Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Pharmaceutical Presents the Results of Phase III Clinical Trial for Oral Contraceptive LF111 (Drospirenone) at a Conference

TOKYO, November 13, 2024 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/ President, Representative Director: Sohta Yamaguchi, hereinafter referred to as "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE:4886), announced that ASKA presented the results of the domestic Phase III clinical trial of LF111 (drospirenone) for Japanese women seeking contraception at the 39th annual meeting of the Japan Society for Menopause and Women's Health on November 9 and 10, 2024. ASKA filed the application for manufacturing and marketing approval for this product as contraceptives to the authorization on June 24, 2024.

Presentation title

Phase III Clinical Trial to Evaluate the Efficacy and Safety of LF111 for Japanese Women Seeking Contraception

Objective

The trial was a multicenter, non-randomized, open-label, uncontrolled Phase III clinical trial aimed at verifying the efficacy (contraceptive effect) and evaluating the safety of LF111 for Japanese women seeking contraception.

Method

LF111 was administered orally once daily for 28 days per cycle for a total of 13 cycles.

Results

The overall Pearl Index, the primary endpoint, met the evaluation criteria set for verifying the contraceptive effect, confirming the efficacy of LF111 in contraception. Adverse effects observed in more than 5% of subjects included intermenstrual bleeding, headache, lower abdominal pain, abdominal pain, severe menstrual bleeding, diarrhea, nausea, and acne.

Conclusion

The administration of LF111 to Japanese women demonstrated a favorable contraceptive effect. Additionally, the safety profile was acceptable, and the drug was well-tolerated.

Currently, the Combined Oral Contraceptive Pill (COCP), which contains two types of female hormones, synthetic estrogen and progestin, is used as an oral contraceptive in Japan. This drug, a progestogen-only pill (POP) containing drospirenone, is approved and marketed in 59 foreign countries (as of November 12, 2023). According to the World Health Organization guidelines, POP carries a lower risk of venous thromboembolism than COCP and is more highly recommended than COCP for smokers, obese women, women with hypertension or valvular disease, or those with a history of deep vein thrombosis or pulmonary embolism.

ASKA expects that this drug will provide a new option for women who wish to use contraception and contribute to the improvement of their quality of life (QOL).

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