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FDA APPROVES PICATO® (ingenol mebutate) GEL, THE FIRST AND ONLY TOPICAL ACTINIC KERATOSIS (AK) THERAPY WITH 2 OR 3 CONSECUTIVE DAYS OF ONCE-DAILY DOSING

New option for the topical treatment of actinic keratosis on the face, scalp, trunk and extremities

Parsippany, NJ –January 25, 2012 – LEO Pharma announced today that the U.S. Food and Drug Administration (FDA) approved Picato® (ingenol mebutate) gel (0.015%, 0.05%) for the topical treatment of actinic keratosis (AK). AK is a precancerous condition caused by cumulative sun exposure that has the potential to progress to squamous cell carcinoma (SCC), the second most common type of skin cancer.[1,2] Picato® 0.015% gel is used once daily on the face and scalp for three consecutive days, and Picato® 0.05% gel is used once daily on the trunk and extremities for two consecutive days.[3] Picato® gel is the first and only topical AK therapy that can be used for as little as two or three days.

According to the American Academy of Dermatology (AAD), 1 in 5 Americans will develop skin cancer in the course of their lifetime.[4] Studies show that about 65 percent of squamous cell carcinomas begin as untreated actinic keratosis,[5] and guidelines from the AAD estimate that 60 percent of predisposed persons older than 40 have at least one actinic keratosis.[6]

“Since there is no way to predict which actinic keratosis will advance to skin cancer, early detection and treatment of lesions are critical,” said ingenol mebutate study investigator Dr. Mark Lebwohl, Department of Dermatology, Mount Sinai Medical Center, New York, New York. “What makes this new solution particularly exciting is the two or three day course of treatment.”

In four phase III clinical studies of more than 1,000 patients with actinic keratosis, a significantly higher proportion of those treated with Picato® gel (n=503) saw complete clearance of AKs in the field of treatment as compared to placebo (n=502). The most common adverse events (AEs) were local skin reactions (LSRs), including erythema, flaking/scaling, crusting and swelling.

“LEO Pharma is committed to helping people achieve healthy skin. We are pleased to introduce Picato® gel, a new treatment option for patients with actinic keratosis, a common precancerous condition,” said John Koconis, President and CEO, LEO Pharma Inc. “The approval of Picato® gel in the United States is another step forward in helping us realize our vision of becoming a preferred dermatology care partner worldwide.”

For more information about Picato® gel, including full prescribing information, please visit www.leo-pharma.us/home/products/LEO-pharma-products.aspx.

About Actinic Keratosis
Actinic keratosis (AK) is a dry, scaly, rough-textured patch or lesion that forms on the outermost layer of the skin after cumulative exposure to ultraviolet (UV) light, such as sunlight. In some cases, the lesions

may be easier to feel than see. The name actinic keratosis literally means “sun-induced rough spot” and therefore the lesions, which can be gray, pink, red or the same color as the skin, are often called sun spots and/or age spots.

A job that requires spending hours of time outside, or everyday activities such as gardening, exercise or attending outdoor sporting events, can lead to sun damage if skin isn’t adequately protected. People at high risk are often fair-skinned men and women over the age of 40 who may have accumulated a significant amount of sun exposure over the course of many years.[1]

About Picato® (ingenol mebutate) gel, 0.015%, 0.05%
Picato® gel is indicated for the topical treatment of actinic keratosis.

To date, 18 clinical trials have been completed for the use of Picato® gel, from phase I trials through pivotal phase III trials. In phase III clinical trials, 60-68 percent of patients with actinic keratosis on the face and scalp saw 75 percent or greater reduction of existing AKs (versus 7-8 percent with placebo), while 44-55 percent of patients with AKs on the trunk and extremities experienced 75 percent or more reduction (versus 7 percent reduction for placebo). Patients treated with Picato® gel saw 37-47 percent complete clearance of lesions on the face and scalp, and 28-42 percent on the trunk and extremities, versus up to 5 percent complete clearance with placebo in all studies. Local skin responses (LSRs) on the face and scalp were observed to peak around day 4 and resolve by day 15 in the majority of patients. LSRs on the trunk and extremities peaked around day 8 and markedly improved by day 29.

The most common adverse events were LSRs and included erythema, flaking/scaling, crusting and swelling. Other AEs occurring in ≥ 2 percent of subjects treated with Picato® gel include pain, pruritus and infection at the application site, as well as periorbital edema and headache.

IMPORTANT SAFETY INFORMATION
For topical use only; not for oral, ophthalmic, or intravaginal use. Eye disorders, including severe eye pain, eyelid edema, eyelid ptosis, periorbital edema can occur after exposure. Patients should wash hands well after applying Picato® gel, and avoid transfer of the drug to the periocular area during and after application. Severe skin reactions in the treated area, including erythema, crusting, swelling, vesiculation/pustulation, and erosion/ulceration, can occur after application. Administration of Picato® gel is not recommended until the skin is healed from any previous drug or surgical treatment. The most common adverse reactions observed in clinical trials (≥2 %) are local skin reactions, application site pain, application site pruritus, application site irritation, application site infection, periorbital edema, nasopharyngitis and headache. There are no adequate and well-controlled studies of Picato® gel in pregnant women. Picato® gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety and effectiveness of Picato® gel for actinic keratosis in patients less than 18 years of age have not been established.

Please see full prescribing information available at www.leo-pharma.us/home/products/LEO-pharma-products.aspx.

About LEO Pharma
LEO Pharma Inc. is a wholly owned subsidiary of LEO Pharma A/S. Founded in 1908, LEO Pharma A/S is an independent, research-based pharmaceutical company. LEO Pharma A/S develops, manufactures and markets pharmaceutical drugs in more than 100 countries globally. The company has its own sales forces in 61 countries and employs more than 4,600 employees worldwide. LEO Pharma A/S is

headquartered in Denmark and is wholly owned by the LEO Foundation. For more information about LEO Pharma, visit www.leo-pharma.com.

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