



Neurocrine Announces Top-Line Results From 702 Study (Lilac PETAL Study) of Elagolix for Treatment of Endometriosis Pain

March 25, 2009

STUDY CONFIRMS EFFICACY IN VALIDATED ENDPOINTS; MIXED RESULTS IN EXPLORATORY ENDPOINTS

COMPANY TO HOST CONFERENCE CALL AND WEBCAST THURSDAY, MARCH 26TH AT 8:00AM ET / 5:00AM PT

SAN DIEGO, March 25 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced top-line efficacy and safety results from its fourth Phase II clinical trial using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis. The 702 study (Lilac PETAL study) randomized 155 patients with a confirmed diagnosis of endometriosis into three treatment arms; elagolix 150 mg once daily, elagolix 250 mg once daily, or placebo. After completion of the initial three months of treatment, placebo recipients were re-randomized to elagolix for an additional three months. The top-line results reflect the three-month placebo-controlled portion of the study.

"It is clear from this study and all of our previous studies that elagolix is a safe and effective treatment for endometriosis sufferers," said Kevin Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "This Phase II study provides the information we need to continue to move this program forward. While limitations were discovered in some of the new exploratory efficacy measures, elagolix again showed strong efficacy in the historical validated endometriosis measures, with an excellent safety profile."

The Lilac PETAL study assessed endometriosis pain through a variety of measures, several of which were never before utilized in an endometriosis trial. These exploratory endpoints included three daily assessments using an electronic diary: a numeric rating scale (NRS) for pain (scale 0-10); a dysmenorrhea pain assessment (scale 0-3); and a non-menstrual pelvic pain assessment (scale 0-3). The NRS is the pain assessment scale suggested by the National Institutes of Health (NIH) and the American Society of Reproductive Medicine. The dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) assessments were suggested by the Food and Drug Administration (FDA). The trial also utilized two validated efficacy endpoints consisting of the Patient Global Impression of Change (PGIC), an assessment of the changes in endometriosis-related pain; and the Endometriosis Health Profile 5 (EHP-5), a disease specific quality of life scale.

The top-line data confirm that elagolix provides endometriosis sufferers with clinical improvement of symptoms, coupled with an excellent safety and tolerability profile. However, certain aspects of the exploratory endpoints, used as an alternative to the validated Composite Pelvic Signs and Symptoms Scale (CPSSS), require additional dialogue with our expert advisors and regulatory authorities.

Efficacy Endpoints: Mean

Change From Baseline to Week 12	Placebo	150 mg	250 mg
Numeric Rating Scale (mean daily pain, 0-10)	-0.90	-1.19	-1.25
Numeric Rating Scale (peak pain, 0-10)	-1.33	-2.45*	-2.75**
Non-Menstrual Pelvic Pain (mean daily pain, 0-3)	-0.24	-0.27	-0.25
Dysmenorrhea (mean daily pain, 0-3)	-0.27	-0.68**	-0.76**
Endometriosis Health Profile (pain dimension, 0-100)	-11	-23*	-20***

Efficacy Endpoints: Status at Week 12

Patient Global Impression of Change (mean score, 1-7)	3.2	2.2**	2.3**
Patient Global Impression of Change (% subjects score ≥ 2)	33%	67%**	62%**

*p < 0.05

