Bimekizumab efficacy through 144 weeks in moderate to severe plaque psoriasis: Patient-reported outcomes from BE RADIANT

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Objective

To evaluate the impact of bimekizumab (BKZ) on patient-reported itching, skin pain, scaling, and health-related quality of life in patients with moderate to severe plaque psoriasis over 3 years.

Introduction

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[1] has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab, adalimumab, and secukinumab (SEC), with established long-term durability of response.[2–6]
- Psoriasis can negatively impact patients' quality of life; it is important to measure patient-reported outcomes (PROs) alongside clinical parameters, to fully capture both the negative impacts of psoriasis and the positive impact of its treatment on patients' lives.[7,8]
- Rapid improvements in and maintenance of high levels of PRO responses, including in the Psoriasis Symptoms and Impacts Measure (P-SIM; a reliable and fit-for-purpose psoriasis-specific PRO)[8] has been shown previously over 96 weeks of BKZ treatment.[9]
- Here, the impact of BKZ on PROs is reported over 144 weeks of the BE RADIANT phase 3b trial.

Methods

- Included patients were randomised to either BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q4W or every 8 weeks (Q8W) to Week 48, or SEC from baseline to Week 48; all patients were eligible to enrol in the open-label extension (OLE), during which they received BKZ Q4W or Q8W (BKZ/BKZ and SEC/BKZ, respectively; **Figure 1**).[5] Patients entering the BE RADIANT OLE are analysed here.
  - Data are also reported for the subset of BKZ/BKZ patients who received BKZ Q4W/Q8W/Q8W (initial/maintenance/OLE), the approved dosing regimen in most patients.[10]
- Mean proportions of patients (referred to as rates) scoring 0 in the itching, skin pain, and scaling P-SIM items (P-SIM=0; no symptom, range 0–10)[8] and scoring 0 or 1 in the Dermatology Life Quality Index (DLQI 0/1; no effect of skin disease on patient's life, range 0–30),[11] are reported to Week 144.
- Data are reported using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results

- Overall, 336 BKZ- and 318 SEC-randomised patients entered the OLE.
  - Of the 336 BKZ/BKZ patients, 177 received BKZ Q4W/Q8W/Q8W.
- Baseline characteristics were similar between groups (**Table 1**).
- Improvements in P-SIM=0 and DLQI 0/1 responses were observed as early as Week 4 in BKZ/BKZ patients (**Figure 2A–D**).
- At Week 48, proportions of patients scoring P-SIM=0 for itching, skin pain, and scaling, and DLQI 0/1 were numerically higher with BKZ versus SEC (**Figure 2A–D**).
- BKZ/BKZ patients maintained high P-SIM=0 and DLQI 0/1 rates from Week 48–144, as did the BKZ Q4W/Q8W/Q8W subset (**Figure 2A–D**).
- After switching to BKZ at Week 48, SEC/BKZ patients reported maintained or numerically higher rates of P-SIM=0 for itching, skin pain, and scaling, and DLQI 0/1. High rates were maintained to Week 144 (**Figure 2A–D**).

Conclusions

BKZ/BKZ patients reported rapid improvements in patient-reported symptoms and health-related quality of life as early as Week 4. High responses observed at Week 48 were durable through Week 144. These results were consistent in the subset of patients receiving the approved BKZ Q4W/Q8W/Q8W dosing regimen.

SEC/BKZ patients reported maintained or numerically higher rates of PRO responses after switching to BKZ at Week 48, which remained high to Week 144, and were similar to rates achieved in BKZ/BKZ patients.

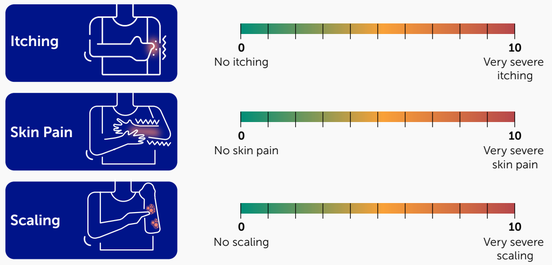
Summary

Conclusions

High levels of PRO responses observed at Week 48 were maintained through 144 weeks of treatment in BKZ/BKZ patients, including for the subset of patients receiving the approved Q4W/Q8W/Q8W dosing regimen.

Patients who switched from SEC to BKZ at Week 48 had improved/maintained PRO responses.

Assessments



The P-SIM is a **reliable, well-defined PRO measure** developed to **capture key signs, symptoms, and impacts of psoriasis**.[8]

The DLQI is a **simple, self-administered PRO** measure developed to **assess health-related quality of life in patients with skin disease, including psoriasis**.[12]

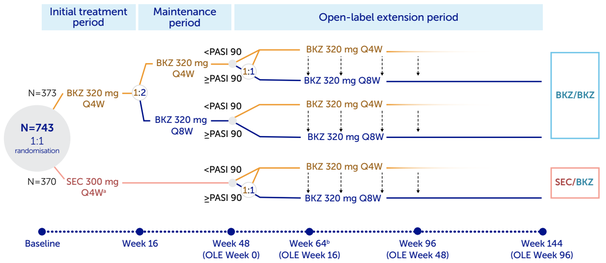
A **P-SIM item score of 0 indicates no symptom**, and a **DLQI score of 0/1 indicates no effect of a skin disease on a patient's life**.[8,11]

Table 1 Baseline characteristics

	BKZ/BKZ (N=336)	SEC/BKZ (N=318)	BKZ Q4W/Q8W/Q8W (N=177)
Age (years), mean ± SD	45.5 ± 14.3	44.5 ± 14.5	44.9 ± 14.2
Male, n (%)	227 (67.6)	209 (65.7)	125 (70.6)
White, n (%)	312 (92.9)	301 (94.7)	169 (95.5)
Weight (kg), mean ± SD	90.2 ± 21.0	89.1 ± 19.5	89.9 ± 20.7
Duration of psoriasis (years), mean ± SD	18.4 ± 13.1	17.5 ± 12.1	18.5 ± 12.8
PASI, mean ± SD	20.3 ± 7.7	19.5 ± 6.1	20.4 ± 8.0
BSA (%), mean ± SD	25.3 ± 16.0	23.0 ± 13.3	24.6 ± 14.8
IGA, n (%)			
3: moderate	214 (63.7)	234 (73.6)	115 (65.0)
4: severe	120 (35.7)	84 (26.4)	60 (33.9)
DLQI total score, mean ± SD	10.9 ± 6.7	11.2 ± 7.3	10.5 ± 6.7
P-SIM score, mean ± SD			
Itching	6.6 ± 2.8	6.6 ± 2.7	6.2 ± 2.9
Skin pain	4.5 ± 3.3	4.6 ± 3.1	4.2 ± 3.3
Scaling	6.7 ± 2.5	6.7 ± 2.4	6.4 ± 2.7
Any prior systemic therapy, n (%)	241 (71.7)	237 (74.5)	131 (74.0)
Prior biologic therapy, n (%)	114 (33.9)	105 (33.0)	56 (31.6)

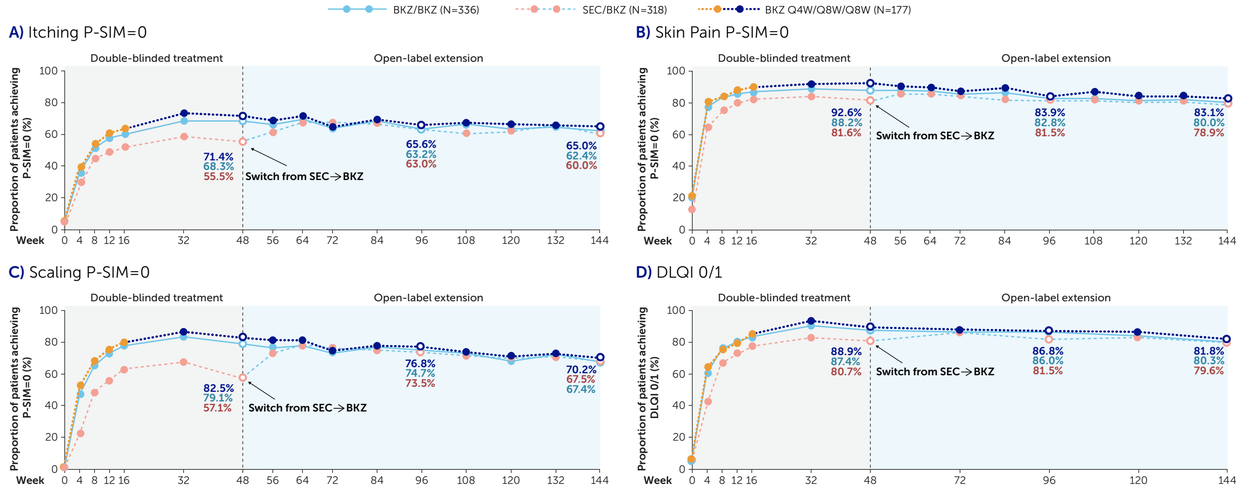
Data presented are for patients who entered the OLE only.

Figure 1 BE RADIANT study design



[a]SEC 300 mg was administered at baseline, Weeks 1, 2, 3, and 4, then Q4W for the remainder of the initial/maintenance treatment periods; [b]Following a protocol amendment, all patients receiving BKZ 320 mg Q4W in the OLE period switched to BKZ 320 mg Q8W at Week 64 or the next scheduled clinic visit.

Figure 2 Proportions of patients scoring P-SIM=0 (no symptom) in itching, skin pain, and scaling, and DLQI 0/1 (no effect of skin disease on a patient's life) (mNRI)



BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SEC:** secukinumab.

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