

# Press Release



## **ASKA Pharmaceutical Achieves the Primary Endpoint of Phase III Clinical Trial on LF111 in Japan**

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**TOKYO, April 11, 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 achieved the primary endpoint of the domestic Phase III clinical trial (hereinafter referred to as the "Trial") on LF111 (generic name: drospirenone) in Japanese women seeking birth control.

ASKA acquired exclusive rights to develop and market the Product for the territories of Japan and Republic of Korea from Insud Pharma (Head Office: Madrid, Spain) in January 2020. ASKA conducted this Trial to evaluate the efficacy (contraceptive effectiveness) and safety of 13 cycles of the drug in Japanese women seeking contraception. As a result, ASKA achieved the overall pearl index, the primary endpoint of the Trial, and the drug's efficacy was verified. Accordingly, ASKA will proceed with preparations for filing for manufacturing and marketing approval in the first quarter of this fiscal year. Furthermore, ASKA will discuss the detailed results of the Trial in articles and at academic conferences.

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).

### **About LF111**

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.

### **About Insud Pharma**

Insud Pharma (<https://www.insudpharma.com/en/>) is a leading Spanish company with a track record in the pharmaceutical and healthcare industry spanning over 45 years. With 9,000 employees worldwide, Insud Pharma's contribution to global public health is enormous, thanks to the medicines and APIs developed and manufactured at its three highly synergic business units: industrial (Chemo), brand (Exeltis) and biotechnology (mAbxience).

**About the Pearl index**

Number of pregnancies per 100 women using the contraceptive method for 1 year (13 cycles) (vs. 100 woman-years)

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**Media Contacts**

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