Press Release

ASKA Pharmaceutical Co., Ltd.

Conference announcement regarding the results of the Phase 2 dose determining study for the “Selective Progesterone Receptor Modulator” CDB-2914 (Ulipristal acetate)

TOKYO, November 19th, 2019 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") has announced the results of the Phase 2 dose determining study for CDB-2914 (generic name: Ulipristal acetate, hereinafter Ulipristal) which has been in development in Japan, at the “64th Annual Meeting of the Japanese Society of Reproductive Medicine” during November 7-8th, 2019.

This study was conducted as a multicenter, placebo-controlled, randomized, double-blind study in 121 Japanese uterine fibroid patients with symptoms of menorrhagia to evaluate the efficacy and safety of Ulipristal.

A Placebo or Ulipristal 2.5 mg, 5 mg, or 10 mg was given orally once a day for 12 weeks under double-blind conditions, and a GnRH agonist "Leuprorelin" 1.88 mg or 3.75 mg was openly given subcutaneously as a reference medication.

The main endpoint, amenorrhea at 12 weeks of administration, was 4.5% in the placebo group, 60.0% in the Ulipristal 2.5 mg group, 72.7% in the 5 mg group, and 88.0% in the 10 mg group. Thus, the amenorrhea rate of each Ulipristal dose group was significantly higher than that of the placebo group, confirming the improvement effect of Ulipristal on menorrhagia.

In addition, a significant dose-dependence was observed between the Ulipristal groups, and the amenorrhea rate for the reference drug “Leuprorelin” was 76.2%.

Adverse events that occurred more than 10% in the Ulipristal group and more frequent than the placebo group were “constipation” and “nasopharyngitis”, which most adverse events were considered to be mild.

Based on the above results, the efficacy and safety of Ulipristal in Japanese patients with uterine fibroids with menorrhagia was confirmed. Thus, we are currently conducting a Phase 3 trial.

The results from the above study is published on the official website of Reproductive medicine and biology.

We would like to thank all patients and healthcare professionals who participated in this study, and we will continue to development as well as provide new treatment options for uterine fibroids.

[About Ulipristal acetate]
Ulipristal acetate is a Selective Progesterone Receptor Modulator which exerts its effect by binding to progesterone receptors selectively. ASKA introduced Ulipristal acetate from Laboratoire HRA Pharma, France and has been developing Ulipristal acetate in Japan as a therapeutic agent for uterine fibroids. Overseas, it has already been approved in more than 100 countries and is used by more than 800,000 uterine fibroma patients.