AbbVie Announces Positive Topline Results from Second Phase 3 Study Evaluating Investigational Elagolix in Women with Uterine Fibroids

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- Second of two pivotal Phase 3 studies (ELARIS UF-II) met primary efficacy endpoint and all ranked secondary endpoints
- Results were consistent with the first Phase 3 study (ELARIS UF-I) and demonstrated elagolix, in combination with low-dose add-back therapy, reduced heavy menstrual bleeding compared to placebo
- Data will be presented at an upcoming medical conference

NORTH CHICAGO, Ill., March 13, 2018 /PRNewswire/ -- AbbVie (NYSE:ABBV), a global research and development-based biopharmaceutical company, in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), announced that the Phase 3 ELARIS UF-II study (M12-817) of elagolix met its primary endpoint. Results from the second of two pivotal Phase 3 studies demonstrated at month six that elagolix (300 mg twice daily), in combination with low-dose hormone (add-back) therapy (estradiol 1.0 mg / norethindrone acetate 0.5 mg), reduced heavy menstrual bleeding with 76.2 percent ($p<0.001$) of women with uterine fibroids achieving clinical response compared to placebo (10.1 percent), as measured by the alkaline hematin method. Clinical response was defined as menstrual blood loss volume of less than 80 mL during month six and a 50 percent or greater reduction in menstrual blood loss volume from baseline to month six. The study also met all ranked secondary endpoints ($p<0.02$) at month six.[1]

Uterine fibroids are the most common type of abnormal growth in a woman's pelvis and can affect up to 80 percent of women by age 50.[2] Fibroids can be asymptomatic, but in approximately 25 percent of women[3], fibroids can cause symptoms, such as heavy menstrual bleeding, painful periods, vaginal bleeding at times other than menstruation, and anemia.[2] African American women are more likely to experience fibroids and do so at a younger age.[4]

"Millions of women currently diagnosed with uterine fibroids are faced with limited non-surgical options," said Dawn Carlson, M.D., M.P.H., vice president, general medicine development. "The results from this study demonstrate elagolix has the potential to be an important oral treatment option for women suffering from uterine fibroids."

Hypoestrogenic effects, such as hot flush and reduction in bone mineral density, from elagolix treatment were observed in the study. The overall safety profile for elagolix was consistent with what was observed in Phase 2 studies and the first Phase 3 study (ELARIS UF-I) in uterine fibroids.[1,5-6] Data from the ELARIS UF-II Phase 3 study will support regulatory submissions for elagolix. Safety data, including most common adverse events, continue to be collected in this ongoing study.

The topline results from this six-month primary analysis were consistent with topline results from the ELARIS UF-I study reported in February 2018 and will be presented at an upcoming medical conference. Women in the study will continue in either post-treatment follow-up or a blinded six-month extension study.

About Uterine Fibroids

Uterine fibroids (also called leiomyomas or myomas) are non-cancerous, hormonally-responsive muscle tissue tumors of the uterus.[3] Fibroids are the most common type of abnormal growth in a woman's pelvis and can affect about 20-80 percent of women by age 50.[2] Fibroids can range in size, shape, number and location.[2] Fibroids can be asymptomatic, but in some women, fibroids can cause symptoms such as heavy menstrual bleeding, painful periods, vaginal bleeding at times other than menstruation, anemia, pain in the abdomen or lower back, pain during sex, difficulty urinating or frequent urination, constipation, rectal pain or difficulty getting pregnant.[2] Treatment options for uterine fibroids include surgery (hysterectomy, myomectomy), hysteroscopy, endometrial ablation, uterine artery embolization, magnetic resonance imaging-guided ultrasound and medical management with treatments such as oral contraceptives, progestins, selective progesterone receptor modulators, and GnRH agonists, some of which are not specifically indicated for the treatment of uterine fibroids.[2]

About Study Design

ELARIS UF-II is the second of two replicate, pivotal, six-month Phase 3 studies evaluating the safety, tolerability and efficacy of elagolix alone (300 mg twice daily) and in combination with low-dose hormone (add-back) therapy (estradiol 1.0 mg / norethindrone acetate 0.5 mg), in women with uterine fibroids. Study participants were premenopausal women, age 18–51 years old, with a diagnosis of uterine fibroids documented by a pelvic transvaginal and transabdominal ultrasound (TAU, TVU). The primary endpoint assessed the reduction in heavy menstrual bleeding compared to placebo as measured by the alkaline hematin method, an objective measurement of total menstrual blood loss based on quantitation of menstrual blood collected on sanitary products. Clinical response was defined as menstrual blood loss volume of less than 80 mL during month six and a 50 percent or greater reduction in menstrual blood loss volume from baseline to month six. The ranked secondary endpoints included measures of bleeding, bleeding suppression and hemoglobin changes. The study was conducted at approximately 100 sites in the United States and Canada.

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 rapidly reversible, dose-dependent inhibition of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) secretion, leading to reduced ovarian production of the ovarian sex hormones, estradiol and progesterone, while on therapy. Elagolix is currently being investigated in diseases that are mediated by ovarian sex hormones, such as uterine fibroids and endometriosis. To date, elagolix has been studied in over 40 clinical studies, totaling more than 3,700 subjects.

Phase 3 studies of elagolix for the management of uterine fibroids are ongoing.

About AbbVie

AbbVie is a global, research and development-based biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.com. Follow @AbbVieUS on Twitter, Facebook or LinkedIn.

Forward-Looking Statements

Some statements in this news release are, or may be considered, 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," of AbbVie's 2017 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 Data on File, ABVRRTI65900

2 National Women's Health Network: Uterine Fibroids. https://www.nwhn.org/uterine-fibroids/. Accessed March 31, 2017.

3 Borah BJ, Nicholson WK, Bradley L, Stewart EA. The impact of uterine leiomyomas: a national survey of affected women. Am J Obstet Gynecol. 2013;209(4):319.e1–319.e20.

4 The American College of Obstetricians and Gynecologists: FAQ Uterine Fibroids. http://www.acog.org/-/media/For-Patients/faq074.pdf?dmc=1&ts=20170329T1658263942. Accessed March 31, 2017.Surrey, E., Taylor, H.S., Giudice, L.C., Singh, S., Abrao, M.S., Lessey, B.A., Duan, W.R., Peloso P.M., Schwefel, B. Chwalisz, K. Long-term safety and efficacy of elagolix treatment in women with endometriosis associated pain: primary results from two phase 3 extension studies. Fert. Sterl. 2017; 108: e95.

5 Archer, D.F., Stewart, E.A., Jain, R.I., Feldman, R.A., Lukes, A.S., North JD, Soliman, A.M., Gao, J., Ng, J.W., Chwalisz, K. Elagolix for the management of heavy menstrual bleeding associated with uterine fibroids: results from a phase 2a proof-of-concept study. Fert. Sterl. 2017; 108 (1):152-160.e4.

6 Stewart EA, Owens C, Duan R, Gao H, Chwalisz K. Elagolix Treatment in Women with Heavy Menstrual Bleeding-associated with Uterine Fibroids: Efficacy and Safety Results from a Phase 2B Study. Poster presented at American Association of Gynecologic Laproscopists: November 12-16th, 2017. Washington, DC.

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