EFFICACY OF MICROENCAPSULATED BENZOYL PEROXIDE (E-BPO) CREAM, 5% IN ELDERLY ROSACEA PATIENTS

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INTRODUCTION

- In a new microencapsulated formulation (E-BPO Cream, 5%), the drug is entrapped in silica microcapsules. This extends drug delivery time to improve efficacy and reduce the potential for skin irritation.[1]
- The efficacy, safety, and tolerability of E-BPO Cream, 5% were evaluated in two identical randomized, double-blind phase 3 trials which demonstrated significant superiority of E-BPO versus vehicle for percentage of patients achieving success (clear or almost clear) on the Investigators Global Assessment (IGA) and reducing the number of lesions.[2]
- E-BPO Cream, 5% was also well tolerated with adverse events (AEs) and cutaneous safety and tolerability comparable to that for vehicle.[2]
- The prevalence of rosacea is higher in the elderly population than the general population,[3,4] but no quantitative data has been published regarding treatment efficacy on papulopustular rosacea in this subpopulation. This report summarizes results from an analysis of younger (<65 years of age) and more elderly (≥65 years old) patients who were included in the two trials of E-BPO Cream, 5%.

METHODS

Patients

733 patients / ≥18 years / 12 weeks

- 733 patients ≥18 years old with moderate or severe disease (IGA grade 3 or 4, ≥15 inflammatory lesions, ≤2 nodules) were randomized (2:1) to once-daily E-BPO Cream, 5% (n=493) or Vehicle Cream (n=240) for 12 weeks.

ASSESSMENTS

- Clinical evaluations were performed at weeks 2, 4, 8, and 12. The primary efficacy endpoints were the proportion of patients with the primary measure of success: "Clear" (0) or "Almost clear" (1) in the IGA relative to baseline at week 12 and absolute change from baseline in inflammatory lesion count at week 12.
- Secondary endpoints include success in both parameters at weeks 2, 4, and 8.
- All analyses were carried out on the intent-to-treat population.
- Adverse events were also recorded and are presented for the safety population.

RESULTS

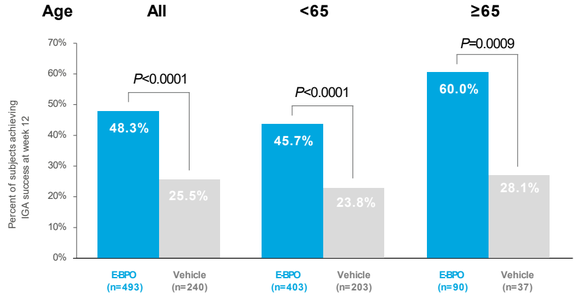
Patients

- A total of 733 patients were enrolled, including 493 who were treated with E-BPO Cream, 5% and 240 who received Vehicle Cream (VC).
- There were 606 patients <65 years old who were enrolled in the trial and 127 patients who were ≥65 years of age.

Efficacy

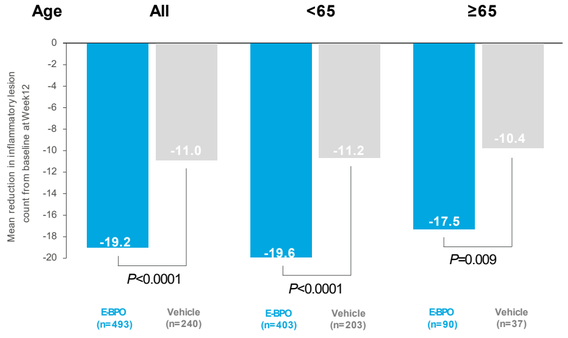
- The analysis indicated that E-BPO Cream, 5% was significantly superior to VC for achievement of IGA success and reduction in inflammatory lesions in both age groups.
- Results for all patients indicated that IGA success was achieved in 48.3% of patients who received E-BPO Cream, 5% vs 24.5% for VC. The respective values for patients <65 years of age were 45.7% and 23.8% and those for patients ≥65 years old were 60.0% and 28.1% (**Figure 1**).
- Results for all patients indicated that the absolute reduction from baseline in inflammatory lesions was –19.2 for patients who received E-BPO Cream, 5% vs –11.0 for VC. The respective values for patients <65 years of age were –19.6 and –11.2 and those for patients ≥65 years old were –17.5 and –10.4 (**Figure 2**) (all *P*<0.001).

Figure 1. Percentage of patients achieving of IGA success at 12 weeks of active treatment



60% of patients ≥65 years of age achieved IGA success at week 12 with E-BPO Cream, 5%

Figure 2. Reductions in inflammatory lesions from baseline to 12 weeks of treatment



Safety and Tolerability

- The safety and tolerability of E-BPO Cream, 5% was comparable to VC in both age groups (**Table 1**).

Table 1. Safety summary

	Age <65 years		Age ≥ 65 years	
Event	E-BPO (N=398) %	Vehicle (N=198) %	E-BPO (N=90) %	Vehicle (N=36) %
Any Treatment-Emergent Adverse Event	19.3	17.7	24.4	11.1
Any Serious Treatment-Emergent Adverse Event	0	0	1.1	2.8
Deaths	0	0	0	0
Discontinued Study Drug Due to a Treatment-Emergent Adverse Event	2.0	1.0	3.3	2.8
Severe Treatment-Emergent Adverse Event	0.8	0	1.1	0
Drug-Related Treatment-Emergent Adverse Event	4.3	1.5	6.7	0
Individual Treatment-Emergent Adverse Events (>2% of patients in any group)	**E-BPO (N=398) %**	**Vehicle (N=198) %**	**E-BPO (N=90) %**	**Vehicle (N=36) %**
Nasopharyngitis	2.3	2.0	3.3	0
Application Site Pain	2.3	1.0	2.2	0
Application Site Erythema	1.8	1.0	4.4	0
Application Site Pruritus	1.0	0.5	2.2	0
Wrist Fracture	0	1.5	2.2	0
Femur Fracture	0	0	0	2.8
Diarrhea	0	0	2.2	0

CONCLUSIONS

This combined analysis of results from the two phase 3, randomized, double-blind controlled studies of E-BPO Cream, 5% indicate that it was efficacious in both older and younger patients with papulopustular rosacea.

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