Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Pharmaceutical Announces Phase 3 Clinical Trial Results for Relugolix Combination Therapy (AKP-022), Meeting Primary Endpoint in Patients with Uterine Fibroids

TOKYO, June 22, 2026 — ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo; President, Representative Director: Sohta Yamaguchi; hereinafter "ASKA Pharmaceutical"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE:4886), today announced that the Phase 3 clinical trial in Japan (the LUNA1 study) of relugolix combination therapy [generic names: relugolix (INN), estradiol (INN), and norethindrone acetate (INN); development code: AKP-022; hereinafter, the "drug candidate"], which was in-licensed from Takeda Pharmaceutical Company Limited (Head Office: Chuo-ku, Osaka; hereinafter "Takeda"), met its primary endpoint in patients with uterine fibroids.

The LUNA1 study was conducted as a Phase 3, randomized, multicenter, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of the drug candidate administered for 24 weeks in patients with uterine fibroids.
In the study, the drug candidate demonstrated a statistically significant improvement over placebo for the primary endpoint, thereby confirming its efficacy. Results for the secondary and other efficacy and safety endpoints were generally consistent with the efficacy and safety profile previously observed for the drug candidate.

Relugolix monotherapy (RELUMINA® Tablets) is already widely used in clinical practice in Japan for the treatment of symptoms associated with uterine fibroids and pain associated with endometriosis. By combining relugolix with estradiol and norethindrone acetate, the drug candidate is being developed with the objective of enabling long-term treatment that has not previously been achievable with relugolix monotherapy.

Regarding the drug candidate, ASKA Pharmaceutical previously announced, by way of separate press releases, the execution of a license agreement with Takeda on September 27, 2021, under which it acquired exclusive development and commercialization rights in Japan for uterine fibroids, and the execution of an additional license agreement on May 31, 2024, granting exclusive development and commercialization rights in Japan for endometriosis.

The drug candidate is currently being developed for both uterine fibroids and endometriosis.
For uterine fibroids, in addition to the LUNA1 study, ASKA Pharmaceutical is conducting a Phase 3 long-term study (the LUNA2 study) to evaluate the safety and efficacy of the drug candidate following 52 weeks of treatment in patients with uterine fibroids. For endometriosis, a Phase 3 clinical trial (the LENA study) is also underway.

Upon completion of the LUNA2 study and based on its results, ASKA Pharmaceutical plans to proceed with preparations for a regulatory filing seeking marketing approval in Japan.

Uterine fibroids are benign tumors commonly observed in women and are often associated with heavy menstrual bleeding, pain, anemia, and other symptoms. As one of its key therapeutic areas, ASKA Pharmaceutical is committed to supporting women's health through its activities in the field of obstetrics and gynecology. ASKA Pharmaceutical believes that the drug candidate has the potential to become a new treatment option for patients with uterine fibroids by improving symptoms associated with the disease and thereby contributing to improvements in patients' quality of life (QOL).

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