DFD-01, a betamethasone dipropionate 0.05% spray, improved quality of life and treatment satisfaction in subjects with moderate psoriasis

Joseph Fowler, MD[1]; Kent Allenby, MD[2]; Srinivas Sidgiddi, MD[2]
[1]Dermatology Specialists Research, Louisville, KY; [2]Promius Pharma, a subsidiary of Dr. Reddy's Laboratories, Princeton, NJ

Introduction

- DFD-01 [Sernivo™ (betamethasone dipropionate) Spray, 0.05%] is a spray formulation approved for the treatment of mild to moderate plaque psoriasis in adults.
- The efficacy and tolerability of DFD-01 have been demonstrated in subjects with extensive, moderate plaque psoriasis (10% to 20% body surface area [BSA]).
- This study assessed quality of life (QoL) and treatment satisfaction ratings of subjects with moderate plaque psoriasis.

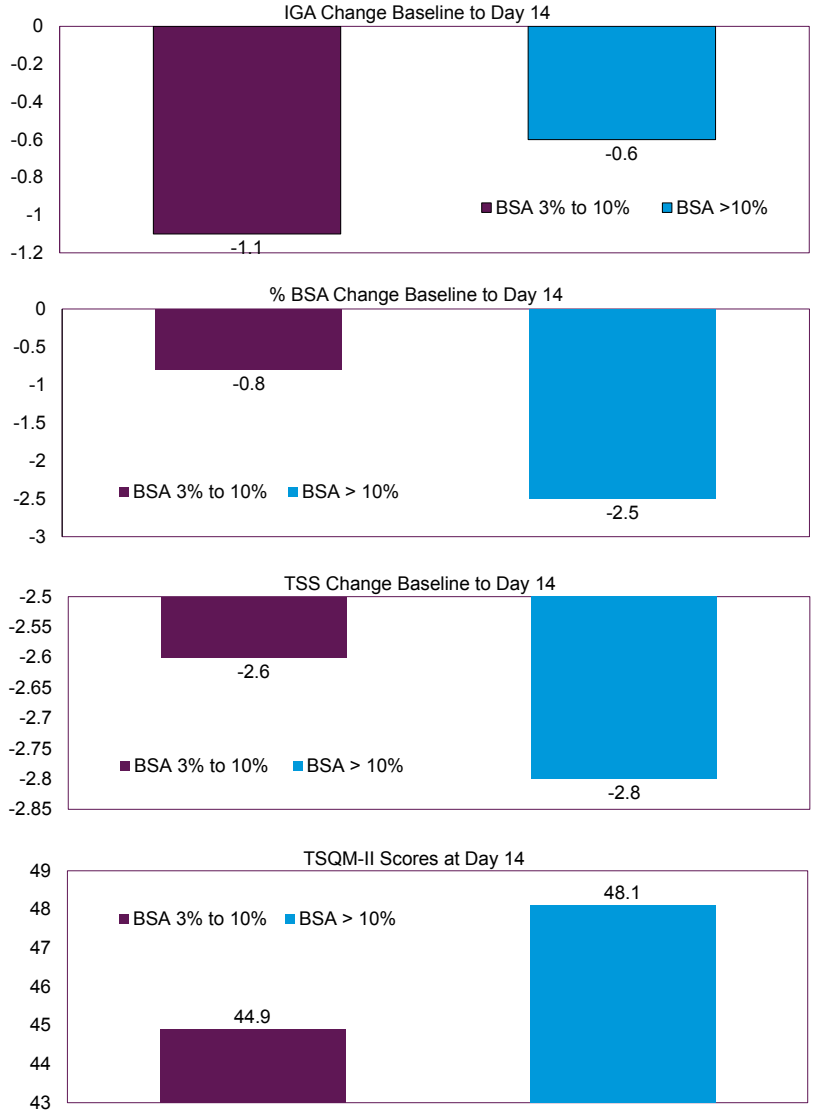
Methods

- In this open-label, multicenter study, adults with moderate plaque psoriasis (IGA = 3; BSA > 3%, excluding intertriginous areas) applied DFD-01 to affected areas twice daily for 28 days. For each subject, investigators identified 2 target lesions representative of overall disease.
- Assessments occurred at days 1 (baseline), 8, 14, and 29. At each visit, disease severity was assessed by IGA, total sign score (TSS) of target lesions, and BSA, and target lesions were photographed.
- QoL was evaluated using the Dermatology Life Quality Index (DLQI), a 10-item questionnaire assessing impact of skin disease on quality of life (scores range from 0 (best) to 30 (worst)[1].
- Patient satisfaction was evaluated using the Treatment Satisfaction Questionnaire for Medication–Version II (TSQM-II), 9-items assessing effectiveness, side effects, convenience, and global satisfaction, yielding scores ranging from 0 (extremely unsatisfied) to 100 (extremely satisfied).
- Primary endpoints were:
  - (1) Change from baseline in clinical response and QoL at day 14
  - (2) Treatment Satisfaction at day 14

Results

- Of 45 subjects enrolled, 24 had low BSA (3%-10%) and 21 had high BSA (>10%).
- 14 days of twice daily DFD-01 treatment was associated with decreased mean values of IGA (-0.9), TSS (-2.7), and BSA (-1.5%).
- Mean IGA reduction was greater in the low BSA group, whereas mean TSS and BSA reductions were greater in the high BSA group.
- DLQI decreased from a mean of 8.9 ± 6.7 at baseline to 3.3 ± 3.6 at day 14. The high BSA group showed greater improvement in QoL.
- Mean TSQM-II score was 46.2 at day 14, with greater treatment satisfaction in the high BSA group (48.1 vs 44.9).

Change in Clinical and QoL Parameters From Baseline to Day 14 (IIT Population)



Conclusions

- DFD-01 was associated with decreased IGA, TSS, and BSA in adults with moderate plaque psoriasis.
- Treatment was associated with improved QoL after 2 weeks of treatment, and subjects reported satisfaction with DFD-01 in both low (3%-10%) and high (>10%) BSA groups.
- DFD-01 treatment resulted in better outcomes in subjects with higher BSA involvement at baseline.

Reference

1. Finlay AY, Khan GK. "The Dermatology Life Quality Index: A simple practical measure for routine clinical use". British Association of Dermatologists Annual Meeting, Oxford, July 1993. *British Journal of Dermatology*, 1993;129(Suppl 42):27.

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