



Neurocrine Biosciences Announces Positive Phase II Results With Its Orally Active GnRH Receptor Antagonist in Endometriosis

April 27, 2006

Expanded Six-Month Phase II Study to be Initiated in 3rd Quarter 2006

SAN DIEGO, April 27 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive results of its 'proof of concept', safety, efficacy and dose-finding Phase II clinical trial using its proprietary, orally-active small molecule Gonadotropin-Releasing Hormone (GnRH) receptor antagonist (NBI-56418).

The 3-month data comes from a multi-center, randomized, double-blind, placebo-controlled trial involving patients with a confirmed diagnosis of endometriosis. The study followed a parallel-group design in which 76 subjects were randomized to one of three treatment groups: placebo, 75 mg of NBI-56418, or 150 mg of NBI-56418 each administered once daily. Dosing started on Day 2 to Day 7 of the menstrual cycle and continued over 12 weeks with assessments of symptoms and signs of disease conducted at 4-week intervals using the Composite Pelvic Sign and Symptoms Score (CPSSS). Assessment of pain intensity was measured daily by a Visual Analog Scale (VAS) and collected by electronic diary. Full data regarding treatment impact on menses, hormones and a variety of metabolic biomarkers will be available at the completion of the ongoing 3-month safety follow-up period.

The primary endpoint of the study was reduction in the CPSSS, a validated clinical endpoint assessing subjective and objective elements of endometriosis. For the CPSSS, which has a maximum possible value of 15, mean values at baseline were 9.1, 8.5 and 8.0 for the placebo, 75 mg and 150 mg groups respectively. After treatment, there were reductions of 3.7 (placebo), 3.9 (75 mg) and 5.0 (150 mg) points in the score at week 12.

A patient-completed VAS was used to record pain intensity on a daily basis. Mean values for each 4-week interval were analyzed. This reveals dose-related improvements of 5 (placebo), 14 (75 mg) and 21 (150 mg) from baseline means of 31.2, 34.9 and 33.5 respectively. From a safety perspective, preliminary information on the adverse event rates show that there is little difference in the percentage of patients with an adverse event across treatment groups. Treatment-related adverse events occurred in 39%; 36%; and 26% of the patients in the placebo, 75 mg and 150 mg groups respectively. There was no increase in hot flashes in the NBI-56418 treated groups compared with placebo.

"We are pleased with the results demonstrating a robust treatment effect with NBI-56418 as shown by two clinical outcome measures. The reductions in scores at the highest dose were at the levels expected for peptide agonists such as Lupron Depot(R), which while efficacious, can lead to numerous undesirable side effects and limit utility. While not fully analyzed, preliminary results show that our GnRH antagonist demonstrated reductions in pain scores at the earlier time points in the study," said Chris O'Brien, M.D., Senior Vice President of Clinical Development for Neurocrine Biosciences.

"We have met our 'proof of concept' criteria in the clinical setting with our GnRH antagonist. Since the effects of estradiol reduction have been previously well correlated with a reduction of pain and other symptoms of endometriosis, we believe our oral GnRH antagonist will have significant therapeutic application in endometriosis. These new data are encouraging and suggest that sufficient estradiol suppression has been achieved for pain reduction while potentially avoiding reduction in bone mineral density and the other undesirable metabolic consequences of GnRH agonist therapies," said Wendell Wierenga, Ph.D. Executive Vice President of Research and Development for Neurocrine Biosciences.

"Based on these data, we are moving ahead to select the dosing regimen for an expanded six-month study in patients with endometriosis. This Phase IIb study will include several hundred patients and is expected to be initiated in the 3rd Quarter of 2006," added Wierenga.

Additional Phase II Clinical Studies Underway with GnRH for Endometriosis

Neurocrine is continuing to enroll patients in a second Phase II study in patients with endometriosis that was initiated in December 2005 to explore once vs. twice daily dosing. This study, a multi-dose, double-blind, placebo-controlled trial, is enrolling 72 patients and is designed to assess safety and efficacy over a three-month period. The primary endpoint of reduction in endometriotic pain will be measured by the CPSSS. Preliminary results are expected to be announced in the 4th Quarter of 2006.

Neurocrine will be initiating a Phase IIb study in the 3rd quarter of 2006 in which patients with endometriosis will receive NBI-56418 for six months. In addition to confirming the effect of NBI-56418 on endometriotic pain, this study is designed to assess the impact of treatment on bone mineral density. The six-month results, together with data from ongoing Phase II studies will be the basis for securing agreement to a registration plan acceptable to the FDA, estimated to occur next year. Finally, the company

recently started a Phase I study in male volunteers as part of the Benign Prostate Hyperplasia development program. The Company expects to provide more details on the six month trial together with ongoing results from the Phase I trial in the 3rd Quarter of 2006.

Background

Nearly 7 million women in the US have endometriosis, many with severe or moderate symptoms. Many patients are believed to be misdiagnosed or undiagnosed. The impact of endometriosis on the lives of sufferers can be significant -- adversely affecting the ability of patients to maintain relationships and employment.

Surgery and medical treatments are currently available for women with endometriosis. Surgery is not acceptable to many patients. Although indicated for endometriosis, medical therapies such as the injectable GnRH agonists leuprolide or injectable progesterone are associated with a range of potentially unacceptable side effects including bone loss. Consequently, prescribing physicians often reserve these medical interventions for patients with severe endometriosis. For the majority of endometriosis patients suffering from moderate or mild symptoms, the remaining treatment options, oral contraceptives and analgesics, are only partially effective.

Based on the large number of endometriosis sufferers and the significant level of unmet need, we believe a highly attractive commercial opportunity exists for a new product that is able to offer patients and prescribers effective control of endometriosis symptoms with limited side effects.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical Company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, diabetes, irritable bowel syndrome, and autoimmunity. 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 including the risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of pharmaceutical products. Specifically, the Company faces risks and uncertainties arising out of its GnRH clinical development program including risk that its lead candidate, NBI-56418, will not proceed to later stage clinical trials; risk that should NBI-56418 may prove unsuitable for continued development, the Company will not be successful in identifying alternative GnRH antagonist products that are safe and effective; risk relating to the Company's dependence on contract manufacturers for GnRH antagonist product clinical drug supply and compliance with regulatory requirements for marketing approval; risks that the Company may be dependent on corporate collaborators for commercial manufacturing and marketing and sales activities for its GnRH antagonist products; uncertainties relating to patent protection for the Company's GnRH antagonist products 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 GnRH antagonist products; risk that the Company will be unable to raise additional funding required to complete development of its GnRH antagonist product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2005. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

CONTACT: Elizabeth Foster or Claudia Woodworth, both of Neurocrine Biosciences, Inc., +1-858-617-7600/

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