Early and Sustained Reductions in Moderate-to-Severe Acne With Fixed-Dose Clindamycin Phosphate 1.2%, Benzoyl Peroxide 3.1%, and Adapalene 0.15% Gel

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SYNOPSIS

- Adherence to acne treatment is highest when the outcome is rapid and substantial[1]
- However, many acne medication regimens may take weeks or months to produce an improvement discernible by patients, leading to lower adherence[2]
- A three-pronged combination approach using once-daily application of an antibiotic, antibacterial, and retinoid may provide faster improvement than stand alone or dual combination products
- The first triple-combination, fixed-dose acne topical in development, clindamycin phosphate 1.2%/benzoyl peroxide (BPO) 3.1%/adapalene 0.15% (IDP-126) gel, was efficacious and safe in 3 clinical studies[3,4]

OBJECTIVE

- To determine threshold lesion reductions for IDP-126 gel and compare to its dyads and vehicle gel

METHODS

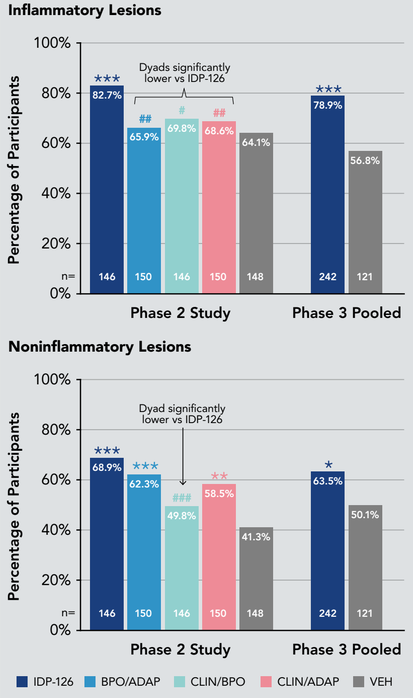
- A phase 2 (N=741; NCT03170388) and two phase 3 (N=183; N=180; NCT04214639; NCT04214652), double-blind, 12-week studies enrolled participants aged ≥9 years with moderate-to-severe acne
- Participants were randomized to receive once-daily IDP-126 or vehicle gel; the phase 2 study included three additional dyad gel randomization arms: BPO/adapalene; clindamycin phosphate/BPO; and clindamycin phosphate/adapalene
- Endpoints included least-squares mean percent change from baseline in inflammatory and noninflammatory lesion counts
- The percentage of participants achieving ≥33%, ≥50%, and ≥75% thresholds in lesion reduction was evaluated

RESULTS

FIGURE 1. ONE-THIRD REDUCTION IN LESION COUNTS: WEEK 4

Participants with ≥33% reduction at week 4

Early reductions in acne lesions by week 4
More participants achieved one-third reduction in lesions with IDP-126 versus dyads and vehicle at week 4

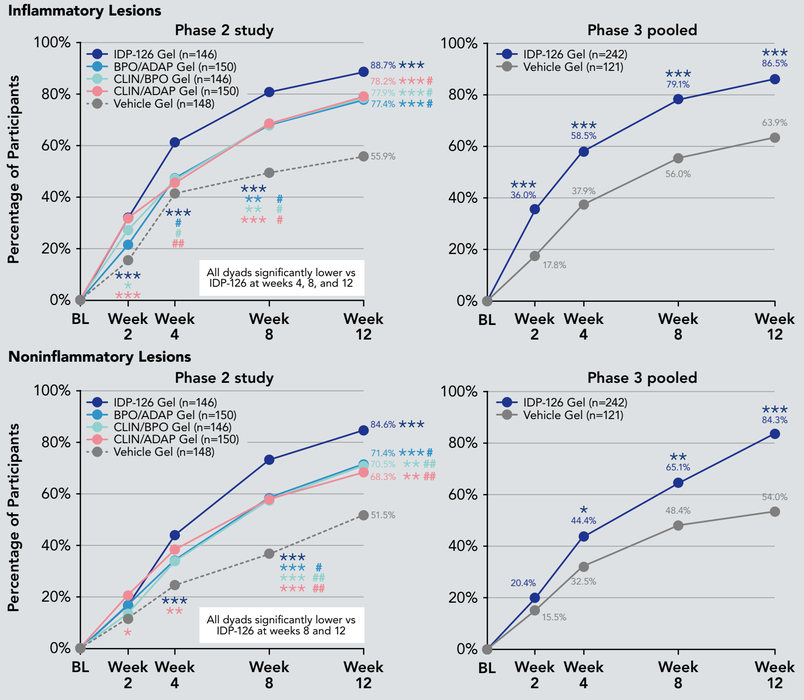


*P<0.05, **P<0.01, ***P<0.001 active treatment vs vehicle.
#P<0.05, ##P<0.01, ###P<0.001 dyads vs IDP-126.
ADAP, adapalene; BPO, benzoyl peroxide; CLIN, clindamycin phosphate; VEH, vehicle.

FIGURE 2. ONE-HALF REDUCTION IN LESION COUNTS: WEEKS 4–12

Participants with ≥50% reduction at all weeks

Early and sustained reductions in acne lesions
More participants achieved one-half reduction in lesions with IDP-126 versus dyads and vehicle as early as week 4, with significant reduction maintained at weeks 8 and 12

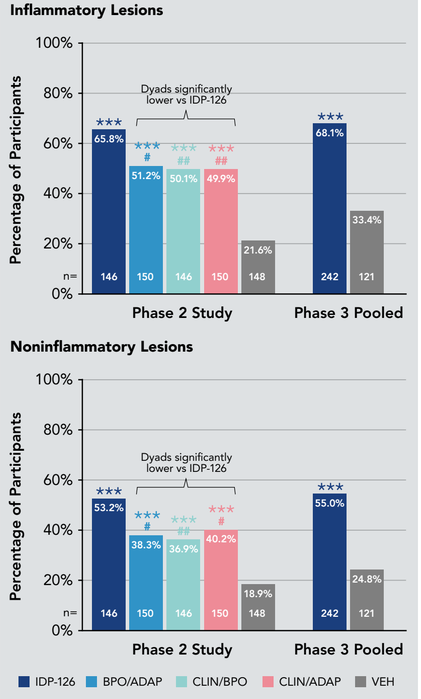


*P<0.05, **P≤0.01, ***P≤0.001 active treatment vs vehicle.
#P<0.05, ##P<0.01 dyads vs IDP-126.
ADAP, adapalene; BPO, benzoyl peroxide; CLIN, clindamycin phosphate; VEH, vehicle.

FIGURE 3. THREE-FOURTHS REDUCTIONS IN LESION COUNTS: WEEK 12

Participants with ≥75% reduction at week 12

Substantial reductions in acne lesions by week 12
Significantly more participants achieved three-fourths reduction in lesions with IDP-126 versus dyads and vehicle at week 12



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ADAP, adapalene; BPO, benzoyl peroxide; CLIN, clindamycin phosphate; VEH, vehicle.

CONCLUSIONS

- Therapeutic effects of IDP-126 gel were rapid and sustained
- Lesion count reductions were greater with IDP-126 versus its dyads and vehicle gel as early as week 4, with substantial reductions observed after 12 weeks of IDP-126 treatment
- This fast-acting feature of IDP-126—coupled with its optimized efficacy, once a day application, and good tolerability—may positively impact treatment adherence

REFERENCES

1. Sevimli Dikicier B. *J Int Med Res.* 2019;47(7):2987-2992.
2. Tuchayi SM. *Patient Prefer Adherence.* 2016;10:2091–2096.
3. Stein Gold L. *Am J Clin Dermatol.* 2022;23(1):93-104.
4. Stein Gold L. *J Am Acad Dermatol.* 2022;87(3):Supp AB50.

AUTHOR DISCLOSURES

Julie Harper has received honoraria from Aclaris, Almirall, BioPharmX, Cassiopea, Cutanea, Dermira, Foamix, Galderma, LaRoche-Posay, Ortho Dermatologics, and Sun. Leon Kircik has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Michael Gold has acted as an investigator, advisor, speaker, and consultant for Ortho Dermatologics. Adelaide A. Hebert has received honoraria from Galderma, LEO Pharma, Amirall, Cassiopea, Ortho Dermatologics, Cutanea, Ferrer, Pfizer, Demira. The UTHealth McGovern Medical School had received research grants from Cassiopea, Demira, Ortho Dermatologics. Jeffrey L Sugarman is a consultant for Ortho Dermatologics, Bausch Health, Regeneron, Sanofi, Verrica, and Pfizer. Lawrence Green has served as investigator, consultant, or speaker for Almirall, Cassiopea, Galderma, Ortho Dermatologics, Sol Gel, Sun Pharma, and Vyne. 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. Hilary Baldwin has served as advisor, investigator, and on speakers' bureaus for Almirall, Cassiopea, Foamix, Galderma, Ortho Dermatologics, Sol Gel, and Sun Pharma. James Q. Del Rosso has served as a consultant, investigator, and/or speaker for Ortho Dermatologics, Abbvie, Amgen, Arcutis, Dermavant, EPI Heath, Galderma, Incyte, LEO Pharma, Lilly, MC2 Therapeutics, Pfizer, Sun Pharma, and UCB. Eric Guenin is an employee of Ortho Dermatologics and may hold stock and/or stock options in its parent company.

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