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**GALDERMA ANNOUNCES POSITIVE PHASE 3 TRIAL RESULTS OF INVESTIGATIONAL ADAPALENE
0.3%/BENZOYL PEROXIDE 2.5% (0.3% A/BPO) FOR THE TREATMENT OF ACNE**

Pivotal Data Presented at This Year's American Academy of Dermatology Meeting

Fort Worth, Texas – March 20, 2015 – Galderma Laboratories, L.P. today announced positive phase 3 trial results of adapalene 0.3%/benzoyl peroxide 2.5% (0.3% A/BPO) topical gel,^{1A} an antibiotic-free, investigational drug developed with a higher concentration of adapalene than that contained in Epiduo® (adapalene /benzoyl peroxide) Gel, 0.1%/2.5%. The investigational drug is being evaluated for the treatment of acne by the Food and Drug Administration (FDA).² The data were presented at the 73rd American Academy of Dermatology (AAD) annual meeting in San Francisco, CA.

The results of the study, in which 503 subjects (ages 12 years and older) were treated with 0.3% A/BPO, 0.1% A/BPO*, or vehicle gel, once daily for 12 weeks,^{1B} showed that the 0.3% A/BPO arm demonstrated a superior success rate compared to vehicle (33.7% vs 11.0%) in patients with moderate and severe acne,^{1C} and also showed a success rate (31.9% vs 11.8%) in patients with severe acne only.^{1D}

The scale used was the investigator global assessment (IGA) that organizes acne into five categories: 0 = clear skin; 1 = almost clear skin; 2 = mild acne severity; 3 = moderate acne severity; 4 = severe acne.³ Unique to this trial, the success rate was defined as percentage of subjects with an IGA of clear/almost clear skin,^{4A} and patients with moderate acne had to experience at least a 2 grade improvement - advancing from an original IGA score of a 3 or 4 at baseline to a final IGA score of 0 or 1 at week 12.^{4B}

“This phase 3 pivotal trial, which observed a fixed-dose combination of adapalene, successfully met its two endpoints consisting of superior efficacy compared to vehicle in the overall patient population (patients with moderate and severe acne), and greater efficacy in the sub-population (patients with

severe acne only),” explained Dr. Jonathan Weiss, MD of Gwinnett Clinical Research Center Inc., Snellville, GA and lead study author. “In other acne studies, the criteria for success rates is typically only a 2 grade improvement; however, in this study, which observed moderate and severe subjects, participants with severe acne had to obtain clear/almost clear skin and a 3 grade IGA improvement, further demonstrating the effectiveness of this treatment.”

Acne is the most common skin condition in the U.S., affecting 40-50 million Americans nationwide.^{5A} While there are effective and antibiotic-free treatment options available for various stages of acne (mild, moderate, severe), patients suffering from moderate and severe acne are more prone to relapse, suggesting there is an unmet need in treating this patient population.⁶

“We are encouraged by these positive Phase 3 data findings and are committed to developing and delivering innovative treatments to dermatologists and their patients,” stated Safia K. Rizvi, Vice President and General Manager, US Pharmaceutical Business, Galderma Laboratories. “Should this acne treatment option be approved by the FDA this year, physicians will have access to a new treatment option that will allow them to further customize acne management according to their patients’ individual needs.”

Study Design

The multicenter, randomized, double-blind, parallel-group, vehicle- and active-controlled study^{1E} assessed the efficacy and safety of 0.3% A/BPO in subjects with moderate and severe acne as well as in the subgroup of subjects with severe acne only.^{1F} 503 subjects (ages 12 years and older) were involved in the study with 251 (50%) subjects experiencing moderate acne, and the remaining 252 (50%) subjects experiencing severe acne.^{1B} Subjects were randomized to apply 0.3% A/BPO, 0.1% A/BPO, or vehicle gel once daily for 12 weeks.^{1G} The co-primary efficacy endpoints were success rate, change in inflammatory (IN) lesion count, and change in (NIN) non-inflammatory lesion count.^{1H}

Study Results

The co-primary efficacy endpoints were met in both the overall population (moderate and severe acne)^{1C} and in the severe population (severe disease only).^{1D} In the overall population, 0.3% A/BPO demonstrated superior success rate to vehicle (33.7% vs 11.0%).^{1C} In addition, superior changes in IN

lesions (-27.0 vs -14.4) and NIN lesion counts (-40.1 vs -18.4) and percent changes in IN lesions (-68.7% vs -39.2%) and NIN lesion counts were observed (-68.3% vs -37.3%, respectively) (all $P < .001$).¹¹

In the severe population, 0.3% A/BPO was superior to vehicle in success rate (31.9% vs 11.8%; $P=0.029$).^{1D} In addition, superior changes in IN lesion (-35.1 vs -15.4) and NIN lesion counts (-45.6 vs -17.2), as well as in percent changes in IN lesion (-74.4% vs -33.0%) and NIN lesion counts (-72.0% vs -30.7%, respectively) (all $P < .001$ unless otherwise noted).¹¹

In the study, the safety profile of 0.3% A/BPO was well tolerated and comparable to that observed for 0.1% A/BPO with mean tolerability scores less than mild. Treatment-related adverse events (AEs) were mild to moderate in severity (15 AEs were reported in 12 subjects [5.5%]). One subject (0.5%) in the 0.3% A/BPO group discontinued treatment due to an AE (atopic dermatitis flare). No treatment-related serious AEs were reported.^{1K}

**It should be noted that while 0.1% A/BPO was included for benchmarking purposes, this study was not designed or powered for formal hypothesis testing of superiority between 0.3% A/BPO vs 0.1% A/BPO; therefore, the study arm for adapalene 0.1%/BPO 2.5% gel is not provided in the poster.^{1L}*

About Acne

Acne is the most common skin condition in the United States, affecting more than 40 to 50 million people.^{5A} Acne appears when pores clog with dead skin cells,^{5B} and can have a wide-ranging negative impact on sufferers that includes both emotional and physical scars.⁷ Acne not only affects teenagers but also can be seen in men and women of all ages⁸ with research showing that the onset of acne is frequently seen in prepubescent patients.⁹

When it comes to acne treatment, long-term use of antibiotics may be a contributing factor to the overall global antibiotic resistance issue.^{10A} Propionibacterium acnes (*P. acnes*), a bacteria linked to acne, is increasingly becoming resistant to topical and oral antibiotics,^{10B} which may potentially cause a decrease in treatment efficacy against acne.^{10C}

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.

Galderma is the operating company of Nestle Skin Health, a global leader focused on enhancing the quality of life by delivering science-based solutions for the health of skin, hair and nails.

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, of which Sophia Antipolis in France is one of the largest dermatology sites in the world, 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 US include Epiduo[®] Gel, Oracea[®] Capsules, Clobex[®] Lotion/Spray/Shampoo, Differin[®] Gel, MetroGel[®] Gel, Vectical[®] Ointment and Cetaphil[®]. For more information, please visit www.galdermausa.com.

1 Weiss J., Stein Gold L. et al. Efficacy and Safety of Adapalene 0.3%/Benzoyl Peroxide 2.5% Topical Gel Versus Vehicle in Moderate And Severe Acne Vulgaris. Poster presented at the 73rd Annual American Academy of Dermatology Meeting.

2 Data on File, Galderma Laboratories, L.P.

3 FDA. Guidance for Industry Acne Vulgaris: Developing Drugs for Treatment. <http://www.fda.gov/downloads/Drugs/.../Guidances/UCM071292.pdf>. Accessed on March 5, 2015.

4 Data on File, Galderma Laboratories, L.P.

5 American Academy of Dermatology. Acne: Who gets and causes. <https://www.aad.org/dermatology-a-to-z/diseases-and-treatments/a---d/acne/who-gets-causes>. Accessed on March 5, 2015.

6 Quéréux G et. al. Prospective study of risk factors of relapse after treatment of acne with oral isotretinoin. *Dermatology*. 2006;212(2):168-76.

AAD Press Release; 3.16.15

LIT Code: EPID-341

7 American Academy of Dermatology. Acne. <https://www.aad.org/dermatology-a-to-z/diseases-and-treatments/a-to-z/acne>. Accessed on March 5, 2015.

8 American Academy of Dermatology. Acne. <https://www.aad.org/media-resources/stats-and-facts/conditions/acne>. Accessed on March 5, 2015.

9 Goldberg JL, et. al. Changing Age of Acne Vulgaris Visits: Another Sign of Earlier Puberty? *Pediatr Dermatol* 2011 Nov;28(6):645-648.

10 Humphrey S. Antibiotic Resistance in Acne Treatment. *Skin Therapy Let.* 2012;17(9). http://www.medscape.com/viewarticle/772258_1. Accessed on March 5, 2015.