February 14, 2020
LEO Pharma K.K.
Kyowa Kirin Co., Ltd.

Sales Collaboration Agreement Reached for Dovobet® Foam Formulation for Psoriasis Vulgaris Treatment in Japan
—Marketing Authorization Application Submitted—

Tokyo, Japan, February 14, 2020 --- LEO Pharma K.K. (Head Office: Tokyo; Representative Director: Stefan Sakurai), LEO Pharma A/S, the parent company of LEO Pharma K.K., (Head Office: Ballerup, Denmark; President and CEO: Catherine Mazzacco) and Kyowa Kirin Co., Ltd. (Head Office: Tokyo; President and CEO: Masashi Miyamoto, Kyowa Kirin) entered into a sales and marketing collaboration agreement to market a new foam formulation for topical application ("the drug") as an additional dosage form of Dovobet® for psoriasis vulgaris treatment on January 29, 2020. In addition, LEO Pharma K.K. announced that it applied for marketing authorization for the drug as an additional dosage form of Dovobet® on February 13, 2020.

Following approval, LEO Pharma K.K. will supply the new drug, as well as continue to supply Dovobet® Ointment and Dovobet® Gel, to Kyowa Kirin, which will be responsible for sales and providing information to medical institutions via its medical representatives. Also, LEO Pharma K.K. and Kyowa Kirin will jointly conduct marketing activities. Kyowa Kirin will share sales profits with LEO Pharma K.K. as well as make sales-based milestone payments.

Dovobet®, a combined topical preparation containing calcipotriol hydrate as active vitamin D_3 and betamethasone dipropionate as a steroid, was developed by LEO Pharma A/S. Originally approved as an ointment for psoriasis vulgaris in Denmark in 2001, Dovobet® has been approved in more than 90 countries, including the U.S., in the years since. It is now used worldwide as one of the first-line options for treating psoriasis vulgaris.

In Japan, Dovobet® Ointment and Dovobet® Gel were approved and launched for the indication of psoriasis vulgaris in 2014 and 2018, respectively. Now a foam-type product with good extensibility for relatively easier and immediate application has been developed for additional convenience and adherence. The companies aim to contribute to improved quality of life for additional patients by adding this foam formulation to its product lineup.

Regulatory approval for Dovobet® as a foam formulation with the brand name Enstilar® has been granted in 37 countries as of July 2019.

LEO Pharma, headquartered in Denmark, is a world leader in medical dermatology, noted for its strong development pipeline, wide range of therapies, and pioneering spirit aimed at helping people achieve healthy skin. LEO Pharma is developing new dermatological therapies for multiple indications, responding to business opportunities created by a significant expansion of the company's product portfolio due to factors such as the acquisition of Bayer's global prescription dermatology business.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About psoriasis vulgaris

Psoriasis is a chronic skin disorder. Typical symptoms include systemic erythema with clearly demarcated lesions, induration and hyperplasia inducing silver white plaques on the skin. Itching, inflammatory arthritis and abnormal nail morphology may also manifest.

About adherence

Adherence refers to whether patients take their medications as prescribed.

About LEO Pharma K.K.

LEO Pharma K.K. was established in June 2010 as the wholly owned Japanese subsidiary of LEO Pharma A/S in Denmark. The company aims to establish a solid position as a specialty pharmaceutical company in Japan with expertise in the field of dermatology.
For more information, visit www.leo-pharma.jp/

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*1 Kubota K, et al. BMJ Open 2015;5:e006450. doi:10.1136/bmjopen-2014-006450