Galderma Receives FDA Approval of Novel Treatment Option for Rosacea Patients

Soolantra® (ivermectin) Cream, 1% found to be well tolerated with powerful results seen as early as two weeks

FT. WORTH, TEXAS – December 23, 2014 – Galderma Laboratories, L.P. today announced that the U.S. Food and Drug Administration (FDA) approved Soolantra® (ivermectin) Cream, 1% for the once-daily topical treatment of inflammatory lesions, or bumps and pimples, of rosacea. Rosacea is a common, but often misunderstood, skin disorder affecting 16 million Americans, predominantly women, ages 30 and older. Although the cause of rosacea is unknown, research suggests that there are multiple triggers for the inflammation associated with the condition, including sun, alcohol, spicy food and exercise. Recent studies have further solidified that generally harmless microscopic Demodex mites may also be a culprit. These mites are normal inhabitants of everyone's skin, but may appear in greater numbers on the faces of people with rosacea.

In clinical studies, Soolantra Cream effects were seen as early as week two with continuous improvement in patients with inflammatory lesions of rosacea. Furthermore, in a separate head to head study with metronidazole 0.75% cream – a current gold standard – Soolantra Cream was shown to be more efficacious from as early as week three onwards. While the mechanism of action of Soolantra Cream is unknown, ivermectin, the active ingredient in Soolantra Cream, has been reported to have both anti-inflammatory and antiparasitic activity.

"Rosacea is a common and challenging condition to manage as it tends to vary from patient to patient, often requiring a tailored approach. For that reason, we are always looking for innovative new treatments," said Linda Stein Gold, M.D., Galderma consultant and clinical investigator for the phase 3 studies of Soolantra Cream. "While some rosacea treatments for the common bumps and pimples of the condition may take more than four weeks to show effect, Soolantra Cream may provide initial results as early as week two."

Rosacea is a chronic and progressive disease. If left untreated, it can worsen, and symptoms, like the inflammatory lesions of rosacea, may become more difficult to treat. In a national study of rosacea patients, 46 percent of sufferers reported that they changed their medication, usually due to lack of improvement. There is an ongoing need for patients and healthcare practitioners to have other effective treatment options for the condition.

The approval of Soolantra Cream was based on two pivotal phase 3, multicenter, randomized, double-blind, 12-week, vehicle-controlled, parallel-group studies where Soolantra Cream met each of its co-primary efficacy endpoints. The onset of treatment effect was observed as early as week two with continuous improvement. In long-term extensions to the 12-week studies, Soolantra Cream was also safe and well-tolerated for an additional 40 weeks (up to 52 weeks in total), which is critical for rosacea patients who often have sensitive skin. Some study subjects experienced skin burning sensation and skin irritation while using Soolantra Cream.

"As a world leader in skin health, Galderma is committed to providing innovative treatment options for clinicians and patients, and the approval of Soolantra underscores these ongoing efforts," said Stuart Raetzman, Chief Executive Officer of Galderma Laboratories, L.P. and Senior Vice President North America. "Our laser focus on skin health has helped us expand upon our rosacea franchise to continue to deliver medicines that offer novel approaches to help address important patient needs."

About Rosacea

Rosacea is a common, inflammatory and vascular disorder affecting the face. Redness, visible blood vessels, bumps, and pimples typically appear in the middle of the face (forehead, nose, cheeks) after age 30 in men and women.

Because of the physical manifestation of rosacea on the face, the condition can cause embarrassment, anxiety and frustration, and can have a negative impact on the patients' social life. Stinging, burning and sensitivity of the skin are common, and in some cases, the eyes can become red, dry and itchy. Triggers for the condition may include spicy foods, alcohol, emotional stress, sun exposure, hot baths and generally harmless, microscopic Demodex mites found on the skin.

If left untreated, rosacea may worsen. If people suspect that they might have rosacea, they should visit their dermatologist or healthcare provider for diagnosis and to discuss what treatment is right for them.

About Galderma - A global company exclusively dedicated to dermatology

Galderma is a global company founded in 1981 committed to delivering innovative medical solutions to meet the dermatological needs of people throughout their lifetime while serving healthcare professionals around the world. The company has 34 wholly-owned affiliates with a worldwide network of distributors and more than 5,000 employees. Galderma's extensive product portfolio is available in 80 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.

With approximately 19 percent 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. Five state-of-the-art R&D centers and five manufacturing sites are dedicated to providing a wide range of innovative medical solutions which meet the highest standards of safety and efficacy.

Strategic brands in the U.S. include Cetaphil®, Epiduo®, Oracea®, Mirvaso®, Clobex®, Differin®, MetroGel®, Vectical®, Tri-Luma® and Pliaglis®.

For more information, please visit: GaldermaUSA.com

Important Safety Information - Soolantra® Cream
Indication: SOOLANTRA® (ivermectin) Cream, 1%, is indicated for the treatment of inflammatory lesions of rosacea. **Adverse Events**: In clinical trials with SOOLANTRA® Cream, the most common adverse reactions (incidence $\leq$ 1 %) included skin burning sensation and skin irritation. **Warnings / Precautions:** Not for oral, ophthalmic or intravaginal use.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit WWW.FDA.GOV/MEDWATCH or call 1-800-FDA-1088