TREATMENT OF PSORIASIS WITH CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE (CAL/BDP) CREAM SHOWED SIGNIFICANTLY HIGHER PROPORTION OF PATIENTS WITH AN ABSOLUTE mPASI ≤2 COMPARED TO CAL/BDP GEL/TOPICAL SUSPENSION IN A POST-HOC ANALYSIS OF TWO PHASE 3 STUDIES

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INTRODUCTION

- Calcipotriene (50 µg/g) and betamethasone dipropionate (0.5 mg/g) (CAL/BDP) is an effective combined treatment for plaque psoriasis, and it has recently become available in an aqueous cream based on PAD Technology™ 1.
- An absolute PASI≤2 has been shown to represent a meaningful clinical and health-related quality of life improvement, and a relevant alternative to relative PASI response for determining treatment success[2-4].

OBJECTIVE

- In this pooled post-hoc analysis we analysed achievement of an absolute mPASI ≤5 or ≤2 of CAL/BDP PAD-cream compared to an active comparator and to vehicle to better evaluate efficacy compared to relative improvement.

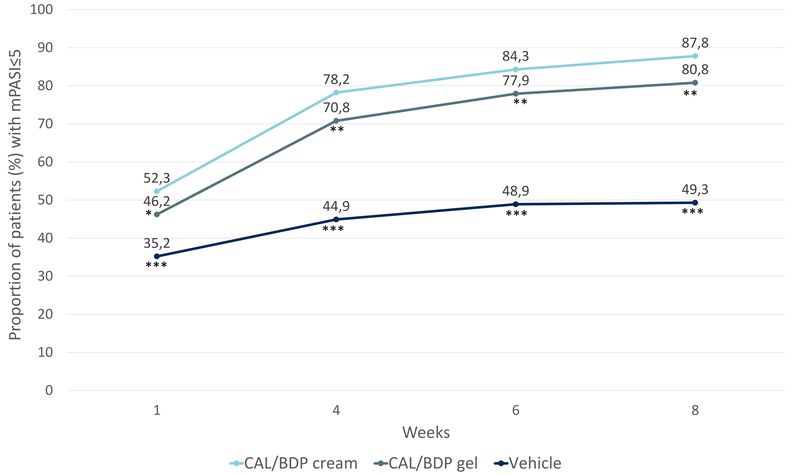
METHODS

- CAL/BDP cream was evaluated in two head-to-head, Phase 3, randomized, multicenter, investigator-blind, parallel-group trials (NCT03308799 and NCT03802344)[5,6] comparing the efficacy of CAL/BDP PAD-cream with CAL/BDP gel/topical suspension (TS) and PAD-cream vehicle.
- Adult patients with mild-moderate psoriasis according to the Physician Global Assessment (PGA) were enrolled and applied trial medication once daily for up to 8 weeks.
- The statistical analysis of the pooled phase 3 data presented herein was performed as a post-hoc analysis based on a modified intention-to-treat population (incl. all patients with at least one assessment of PGA after starting treatment) using multiple imputation.

RESULTS

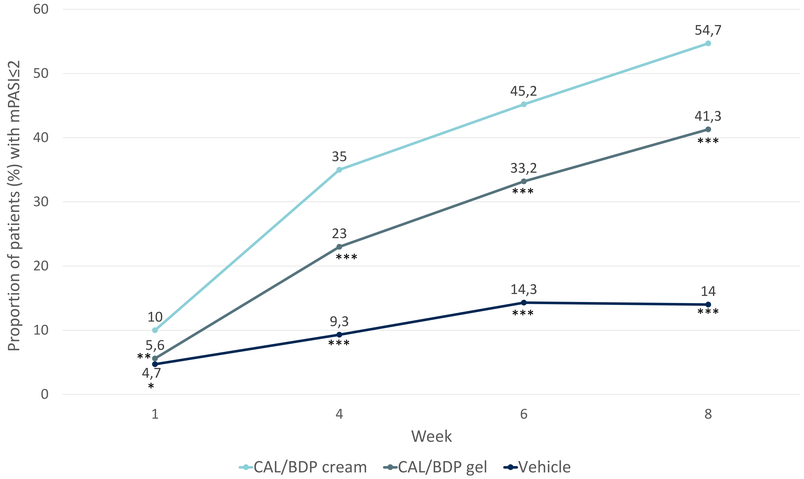
- 1271 patients were included in this analysis; 551 patients in the CAL/BDP PAD-cream group, 542 patients in the CAL/BDP gel/TS group and 178 patients in the vehicle group.

Figure 1. Proportion of patients with mPASI ≤ 5



P-values represent comparison between CAL/BDP PAD-cream and CAL/BDP gel/TS as well as between CAL/BDP PAD-cream and vehicle: * p<0.05, ** p<0.01, *** p<0.0001

Figure 2. Proportion of patients with mPASI ≤ 2



P-values represent comparison between CAL/BDP PAD-cream and CAL/BDP gel/TS as well as between CAL/BDP PAD-cream and vehicle: * p<0.05, ** p<0.01, *** p<0.0001

- At Week 8, the proportion of patients achieving a mPASI≤5 was significantly higher for the CAL/BDP PAD-cream group (87.8%) compared to the PAD-cream vehicle group (49.3%, p<0.0001) and the CAL/BDP gel/TS group (80.8%; p=0.0020). At Week 1, 4, and 6 there were also significant differences between CAL/BDP PAD-cream and CAL/BDP gel/TS (p=0.0416, p=0.0062 and p=0.0082 respectively) **(Figure 1)**.
- The proportion of patients achieving an mPASI≤2 was significantly higher for CAL/BDP PAD-cream (54.7%) compared to PAD-cream vehicle (14%; p<0.0001), and CAL/BDP TS/gel (41.3%; p<0.0001) at Week 8. The difference between CAL/BDP PAD-cream and CAL/BDP gel/TS was also significant at Week 1 (p=0.0069), 4 (p<0.0001) and 6 (p<0.0001) **(Figure 2)**.

CONCLUSIONS

- CAL/BDP PAD-cream is an effective and convenient psoriasis treatment based on PAD Technology™ 1.
- In this post-hoc analysis of pooled phase 3 data, treatment with CAL/BDP PAD-cream showed significantly higher proportion of patients with an absolute mPASI ≤5 and ≤2 already at Week 1 and throughout to Week 8 compared to treatment with CAL/BDP gel/TS.

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ABBREVIATIONS

PGA, Physician Global Assessment; mPASI, modified PASI; BDP, betamethasone dipropionate; CAL, calcipotriene; TS, topical suspension; PAD, Polyaphron Dispersion