Efficacy of a Novel Formulation of Betamethasone Dipropionate 0.05% Spray Versus Augmented Betamethasone Dipropionate 0.05% Lotion in Patients ≥ 18 Years of Age with Moderate Plaque Psoriasis: A Pooled Analysis

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INTRODUCTION

Betamethasone dipropionate 0.05% spray (**BDS** - Sernivo®, Primus Pharmaceuticals) is a novel mid-potent formulation indicated for the treatment of plaque psoriasis. In vitro testing has proven greater residence time for BDS within the skin compared to super-high potency augmented betamethasone dipropionate 0.05% lotion (**BDL** - Diprolene®, Organon).[1] In two identically designed Phase 3 trials, BDS showed statistically significant superiority over vehicle in both studies, and equivalence to BDL in Study 1 in terms of treatment success.[2-4] Data from these two Phase 3 trials have been pooled to further evaluate the effectiveness of BDS versus BDL.

OBJECTIVE

To further assess the efficacy of BDS versus BDL in patients with moderate plaque psoriasis using pooled data from two Phase 3 clinical trials.

METHODS

Pooled efficacy analysis included patients with stable disease (present for ≥ 3 months), an Investigator Global Assessment (IGA) = 3, and a Body Surface Area (BSA) of 10-20% who received either BDS (N = 356) or BDL (N = 90). Efficacy included the proportion of patients with success defined as an IGA = 0 or 1 (none or minimal) and ≥ 2-grade improvement at day 15; the proportion of patients with a TSS_{50} (Total Sign Score improvement of at least 50%); the proportion of patients with a TSS = 0 or 1 (clear or slight to mild) stratified by sign; and the relative proportion of patients receiving BDS (within group) with a TSS = 0 or 1 stratified by sign. Statistical analysis included a Fisher's Exact (2-tail) test for categorical data.

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DISCLOSURES:

LSG
Investigator, Advisor, and/or Speaker for Arcutis, Dermavant, Leo, Ortho Derm, Pfizer, Primus Pharmaceuticals

JSW
Research Grants: Almirall, Dr. Reddy's Lab, Galderma, Ortho, Promius
Consulting: Cutera, Dr. Reddy's Lab, EPI Health, Galderma, Novan, Ortho, Promius
Advisory Boards: Dr. Reddy's Lab, Galderma, Ortho, Promius

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Speaker: Galderma, Incyte, Pfizer
Honoraria: Galderma, Incyte, Sol-Gel

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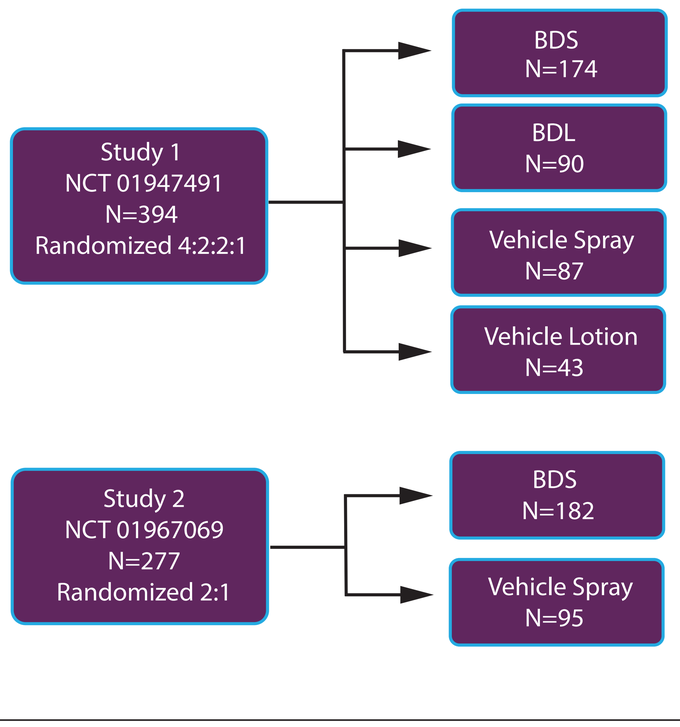
Figure 1. Trial Designs



RESULTS

Success based on IGA was greater for BDS versus BDL at days 4 (2.2% versus 1.1%, P = 0.6941), 8 (11.5% versus 6.7%, P = 0.2480), and 15 (20.2% versus 18.9%, P = 0.8829), but not statistically significant. The proportion of patients with a TSS_{50} was greater for BDS at days 4 (13.2% versus 5.6%, P = 0.0438), 8 (34.7% versus 29.2%, P = 0.3789), and 15 (51.0% versus 42.0%, P = 0.1523) with statistical significance at day 4.

The proportion of patients with a TSS = 0 or 1 stratified by sign is presented in **Table 1.** Statistically significant superiority was observed in patients receiving BDS versus BDL for erythema at day 4, and scaling at days 4 and 15.

Within group (BDS) comparisons for each TSS sign are presented in **Table 2.** The proportion of patients with a TSS = 0 or 1 was statistically greater for scaling versus erythema and plaque elevation at all time points.

Table 1.
BDS versus BDL: A Pooled Analysis of Sign Scores (ITT Population)

Sign	Study Day	Success/Failure	BDS	BDL	p-value[a]
Erythema	Baseline	Success (0 or 1) Failure	8/356 (2.2%) 348/356 (97.8%)	1/90 (1.1%) 89/90 (98.9%)	0.6941
	Day 4	Success (0 or 1) Failure	84/356 (23.6%) 272/356 (76.4%)	11/90 (12.2%) 79/90 (87.8%)	**0.0206**
	Day 8	Success (0 or 1) Failure	169/346 (48.8%) 177/346 (51.2%)	34/89 (38.2%) 55/89 (61.8%)	0.0754
	Day 15	Success (0 or 1) Failure	214/347 (61.7%) 133/347 (38.3%)	48/88 (54.5%) 40/88 (45.5%)	0.2255
Scaling	Baseline	Success (0 or 1) Failure	12/356 (3.4%) 344/356 (96.6%)	3/90 (3.3%) 87/90 (96.7%)	1.0000
	Day 4	Success (0 or 1) Failure	141/356 (39.6%) 215/356 (60.4%)	23/90 (25.6%) 67/90 (74.4%)	**0.0144**
	Day 8	Success (0 or 1) Failure	213/346 (61.6%) 133/346 (38.4%)	51/89 (57.3%) 38/89 (42.7%)	0.4680
	Day 15	Success (0 or 1) Failure	254/347 (73.2%) 93/347 (26.8%)	54/88 (61.4%) 34/88 (38.6%)	**0.0355**
Plaque Elevation	Baseline	Success (0 or 1) Failure	18/356 (5.1%) 338/356 (94.9%)	2/90 (2.2%) 88/90 (97.8%)	0.3915
	Day 4	Success (0 or 1) Failure	99/356 (27.8%) 257/356 (72.2%)	19/90 (21.1%) 71/90 (78.9%)	0.2294
	Day 8	Success (0 or 1) Failure	177/346 (51.2%) 169/346 (48.8%)	43/89 (48.3%) 46/89 (51.7%)	0.6369
	Day 15	Success (0 or 1) Failure	228/347 (65.7%) 119/347 (34.3%)	51/88 (58.0%) 37/88 (42.0%)	0.2131

[a] P-values derived from Fisher's Exact (2-tail) test.
Executed on 30DEC22:13:06; SAS (v9.4)

Table 2.
BDS Within Group: A Pooled Analysis of Sign Scores (ITT Population)

Sign	Success	Day 4	Day 8	Day 15
Erythema	Success (0 or 1)	84/356 (23.6%)	169/346 (48.8%)	214/347 (61.7%)
Scaling	Success (0 or 1)	141/356 (39.6%)	213/346 (61.6%)	254/347 (73.2%)
Plaque Elevation	Success (0 or 1)	99/356 (27.8%)	177/346 (51.2%)	228/347 (65.7%)
Scaling vs Erythema	p-value[a]	< 0.0001	0.0010	0.0016
Erythema vs Plaque Elevation	p-value[a]	0.2298	0.5946	0.3048
Scaling vs Plaque Elevation	p-value[a]	0.0011	0.0073	0.0392

[a] P-values derived from Fisher's Exact (2-tail) test.
Executed on 30DEC22:13:06; SAS (v9.4)

CONCLUSIONS

Success was similar between a novel mid-potent formulation of betamethasone dipropionate 0.05% spray (BDS) and super-high potency augmented betamethasone dipropionate 0.05% lotion (BDL). Patients receiving BDS achieved greater treatment efficacy regarding scaling than those receiving BDL. BDS was most successful within group in the treatment of scaling versus erythema and plaque elevation.

PRIMUS PHARMACEUTICALS