Efficacy and Safety of Triple-Combination Clindamycin Phosphate 1.2%/Benzoyl Peroxide 3.1%/Adapalene 0.15% Polymeric Gel in Pediatric Participants with Acne

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SYNOPSIS

Prevalence of acne is near-universal during teen years, acne is an adolescent with profound psychosocial impacts, and younger age is associated with greater acne severity.

Managing acne in younger patients is complicated by low rates of treatment adherence and potential for severe scarring with topical treatments. Thus!

Combining topical therapies that have multiple mechanisms of action can improve efficacy and formulation into a single fixed-combination product can improve adherence to acne treatment.

In this phase 2, double-blind, 12-week study (IDP-126, clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15%; IDP-126 polymeric gel)—the first fixed-dose triple-combination topical formulation in development for acne (Figure 1)—was well tolerated and demonstrated superior efficacy to vehicle and all three of the component dyad combination gels.

METHODS

OBJECTIVE

The objective of this post hoc analysis was to evaluate efficacy and safety of IDP-126 in children and adolescents (aged 9-17 years) with acne

METHODS

In this phase 2, double-blind, 12-week study (IDP-126), eligible participants were aged 9 to 17 years with moderate-to-severe acne were randomized to vehicle (n = 21), adapalene 0.15% gel, vehicle gel, or 1 of 3 component dyad combination gels (BPO/ADAP, CLIN/BPO, or CLIN/ADAP).

Corticosteroid hydrocortisone, metronidazole ointment (2% cream), and tetracycline hydrochloride (250 mg tablets) were provided as needed for optional instructions' clearing of skin.

TEAE rates were similar between pediatric participants and the overall study population (Table 1).

Safety

Any TEAEs were similar among pediatric participants and the overall population (Table 4).

No serious adverse events were considered related to treatment.

The IDP-126 study drug discontinuation rate was 1% (1 of 117 participants, 1.7%) and the overall rate was 4.2%.

RESULTS

Participants

42 pediatric participants were enrolled (IDP-126 n = 146, BPO/ADAP n = 150, CLIN/BPO n = 146, CLIN/ADAP n = 148, vehicle n = 148). The mean age was ~14.9 years. In the overall study population, 52% were female, 22% were male, 14% were male, and 11% were female. The race/ethnicity distribution was 46% White, 23% African American, 11% Hispanic/Latino, and 11% Asian, not Hispanic/Latino. The Acne Treatment and Research Center, Brooklyn, NY.

Efficacy

At week 12, participants treated with IDP-126 experienced 19.8% mean reduction from baseline in inflammatory and noninflammatory lesion counts, regardless of age (P = 0.003, both).

More pediatric participants (92.9%) had a baseline EGSS score >11, which is considered to be the overall study population (89%).

Treatment compliance was 100% across the treatment groups.

No serious adverse events were considered related to treatment.

The IDP-126 study drug discontinuation rate was 3% (4 of 117 participants, 3.4%) and the overall rate was 4.2%.

Efficacy

In pediatric participants with moderate-to-severe acne, IDP-126—the first fixed-dose, triple-combination clindamycin phosphate 1.2%/benzoyl peroxide 3.1%/adapalene 0.15% polymeric gel—demonstrated superior efficacy to vehicle and all three of the component dyad combination gels.

In pediatric participants, over half achieved treatment success and mean lesion reductions were at least 70% by week 12 with IDP-126, similar to the overall study population.

To our knowledge, such improvements have not been observed with any FDA-approved topical acne treatment, though study populations may differ.

The superior efficacy and favorable safety profile of triple-combination IDP-126 gel development is an area of interest for future research.

CONCLUSIONS

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REFERENCES


AUTHOR DISCLOSURES

The authors reported no relevant financial relationships. Each author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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