

CALCIPOTRIENE (CAL) AND BETAMETHASONE DIPROPIONATE (BDP) CREAM DEMONSTRATES HIGH EFFICACY AND CONVENIENCE IN SKIN OF COLOR PATIENTS WITH PLAQUE PSORIASIS

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INTRODUCTION

- Investigating the safety and efficacy of psoriasis therapies in diverse populations is important, given the potential for pharmacogenomic differences that may influence treatment outcomes. Skin type, racial/ethnic, genetic and socioeconomic factors, are potential considerations when making treatment choices.
- CAL/BDP (CAL 0.005%/BDP 0.064% w/w) is an effective medication for psoriasis and is now available in an aqueous cream made possible by PAD™ Technology. Here we describe the efficacy and convenience of CAL/BDP cream in skin of color patients with plaque psoriasis.

METHODS

- Patients with mild to moderate plaque psoriasis were enrolled in a Phase 3, randomized, multicenter, investigator-blind, parallel-group trial (NCT03308799) comparing CAL/BDP cream to CAL/BDP topical suspension (TS) and cream vehicle.
- Patients were instructed to apply the trial medication topically to affected areas of the body once daily for up to 8 weeks.
- Physician Global Assessment (PGA) treatment success (2-grade improvement and clear or almost clear) was the primary endpoint.
- In this subgroup analysis, we describe the efficacy and convenience of CAL/BDP cream in skin of color patients (Fitzpatrick skin type classification IV-VI and African American) compared to the total study population.
- Statistical analyses were based on a modified intent-to-treat (MITT) population (including all patients with at least one assessment of PGA after starting treatment).

RESULTS

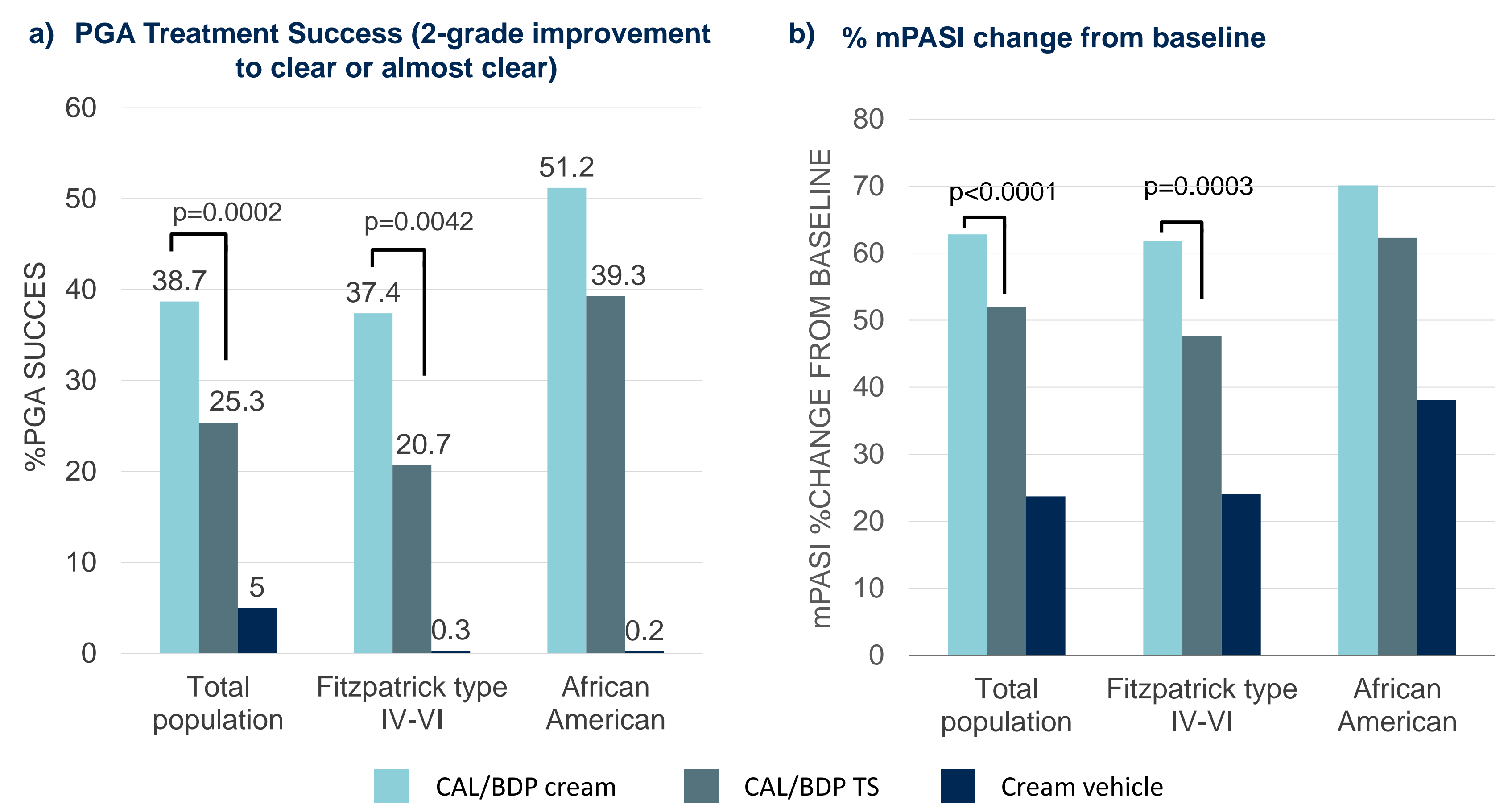
- Of the 784 participants in the study, 280 were categorized as Fitzpatrick skin type IV-VI and 64 patients were African American. The patient populations included in this subgroup analysis are presented in **Table 1**.

Table 1. Patient Populations

	CAL/BDP Cream	CAL/BDP TS	Cream Vehicle
Total Population (MITT)	338	334	112
Fitzpatrick skin type IV-VI	129	114	37
African American	34	20	10

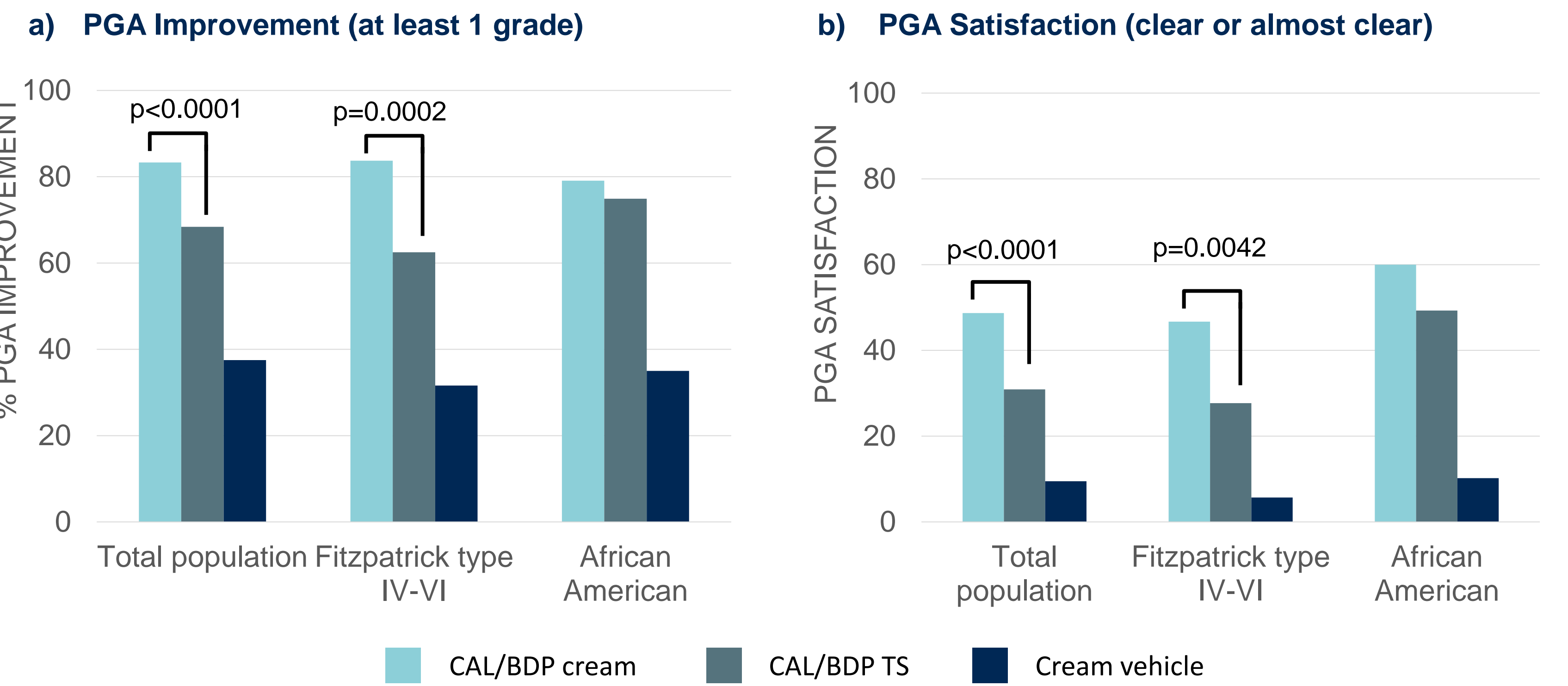
PGA, Physician Global Assessment. mPASI, modified PASI. PTCS, Psoriasis Treatment Convenience Scale. BDP, betamethasone dipropionate; CAL, calcipotriene; TS, Topical Suspension. MITT, modified intent-to-treat population including all patients with at least one PGA assessment after starting treatment.

Figure 1. PGA Success (a) and % mPASI change from baseline (b) after 8 weeks of treatment



- The proportion of patients (37.4%) in the Fitzpatrick type IV-VI group achieving PGA success after 8 weeks of treatment with CAL/BDP cream was similar to the total population (38.7%) and significantly different from CAL/BDP TS (p=0.0042) and cream vehicle (p=0.0013). PGA success was seen in 51.2% of African American patients (**Figure 1a**).
- The change from baseline in mPASI after 8 weeks of treatment with CAL/BDP cream was 61.8% in the Fitzpatrick type IV-VI group, 70.1% in the African American group and 62.9% in the total population (**Figure 1b**).

Figure 2. PGA Improvement (a) and PGA Satisfaction (b) after 8 weeks of treatment



- PGA Improvement of at least 1 grade was seen after 8 weeks of treatment with CAL/BDP cream in 83.7% of patients in the Fitzpatrick type IV-VI group, in 79.1% of African American patients and 83.3% of the total trial population (**Figure 2a**).
- At 8 weeks of treatment with CAL/BDP cream, 46.7% in the Fitzpatrick type IV-VI group, 60.0% of the African American patients and 48.7% of the total population achieved PGA Satisfaction (clear or almost clear) (**Figure 2b**).
- Measured by the Psoriasis Treatment Convenience Scale (PTCS)¹, patients scored the treatment convenience of CAL/BDP cream significantly higher than CAL/BDP TS in the total population, the African American and the Fitzpatrick type IV-VI groups. Skin of color patients scored most of the individual PTCS questions higher, including greater overall satisfaction, than patients in the total trial population (**Figure 3**).

Figure 3. PTCS scores (a high score indicates a positive response for all questions)

#	Question	Total population		Fitzpatrick IV-VI		African American	
		Cream	TS	Cream	TS	Cream	TS
1	How easy was the treatment to apply to the skin?	9.4	9.1	9.5	9.2	9.7	9.1
2	How greasy was the treatment when applying it to the skin?	7.5	6.0	7.9	5.9	7.8	5.4
3	How moisturized did your skin feel after applying the treatment?	8.1	7.7	8.2	7.6	8.9	8.1
4	How greasy did your skin feel after applying the treatment?	7.5	6.1	7.6	5.8	8.1	5.7
5	How much did treating your skin disrupt your daily routine?	9.0	8.7	8.9	8.7	9.0	8.6
6	Overall, how satisfied were you with the medical treatment?	8.9	8.0	9.0	7.7	9.2	8.6

CONCLUSIONS

- CAL/BDP cream is an innovative topical treatment for plaque psoriasis based on PAD™ Technology.
- This subgroup analysis shows that skin of color patients treated with CAL/BDP cream have similar efficacy to the total trial population.
- Patient convenience and satisfaction for CAL/BDP cream were scored similarly or higher in patients with skin of color than in the total trial population and compared to CAL/BDP TS.

REFERENCES

¹Feldman SR, Præstegaard M, Andreassen AH, Selmer J, Holm-Larsen T. Validation of the Self-Reported Psoriasis Treatment Convenience Scale (PTCS). *Dermatol Ther (Heidelb)*. 2021 Dec;11(6):2077-2088.

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