

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™ Technology¹. 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.²
- 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 post-hoc subgroup analysis, we describe the efficacy and convenience of CAL/BDP cream in skin of color patients (Fitzpatrick skin type classification IV-VI and “Black or 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 “Black or African American”. The patient populations included in this subgroup analysis are presented in **Table 1**. The number of participants who self-identified as “Black or African American” was limited and the distribution was not balanced between the treatment groups; therefore, the results from this subgroup are not presented in the graphs.

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.

Table 1

Patient Populations in Subgroup Analysis				
	CAL/BDP Cream	CAL/BDP TS	Cream Vehicle	Total
Total Population (mITT)	338 (43.1%)	334 (42.6%)	112 (14.3%)	784
Total Population, Safety Set	342 (43.1%)	337 (42.4%)	115 (14.5%)	794
Fitzpatrick skin type IV-VI (mITT)	129 (16.5%)	114 (14.5%)	37 (4.7%)	280 (35.7%)
Fitzpatrick skin type IV-VI, Safety Set	131 (16.5%)	116 (14.6%)	39 (4.9%)	286 (36.0%)
Black or African American (mITT)	34 (4.3%)	20 (2.6%)	10 (1.3%)	64 (8.2%)

Figure 1. (a) Type IV-VI group achieved more PGA success after 8 weeks of treatment with CAL/BDP cream than CAL/BDP TS group or cream vehicle group (b) Change from baseline in mPASI after 8 weeks of treatment with CAL/BDP cream was 61.8% in the Type IV-VI group similar to the total population

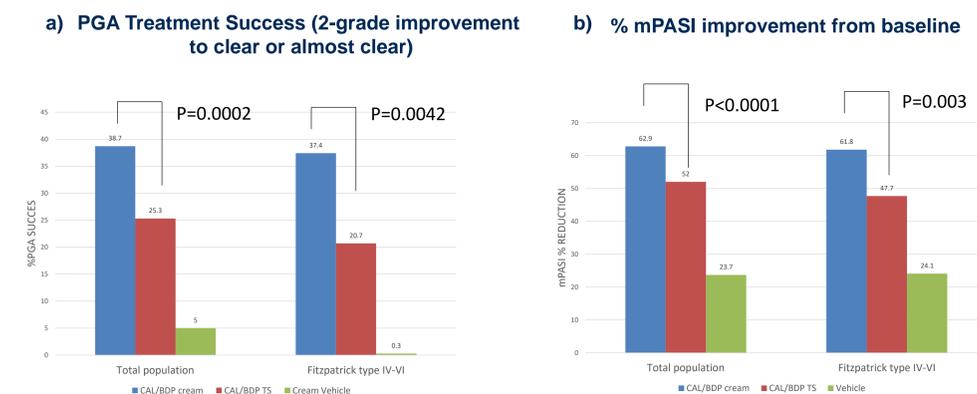


Figure 2. PGA improvement of at least 1 grade and PGA 0 (clear) or 1 (almost clear) showed similar trends with PGA success

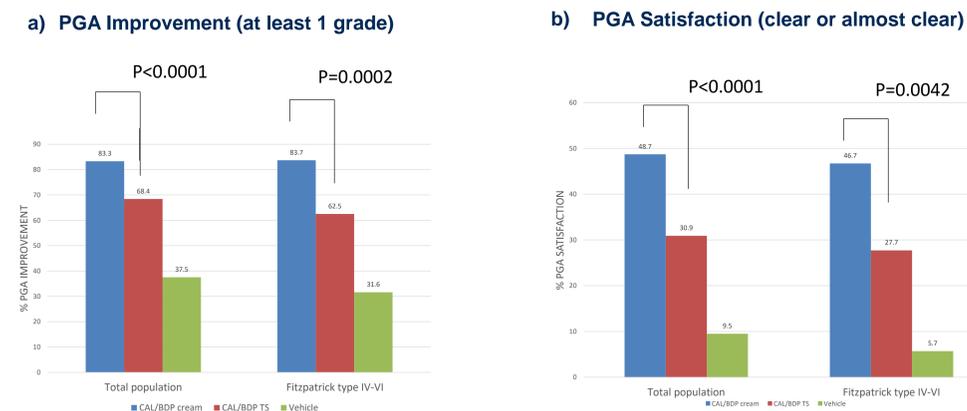


Table 2. Psoriasis Treatment Convenience Scale (PTCS)² was significantly higher in CAL/BDP cream than CAL/BDP TS in the total population and the Fitzpatrick type IV-VI groups.

Question	Total population		Fitzpatrick IV-VI		Black or 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
Total Score (mITT, LOCF)	41.5	37.5 (p<0.0001)	41.8	36.9 (p<0.0001)	43.5	36.9
6 Overall, how satisfied were you with the medical treatment	8.9	8.0	9.0	7.7	9.2	8.6

• “Black or African American” patients scored higher in most of the individual scores than the total population, but the results should be interpreted cautiously due to the limited population size (see Table 1).

Table 3. Skin of Color Patients Demonstrated Similar AE Profile to the Total Population

	CAL/BDP cream	CAL/BDP TS	Cream vehicle
Total Population: Subjects with any TEAE, n (%)	90 (26.3)	76 (22.6)	32 (27.8)
Fitzpatrick skin type IV-VI: Subjects with any TEAE, n (%)	36 (27.5)	28 (24.1)	6 (15.4)
Total Population: Subjects with any treatment-related TEAE, n (%)	12 (3.5)	11 (3.3)	5 (4.3)
Fitzpatrick skin type IV-VI: Subjects with any treatment-related TEAE, n (%)	4 (3.1)	4 (3.4)	0 (0.0)

CONCLUSIONS

- This post hoc 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.
- A limitation of the study is the number of African American patients is too small for statistical or descriptive comparison.

REFERENCES

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