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AbbVie Receives U.S. FDA Approval of ORILISSA™ (elagolix) for the Management of Moderate to Severe Pain Associated with Endometriosis

- ORILISSA™ (elagolix) is the first FDA-approved oral treatment for the management of moderate to severe pain associated with endometriosis in over a decade
- ORILISSA is available in two oral dosages-150 mg once daily and 200 mg twice daily, taken with or without food
- FDA approval is supported by the largest endometriosis Phase 3 study program conducted to date
- ORILISSA is expected to be available in U.S. retail pharmacies in early August 2018

NORTH CHICAGO, Ill., July 24, 2018 /PRNewswire/ -- AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), announced that the U.S. Food and Drug Administration (FDA) approved ORILISSA™ (elagolix), the first and only oral gonadotropin-releasing hormone (GnRH) antagonist specifically developed for women with moderate to severe endometriosis pain.[1,2] The FDA approved ORILISSA under priority review. ORILISSA represents the first FDA-approved oral treatment for the management of moderate to severe pain associated with endometriosis in over a decade and is expected to be available in U.S. retail pharmacies in early August 2018.

"ORILISSA represents a significant advancement for women with endometriosis and physicians who need more options for the medical management of this disease," said Michael Severino, M.D., Executive Vice President, Research and Development and Chief Scientific Officer, AbbVie. "The approval of ORILISSA demonstrates AbbVie's continued commitment to address serious diseases and unmet needs."

Endometriosis is one of the most common gynecologic disorders in the U.S.[3] It affects an estimated one in 10 women of reproductive age and can be associated with pain symptoms that can be debilitating.[3,4] Women can suffer for up to six to 10 years and visit multiple physicians before receiving a proper diagnosis.[5,6]

Endometriosis-associated pain is often managed with medicines such as oral contraceptives, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids and hormonal therapies, which can work for some women but very few are specifically indicated for the treatment of endometriosis.[3,7] In more extensive cases, surgical interventions (e.g., laparotomy, laparoscopy or hysterectomy) are often pursued, and may not be curative for all individuals.[8]

"Endometriosis is often characterized by chronic pelvic pain that can impact women's daily activities," said Hugh S. Taylor, M.D., study investigator and Chair of the Department of Obstetrics, Gynecology and Reproductive Sciences, Yale School of Medicine. "Women with endometriosis may undergo multiple medical treatments and surgical procedures seeking pain relief and this approval gives physicians another option for treatment based on a woman's specific type and severity of endometriosis pain."

The approval is supported by data from two replicate studies in the largest endometriosis Phase 3 study program conducted to date, which evaluated nearly 1,700 women with moderate to severe endometriosis pain. Clinical trial data demonstrated ORILISSA significantly reduced the three most common types of endometriosis pain: daily menstrual pelvic pain, non-menstrual pelvic pain and pain with sex. A higher proportion of women treated with ORILISSA 150 mg once daily and 200 mg twice daily were responders for daily menstrual pain and non-

menstrual pelvic pain compared to placebo in a dose-dependent manner at month three. Women were defined as responders if they experienced a reduction in daily menstrual pain and non-menstrual pelvic pain with no increase in analgesic use (nonsteroidal anti-inflammatory drug or opioid) for endometriosis-associated pain.

Both ORILISSA treatment groups showed statistically significant greater mean decreases from baseline compared to placebo in daily menstrual pain and non-menstrual pelvic pain at month six. Women in the Phase 3 studies also provided a daily self-assessment of their endometriosis pain using a numeric rating scale (NRS) and women taking ORILISSA 150 mg once daily and 200 mg twice daily reported a statistically ($p < 0.001$) significant reduction from baseline in NRS scores compared to placebo at month three. Clinical trial data also demonstrated women taking ORILISSA 200 mg twice daily showed statistically significant greater reduction in pain with sex from baseline to month three compared to placebo.

The recommended duration of use for ORILISSA is up to 24 months for the 150 mg once daily dose and up to six months for the 200 mg twice daily dose, as it causes a dose-dependent decrease in bone mineral density (BMD). BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment. For women with moderate hepatic impairment, the recommended dosage is 150 mg once daily for up to six months. ORILISSA is recommended to be taken orally at approximately the same time each day, with or without food.

"Together with AbbVie, we are proud to offer a treatment option for the many women suffering from pain associated with endometriosis," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "Neurocrine discovered ORILISSA nearly twenty years ago and through our partnership with AbbVie, the approval of ORILISSA reflects our joint commitment to develop therapies for difficult to manage conditions in underserved patient populations."

About ORILISSA™ (elagolix)

ORILISSA is approved by the U.S. Food and Drug Administration (FDA) for the management of moderate to severe pain associated with endometriosis.[1]

ORILISSA is an orally-administered, nonpeptide small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of ovarian sex hormones, estradiol and progesterone.[1]

Please click here (http://www.rxabbvie.com/pdf/orilissa_pi.pdf) for full Prescribing Information, including the Medication Guide.

USE:
ORILISSA is a prescription medicine used to treat moderate to severe pain associated with endometriosis. It is not known if ORILISSA is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION:

What is the most important information I should know about ORILISSA?
Take ORILISSA exactly as your healthcare provider tells you.

ORILISSA may cause serious side effects, including:

- **Bone Loss (decreased Bone Mineral Density (BMD))**
  While you are taking ORILISSA, your estrogen levels will be low. This can lead to BMD loss. Your BMD may improve after stopping ORILISSA but may not recover completely. It is unknown if these bone changes could increase your risk for broken bones as you age. Your healthcare provider may order a DXA scan to check your BMD.
- **Effects on Pregnancy**
  Do not take ORILISSA if you are trying to become or are pregnant as your risk for early pregnancy loss may increase. **If you think you are pregnant**, stop taking ORILISSA right away and call your healthcare provider. ORILISSA may change your menstrual periods (irregular bleeding or spotting, a decrease in menstrual bleeding, or no bleeding at all), making it hard to know if you are pregnant. Watch for other signs of pregnancy such as breast tenderness, weight gain and nausea. ORILISSA does not prevent pregnancy. You will need to use effective hormone-free birth control (such as condoms or spermicide) while taking ORILISSA and for one week after stopping ORILISSA. Birth control pills that contain estrogen may make ORILISSA less effective. It is unknown how well ORILISSA works while on progestin-only birth control.

Do not take ORILISSA if you:

- are or may be pregnant, have osteoporosis, have severe liver disease, or take medicines known as strong OATP1B1 inhibitors such as cyclosporine or gemfibrozil. If you are unsure if you are taking one of these medicines, ask your healthcare provider.

What should I tell my healthcare provider before taking ORILISSA?
Tell your healthcare provider of all your medical conditions, including if you:

- have or have had broken bones, have other conditions or take medicine that may cause bone problems, have or have had depression, mood problems or suicidal thoughts or behavior, have liver problems, think you may be pregnant, or are breastfeeding or plan to be. It is unknown if ORILISSA passes into breastmilk. Talk to your healthcare provider about the best way to feed your baby if you take ORILISSA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take birth control pills. Your healthcare provider may advise you to change the pills you take or your method of birth control.

What are the possible side effects of ORILISSA?

ORILISSA can cause serious side effects including:

- **suicidal thoughts, actions, or behavior, and worsening mood.** Call your healthcare provider right away, or call 911 if an emergency, if you have any of these symptoms, especially if they are new, worse, or bother you: thoughts about suicide or dying, try to commit suicide, new or worse depression or anxiety, or other unusual changes in behavior or mood. You or your caregiver should pay attention to any changes, especially sudden changes in your mood, behaviors, thoughts, or feelings.
- **abnormal liver tests.** Call your healthcare provider right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), dark amber-colored urine, feeling tired, nausea and vomiting, generalized swelling, right upper stomach area pain, bruising easily.

The most common side effects of ORILISSA include: hot flashes or night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression and mood changes.

These are not all the possible side effects of ORILISSA. This is the most important information to know about ORILISSA. For more information, talk to your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Call your healthcare provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

If you cannot afford your medication, contact www.pparx.org (http://www.pparx.org/) for assistance.

About Endometriosis

Endometriosis occurs when tissue similar to that normally found in the uterus begins to grow outside of the uterus, leading to a range of symptoms, including painful periods, pelvic pain in between periods and pain with sex.[4] 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.[4,5] Estrogen fuels the growth of lesions.[5]

For more information on endometriosis, visit our press kit here (https://news.abbvie.com/presskits/endometriosis.htm).

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 (http://www.facebook.com/abbviecareers) or LinkedIn (http://www.linkedin.com/company/abbvie) .

About Neurocrine Biosciences, Inc.

Neurocrine Biosciences, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders. The company discovered, developed and markets INGREZZA® (valbenazine), the first FDA approved product indicated for the treatment of adults with tardive dyskinesia, a movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA™ (elagolix), the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, is marketed by AbbVie as part of a collaboration to develop and commercialize elagolix for women's health. Neurocrine's clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH). For more information and the latest updates from Neurocrine, please visit www.neurocrine.com (http://www.neurocrine.com/) .

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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<< Back

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