Neurocrine Biosciences Announces Successful Elagolix PETAL Study in Endometriosis

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Phase II Study Meets Primary Bone Mineral Density and Secondary Efficacy Endpoints Company to Host Conference Call and Webcast Wednesday, September 3rd at 8:30 am ET / 5:30 am PT

SAN DIEGO, Sept 02, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive safety and efficacy results from its third Phase II clinical trial using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis. The PETAL study enrolled 252 patients, with a confirmed diagnosis of endometriosis, into three treatment groups; elagolix 150 mg once daily, elagolix 75 mg twice daily, or depo-subQ provera 104(TM) (DMPA) for six months of treatment.

The primary endpoint for the PETAL study was the percent change from baseline in mean bone mineral density (BMD) at Month 6 measured via dual energy X-ray absorptiometry (DXA). Pursuant to discussion with the FDA, the pre-specified statistical analysis plan sought to demonstrate that at Month 6, the lower bound of the 95% confidence interval did not exceed a -2.2% change in BMD from baseline. In women randomized to elagolix 150 mg once daily, the mean percent change from baseline at Month 6 was -0.11% for the spine (lower bound -0.70%) and -0.47% for the femur (lower bound -0.96%). The mean percent change from baseline at Month 6 for the elagolix 75 mg twice daily dosing arm was -1.30% for the spine (lower bound -1.86%) and -0.99% for the femur (lower bound -1.46%).

"The PETAL study demonstrates that elagolix did not induce significant bone loss over a six month treatment of patients with endometriosis, while providing both rapid and significant pain reduction in endometriosis symptoms," said Chris O'Brien, MD, Chief Medical Officer at Neurocrine. "Additionally, this study confirms our decision to move forward with once daily dosing."

Secondary endpoints for the PETAL study were evaluated to assess the improvement of endometriosis symptoms following treatment with elagolix. Improvement in endometriosis symptoms was documented using several different scales for endometriosis pain. The following were assessed before, during and after the six months of treatment:

-- Total Composite Pelvic Sign and Symptoms Score (CPSSS), a validated 0-15 scale that assesses five components of endometriosis pain severity, each on a 0-3 scale.
-- Dysmenorrhea (pelvic pain during menstruation), a component of the CPSSS; 0-3 scale (0=absence of pain, 1=mild pain, 2=moderate pain, 3=severe pain)
-- 98% of patients at baseline had moderate or severe dysmenorrhea.
-- Non-menstrual pelvic pain (pelvic pain outside of menstruation), a component of the CPSSS; 0-3 scale (0=absence of pain, 1=mild pain, 2=moderate pain, 3=severe pain)
-- 97% of patients at baseline had moderate or severe non-menstrual pelvic pain.
-- Responder Rate, percentage of patients who had a one point or greater decrease in pain score.
-- Visual Analog Scale (VAS) to assess pelvic pain levels using daily electronic diary.

Elagolix provided a clinically meaningful and statistically significant reduction in endometriosis pain from baseline as shown below. The magnitude of improvement is comparable to that demonstrated with the currently approved agents, leuprolide and DMPA.

	Screening Baseline	Elagolix 150mg qd	Elagolix 75mg bid	DMPA
CPSSS	9.1			
Week 4 mean		-3.9*	-3.7*	-3.8*
Week 24 mean		-5.5*	-5.2*	-5.3*
Dysmenorrhea	2.4			
Week 24 mean		-1.5*	-1.4*	-1.7*
Responder Rate		86%	74%	86%
Non-Menstrual Pelvic Pain	2.2			
Week 24 mean		-1.2*	-1.2*	-1.1*
Responder Rate		86%	77%	77%
VAS	78.7			
Week 24 mean		-31.8*	-33.4*	-35.5*

*ITT Analysis, p