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 pruritic.1
- While topical therapy is the regimen of choice for patients with less extensive disease,1,3 very few of these therapies have been demonstrated effective for mild psoriasis. – Treatment in this population requires that visible disease be completely cleared (i.e., improvement of Investigator’s Global Assessment (IGA) score from 2 to 0.5).3
- Corticosteroids and vitamin D analogues are among the most common treatments that are either used alone or in combination.1,3
- Topical, fixed-combination calcipotriene (0.5 µg/g) plus betamethasone dipropionate (0.05 mg/g; Cal/BD) cutaneous foam is indicated for the treatment of plaque psoriasis in patients 12 years and older.2
- In a Phase II, 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 relief.2

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

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 disease severities within this population.
- Both mean BSA and mean mPASI at baseline were comparable between groups.

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 1 with Cal/BD foam vs foam vehicle (8.2% vs 0.0% data not shown)

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 foam vehicle:
- 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 foam vehicle (48% vs 7.1%, P<.023) at Week 4 (Figure 4).

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 population.
- 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.

References

Disclosures
- Dr. Veverka, Dr. Hansen, and Dr. Yaloumis are employees of LEO Pharma Inc. Dr. Gold has served as a research investigator, consultant, and symposium speaker for LEO Pharma Inc., and has served as a consultant for Janssen Scientific Communications, LLC, and Cenkos Pharma.

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Abbreviations
BSA, body surface area; BQD, body surface area; mPASI, Minimal Psoriasis Area Severity Index; D, data on file; E, efficacy; I, incidence; mPASI, minimal psoriasis area severity index; P, p value; SD, standard deviation; S, safety; SD, standard deviation; T, treatment; U, unblinded; V, vehicle.