



Elagolix Successful in Six Month Lilac Petal Study; Safety and Efficacy Confirmed in Patients With Endometriosis

July 29, 2009

SAN DIEGO, July 29 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced new six month safety and efficacy results from its fourth Phase II clinical trial using its proprietary, orally-active non-peptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis. Consistent with previously reported six month (Petal Study) and three month (Lilac Petal Study) results, a favorable safety profile and clinically meaningful efficacy have again been confirmed through month six of the Lilac Petal Study. This newly available data also provides clinical confirmation of Neurocrine's extensive pharmacologic modeling related to the elagolix dose-response continuum. The outcome of primary interest at month six was the impact of the elagolix 250 mg dose on bone mineral density (BMD) as measured by dual energy X-ray absorptiometry (DXA) scanning.

Over the six month treatment period, elagolix 150 mg once daily had minimal impact on BMD (-0.80% mean change from baseline, femur; -0.66% mean change from baseline, spine). The 250 mg once daily dose, as expected, had slightly greater percentage change from baseline at month six (-1.0% femur, -1.6% spine). The 150 mg once daily BMD profile in this Lilac Petal Study is consistent with that previously demonstrated in the six-month Petal Study.

"We selected the 150 mg and 250 mg once daily doses for this study based upon predictions generated from extensive modeling of dose, estradiol and bone mineral density relationships. Prior to this study we anticipated that the 250 mg dose would provide exposure such that we would start to see an increased impact on bone mineral density in a small portion of study subjects. The Lilac Petal data confirm that our modeling of the dose-response curve was accurate," said Chris O'Brien, Chief Medical Officer of Neurocrine Biosciences, "Most importantly, we find that the 250 mg once-daily dose, chosen to inform us about the upper limit of dosing, met the pre-defined threshold for bone impact."

From an efficacy standpoint, the exploratory daily pain scales for Dysmenorrhea and Non-Menstrual Pelvic Pain demonstrated that women had minimal endometriosis pain symptoms at month six (mean scores of approximately 0.5 for both doses and both of the 0-3 scales). The overall assessment of benefit using the Patient Global Impression of Change (PGIC) revealed that 80% of elagolix 150 mg subjects and 79% of elagolix 250 mg subjects were "Much Improved" or "Very Much Improved" after six months of treatment. Subjects treated with elagolix also reported considerable improvement on the Endometriosis Health Profile (EHP-5), a validated endometriosis-specific scale which reveals the impact of treatment on a variety of health outcome domains. The core pain dimension of the EHP-5 documented the marked improvement of endometriosis-related pain and its impact on daily function for both doses of elagolix. The symptom improvement demonstrated by all of the efficacy assessments was maintained over the entire study duration and consistent with results across the entire Phase II program.

Dr. O'Brien also commented, "The magnitude of improvement and the related responder rates across the numerous efficacy scales were similar for both the 150 mg and 250 mg doses of elagolix and, given the superior bone safety profile, the 150 mg once daily dose appears to be the optimal choice for upcoming Phase III trials."

There were no signals of dose limiting adverse events or changes in clinical chemistry, hematology, urinalysis and ECG testing evident for either dose of elagolix; treatment over six months was generally safe and well tolerated. Discontinuation due to adverse events was 2.9% for 150 mg, 5.6% for 250 mg. Adverse Events reported by the 150 mg and 250 mg groups included nausea (8.7% and 8.3% respectively) and headache (8.7% and 5.6%), both consistent with prior trials. There were no drug-related Serious Adverse Events. After six months of treatment, the median values for serum estradiol were 41 pg/ml (150 mg) and 21 pg/ml (250 mg) in keeping with the dose-response modeling.

The Lilac Petal Study included six months of treatment; the initial three months randomized 155 subjects to one of three dosing arms (placebo, 150mg elagolix once daily, 250mg elagolix once daily). The primary endpoint (efficacy evaluation of elagolix vs. placebo) was previously reported at the conclusion of the month three placebo-controlled phase. A total of 125 subjects continued into the second three months of the trial; 38 subjects were re-randomized from their initial assignment of placebo to elagolix 150 mg (n=18) or elagolix 250 mg (n=20) once daily in a double-blind fashion. Those subjects who were initially randomized to elagolix continued under double-blind conditions.

Neurocrine will discuss these clinical trial results as part of its second quarter earnings call scheduled for July 30, 2009 at 8:30 a.m. Eastern Daylight Time (5:30 a.m. Pacific Daylight Time). Participants can access the live conference by dialing 1-800-895-0198 (US) or 785-424-1053 (International) using the conference passcode 7NEURO. The call can also be accessed via the webcast through the Company's website at <http://www.neurocrine.com>.

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, benign prostatic hyperplasia (BPH), irritable bowel syndrome (IBS) 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 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: Neurocrine Biosciences, Inc.

CONTACT:

Neurocrine Biosciences,
Investor Relations,
+1-858-617-7600

Web Site: <http://www.neurocrine.com>