Treatment with fixed combination calcipotriol 50 µg/g and betamethasone dipropionate 0.5 mg/g foam provides rapid and significant itch relief in patients with psoriasis

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Introduction

- A foam formulation of fixed combination calcipotriol 50 µg/g (Cal) and betamethasone 0.5 mg/g (as dipropionate; BD) has been developed as a treatment option for patients with psoriasis[1]
- The Phase III PSO-FAST (Cal/BD foam in PSOriasis vulgaris, a Four-week, vehicle-controlled, efficacy And Safety Trial) study demonstrated that Cal/BD foam provides significantly greater efficacy than vehicle in patients with psoriasis[2]
- Itch is a common and distressing aspect of psoriasis that negatively impacts on a patient's quality of life, causing discomfort, potentially aggravating the lesion, and often leading to sleep loss[3,4]
- In this sub-analysis of the PSO-FAST study we assessed changes in itch during treatment with Cal/BD foam, in patients who had clinically relevant itch at baseline (defined as visual analogue scale [VAS] score of >30)[5]

Methods

STUDY DESIGN AND PATIENTS

- PSO-FAST was a Phase III, multicentre, double-blind, randomized study conducted at 27 sites in the United States (NCT01866163)[2]
- Patients were randomized (3:1) to Cal/BD foam or foam vehicle once daily for up to 4 weeks
- Patient eligibility: aged ≥18 years; at least mild psoriasis, according to the Physician's Global Assessment of disease severity; modified Psoriasis Area and Severity Index (mPASI) score of ≥2; and, 2–30% body surface area (BSA; trunk and/or limbs) affected by psoriasis

ITCH ASSESSMENT

- Itch was evaluated based on a VAS (range 0–100 mm, where 0 is no itch and 100 mm is the worst itch imaginable)
- Patients assessed maximal itch intensity over the 24-hour period prior to days 3 and 5, and at weeks 1, 2, and 4 using a subject diary

STATISTICAL ANALYSIS

- Patients included in this sub-analysis were those with a baseline itch VAS score >30, ie, of clinical relevance[5]
- Change in VAS scores from baseline for Cal/BD and vehicle foam treatment groups were compared using analysis of variance (ANOVA), adjusting for baseline score and pooled centres
- The proportion of patients achieving a 70% reduction in itch were compared between treatment groups using the Mantel-Haenszel method, adjusting for pooled centres

Results

PATIENTS

- In total, 323 patients were randomized to Cal/BD foam, and 103 to vehicle
  - Of these, 225/323 (70%) patients in the Cal/BD foam treatment group, and 75/103 (73%) patients in the vehicle group had a baseline itch VAS score of >30
- Among patients with baseline itch VAS score of >30, mean (±SD) baseline score was 66.1 ± 19.9 in the Cal/BD foam group and 69.9 ± 18.1 in the vehicle group
- Treatment groups were generally well balanced in terms of demographic and baseline factors, although the gender balance was different between Cal/BD foam and vehicle (Table 1)

Table 1. Baseline demographic and clinical characteristics of patients with baseline itch score >30

	Cal/BD foam (n=225)	Vehicle (n=75)
Age, years	50.6 (14.0)	45.6 (12.9)
Male:Female, n (%)	132:93 (59:41)	28:47 (37:63)
Race, n (%)		
White	194 (86.2)	65 (86.7)
Duration of psoriasis, years	15.1 (13.5)	15.0 (11.1)
BSA affected, %	8.1 (7.0)	8.3 (6.8)
PGA, n (%)		
Mild	29 (12.9)	11 (14.7)
Moderate	174 (77.3)	53 (70.7)
Severe	22 (9.8)	11 (14.7)
mPASI score	7.8 (5.0)	8.4 (7.3)

Data are shown as mean (standard deviation [SD]), unless otherwise stated

ASSESSMENT OF ITCH

- Patients receiving Cal/BD foam reported significant and rapid reduction in itch relief compared with patients receiving vehicle
  - Itch relief was observed by day 3 and continued to improve during the 4-week study (Figure 1; Table 2)
- Significant treatment differences were noted at the first assessment on day 3 (P=0.019) and were maintained at all subsequent time points throughout treatment (Figure 1; Table 2)

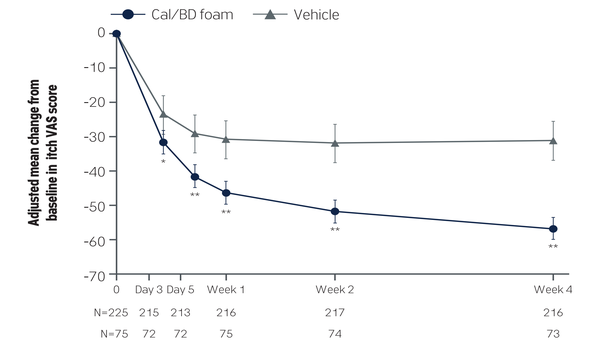

Figure 1. Adjusted mean change in itch VAS scores over 4 weeks in patients with baseline itch score >30 (observed cases)

Bars represent 95% confidence intervals (CI);
*P=0.019; **P<0.001 Cal/BD foam vs vehicle

Table 2. Adjusted mean itch VAS scores during treatment in patients with baseline itch score >30

	Cal/BD foam, mean change	Vehicle, mean change	Mean difference (95% CI)	*P* value
Day 3	−31.4	−23.5	−7.86 (−14.41, −1.30)	0.019
Day 5	−41.4	−29.1	−12.25 (−18.65, −5.85)	<0.001
Week 1	−46.2	−30.8	−15.42 (−21.82, −9.01)	<0.001
Week 2	−51.7	−31.9	−19.82 (−26.16, −13.47)	<0.001
Week 4	−56.7	−31.1	−25.60 (−31.96, −19.25)	<0.001

CI, confidence interval

- At week 4, 84.7% of patients using Cal/BD foam achieved a 70% reduction in their itch (Figure 2)
  - This was statistically significantly greater than vehicle (39.7%; OR 7.6; 95% CI 4.2, 14.0; P<0.001)

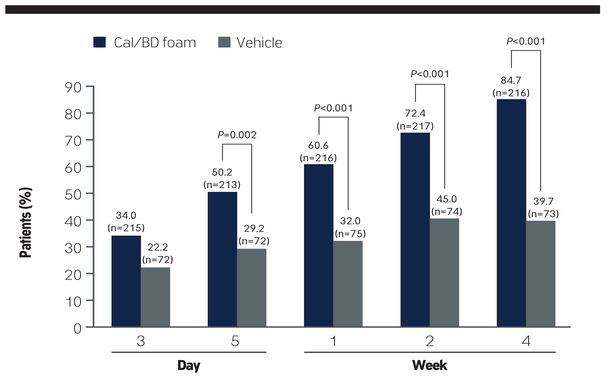

Figure 2. Proportion of patients with baseline itch score >30 achieving a 70% reduction in itch by visit (observed cases)

Conclusions

- **Itch is considered one of the most distressing symptoms of psoriasis, but current treatment options are limited[4]**
- **This analysis of patients with psoriasis who had clinically relevant itch at baseline demonstrates that Cal/BD foam leads to rapid and significant relief of itch, which continues to improve throughout treatment**
- **These findings expand on the primary efficacy results of the PSO-FAST study, showing that Cal/BD foam is highly efficacious and well tolerated in patients with psoriasis[2,6-9]**

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