

Press Release



ASKA Pharmaceutical Initiates Domestic Phase I/II Clinical Trial of Relugolix Combination Tablet (AKP-022)

TOKYO, July 20, 2023 - ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/President, Representative Director: Sohta Yamaguchi, "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd., announced that ASKA has initiated a Phase I/II clinical trial of relugolix combination tablet [generic name: relugolix (INN), estradiol (INN), norethindrone acetate (INN), development code: AKP-022], in-licensed from Takeda Pharmaceutical Company Limited ("Takeda"), in Japan.

This study is a domestic Phase I/II clinical study to evaluate the pharmacokinetics, pharmacodynamics, and safety of repeated administration of AKP-022 or relugolix in healthy premenopausal Japanese adult female subjects.

On September 27, 2021, ASKA Pharmaceutical announced that it entered into a license agreement with Takeda for the exclusive rights to develop and market relugolix combination tablet for the treatment of uterine fibroids in Japan.

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist developed by Takeda. ASKA has already obtained the exclusive marketing right for uterine fibroids and the exclusive development and marketing rights for endometriosis in Japan of relugolix single agent. In January 2019, ASKA launched "RELUMINA Tablets 40mg" for the treatment of uterine fibroid-related symptoms (menorrhagia, lower abdominal pain, lower back pain, and anemia). Furthermore, ASKA received an additional indication for RELUMINA for the Improvement of pain associated with endometriosis in December 2021.

Although relugolix single-agent therapy is effective due to its estrogen-lowering effect, it should not be administered for longer than 6 months because bone loss may occur as a side effect of the estrogen-lowering effect. Relugolix combination tablet contains estradiol (estrogen) to inhibit bone loss and norethindrone acetate (progestin) to inhibit estrogen-induced endometrial proliferation. The drug is being developed with the expectation that it will enable long-term treatment beyond 6 months.

Uterine fibroids are benign tumors associated with menorrhagia, pain, and anemia. The disease is known as a potential cause of infertility. It most often develops in women in their 30s and 40s, and it is estimated that more than 2 million women are affected in Japan.

ASKA promotes health support for women with obstetrics and gynecology as one of its key therapeutic areas. ASKA believes relugolix combination tablet will provide a new option for treating endometriosis.

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