

# Press Release



## **Announcement regarding the manufacturing and marketing approval for GnRH antagonist “RELUMINA® Tablets 40mg”, a treatment agent for uterine fibroids in Japan**

**TOKYO, January 8th, 2019** – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") and Takeda Pharmaceutical Company Limited (Head Office: Chuo-ku, Osaka, President: Christophe Weber, hereinafter "Takeda") have announced that the gonadotropin-releasing hormone (GnRH) antagonist “RELUMINA® Tablets 40mg” (generic name: Relugolix, development code: TAK-385, hereafter “RELUMINA”) has gained manufacture and marketing approval from the Ministry of Health, Labour and Welfare (hereafter “MHLW”) as a treatment agent to improve uterine fibroid related symptoms (menorrhagia, lower abdominal pain, back pain, anemia).

Takeda conducted Phase 3 clinical trials (TAK-385/CCT-002 trial and 3008 trial) in Japan for the indication of uterine fibroids, and with those results, applied for manufacturing and marketing approval to the MHLW in February of 2018.

In May of 2018, ASKA and Takeda entered into a license agreement to grant ASKA exclusive commercialization rights for uterine fibroids, and exclusive development and commercialization rights for endometriosis within Japan.

### [About RELUMINA]

By antagonizing the GnRH receptors in the pituitary, RELUMINA inhibits the secretion of Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) which suppresses estrogen and progesterone and is believed to improve uterine fibroid related symptoms (menorrhagia, lower abdominal pain, back pain, anemia). RELUMINA is taken orally once a day for uterine fibroids.

Product name	RELUMINA® Tablets 40mg
Generic name	Relugolix
Indication	To improve the following symptoms related to uterine fibroids: menorrhagia, lower abdominal pain, back pain, anemia.
Dosage and administration	Generally, 40mg of Relugolix once a day before meal via PO for adults. First dose should be given between the 1 <sup>st</sup> ~ 5 <sup>th</sup> day of the menstrual cycle.

### [Notice]

The purpose of this release is to disclose management information, and not to advertise or promote any products in any form or shape.

[About ASKA Pharmaceutical Co., Ltd.]

Since its establishment in 1920, ASKA Pharmaceutical has been a specialty pharma that focuses on, and provides products related to therapeutic areas in Internal medicine, Obstetrics and gynecology, and Urology, and is expanding its lineup.

For more information, please visit <https://www.aska-pharma.co.jp/english/>

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