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Press Release



ASKA Obtains Marketing Authorization of Emergency Contraceptive Pill NORLEVO® as Switch to OTC Use and Daiichi Sankyo Healthcare Handles Distribution and Sales

TOKYO, October 20, 2025 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/ President, Representative Director: Sohta Yamaguchi, hereinafter "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886), and Daiichi Sankyo Healthcare Co., Ltd. (Head Office: Chuo-ku, Tokyo; Representative Director and President: Takahiro Uchida), jointly announce the marketing authorization and distribution as a switch to OTC use of the emergency contraceptive pill "NORLEVO®", a trademark owned by Perrigo Company plc,.

Through the collaboration of ASKA, Daiichi Sankyo Healthcare, and Perrigo Company plc, a significant step is being taken to empower Japanese women in the area of reproductive health. Driven by a shared mission to enable informed choices, the switch to OTC use of NORLEVO® marks a key milestone in advancing Sexual Reproductive Health and Rights (SRHR), reinforcing our commitment to self-care, accessibility, and individual well-being.

The impact of this matter on FY2025 is currently being examined. If any impact arises, it will be promptly disclosed.

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News Release





ASKA Obtains Marketing Authorization of Emergency Contraceptive Pill NORLEVO® as Switch to OTC Use and Daiichi Sankyo Healthcare Handles Distribution and Sales

TOKYO, October 20, 2025 – ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/ President, Representative Director: Sohta Yamaguchi, hereinafter "ASKA"), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. (TSE: 4886) is pleased to announce that ASKA has obtained the marketing authorization as a switch to OTC use of the emergency contraceptive pill commercialized under the trademark "NORLEVO®", owned by Perrigo Company plc, pioneer in the over-the-counter (OTC) self-care market (hereinafter the "Product"). Furthermore, following the authorization, Daiichi Sankyo Healthcare Co., Ltd. (Head Office: Chuo-ku, Tokyo/ President: Takahiro Uchida, hereinafter "Daiichi Sankyo Healthcare") will proceed to preparations for the launch of the Product as a distributor and will enhance the information provision system.

Regarding the switch to OTC use of the emergency contraceptive pills, the examination began in 2016 when the request related to the switch to OTC use of emergency contraceptive pills was submitted to the "the Evaluation and Review Committee on the Transfer from Prescription to Pharmaceuticals Requiring Guidance/OTC Pharmaceuticals" (the Evaluation and Review Committee). In 2023, a survey project to prepare an environment for the proper sale of emergency contraceptive pills (test sales of emergency contraceptive pills) was launched.

Under these circumstances, in order to build a system that can respond to various requests, ASKA filed an application for new marketing approval last year and has now obtained authorization for the switch to OTC use (pharmaceuticals requiring guidance).

Daiichi Sankyo Healthcare will strive to promote the proper usage of the Product to ensure correct and safe use based on the knowledge acquired through the sales of numerous Rx-to-OTC switched products.

The product specifications and sales timing will be announced at a later date.

Reference

1. About Emergency Contraceptive NORLEVO®

NORLEVO® (INN: levonorgestrel) is a Rx-to-OTC switched product of the first emergency contraceptive pill approved in Japan as a contraceptive to be taken after unprotected sexual intercourse (UPSI) or contraceptive failure. ASKA distributed the Product from Laboratoire HRA Pharma (now a Perrigo Company plc) in France and launched it as an ethical pharmaceutical drug in May 2011. Also known as the "morning after pill," it prevents unwanted pregnancy if taken within 72 hours of UPSI (81% pregnancy prevention rate).

Taking NORLEVO® after UPSI or contraceptive failure inhibits or delays ovulation, such that no egg is released hence it won't meet the sperm - therefore it can help prevent pregnancy before it starts. If ovulation has already occurred, no emergency contraception pill will work. NORLEVO® does not cause an abortion and cannot interrupt an existing pregnancy.

Emergency contraceptive pill is designated as an "essential drug" by the World Health Organization (WHO) and can be purchased without a prescription in about 90 countries and regions worldwide. In Japan, authorization was granted for the manufacture and sale of emergency contraceptive as a drug requiring special instructions at the Second Meeting of the Pharmaceutical Affairs Council's Subcommittee on Pharmaceuticals Requiring Guidance/OTC Pharmaceuticals in 2025.

2. About ASKA Pharmaceutical Co., Ltd.

ASKA Pharmaceutical is engaged in business focusing on new drugs, specializing in the three key therapeutic areas of internal medicine, obstetrics and gynecology, and urology, under the corporate philosophy: "Contribute toward the improvement of people's health and progress in medicine through the development of innovative products."

ASKA will solidify its position as a competitive specialty pharma company and contribute to people's health by responding to changing social needs, based on our contributions through pharmaceuticals.

3. About Daiichi Sankyo Healthcare Co., Ltd.

Daiichi Sankyo Healthcare operates its Over-The-Counter (OTC) drug business based on the Daiichi Sankyo Group's corporate philosophy of "creating innovative pharmaceuticals addressing diverse medical needs," offering products that consumers can choose and purchase for themselves.

Currently, the company is expanding its business areas beyond OTC pharmaceuticals to include functional skincare, oral care, and food products, embracing its corporate slogan, "Fit for You – Join us in creating a healthier lifestyle that fits you perfectly," and working toward its realization.

Through these initiatives, Daiichi Sankyo Healthcare promotes "self-care," where individuals protect and manage their own health, contributing to the realization of a society in which everyone can remain healthier and more beautiful.

4. About Perrigo Company plc

Perrigo Company plc is a leading pure-play self-care company with over a century of experience in providing high-quality health and wellness solutions to consumers primarily in North America, Europe and in Asia. As a pioneer in the over-the-counter (OTC) self-care market, Perrigo offers trusted self-care solutions that can be used without the need for a prescription, ensuring accessibility and choice for consumers across molecules, dosage forms, and value tiers.

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^{*} The Daiichi Sankyo Group is engaged in the business of innovative pharmaceuticals, vaccines, and OTC drugs.