Press Release

ASKA Pharmaceutical Co., Ltd.

Announcement regarding the “Selective Progesterone Receptor Modulator” CDB-2914 (Ulipristal acetate), Phase 3 Comparative Results

TOKYO, November 26th, 2019 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") has announced that it has achieved the main endpoints in the Phase 3 comparative study (hereinafter “Main study”) of CDB-2914 (generic name: Ulipristal acetate, hereinafter “Ulipristal”), an oral uterine fibroid therapeutic agent currently under development in Japan.

The Main study was to compare and evaluate the efficacy and safety of Ulipristal for 12 weeks in patients with uterine fibroids who have symptoms of menorrhagia with a GnRH agonist Leuprorelin acetate (hereinafter "Leuprorelin").

As a result of the Main study, one of the main endpoints, as well as an index for improvement in menorrhagia, "Amenorrhea rate at 12 weeks of administration", showed that Ulipristal was non-inferior to Leuprorelin. It also showed that amenorrhea was achieved in a shorter time period in the Ulipristal administered group than that of Leuprorelin administered group. Additionally, good tolerability as well as no major safety concerns was confirmed. The detailed data regarding this study are planned to be announced at future academic conferences as well as in academic journals.

Currently, we are conducting a Phase 3 trial to evaluate the efficacy and safety of Ulipristal for long-term use in patients with uterine fibroids with menorrhagia.

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.