



## **AbbVie Receives U.S. FDA Priority Review for Investigational Oral Treatment Elagolix for the Management of Endometriosis with Associated Pain**

October 27, 2017

- FDA grants priority review to medicines it determines have potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease
- Priority designation shortens the review period from the standard 10 months to six months from the acceptance of the NDA<sup>1</sup>
- If approved, elagolix will be the first new oral medical management treatment option for endometriosis-associated pain in more than a decade

NORTH CHICAGO, Ill., Oct. 27, 2017 /PRNewswire/ -- AbbVie (NYSE:ABBV), a research and development based global biopharmaceutical company in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), today announced that the U.S. Food and Drug Administration (FDA) has granted priority review for elagolix, an investigational, orally administered gonadotropin-releasing hormone (GnRH) antagonist, being investigated for the management of endometriosis with associated pain. The FDA grants priority review to medicines that it determines have potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease<sup>1</sup>. AbbVie expects the Prescription Drug User Fee Act (PDUFA) date for the FDA to complete its review will be in Q2 2018.

"We are pleased that elagolix has been granted priority review by the FDA and will continue to work closely with the agency to hopefully bring this treatment to women suffering from endometriosis as soon as possible," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie.

The NDA is supported by data from the largest prospective randomized clinical trials conducted to date for endometriosis. The safety and efficacy of elagolix were evaluated in nearly 1,700 women with moderate-to-severe endometriosis-associated pain.

### **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 3,000 subjects. The FDA granted priority review for AbbVie's NDA for endometriosis in Q4 2017. Phase 3 trials of elagolix for the management of uterine fibroids are ongoing.

### **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>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>2,3</sup> Estrogen fuels the growth of lesions.<sup>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>3</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 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 [@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 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.

<sup>1</sup> U.S. Food and Drug Administration. Priority Review. <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm>. Accessed September 29, 2017.

<sup>2</sup> The American College of Obstetricians and Gynecologists. ACOG Education Pamphlet AP013: Endometriosis. Washington, DC: September 2008. ISSN 1074-8601.

<sup>3</sup> Giudice LC. Clinical practice: Endometriosis. New England Journal of Medicine. 2010; 362:2389–2398.

<sup>4</sup> Greene, AD, Lang, SA, Kendziorowski, JA, Sroga-Rios, JM, Herzog, TJ, Burns, KA. Endometriosis: where are we and where are we going? Reproduction. 2016; 152 (3):R63-78.

<sup>5</sup> Mayo Clinic. Diseases & Conditions: Endometriosis Fact Sheet. <http://www.mayoclinic.org/diseases-conditions/endometriosis/diagnosis-treatment/treatment/txc-20236449>. Accessed June 1, 2017.

The AbbVie logo is displayed in a large, dark blue, lowercase sans-serif font. The letters are bold and closely spaced, with a distinctive rounded 'v' and 'i'.

SOURCE AbbVie

**Contact(s)**

**Media**

Toni Haubert  
antoINETTE.haubert@abbvie.com  
(847) 936-5382

**Investors**

Liz Shea  
liz.shea@abbvie.com  
(847) 935-2211