Galderma Laboratories, L.P. today announced the completion of two independent Phase 3 clinical trials that evaluated the efficacy and safety of CD07805/47, a proprietary topical gel under investigation in adults with moderate to severe facial erythema (redness) of rosacea. Rosacea is a chronic, inflammatory and vascular condition of the face and eyes characterized by persistent erythema, flushing, inflammatory lesions and visible blood vessels that affects at least 16 million Americans\(^1\) and with estimates of prevalence ranging from less than 1% to more than 20% of the adult population in other countries globally.\(^2\)

The results of the two randomized, vehicle-controlled, multicenter Phase 3 trials that investigated the efficacy and safety of CD07805/47 applied topically once daily vs. vehicle (control) in adult patients with moderate to severe facial erythema of rosacea confirmed results observed in prior Phase 2 studies.

“The facial erythema associated with rosacea can have a negative psychosocial impact on patients, giving rise to anxiety and creating low self-confidence and embarrassment,” said Joseph F. Fowler, M.D., Clinical Professor of Dermatology at the University of Louisville. “Novel therapeutic approaches to address this can provide a significant impact on patient care.”

“Galderma is committed to partnering with healthcare providers to drive innovation and develop treatments for patients with dermatologic conditions,” said Francois Fournier, President of Galderma Laboratories, L.P. “These results are encouraging because this investigational treatment has the potential to one day address unmet needs in this highly prevalent condition.”

Galderma intends to submit a New Drug Application for CD07805/47 to the U.S. Food & Drug Administration and to the European Medicines Agency.

**Rosacea**\(^3\)

Rosacea is a chronic, inflammatory and vascular disorder affecting the face. The characteristic skin lesions (erythema, visible blood vessels, papules and pustules) appear in the middle of the face (forehead, nose, cheeks) between the ages of 20 and 50, but typically are most common in men and women after 30.\(^1\)
The pathophysiology of rosacea is poorly understood and may be multifactorial, involving vascular reactivity and immune system responses. Many of the most cited pathogenic theories on the etiology of rosacea focus on abnormalities in cutaneous vascular homeostasis. These theories are based on the prominent transient and non-transient facial erythema observed in a majority of patients with rosacea. Disease manifestations are thought to arise from cutaneous vasomotor instability, the term commonly used to refer to abnormal involuntary dilatation and reactivity of small subcutaneous resistance arteries. The etiology of vasomotor instability in patients with rosacea is unknown. Triggers for the condition may include spicy food, alcohol, weather changes, sun, and hot showers, which often have a negative impact on the patients’ social life. Stinging, burning, sensitivity of the skin and inability to tolerate cosmetics are also very common, and in some cases, the eyes can become red, dry and itchy. If left untreated, the condition may worsen.2

About Galderma

Galderma is a global pharmaceutical company founded in 1981 and exclusively focused on dermatology. The company has 31 wholly-owned affiliates with a worldwide network of distributors and 4,000 employees. Galderma’s extensive product portfolio is available in 70 countries and treats a range of dermatological conditions including: acne, rosacea, onychomycosis, psoriasis & steroid-responsive dermatoses, pigmentary disorders, skin cancer and medical solutions for skin senescence. In 2011, Galderma acquired Q-Med, a Swedish medical device company specialized in aesthetics, strengthening Galderma’s presence in the aesthetic and corrective market. With approximately 19% of revenues invested each year to discover and develop new products and access innovative technologies, the company is one of the world’s leading investors in dermatology R&D. Four state-of-the-art R&D centers, of which Sophia Antipolis in France is one of the largest dermatology sites in the world, and four manufacturing sites, are dedicated to providing a wide range of innovative medical solutions which meet the highest standards of safety and efficacy. Strategic global brands include Epiduo, Oracea, Clobex, Differin, Rozex/MetroGel, Silkis/Vectical, Tri-Luma, Loceryl, Cetaphil, Metvix, Azzalure, Dysport*, Restylane and Emervel.

*Dysport is a trademark of Ipsen

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