Press Release

ASKA Pharmaceutical Co., Ltd.

Application for approval regarding the “Selective Progesterone Receptor Modulator”, CDB-2914 (Ulipristal acetate)

TOKYO, December 24th, 2019 - ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo, President: Takashi Yamaguchi, hereinafter "ASKA") has announced that it has submitted a manufacturing and marketing approval application for CDB-2914 (generic name: Ulipristal acetate, hereinafter "Ulipristal"), which is an oral uterine fibroid treatment medication currently under development within Japan.

The application was based on the results obtained from clinical trials conducted in Japan. The clinical trials where a Phase 2 dose responsive study, a Phase 3 comparison study with a GnRH agonist, and a Phase 3 long-term drug administration study, which indicated that Ulipristal possesses good tolerability and that it was effective in improving menorrhagia symptoms that resulted from uterine fibroids.

We would like to thank all the patients and healthcare professionals who participated in this series of clinical trials, and will continue to seek approval in order to provide additional treatment options for the treatment of 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.