Proactive management using calcipotriene/betamethasone dipropionate foam in patients with plaque psoriasis prolongs time with a health-related quality of life improvement, compared with reactive management

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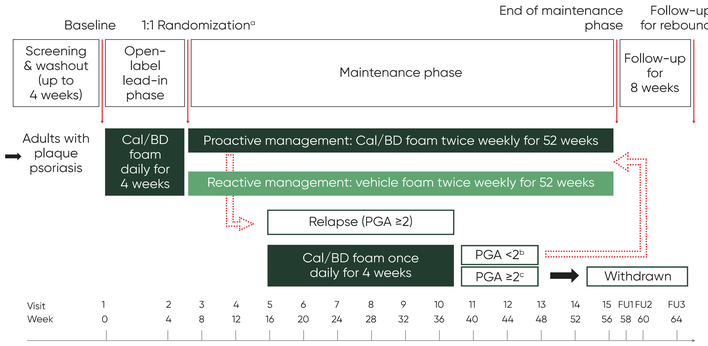
Introduction

- An unmet need exists for the long-term management of plaque psoriasis with topical therapies[1]
  - Conventional long-term management with topical treatments uses a reactive approach where the treatment is used after relapse has occurred versus a proactive approach to maintain remission[2]
  - Proactive management is a well-established treatment concept for moderate-to-severe atopic dermatitis[3]
- The phase 3 PSO-LONG study showed that proactive management versus reactive management using calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) foam for up to 52 weeks in adults with psoriasis delayed time to first relapse, significantly extended time in remission, and reduced the number of relapses per year[4]
- Cal/BD foam was well tolerated throughout the PSO-LONG trial[4]
- The patient-reported outcome measure Dermatology Life Quality Index (DLQI) evaluates patient perception of psoriasis on health-related quality of life[5]
- In this post hoc analysis of PSO-LONG, we evaluated whether initial DLQI responses obtained following open-label, once-daily, 4-week treatment using Cal/BD foam were better sustained using subsequent proactive management or reactive management

Methods

- PSO-LONG (NCT02899962) included an initial 4-week open-label phase (once-daily Cal/BD foam) and a 52-week, double-blind, maintenance phase where patients were randomized to twice-weekly Cal/BD foam or vehicle foam, with a 4-week once-daily Cal/BD foam rescue treatment for relapse (Physician Global Assessment [PGA] ≥2) (proactive management or reactive management, respectively) (**Figure 1**)
- The proportion of patients achieving DLQI 0/1 following the open-label phase was assessed during the maintenance phase to evaluate how long patients sustained their initially gained responses
  - The full analysis set was used for the assessment of those patients where a DLQI measure was available
  - Hazard ratios and survival analysis curves for time with response in each group were evaluated

Figure 1. Trial design



[a]Patients with treatment success at end of open-label lead-in phase (PGA score 'clear'/'almost clear' [PGA <2] with ≥2-grade improvement from baseline) were randomized 1:1 in the maintenance phase; [b]Following 4 weeks of once-daily rescue treatment, patients who regained PGA<2 ('clear'/'almost clear') re-started the twice-weekly maintenance treatment according to the original randomization scheme; [c]Patients who did not regain a PGA score <2 ('clear'/'almost clear') following 4 weeks of once-daily rescue treatment were withdrawn from the trial

Cal/BD, calcipotriene 0.005%/betamethasone dipropionate 0.064%; FU, follow-up; PGA, Physician Global Assessment

Results

- The full analysis set included 521 patients with predominantly PGA-moderate psoriasis (85.2%) (**Table 1**)

Table 1. Patient demographics and baseline characteristics

Category	N=521
Sex, n (%)	
Female	170 (32.6)
Male	351 (67.4)
Race, n (%)	
White	470 (90.2)
Asian	33 (6.3)
Black/African American	7 (1.3)
Native Hawaiian or other Pacific Islander	3 (0.6)
Missing	8 (1.5)
Age (y), mean (SD)	52.3 (14.4)
PGA, n (%)	
Mild	43 (8.3)
Moderate	444 (85.2)
Severe	34 (6.5)
mPASI, mean (SD)	7.8 (3.8)
BSA, mean (SD)	8.2 (6.2)

BSA, body surface area; mPASI, modified Psoriasis Area and Severity Index; PGA, Physician Global Assessment; SD, standard deviation

- During the open-label phase, 253 (49%) of 516 patients whose DLQI was measured both at baseline and at week 4 achieved DLQI 0/1
- During the maintenance phase, proactive management significantly reduced the risk of patients losing their initially gained DLQI 0/1 responses by 48% **(Table 2)**
  - Median time to lost response was almost 3.5 times shorter for the reactive management group (197 days with proactive management vs. 57 days with reactive management)

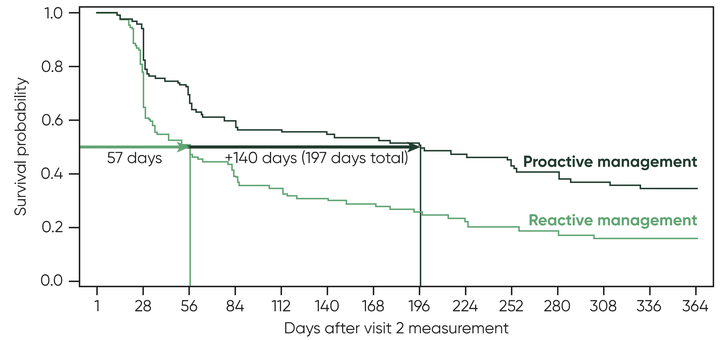
Table 2. DLQI response estimate

	Proactive management (n=120)	Reactive management (n=133)
Hazard ratio[a]	0.52	
95% CI	0.38–0.71	
P value	<0.001	
Median time with DLQI 0/1	197	57

[a]Estimates were obtained from a proportional hazard model with treatment group, trial site and DLQI total score at visit 2 as factors
DLQI, Dermatology Life Quality Index

- Patients undergoing proactive management had a higher chance of sustaining the initial response compared with patients undergoing reactive management **(Figure 2)**

Figure 2. Estimated survival curve for time to first DLQI >1



Number of patients at risk of first event

Proactive management	120	114	86	67	63	59	54	50	44	40	35	30	28	23
Reactive management	133	106	65	49	36	32	28	23	21	16	14	11	11	6

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Cal/BD, calcipotriene.0.005%/betamethasone dipropionate 0.064%; DLQI, Dermatology Life Quality Index

Conclusions

- In a subset of patients achieving a DLQI 0/1, health-related quality of life response following the initial open-label, once-daily, 4-week Cal/BD foam treatment, subsequent proactive management with Cal/BD foam significantly prolonged time with a DLQI response versus reactive management
- The prolonged DLQI response with proactive management versus reactive management with Cal/BD foam may be attributed to improvements in efficacy

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Disclosures

All authors met the ICMJE authorship criteria and had full access to the relevant data. Neither honoraria nor payments were made for authorship. **Linda Stein Gold** has served as consultant, advisory board member, investigator, and/or speaker for LEO Pharma, Arcutis, Dermavant, Pfizer, AbbVie, Eli Lilly and Company, and Ortho Derm. **Ahmad Jalili** has served a consultant, advisor, investigatar and/or speaker for AbbVie, Almirall, Amgen, Boehringer Ingelheim, BMS, Celgene, Eli Lilly and Company, GSK, LEO Pharma, Janssen-Cilag, MSD, Novartis and Sanofi. **Dominique Lons Danic** has served as a consultant for and/or received speaking fees or grants from Novartis, Eli Lilly and Company, AbbVie, LEO Pharma, Janssen, and Sanofi. **Piergiacomo Calzavara-Pinton** has served as an advisory board member or lectured for Galderma, Almirall, LEO Pharma, Sanofi, Meda, and AbbVie. **Nanna Nyholm** and **Henrik Thoning** are employees of LEO Pharma. Fixed-dose combination calcipotriene (Cal) 0.005%/betamethasone dipropionate (BD) 0.064% foam is approved for the treatment of psoriasis vulgaris (plaque psoriasis) for up to 4 weeks in patients 12 years and older in the United States

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