Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

Notice Regarding the Publication on a Phase 3 Comparative Study for GnRH Antagonist RELUMINA® Tablets (Relugolix) for Endometriosis

TOKYO, December 16th, 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 the results of a Phase 3 comparative study regarding Relugolix for endometriosis (hereinafter referred to as "the study") has been published in the journal of Fertility and Sterility.

Relugolix has been approved for the treatment of Uterine Fibroids and its associated symptoms (Excessive menstruation, Lower abdominal pain, Back pain, and Anemia) in January 2019.
In addition, an application for marketing approval for the indication of Endometriosis was filed in January 2021.

The comparative study was conducted to 335 endometrial patients with pelvic pain. The study was designed as a parallel, multicenter, randomized, double-blind, double-dummy study with an active-control. Patients were randomly assigned in a 1:1 ratio to receive either Relugolix 40 mg administered orally once a day for 24 weeks, or GnRH (gonadotropin-releasing hormone) agonist Leuprorelin acetate of 3.75 mg or 1.88 mg (hereinafter referred to as "Leuprorelin") which was administered subcutaneously once every four weeks until week 24.
The study evaluated and compared the efficacy and safety of Relugolix to that of Leuprorelin. The primary endpoint, which was “the change in the maximum Visual Analog Scale (VAS) score (“0” for no pain, and “100” for worst pain imaginable) for pelvic pain from baseline until 28 days before the end of treatment”, indicated a change of -52.6 in the Relugolix group and -57.5 in the Leuprorelin group. The 95% confidence interval of the change in the maximum VAS score between the groups was 4.9 (1.2, 8.7), indicating that Relugolix was not inferior to that of Leuprorelin.
The study also showed that Relugolix was well tolerated, with no significant new safety concerns.

For the full publication, please refer to https://www.fertstert.org/article/S0015-0282(21)02214-7/fulltext

ASKA would like to express its sincere gratitude to all patients and medical professionals who participated in the study and will continue to work towards obtaining approval in-order to provide new treatment options to endometrial patients in Japan.

<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 is expected to improve 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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