Press Release

ASKA Pharmaceutical Co., Ltd.

GnRH antagonist TAK-385
Announcement of phase 3 comparative study results for endometriosis

TOKYO, November 25, 2020 - ASKA Pharmaceutical Co., Ltd. (Headquarter: Minato-ku, Tokyo/Representative Director: Takashi Yamaguchi) announces that it has achieved the primary endpoint in a Japanese phase 3 comparative study of the GnRH antagonist TAK-385 (generic name: Relugolix) under development in patients with endometriosis.

This study was conducted to evaluate the efficacy and safety of TAK-385 compared with GnRH agonist leuprorelin acetate (leuprorelin) after 24 weeks of treatment in endometriotic patients with pelvic pain.

As a result of this study, the change in VAS (Visual Analogue Scale, an index of pain) score in endometriotic pelvic pain at the end of the treatment period of the primary endpoint showed non-inferiority of TAK-385 to leuprorelin. In addition, the study did not identify any major safety concerns and confirmed good tolerability.

We gratefully acknowledge the patients and healthcare professionals who participated in this study, and we will continue to strive to provide Japanese patients with new options for the treatment of endometriosis.

<About Relugolix>

Relugolix inhibits the secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) by inhibiting GnRH receptors in the pituitary gland. As a result, the sex hormones estrogen and progesterone are suppressed, which are expected to improve pelvic pain, a major symptom of endometriosis. Relugolix is a once-daily oral drug that is expected to be a useful treatment for patients suffering from symptoms associated with endometriosis. Relugolix was approved for marketing as a therapeutic drug (RELUMINA® Tablets 40 mg) for the treatment of uterine fibroid-related symptoms (menorrhagia, lower abdominal pain, low back pain, and anaemia) in January 2019.

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