

Press Release



Notification of additional indication approved in the Marketing Authorization for GnRH Antagonist RELUMINA® Tablets (Relugolix) for the treatment of Endometriosis

TOKYO, December 24th, 2021 - ASKA Pharmaceutical Co., Ltd. (Headquarter: Minato-ku, Tokyo/President, Representative Director: Sohta Yamaguchi, "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (Headquarter: Minato-ku, Tokyo/President, Representative Director: Takashi Yamaguchi), announces that RELUMINA® (Relugolix) has received an additional indication approved within the marketing authorization for endometriosis.

RELUMINA® (Relugolix) has already been approved for the treatment of Uterine Fibroids and its associated symptoms (Excessive menstruation, Lower abdominal pain, Back pain, and Anemia) in January 2019.

ASKA Pharmaceutical Co., Ltd. believes RELUMINA® (Relugolix) will provide a new option for the treatment of endometriosis and will contribute to improve patients' Quality of Life (QOL).

Summary of additional approval

(The underlined items below are the contents of approval.)

Product Name: RELUMINA® Tablets 40mg

Generic Name: Relugolix

Indications : Uterine Fibroids and its associated symptoms (Excessive menstruation, Lower abdominal pain, Back pain, and Anemia).

Improvement of Pain Associated with Endometriosis

Dosage and Administration:

Generally, 40mg of Relugolix once a day before meal via PO for adults.

First dose should be given between the 1st ~ 5th day of the menstrual cycle.

<About RELUMINA® Tablets>

RELUMINA® inhibits the secretion of luteinizing hormone and follicle-stimulating hormone by blocking the GnRH receptor in the pituitary gland. As a result, the two sex hormones, estrogen and progesterone are suppressed, which improves pelvic pain, a major symptom of endometriosis. This once-daily oral drug is expected to be a useful treatment for patients suffering from symptoms associated with endometriosis.

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