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DATA SHOW NEW Epiduo™ (ADAPALENE/BPO) IS HIGHLY EFFECTIVE AND SIMPLIFIES ACNE THERAPEUTICS

At the 17th Annual EADV Congress in Paris, experts highlighted the excellent efficacy and safety profile of Epiduo™ (adapalene 0.1% / benzoyl peroxide 2.5%), a new once-daily topical gel for treatment of acne. Large-scale clinical trials have shown that Epiduo™ has a statistically significantly greater effect in reducing acne lesions compared to either adapalene or benzoyl peroxide (BPO) alone, with differences in lesion counts observed after 1 week.¹⁻³ Further, Epiduo™ has a tolerability profile that is comparable to adapalene.¹⁻³ Because of these properties and the cosmetic elegance of the formulation, patients report being highly satisfied with Epiduo™.

At the EADV symposium titled “*A New Era in Acne Management: How to Integrate New Drugs into Clinical Practice*”, data from two large scale trials of Epiduo™ were presented.^{1,2} The first, published by Thiboutot and coworkers,¹ was a multicenter, randomized, double-blind study of Epiduo™ in 517 subjects with moderate acne. Lesion counts were significantly lower in the group treated with Epiduo™ compared with other treatment groups with a statistically significant difference observed as early as week 1.¹ In addition, patients treated with Epiduo™ were significantly more

likely to have their acne completely or almost clear.¹ The frequency of adverse events and cutaneous tolerability for Epiduo™ were comparable to that observed with adapalene monotherapy.¹ These results were confirmed in the phase III study of Epiduo™ (n=1668) which had a similar design.² Beginning at week 4 and continuing through the duration of the study, Epiduo™ was associated with significantly higher success rates (clear/almost clear rating) compared with the other three treatment arms (P<.01 for all comparisons). At the 12 week timepoint, the median reduction in total lesions with Epiduo™ was -61% compared with -50% each for the adapalene and BPO arms and 32% for the vehicle arm (P<.001).²

“Dermatologists have long been awaiting the combination of a topical retinoid plus BPO, as this targets three of four major pathophysiologic factors in acne and gives an antimicrobial effect without an antibiotic,” said **Pr Harald Gollnick**, MD, co-chair of the symposium and Chair of the Department of Dermatology and Venereology at Otto-von-Guericke-Universität in Magdeburg, Germany. *“In addition, the anti-comedogenic actions of adapalene target acne precursor lesions – microcomedones – to help prevent the formation of new acne lesions.”* Co-chair **Pr Brigitte Dréno**, MD, PhD, from the Hôtel-Dieu in Nantes, France, agreed, and added *“My patients have been very pleased with the excellent clinical results and the ease of use and. They like once-daily treatment, and appreciate that there is no need to apply multiple creams or wait after cleansing when applying Epiduo™. I believe this compares very favorably with my patients’ perceptions of other acne treatments.”*

About the symposium

In “*A New Era in Acne Management: How to Integrate New Drugs into Clinical Practice*,” co-chairs **Pr Harald Gollnick**, MD, from Otto-von-Guericke-Universität in Magdeburg, Germany, and **Pr Brigitte Dréno**, MD, PhD, from the Hôtel-Dieu in Nantes, France were joined by **Pr Vincenzo Bettoli**, MD from the University of Ferrara in Ferrara, Italy, and **Christian Loesche**, MD, from Galderma Research and Development in Sophia Antipolis, France. Presentations covered how new insights into acne pathophysiology can help target drug utilization and development of new agents, the role of recently approved acne drugs, considerations in developing topical acne products, and clinical trial data with new Epiduo™.

About the 17th Annual EADV Congress

The 17th Annual Congress of the European Academy of Dermatology and Venereology (EADV) was held in Paris, France, from Wednesday 17th September 2008 to Sunday 21st September 2008. The Congress was held at the Palais des Congrès (Paris Convention Centre). The EADV has a core objective of advancing excellence in clinical care, research, education, and training in the fields of Dermatology and Venereology. The 17th Annual Congress was attended by more than 9,000 physicians specializing in Dermatology and Venereology from all over the world.

About Galderma

Galderma, created in 1981 as a joint venture between Nestlé and L'Oréal, is an international pharmaceutical company dedicated to the research, development and marketing of therapeutic, corrective and aesthetic solutions for dermatology patients. Galderma's expertise covers a broad spectrum of skin, hair and nail diseases, with a focus on acne, rosacea, psoriasis and steroid-responsive dermatoses, onychomycosis, pigmentary disorders, skin cancers and medical solutions for skin senescence.

The Company is present in 65 countries with 2800 employees (among which 1000 medical sales representatives). In 2007, Galderma had global revenues of 735 million euros and committed 14.1% of revenues to R&D. With a main research and development center in Sophia Antipolis, France, Galderma has one of the largest R&D facilities devoted exclusively to dermatology.

Galderma's key brands, the drivers of the portfolio, are: Differin®, the company's first home-grown product indicated for topical treatment of acne, Rozex®/MetroGel® 1% (rosacea), Oracea® (rosacea), Clobex® (psoriasis), Tri-Luma® (pigmentary disorders), Loceryl® (onychomycosis) and Cetaphil® (therapeutic skin care line). Recently launched products include Pliaglis™, a topical anaesthetic for dermatological procedures in the United States, Epiduo®, an innovative combination product for the treatment of acne in Europe and Argentina and Dysport®, a muscle relaxant (botulinum toxin type A product) for use in aesthetic medicine and dermatological indications in Brazil and Argentina.

The Company's international website is www.galderma.com.

References

- 1 Thiboutot DM, Weiss J, Bucko A, et al. Adapalene-benzoyl peroxide, a fixed-dose combination for the treatment of acne vulgaris: results of a multicenter, randomized double-blind, controlled study. *J Am Acad Dermatol.* 2007;57:791-799.
- 2 Data on file, Galderma Laboratories.
- 3 Pariser DM, Westmoreland P, Morris A, Gold MH, Liu Y, Graeber M. Long-term safety and efficacy of a unique fixed-dose combination gel of adapalene 0.1% and benzoyl peroxide 2.5% for the treatment of acne vulgaris. *J Drugs Dermatol.* 2007;6:899-905.