Impact of Age or Sex on Efficacy and Safety of a Fixed-Dose Clindamycin Phosphate 1.2%/Benzoyl Peroxide 3.1%/Adapalene 0.15% Gel in Participants With Moderate-to-Severe Acne

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BACKGROUND AND RATIONALE

- Patient age or sex may impact the efficacy and tolerability of topical acne treatments[1-3]
  - Managing acne in younger patients is complicated by low rates of treatment adherence[4] and the potential for more irritation with topical treatments than in adults[5]
  - Among adults, females may be more susceptible to dry skin, making irritation with topical treatment a significant concern[6]
- IDP-126 fixed-dose polymeric mesh gel (clindamycin phosphate 1.2%/benzoyl peroxide [BPO] 3.1%/adapalene 0.15%) is the first triple-combination, fixed-dose, topical acne treatment in development
- IDP-126 demonstrated superior efficacy to vehicle and component dyads, with good safety and tolerability, in a phase 2[7] and two phase 3 studies of participants with moderate-to-severe acne

OBJECTIVE

- To assess the impact of age or sex on efficacy and safety/tolerability of IDP-126 gel

METHODS

- In two phase 3, double-blind, randomized studies (NCT04214639, NCT04214652), eligible participants aged ≥9 years with moderate-to-severe acne were randomized 2:1 to receive IDP-126 or vehicle gel once daily for 12 weeks
  - CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oreal, NY) were provided as needed for optimal skin moisturization/cleaning
- Data from these studies were pooled and analyzed post hoc by participant age (pediatric, <18 years; adult, ≥18 years) or sex
- Endpoints included treatment success (≥2-grade reduction from baseline in Evaluator's Global Severity Score [EGSS] and a score of 0 [clear] or 1 [almost clear]) and least-squares mean percent change from baseline in inflammatory and noninflammatory lesion counts
  - Acne severity was assessed via EGSS, which was scored as: 0 (clear) = Normal, clear skin/no evidence of acne; 1 (almost clear) = Rare noninflammatory lesions, with rare noninflamed papules; 2 (mild) = Some noninflammatory lesions, with few inflammatory lesions; 3 (moderate) = Noninflammatory lesions predominate, with multiple inflammatory lesions: several/many comedones and papules/pustules, ≤1 nodulocystic lesion; 4 (severe) = Inflammatory lesions more apparent, many comedones/papules/pustules, ≤2 nodulocystic lesions
- Treatment-emergent adverse events (TEAEs) and cutaneous safety/tolerability were also assessed

RESULTS

Participants

- The 363 participants in the overall pooled population were evenly divided between pediatric and adult participants (n=178 and 185, respectively); overall, almost 60% were female (n=212)
- Across all subgroups, most participants were White (68.6%-78.7%) and non-Hispanic (76.9%-79.5%), with baseline EGSS score of 3 (moderate; 87.4%-93.9%)

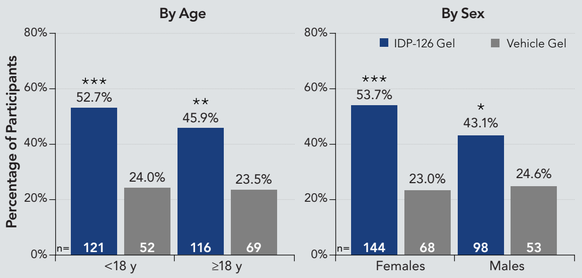
Efficacy

- At week 12, over half of pediatric and almost half of adult IDP-126-treated participants achieved treatment success, versus one-fourth with vehicle; results by sex were similar (**Figure 1**)
- At week 12, IDP-126 provided >70% reductions in inflammatory/noninflammatory lesions in all subgroups; reductions were significantly greater versus vehicle (**Figure 2**)
- Differences in rates of treatment success and percent reductions from baseline in inflammatory and non-inflammatory lesions were not statistically significant between IDP-126–treated age or sex subgroups
- Images of representative IDP-126–treated participants from each subgroup are shown in **Figure 3**

Safety and Tolerability

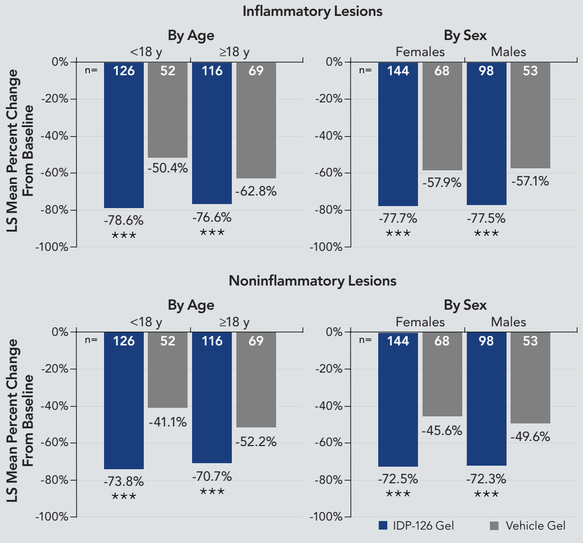
- TEAE rates/severity/relationship to study drug, and the most common TEAEs, were similar across age and sex subgroups (**Table 1**)
  - Most TEAEs were of mild-to-moderate severity (data not shown)
- Rates of IDP-126 discontinuations due to TEAEs were low (<4%) in all subgroups
- Mean scores for cutaneous safety and tolerability assessments (erythema, scaling, hyperpigmentation, hypopigmentation, itching, burning, and stinging) were <1 (mild) at all study visits (data not shown)

FIGURE 1. Treatment Success[a] at Week 12 (ITT Population)



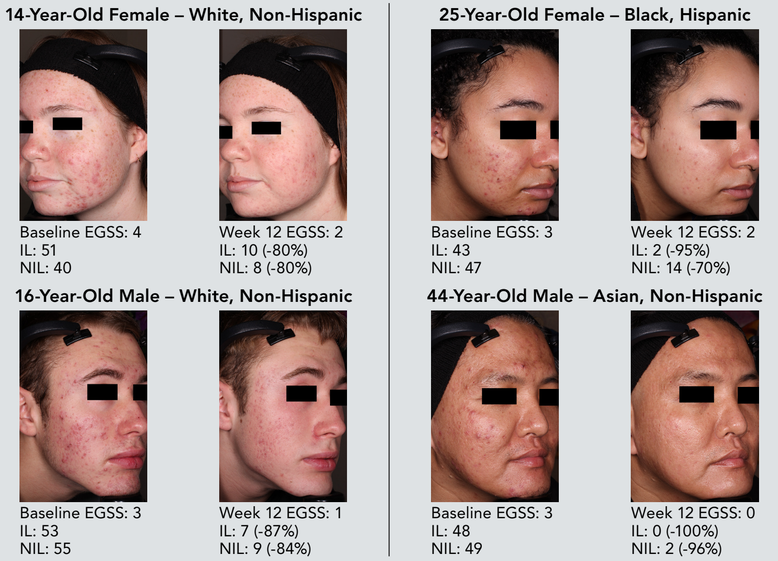
*P<0.05; **P<0.01; ***P≤0.001 vs vehicle.
[a]Defined as percentage of participants achieving ≥2-grade reduction from baseline in EGSS and a score of 0 (clear) or 1 (almost clear).
Values have been adjusted for multiple imputation.
EGSS, Evaluator's Global Severity Score; IDP-126, clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%; ITT, intent to treat.

FIGURE 2. Lesion Reductions From Baseline to Week 12 (ITT Population)



***P≤0.001 vs vehicle.
Values have been adjusted for multiple imputation.
IDP-126, clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%; ITT, intent to treat; LS, least squares.

FIGURE 3. Acne Improvements with IDP-126 Gel



Individual results may vary.
EGSS, Evaluator's Global Severity Score; IDP-126, clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%; IL, inflammatory lesions; NIL, noninflammatory lesions.

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

	<18 years		≥18 years		Females		Males	
n (%)	IDP-126 (n=126)	VEH (n=52)	IDP-126 (n=116)	VEH (n=69)	IDP-126 (n=144)	VEH (n=68)	IDP-126 (n=98)	VEH (n=53)
TEAEs	32 (25.4)	3 (5.8)	34 (29.3)	7 (10.1)	39 (27.1)	6 (8.8)	27 (27.6)	4 (7.5)
Related	23 (18.3)	0	25 (21.6)	2 (2.9)	28 (19.4)	2 (2.9)	20 (20.4)	0
Not related	9 (7.1)	3 (5.8)	9 (7.8)	5 (7.2)	11 (7.6)	4 (5.9)	7 (7.1)	4 (7.5)
Serious AEs	0	0	0	0	0	0	0	0
Discontinued drug/study due to TEAE	3 (2.4)	0	4 (3.4)	0	4 (2.8)	0	3 (3.1)	0
Most common treatment-related TEAEs (≥2% participants in any treatment)								
AS pain	16 (12.7)	0	15 (12.9)	1 (1.4)	16 (11.1)	1 (1.5)	15 (15.3)	0
AS dryness	3 (2.4)	0	4 (3.4)	0	3 (2.1)	0	4 (4.1)	0
Erythema	3 (2.4)	0	3 (2.6)	0	2 (1.4)	0	4 (4.1)	0
AS irritation	1 (0.8)	0	4 (3.4)	0	4 (2.8)	0	1 (1.0)	0
Xerosis	0	0	3 (2.6)	1 (1.4)	3 (2.1)	1 (1.5)	0	0
AS exfoliation	2 (1.6)	0	2 (1.7)	0	3 (2.1)	0	1 (1.0)	0

AS, application site; IDP-126, clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15% gel; TEAE, treatment-emergent adverse event; VEH, vehicle gel.

CONCLUSIONS

- The innovative fixed-dose, triple-combination IDP-126 gel (clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%) was efficacious and well tolerated, regardless of age or sex, in participants with moderate-to-severe acne
  - At week 12, approximately half of participants achieved treatment success with IDP-126 gel versus less than one fourth with vehicle
  - In all subgroups, IDP-126 provided over 70% reductions from baseline in inflammatory and noninflammatory lesions
- The efficacy and favorable safety profile of IDP-126 gel in children, adults, females and males demonstrate its potential as a topical treatment option for acne in a variety of patient populations

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AUTHOR DISCLOSURES

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