AbbVie Receives Health Canada Approval of ORILISSA™ (elagolix) for the Treatment of Moderate to Severe Pain Associated with Endometriosis

October 5, 2018

- *Endometriosis affects up to one in 10 women of reproductive age in Canada.*[1]
- *7 out of 10 women being managed for endometriosis have unresolved pain throughout the month.*[2]
- *The approval of ORILISSA is supported by data from two replicate Phase 3 studies, which evaluated nearly 1,700 women.*
- *In clinical trials, ORILISSA™demonstrated sustained relief over 12 months across the two most common types of pain: dysmenorrhea and non-menstrual pelvic pain.*[3]

MONTREAL, Oct. 5, 2018 /CNW/ - AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, in cooperation with Neurocrine Biosciences, Inc. (NASDAQ: NBIX), announced that Health Canada approved ORILISSA™ (elagolix), the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist, for the treatment of moderate to severe pain associated with endometriosis.[3]

ORILISSA (elagolix) is a novel, orally administered, highly potent, short-acting, selective, non-peptide small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist that blocks endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of ORILISSA results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulation hormone (FSH) levels, leading to decreased blood levels of the ovarian sex hormones, estradiol and progesterone. LH and FSH suppression begins within hours of administration and is readily reversible upon discontinuation of ORILISSA.[3]

"Endometriosis causes a significant impact on the quality of life of women because of the debilitating and incapacitating pain. Women living with endometriosis can be sidelined by this disease," says Dr. Nicholas A. Leyland, BASc, MD, MHCM, FRCSC, Chair of the Department of Obstetrics and Gynaecology, McMaster University. "Since there is no cure, the goal of treatment is to alleviate the symptoms and improve a woman's quality of life. With ORILISSA, we are now able to offer our patients an additional new option that can help them resume living their lives."

Endometriosis causes chronic pelvic pain and is sometimes associated with infertility. It affects up to one in 10 women of reproductive age in Canada.1 Furthermore, 7 out of 10 women being managed for endometriosis have unresolved pain throughout the month. [2]

"Endometriosis is a complex and incurable disease. This is why early diagnosis is extremely important. Currently, on average, it takes seven to nine years of complaining about symptoms to medical professionals to receive a diagnosis of endometriosis. Therefore, earlier diagnosis and treatment can help mitigate years of unnecessary suffering," explains Philippa Bridge-Cook, Ph.D., The Endometriosis Network Canada. "In addition, patients coping with symptoms without a diagnosis can sometimes face dismissal of their symptoms from friends, family, and even medical professionals. This can lead to feelings of isolation, anxiety, and depression."

The approval of ORILISSA 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 two most common types of endometriosis pain: dysmenorrhea and non-menstrual pelvic pain. 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.[3]

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 during sexual intercourse from baseline to month three compared to placebo. The most frequent (≥10%) adverse reactions reported in clinical trials with ORILISSA (elagolix) were hot flush, headache and nausea.[3]

The recommended duration of use for ORILISSA is up to 12months 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.[3]

"The approval of ORILISSA demonstrates AbbVie's continued commitment to women living with endometriosis. We are proud of our heritage in women's health and strive to fill the unmet medical need by providing a safe and efficacious treatment," says Stéphane Lassignardie, General Manager of AbbVie Canada.

ORILISSA is expected to be available in Canadian retail pharmacies in early November 2018.

About AbbVie Care
Canadian women prescribed ORILISSA will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature care program. The program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services, lab work reminders and coordination, personalized education and ongoing disease management support throughout the treatment and beyond. For more information, please visit www.abbviecare.ca.

About AbbVie

AbbVie is a global, research and development-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.ca and www.abbvie.com. Follow @abbvieCanada and @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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.

[1]YourPeriod.ca - https://www.yourperiod.ca/endometriosis/what-is-endometriosis/

[2]De Graaff AA, D'Hooghe TM, Dunselman GAJ, Dirksen CD, Hummelshoj L, WERF EndoCost Consortium, Simoens S. The significant effect of endometriosis on physical, mental and social wellbeing: results from an international cross-sectional survey. Hum Reprod. 2013;28(10):2677-2685.

[3]Orilissa Product Monograph, AbbVie Corporation, October 5, 2018.

SOURCE AbbVie Canada

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Organization Profile

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