Neurocrine Biosciences Announces the Start of Second Phase III Study of Elagolix in Endometriosis

August 29, 2013

SAN DIEGO, Aug. 29, 2013 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced that the second Phase III pivotal trial to evaluate elagolix for the treatment of endometriosis has been initiated by AbbVie. This second Phase III trial is similar in design to the initial Phase III trial which is scheduled to provide top-line data in the third quarter of 2014 and complete in 2015.

"We are pleased that the second Phase III study in endometriosis has been launched," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences. "The two Phase III trials will serve as the foundation for the anticipated NDA filing which is on track for 2016."

The second Phase III trial is a 24-week multinational, randomized double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 788 women, age 18-49, with moderate-to-severe endometriosis-associated pain. It will be conducted at more than 200 sites globally.

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.

About Endometriosis

Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain, related both to menstruation (dysmenorrhea) as well as chronic pelvic pain throughout the menstrual cycle, and is a leading cause of infertility. The World Endometriosis Research Foundation estimates that there are approximately 100 million women worldwide who suffer from endometriosis. The annual direct and indirect costs of endometriosis are estimated to exceed $20 billion in the United States alone.

About Elagolix

Elagolix inhibits gonadotropin releasing hormone (GnRH) receptors in the pituitary gland and ultimately reduces circulating sex hormone levels. To date, elagolix has been studied in over 20 clinical trials totaling more than 1,000 subjects. At the time of expected NDA filing for endometriosis, elagolix will have been studied in over 25 clinical trials and in excess of 3,000 subjects. A Phase IIb trial of elagolix for the treatment of uterine fibroids is also ongoing.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. is a clinical stage drug discovery company primarily focused on neurological and endocrine based diseases and disorders. The Company discovers and develops innovative pharmaceuticals, in diseases with high unmet medical needs or where the existing drug classes are inadequate, through a disciplined yet entrepreneurial process. Utilizing a portfolio approach to drug discovery, Neurocrine has multiple small molecule drug candidates at various stages of pharmaceutical development. Neurocrine's two lead late stage clinical programs are elagolix, a GnRH antagonist for women's health that is partnered with AbbVie Inc., and a wholly owned VMAT2 inhibitor for the treatment of movement 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 uterine fibroid 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 and report on Form 10-Q for the quarter ended June 30, 2013. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Investor Relations, (858) 617-7600