EFFICACY AND SAFETY OF MICROENCAPSULATED BENZOYL PEROXIDE (E-BPO) CREAM, 5% IN PAPULOPUSTULAR ROSACEA: RESULTS FROM TWO PHASE 3, VEHICLE-CONTROLLED TRIALS

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Introduction

The skin of patients with rosacea is highly sensitive to dietary, environmental, and topical factors. Benzoyl Peroxide (BPO) has shown variable efficacy for treating rosacea in small studies but is associated with itching and burning at treatment sites.[1-3] In the E-BPO Cream, 5% formulation, BPO is microencapsulated with a silica base shell. This prevents direct contact of BPO crystals with the skin leading to reduced potential for irritation. This new E-BPO formulation has been evaluated in two identical, double-blind, vehicle-controlled phase 3 trials (SGT 54-01 and SGT 54-02) of patients with papulopustular rosacea (inflammatory lesions of rosacea).

Methods

- 733 patients ≥18 years old with moderate or severe disease (Investigator Global Assessment [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 (VC) (n=240) for 12 weeks.
- Clinical evaluations were performed at weeks 2, 4, 6, 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.

Results

- In study SGT 54-01, patients in the E-BPO Cream, 5% had baseline mean inflammatory lesion counts of 25.7 vs 26.3 of the VC group. The respective values in study SGT 54-002 were 29.8 and 27.5.

Figure 1. Success in IGA at Week 12

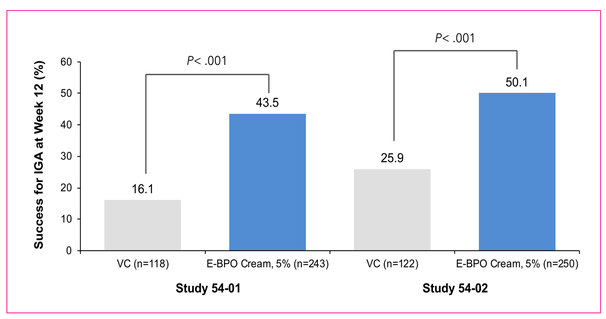
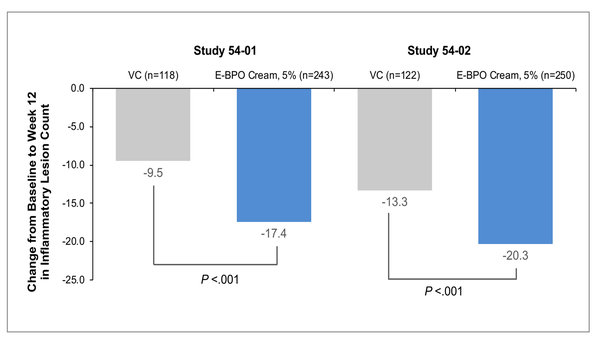


Figure 2. Decline in Lesion Count



IMPROVEMENT OVER TIME

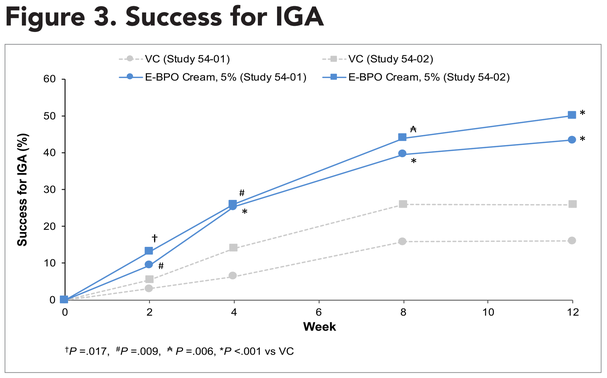
Table 1. Baseline demographic and clinical characteristics.

	Study 54-01		Study 54-02	
	E-PBO Cream, 5% (n=243)	VC (n=118)	E-PBO Cream, 5% (n=250)	VC (n=122)
Age, years				
Mean (SD)	52.8 (13.21)	52.4 (13.26)	49.5 (14.04)	51.5 (12.55)
Median (range)	54.0 (19-81)	52.5 (24-85)	50.0 (18-79)	50 (22-84)
Sex, n (%)				
Male	60 (24.7)	35 (29.7)	69 (27.6)	35 (28.7)
Female	183 (75.3)	83 (70.3)	181 (72.4)	87 (71.3)
Race, n (%)				
Amer. Indian/Alaska Nat.	0	0	0	2 (1.6)
Asian	9 (3.7)	2 (1.7)	20 (8.0)	8 (6.6)
Black/African American	0	0	2 (0.8)	0
Nat. Hawaiian/Pac. Islander	0	0	3 (1.2)	2 (1.6)
White	233 (95.9)	116 (98.3)	220 (88.0)	110 (90.2)
Multiple/Other	1 (0.4)	0	5 (2.0)	0
IGA Severity (%)				
Moderate	210 (86.4)	104 (88.1)	227 (90.8)	112 (91.8)
Severe	33 (13.6)	14 (11.9)	23 (9.2)	10 (8.2)
Lesion Count				
Mean (SD)	25.7 (11.07)	26.3 (12.45)	29.8 (14.00)	27.5 (13.04)
Median (range)	22.0 (15-69)	21.0 (15-70)	25.0 (15-70)	22.5 (15-70)

Nat., Native; Pac. Pacific; SD, standard deviation

- In SGT-54-01, the proportions of patients with moderate or severe IGA at baseline were 86.4% and 13.6%, respectively, for E-BPO Cream, 5%, and 88.1% and 11.9%, respectively, for Vehicle Cream.
- In study SGT 54-02, the respective values were 90.8% and 9.2% for E-BPO Cream, 5%; and 91.8% and 8.2% for Vehicle Cream. E-BPO Cream, 5% demonstrated statistically significant improvement in both co-primary endpoints vs Vehicle Cream at 4 weeks, 8 weeks, and 12 weeks.
- E-BPO Cream, 5% was also significantly superior to Vehicle Cream at 2 weeks and every subsequent evaluation (**Figures 1, 2, and 3**).
- The safety of E-BPO Cream, 5% was comparable to that of VC.
- Adverse events (AEs) were primarily mild to moderate in severity and those reported most frequently were application site erythema and pain.

Figure 3. Success for IGA



- There were no treatment-related serious AEs and 10 subjects (9 E-BPO, Cream 5%, 1 VC) discontinued due to AEs. Prospective patient evaluations also indicated that tolerability of E-BPO Cream, 5% for dryness, scaling, itching, and burning/stinging was at least equivalent to that for VC.

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CONCLUSION

Results from these two randomized, double-blind controlled trials demonstrated significant efficacy, rapid onset of action as early as week 2, and good safety and tolerability for E-BPO Cream, 5%. They strongly support silica microencapsulation for improving the tolerability and potentially also the efficacy of BPO for the treatment of papulopustular rosacea.