Long-Term Efficacy and Tolerability of Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% for Acne: A 24-Week Trial

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SYNOPSIS

- Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% gel (CAB; Cabtreo®; Ortho Dermatologics) is the only triple-combination, fixed-dose topical acne treatment approved by the US Food and Drug Administration[1]
- CAB demonstrated superior efficacy to vehicle and component dyads, with favorable safety/tolerability in a phase 2 and two phase 3 studies of moderate to severe acne[2-4]
  - By week 12, approximately 50% of CAB-treated participants achieved treatment success, and inflammatory lesions were reduced by >70%
- As acne is a chronic, often relapsing condition,[5] the 3-month treatment course typically used in clinical trials may not be representative of real-world treatment, which can require 6 months for maximum benefits to be seen[6]
- Furthermore, acne sequelae can persist long after lesion resolution and may be more distressing to patients than active acne lesions[7]

OBJECTIVE

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

METHODS

- This 24-week, single-center, open-label trial assessed once-daily CAB
- Inclusion criteria included participants aged ≥12 years with moderate to severe acne (Investigator's Global Assessment [IGA] score 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

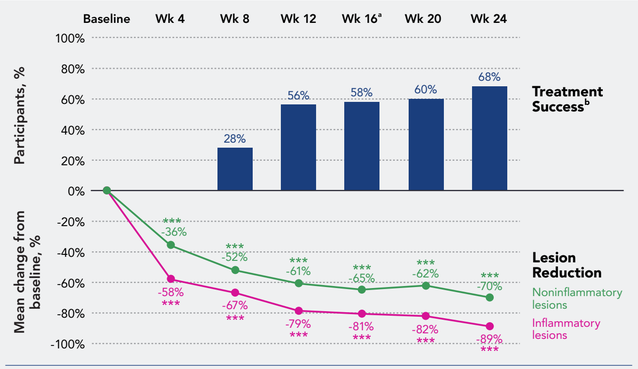
Participants

- A total of 25 participants were enrolled and completed the trial; all had moderate acne at baseline
- Mean age was 23.9 years (range, 12–51 years), and 80% of participants were female
- A total of 18 participants were African American, 6 were Caucasian, and 1 was Asian
- All Fitzpatrick skin types were represented (I–II, 24%; III–IV, 20%; V–VI, 56%)

Efficacy

- At week 24, 68% 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)
- Significant reductions from baseline in lesion counts were observed as early as week 4, with cumulative improvement through week 24 ($P<0.001$, all; **Figure 1 bottom**)
- Participant photographs demonstrating acne improvement from baseline to week 24 are shown in **Figure 2**

FIGURE 1. Long-Term Efficacy of CAB Gel



***$P<0.001$ vs baseline.
Significance was not evaluated for treatment success, though mean reduction from baseline in IGA was significant at each week postbaseline ($P<0.001$; data not shown).
[a]One participant had missing data at week 16 (missed visit).
[b]Defined as percentage of participants achieving ≥2-grade reduction from baseline in IGA score and a score of 0 (clear) or 1 (almost clear).
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; IGA, Investigator's Global Assessment.

FIGURE 2. Acne Improvements at Week 24 With CAB Gel

Individual results may vary.
Photographic Images ©2025. Courtesy of Trial Investigator.
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; IGA, Investigator's Global Assessment; IL, inflammatory lesion; NIL, noninflammatory lesion.

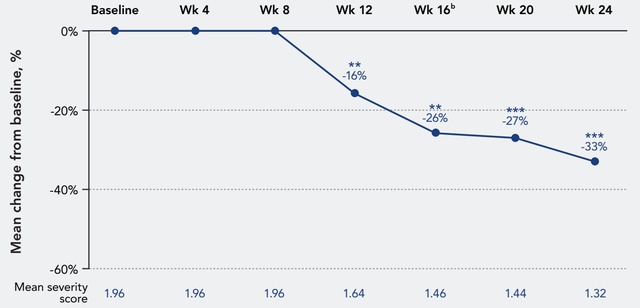
Safety

- No adverse events or adverse experiences occurred during the trial

Investigator-assessed scarring and skin appearance

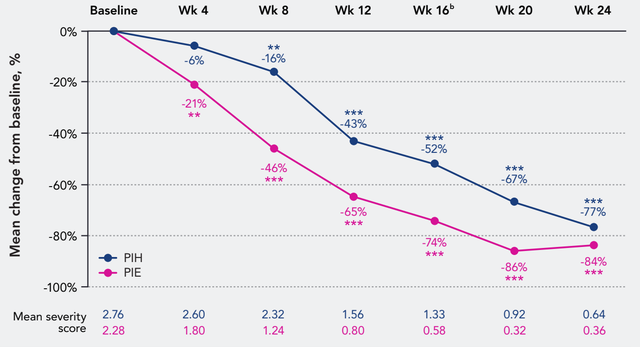
- Significant improvement in facial scarring was observed by week 12, with a 33% reduction from baseline at week 24 (**Figure 3**)
- Significant improvements from baseline in dyspigmentation were noted early, with 77% and 84% reductions from baseline at week 24 in PIH and PIE, respectively (**Figure 4**)
- There were no increases in skin dryness (data not shown)

FIGURE 3. Improvement in Acne Scarring[a] With CAB Gel



**$P<0.01$; ***$P=0.001$ vs baseline.
Mean absolute severity scores are noted below each figure.
[a]Assessed by investigator using the Goodman Qualitative Scar Scale: 0=none; 1=macular disease; 2=mild disease; 3=moderate disease; 4=severe disease.
[b]One participant had missing data at week 16 (missed visit).
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%.

FIGURE 4. Improvement in Dyspigmentation[a] With CAB Gel



**$P<0.01$; ***$P<0.001$ vs baseline.
Mean absolute severity scores are noted below each figure.
[a]Assessed by investigator using a 5-point scale: 0=none; 1=minimal; 2=mild; 3=moderate; 4=severe.
[b]One participant had missing data at week 16 (missed visit).
CAB, clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%; PIH, postinflammatory hyperpigmentation; PIE, postinflammatory erythema.

Participant-assessed tolerability

- There were no statistically significant tolerability issues identified by participants ($P>0.10$, all)
  - Mean postbaseline scores ranged from 0–0.08 for swelling, 0–0.16 for itching, and 0–0.24 for redness and burning (where 0=none and 1=minimal)

CONCLUSIONS

- This single-center trial confirms and expands on findings from 12-week clinical trials of CAB gel,[2-4] demonstrating significant and continuing improvements in acne lesions, scarring, PIH, and PIE through 24 weeks of treatment with no new safety/tolerability signals
  - Approximately two-thirds of participants achieved treatment success
  - CAB gel led to 89% reductions in inflammatory lesions and 70% reductions in noninflammatory lesions by week 24
  - Qualitatively assessed facial scarring severity decreased by 33%, with 77% reduction in PIH and 84% reduction in PIE
- CAB gel is an appropriate and effective option for the long-term topical treatment of acne vulgaris

REFERENCES

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AUTHOR DISCLOSURES

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