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Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA to Initiate Domestic Phase III Clinical Trial of Relugolix Combination Tablet for Endometriosis

TOKYO, June 25, 2025 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/ President, Representative Director: Sohta Yamaguchi, "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886), announced that ASKA will initiate a Phase III clinical trial 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").

On September 27, 2021, ASKA announced that it entered into a license agreement with Takeda for the exclusive development and commercialization rights of the relugolix combination tablet for uterine fibroid treatment in Japan. Moreover, on May 31, 2024, it announced the conclusion of a license agreement to additionally acquire the exclusive development and commercialization rights for endometriosis treatment in Japan.

ASKA is currently conducting domestic phase III clinical trials of this drug for uterine fibroids to evaluate its efficacy and safety in improving symptoms of heavy menstrual bleeding. The newly initiated phase III clinical trial for endometriosis will be conducted at medical institutions in Japan with improvement of symptoms such as pelvic pain as the primary endpoint.

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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