

Launch of Dovobet[®] Foam for Psoriasis Vulgaris in Japan

Tokyo, Japan, June 18, 2021— LEO Pharma K.K. (Head Office: Tokyo; Representative Director: Tord Labuda) and Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") today announced that a new product, Dovobet[®] Foam, is launched on June 18, 2021. Dovobet Foam was approved for the treatment of psoriasis vulgaris as an additional dosage form of Dovobet by MHLW (Ministry of Health, Labour and Welfare) in Japan, January 6, 2021.

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, (Head Office: Ballerup, Denmark; President and CEO: Catherine Mazzacco) the parent company of LEO Pharma K.K. It was approved as an ointment for psoriasis vulgaris in Denmark in 2001 and approved as a gel in the US in 2008. And it has been approved and used in more than 90 countries. In Japan, Dovobet Ointment and Dovobet Gel were approved and launched for the indication of psoriasis vulgaris in 2014 and 2018, respectively.

Dovobet Foam has been developed for providing new treatment options from the perspective of convenience and compliance, while ensuring the efficacy of existing ointments. Regulatory approvals as the foam formulation with the brand name Enstilar have been granted in other more than 40 countries since its first approval in the US in 2015. The companies aim to contribute to improved quality of life for more patients by adding this new solution.

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

[Summary of Dovobet[®] Foam]

Brand name	Dobovet [®] Foam
Nonproprietary Name	Calcipotriol Hydrate / Betamethasone Dipropionate
Composition	1 g contains 52.2 µg of calcipotriol hydrate (50.0 µg as calcipotriol) and 0.643 mg of betamethasone dipropionate
Indications	Psoriasis vulgaris
Dosage	Usually, apply an appropriate amount to the affected area once a day.
Precautions related to usage / dose	<ol style="list-style-type: none"> 1. Do not use more than 90 g per week. 2. The efficacy and safety of this drug when administered for more than 4 weeks have not been established. When treating with this drug, observe the progress carefully and do not continue to use it indiscriminately.
Package	1×60 g
Approval date	January 6, 2021
NHI price listing date	June 18, 2021
NHI price	221.30 yen / g
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 a wholly owned Japanese corporation of LEO Pharma A/S in Denmark. LEO Pharma K.K. is conducting business activities to establish a solid position in Japan as a specialty pharmaceutical company specializing in dermatology. More details: <http://www.leo-pharma.jp/>

**About Kyowa Kirin**

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a more than 70-year heritage, we apply cutting-edge science including an expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology, Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com>.