

# News release

## Approval of Dovobet® Foam for Psoriasis Vulgaris in Japan

**Tokyo, Japan, January 13, 2021** -- Kyowa Kirin Co., Ltd. (President and CEO: Masashi Miyamoto, Kyowa Kirin, TSE: 4151) today announced that LEO Pharma K.K. (Head Office: Tokyo; Representative Director: Stefan Sakurai) has received an approval for manufacturing and marketing Dovobet® Foam for the treatment of psoriasis vulgaris as an additional dosage form of Dovobet® from Japan's Ministry of Health, Labour and Welfare (MHLW).

Dovobet®, a combined topical preparation containing calcipotriol hydrate as active vitamin D3 and betamethasone dipropionate as a steroid, was developed by LEO Pharma A/S, the parent company of LEO Pharma K.K., (Head Office: Ballerup, Denmark; President and CEO: Catherine Mazzacco).

In Japan, Dovobet® Ointment and Dovobet® Gel were approved and launched for the indication of psoriasis vulgaris in 2014 and 2018, respectively. Kyowa Kirin expects that the foam-type product with good extensibility for relatively easier and immediate application would contribute to additional convenience and medication adherence. Additionally, regulatory approval for Dovobet® as a foam formulation with the brand name Enstilar® has been granted in more than 40 countries.

LEO Pharma K.K. and Kyowa Kirin have a sales and marketing collaboration agreement to market Dovobet® Foam as well as Dovobet® Ointment and Dovobet® Gel. LEO Pharma K.K. will be responsible for the product supply and Kyowa Kirin will be responsible for sales and providing information to health care professionals via its medical representatives. Also, LEO Pharma K.K. and Kyowa Kirin will jointly conduct marketing activities.

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.

### 【Summary of Dovobet® Foam】

Product Name	Dovobet® Foam
Nonproprietary Name	Calcipotriol hydrate / Betamethasone dipropionate
Composition	1 g contains 52.2 µg calcipotriol hydrate (as 50.0 µg calcipotriol), 0.643 mg betamethasone dipropionate
Indication	Psoriasis vulgaris
Dosage and Administration	Usually applied once daily in the required amount to the affected site
Packaging	1 x 60 g
Approval date	January 6, 2021
Distributed by	Kyowa Kirin Co., Ltd.
Marketing authorization holder	LEO Pharma K.K.

**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 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 <http://www.leo-pharma.jp/>