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Press Release

ASKA Pharmaceutical Holdings Co., Ltd.

ASKA Pharmaceutical Initiates Phase III Clinical Trial of Drospirenone Formulation (LPRI-CF113) in Japan

— Initiation of a Randomized Head-to-Head Trial (RCT) Comparing Progestin Therapies in Patients with Dysmenorrhea —

TOKYO, November 4, 2026 – ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886, Head Office: Minato-ku, Tokyo / President, Representative Director: Sohta Yamaguchi) hereby announces that its subsidiary, ASKA Pharmaceutical Co., Ltd. ("ASKA Pharmaceutical") has initiated a Phase III clinical trial in Japan PROFILE-D* in patients with dysmenorrhea for LPRI-CF113 (the "Drug"), a novel drospirenone formulation in the obstetrics and gynecology field developed by Insud Pharma (Head Office: Madrid, Spain).

PROFILE-D is a randomized controlled trial (RCT) designed to evaluate the efficacy and safety of the Drug against an existing progestin formulation in patients with dysmenorrhea. Many dysmenorrhea treatments approved in Japan have been evaluated in placebo-controlled trials. This will be the first clinical trial in Japan to directly compare the Drug with an existing progestin formulation.
The Drug is a continuous-use progestin formulation based on a biphasic drospirenone regimen. ASKA Pharmaceutical is developing the Drug, licensed from Insud Pharma, in Japan for the treatment of dysmenorrhea. On March 10, 2025, ASKA Pharmaceutical announced the initiation of a Phase I/II clinical trial of the Drug in Japan. The transition to a Phase III clinical trial represents an important step in the development of the Drug.
Dysmenorrhea is a significant health issue affecting many women and can substantially impact daily life, education, and employment. As a specialty pharmaceutical company focused on obstetrics and gynecology, ASKA Pharmaceutical aims to create a new treatment option through the development of the Drug and contribute to improving women's health and quality of life.

The impact of this matter has already been reflected in the Company's consolidated earnings forecast for the fiscal year ending March 31, 2027.

* Origin of the Trial Name
The name PROFILE-D is derived from "Profile of Progestin Therapies in Dysmenorrhea: A Randomized Head-to-Head Trial Comparison of Biphasic Drospirenone and Monophasic Dienogest."
The term "PROFILE" refers to the characteristics and distinctive features of the therapies and

reflects the aim of this trial to clarify the characteristics of progestin therapies for dysmenorrhea. The letter “D” represents Drospirenone, Dienogest, the comparator, and Dysmenorrhea.

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).

Media Contacts
ASKA Pharmaceutical Holdings Co., Ltd.
Group Management Department
Tel: +81-3-5484-8366
Email: kouhou@aska-pharma.co.jp