

New Phase 4 OSCAR Trial Data Showed that Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% Decreased Acne Lesions Therefore Reducing the Risk of Scars in Moderate-to-Severe Acne Patients

Data Reinforces Importance of Scar Prevention as an Important Goal of Acne Treatment

FT. WORTH, Texas – (April 30, 2018) – Galderma, a global leader focused on medical solutions for skin health, announces positive results from OSCAR, a phase 4 trial, a multicenter, randomized, investigator-blinded, vehicle-controlled, intra-individual comparison study (right/left half-face).¹ The purpose of OSCAR was to evaluate the efficacy of Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% in the treatment of moderate-to-severe acne and to understand if, by decreasing active acne lesions, Epiduo Forte Gel could thereby decrease the risk of atrophic (depressed) acne scars.¹ The OSCAR results were published in the *American Journal of Clinical Dermatology*.

Results demonstrated Epiduo Forte Gel significantly decreased acne lesions, as measured over a period of 24 weeks vs. vehicle ($P < .0001$), with acne lesion reduction as early as week one.¹ At week 24, a significantly larger percentage of subjects were Investigator's Global Assessment (IGA) clear/almost clear with Epiduo Forte Gel treatment (64.2 percent vs. 19.4 percent vehicle, $P < .0001$).^{2,3} Furthermore, by rapidly and effectively treating acne, Epiduo Forte Gel also reduced the risk of atrophic acne scars in patients with moderate-to-severe acne.¹ Through the effective reduction of acne lesions, the overall Scar Global Assessment (SGA) also improved by week 24 in the portion of the face treated with Epiduo Forte Gel (32.9 percent clear/almost clear vs. 16.4 percent vehicle, $P < .01$).^{2,3} According to a patient satisfaction survey, overall, 90.1 percent were satisfied to very satisfied with Epiduo Forte Gel vs. 59 percent with vehicle.²

"Acne scarring impacts approximately 40 percent of people who currently have acne.⁴ While significant advances have been made in treating acne, there is an unmet need to understand how we can best reduce the risk of acne scarring,"⁵ said Jerry Tan, M.D., fellowship certified specialist in dermatology and adjunct professor, Schulich School of Medicine and Dentistry, Department of Medicine, University of Western Ontario, principal investigator of the OSCAR trial, and paid Galderma consultant. "Results from the OSCAR study show that treating acne lesions early and effectively with Epiduo Forte Gel can reduce the risk of atrophic acne scars."^{1,6}

Acne is the most common skin condition in the United States, affecting up to 50 million Americans annually, including approximately 85 percent of teenagers and young adults.⁷ Not only can acne be associated with embarrassment, anxiety and depression, it also has the potential to leave permanent physical scars.^{7,8,9} Scarring can occur with any acne severity.¹⁰ In fact, nearly six percent of acne lesions may become scars and the risk for acne scarring increases with delays in treatment.^{11,12}

"We are pleased to share these positive findings that underscore the efficacy and tolerability of Epiduo Forte Gel in the treatment of acne,"^{1,13} said Chris Chapman, Vice President and General Manager of Galderma's U.S. Prescription Business. "We hope that the learnings from the OSCAR study will help empower clinicians to view scar risk reduction as a key consideration within the acne treatment paradigm."^{1,6}

In the study, Epiduo Forte Gel was safe and well tolerated with the most common treatment-related adverse event (AE) being mild to moderate skin irritation (15 percent vs. six percent, vehicle).^{1,13} There were no serious or severe AEs in the study, and the vast majority of related AEs were mild in intensity.¹

For more information on Epiduo Forte Gel, visit www.EpiduoForte.com.

About the OSCAR Study

The OSCAR study was a multicenter, randomized, investigator-blinded, vehicle-controlled, intra-individual comparison study (right/left half-face).¹ Subjects received 24 weeks of treatment with Epiduo Forte Gel or vehicle (half-face) and full-face skin care.¹ At 24 weeks, based on satisfactory investigator-assessed efficacy and subject agreement, subjects could be treated with once-daily Epiduo Forte Gel on the full face for up to 24 additional weeks with two additional visits at weeks 36 and 48.¹ Assessments included acne lesions, Investigator Global Assessment (IGA), investigator atrophic acne scar count, Scar Global Assessment (SGA), and safety/tolerability.¹

About Epiduo® Forte Gel

Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is a once-a-day prescription medication, FDA approved for the treatment of acne vulgaris. It combines two powerful medicines to treat tough acne now and helps prevent recurring acne from forming by unclogging pores and killing bacteria without the use of antibiotics.

Epiduo Forte Gel contains the highest concentration of the retinoid adapalene to reduce the inflammation associated with moderate to severe acne. If left untreated, inflammatory acne can lead to permanent scarring.^{7,8}

About Acne and Acne Scarring

Acne is the most common skin condition in the United States, affecting up to 50 million Americans annually and approximately 85 percent of teenagers and young adults.⁷ It is caused by a combination of sebum (oil) and dead skin cells, which clog pores, allowing the bacteria associated with acne (*p. acnes*) to grow.^{7,14} Approximately 40 percent of people with acne have scars.⁴ Notably, each acne lesion has a nearly six percent risk of becoming a scar.¹¹ Acne scars can begin early on in the course of the disease of acne and new scar formation can persist continuously until acne resolves, reinforcing the importance of early and effective treatment to avoid acne leaving a lasting mark.^{6,7,15} Not only can acne leave physical scars, it can also leave psychological and emotional scars including negative impacts on self-image and psychological well-being, anxiety, depression, lower self-esteem and negative emotions.^{7,8,16}

About Galderma

Galderma, Nestlé Skin Health's medical solutions business, was created in 1981 and is now present in more than 100 countries with an extensive product portfolio to treat a range of dermatological conditions. The company partners with health care practitioners around the world to meet the skin health needs of people throughout their lifetime. Galderma is a leader in research and development of scientifically-defined and medically-proven solutions for the skin.

Contact

Shannon Iwaniuk
Corporate Communications, Galderma Laboratories, L.P.

Important Safety Information

Indication: Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% is indicated for the topical treatment of acne vulgaris. **Adverse Events:** In the pivotal study, the most commonly reported adverse reactions ($\geq 1\%$) in patients treated with Epiduo® Forte Gel were skin irritation, eczema, atopic dermatitis and skin burning sensation. **Warnings/Precautions:** Patients using Epiduo® Forte Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of Epiduo® Forte Gel and may necessitate discontinuation. When applying Epiduo® Forte Gel, care should be taken to avoid the eyes, lips and mucous membranes.

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.

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¹ Data on File: RD.03.SPR.105061, Statistical Report – Part 1. September 2017.

² Data on File: RD.03.SPR.105061, Tables 14.2. August 24, 2017.

³ Data on File: EPI.P-RD105061-04. OSCAR Study Poster, Dreno. Hawaii Dermatology Meeting, 2018.

⁴ Dréno B, et al. How people with facial acne scars are perceived in society: an online survey. *Dermatol and Therapy*, 2016.6(2),207-218. doi:10.1007/s13555-016-0113-x

⁵ Dréno, Brigitte, et al. Prevention and reduction of atrophic acne scars with adapalene 0.3%/benzoyl peroxide 2.5% gel in subjects with moderate or severe facial acne: results of a 6-month randomized, vehicle-controlled trial using intra-individual comparison. *Am J Clinical Dermatol* 2018: 1-12.

⁶ Thiboutot D, et al. New insights into the management of acne: an update from the global alliance to improve outcomes in acne group. *J Am Acad Dermatol*. 2009;60(5 Suppl):S1-50

⁷ American Academy of Dermatology. Acne. <https://www.aad.org/media/stats/conditions>. Accessed March 19, 2018.

⁸ Tan, J., et al. Development of an atrophic acne scar risk assessment tool. *J Eur Acad Dermatol Venereol*. 2017 doi: 10.1111/jdv.14325

⁹ Magin, Parker, et al. Psychological sequelae of acne vulgaris: results of a qualitative study. *Canadian Family Physician*. 52.8 (2006): 978-979.

¹⁰ Layton, et al. A clinical evaluation of acne scarring and its incidence. *Clin Exp Dermatol*. 1994;19:303

¹¹ Tan, Jerry, et al. Prospective study of pathogenesis of atrophic acne scars and role of macular erythema. *J drugs in dermatol*. 2017:566-572.

¹² Tan J, et al. Development and validation of a scale for acne scar severity (SCAR-S) of the face and trunk. *J Cutan Med Surg*. 2010;14:156-160.

¹³ Data on File: RD.03.SPR.105061, Tables 14.3. September 22, 2017.

¹⁴ Mayo Clinic. Acne. <https://www.mayoclinic.org/diseases-conditions/acne/symptoms-causes/syc-20368047>. Accessed March 19, 2018.

¹⁵ Tan J, Kang S, Leyden J. Prevalence and risk factors of acne scarring among patients consulting dermatologists in the united states. *J of Drugs in Dermatol*. 2 2017 16(2), p. 97-102.

¹⁶ Gupta MA, Gupta AK. Depression and suicidal ideation in dermatology patients with acne, alopecia areata, atopic dermatitis and psoriasis. *Br J Dermatol*. 1998;139(5):846-850.