

CALCIPOTRIENE (CAL) AND BETAMETHASONE DIPROPIONATE (BDP) CREAM (CAL 0.005%/BDP 0.064% W/W) IMPROVES PLAQUE PSORIASIS AT WEEK ONE IN A PHASE 3 TRIAL

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INTRODUCTION

- Improved adherence to therapy is one of the greatest unmet needs associated with topical psoriasis medication. Early onset of action and convenience are key adherence drivers¹. Scaling and itching are burdensome psoriasis symptoms², and rapidly effective treatment could improve adherence and quality of life.
- Calcipotriene (CAL) and betamethasone dipropionate (BDP) cream is an effective and highly convenient psoriasis treatment made possible by PAD™ Technology.

METHODS

- We compared the onset of action, efficacy and safety of CAL/BDP cream vs vehicle and active comparator CAL/BDP Topical Suspension (TS) in 796 adults with mild to moderate plaque psoriasis (physician global assessment (PGA) 2 or 3) enrolled in a Phase 3, randomized, multicenter, investigator-blind, parallel-group trial (NCT03308799).
- Patients were instructed to apply the trial medication topically to affected areas of the body once daily for up to 8 weeks.
- Statistical analyses were based on an intent-to-treat (ITT) population or modified ITT (including all patients with at least one assessment of PGA after starting treatment). For PGA, mPASI, itch and DLQI multiple imputation for missing data were applied. For PTCS last observation carried forward for missing data were applied. Scaliness was based on observed cases.

RESULTS

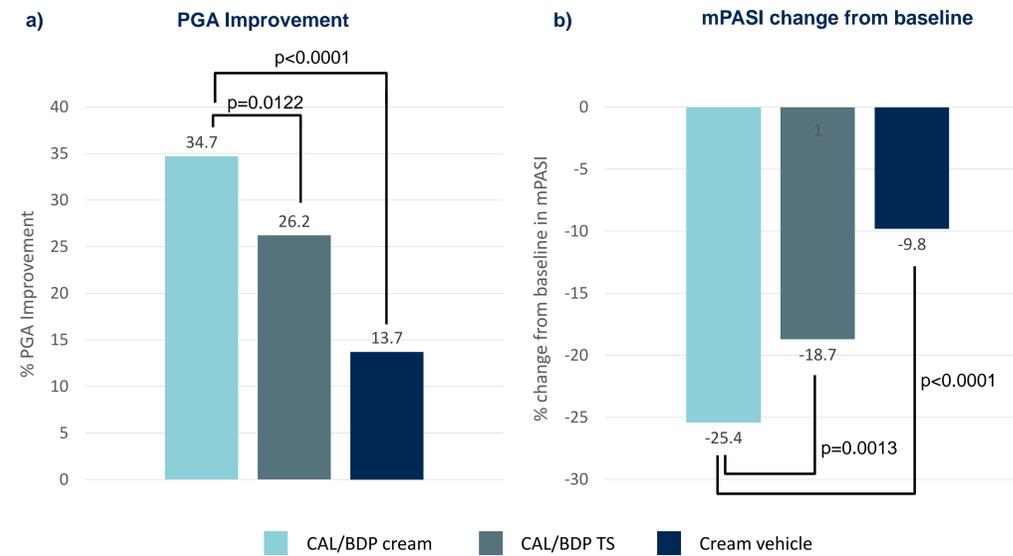
- The patient populations included in this analysis are presented in **Table 1**.
- PGA improved at least 1-grade after one week of treatment in 34.7% of patients with CAL/BDP cream compared to 26.2% in the CAL/BDP TS group (p=0.0122) and 13.7% in the vehicle group (p<0.0001) (**Figure 1a**).
- The mPASI score decreased more in the CAL/BDP group (25.4% change from baseline) after one week of treatment compared to the CAL/BDP TS group (18.7%; p=0.0013) and the vehicle group (9.8%; p<0.0001) (**Figure 1b**).

Table 1. Patient Population

	CAL/BDP Cream	CAL/BDP TS	Cream Vehicle
ITT Population	342	337	115
Modified ITT Population	338	334	112

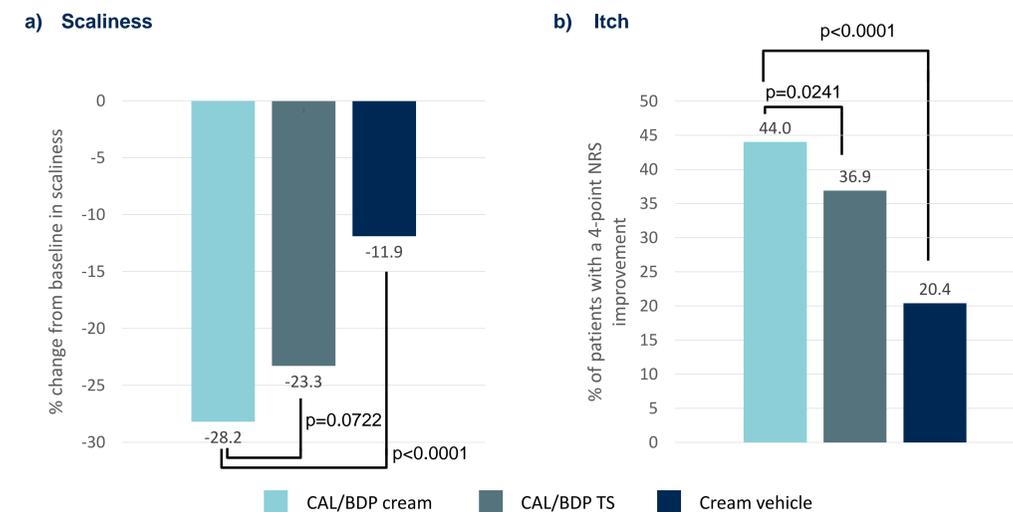
PGA, Physician Global Assessment. mPASI, modified PASI. DLQI, Dermatology Life Quality Index. PTCS, Psoriasis Treatment Convenience Scale. NRS, Numerical Rating Scale. BDP, betamethasone dipropionate; CAL, calcipotriene; TS, Topical Suspension. MITT, modified intent-to-treat population including all patients with at least one PGA assessment after starting treatment.

Figure 1. (a) PGA Improvement and (b) mPASI change from baseline, after one week of treatment



- Improvement of mPASI at week 1 was supported by a reduction in scaliness of 28.2% in patients treated with CAL/BDP cream compared to 23.3% (p=0.0722) in patients treated with CAL/BDP TS and 11.9% in patients treated with vehicle (p<0.0001) (**Figure 2a**).
- Further, a greater proportion of patients (44.0%) treated with CAL/BDP cream achieved at least a 4-point improvement in peak pruritus Numerical Rating Scale (NRS) score during the first week of treatment in comparison to CAL/BDP TS (36.9%; p=0.0241) and vehicle (20.4%; p<0.0001) (**Figure 2b**).

Figure 2. Scaliness (a) and Itch (b) after one week of treatment



- Patients scored the psoriasis treatment convenience of CAL/BDP cream significantly higher than for CAL/BDP TS.
- Finally, more patients in the CAL/BDP cream group (44.8%) achieved a clinically relevant 4-point improvement in Dermatology Life Quality Index (DLQI) at week 1 than with CAL/BDP TS (40.4%; p=0.0476) or vehicle (29.7%) (**Figure 3**).

Figure 3. DLQI Improvement at week 1

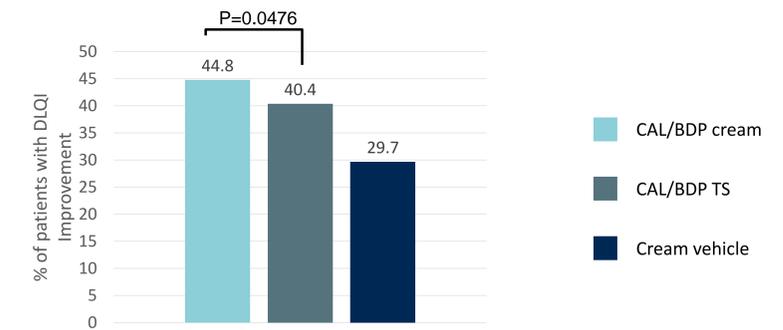
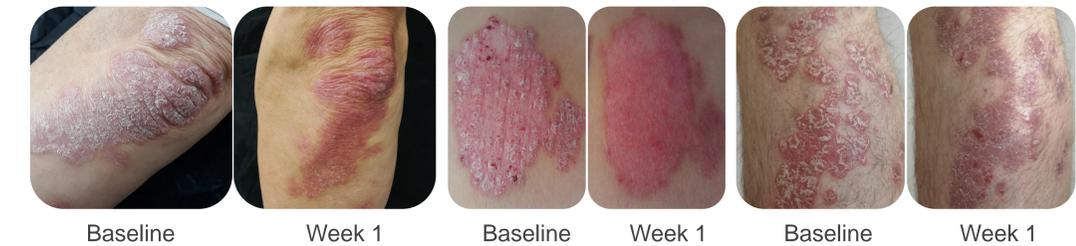


Figure 4. Improvement of plaque psoriasis after one week of treatment with CAL/BDP cream in patients with psoriasis



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

CONCLUSIONS

- CAL/BDP cream is an innovative topical treatment for plaque psoriasis based on PAD™ Technology.
- In this head-to-head trial, CAL/BDP cream demonstrated a faster onset of action than CAL/BDP TS. Rapid improvement of both clinical (PGA and mPASI) and patient reported outcomes (itch, DLQI, and psoriasis treatment convenience) provides potential for CAL/BDP cream to facilitate increased adherence to treatment and better treatment outcomes for patients with psoriasis.

REFERENCES

- Feldman SR. *Cutis*. 2013.
- Korman et al., *Clin Exp Dermatol*. 2016.

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