

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

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## SYNOPSIS

- Acne vulgaris is a common skin condition with significant clinical impact in Asian patients, for whom treatment may involve unique considerations<sup>1</sup>
- Clinical presentation and sequelae of acne can vary by patient population; for instance, Asian individuals with darker skin phototypes are at increased risk of postinflammatory hyperpigmentation<sup>2</sup>
- Topical clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (CAB; Cabtreo<sup>®</sup>, Ortho Dermatologics) gel is the only fixed-dose, triple-combination formulation approved for acne treatment<sup>3</sup>
- CAB gel showed superior efficacy than vehicle and component dyads with good safety/tolerability in phase 2 and 3 clinical trials of participants with moderate to severe acne<sup>4-6</sup>

## OBJECTIVE

- Post hoc analyses were performed to determine the efficacy, safety, and tolerability of CAB gel in participants who self-identified as Asian

## METHODS

- Data were pooled from two phase 2 (NCT03170388, NCT04892706) and two phase 3 (NCT04214652, NCT04214639) double-blind, 12-week trials
- A total of 1115 enrolled participants aged ≥9 years (≥12 years in NCT04892706) with moderate to severe acne were randomized to once-daily CAB or vehicle gel; additional randomization arms from one phase 2 trial (NCT03170388) were not included in this analysis
- CeraVe<sup>®</sup> hydrating cleanser and CeraVe<sup>®</sup> moisturizing lotion (L’Oreal, New York) were provided as needed for optimal moisturization/cleaning of the skin
- Post hoc analyses were performed in participants who self-identified as Asian
- Endpoints included 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 and noninflammatory lesion counts
- Treatment-emergent adverse events (TEAEs) and cutaneous safety (investigator-assessed) and tolerability (participant-assessed) were evaluated

## RESULTS

### Participants

- The analysis included 96 Asian participants (CAB gel, n=47; vehicle gel, n=49)
- Of Asian participants, 57.3% were female, age ranged from 12–55 years, and 85.4% had moderate acne at baseline (EGSS=3)

### Efficacy

- Images showing acne improvement in CAB-treated Asian participants are shown in Figure 1
- At week 12, significantly more Asian participants treated with CAB gel achieved treatment success than those receiving vehicle (66.5% vs 23.4%; P<0.001; Figure 2)
- CAB-treated Asian participants experienced >80% reductions in inflammatory and noninflammatory lesion counts (87.7% and 80.3%, respectively), significantly greater compared with those receiving vehicle (58.3% and 55.7%; P≤0.001, both; Figure 3)

FIGURE 1. Acne Improvements With CAB Gel in Asian Participants

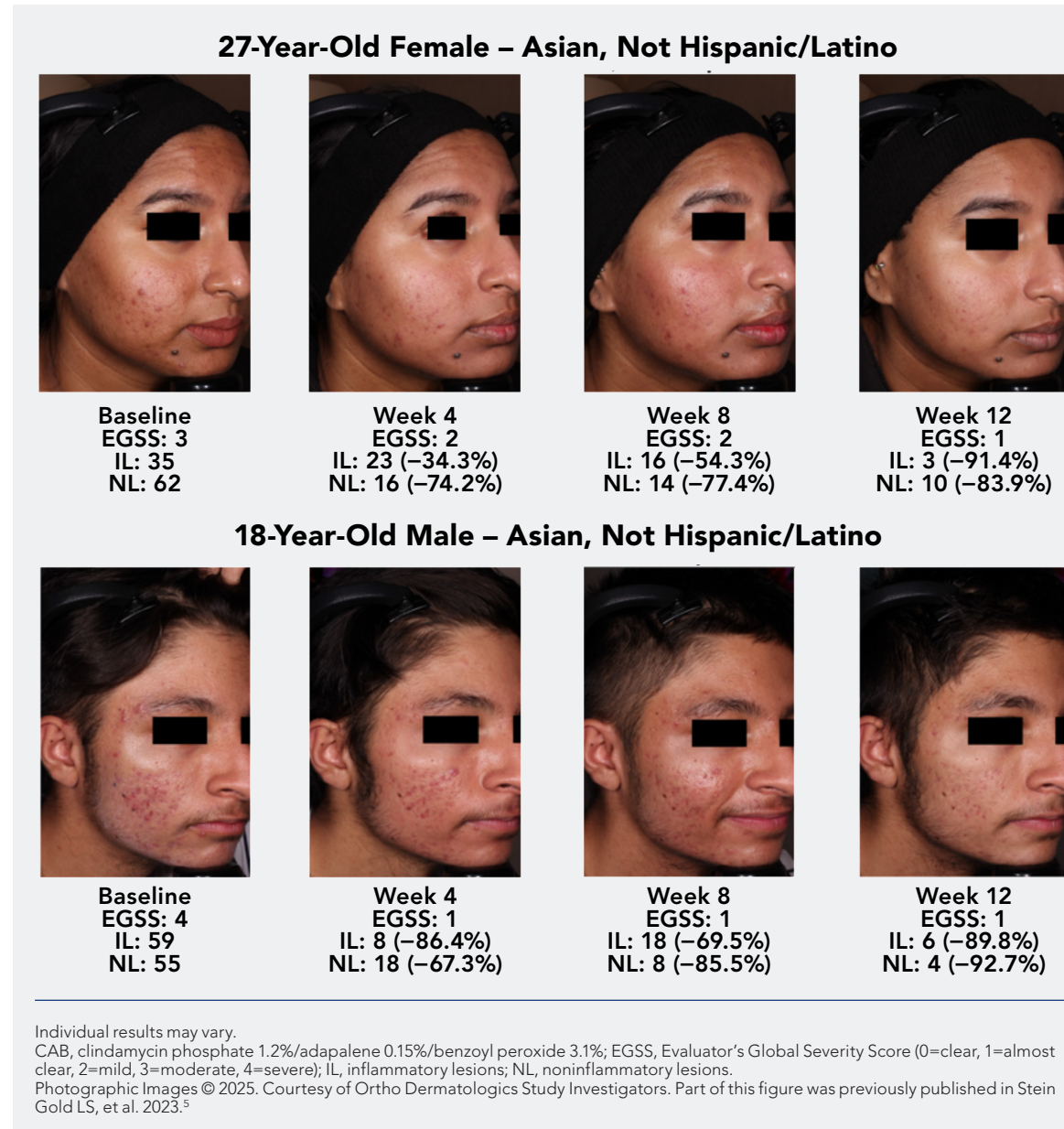


FIGURE 2. Treatment Success<sup>a</sup> by Visit (ITT Population, Pooled)

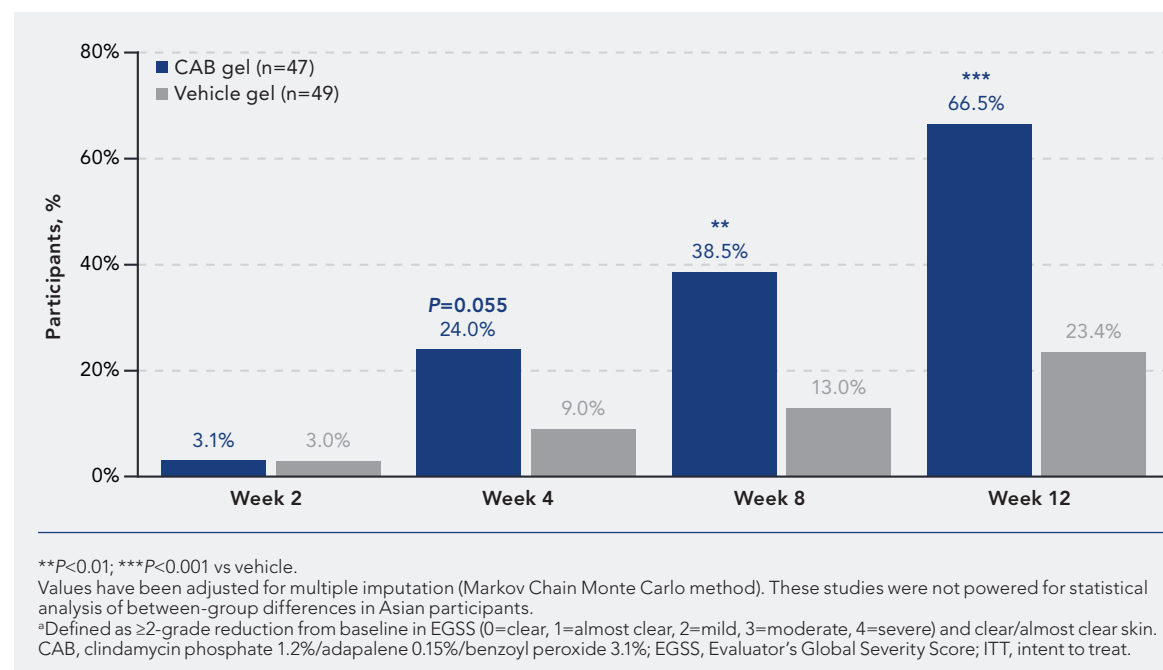
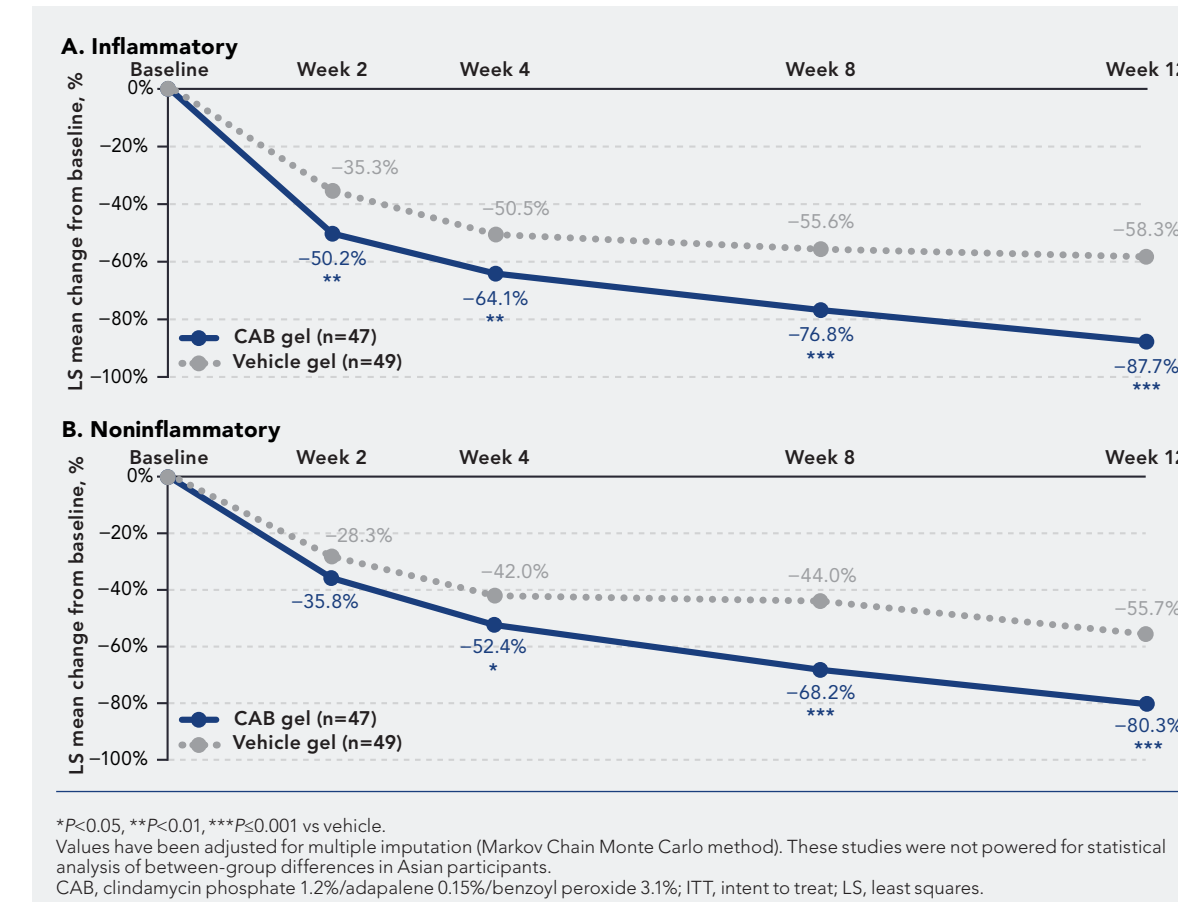


FIGURE 3. Acne Lesion Reductions by Visit (ITT Population, Pooled)



## Safety

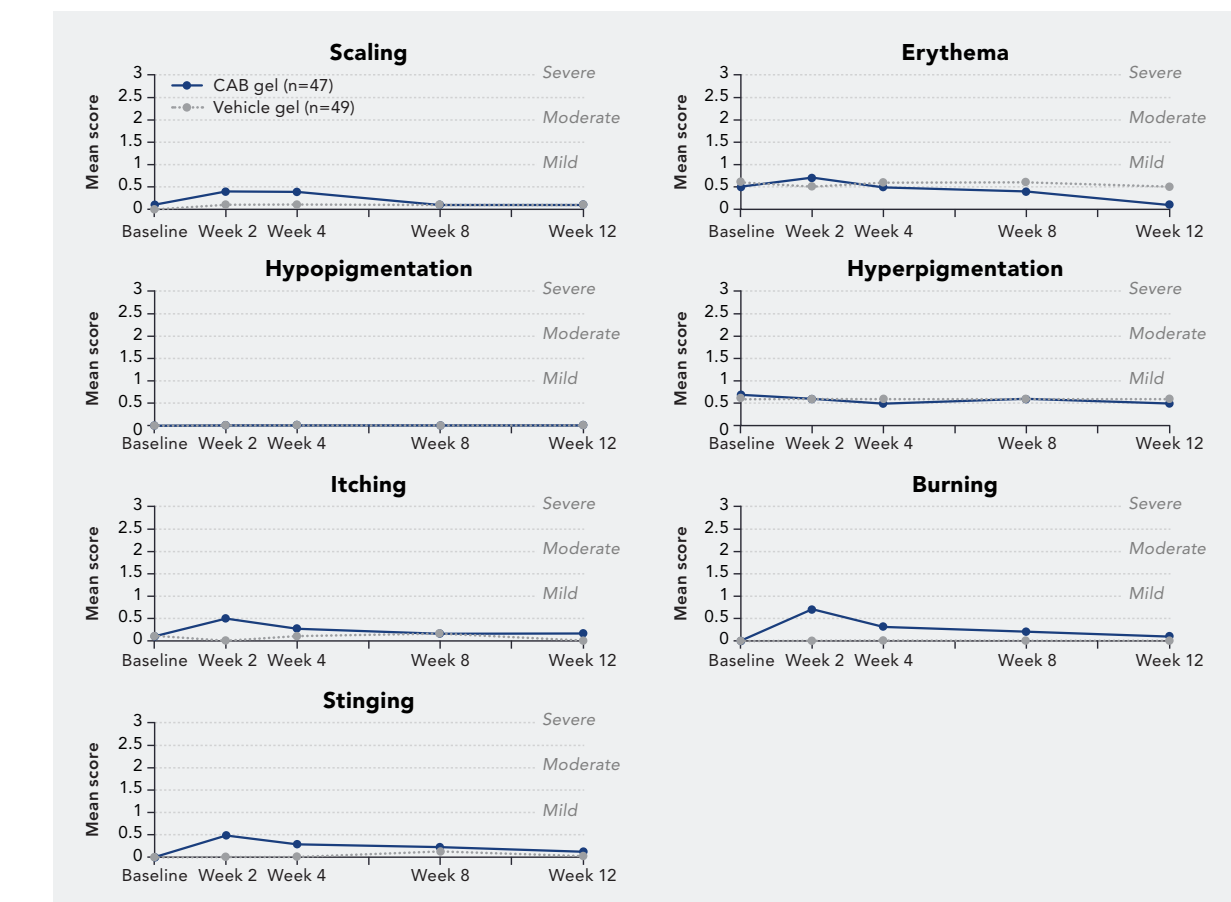
- The rate of TEAEs in CAB-treated Asian participants was similar to those in the overall study populations (27.7% vs 24.6%–36.2%<sup>4,5</sup>; Table 1)
- The majority of TEAEs were categorized as mild or moderate, with no reports of serious adverse events
- With CAB treatment, mean scores for cutaneous safety and tolerability assessments were <1 (mild) at all time points (Figure 4)
- Hyperpigmentation mean scores stayed below the baseline value (0.7; 1=mild) at all time points

TABLE 1. Summary of Adverse Events Through Week 12 (Safety Population, Pooled)

| Participants, n (%)                              | CAB Gel (n=47)       | Vehicle Gel (n=49) |
|--|----------------------|--------------------|
| Reporting any TEAEs                              | 13 (27.7)            | 5 (10.2)           |
| Related  | 9 (19.1)             | 0                  |
| Reporting any SAEs                               | 0                    | 0                  |
| Discontinued study or drug due to AEs            | 1 (2.1) <sup>a</sup> | 0                  |
| TEAE severity                                    |                      |                    |
| Mild   | 9 (19.1)             | 3 (6.1)            |
| Moderate   | 3 (6.4)              | 2 (4.1)            |
| Severe   | 1 (2.1)              | 0                  |
| Most common treatment-related TEAEs <sup>b</sup> |                      |                    |
| Application site pain                            | 5 (10.6)             | 0                  |
| Application site dryness                         | 3 (6.4)              | 0                  |

<sup>a</sup>Discontinuation from the study drug was due to an adverse event of site application pain, which resolved 1 day after drug withdrawal. <sup>b</sup>Reported in ≥3% of participants in any treatment group. AE, adverse event; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

FIGURE 4. Cutaneous Safety and Tolerability (Safety Population, Pooled)



## CONCLUSIONS

- In Asian participants with moderate to severe acne treated with CAB, 66.5% achieved treatment success, and average acne lesion reductions were >80% by week 12, with favorable safety and tolerability
- These improvements are numerically greater than the results seen in the overall study populations.<sup>4-6</sup> Given its high efficacy and favorable tolerability, triple-combination CAB gel is well suited for the treatment of acne in Asian patients
- This analysis adds valuable information on CAB gel use in different patient populations, adding to the limited literature evaluating acne treatments in Asian individuals

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## AUTHOR DISCLOSURES

George Han is or has been an investigator, consultant/advisor, or speaker for AbbVie, Athenex, Boehringer Ingelheim, Bond Avillon, Bristol Myers Squibb, Celgene, Eli Lilly, Novartis, Janssen, LEO Pharma, MC2, Ortho Dermatologics, PellePharm, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB. Andrew F. Alexis received grants (funds to institution), royalties, or equipment from and served as a speaker or consultant/advisor for LEO Pharma, Amgen, Arcutis, Dermavant, AbbVie, Castle, Incyte, Genentech, Galderma, Pfizer, Sanofi-Regeneron, Beiersdorf, Ortho Dermatologics, L’Oreal, Bristol Myers Squibb, Bausch Health, UCB, Johnson & Johnson, Allergan, Almirall, VisualDx, Eli Lilly, Swiss American, Apogee, Canfield, Alphyn, Boehringer Ingelheim, Symrise, Novartis, HairDays, Botanix, Alumis, Regeneron, Sanofi-Genzyme, Janssen, Aerolase, Scientis, Springer, Wiley-Blackwell, Wolters Kluwer Health, and Elsevier. Neal Bhatia has served as advisor, consultant, and investigator for AbbVie, Almirall, Biofrontera, Bi, Brickell, BMS, EPI Health, Ferrandis, Galderma, Incyte, SDN, J&J, LaRoche-Posay, LEO Pharma, Ortho Dermatologics, Regeneron, Sanofi, Sun Pharma, Verica, and Vyne. Valerie D. Callender has served as an investigator, consultant, or speaker for Acne Store, Almirall, Aerolase, AbbVie, Allergan Aesthetics, Avava, Avita Medical, Beiersdorf, Cutera, Dermavant, Eirion Therapeutics, Lilly, Galderma, Janssen, Jeune Aesthetics, L’Oreal, Ortho Dermatologics, Pfizer, Prolineum, Regeneron, Scientis, Sente, SkinBetter Science, SkinCeuticals, Symatse, Teoxane, and UpToDate. Hilary Baldwin has served as advisor, investigator, and on speakers bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company. Linda Stein Gold has served as investigator/consultant or speaker for AbbVie, Arcutis, Dermavant, Incyte, LEO Pharma, Lilly, Novartis, Ortho Dermatologics, Pfizer, Sun Pharma, and UCB.