Full Title: A Phase 3 Study to Evaluate the Safety and Efficacy of Elagolix for the Management of Heavy Menstrual Bleeding Associated with Uterine Fibroids in Premenopausal Women

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Study Objectives: To assess the safety and efficacy of elagolix 150 mg QD compared to placebo in reducing HMB associated with uterine fibroids in premenopausal women.

Inclusion Criteria:
- Subjects is a premenopausal female, 18 to 51 years of age at the time of Screening
- Uterine fibroids documented by a pelvic ultrasound (TAU, TVU) assessed by a central reader and verification that a uterine fibroid meets size criteria
- Menstrual cycles with interval of 24 to 38 days in length for the 3 consecutive months prior to Screening
- Subjects must be > 6 months post-partum, post-abortion, post-pregnancy, and post lactation at the time of entry into the Screening Period
- Menstrual cycles with interval of 24 to 38 days in length or the 3 consecutive months prior to Screening
- Negative urine and/or serum pregnancy test(s) during the Washout (if applicable) and/or Screening Periods, and a negative urine pregnancy test immediately before administration of the first dose of study drug

Exclusion Criteria:
- Diagnosis of hepatitis B or C, hereditary blood coagulation disorder, osteoporosis or other metabolic bone disease
- Presence of myomectomy, uterine artery embolization, or high-intensity focused ultrasound (HIFU) within 6 months prior to Screening or an endometrial ablation within 6 months prior to Screening
• Active pelvic inflammatory disease
• Surgical history of hysterectomy (with or without oophorectomy), bilateral oophorectomy, bariatric surgical procedures of any type within 6 months prior to screening
• Use of copper intrauterine device, systemic corticosteroids for > 14 days within 3 months prior to Screening

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Open to Enrollment

Keywords  
Uterine fibroids, Elagolix, heavy menstrual bleeding, HMB