

Press Release



Licensing Agreement for Relugolix Combination Tablet for Endometriosis in the Gynecologic Disease Area

TOKYO, May 31, 2024 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/Representative Director: Sohta Yamaguchi, “ASKA”), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886), announced that ASKA has entered into a license agreement (the “Agreement”) to additionally acquire exclusive development and marketing rights for the relugolix combination tablet in-licensed from Takeda Pharmaceutical Company Limited (Head Office: Chuo-ku, Osaka, “Takeda”) for the treatment of endometriosis in Japan, with the aim of maximizing product value.

ASKA announced on September 27, 2021 that it has entered into a license agreement for exclusive development and commercialization on the relugolix combination tablet for uterine fibroids in Japan. The Ph I/II clinical trial for uterine fibroids is underway.

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist originated by Takeda. ASKA has already obtained exclusive development and marketing rights of relugolix monotherapy for both uterine fibroids and endometriosis in Japan. 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). In December 2021, ASKA has received an additional indication for endometriosis.

Relugolix monotherapy is effective because it lowers estrogen levels. However, since bone loss may occur owing to the estrogen-lowering effect, these products should not be administered for more than six months in principle. The relugolix combination tablet includes estrogen to prevent bone loss and progesterin to inhibit estrogen-induced endometrial proliferation. This combination is expected to allow for treatment durations longer than six months.

Under this Agreement, ASKA will pay Takeda royalties on sales in exchange for exclusive development and marketing rights on the relugolix combination tablet for endometriosis in addition to uterine fibroids in Japan. Further details regarding this Agreement are not disclosed.

Endometriosis is characterized by symptoms such as menstrual pain, lower back pain, bowel pain, and painful intercourse, and can also cause infertility. It often occurs in the 20s-40s, and it is reported that there are approximately 1 million women diagnosed with endometriosis in Japan. ASKA supports women's health, and relugolix combination tablet is considered to offer a new option for the treatment of endometriosis.

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