AbbVie Announces Positive Pivotal Phase 3 Data Demonstrating Investigational Medicine Elagolix Reduces Menstrual and Non-Menstrual Pelvic Pain Associated with Endometriosis at the American Society for Reproductive Medicine Scientific Congress

October 19, 2016

- Elagolix shows superiority compared to placebo in reducing daily menstrual and non-menstrual pelvic pain associated with endometriosis
- Clinical development program includes the largest endometriosis clinical trials conducted to date, with nearly 1,700 patients in two pivotal trials
- FDA New Drug Application anticipated in 2017

NORTH CHICAGO, Ill. , Oct. 19, 2016 /PRNewswire/ -- AbbVie (NYSE: ABBV), a global biopharmaceutical company in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), today announced detailed results from two replicate pivotal Phase 3 clinical trials evaluating the efficacy and safety of Elagolix in premenopausal women who suffer from endometriosis. The data demonstrate that, compared to placebo at month three and month six, patients treated with Elagolix reported statistically significant reductions in scores for menstrual pain (dysmenorrhea, DYS) and non-menstrual pelvic pain (NMPP) associated with endometriosis as measured by the Daily Assessment of Endometriosis Pain scale. The results were presented at the 72nd American Society for Reproductive Medicine Scientific Congress & Expo (ASRM) in Salt Lake City, as well as additional abstracts.

"Endometriosis is often characterized by chronic pelvic pain, and can have a significant impact on patient function and quality of life," said Hugh S. Taylor, M.D., study investigator and Chair of the Department of Obstetrics, Gynecology and Reproductive Sciences, Yale School of Medicine. "The results presented today are encouraging for patients and demonstrate that Elagolix has the potential to be an important treatment option for women suffering from pain related to endometriosis."

In the two studies, both doses of Elagolix administered orally demonstrated a statistically significant (p ? 0.001) improvement versus placebo in the percentage of DYS and NMPP responders. In the first study, at month three, 46 percent of patients treated with 150 mg once daily and 76 percent of patients treated with 200 mg twice daily of Elagolix were classified as DYS responders, versus 20 percent of patients in the placebo group. Fifty percent of patients treated with 150 mg once daily and 55 percent of patients treated with 200 mg twice daily of Elagolix were classified as NMPP responders, versus 36 percent of patients in the placebo group. The second pivotal Phase 3 study demonstrated similar results.

"These results from the largest clinical trials ever conducted in endometriosis support AbbVie's continued efforts to pursue regulatory filing of Elagolix as a potential new treatment option for the disease's most prevalent symptoms," said Rob Scott, M.D., Vice President, Development and Chief Medical Officer, AbbVie. "There have been few recent scientific advancements for patients suffering from endometriosis and physicians are in need of additional treatment options to help manage this chronic and painful disease."

At ASRM, AbbVie will present multiple abstracts highlighting primary and secondary efficacy and safety endpoint data from the Phase 3 studies as well as research on the economic burden of endometriosis and endometriosis-related surgery in women in the United States. AbbVie plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) for endometriosis in 2017.

The safety profile of Elagolix was consistent across both Phase 3 trials and also consistent with prior Elagolix studies. In the first study, the most frequently reported adverse events (AEs) assessed over six months were hot flush (7%, 24%, 42% for placebo, 150 mg once daily and 200 mg twice daily, respectively), headache (10%, 15%, 17% for placebo, 150 mg once daily and 200 mg twice daily, respectively), and nausea (14%, 10%, 16% for placebo, 150 mg once daily and 200 mg twice daily, respectively). As anticipated by its mechanism of action, some AEs, such as hot flush were dose-dependent. The majority of hot flushes (>50%) were mild in severity. Discontinuations due to AEs were 5.9 percent and 6.1 percent for placebo in study 1 and study 2, respectively, 6.4 percent and 4.4 percent for 150 mg once daily in study 1 and study 2, respectively and 9 percent and 10 percent for 200 mg twice daily in study 1 and study 2, respectively.

Trial Design

The first pivotal Phase 3 trial (M12-665) was a 24-week, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of Elagolix in 872 women, age 18 to 49, with moderate-to-severe endometriosis-associated pain. It was conducted at 175 sites in the United States, Puerto Rico and Canada. An extension study (M12-667) permitted some women to be treated for an additional six months with these doses.

The second pivotal Phase 3 trial (M12-671) employed the same design as the first pivotal Phase 3 trial, was multinational, and included 815 women with moderate-to-severe endometriosis-associated pain across 226 sites in 13 countries (US and 12 ex-US countries). There was equal representation of enrollment from US and Ex-US countries. An extension study (M12-821) permitted some women to be treated for an additional 6 months with these doses. Together, these two Phase 3 pivotal studies evaluated the safety and efficacy of Elagolix in nearly 1,700 women with moderate-to-severe endometriosis associated pain, representing the largest prospective randomized endometriosis trials conducted to date.

About Endometriosis

Endometriosis occurs when the cells that normally line the uterus begin to grow outside of the uterus, leading to chronic pelvic pain, pain with intercourse and heightened pain with menses.[1] These growths are called lesions and can occur on the ovaries, the fallopian tubes, or other areas near the uterus, such as the bowel or bladder.[2,3] There is no cure for endometriosis, and the associated pain is currently managed with oral contraceptives, progestins, danazol, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and GnRH agonists, many of which are not specifically indicated for the treatment of endometriosis. In more extensive cases, surgical interventions (e.g., laparotomy or laparoscopy) are often pursued, and may not be curative for all individuals.[4]

About Elagolix

Elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, is an orally administered, short-acting molecule that blocks endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration results in rapid, reversible, dose-dependent inhibition of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) secretion, leading to reduced ovarian production of the sex hormones, estradiol and progesterone, while on therapy. Elagolix is currently being investigated in diseases that are mediated by sex hormones, such as uterine fibroids and endometriosis. To date, Elagolix has been studied in over 40 clinical trials totaling more than 3,000 subjects. Phase 3 trials of Elagolix for the management of uterine fibroids are ongoing.

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. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 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 2015 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.

[1] Mayo Clinic. Diseases and Symptoms: Endometriosis Fact Sheet. http://www.mayoclinic.org/diseases-conditions/endometriosis/basics/symptoms/con-20013968. Accessed February 1, 2016.

[2] MM, Silverberg K, Olive DL. Endometriosis and Adenomyosis. IN: Copeland LJ, Jarrell JF, eds. Textbook of Gynecology. 2nd ed. Philadelphia, PA: WB Saunders; 2000:687-722.

[3] The American College of Obstetricians and Gynecologists. ACOG Education Pamphlet AP013: Endometriosis. Washington, DC: September 2008. ISSN 1074-8601.

[4] Mayo Clinic. Diseases & Conditions: Endometriosis Fact Sheet. http://www.mayoclinic.org/diseases-conditions/endometriosis/diagnosis-treatment/treatment/txc-20236449. Accessed February 1, 2016.

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