Bimekizumab On-Treatment Remission as Defined by the National Psoriasis Foundation: 1-Year Results Versus Ustekinumab and Secukinumab in Patients with Moderate to Severe Plaque Psoriasis

April Armstrong,[1] Lourdes Pérez-Chada,[2] Mark Lebwohl,[3] Deepak M.W. Balak,[4] George M. Lewitt,[5] Richard B. Warren,[6] Richard G. Langley,[7] Diamant Thaçi,[8] George Han,[3] Heather Herr,[9] Balint Szilagyi,[10] Sarah Kavanagh,[11] Andrew Blauvelt[12]

[1]University of California Los Angeles (UCLA), Los Angeles, CA, USA; [2]Department of Dermatology, Brigham and Women's Hospital, Boston, MA, USA; [3]Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [4]Department of Dermatology, Leiden University Medical Center, Leiden, The Netherlands; [5]Illinois Dermatology Institute, DeNova Research, Chicago, IL, USA; [6]Dermatology Centre, Northern Care Alliance NHS Foundation Trust & Division of Musculoskeletal and Dermatological Sciences, Manchester NIHR Biomedical Research Centre, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK; [7]Division of Clinical Dermatology & Cutaneous Science, Department of Medicine, Dalhousie University, Halifax, NS, Canada; [8]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [9]UCB, Smyrna, GA, USA; [10]UCB, Monheim am Rhein, Germany; [11]UCB, Morrisville, NC, USA; [12]Blauvelt Consulting LLC, Annapolis, MD, USA

Objectives

To report National Psoriasis Foundation (NPF)-defined on-treatment remission rates for bimekizumab (BKZ) versus ustekinumab (UST) and BKZ versus secukinumab (SEC), from two head-to-head phase 3/3b trials, through 1 year.

To evaluate the cumulative health-related quality of life benefits of treatment in patients in remission versus those not in remission.

Background

- Defining remission in psoriasis is important for benchmarking treatment responses and facilitating an understanding of a disease state where patients experience little to no disease.[1]
- A recent NPF consensus-based definition of on-treatment remission has emerged, which requires the continuous achievement for at least 6 months of either 0% body surface area (BSA) involvement or an Investigator's Global Assessment (IGA) score of 0.[1]

Methods

- Patients who completed the BE VIVID and BE RADIANT studies (**Figure 1**; study designs have been published previously)[2,3] with no missing BSA or IGA measurements were included.
- We present proportions of patients achieving NPF-defined on-treatment remission in the first year of treatment and at specific time points up to 1 year.
- To understand the impact of achieving remission on patients' lives, we report:
  - Total area under the curve (AUC) through 52/48 weeks for Dermatology Life Quality Index 0 or 1 (DLQI 0/1), indicating no effect of skin disease on a patient's life,[4,5] and the estimated number of days with DLQI 0/1 for patients receiving BKZ;
  - The estimated number of days with a Psoriasis Symptoms and Impact Measure (P-SIM) score of 0 in the itching and skin pain items from BE RADIANT.
- Data are reported as observed case (OC).

Results

- Baseline characteristics of included patients were broadly similar between BKZ- and UST-/SEC-treated patients (**Table**).

Proportions of patients achieving NPF-defined on-treatment remission

- In total, 64.9% of BKZ- versus 30.0% of UST-treated patients in BE VIVID and 62.6% of BKZ- versus 45.4% of SEC-treated patients in BE RADIANT achieved NPF-defined on-treatment remission at any time during the first year of treatment (**Figure 2A**, **C**).
- At Week 28, which was the earliest timepoint at which NPF-defined on-treatment remission could be observed, 12.4% of BKZ- versus 0% of UST-treated patients in BE VIVID and 10.4% of BKZ- versus 3.8% of SEC-treated patients in BE RADIANT achieved remission (**Figure 2B**, **D**).
- At Year 1 (Week 52) of BE VIVID, 55.8% of BKZ- versus 26.7% of UST-treated patients achieved remission (**Figure 2B**); at Year 1 (Week 48) of BE RADIANT, 57.4% of BKZ- versus 40.8% of SEC-treated patients achieved remission (**Figure 2D**).

Cumulative health-related quality of life benefits in patients achieving versus not achieving remission

- In BE VIVID and BE RADIANT, patients in NPF-defined remission at any time during the first year of BKZ treatment experienced an additional 56 days (~8 weeks) and 32 days (~5 weeks) of DLQI 0/1 versus those not in remission, respectively (**Figure 3**).
- In BE RADIANT, patients who achieved NPF-defined remission at any time during the first year of BKZ treatment experienced an additional 80 days (~11 weeks) with no itching and 45 days (~6 weeks) with no skin pain versus those not in remission.
  - As P-SIM=0 data were only collected to Week 16 in BE VIVID, an AUC analysis could not be conducted for this population.

Conclusions

More bimekizumab versus ustekinumab/secukinumab-treated patients achieved NPF-defined on-treatment remission during Year 1 of treatment.

Patients in remission during Year 1 of treatment reported more days with no itching, skin pain, or impact of skin disease on their lives versus those not in remission.

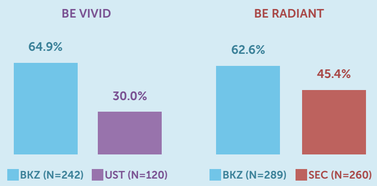
Bimekizumab's ability to provide rapid and sustained remission while on therapy reinforces its role as a beneficial treatment option for patients with psoriasis.

Summary

NPF on-treatment remission is defined as **≥6 months** of:

BSA=0% OR IGA=0

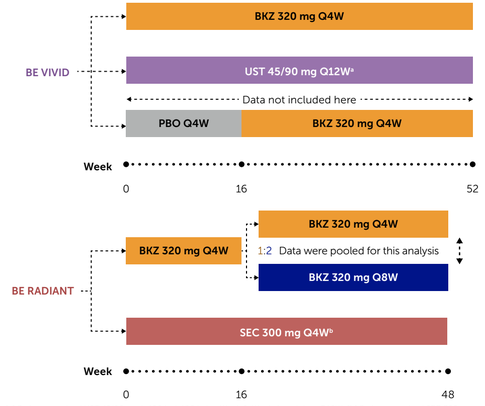
In both **BE VIVID** and **BE RADIANT**, a greater proportion of **BKZ** versus **UST**/**SEC**-treated patients achieved **NPF-defined remission at any time during the first year of treatment**:



Patients who achieved NPF-defined remission at any time during the first year of BKZ treatment experienced **greater time in DLQI 0/1** versus those not in remission:

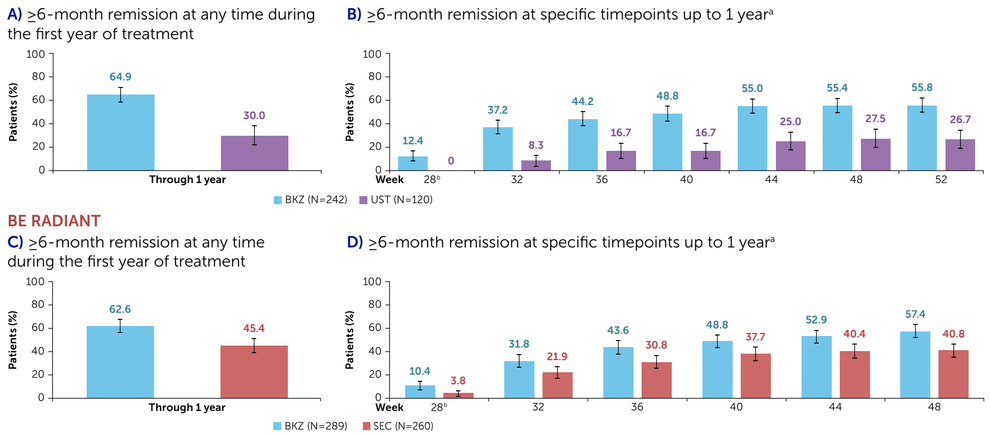
BE VIVID: +8 weeks DLQI 0/1 **BE RADIANT: +5 weeks DLQI 0/1**

Figure 1 BE VIVID and BE RADIANT study designs



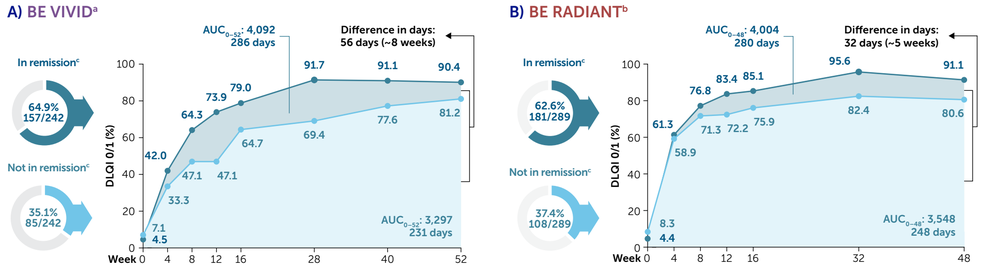
[a] Patients received UST 45/90 mg (≤100 kg/>100 kg) at Week 0, Week 4, and then Q12W; **[b]** Patients received SEC 300 mg weekly to Week 4, then Q4W.

Figure 2 Proportions of patients achieving NPF-defined on-treatment remission (≥6 months of BSA=0% or IGA=0; OC)



Remission is defined as continuous achievement of BSA=0% or IGA=0 over a minimum 6-month (168-day) period. Included patients had no missing BSA or IGA measurements. Error bars represent 95% confidence intervals. **[a]** A patient is classified as being in remission at a particular week if they had BSA=0% or IGA=0 at that week and for the preceding 6 months; **[b]** Patients were required to have BSA ≥10% and IGA ≥3 at baseline to be eligible for inclusion; Week 28 is the earliest possible timepoint remission could be observed.

Figure 3 DLQI 0/1 (AUC) by NPF-defined on-treatment remission status (≥6 months of BSA=0% or IGA=0; OC)



Remission is defined as continuous achievement of BSA=0% or IGA=0 over a minimum 6-month (168-day) period. DLQI 0/1 rates were reported using OC as very few datapoints were missing. **[a]** One patient from the group who did not have remission at any time during the first year had missing DLQI data at Week 4; **[b]** One patient from the group who had remission at any time during the first year had missing DLQI data at Week 48, and one patient from the group who did not have remission at any time during the first year had missing DLQI data at Week 4; **[c]** This was among patients receiving BKZ at any time during the first year.

Table Baseline characteristics of included patients

Mean (SD), unless otherwise specified	BE VIVID		BE RADIANT	
	BKZ N=242	UST N=120	BKZ N=289	SEC N=260
Age, years	45.8 (14.2)	47.2 (13.6)	45.6 (14.4)	44.8 (14.6)
Sex, male, n (%)	177 (73.1)	86 (71.7)	190 (65.7)	167 (64.2)
Racial group, White, n (%)	176 (72.7)	91 (75.8)	267 (92.4)	246 (94.6)
Weight, kg	88.3 (22.0)	87.4 (21.8)	90.4 (21.2)	89.1 (19.4)
Duration of psoriasis, years	16.7 (11.5)	17.6 (11.2)	18.6 (13.6)	17.8 (12.0)
PASI	22.6 (8.6)	20.7 (8.0)	20.3 (7.4)	19.3 (5.8)
BSA, %	29.9 (16.8)	26.2 (16.3)	25.0 (15.8)	22.6 (12.7)
IGA, n (%)				
3: Moderate	147 (60.7)	75 (62.5)	191 (66.1)	198 (76.2)
4: Severe	94 (38.8)	45 (37.5)	96 (33.2)	62 (23.8)
DLQI total score	10.1 (6.3)	10.7 (6.7)	10.9 (6.6)	11.1 (7.0)
Any prior systemic therapy, n (%)	209 (86.4)	97 (80.8)	209 (72.3)	195 (75.0)
Any prior biologic therapy, n (%)	99 (40.9)	46 (38.3)	96 (33.2)	90 (34.6)

AUC: area under the curve; **BKZ:** bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **NPF:** National Psoriasis Foundation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **Q12W:** every 12 weeks; **SD:** standard deviation; **SEC:** secukinumab; **UST:** ustekinumab.

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Dermatology Life Quality Index 2004. https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index. **Author Contributions:** All authors had substantial contributions to the study conception/design or acquisition/analysis/interpretation of data, drafted the publication or reviewed it critically for important intellectual content, and approved the final publication. **Author Disclosures: AA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Johnson & Johnson, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB. **LPC:** Has served as a consultant, scientific advisor, and/or speaker for Bristol Myers Squibb, Janssen, and Takeda. **ML:** Employee of Mount Sinai; receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant, Eli Lilly and Company, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; 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