



## AbbVie Presents Pivotal Phase 3 Data on Investigational Treatment Elagolix at the World Congress on Endometriosis

May 17, 2017

- Primary and secondary efficacy and safety data to be presented from two pivotal Phase 3 studies evaluating the use of elagolix in endometriosis-associated pain

- New hormone and ovulation data will also be presented from a Phase 1 clinical study

NORTH CHICAGO, Ill., May 17, 2017 /PRNewswire/ -- AbbVie (NYSE: ABBV), a global biopharmaceutical company, in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), today announced that data from two replicate Phase 3 studies evaluating the efficacy and safety of elagolix, an investigational, orally administered gonadotropin-releasing hormone (GnRH) antagonist, in premenopausal women with endometriosis, will be presented at the 13th World Congress on Endometriosis in Vancouver, Canada. New data highlighting the effects of two different elagolix doses and dosing regimens on ovarian sex hormones and ovulation will also be presented.

"Endometriosis is associated with painful symptoms that can be debilitating and there have been few recent medical advancements for women suffering from this disease," said Rob Scott, M.D., Vice President, Development and Chief Medical Officer, AbbVie. "These results highlight the efficacy and safety profile of elagolix and demonstrate its potential to be an important treatment option for women suffering from endometriosis."

### AbbVie Oral Presentations:

- *Elagolix, an Oral Gonadotropin-Releasing Hormone Antagonist, for the Management of Endometriosis-Associated Pain: Safety and Efficacy Results From Two Double-Blind, Randomized, Placebo-Controlled Studies*; Taylor H et al.; Session MS08: Advances in Medical Treatments; Friday, May 19, 2017; 1:15PM to 3:15PM PT
- *The Effect of Elagolix on Bone Mineral Density: Safety Results From Two Randomized, Placebo-Controlled Studies in Women With Endometriosis-Associated Pain*; Duan W.R., et al.; Session MS08: Advances in Medical Treatments; Friday, May 19, 2017; 1:15PM to 3:15PM PT
- *The Effect of Elagolix on the Endometrium: Results From Two Randomized, Placebo-Controlled Studies in Women With Endometriosis-Associated Pain (EAP)*; Lessey B et al.; Session FC08: Endometrium; Saturday, May 20, 2017; 10:45AM to 11:45AM PT

### AbbVie Posters:

- *Use of Elagolix For the Management of Endometriosis-Associated Pain: Secondary Efficacy Results From Two Randomized, Placebo-Controlled Studies*; Taylor H et al.; Poster #PS02-094; Thursday, May 18 and Friday, May 19, 2017; 5:15PM to 6:30PM PT
- *Effects of Elagolix, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, on Gonadotropins and Ovarian Sex Hormones in Healthy Premenopausal Women*; Ng J et al.; Poster #PS02-003; Thursday, May 18 and Friday, May 19, 2017; 5:15PM to 6:30PM PT
- *Effects of Elagolix, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, on Ovulation, Ovarian Activity, and Ovarian Reserve in Healthy Premenopausal Women*; Ng J et al.; Poster #PS02-004; Thursday, May 18 and Friday, May 19, 2017; 5:15PM to 6:30PM PT
- *The Effect of Elagolix on Estradiol: Results From Two Randomized Phase 3 Studies in Women With Endometriosis-Associated Pain (EAP)*; Ng J et al.; Poster #PS02-014; Thursday, May 18 and Friday, May 19, 2017; 5:15PM to 6:30PM PT

### About Endometriosis

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>1,2</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>1,3</sup> There is no cure for endometriosis,<sup>4</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>5</sup> In more extensive cases, surgical interventions (e.g., laparotomy or laparoscopy) are often pursued, and may not be curative for all individuals.<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 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. AbbVie plans to submit a New Drug Application to the U.S. Food and Drug Administration (FDA) for endometriosis in 2017. Phase 3 trials of elagolix for the management of uterine fibroids are ongoing.

#### **About AbbVie**

AbbVie is a global, research-driven 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 [@abbvie](#) on Twitter, [Facebook](#) or [LinkedIn](#).

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

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

3 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.

4 Nnoaham KE, Hummelshoj L., Webster P, d'Hooghe T, de Cicco Nardone F, de Cicco Nardone C, Jenkinson C, Kennedy SH, Zondervan KT, World Endometriosis Research Foundation Global Study of Women's Health, consortium. Impact of endometriosis on quality of life and work productivity: a multicenter study across ten countries. *Fertility and Sterility*. 2011;96:366-373.

5 Giudice LC. Clinical practice: Endometriosis. *New England Journal of Medicine*. 2010;362:2389-2398.

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/abbvie-presents-pivotal-phase-3-data-on-investigational-treatment-elagolix-at-the-world-congress-on-endometriosis-300458986.html>

SOURCE AbbVie

#### **Related Links**

<http://www.abbvie.com>