AbbVie Announces Positive Top-Line Results From Phase 3 Study of Investigational Medicine Elagolix in Patients with Endometriosis

January 8, 2015
- Study meets co-primary efficacy endpoints; results show treatment with elagolix reduces endometriosis-associated pain (dysmenorrhea and non-menstrual pelvic pain) compared to placebo
- Results from the first of two six-month, Phase 3 studies
- Full data to be presented at a future date

NORTH CHICAGO, Ill., Jan. 8, 2015 /PRNewswire/ -- AbbVie (NYSE: ABBV), in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), announced positive top-line results from the first of two ongoing Phase 3 clinical trials, designed to evaluate the efficacy and safety of elagolix in premenopausal women with endometriosis. Results from the trial show that after six months of treatment, both doses of elagolix (150 mg once daily and 200 mg twice daily) met the study's co-primary endpoints ($p<0.001$) of reducing scores of non-menstrual pelvic pain (NMPP) and menstrual pain (or dysmenorrhea), associated with endometriosis, at month three, as well as month six, as measured by the Daily Assessment of Endometriosis Pain scale.

Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related to menstruation as well as chronic pelvic pain throughout the menstrual cycle, and is a leading cause of infertility. The World Endometriosis Research Foundation estimates that endometriosis affects one in ten women during their reproductive years, representing approximately 176 million women worldwide.

"Endometriosis is a condition in which the tissue that normally lines the inside of a woman's uterus grows outside the uterus, and is often associated with severe, and at times, debilitating pain," said Michael Severino, M.D., Executive Vice President, Research and Development and Chief Scientific Officer, AbbVie. "The positive results from this trial represent a significant milestone in the development of elagolix as a potential new treatment option for patients suffering from endometriosis."

The observed safety profile of elagolix in this Phase 3 trial was consistent with observations from prior studies. Among the most common adverse events (AEs) were hot flush, headache, nausea and fatigue. While most AEs were similar across treatment groups, some, such as hot flush and bone mineral density (BMD) loss were dose-dependent. Overall discontinuation rates were similar across treatment groups and discontinuations specifically due to AEs were 5.9 percent, 6.4 percent, and 9.7 percent for placebo, 150 mg once daily and 200 mg twice daily, respectively.

The top-line results are from a six-month, group-level analysis. Patients in the trial will continue on in either post-treatment follow-up or a blinded six-month extension study. AbbVie intends to present detailed results from this trial at a future medical conference.

Trial Design
The Phase 3 trial (M12-665) is a 24-week, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 872 women, age 18 to 49, with moderate-to-severe endometriosis-associated pain. It is being conducted at approximately 160 sites in the United States, Puerto Rico and Canada.

A second Phase 3, randomized, multinational, double-blind, placebo-controlled trial (M12-671) evaluating elagolix in patients with moderate-to-severe endometriosis-related pain is ongoing and results are expected in late 2015.

About Elagolix
Elagolix, currently being investigated in patients with pain from endometriosis, inhibits gonadatropin releasing hormone (GnRH) receptors in the pituitary gland and ultimately reduces circulating sex hormone levels. To date, elagolix has been studied in over 40 clinical trials totaling more than 3,000 patients. A Phase 2b trial of elagolix for the treatment of uterine fibroids is also ongoing.

Elagolix is the proposed International Nonproprietary Name (INN).

About AbbVie
AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie employs approximately 25,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

Forward-Looking Statements
Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry.

Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2013 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission.

AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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