Psoriasis Patients on Chronic Biologic Therapy May Benefit From Additional Treatment—Study Design and Baseline Characteristics

Jerry Bagel, MD; James Zapata; Elise Nelson, LPN, CCRC; and Brian Keegan, MD, PhD

Psoriasis Treatment Center of Central New Jersey, East Windsor, New Jersey

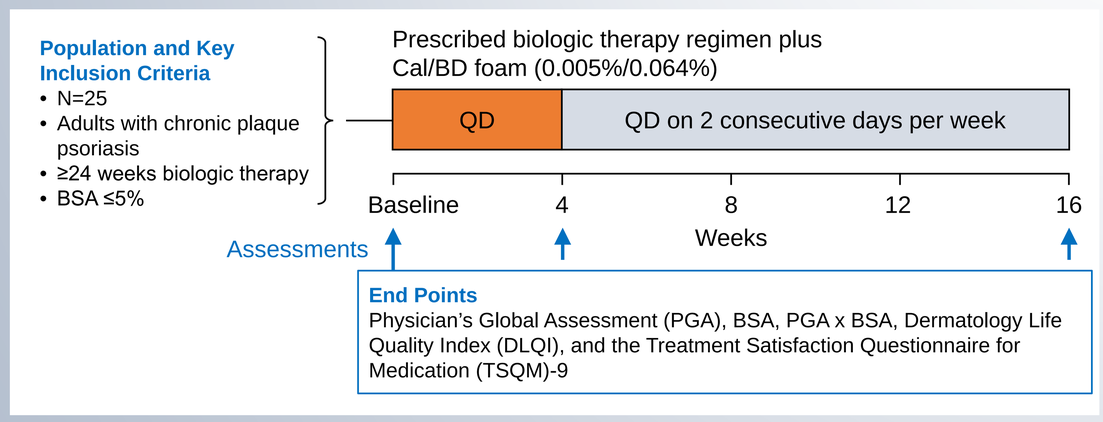
Background

- More than 50% of patients with psoriasis are dissatisfied with their treatment, including biologic treatment[1]
- Greater disease clearance is desired by patients and is supported by the recent treat-to-target recommendations from the Medical Board of the National Psoriasis Foundation[1]
- Accordingly, patients receiving biologic therapy for psoriasis may benefit from adjunctive therapy with topical agents[2,3]
- Treatment with the foam formulation of calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) as a fixed combination topical product is significantly more effective than calcipotriene or betamethasone monotherapy, and is superior to ointment and gel formulations of Cal/BD[4-6]
- Patients with psoriasis who have been treated with biologic therapy for at least 24 weeks are currently being enrolled in a real-world study designed to assess the efficacy and safety of Cal/BD foam as adjunctive therapy
- Described here is the design for this study, as well as the residual disease activity observed in these patients at enrollment

Methods

- 25 adults with psoriasis (body surface area [BSA] ≤5%) being treated with biologic agents for ≥24 weeks have been enrolled in an open-label, single-arm, observational study (**Figure 1**)
- In addition to their biologic therapy, all patients will receive Cal/BD foam QD for 4 weeks, followed by Cal/BD foam on 2 consecutive days weekly for an additional 12 weeks
- The end points will be assessed at baseline, week 4, and week 16
- Safety evaluations include assessments of local skin reactions and adverse events (AEs)

Figure 1. Study Design



Demographics

- 18 men and 7 women; mean age, 53 years (**Table 1**)
- Most of the patients are Caucasian (84%), with the remaining patients being Hispanic (16%)
- On average, patients have had a 24-year history of psoriasis

Table 1. Baseline Demographics

	Patients (N=25)
Age, years	53 (11)
Sex	
Female	7 (28%)
Male	18 (72%)
Race	
Caucasian	21 (84%)
Hispanic	4 (16%)
Years of psoriasis	24 (13)

Data are median (SD) or n (%).

Disease Characteristics

- Approximately half of the patients are being managed with ustekinumab as their biologic agent (**Table 2**)
- At enrollment, the patients were experiencing psoriasis disease activity that warranted either adding therapy or switching to a different biologic agent
  - Based on PGA, BSA, and PGA x BSA scores
  - Only 3 patients (12%) met the treat-to-target criterion of BSA ≤1%

Table 2. Baseline Disease Characteristics

	Patients (N=25)
Biologics in use at baseline	
Ustekinumab	13 (52%)
Adalimumab	5 (20%)
Secukinumab	5 (20%)
Etanercept	1 (4%)
Ixekizumab	1 (4%)
PGA	3 (2-3)
BSA, %	3 (2-4)
PGA x BSA	8 (6-12)

Data are mean (IQR) or n (%).
IQR=interquartile range, representing the range of values between the 25th and 75th percentiles of the study population.

Quality of Life and Lesion Description

- The health-related quality of life of the patients continues to be affected by psoriasis despite ≥24 weeks of biologic therapy, as indicated by their DLQI scores (**Table 3**)
- Itching and burning/stinging of the psoriatic lesions is present in the majority of the patients
- 40% of the patients experience dryness in their lesions, as observed by the investigator
- None of the patients had skin atrophy, striae, telangiectasiae health-related quality of life of the patients, or folliculitis at baseline

Table 3. Baseline Observations

	Patients (N=25)
DLQI[a]	3 (1-4)
Psoriasis itching score ≥1[a]	17 (68%)
Psoriasis burning/stinging score ≥1[a]	5 (20%)
Psoriasis dryness score ≥1[b]	10 (40%)

Data are median (IQR) or n (%).
[a]As reported by the patient.
[b]As observed by the investigator.

Conclusions

- **This study reveals that despite ≥24 weeks of stable biologic therapy for psoriasis, significant disease activity remains in this unique, real-world patient population, highlighting an unrecognized, unmet medical need**
- **Residual disease activity was demonstrated by several measures, including scores up to 4 for PGA, 5 for BSA, and 16 for DLQI**
- **Patients with psoriasis desire disease clearance. The disease activity experienced by the patients in this study warrants additional treatment to better control the disease**
- **The itching, burning, and dryness experienced by the majority of the patients compromised their quality of life**
- **The effect of Cal/BD foam in clearing residual disease activity for this unique patient population on stable biologic therapy is being investigated in this study**
- **This study will help to better elucidate the disease characteristics and optimal management of this patient population**

References

1. Armstrong AW, Bagel J, Van Voorhees AS, et al. *JAMA Dermatol.* 2015;151(4):432-438.
2. Menter A, Korman NJ, Elmets CA, et al. *J Am Acad Dermatol.* 2009;60(4):643-659.
3. Bagel J, Stein Gold L. J Drugs Dermatol. 2017;16:1209-1222.
4. Lebwohl M, Tyring S, Bukhalo M, et al. *J Clin Aesthet Dermatol.* 2016;9(2):34-41.
5. Paul C, Stein Gold L, Cambazard F, et al. *J Eur Acad Dermatol Venereol.* 2017;31(1):119-126.
6. Leonardi C, Bagel J, Yamauchi P, et al. *J Drugs Dermatol.* 2015;14(12):1468-1477.

Acknowledgments and Disclosures

This study was supported by LEO Pharma

Editorial support was provided by *p*-value communications

Dr. Bagel is an advisor, consultant, investigator, and speaker for AbbVie, Amgen, Celgene, Janssen, Eli Lilly, LEO Pharma, Novartis, and Regeneron; he is an investigator and consultant for Pfizer and an investigator for Valeant, Lycera, UCB, and Actelion; he is Founder of Windsor Dermatology

Dr. Keegan is an investigator and speaker for AbbVie, Janssen, Eli Lilly, Novartis, Pfizer, Actelion, and Valeant and a speaker for Allergan and Promius

Poster presented at the 2018 Winter Clinical Dermatology Conference in Maui, HI; January 12-17, 2018.