

Triple-Combination Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel for Acne: Clinical Efficacy and Application Characteristics

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SYNOPSIS

- Triple-combination therapies for acne that include an antibiotic, topical retinoid, and benzoyl peroxide (BPO) are among the most effective, with meta-analyses demonstrating greater efficacy with triple-combinations than dual-combinations or topical monotherapy¹
- However, complicated treatment regimens may lead to reduced treatment adherence²
- Application characteristics of topical formulations can impact treatment tolerability and factor heavily into patient acceptance and adherence to treatment³
- Clindamycin phosphate 1.2%/adapalene 0.15%/BPO 3.1% (CAB; Cabtreo™, Ortho Dermatologics) gel was developed to deliver three active ingredients in an easy-to-use formulation, and is the first fixed-dose triple-combination product approved for the treatment of acne

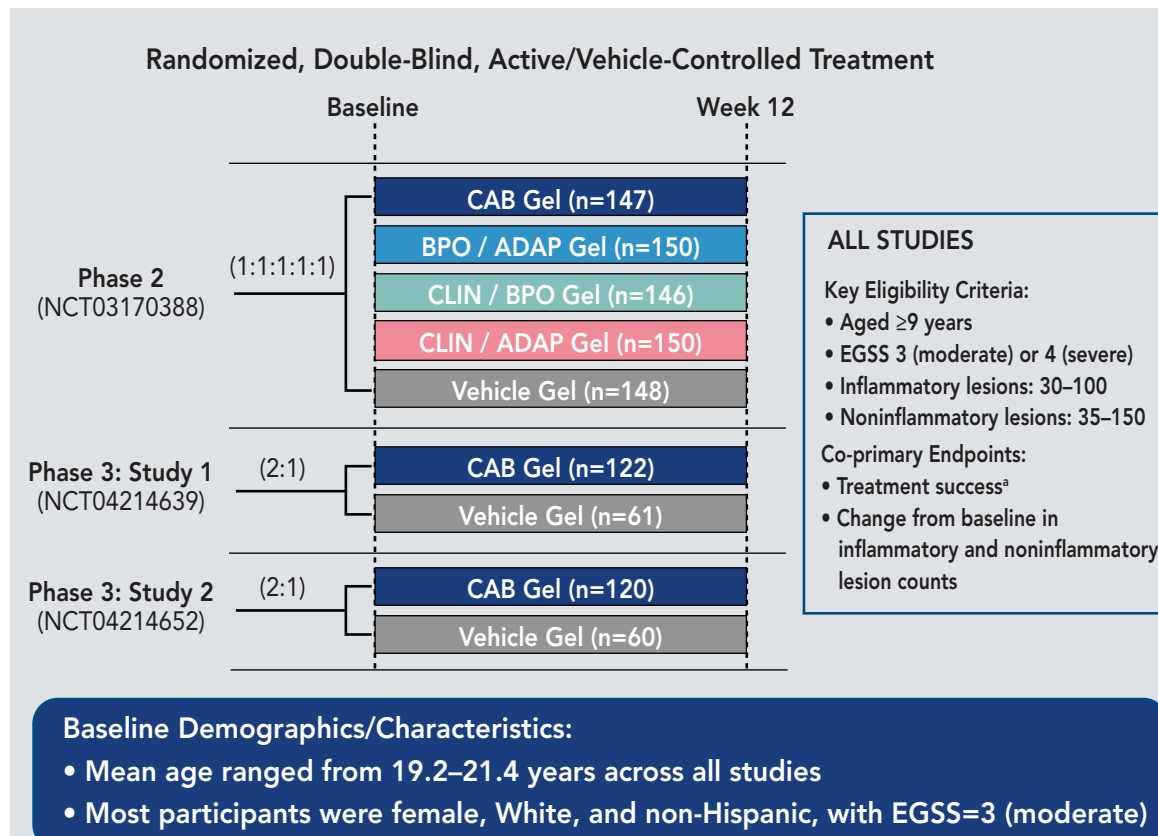
OBJECTIVES

- Review efficacy of CAB gel in phase 2 and phase 3 clinical trials of participants with moderate-to-severe acne
- Compare the application characteristics of CAB gel to layered application of its individual active ingredients

EFFICACY IN PHASE 2 AND PHASE 3 CLINICAL STUDIES

- Efficacy of CAB gel was assessed in one phase 2 and two phase 3 clinical studies of participants with moderate-to-severe acne (Figure 1)^{4,5}
- At week 12, ~50% of CAB-treated participants achieved treatment success, significantly greater than with vehicle or dyad combinations of active ingredients (Figure 2)
- CAB was also associated with >70% reductions from baseline in inflammatory and noninflammatory lesions, significantly greater than with vehicle or dyads (Figure 3)

FIGURE 1. Randomized, Double-Blind, 12-Week Studies of CAB Gel: Treatments and Participants



*Defined as the percentage of participants achieving ≥2-grade reduction from baseline in EGSS and a score of 0 (clear) or 1 (almost clear skin). N values shown are for randomized populations.
ADAP, adapalene 0.15%; BPO, benzoyl peroxide 3.1%; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/BPO 3.1% gel; CLIN, clindamycin phosphate 1.2%; EGSS, Evaluator's Global Severity Score.

FIGURE 2. Treatment Success^a at Week 12 (ITT Populations)

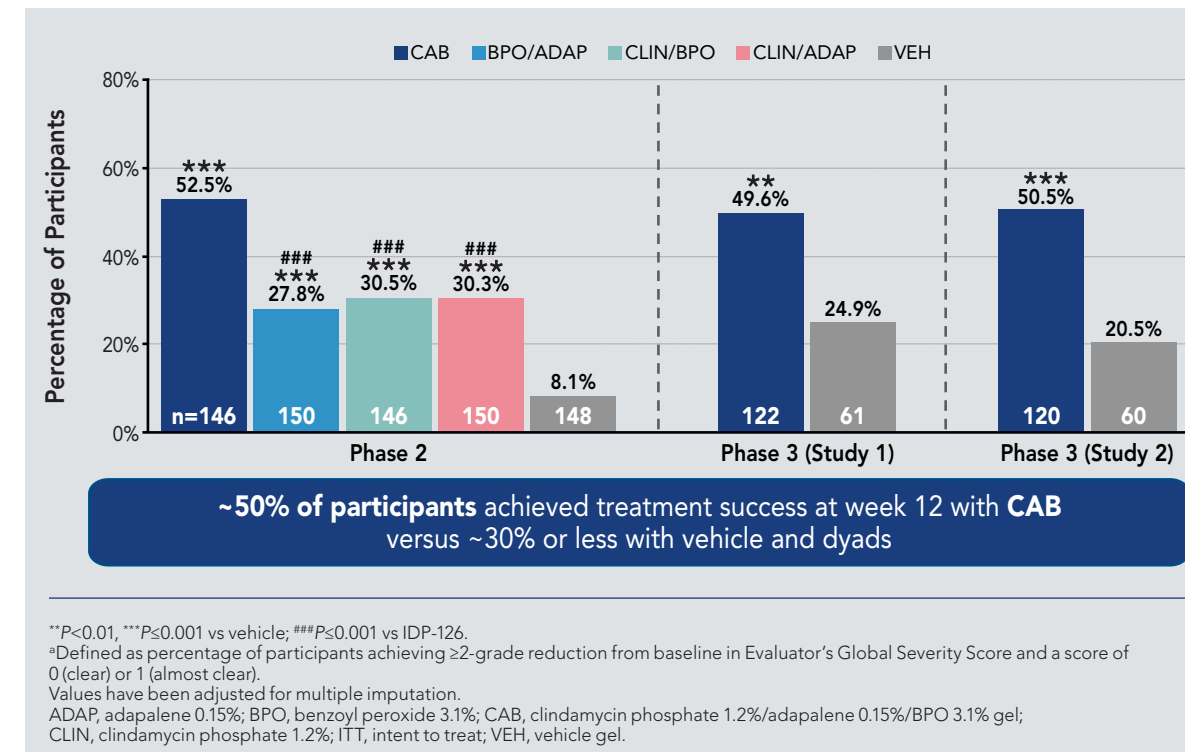
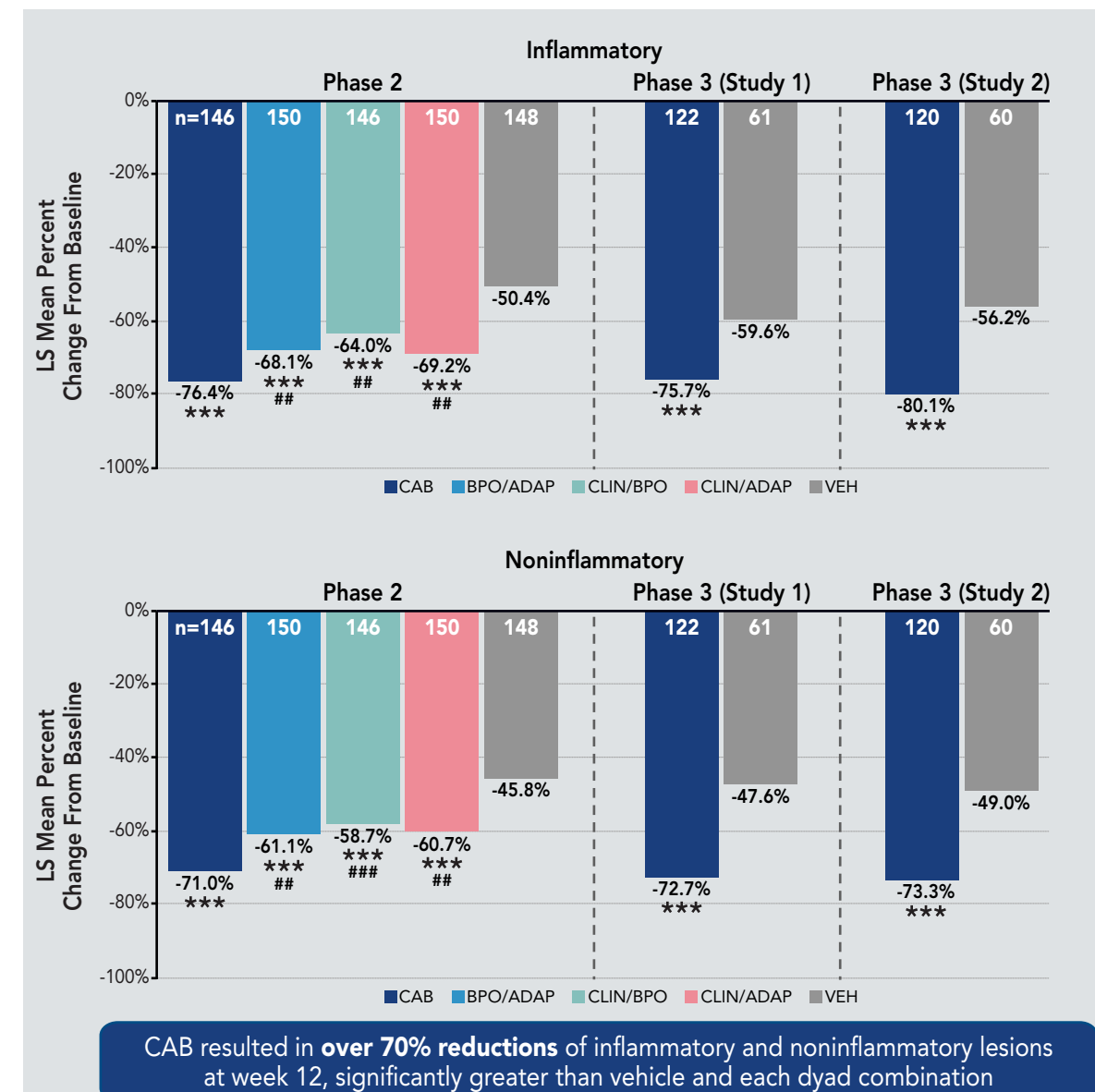


FIGURE 3. Mean Percent Changes from Baseline in Lesion Counts at Week 12 (ITT Populations)



***P<0.001 vs vehicle; **P<0.01, ***P<0.001 vs IDP-126. Values have been adjusted for multiple imputation.
ADAP, adapalene 0.15%; BPO, benzoyl peroxide 3.1%; CAB, clindamycin phosphate 1.2%/adapalene 0.15%/BPO 3.1% gel; CLIN, clindamycin phosphate 1.2%; ITT, intent to treat; LS, least-squares; VEH, vehicle gel.

APPLICATION CHARACTERISTICS OF CAB GEL

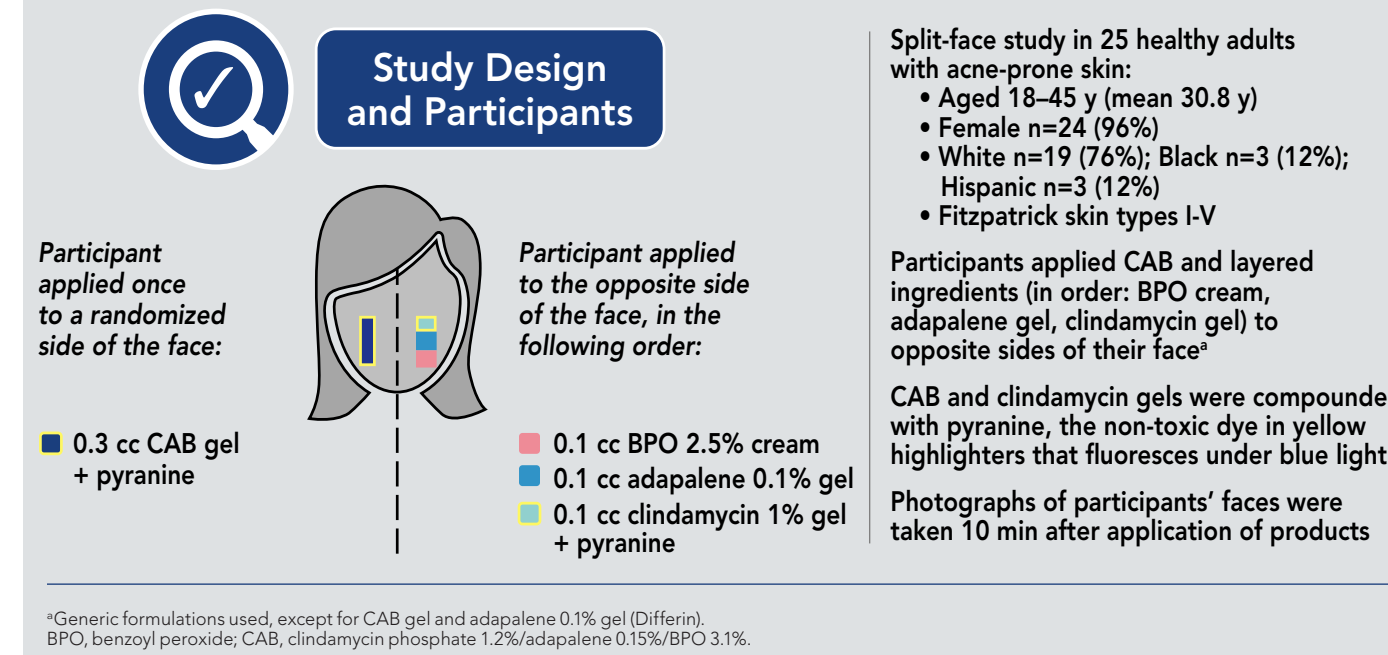
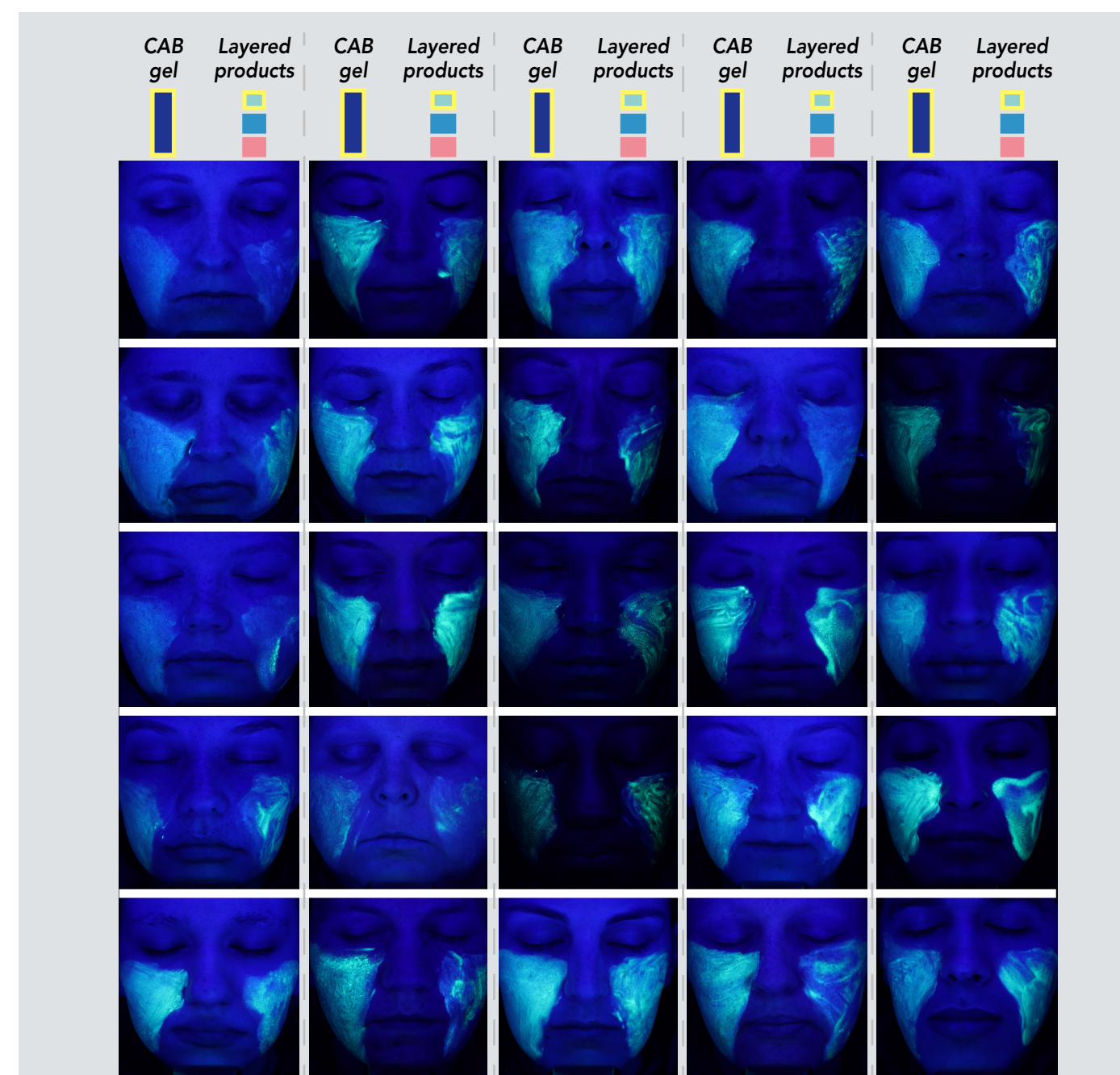
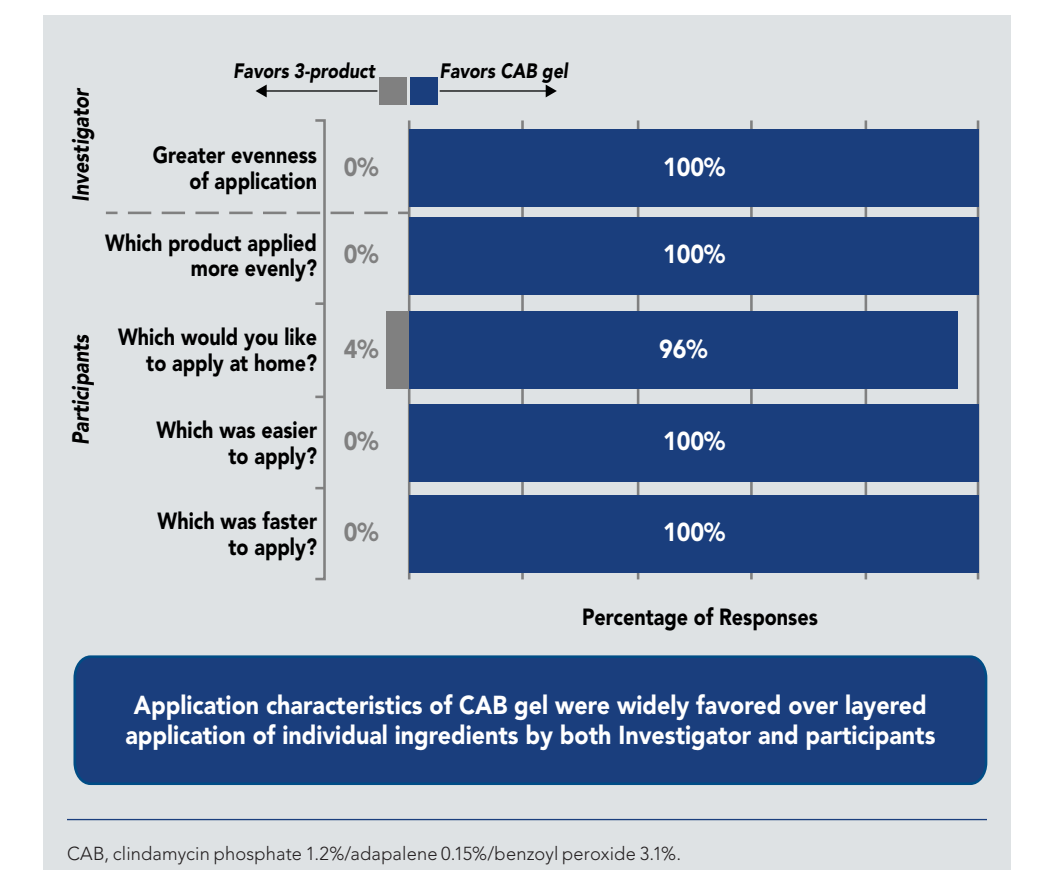


FIGURE 4. Participant Photographs



CAB gel and layered ingredients were applied to randomized sides of the face. Select photographs have been flipped so that all images show CAB gel on participants' right side (left side of photo) and layered products on participants' left side (right side of photo). CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%.

FIGURE 5. Assessments of Application Characteristics



CONCLUSIONS

- In phase 2 and phase 3 clinical trials, fixed-dose triple-combination CAB gel demonstrated significantly greater efficacy than vehicle or dyad combinations of active ingredients in the treatment of moderate-to-severe acne^{4,5}
- In a split-face study, CAB gel applied more evenly and was preferred by participants over separate applications of its three active ingredients
 - Patients are unlikely to adhere to a treatment regimen requiring application of three separate products²
 - Ease of use and uniform spread of topical formulations contribute to treatment tolerability and adherence³
- By addressing three of the main acne pathogenic pathways in a single, easy-to-apply formulation, CAB may improve efficacy of and adherence to acne treatment

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AUTHOR DISCLOSURES

Zoe Draelos has received funding from 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 H Kircik has served as either a consultant, speaker, advisor or an investigator for Allergan, Almirall, Epi Health, Galderma, Novartis, Ortho Dermatologics, and Sun. Emil Tanghetti has served as speaker for Novartis, Ortho Dermatologics, Sun Pharma, Lilly, Galderma, AbbVie, and Dermira; served as a consultant/clinical studies for Hologic, Ortho Dermatologics, and Galderma; and is a stockholder for Accure.