

CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE CREAM DEMONSTRATES HIGH TREATMENT SUCCESS IN PATIENTS WITH SCALP PSORIASIS

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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

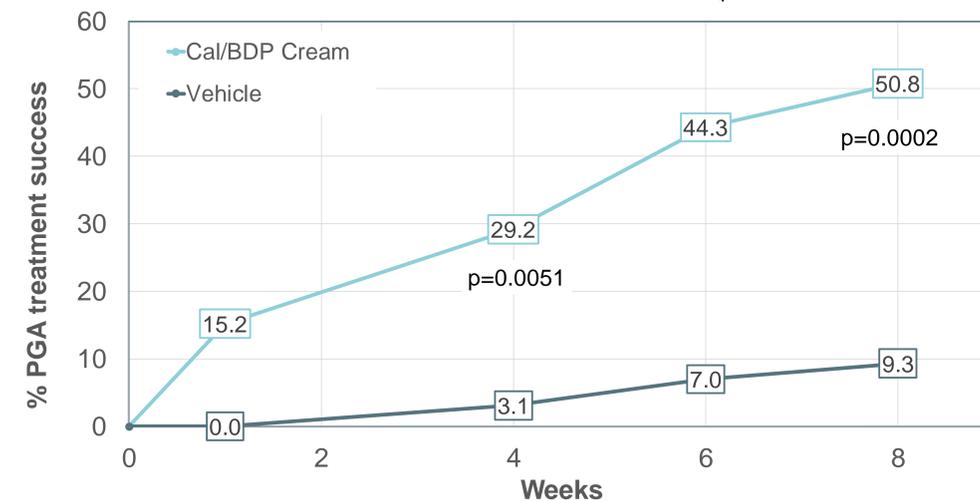
- Efficacy analyses of scalp psoriasis, included patients with scalp involvement of at least 10% and a PGA on the scalp of at least mild severity (grade 2) at baseline (CAL/BDP cream n=112; vehicle n=38; **Table 1**).
- The PGA treatment success on the scalp was significantly greater for CAL/BDP cream (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**).

Table 1. Number of patients and baseline disease

	CAL/BDP Cream	Vehicle
Number of patients in the full analysis set	213	68
Number of patients in the Scalp Analyses	112	38
PGA on the scalp at baseline:		
Mild (PGA grade 2)	55	17
Moderate (PGA grade 3)	53	21
Severe (PGA grade 4)	4	0

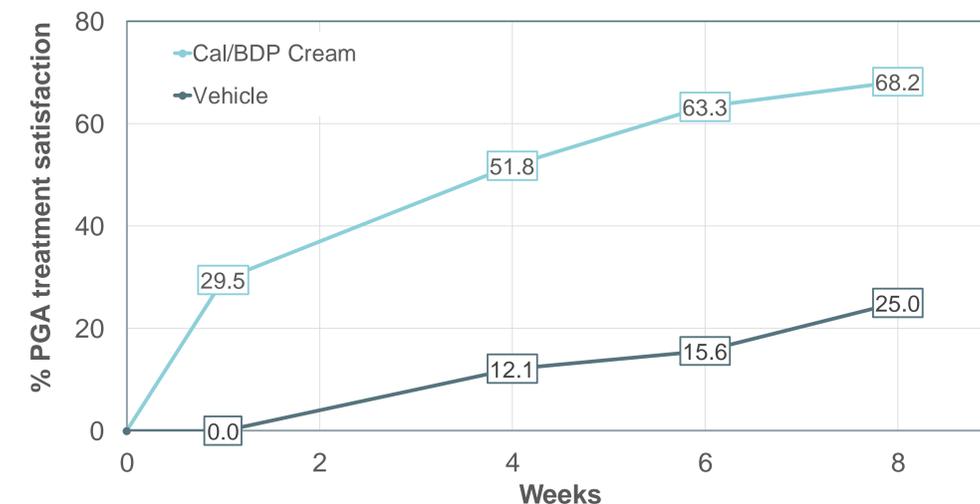
PGA, Physician's Global Assessment. BDP, betamethasone dipropionate; CAL, calcipotriene.

Figure 1. PGA treatment success on the scalp by weeks of treatment



Full analysis set, scalp psoriasis subgroup, Treatment policy strategy, Multiple imputations. P-values represent comparison between CAL/BDP cream and vehicle

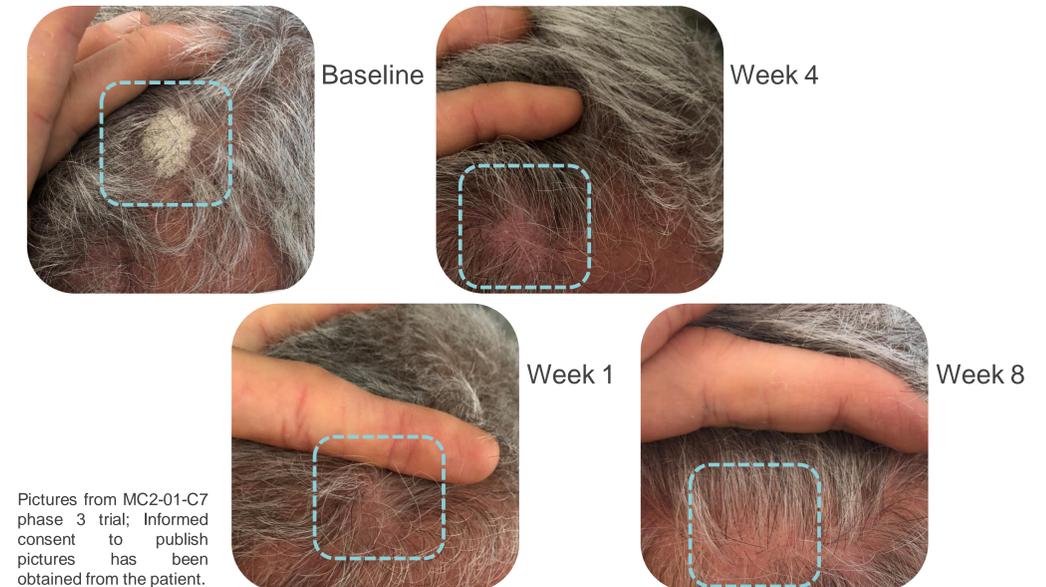
Figure 2. PGA treatment satisfaction on the scalp by weeks of treatment



Full analysis set, scalp psoriasis subgroup, Observed cases.

- 29.5% of patients in the CAL/BDP cream group achieved PGA treatment satisfaction (clear or almost clear) on the scalp already at week 1, increasing to 68.2% at week 8 compared to 25.0% in the vehicle group (**Figure 2**).
- **Figure 3** shows representative examples of patients achieving PGA treatment success on the scalp at Week 1 and clearance at Week 4 after treatment with CAL/BDP cream.
- Overall, safety assessments during the trial demonstrated that CAL/BDP cream was well-tolerated.

Figure 3. Improvement of scalp psoriasis after treatment with CAL/BDP cream



Pictures from MC2-01-C7 phase 3 trial; Informed consent to publish pictures has been obtained from the patient.

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.

ACKNOWLEDGEMENTS

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