INTRODUCTION

In a new microencapsulated formulation (E-BPO Cream, 5%), the drug is entraped in silica microspheres. The extended drug delivery time may improve efficacy and patient retention.

The efficacy, safety, and tolerability of E-BPO Cream, 5% were evaluated in two identical, double-blind, phase 3 trials which demonstrated significant superiority of this formulation compared to vehicle. The percentage of patients who completed the study was 85.7% according to an on-treatment analysis which included those discontinued due to unencapsulated BPO over vehicle for percentage of patients achieving clear or almost clear on the Investigators Global Assessment (IGA) and reducing the number of lesions 2-3 times.

Patients met the following criteria when entering the phase 3 trials:

- 10 patients (1.9%) experienced serious AEs, none of which were considered related.
- The results of the RosaQoL questionnaire showed mean decreases of 11.5 (SD = 17.2, median = 0 days) and 1.16 (SD = 1.16) (p <0.05 for both comparisons).
- The mean time to first retreatment (days) was 125.1 (SD = 99.3, median = 122.5 days) and the mean number of retreatments was 1.16. The respective values for patients with a score of 1 at 120 days were 92.6 days (SD = 72.2, median = 51 days) and 1.66 (SD = 1.50) (p <0.05 for both comparisons).
- The results of the Rosacea Quality of Life Questionnaire clearly showed mean decreases (improvements) from baseline to week 40 in all of the domains assessed.
- Retreatment was initiated at the time of IGA failure, as defined as achievement of clear or almost clear at the week 40 visit.
- All AEs were mild or moderate in severity and were not considered serious.
- The long-term efficacy and safety of E-BPO Cream, 5% were evaluated in two identical, double-blind studies and 66.5% of those who received E-BPO Cream, 5% in the phase 3 trial had no or mild relapse.
- The patients were instructed to apply the product daily.

RESULTS

Patients

- A total of 547 patients were enrolled, including 383 previously treated with E-BPO Cream, 5% and 164 previously treated with vehicle.
- The efficacy, safety, and tolerability assessments rating (itching and burning/stinging) on scales ranging from 0 (none) to 3 (severe).
- IGA success was defined as achievement of clear or almost clear at the week 40 visit.
- The results of the RosaQoL questionnaire showed mean decreases (improvements) from baseline to week 40 in all of the domains assessed.
- For patients with a score of 0 at the beginning of the extension (n=48), there was an increase from baseline to week 40 in the percentage of patients with no or mild erythema (10.1% to 76.2%). The proportion of patients with mild or no telangiectasia at baseline was 56.2% and this increased to 81.0% at week 40.
- The results of the Rosacea Quality of Life Questionnaire clearly showed mean decreases (improvements) from baseline to week 40 in all of the domains assessed.
- Retreatment was initiated at the time of IGA failure, as defined as achievement of clear or almost clear at the week 40 visit.

Methods

- Patients met the following criteria when entering the phase 3 trials:
- The authors gratefully acknowledge the editorial and data analysis contributions of Robert Rhoades, PhD and Thomas Prunty, CMPP of AraMed Strategies whose assistance was

ACKNOWLEDGMENTS

REFERENCES

CONCLUSIONS

The results from this long-term extension of two phase 3 randomized controlled trials demonstrated progressive clinical improvement, as reflected by percentage of patients achieving IGA success and reduction in erythema as well as good cutaneous safety and tolerability with E-BPO Cream, 5% applied for up to 52 weeks in patients with rosacea.