Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Versus Adapalene 0.3%/Benzoyl Peroxide 2.5% Gels for Moderate-to-Severe Acne: Comparative Patient Journey

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SYNOPSIS AND OBJECTIVE

- Combination topical therapies for acne targeting multiple pathogenic pathways may improve efficacy[1] and are recommended for most patients by the American Academy of Dermatology[2]
- Clindamycin phosphate (CLIN) 1.2%/adapalene (ADAP) 0.15%/benzoyl peroxide (BPO) 3.1% (CAB) gel is the only fixed-dose, triple-combination topical formulation approved for the treatment of acne
- In 3 published clinical studies of participants with moderate-to-severe acne, CAB gel demonstrated superior efficacy to vehicle and component dyad gels, with good safety and tolerability[3,4]
- Here, we document the treatment journey of clinical trial participants who were treated with either CAB gel or branded ADAP 0.3%/BPO 2.5% gel

METHODS

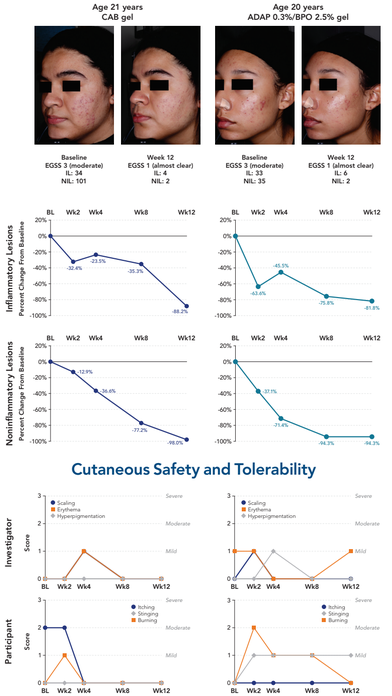
- In a phase 2, double-blind, 12-week study (NCT04892706), eligible participants ≥12 years of age with moderate-to-severe acne were randomized to once-daily CAB (Ortho Dermatologics), branded ADAP 0.3%/BPO 2.5% (ADAP/BPO; Galderma), or vehicle gel
  - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal) were provided as needed for optimal moisturization/cleaning of the skin
- Outcomes included the percentage of participants achieving treatment success at week 12 (defined as ≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and clear/almost clear skin) and change from baseline in inflammatory (IL) and noninflammatory lesions (NIL)
- Treatment-emergent adverse effects (TEAEs) and cutaneous safety/tolerability were also evaluated through week 12
  - Investigator-assessed cutaneous safety (scaling, erythema, and hyperpigmentation) and participant-reported tolerability (itching, burning, and stinging) were evaluated via a 4-point scale (0=none; 3=severe)
- Descriptive data are summarized for 4 pairs of participants treated with either CAB gel or ADAP/BPO gel; each pair was matched based on baseline demographic characteristics, acne severity, and lesion counts

RESULTS

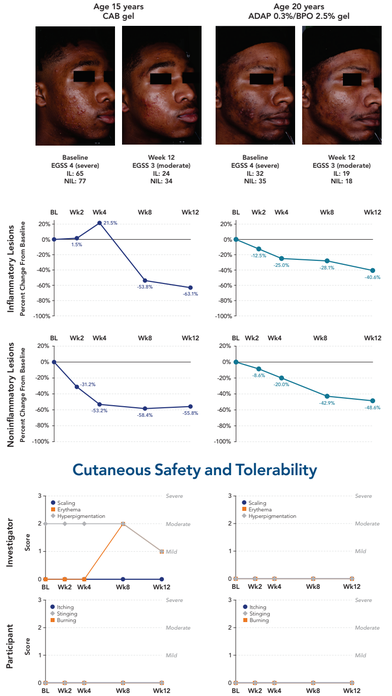
- Photographs, demographic and baseline disease characteristics, efficacy results, and cutaneous safety and tolerability assessments are presented for each of the 4 pairs of matched participants; ages ranged from 13-21 years
- At week 12, treatment success was achieved by 3 out of 4 CAB-treated participants and 1 out of 4 ADAP/BPO-treated participants
- IL reductions from baseline ranged from 63.1% to 100% with CAB and 40.6% to 81.8% with ADAP/BPO, respectively
- NIL reductions for CAB and ADAP/BPO ranged from 55.8% to 98.0% and 32.4% to 94.3%, respectively
- The only treatment-related TEAE among all participants was moderate stinging reported by 1 participant treated with CAB, which resolved; no serious TEAEs were reported
- Transient increases in cutaneous safety and tolerability scores were observed at weeks 2, 4, or 8 in participants from both treatment groups
  - No CAB-treated participants reported itching, burning, or stinging at week 12
- Results represent participant-level data; individual results may vary

PARTICIPANT PAIR 1:
White Females, Not Hispanic or Latina

PARTICIPANT PAIR 2:
White Females, Hispanic or Latina



PARTICIPANT PAIR 3:
Black Males, Not Hispanic or Latino



PARTICIPANT PAIR 4:
White Males, Not Hispanic or Latino

CONCLUSIONS

- In 4 pairs of patients matched for baseline demographics and disease characteristics:
  - More patients achieved treatment success with CAB gel than with branded ADAP 0.3%/BPO 2.5% gel
  - IL and NIL reductions were also greater in patients treated with CAB gel versus branded ADAP 0.3%/BPO 2.5% gel
- Despite the addition of a third active ingredient in CAB gel, patterns of safety and tolerability were similar for both treatments
- Together with efficacy and safety data from CAB gel clinical trials, these data illustrate the potential benefit of CAB gel as the only triple-fixed combination treatment option in the acne armamentarium

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ABBREVIATIONS

ADAP, adapalene; BL, baseline; BPO, benzoyl peroxide; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel; CLIN, clindamycin phosphate; EGSS, Evaluator's Global Severity Score (0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe); IL, inflammatory lesion; NIL, noninflammatory lesion; TEAE, treatment-emergent adverse effect; Wk, week.

AUTHOR DISCLOSURES

Lawrence Green has served as investigator, consultant, or speaker for Almirall, Cassiopea, Galderma, Ortho Dermatologics, Sol Gel, Sun Pharma, and Vyne. 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. Julie Harper has received honoraria from Almirall, Cutera, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun Pharma. Hilary Baldwin has served as advisor, investigator, and on speakers bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Neal Bhatia has served as advisor, consultant, and investigator for AbbVie, Almirall, Biofrontera, BI, Brickell, BMS, EPI Health, Ferndale, Galderma, InCyte, ISDIN, J&J, LaRoche-Posay, LEO Pharma, Ortho Dermatologics, Regeneron, Sanofi, Sun Pharma, Verrica, and Vyne. Zoe Draelos received funding from Ortho Dermatologics. Lawrence Eichenfield has received honoraria for consulting services from AbbVie, BMS, 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. Edward Lain has served as investigator, consultant and/or speaker for Ortho Dermatologics, AbbVie, Almirall, Amgen, Arcutis, Dermavant, EPI Health, Galderma, Incyte, LEO Pharma, Novartis, Eli Lilly, Pfizer, Sun Pharma, UCB, Endo International, ChemoCentryx, Biorasi, Sirnaomics, Evelo Biosciences, Concert Pharmaceuticals, Cara Therapeutics, Castle Biosciences, Mindera, Biofrontera, Alfasigma, AiViva Biopharma, Anaptys Bio, Bausch Health, Dr Reddy's, and Trevi Therapeutics. William Philip Werschler has served as an investigator for Ortho Dermatologics. Karol Wroblewski has nothing to disclose. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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