

Treatment Success in Mild Psoriasis Patients With Fixed-Combination Calcipotriene and Betamethasone Dipropionate (Cal/BD) Foam: Results From the PSO-FAST Trial

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Introduction

- Psoriasis is a chronic skin disease affecting approximately 2% of the worldwide population characterized by sharply demarcated, scaling, and erythematous plaques that may be painful and often severely pruritic¹
- While topical therapy is the regimen of choice for patients with less extensive disease,² very few of these therapies have been demonstrated effective for mild psoriasis
 - Treatment success in this population requires that visible disease be completely cleared (i.e., improvement of Investigator's Global Assessment (IGA) score from 2 to 0)
- Corticosteroids and vitamin D analogues are among the most common treatments that are either used alone or in combination^{2,3}
- Topical, fixed-combination calcipotriene (50 µg/g) plus betamethasone dipropionate (0.5 mg/g; Cal/BD) cutaneous foam is indicated for the treatment of plaque psoriasis in patients 12 years and older⁴
 - In a Phase III, double-blind, randomized study that included patients with all severities of psoriasis (PSO-FAST), Cal/BD foam was efficacious and well tolerated, and also provided rapid treatment responses with significant itch relief³

Objective

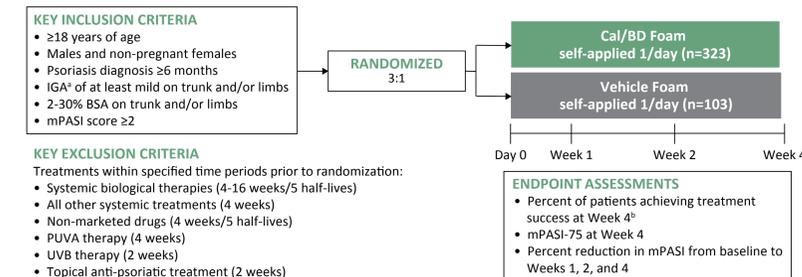
- To compare the efficacy of treatment with Cal/BD foam to that of treatment with vehicle for up to 4 weeks in patients with mild psoriasis vulgaris by performing a post hoc analysis of the PSO-FAST trial

Materials and Methods

Study Design

- PSO-FAST was a Phase III, randomized, multicenter (US), double-blind, vehicle-controlled, 4-week study (NCT01866163)
- 426 patients were randomized (3:1) to Cal/BD foam or foam vehicle once daily for up to 4 weeks

Figure 1. Study Design



^aInvestigator's Global Assessment (IGA) of disease severity was scored on a 5-point scale: 0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe. ^bTreatment success for patients with mild disease severity at baseline was defined as clear (IGA=0).

Results

Patient Population

- At baseline, 65/426 patients had mild plaque psoriasis
- Baseline demographics and disease characteristics are shown in **Table 1**
- Overall, treatment groups were well balanced for patient characteristics and baseline demographics within this subpopulation
- Both mean BSA and mean mPASI at baseline were comparable between groups

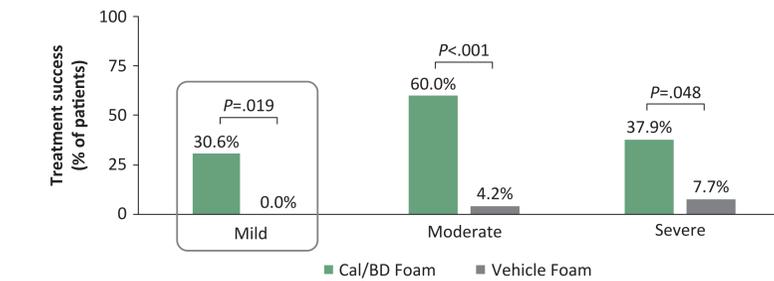
Table 1. Baseline Demographics and Disease Characteristics for Randomized Patients With Mild Psoriasis (IGA=2)

| Baseline Characteristic | Cal/BD Foam (n=50) | Vehicle Foam (n=15) | Overall (N=65) |
|-----------------------------|--------------------|---------------------|----------------|
| Mean Age, years | 48.6 | 42.2 | 47.2 |
| Median Age, years (range) | 52.5 (19-79) | 38.0 (20-74) | 50.0 (19-79) |
| Male, % | 56.0 | 46.7 | 53.8 |
| Fitzpatrick Skin Type, % | | | |
| Type I | 2.0 | 0.0 | 1.5 |
| Type II | 42.0 | 20.0 | 36.9 |
| Type III | 26.0 | 40.0 | 29.2 |
| Type IV | 18.0 | 20.0 | 18.5 |
| Type V | 6.0 | 20.0 | 9.2 |
| Type VI | 6.0 | 0.0 | 4.6 |
| Mean BMI, kg/m ² | 31.5 | 31.5 | 31.5 |
| Mean PSO Duration, years | 16.0 | 9.1 | 14.4 |
| Mean BSA, % (SD) | 4.5 (2.6) | 5.7 (4.2) | 4.8 (3.1) |
| Mean mPASI (range) | 4.7 (2-16) | 5.0 (2-8) | 4.7 (2-16) |

Efficacy: IGA Treatment Success

- At Week 4, significantly more patients with mild psoriasis achieved treatment success with Cal/BD foam than foam vehicle (30.6% vs 0.0%, $P<.001$) (**Figure 2**)
 - Treatment success was observed as early as Week 2 with Cal/BD foam vs vehicle (8.2% vs 0%) (data not shown)

Figure 2. IGA Treatment Success at Week 4 for Patients With Mild, Moderate, or Severe Psoriasis at Baseline

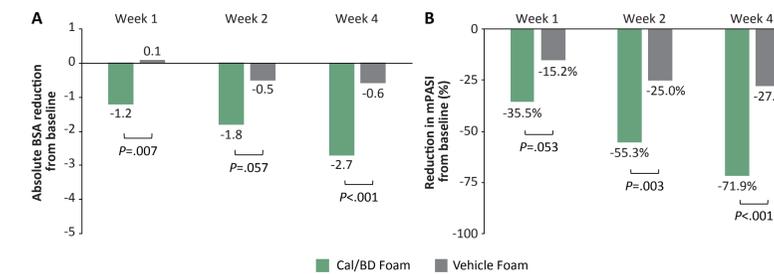


Mantel-Haenszel odds of treatment success in Cal/BD group relative to vehicle group.

Efficacy: Severity Outcomes

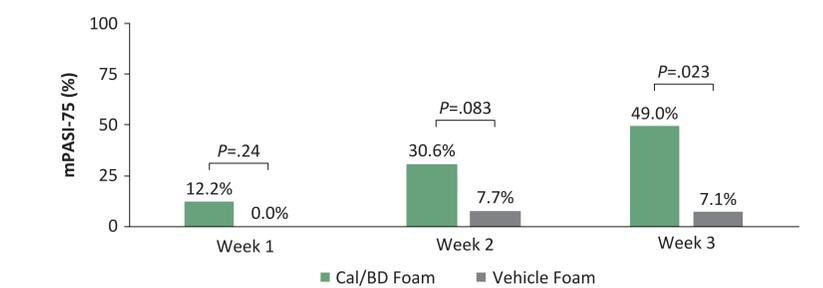
- Mild patients achieved significantly greater reductions in BSA (**Figure 3A**) and mPASI scores (**Figure 3B**) relative to baseline with Cal/BD foam vs vehicle foam
 - The significant improvements were seen as early as Week 1 and persisted to Week 4
- mPASI-75 was significantly greater with Cal/BD foam vs vehicle foam (49% vs 7.1%, $P=.023$) at Week 4 (**Figure 4**).

Figure 3. Psoriasis Severity Outcomes for Patients With Mild PSO at Baseline



A, Absolute Reduction in BSA From Baseline to Weeks 1, 2, and 4. B, Percent Reduction in mPASI From Baseline to Weeks 1, 2, and 4.

Figure 4. mPASI-75 for Patients With Mild Disease Severity at Baseline



Mantel-Haenszel odds of treatment success in Cal/BD group relative to vehicle group, adjusted for pooled center.

Conclusions

- In this post hoc analysis, once-daily fixed-dose combination Cal/BD foam was efficacious in treating mild plaque psoriasis
 - Importantly, while numerous other topical and systemic therapies are available for psoriasis, very few have demonstrated efficacy in this subpopulation
- These important results establish treatment success for Cal/BD foam in mild psoriasis, a population in which efficacy is difficult to demonstrate since the treatment must completely clear visible disease to be considered effective
- The once-daily, Cal/BD foam may provide a valuable treatment option for patients with mild plaque psoriasis

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Disclosures

Drs. KA Veverka, JB Hansen and M Yaloumis are employees of LEO Pharma Inc. Dr. Kircik has served as a research investigator, speaker, and consultant for LEO Pharma, Inc. Dr. L Stein Gold serves as a consultant, speaker, advisory board participant, or investigator for LEO Pharma inc., Taro Pharmaceutical Industries Ltd., and Mayne Pharma.

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Abbreviations

BMI, body mass index; BSA, body surface area; Cal/BD, calcipotriene/betamethasone dipropionate; IGA, Investigator's Global Assessment; mPASI, modified (excluding head) psoriasis area and severity index; mPASI-75, 75% reduction in the mPASI; PSO, psoriasis; PUVA, psoralen combined with Ultraviolet A; SD, standard deviation; UVB, Ultraviolet B.

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