

Long-Term Efficacy and Tolerability of Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel for Acne: Pooled Results From Two 6-Month Studies

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SYNOPSIS

- Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide (BPO) 3.1% gel (CAB; Cabtreo[®], Ortho Dermatologics)—the only approved triple-combination acne topical¹—demonstrated superior efficacy to vehicle and component dyads, with favorable safety/tolerability in phase 2 and phase 3 trials of moderate to severe acne²⁻⁴
- After 12 weeks of treatment, approximately 50% of CAB-treated participants achieved treatment success, and acne lesions were reduced by >70%
- However, the 3-month treatment course typically used in clinical trials may not be representative of real-world treatment, which may take 6 months for maximum benefits to be observed in some cases⁵
- Furthermore, acne sequelae can persist long after lesion resolution and may be more distressing to patients than active acne lesions⁶
- As such, the long-term use of CAB gel was assessed in a 24-week open label study (n=25), which demonstrated that CAB was efficacious, well tolerated, and significantly improved acne-related scarring and dyspigmentation⁷
- To confirm and extend these findings, a second, identically designed study was conducted

OBJECTIVE

- To evaluate the long-term efficacy/safety of CAB gel and the reduction in acne sequelae (scarring and dyspigmentation) following 24 weeks of CAB treatment

METHODS

- Two identical, 24-week, open-label, post-marketing, single-center studies evaluated once-daily CAB gel in participants aged ≥12 years with moderate or severe acne (Investigator's Global Assessment [IGA] of 3 or 4)
- Endpoints included the following:
 - Primary efficacy: IGA improvement from baseline at week 24
 - Secondary efficacy: inflammatory and noninflammatory lesion count reduction from baseline at week 24
 - Safety: incidence of adverse events
 - Investigator-assessed acne scarring (via Goodman Qualitative Scar Scale)
 - Investigator-assessed skin appearance: postinflammatory hyperpigmentation (PIH), postinflammatory erythema (PIE), and dryness
- Participant-assessed tolerability: itching, burning, redness, and swelling

RESULTS

Participants

- A total of 50 participants were enrolled across the 2 studies; 45 participants completed the studies

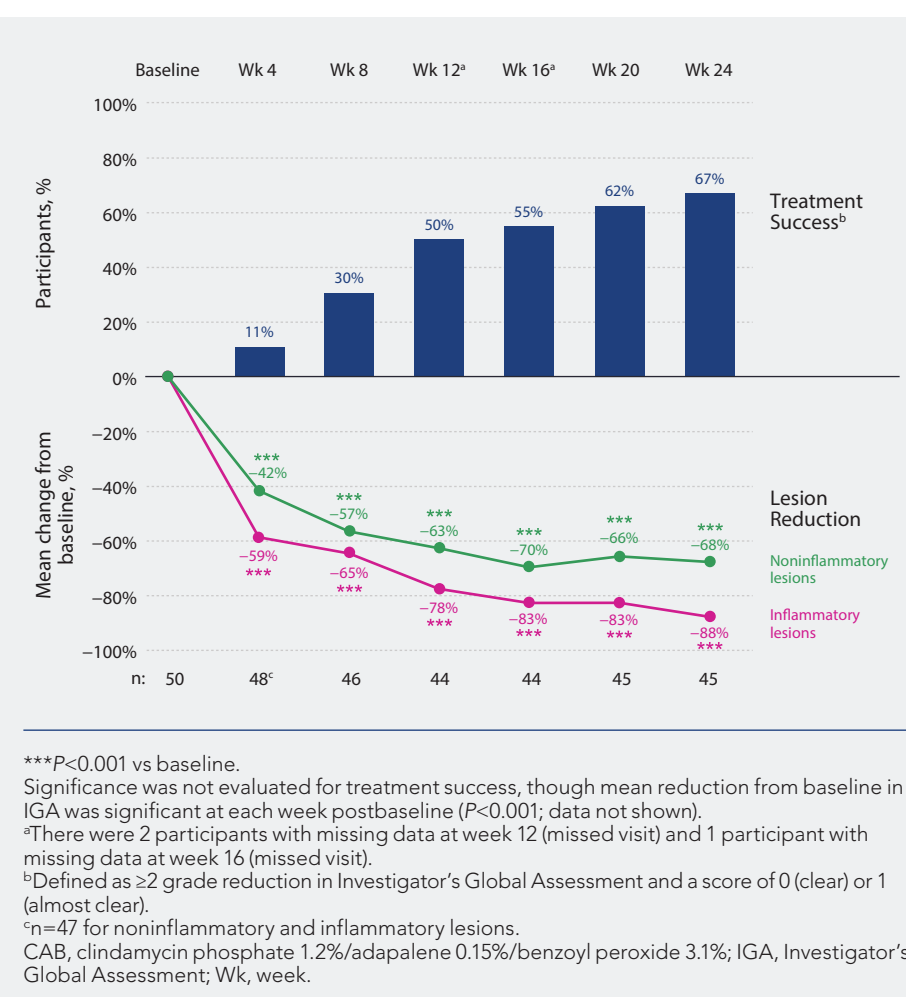
- Mean age was 21.8 years, most participants were female (n=38; 76%), and all Fitzpatrick skin types were represented (I-II, n=21; III-IV, n=9; V-VI, n=20)
- At baseline, a majority of participants had moderate acne (88%; IGA=3)

- Of the 5 participants that discontinued the study, 2 did so for personal reasons and 3 due to study drug-related side effects (see Safety section)

Efficacy

- At week 24, 67% of participants treated with CAB achieved treatment success (Figure 1 top)
- Mean reduction from baseline in IGA was significant at week 4 through week 24 (P<0.001, all; data not shown)
- Inflammatory and noninflammatory lesions were significantly reduced from baseline as early as week 4, with cumulative improvement through week 24 (P<0.001, all; Figure 1 bottom)

FIGURE 1. Long-Term Efficacy of CAB Gel



- Participant photographs demonstrating acne improvement are shown in Figure 2

FIGURE 2. Acne Improvements at Week 24 With CAB Gel



Safety

- A total of 7 adverse events occurred: 4 were related to the study product, and 3 led to study discontinuation (n=2, BPO allergy; n=1, irritant contact dermatitis to BPO)

Investigator-assessed scarring and skin appearance

- Significant improvement in facial scarring was observed by week 12, with a 33% reduction from baseline by week 24 (Figure 3)
- Significant improvements from baseline in dyspigmentation were noted as early as week 4, with 71% and 77% reductions from baseline at week 24 in PIH and PIE, respectively (Figure 4)
- Mean scores for skin dryness remained low (<0.15; 1=minimal) across all time points

FIGURE 3. Improvement in Acne Scarring^a With CAB Gel

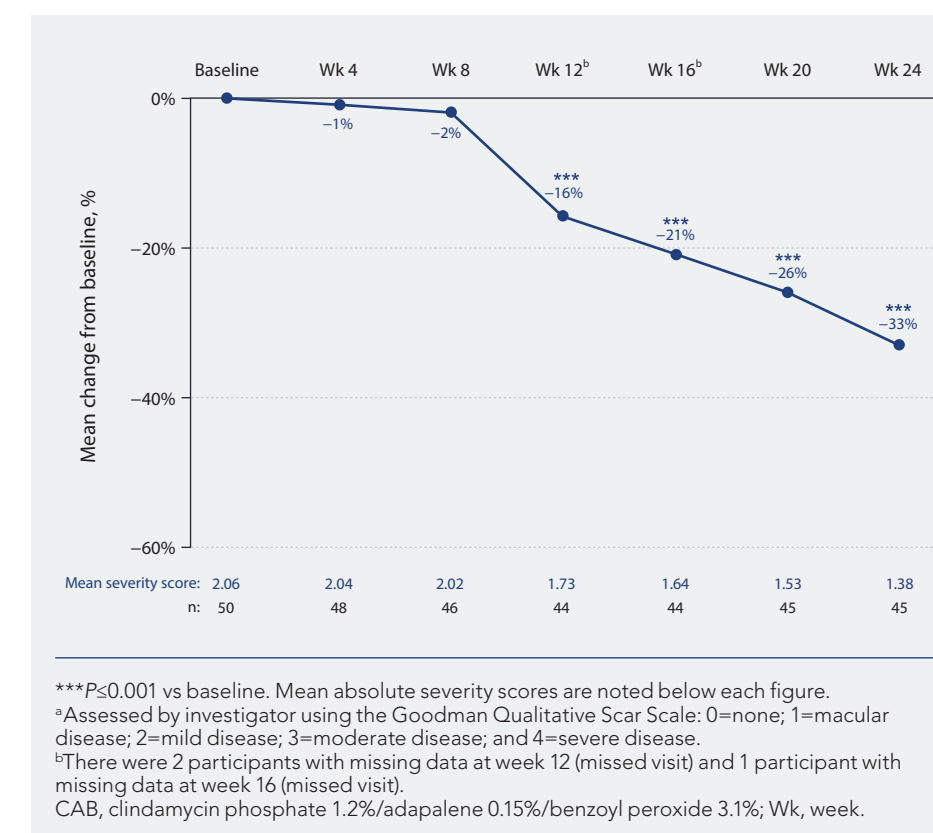
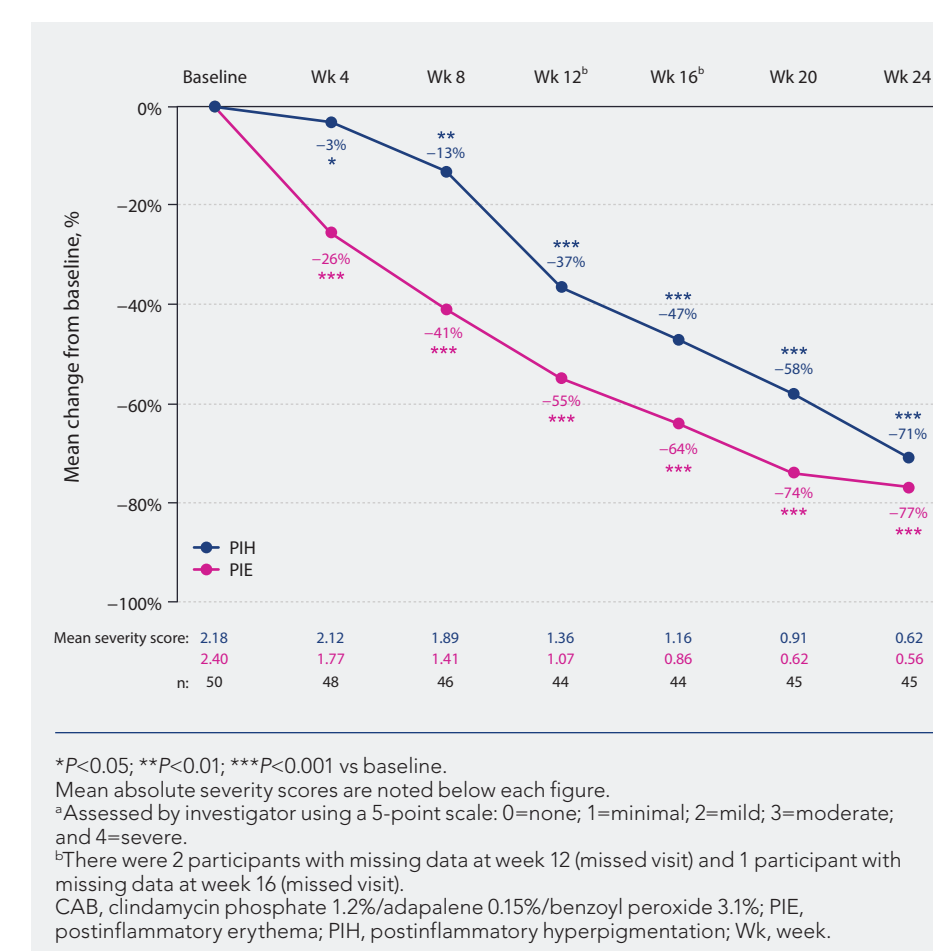


FIGURE 4. Improvement in Dyspigmentation^a With CAB Gel



Participant-assessed tolerability

- Most participants (>70%) reported no itching, burning, redness, or swelling with CAB application throughout the studies
- No participants rated their reactions to treatment as severe at any week, with <7% reporting moderate burning and redness at any point in the studies
- Mean tolerability scores were <0.45 across all timepoints

Clindamycin susceptibility of *Cutibacterium acnes*

- CAB gel did not lead to the development of antibiotic resistance as only the 5 participants with clindamycin-resistant *Cutibacterium acnes* isolates at baseline also had resistant isolates at week 24⁸
- CAB gel was efficacious in these 5 participants (IGA decrease, 1-3 points; lesion reductions, 40%-100%)⁸

CONCLUSIONS

- This pooled analysis of 2 single-center, 24-week, open-label studies confirms and expands findings from 12-week clinical trials²⁻⁴ and the first 24-week study of CAB gel⁷
- CAB demonstrated significant and continuing improvements in acne lesions, scarring, PIH, and PIE through 24 weeks of treatment with no new safety/tolerability signals
- A total of 67% of participants treated with CAB achieved treatment success, with 68% reductions in noninflammatory lesions and 88% reductions in inflammatory lesions
- Facial scarring, PIH, and PIE decreased by 33%, 71%, and 77%, respectively
- CAB gel is an appropriate and effective option for the long-term topical treatment of acne vulgaris

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AUTHOR DISCLOSURES

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