INTRODUCTION

• Calcipotriene and betamethasone dipropionate (50 microgram/g CAL and 0.5 mg/g BDP) cream (CAL/BDP cream) is based on PAD™ Technology enabling development of an easy to apply, aqueous cream of CAL and BDP, despite their known pH-related instability when combined in the presence of water.

• The objective of this subgroup analysis is to present data from a Phase 3 trial conducted in Europe on the efficacy of CAL/BDP cream in scalp psoriasis.

METHODS

• Efficacy and safety of CAL/BDP cream was evaluated in a Phase 3, randomized, multicenter, investigator-blind, parallel-group trial. Patients were instructed to apply the trial medication topically once daily to affected areas for up to 8 weeks.

• Efficacy analyses of scalp psoriasis, included patients with scalp involvement of at least 10% and a Physician’s Global Assessment (PGA) on the scalp of at least mild severity (grade 2).

• The percentage of patients with PGA success on the scalp was defined as a minimum two-grade decrease from Baseline to Week 8 in PGA score of psoriasis severity on the scalp to clear (grade 0) or almost clear (grade 1).

• Statistical analyses of PGA treatment success were based on multiple imputations and a treatment policy strategy on the Full Analysis Set, scalp psoriasis subgroup using a logistic regression model including randomized treatment and analysis site as independent variables.

• PGA treatment satisfaction defined as clear (grade 0) or almost clear (grade 1) disease was analyzed using descriptive statistics based on Observed Cases.

RESULTS

• Efficacy analyses of scalp psoriasis, included patients with scalp involvement of at least 10% and a PGA on the scalp of at least mild severity (grade 2) at baseline (CAL/BDP cream n=112; vehicle n=38; Table 1).

• The PGA treatment success on the scalp was significantly greater for CAL/BDP cream (50.8%) than for vehicle (9.3%) at Week 8 (p=0.0002) with comparable differentiation between the two arms also present at Week 4 (p=0.0051) and Week 6 (Figure 1).

• At Week 1, 17 (15.2%) patients in the CAL/BDP cream group and 0 (0.0%) patients in the vehicle group achieved PGA treatment success on the scalp (Figure 1).

CONCLUSIONS

• The scalp is a common location of involvement of plaque psoriasis and successful management of scalp psoriasis includes topical therapies that are effective and acceptable to the patient.

• CAL/BDP cream is a novel topical treatment for plaque psoriasis based on PAD™ Technology.

• CAL/BDP cream demonstrated high PGA treatment success and satisfaction, fast onset of action and a favourable safety profile in patients with scalp psoriasis.

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