



## AbbVie Presents New Investigational Data for Elagolix at the 2018 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting

April 27, 2018

- Seven presentations of elagolix data highlight AbbVie's research in endometriosis and uterine fibroids
- Primary and secondary efficacy and safety data to be presented from two extension Phase 3 studies evaluating the use of elagolix in women with endometriosis with associated moderate to severe pain
- New productivity data from a Phase 2b study evaluating elagolix in women with uterine fibroids will also be presented

NORTH CHICAGO, Ill., April 27, 2018 /PRNewswire/ -- AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), today announced that data for elagolix, an investigational, orally administered gonadotropin-releasing hormone (GnRH) receptor antagonist, will be presented at the 2018 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting in Austin, TX.

"We strive to improve care for women living with endometriosis and uterine fibroids," said Dawn Carlson, M.D., M.P.H., vice president, general medicine development. "These presentations highlight safety and efficacy data for elagolix and demonstrate AbbVie's commitment in the field of women's health."

Primary and secondary efficacy and safety data from two extension Phase 3 studies evaluating the use of elagolix in women with endometriosis with associated moderate to severe pain will be showcased. In addition, new data highlighting rescue analgesic use, fatigue scores and pain burden from pivotal Phase 3 studies of elagolix in women with endometriosis and new data from a Phase 2b study highlighting the impact of elagolix on productivity in women with uterine fibroids will also be presented. Elagolix is not approved by regulatory authorities and its safety and efficacy have not been established.

### Oral Presentations

- *Long-Term Safety and Efficacy of Elagolix Treatment in Women with Endometriosis-Associated Pain – #11OP; Surrey et al.*; Saturday, April 28, 2018; 9:00AM to 9:10AM CT

### Posters

- *Endometrial Evaluation in Elagolix-Treated Women With Uterine Fibroids and Heavy Menstrual Bleeding – #25G; Carr et al.*; Saturday, April 28, 2018; 9:00AM to 10:00AM CT
- *Elagolix Reduces Productivity Losses in Uterine Fibroids Patients with Heavy Menstrual Bleeding – #33G; Diamond et al.*; Saturday, April 28, 2018; 9:00AM to 10:00AM CT
- *Elagolix Reduces Fatigue in Patients with Moderate to Severe Endometriosis Pain – #34G; Diamond et al.*; Saturday, April 28, 2018; 9:00AM to 10:00AM CT
- *Decreased Rescue Analgesic Use with Elagolix Treatment in Women with Endometriosis-Associated Pain – #35G; Taylor et al.*; Saturday, April 28, 2018; 9:00AM to 10:00AM CT
- *Long-term Effect of Elagolix on Bone Mineral Density in Women with Endometriosis-Associated Pain – #38G; Archer et al.*; Saturday, April 28, 2018; 9:00AM to 10:00AM CT
- *Baseline Burden of Endometriosis-Associated Pain Among Women in Two Phase 3 Elagolix Studies – #10Q; Leyland et al.*; Sunday, April 29, 2018; 3:30PM to 4:30PM CT

### About Endometriosis

Endometriosis is a chronic and painful disease that affects an estimated 1 in 10 women of reproductive age.<sup>1</sup> Endometriosis occurs when tissue similar to that normally found in the uterus begins to grow outside of the uterus, leading to long-term pelvic pain (during or between periods), pain with intercourse and other painful symptoms.<sup>1</sup> 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.<sup>1, 2</sup> Estrogen fuels the growth of lesions.<sup>2</sup> There is no cure for endometriosis,<sup>3</sup> 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.<sup>1,4</sup> In more extensive cases, surgical interventions (e.g., laparotomy or laparoscopy) are often pursued, and may not be curative for all individuals.<sup>4</sup>

### About Uterine Fibroids

Uterine fibroids (also called leiomyomas or myomas) are non-cancerous, hormonally-responsive muscle tissue tumors of the uterus.<sup>5</sup> Fibroids are the most common benign tumors in women and can affect up to 80 percent of women by age 50.<sup>6,7</sup> African American women are more likely to experience fibroids and do so at a younger age.<sup>7</sup> Fibroids can range in size, shape, number and location.<sup>5</sup> Fibroids can cause symptoms that affect daily life in approximately 25% of women.<sup>7</sup> Symptoms may include 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.<sup>5</sup> 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 gonadotropin-releasing hormone (GnRH) agonists, some of which are not specifically indicated for the treatment of uterine fibroids.<sup>5</sup>

### 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 readily 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 trials totaling more than 3,700 subjects. In Q4 2017, the FDA granted priority review for AbbVie's NDA for endometriosis. The Prescription Drug User Fee Act (PDUFA) date for the FDA to complete its review is in Q3 2018. Phase 3 trials 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](http://www.abbvie.com). Follow [@AbbVieUS](https://twitter.com/AbbVieUS) on Twitter, [Facebook](https://www.facebook.com/AbbVieUS) or [LinkedIn](https://www.linkedin.com/company/abbvie).

### 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.

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<sup>1</sup> The American College of Obstetricians and Gynecologists. ACOG Education Pamphlet AP013: Endometriosis. Washington, DC: September 2008. ISSN 1074-8601.

<sup>2</sup> Giudice, LC. Clinical practice: Endometriosis. New England Journal of Medicine. 2010; 362:2389–2398.

<sup>3</sup> Greene, AD, Lang, SA, Kendzierski, JA, Sroga-Rios, JM, Herzog, TJ, Burns, KA. Endometriosis: where are we and where are we going? Reproduction. 2016; 152 (3):R63-78.

<sup>4</sup> Mayo Clinic. Diseases & Conditions: Endometriosis Fact Sheet. March 9, 2018. <https://www.mayoclinic.org/diseases-conditions/endometriosis/symptoms-causes/syc-20354656>. Accessed April 18, 2018.

<sup>5</sup> 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.

<sup>6</sup> National Women's Health Network: Uterine Fibroids. <https://www.nwhn.org/options-shrink-fibroids/>. Accessed April 18, 2018.

<sup>7</sup> Borah BJ, Nicholson WK, Bradley L, Stewart EA. The impact of uterine leiomyomas: a national survey of affected women.

SOURCE AbbVie

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