

Efficacy and Safety of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Participants with Moderate-to-Severe Acne: The Patient Journey

Hilary Baldwin, MD^{1,2}; Julie C Harper, MD³; Joshua A Zeichner, MD⁴; Zoe D Draelos, MD⁵; Lawrence F Eichenfield, MD^{6,7}; Michael Gold, MD⁸; Linda Stein Gold, MD⁹; Leon H Kircik, MD^{4,10,11}; Eric Guenin, PharmD, PhD, MPH¹²

¹The Acne Treatment and Research Center, Brooklyn, NY; ²Robert Wood Johnson University Hospital, New Brunswick, NJ; ³Dermatology & Skin Care Center of Birmingham, Birmingham, AL; ⁴Icahn School of Medicine at Mount Sinai, New York, NY; ⁵Dermatology Consulting Services, PLLC, High Point, NC; ⁶University of California, San Diego School of Medicine, La Jolla, CA; ⁷Rady Children's Hospital, San Diego, CA; ⁸Tennessee Clinical Research Center, Nashville, TN; ⁹Henry Ford Hospital, Detroit, MI; ¹⁰Indiana University School of Medicine, Indianapolis, IN; ¹¹Physicians Skin Care, PLLC, DermResearch, PLLC, and Skin Sciences, PLLC, Louisville, KY; ¹²Ortho Dermatologics*, Bridgewater, NJ
*Ortho Dermatologics is a division of Bausch Health US, LLC

SYNOPSIS AND OBJECTIVE

- Acne—which can lead to scarring and/or dyspigmentation¹—is difficult to treat due to its long treatment time course, chronicity, and low patient adherence²⁻⁴
- The main goal of treatment is to clear lesions quickly to manage and/or mitigate persistent sequelae⁵
- Topical clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (CAB) gel is the only fixed-dose, triple-combination formulation approved for the treatment of acne
- In three published clinical studies of participants with moderate-to-severe acne, CAB gel demonstrated superior efficacy to vehicle and component dyads, with good safety/tolerability^{6,7}
- Herein are presented detailed efficacy and safety data by visit from 5 clinical study participants with moderate-to-severe acne to document their treatment journey with CAB

METHODS

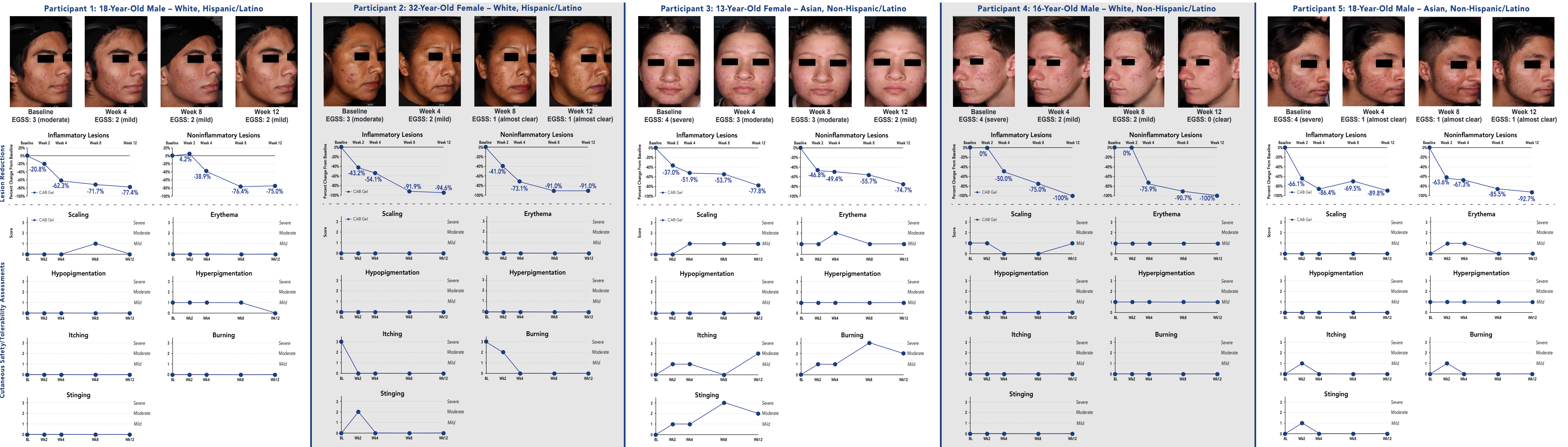
- In two phase 3 randomized, double-blind, 12-week studies (NCT04214639; NCT04214652), eligible participants ≥9 years of age with moderate-to-severe acne were randomized (2:1) to once-daily CAB or vehicle gel
 - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal moisturization/cleaning of the skin
- Endpoints included percentage of participants achieving treatment success (defined as ≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and clear/almost clear skin) and percent change from baseline in inflammatory/noninflammatory lesion counts at week 12
- Dosing compliance (defined as a participant not missing more than 5 consecutive days dosing and applying 80-120% of expected applications), treatment-emergent adverse events (TEAEs), and cutaneous safety and tolerability were also assessed
- Descriptive efficacy, safety, and tolerability data from each of the selected cases who completed 12 weeks of CAB treatment are summarized

RESULTS

- In the overall phase 3 populations, 50% of CAB-treated participants achieved treatment success at week 12, with >70% reductions in inflammatory and noninflammatory lesion counts; most TEAEs were of mild-to-moderate severity⁷
- Photographs, efficacy results, and cutaneous safety and tolerability assessments are shown for each of the five CAB-treated phase 3 participants by visit
 - Demographic characteristics and EGSS scores are presented with the participant photographs; photographs were not taken at week 2
 - Investigator-assessed cutaneous safety (scaling, erythema, hypopigmentation, and hyperpigmentation) and participant-reported tolerability (itching, burning, and stinging) were evaluated via a 4-point scale where 0=none and 3=severe
 - Individual results may vary
- All 5 participants were compliant with CAB treatment (100%, n=4; 97.4%, n=1)
- None of the participants reported any TEAEs or serious adverse events

CONCLUSIONS

- In the overall phase 3 populations, fixed-dose, triple-combination CAB gel has demonstrated good efficacy, safety, and tolerability⁷
- All cases presented here achieved substantial (>70%) acne lesion reductions, with 4 of the 5 achieving treatment success or a 2-grade reduction in EGSS by week 12
- While patterns in cutaneous safety/tolerability were more variable across the cases, transient increases with CAB generally resolved to baseline values within two months of treatment
- These clinical study cases reinforce the importance of patient education regarding the efficacy and safety of acne treatment,⁵ including:
 - Importance of treatment adherence
 - Managing patient expectations (eg, can take months to achieve clear skin)
 - Potential for increased cutaneous effects, which are often transient



ABBREVIATIONS

- Layton A, et al. *JAAD Int.* 2021;5:41-48.
- Reynolds RV, et al. *J Am Acad Dermatol.* 2024;90(5):1006.e1-1006.e30.
- Zaenglein AL. *N Engl J Med.* 2018;379(14):1343-1352.
- Moradi Tachayi S, et al. *Patient Prefer Adherence.* 2016;10:2091-2096.

REFERENCES

- Del Rosso, JQ, et al. Therapeutic Recommendations for the Treatment of Acne Vulgaris in the US. Poster presented at the 2024 Fall Clinical Dermatology Conference for Physician Assistants & Nurse Practitioners.
- Stein Gold L, et al. *Am J Clin Dermatol.* 2022;23(1):93-104.
- Stein Gold L, et al. *J Am Acad Dermatol.* 2023;89(5):927-935.

AUTHOR DISCLOSURES

Hilary Baldwin has served as advisor, investigator, and on speakers' bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Julie Harper has received honoraria from Alclaris, Almirall, BioPharmX, Cassiopea, Cutanea, Dermira, Foamix, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun Pharma. Joshua Zeichner has served as advisor, consultant, or speaker for AbbVie, Allergan, Dermavant, Dermira, EPI Health, Galderma, Incyte, Johnson and Johnson, L'Oreal, Ortho Dermatologics, Pfizer, Procter and Gamble, Regeneron, Sun Pharma, UCB, Unilever, and Vyne. Zoe Draelos received funding from Ortho Dermatologics. Lawrence Eichenfield has received honoraria for consulting services from AbbVie, BMS, Almirall, Amgen, Arcutis, Dermata, Dermira, Dermavant, Eli Lilly, Forte Pharma, Galderma, Incyte,

J&J, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi Genzyme, and Ortho Dermatologics; and study support (to institution) from AbbVie, Amgen, Bausch Health, Dermata, Dermira, Eli Lilly, Galderma, Incyte, Pfizer, Regeneron Pharmaceuticals, Inc., and Sanofi Genzyme. Michael Gold has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Linda Stein Gold has served as investigator/consultant or speaker for Ortho Dermatologics, Leo Pharma, Dermavant, Incyte, Novartis, AbbVie, Pfizer, Sun Pharma, UCB, Arcutis, and Lilly. Leon Kircik has served as either a consultant, speaker, advisor or an investigator for Allergan, Almirall, Epi Health, Galderma, Novartis, Ortho Dermatologics, and Sun Pharma. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.