Press Release

ASKA Pharmaceutical Co., Ltd.

Application for the additional indication of endometriosis for the “GnRH antagonist”, RELUMINA® (Relugolix)

TOKYO, January 28th, 2021 - ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") announced that it has submitted a manufacturing and marketing approval application for the additional indication of endometriosis for RELUMINA® (generic name: Relugolix) which was approved for marketing as a therapeutic drug for the treatment of uterine fibroid-related symptoms (menorrhagia, lower abdominal pain, low back pain and anemia) in January 2019.

The application was based on the results from the clinical studies for patients with endometriosis in Japan, and the results demonstrated that RELUMINA® had good tolerability and was effective in improving pelvic pain associated with endometriosis.

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

<About RELUMINA®>

RELUMINA® 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. RELUMINA® is a once-daily oral drug that is expected to be a useful treatment for patients suffering from symptoms associated with endometriosis.

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