

Press Release



Announcement of phase 3 comparative study results for GnRH antagonist 「RELUMINA Tablets (Relugolix)」 regarding endometriosis

TOKYO, March 15th, 2021 – ASKA Pharmaceutical Co., Ltd. (Headquarter: Minato-ku, Tokyo/Representative Director: Takashi Yamaguchi) has announced the Phase 3 comparative study results for RELUMINA (generic name: Relugolix) at the "42nd meeting of the JAPAN SOCIETY OF ENDOMETRIOSIS" general oral presentation held from February 11 to February 17, 2021.

RELUMINA was approved for marketing as a therapeutic drug for the treatment of uterine fibroid-related symptoms (menorrhagia, lower abdominal pain, lower back pain, and anemia) in January of 2019.

As of January 2021, ASKA has applied for a partial modification to the approval status of RELUMINA regarding its manufacturing and marketing approval for Endometriosis.

The Phase 3 study was a multicenter, randomized double-blind, double-dummy, active medication-controlled, parallel comparative study with 335 patients who experience pelvic pain and were diagnosed with endometriosis.

RELUMINA was administered once a day P.O for 24 weeks, or the comparative GnRH agonist leuprorelin acetate (leuprorelin) was given once every 4 weeks subcutaneously for comparison and evaluation.

As a result of this study, the primary endpoint's change from baseline in the maximum VAS (Visual Analogue Scale, an index of pain: 0 for no pain and 100 for most severe pain) score regarding endometriosis pelvic pain at the end of the treatment period (final 28 days), was -52.6 for the RELUMINA group and was -57.5 for the leuprorelin group.

The difference between the groups 95% confidence interval (95%CI) was 4.9 (1.2, 8.7), indicating non-inferiority to leuprorelin.

In addition, there were no new serious safety issues found indicating and confirming RELUMINA's tolerability profile.

We would like to express our sincere gratitude all the patients and healthcare professionals who participated in this study.

We will continue our very best to obtain approval and bring new treatment options to patients with endometriosis.

<About RELUMINA >

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.