Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Initiates Domestic Phase III Clinical Trial of Relugolix Combination Tablet (AKP-022)

TOKYO, December 16, 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 initiated a Phase III clinical trial program (LUNA Program) in Japan for the relugolix combination tablet [generic name: relugolix (INN), estradiol (INN), norethindrone acetate (INN), development code: AKP-022] in-licensed from Takeda Pharmaceutical Company Limited (Head Office: Chuo-ku, Osaka, "Takeda").

The LUNA program consists of the LUNA1 study (Phase III comparative verification study) to verify the efficacy and the LUNA2 study (Phase III long-term administration study) to verify the safety of the relugolix combination tablet. The program is designed to be administered to uterine fibroid patients with menorrhagia.

ASKA announced on September 27, 2021, that it has entered into a license agreement for exclusive development and commercialization of the relugolix combination tablet for uterine fibroids in Japan. Moreover, ASKA announced on May 31, 2024, that it has entered into a license agreement for exclusive development and commercialization of the relugolix combination tablet for the endometriosis treatment in Japan.

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist originated by Takeda. ASKA has already obtained exclusive development and marketing rights for 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 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 estradiol (estrogen) to prevent bone loss and norethindrone acetate (progestin) to inhibit estrogen-induced endometrial proliferation. This combination is expected to allow for treatment durations longer than six 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 that the relugolix combination tablet will provide a new option for uterine fibroid treatment.

Note: **L**ong-term **U**terine fibroid treatment with **N**ew relugolix combination therapy **A**ssessment in Japan is abbreviated as “LUNA.” LUNA means “moon” in Latin, and it harmonizes with the image of the moon, which symbolizes women's health and the hormonal cycle. LUNA also includes the meaning of evaluating a new long-term treatment for uterine fibroids using a combination of relugolix/estradiol/norethindrone acetate.

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