MICROENCAPSULATED BENZOYL PEROXIDE 3%, MICROENCAPSULATED TRETINOIN 0.1% CREAM: EFFICACY FOR PEDIATRIC AND ADOLESCENT PATIENTS

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INTRODUCTION

- Benzoyl peroxide (BPO) is recommended for treatment of acne of all severities.[1] It is bactericidal against *C. acnes* on the skin and within hair follicles with no risk for development of resistance,[1,2] and it also has mild keratolytic effects.[3]
- BPO is widely used as a single agent in many different vehicles,[4] and in combination with other medications.[3,5] Multiple analyses have indicated that the efficacy of BPO is enhanced when used in combination with topical retinoids, such as tretinoin.[6,7] However, BPO usually causes degradation of tretinoin, reducing its effectiveness.[8]
- E-BPO/E-ATRA is an investigational, antibiotic-free, fixed-dose combination cream containing microencapsulated BPO 3% (E-BPO) and microencapsulated tretinoin 0.1% (E-ATRA). The use of Sol-Gel's microencapsulation technology platform provides a stable combination of BPO and tretinoin, extending drug delivery time, and reducing potential irritation caused by direct application of the drugs to the skin.
- The efficacy, safety, and tolerability of E-BPO/E-ATRA have been demonstrated in two phase 3 randomized, vehicle-controlled trials.[9] This result provides an analysis of the effectives of E-BPO/E-ATRA in patients of different ages based on analysis of results from those two studies, with a focus on pediatric and adolescent patients.

METHODS

Design

2x trials / 12 weeks / 63 sites across US

- Two multicenter, randomized, double-blind, parallel-group vehicle-controlled trials (SGT-65-04 and SGT-65-05) carried out at 63 sites across the United States (**Figure 1**).

Figure 1. Study design

E-ATRA, microencapsulated tretinoin; E-BPO, microencapsulated benzoyl peroxide; IGA, Investigator's Global Assessment; QD, once daily.

Endpoints

- Co-Primary Efficacy Endpoints
  - Proportion of patients who achieved a two-grade reduction from baseline and grade 0 (Clear) or grade 1 (Almost Clear) at Week 12 on a 5-point IGA scale.
  - Absolute change in inflammatory lesion counts from baseline at Week 12.
  - Absolute change in non-inflammatory lesion counts from baseline at Week 12.

Data Analysis

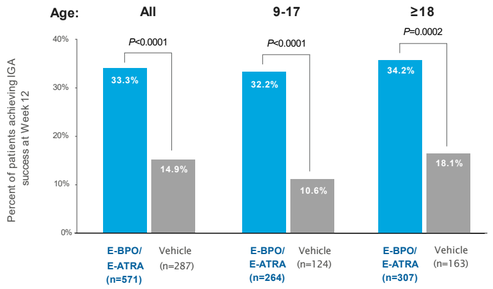
- All efficacy analyses were carried out using the intent-to-treat population. Safety analyses were carried out using the safety population.
- All results are reported as effects of E-BPO/E-ATRA vs vehicle (point estimates of the difference between treatments).

RESULTS

Achievement of IGA Success

- The efficacy of E-BPO/E-ATRA in pediatric and adolescent patients (9-17 years of age) was at least equivalent to that for the entire population.

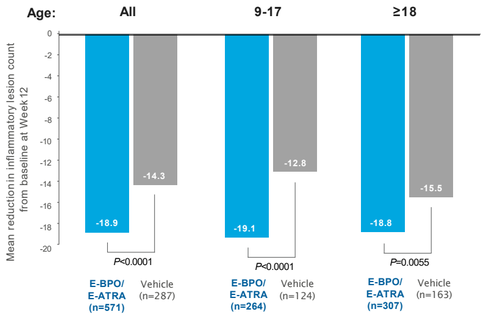
IGA treatment success at week 12



Reduction in Inflammatory Lesions

- The efficacy of E-BPO/E-ATRA in pediatric and adolescent patients (9-17 years of age) was at least equivalent to that for the entire population.

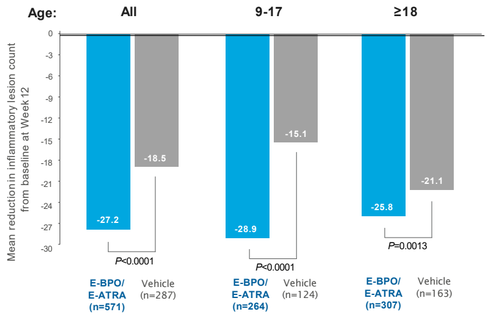
Absolute mean change from baseline in inflammatory lesions at week 12



Reduction in Non-inflammatory Lesions

- The efficacy of E-BPO/E-ATRA in pediatric and adolescent patients (9-17 years of age) was at least equivalent to that for the entire population.

Absolute mean change from baseline in non-inflammatory lesions at week 12



CONCLUSIONS

- **E-BPO/E-ATRA cream, combines, for the first time, two of the safest and most effective topical agents available for the treatment of acne into a single application.**
- **Pooled results from the two phase 3 trials of E-BPO/E-ATRA demonstrated that this new microencapsulated formulation of BPO and tretinoin was efficacious in pediatric and adolescent patients who comprise a very large segment of the overall population with acne and about 45% of the patients in the phase 3 trials.**

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