AbbVie and Neurocrine Biosciences Announce PDUFA Target Date of Q3 2018 for Elagolix in Endometriosis-Associated Pain

April 10, 2018

- FDA requires extended time for review of additional information in New Drug Application (NDA)
- Elagolix clinical trial program largest prospective randomized endometriosis trial conducted to date
- Based on AbbVie's review of the data, the company remains confident in NDA and continues to work with FDA to bring elagolix to patients
- Regulatory submissions for elagolix in uterine fibroids remain on track

NORTH CHICAGO, Ill., April 10, 2018 /PRNewswire/ -- AbbVie (NYSE:ABBV), a global research and development-based biopharmaceutical company in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), announced notification by the U.S. Food and Drug Administration (FDA) that it requires extended time to review additional information regarding the results of liver function tests provided by AbbVie in connection with its New Drug Application (NDA) for elagolix in endometriosis-associated pain. The Prescription Drug User Fee Act (PDUFA) date has been extended three months to Q3 2018.

In Q4 2017, the FDA granted priority review for AbbVie's NDA for endometriosis. The 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. If approved, elagolix will be the first new oral medical management treatment option for endometriosis-associated pain in more than a decade.

"Based on our review of the data, we remain confident in our New Drug Application for elagolix in the treatment of endometriosis-associated pain," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "Elagolix has the potential to be an important new treatment option for women suffering from endometriosis and we are committed to working with the FDA to bring this therapy to patients."

The NDA for elagolix 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. Clinical trial data demonstrated elagolix was well-tolerated and significantly reduced the three types of endometriosis-associated pain – daily menstrual pelvic pain, non-menstrual pelvic pain and painful intercourse.

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.

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.[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.[1,2] Estrogen fuels the growth of lesions.[2] There is no cure for endometriosis,[3] 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.[2] In more extensive cases, surgical interventions (e.g., laparotomy or laparoscopy) are often pursued, and may not be curative for all individuals.[4]

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.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. The Company's three late-stage clinical programs are: elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA, a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette syndrome.

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

[2] Giudice LC. Clinical practice: Endometriosis. New England Journal of Medicine. 2010; 362:2389–2398.

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

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

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