

**Galderma Announces Positive Results of Phase 3 Trials of Investigational Ivermectin 1% Targeting Papulopustular Rosacea**

*Efficacy and Safety Data Presented at Late-Breaking Session of American Academy of Dermatology Meeting*

DENVER – March 22, 2014 – Galderma Laboratories, L.P. today announced the results of two pivotal phase 3 trials of ivermectin 1%, an investigational drug being evaluated for the treatment of papulopustular (inflammatory) rosacea. The data were presented at a Late-Breaking session of the 72<sup>nd</sup> annual meeting of the American Academy of Dermatology (AAD). The results of the studies, in which 910 subjects applied ivermectin 1% cream once daily for 12 weeks, demonstrate that ivermectin is safe and effective.

Both pivotal studies of ivermectin 1% cream significantly met their co-primary efficacy endpoints of treatment success as defined by Investigator Global Assessment (IGA) rating of clear skin, and change in inflammatory lesion count. In the studies, ivermectin 1% showed comparable tolerability and safety to its vehicle. Onset of treatment effect was observed at week four in both studies.

“Currently, there are a limited number of safe and efficacious topical medications available to treat chronic papulopustular rosacea,” said Stuart Raetzman, Chief Executive Officer of Galderma Laboratories, L.P. and Vice President North America. “We at Galderma are hopeful that the positive phase 3 data from the ivermectin 1% studies will lead to an additional effective treatment option for our healthcare provider partners.”

**Study Design**

Both pivotal studies were phase 3 randomized, double-blind, 12-week vehicle controlled parallel –group studies assessing the efficacy and safety of ivermectin 1% cream in subjects with papulopustular rosacea.

**Study Results**

Both pivotal studies met their co-primary efficacy endpoints. The effect was significant ( $p < 0.001$ ) in all primary and sensitivity analyses at Week 12 (ITT-LOCF). Onset of treatment effect was observed at week 4 in each study. The first co-primary endpoint was success rate (percent of subjects rated clear or almost clear on the IGA rating scale) at Week 12. In Study 1, 173 subjects (38.4%) were assessed as success with ivermectin 1% versus 27 subjects (11.6%) with vehicle ( $p < 0.001$ ). Statistical significance was observed from Week 4 with success in 49 (10.9%) and 13 (5.6%) patients for ivermectin 1% and vehicle, respectively. The results were consistent between the studies.

The second co-primary endpoint was reduction in inflammatory lesions, and both studies also demonstrated that ivermectin 1% was significantly superior to vehicle in reducing lesion counts, with

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statistical significance apparent at week 2 and continuing for the duration of the study. Trial patients using ivermectin 1% also showed an average reduction of more than 20 lesions versus a reduction of 12 and 13.4 lesions respectively in the control groups.

In both studies, ivermectin 1% showed comparable tolerability and safety to the control group vehicle. In Studies 1 and 2 in the ivermectin 1% cream group, 4.2% and 2.6% respectively of patients that reported adverse events (AEs) were considered to have AEs related to study treatment. In the vehicle group, 7.8% and 6.5% of reported AEs were treatment-related AEs respectively. There were no treatment-related serious AEs. The most common related AE in Study 1 was sensation of skin burning (1.8% in ivermectin 1%, 2.6% for vehicle) and the most common related AEs in Study 2 were pruritus and dry skin (0.7% and 0.9% respectively).

### **About Rosacea**

Rosacea is a chronic, inflammatory and vascular disorder affecting the face. Redness, visible blood vessels, bumps, and blemishes typically appear in the middle of the face (forehead, nose, cheeks) after age 30 in men and women. Rosacea affects an estimated 16 million Americans.

Triggers for the condition may include spicy foods, alcohol, emotional stress, sun exposure, and hot baths. 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, sensitivity of the skin is common, and in some cases, the eyes can become red, dry and itchy. 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 treatment.

### **About Galderma**

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 33 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% 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.

For more information, please visit: [GaldermaUSA.com](http://GaldermaUSA.com)