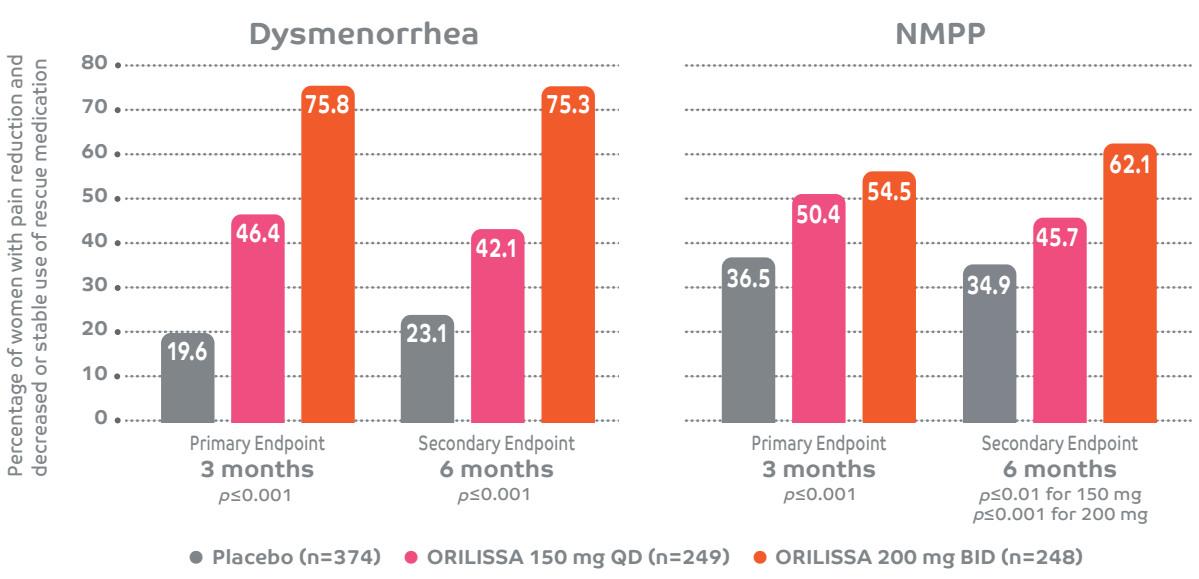
The first and only oral GnRH receptor antagonist for the treatment of moderate to severe pain associated with endometriosis.[1]

Dear Healthcare Professional,

In a 6-month period, ORILISSA 150 mg QD demonstrated a sustained reduction in non-menstrual pelvic pain (NMPP) and dysmenorrhea in women with endometriosis-associated pain.[2,3]*

Introducing NEW Pr Orilissa™ elagolix tablets

ELARIS EM-I: Response rates vs. placebo were defined as the proportion of women who had clinically meaningful pain-score reduction in dysmenorrhea and/or NMPP and stable/decreased rescue analgesic use.[2,3]†



Figures adapted from ORILISSA Product Monograph and Taylor, H.S., *et al.*

Study details: The efficacy and safety of ORILISSA (elagolix) 150 mg once daily and 200 mg twice daily in the management of moderate to severe pain associated with endometriosis was demonstrated in two double-blind, randomized, placebo-controlled, multicentre, Phase 3 studies (Study M12-665 [ELARIS EM-I] and M12-671 [ELARIS EM-II]). Premenopausal women 18 to 49 years of age with endometriosis were eligible for enrollment if they reported 2 or more days of dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) scores ≥2, a mean daily NMPP score of at least 0.5, and either a mean daily NMPP score of at least 1.0 or at least 4 days of moderate or severe NMPP in the last 35 days of the screening period. Each placebo-controlled study assessed the reduction in endometriosis-associated pain over 6 months of treatment.

A total of 872 patients in Study M12-665 and 817 patients in Study M12-671 were randomized to placebo or one of the two elagolix doses. At baseline, patients were in their 30s and the majority were white in both studies. The majority of patients used NSAIDs and/or opioids for pain management at baseline. There were no significant differences between treatment groups among baseline demographic characteristics in each study.[2,3]

To discover more, please view the "Clinical Trials" section of the PrORILISSA™ Product Monograph.

If you have any further questions, please contact AbbVie Medical Information at 1-888-704-8271 or medicalquestions@abbvie.com

*ORILISSA 200 mg is currently commercially unavailable in Canada.

† The clinically meaningful reductions corresponded to patients' assessment of pain as "much improved", or "very much improved."

QD: once daily; BID: twice daily

Indication and clinical use:

ORILISSA (elagolix) is indicated for the treatment of moderate to severe pain associated with endometriosis. The safety and effectiveness of ORILISSA in patients less than 18 years of age has not been established. ORILISSA is not indicated in postmenopausal women and has not been studied in women over 65 years of age.

Contraindications:

- Women who are, suspected to be, or may become pregnant
- Women with undiagnosed vaginal bleeding
- Women with known osteoporosis, due to the risk of further bone loss
- Women with severe hepatic impairment (Child-Pugh C)
- Concomitant use of ORILISSA and strong organic anion transporting polypeptide (OATP)1B1 inhibitors

Relevant warnings and precautions:

- Women should use an effective method of contraception not containing estrogen while being treated with ORILISSA
- ORILISSA 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
- Dose-dependent elevations in hepatic transaminases levels at least 3 times the upper limit of the reference range occurred with ORILISSA
- Exclude pregnancy before initiating treatment with ORILISSA
- Changes in bleeding patterns
- Risk of suicidal ideation, suicidal behaviour and exacerbation of mood disorders; discontinuation of treatment may be required
- Risk of reduced efficacy with estrogen-containing contraceptives
- Risk of reduced ability to recognize pregnancy

For more information:

Please consult the Product Monograph at http://www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/ORILISSA_PM_EN.PDF for important information relating to adverse reactions, drug interactions and dosing and administration which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-888-704-8271 or 514-906-9771.

Regards,

Brendon Bibby

Senior Brand Manager, Women's Health

References: 1. Data on file. ORILISSA first and only claim. Signed November 15, 2018. **2.** ORILISSA Product Monograph. AbbVie Corporation. October 4, 2018. **3.** Taylor, H.S., *et al.* Treatment of endometriosis-associated pain with Elagolix, an oral GnRh antagonist. *NEJM*. 2017. 377;1: 28-400.

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