjects. There were no elagolix treatment-related Serious Adverse Events.

Daisy PETAL Study Design

The US based Daisy PETAL study enrolled 137 endometriosis subjects into one of two treatment groups; elagolix 150 mg or placebo once daily for two months of treatment, in a double-blind design. Subjects then continued for four months of open-label elagolix treatment and assessments. Co-primary efficacy endpoints of dysmenorrhea (pelvic pain during menstruation) and non-menstrual pelvic pain (pelvic pain outside of menstruation) were evaluated to assess the improvement of baseline endometriosis symptoms following treatment with elagolix at Week 8 (vs. placebo) and at Week 24 for all study participants. These endpoints were employed based on extensive discussions with the Division of Reproductive and Urologic Products at the FDA; each utilized a daily scale (0-3) via daily electronic diary. Dyspareunia (painful intercourse) was also assessed using a daily scale (0-3) as an exploratory measure. The PGIC, EHP- 5 and the CPSSS were assessed as secondary efficacy endpoints.

End of Phase II Meeting

Additionally, the elagolix end of Phase II meeting with the FDA has been moved to the end of the first quarter of 2011.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including endometriosis, anxiety, depression, pain diabetes, irritable bowel syndrome, insomnia 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 June 2010, Abbott and Neurocrine announced a global collaboration agreement to develop and commercialize elagolix and all next-generation GnRH antagonists for women's and men's health.

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 elagolix clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase III clinical trials; risk associated with the Company's dependence on corporate collaborators for Phase III 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, 2009 and reports on Form 10-Q for the quarter ended September 30, 2010. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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