

July 16, 2008
Galderma KK
Shionogi & Co., Ltd.

Marketing and Manufacturing Approval for Differin[®] Gel 0.1%
A topical treatment for acne vulgaris

July 16, 2008 – Galderma KK (Head Office: Tokyo; President: Humberto C. Antunes) today announced that it received marketing and manufacturing approval for Differin[®] Gel 0.1% containing active ingredient, Adapalene; a novel topical treatment for acne vulgaris. It is scheduled to launch the product pending its price listing on National Health Insurance (NHI). Galderma and Shionogi (Head Office: Osaka; President: Isao Teshirogi) will co-promote the product with their respective sales forces while Shionogi retains exclusive sales and distribution rights for the product for a period of 8 years from the date of launch..

Differin[®] Gel 0.1% is indicated for the topical treatment of acne vulgaris, which contains a naphthoic acid derivative that possesses retinoid-like activities discovered and developed by Galderma. It is mechanistically suggested that Adapalene binds to specific retinoic acid nuclear receptors (RAR) and normalizes the differentiation of follicular epithelial cells resulting in reducing microcomedo formation linked to comedones, non-inflammatory lesions (comedones appear as blackheads or whiteheads) and subsequently emerging inflammatory lesions (usual red lesions).

This product is currently marketed in more than 80 countries, where it has become an important therapy for more than 22 million patients since initial launch in France in 1995. The clinical studies conducted in Japan was the

largest studies of acne vulgaris and enrolled 238 and 644 Japanese patients in phase II and III clinical studies, respectively. As a result, Differin[®] Gel 0.1% is a first-in-class topical retinoid which acquired marketing and manufacturing approval for the treatment of acne vulgaris in Japan.

With the introduction of Differin[®] Gel 0.1% in Japan, Galderma KK and Shionogi aim to increase the awareness of Doctors on acne and its treatment, and to provide comprehensive scientific information to healthcare providers with the goal of improving treatment outcomes as well as the quality of life of Japanese acne patients.

For Reference:

About Acne

Acne is a chronic, inflammatory disease of the pilo-sebaceous unit, most commonly characterized by the formation of non-inflammatory and inflammatory lesions, particularly on the face. The disease leaves numerous physical consequences (scarring) and psychological consequences, justifying the need for a precise diagnosis of the type and severity of the acne, and appropriate, personalized treatment for each individual patient. There are different types of acne, but the most common is acne vulgaris.

Product Overview

Product Name:	Differin [®] Gel 0.1%
Generic Name:	Adapalene
Indication:	Acne vulgaris
Dosage and Administration:	An appropriate amount of gel is applied on the affected areas once daily after facial cleansing
Form and Content:	White gel containing 0.1% adapalene
Approval Date:	July 16, 2008

About Galderma

Galderma is an international pharmaceutical company specializing in the research, development, manufacturing and marketing of therapeutic, corrective and aesthetic solutions for dermatology patients based on the corporate mission, "Committed to the future of dermatology". Created in 1981, Galderma is a 50/50 joint venture between Nestle; the world's largest food company and L'Oreal; the world's largest cosmetic company, a global pharmaceutical company specializing in dermatology.

Its expertise spans a broad spectrum of skin, hair and nail diseases, with a focus on acne, rosacea, psoriasis / steroid-responsive dermatoses, onychomycosis, pigmentary disorders, skin cancers and medical solutions for skin senescence.

The company had global revenues of 735 million EUR (approximately 121 billion yen) in 2007 (increased 12.7 percent compared with the previous year) and commits 14.1 percent of its annual revenues to R&D for its sustained growth.

Galderma KK, the fully-owned Japanese arm of Galderma, was established in 1996. The company has been marketing PEKIRON®, a topical anti-fungal product under a licensing agreement with Kyorin Pharmaceutical since 2002.

For more information, please see the website <http://www.galderma.jp>.

For further information:

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