AbbVie Initiates Enrollment in Phase 3 Clinical Program for Elagolix in Patients with Uterine Fibroids

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- The Elagolix Phase 3 uterine fibroid clinical development program includes two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study.

- Primary endpoint is percent of subjects with reduction in uterine blood flow as measured by the alkaline hematin method.

NORTH CHICAGO, Ill., Jan. 28, 2016 /PRNewswire/ -- AbbVie (NYSE: ABBV), in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), today announced the initiation of the first of two planned Phase 3 clinical studies evaluating the safety and efficacy of Elagolix alone or in combination with add-back therapy compared to placebo. These studies are designed to assess the change in menstrual blood loss utilizing the alkaline hematin method, comparing baseline to month six of treatment. Additional secondary efficacy endpoints are being evaluated; including assessing changes in fibroid volume, monthly blood loss and hemoglobin levels. Bone mineral density will also be assessed.

"There are limited, non-surgical treatment options for women suffering from heavy menstrual bleeding associated with uterine fibroids. AbbVie is eager to further explore Elagolix's potential to address this unmet need," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie.

The Elagolix Phase 3 uterine fibroid clinical development program is part of AbbVie's pipeline and includes two replicate, randomized, parallel, double-blind, placebo-controlled clinical trials. Each trial is expected to enroll approximately 400 subjects for an initial six-month placebo-controlled dosing period, after which, subjects who are eligible will have an option to continue for an additional six-month dosing period in a safety and efficacy extension study. AbbVie will make a $15MM milestone payment to Neurocrine Biosciences upon enrollment of the first patient.

Uterine fibroids (also called leiomyomas or myomas) are noncancerous muscle tissue tumors of the uterus.[1] Fibroids are most common in women aged 30-40 years but can occur at any age.[1] They can range in size from nearly undetectable to bulky masses that can distort the uterus.[2] Fibroids can be asymptomatic but in some women cause symptoms such as: longer, more frequent, or heavy menstrual bleeding; menstrual pain; vaginal bleeding at time other than menstruation; pain in the abdomen or lower back; pain during sex; difficulty urinating; frequent urination; constipation or rectal pain.[1]

About Elagolix
Elagolix is an orally administered gonadotropin-releasing hormone (GnRH) antagonist that 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. Phase 3 trials of Elagolix for the management of endometriosis-associated pain are also ongoing.

About AbbVie
AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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 2014 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]American Congress of Obstetricians and Gynecologist. Frequently Asked Questions about Gynecologic Problems Uterine Fibroid Fact Sheet. http://www.acog.org/Patients/FAQs/Uterine-Fibroids. Accessed January 25, 2016.

[2] Mayo Clinic. Diseases and Conditions: Uterine Fibroids. http://www.mayoclinic.org/diseases-conditions/uterine-fibroids/basics/symptoms/con-20037901. Accessed January 25, 2016.

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