

Galderma Announces Results of ALAMO: A Real-World, Phase 4 Study Demonstrating Efficacy and Safety of Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% Plus Oral Doxycycline 200 mg in Treating Severe Inflammatory Acne

Study Results Published in Journal of Drugs in Dermatology

FT. WORTH, Texas – (May 7, 2018) – Galderma, a global leader focused on medical solutions for skin health, announces the publication of results from the Phase 4 ALAMO study, which evaluated the efficacy and safety of Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3%/2.5% plus oral doxycycline 200 mg in patients with severe inflammatory acne (non-nodulocystic/non-conglobate) during a 12-week treatment period.¹ The study results were published in the *Journal of Drugs in Dermatology*.

In this study, the primary efficacy endpoint of reduction in number of inflammatory lesions at the end of the 12-week treatment period was met.¹ Results showed a large reduction in lesion count with Epiduo Forte Gel plus doxycycline in the study participants, with a 66.2 percent reduction in inflammatory lesions, a 58.7 percent reduction in non-inflammatory lesions, and a 62.6 percent reduction in total lesions at week 12 compared to baseline ($P < 0.0001$).¹ Additionally, 37.1 percent of study participants were clear or almost clear of acne as measured by the Investigator's Global Assessment (IGA) success rate ($P < 0.0001$; IGA Score = 0 or 1).¹ At 12 weeks, 80.1 percent of study participants were no longer considered by their investigator to be candidates for oral isotretinoin, a prescription treatment for severe acne.¹

"Severe inflammatory acne is notoriously difficult to treat.^{2,3} These real-world study results are encouraging and provide positive efficacy results with the combination treatment of Epiduo Forte Gel plus oral doxycycline 200 mg,"¹ said Linda Stein Gold, M.D., ALAMO investigator, Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Mich., and paid Galderma consultant.

Acne is the most common skin condition in the United States, affecting up to 50 million Americans annually, and severe acne can be difficult to treat.^{2,4} Not only can acne be associated with embarrassment, anxiety and depression,^{5,6} it also has the potential to leave permanent physical scars.⁴ The risk of acne scarring increases with delays in treatment.⁷

"While many treatment options are available for mild to moderate acne,³ there are few effective, convenient and safe treatment options for the first-line treatment of severe acne as recommended by the American Academy of Dermatology,"^{1,2} said Chris Chapman, Vice President and General Manager of Galderma's U.S. Prescription Business. "We are pleased with the positive ALAMO clinical findings, which demonstrate how individuals with difficult-to-treat, severe acne respond to and benefit from Epiduo Forte Gel in combination with oral doxycycline.¹ These real-world data underscore our commitment to providing healthcare providers and patients with innovative treatment options for acne."

After 12 weeks of treatment, 90.2 percent of study participants reported moderate (28.8 percent; severity scale: 2), marked (44.2 percent; severity scale: 1) or complete (17.2 percent; severity scale: 0) improvement in their acne using the Assessment of Acne Improvement, an efficacy-related subject-

reported survey that uses a scale of 0 to 5 (with 0 indicating complete improvement and 5 indicating worse).^{1,8} Additionally, 81.4 percent were “satisfied” or “very satisfied” with the effectiveness of Epiduo Forte Gel.¹ The safety data from ALAMO are consistent with the known safety profile of Epiduo Forte Gel.^{1,9} No serious or severe adverse events (AEs) were reported, and most AEs were mild in intensity.¹ The most common treatment-emergent AEs were skin burning sensation and erythema (redness), reported by 3.4 and 2.9 percent of study participants, respectively.¹

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

About the ALAMO Study

The open-label, single-arm, multi-center, investigational Phase 4 ALAMO study evaluated the efficacy and safety of Epiduo Forte Gel plus oral doxycycline 200 mg (50-mg tablets, two tablets twice daily) given over 12 weeks to treat severe, inflammatory acne (non-nodulocystic and non-conglobate).¹ A total of 23 U.S. sites enrolled 186 patients; 185 patients received a baseline assessment, and 175 patients received at least one dose of the study drug (97 females and 78 males).¹ Study participants were age 12 and older with severe inflammatory acne (IGA score = 4) who were considered to be candidates for oral isotretinoin.¹ Study participants had four or fewer nodules/cysts greater than 1 cm in diameter on the face.¹ More than half of the patients (56 percent; 98) were age 17 or younger, and 25.1 percent (44) were ages 18-24. Of the study participants, 18.9 percent (33) were Hispanic or Latino, and 13.7 percent (24) were African American.¹

The primary efficacy endpoint was reduction in the number of inflammatory lesions at the end of the 12-week treatment period.¹ Secondary efficacy endpoints included the IGA success rate at weeks 4, 8 and 12; percent reduction in total, inflammatory, and non-inflammatory lesions at weeks 4, 8 and 12; number and percent of patients who, in the opinion of the investigator, were candidates for oral isotretinoin at weeks 0, 4, 8 and 12; reduction in the number of total, inflammatory and non-inflammatory lesions at weeks 4, 8 and 12; and patient assessment of acne improvement at week 12.¹ Other assessments included a patient satisfaction questionnaire at week 12; a patient’s assessment of acne improvement and acne-specific quality of life questionnaire at week 12; Dermatology Life Quality Index (DLQI™) and Children’s Dermatology Life Quality Index (cDLQI™) at baseline and week 12; and facial photography of all subjects at baseline, week 4 and week 12.^{1,8}

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.^{4,5}

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.⁴ 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.^{4,10} Approximately 40 percent of people with acne have scars.¹¹ Notably, each acne lesion has a nearly six percent risk of becoming a scar.¹² 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.^{4,13,14} 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.^{4,5,15}

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.
shannon.iwaniuk@galderma.com

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 Del, JQ Rosso, et al. Efficacy and safety of adapalene 0.3%/benzoyl peroxide 2.5% gel plus oral doxycycline in subjects with severe inflammatory acne who are candidates for oral isotretinoin. *Journal of drugs in dermatology: JDD*. 17.3 (2018): 264-273.

² American Academy of Dermatology. What can clear severe acne. <https://www.aad.org/public/diseases/acne-and-rosacea/severe-acne>. Accessed March 8, 2018.

³ Stein Gold L, et al. Moderate and severe inflammatory acne vulgaris effectively treated with single-agent therapy by a new fixed-dose combination adapalene 0.3 %/benzoyl peroxide 2.5 % gel: a randomized, double-blind, parallel-group, controlled study. *Am J Clinical Dermatol*. 2016;17:293-303. doi:10.1007/s40257-016-0178-4.

⁴ American Academy of Dermatology. Acne. <https://www.aad.org/media/stats/conditions>. Accessed March 8, 2018.

⁵ Tan, J., et al. Development of an atrophic acne scar risk assessment tool. *J Eur Acad Dermatol Venereol*. 2017. doi:10.1111/jdv.14325

⁶ Magin, Parker, et al. Psychological sequelae of acne vulgaris: results of a qualitative study. *Canadian Family Physician*. 52.8 (2006): 978-979.

⁷ 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.

⁸ Clinical Study Report GLI.04.SPR.US10355. Galderma R&D.

⁹ Epiduo Forte Gel PI

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- ¹¹ 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
- ¹² Tan, Jerry, et al. Prospective study of pathogenesis of atrophic acne scars and role of macular erythema. *J drugs in dermatol*. 2017:566-572.
- ¹³ 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.
- ¹⁴ 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.
- ¹⁵ 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.