Safety and Tolerability of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Black Participants With Acne

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SYNOPSIS

Acne is one of the major causes of inflammation-associated sequelae such as post-inflammatory hyperpigmentation (PIH) and scarring, particularly in individuals with melanin-rich skin.1,2 Effective and rapid management of acne in patients with darker skin tones must be balanced with the need to minimize treatment-related irritation, which can also cause hypopigmentation.2 Clindamycin phosphate 1.2%/Adapalene 0.15%/benzoyl peroxide 3.1% (IDP-126) polymeric mesh gel is the first fixed-dose, triple combination topical acne product in development that addresses the major pathological abnormalities in acne patients: (a) a three-progression approach to acne treatment—combining an antibiotic, antibacterial agent, and retinoid in a single formulation—has been investigated as a means to provide greater efficacy than single-drug treatments while potentially reducing antibiotic resistance.3,4 (b) In children, adolescents, and adults with moderate-to-severe acne, IDP-126 led to significant reductions in acne from baseline to week 12 versus vehicle gel and its component dyads, with over half of IDP-126 participants achieving treatment success.5,6 (c) Minimizing irritation is a key goal in managing acne in patients with skin of color, given the higher risk of pigmentary alterations in melanin-rich skin.1,2

RESULTS

Participants and Adverse Events

The pooled intent-to-treat population included 363 participants, of whom 56 (15.9%) self-identified as Black; the safety population included all 34 Black participants. TEAEs were mild or moderate in severity in all Black IDP-126-treated participants, with no serious adverse events reported and no TEAEs that led to discontinuation (Table 1). The most common treatment-related TEAEs in IDP-126-treated Black participants were application site pain and application site pruritus. Adverse event reports in Black participants were generally similar to the overall population.7

FIGURE 1. Investigator-Assessed Cutaneous Safety in Black Participants (Safety Population, Pooled)

TABLE 1. Black Participants Reporting Any Treatment-Emergent Adverse Event (Safety Population, Pooled)

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Figure 1: Investigator-Assessed Cutaneous Safety in Black Participants (Safety Population, Pooled)

CONCLUSIONS

Minimizing irritation is a key goal in managing acne in patients with skin of color, given the higher risk of pigmentary alterations in melanin-rich skin.1,2 Clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% (IDP-126) gel was safe and well tolerated in Black participants after 12 weeks of once-daily treatment.5,6 IDP-126 treatment led to improvements in investigator-assessed severity in Black participants, with no substantial increases in hyperpigmentation, and no incidences of hypopigmentation.5,6 Despite the limited number of self-identified Black participants in these phase 3 studies, post hoc analyses add valuable information to the literature describing treatment effects and tolerability of fixed-dose combination acne products in Black individuals.5,6

REFERENCES


AUTHOR DISCLOSURES

The following disclosures were submitted with the manuscript. However, any financial relationships that may fall within the scope of the COI policy are not listed in this section. They were not required to disclose any presentation or publication in the past 2 years associated with the study. To view the full list of COIs, visit https://jaad.org/coi.

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