Neurocrine Biosciences Announces the Start of Phase IIb Study of Elagolix in Uterine Fibroids

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STUDY WILL EVALUATE SIX MONTHS OF TREATMENT IN 280 SUBJECTS

SAN DIEGO, March 27, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced that a Phase IIb clinical trial to evaluate elagolix for the treatment of uterine fibroids has been initiated. Elagolix is an oral gonadotropin-releasing hormone (GnRH) antagonist, in development by AbbVie for the treatment of uterine fibroids and endometriosis. Neurocrine and AbbVie entered into a collaboration and license agreement for elagolix during 2010.

"Based on the positive data from the uterine fibroids Phase IIa trial, AbbVie has progressed elagolix into Phase IIb for uterine fibroids," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "We are pleased with this advancement, as well as the ongoing Phase III program in endometriosis, and look forward to the continued development of elagolix in these two disease states which both have high unmet medical needs."

The Phase IIb uterine fibroids study is a randomized, parallel, double-blind, placebo-controlled clinical trial evaluating elagolix in women with heavy uterine bleeding associated with uterine fibroids. This study will evaluate 280 subjects over a six-month placebo-controlled dosing period. The primary efficacy endpoint of the study is an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints will be evaluated including assessing the change in fibroid volume and hemoglobin. Bone mineral density will be assessed via DXA scan at baseline, the conclusion of dosing, and six months post-dosing.

About Uterine Fibroids

Uterine fibroids are benign hormonally responsive tumors that form in the wall of the utervus. They are the most common type of abnormal growth found in a woman's pelvis and are most frequent in women aged 30–50 years. Uterine fibroids can cause pelvic pain, reproductive problems, and severe bleeding that can lead to anemia. Due to the severity of symptoms, treatment sometimes includes a variety of surgical interventions. Uterine fibroids is a leading indication for hysterectomy in the United States, with approximately 250,000 hysterectomies performed each year related to uterine fibroids.

About Neurocrine Biosciences

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, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, 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 include, but are not limited to, risk that elagolix will not proceed to later stage clinical trials for uterine fibroids; risk that the elagolix clinical trials will fail to demonstrate that elagolix is safe and effective for the treatment of uterine fibroids; risk that elagolix Phase III clinical trials will be delayed or not successfully initiated; risk that elagolix Phase III clinical trials will fail to demonstrate that elagolix is safe and effective for the treatment of endometriosis; risk associated with the Company's dependence on corporate collaborators for clinical 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, 2012. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

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