DFD-01, a VCA midpotent betamethasone dipropionate 0.05% emollient-like spray formulation, demonstrates earlier onset of action compared with a super potent topical steroid for the treatment of moderate psoriasis

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Introduction

- Typically, topical steroids that are considered super potent by vasoconstrictor assay (VCA) have demonstrated the highest efficacy along with a higher potential for HPA axis suppression.
- DFD-01, a VCA midpotent topical steroid, [Sernivo™ (betamethasone dipropionate) Spray, 0.05%], approved for the treatment of mild to moderate plaque psoriasis in adults, was formulated to achieve a balance of steroid penetration to and persistence within the dermis and epidermis while minimizing absorption into the systemic circulation.
- DFD-01, an emollient-like spray formulation was compared with a super potent augmented betamethasone dipropionate 0.05% steroid lotion (AugBD) for the treatment of moderate plaque psoriasis.
- Early response to treatment is the focus of this *post hoc* analysis

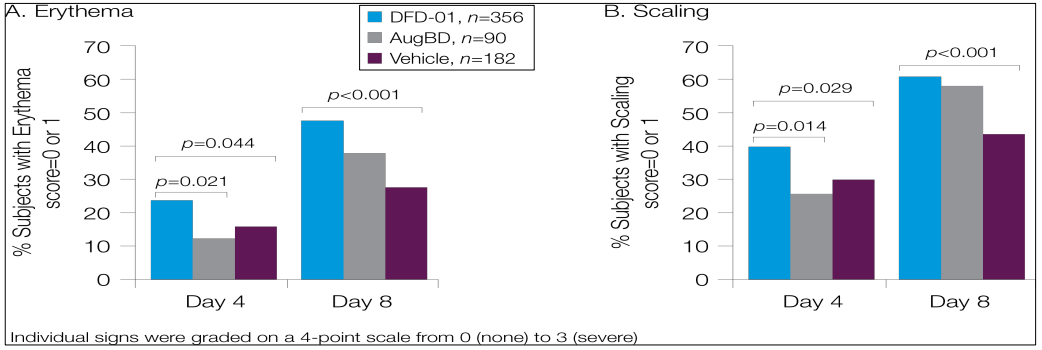
Methods

- Data from two phase 3, randomized, clinical trials enrolling adults with moderate plaque psoriasis (IGA=3; 10% to 20% BSA) were pooled.
- Subjects were randomized to receive DFD-01, AugBD, or Vehicle Spray (Vehicle) and products were applied to all affected areas on the body excluding face, scalp, and intertriginous areas twice daily for 14 or 29 days. DFD-01 was applied for 29 days and AugBD was applied for 14 days per their respective labels.
- Treatment success at days 4 and 8 was defined as IGA=0 or 1 and ≥2 grade improvement from baseline.
- Reduction in total sign score (TSS) for a target lesion (the sum of erythema, plaque and elevation scores), individual sign scores, TSS_{50} and TSS≤1 for any sign, were also assessed. Analysis was by Fisher's exact test.

Results

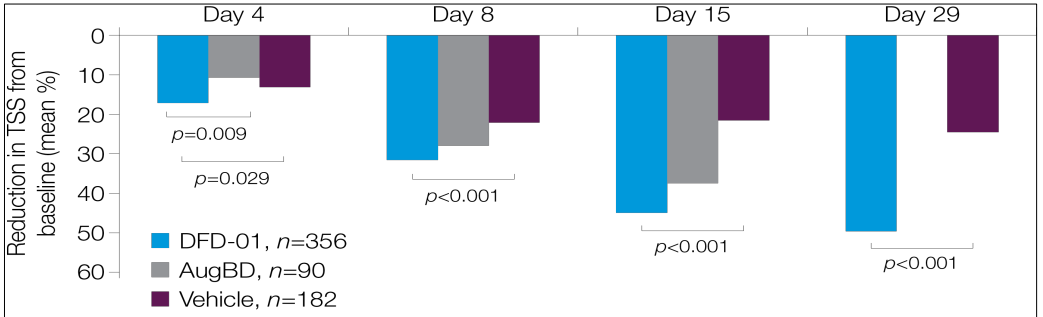
- 356 subjects were randomized to DFD-01, 90 subjects to AugBD, and 182 subjects to Vehicle.
- Individual sign scores all showed improvement with treatment, and DFD-01 showed significantly greater effect than AugBD at day 4 for erythema (23.6% vs 12.2%, *P*=.021) and scaling (39.6% vs 25.6%, *P*=.014) (Figure 1).
- Reduction in TSS was greater with DFD-01 than with AugBD at day 4 (-17.3% vs -10.6%, *P*=.009) (Figure 2).
- At day 4 DFD-01 was also significantly different from AugBD for both TSS_{50} (13.2% vs 5.6%, *P*=.044) and TSS≤1 for any sign (13.8% vs 5.6%, *P*=.031).

Figure 1. Pooled Analysis of Early Onset of Relief of Erythema and Scaling



Individual signs were graded on a 4-point scale from 0 (none) to 3 (severe)

Figure 2. Pooled Analysis Reduction in TSS



ITT population. Total sign score is defined as the sum of erythema, scaling, and plaque elevation scores

Conclusions

- Midpotent DFD-01 (betamethasone dipropionate 0.05% spray) showed efficacy on global measures of IGA, TSS and TSS_{50} with significant improvement at day 4 on all outcomes compared to baseline
- At day 4 TSS improvement was greater with DFD-01 compared with super potent augmented betamethasone dipropionate 0.05% lotion.

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