Efficacy and Safety of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Black Participants With Moderate to Severe Acne

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SYNOPSIS

- Highly pigmented skin can be at a greater risk of acne-related sequelae, including dyspigmentation and scarring, which may be more distressing than the acne itself[1-3]
- Early and aggressive acne treatment with minimal irritation is important for the management and prevention of hyperpigmentation in patients with skin of color[4]
  - Therefore, therapeutic strategies for people with skin of color include targeting multiple aspects of acne pathogenesis and considering drug tolerability[1,2,4]
- Topical clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel (CAB; Cabtreo®; Ortho Dermatologics) is the only fixed-dose, triple-combination formulation approved by the US Food and Drug Administration for the treatment of acne[5]
- In one phase 2 and two phase 3 trials,CAB demonstrated superior efficacy to vehicle and component dyads with good safety and tolerability in participants with moderate to severe acne[6,7]

OBJECTIVE

- This post hoc analysis of 4 clinical trials assessed efficacy and safety of CAB vs vehicle in participants who self-identified as "Black or African American" (hereafter referred to as Black)

METHODS

- Data were pooled from two phase 2 (NCT03170388, N=741; NCT04892706, N=686) and two phase 3 (NCT04214652, N=180; NCT04214639, N=183) double-blind, randomized, 12-week trials
  - Eligible participants aged ≥9 years (≥12 years in NCT04892706) with moderate to severe acne were randomized to receive 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
- Post hoc analyses were conducted among Black participants in the CAB or vehicle treatment groups; one of the phase 2 trials had dyad treatment groups that were not included owing to the limited number of Black participants
- Efficacy endpoints included percentage of participants achieving treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and clear/almost clear skin) and least squares mean percent change from baseline in inflammatory/noninflammatory lesions
- Treatment-emergent adverse events (TEAEs) and discontinuations due to adverse events (AEs) were assessed
- Investigator-assessed cutaneous safety (hyperpigmentation, hypopigmentation, erythema, and scaling) and participant-assessed cutaneous tolerability (itching, burning, and stinging) were graded on a 4-point scale (0=none to 3=severe)

RESULTS

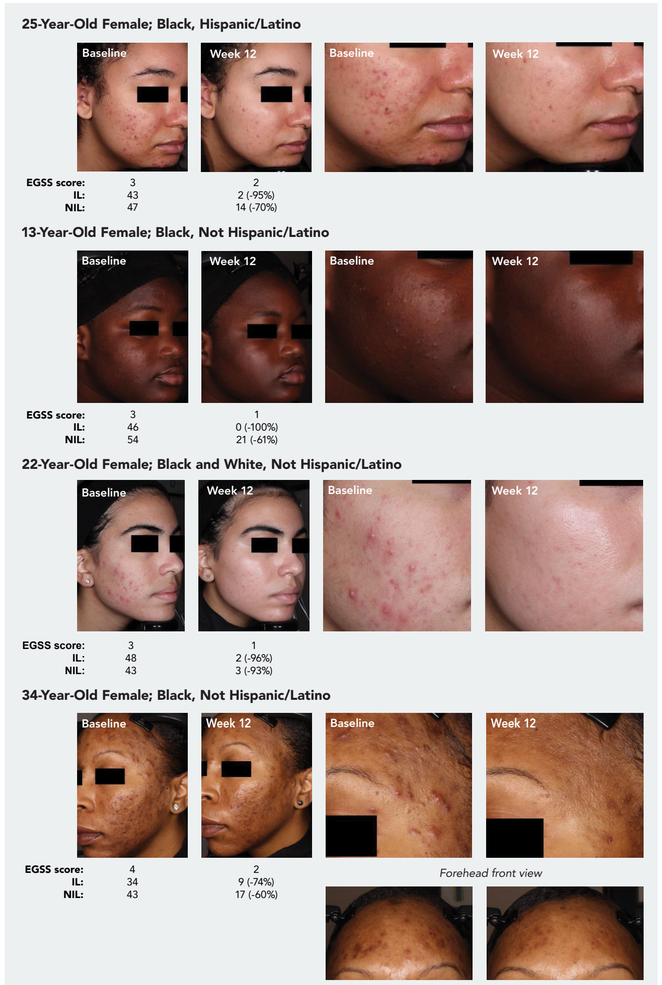
Participants

- Of 1115 participants randomized to CAB or vehicle gel, 156 (14%) self-identified as Black (CAB, n=88; vehicle, n=68)
- Median age ranged from 10 to 49 years, and the majority of participants were female (>70%) or non-Hispanic/Latino (>90%)
- Most participants (>88%) had moderate acne (EGSS=3)

Efficacy

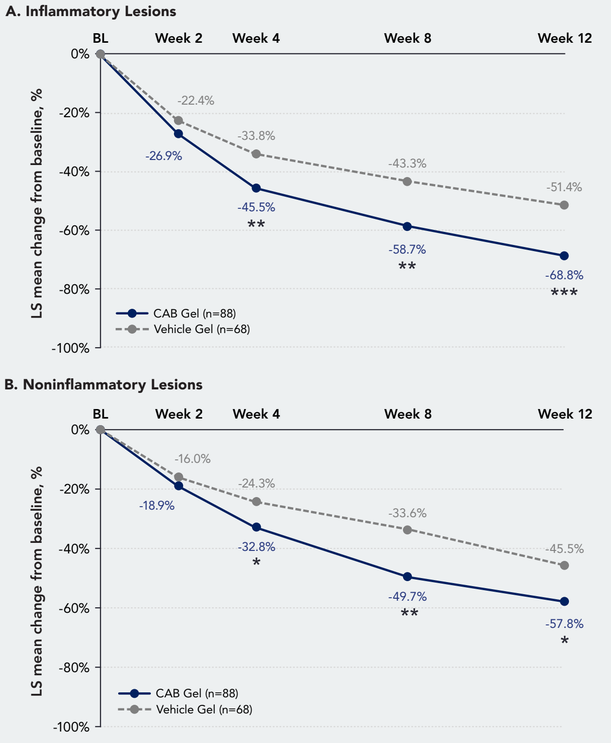
- Images depicting acne improvement in Black participants treated with CAB are shown in **Figure 1**
- Reductions in inflammatory and noninflammatory lesions were significantly greater with CAB vs vehicle at week 12 (68.8% vs 51.4% and 57.8% vs 45.5%, respectively; *P*<0.05, both; **Figure 2**)
- At week 12, rates of treatment success were numerically greater in participants treated with CAB compared with vehicle (32.0% vs 18.3%; *P*=0.07)

FIGURE 1. Acne and Hyperpigmentation Improvements at Week 12 With CAB Gel



Individual results may vary.
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; EGSS, Evaluator's Global Severity Score (0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe); IL, inflammatory lesion; NIL, noninflammatory lesion.
Photographic Images © 2023. Courtesy of Ortho Dermatologics Trial Investigators. Part of this figure was previously published in Stein Gold LS, et al. 2022.[9]

FIGURE 2. Acne Lesion Reductions by Visit (ITT Population, Pooled)



*P<0.05, **P<0.01, ***P<0.001 vs vehicle.
Values have been adjusted for multiple imputation (Markov Chain Monte Carlo method). These trials were not powered for statistical analysis of between-group differences in Black participants.
BL, baseline; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; ITT, intent to treat; LS, least squares.

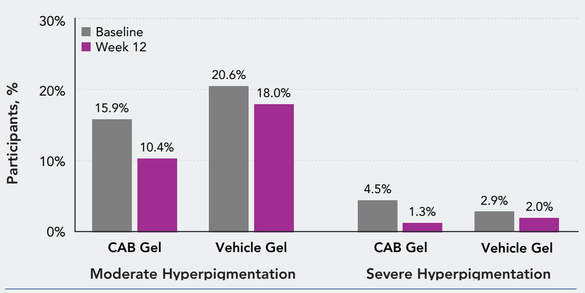
Safety

- TEAEs were mild to moderate in severity, and the rates of TEAEs in Black participants were lower than those observed in the overall trial populations (20.5% vs 24.6–36.2%[6,7])
- No participants discontinued the study due to AEs
- As anticipated, transient increases in erythema, itching, burning, and stinging occurred between weeks 2 and 8 but returned to near-baseline values by week 12 in CAB-treated participants (data not shown)

Hyperpigmentation

- Just under half of participants in the CAB group (48.8%) presented with hyperpigmentation at baseline
- Mean hyperpigmentation scores remained at or below the baseline value (0.7; 1=mild) for all postbaseline visits (data not shown)
- CAB treatment was associated with a larger decrease in rates of "moderate" or "severe" hyperpigmentation from baseline to week 12 compared with vehicle (**Figure 3**)

FIGURE 3. Rates of Moderate or Severe Hyperpigmentation (Safety Population, Pooled)



Baseline: CAB n=88, vehicle n=68; week 12: CAB n=77, vehicle n=50.
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%.

CONCLUSIONS

- Results from this analysis in self-identified Black participants—combined with previous post hoc analyses in participants with skin of color[8,9]—demonstrate that triple-combination CAB is an efficacious, safe, and tolerable acne treatment for patients of different racial and ethnic groups
- Nearly one-third of Black participants treated with CAB achieved treatment success at week 12 vs less than one-fifth of those treated with vehicle
- CAB was associated with 70% reductions in inflammatory lesions and nearly 60% reductions in noninflammatory lesions at week 12, with statistical separation from vehicle occurring as early as week 4
  - The primary trials were not powered to detect significant differences between CAB and vehicle gel in this post hoc analysis of Black participants; therefore, *P* values are for informative purposes only
- There were no mean increases in hyperpigmentation score, and rates of "moderate" or "severe" hyperpigmentation decreased with CAB treatment

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