



Neurocrine Announces Top-Line Results From 703 Study (Tulip PETAL Study) of Elagolix for Treatment of Endometriosis Pain

December 9, 2009

Primary Efficacy and Safety results consistent with previous studies Company to host conference call and webcast today at 5:00PM ET / 2:00PM PT

SAN DIEGO, Dec 09, 2009 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced top-line efficacy and safety results from the Tulip PETAL Study (703 Study), its fifth Phase 2 clinical trial using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis.

"The efficacy and safety data from the Tulip PETAL Study are consistent with what we have seen in our previous elagolix studies. Women recognize significant improvement in endometriosis symptoms across multiple time points using elagolix, coupled with an excellent safety profile," said Chris O'Brien, M.D., Chief Medical Officer at Neurocrine. "Although certain daily efficacy scales employed in this trial will not be used in subsequent trials, we have and will continue to obtain important information from this Phase 2 study. Given the placebo response in some of the secondary efficacy endpoints, we plan to perform extensive analyses to understand the differences between North American and Central Eastern European clinical trial sites and subjects, the impact of trial design differences and patient baseline characteristics, and continue our assessment of appropriate statistical methods as we plan for our pivotal trials."

Tulip PETAL Study Design and Baseline Characteristics

The Tulip PETAL study was conducted in six countries in the Eastern European region (Romania, Poland, Ukraine, Hungary, Russia and Bulgaria). The study randomized 174 patients with a laparoscopic diagnosis of endometriosis into four treatment arms: elagolix 150 mg once daily, elagolix 250 mg once daily, leuprorelin monthly depot (Prostap SR(R)), or placebo; in a double-blind, double-dummy design. After completion of the initial three months of treatment, placebo and leuprorelin depot recipients were re-randomized in a double-blind manner to one of the elagolix arms for an additional three months. The top-line results reflect the initial three-month portion of the study. Unlike the previous Lilac PETAL Study (702 Study), the Tulip PETAL Study did not include a single-blind placebo lead-in phase prior to the first three months of treatment. The study was designed to compare active treatments to placebo and was not powered for active treatment group comparisons.

The study population overall had less severe endometriosis compared to the Company's prior endometriosis clinical trials; the mean Composite Pelvic Signs and Symptoms Scale (CPSSS) score was 8.1 (0-15 scale). The mean baseline daily score for Dysmenorrhea was 1.3, while the daily Non-Menstrual Pelvic Pain mean score was 0.89; both measured on a 0-3 scale.

Efficacy Endpoint Results

LS Mean Change From Baseline	Placebo	Elagolix 150 mg	Elagolix 250 mg	Leuprorelin
Non-Menstrual Pelvic Pain (mean daily score, 0-3)	-0.13	-0.27 [^]	-0.28 [*]	-0.32 [*]
Dysmenorrhea □ (mean daily score, 0-3)	-0.30	-0.75 ^{**}	-0.86 ^{**}	-1.00 ^{**}

[^] p=0.06, ^{*}p<0.05, ^{**}p<0.0001; (active vs. placebo)

The preliminary data confirm that elagolix and leuprorelin are associated with reductions in Dysmenorrhea and Non-Menstrual Pelvic Pain daily scores when compared to placebo. As shown with all previous elagolix trials, symptoms of dysmenorrhea improved significantly in both elagolix treatment groups and with leuprorelin compared to placebo (p<0.0001). Additionally, the percentage of dysmenorrhea pain-free days was markedly higher in the elagolix treatment groups when compared to placebo (elagolix 150 mg, elagolix 250 mg, and leuprorelin, p<0.0001). Although statistical significance was achieved with the non-menstrual pelvic pain scale in this trial, the numeric changes are small, the dynamic range of the scale is small and, as previously stated, we do not intend to use this scale in subsequent trials.

Additional Efficacy Endpoint Results

The Patient Global Impression of Change showed a significant improvement at both Week 4 and Week 8 for the elagolix and leuprorelin arms, but the study had an unexpectedly high placebo effect in Week 12. On this 1-7 scale, a score of 4 is "no change," 3 is "minimally improved," 2 is "much improved," and 1 is "very much improved."

Patient Global Impression of Change Mean Score	Week 4	Week 8	Week 12
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Placebo	3.4	2.8	2.6
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Elagolix 150mg	3.0*	2.5	2.4
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Elagolix 250mg	2.9*	2.2*	2.2
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Leuprorelin	3.3	2.3*	2.1*
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*p<0.05; (active vs. placebo)

While the magnitude of improvement was similar to that in previous studies with elagolix, it appears that differences in population and study design may have contributed to the larger than expected response in the placebo recipients at Week 12. Full unblinding at the individual subject level, after the Week 30 visit, will allow for a detailed analysis of the nuances in the Week 12 placebo response with this scale.

Safety Profile

Elagolix was generally safe and well tolerated. The most common adverse events reported more often with elagolix than with placebo were nausea and headache (less than or equal to 12%), consistent with previous clinical studies of elagolix. These events were generally mild or moderate, transient and not associated with study discontinuation. There were no treatment-related Serious Adverse Events.

Hot flash frequency, recorded via an electronic diary after daily prompt, was greatest with leuprorelin (>4 per day during the third month). The mean hot flash frequency during the 3-month treatment period was 0.4 (placebo), 0.9 (elagolix 150 mg), 1.7 (elagolix 250 mg) and 2.6 (leuprorelin).

"These data add to the already excellent safety profile of elagolix gathered from more than 800 subjects who have participated in Phase 1 and 2 studies to date," says Kevin Gorman, Chief Executive Officer at Neurocrine. "Most importantly, we were very pleased to have a productive meeting with the FDA this summer. We now have an alternative assessment of non-menstrual pain in keeping with the Division's recommendations."

Six-Month Tulip PETAL Study Data

Treatment impact on bone mineral density after 6-months treatment will be reported upon study completion.

Daisy PETAL Study (901 Study)

In September 2009, Neurocrine initiated an additional Phase 2 study, the Daisy PETAL Study (901 Study) in the United States. This trial is currently randomizing up to 120 subjects at 37 centers and using a modification to the daily scales for Non-Menstrual Pain and Dysmenorrhea based upon our August 2009 discussions with the Division of Reproductive and Urologic Products at the FDA. Preliminary review of blinded data from the screening period indicates that the Non-Menstrual Pain scale has a wide dynamic range and therefore should be more appropriate for pivotal trials than the scale used in the 702 and 703 studies. The Company will use the top-line data, expected in May 2010, from the Daisy PETAL Study to inform our Phase 3 protocol design which it intends to submit as a Special Protocol Assessment to the FDA.

Conference Call and Webcast Information

The Company will host a live conference call and webcast to provide additional details of this study today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants can access the live conference call by dialing 1-800-862-9098(US) or 785-424-1051(International) using the conference ID: 7GNRH1. The call can also be accessed via the webcast through the Company's website at <http://www.neurocrine.com>.

If you are unable to attend the Webcast and would like further information on this announcement please contact the Investor Relations Department at Neurocrine Biosciences at (858) 617-7600. A replay of the Conference Call will be available approximately one hour after the conclusion of the call by dialing 1-800-688-7339(US) or 402-220-1347(International) using the

conference ID: 7GNRH1. The call will be archived for two weeks.

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 elagolix program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's elagolix program include, but are not limited to, risk that the Company's ongoing elagolix Phase 2 clinical trial will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase 3 clinical trials on the timelines projected or at all; risk associated with the Company's dependence on a corporate partner for elagolix Phase 3 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 partners for development, commercial manufacturing and marketing and sales activities for the Company's partnered programs; 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 reports of 10-Q for the quarter ended September 30, 2009. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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