# Bimekizumab versus secukinumab continuous maintenance of PASI 90 and PASI 100 responses through one year in patients with moderate to severe plaque psoriasis: Post-hoc results from the BE RADIANT phase 3b trial

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## Synopsis

- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, whilst SEC is a widely used monoclonal IgG1 antibody that targets IL-17A.[1]
- BE RADIANT (NCT03536884) was the first phase 3 study to compare inhibition of IL-17A and IL-17F with inhibition of IL-17A alone.[2]
- Patient surveys have confirmed that maintaining a long-lasting response is a key treatment goal for patients who have already achieved skin clearance.[3,4]

## Objective

**To assess the continuous maintenance of Week 16 responses with bimekizumab (BKZ) versus secukinumab (SEC) treatment at every visit to Week 48 in patients with moderate to severe plaque psoriasis.**

## Methods

- BE RADIANT was a phase 3b, randomized trial, consisting of a 48-week double-blinded, active comparator-controlled period followed by an ongoing open-label extension (**Figure 1**).[2] Patients who did not enter the open-label extension entered a safety follow-up period.
- This analysis includes patients who achieved an improvement from baseline in the Psoriasis Area and Severity Index (PASI) of ≥90% (PASI 90) or 100% (PASI 100) at Week 16 and continued to receive study medication at Week 16 or later, reported with BKZ dose groups pooled.
- We report the proportion of responders who continued to achieve their treatment response at every study visit up to and including Week 48, as well as PASI 100 responders who maintained PASI 90.
  - Further analyses of the BKZ-treated PASI 90 responders are also reported.
- Missing data are primarily accounted for using non-responder imputation (NRI), whereby patients with missing data at a given week are considered non-responders at subsequent timepoints.
- Supporting analyses are also reported in table form:
  - Modified non-responder imputation (mNRI): patients who discontinued treatment 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.
  - Observed case (OC): analyzed in patients with observed PASI data at Week 48; patients with missing data at previous weeks were considered non-responders at subsequent timepoints.

## Results

- At baseline, 373 patients were randomized to BKZ, and 370 were randomized to SEC.
- At Week 16, 319/373 (85.5%) BKZ-randomized and 273/370 (73.8%) SEC-randomized patients achieved PASI 90, whilst 230/373 (61.7%) BKZ-randomized and 180/370 (48.6%) SEC-randomized patients achieved PASI 100; baseline demographics are shown in **Table 1**.
- PASI 90 was continuously maintained by PASI 90 responders through Weeks 16–48 by 75.9% BKZ-treated and 64.8% SEC-treated Week 16 responders (**Figure 1**; **Table 2**).
  - Among those classed as having lost response at ≥1 visit by NRI analysis (24.1%), just over half were due to missing visits or discontinuation rather than observed responses below PASI 90, as shown in the heat map (**Figure 3**).
  - Very few patients dropped below PASI 75 beyond Week 16 (**Figure 3**).
- PASI 100 was continuously maintained by PASI 100 responders through Weeks 16–48 by 60.4% BKZ-treated and 51.7% SEC-treated Week 16 responders (**Table 2**).
  - Among Week 16 PASI 100 responders, PASI 90 was continuously maintained at each study visit through Weeks 16–48 by 80.9% of BKZ-treated and 73.3% of SEC-treated patients.
- Analyses using mNRI and OC imputation showed similar trends, with more BKZ-randomized patients maintaining PASI 90 and PASI 100 responses compared with SEC-randomized patients (**Table 2**).

## Conclusions

**A higher proportion of BKZ-randomized patients achieved PASI 90 and PASI 100 at Week 16, compared with SEC-randomized patients. Of the PASI 90 and PASI 100 Week 16 responders, a higher proportion continuously maintained their response with BKZ compared to SEC.**

**Among the BKZ-treated PASI 90 responders, 75.9% continuously maintained their response over 1 year and of the remainder, around half only lost response at 1 visit and very few dropped below PASI 75.**


## Summary

We report the proportions of patients with psoriasis who **continuously maintained their treatment response** from Week 16 through Week 48

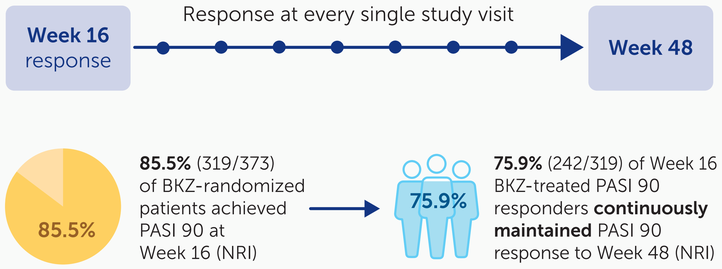


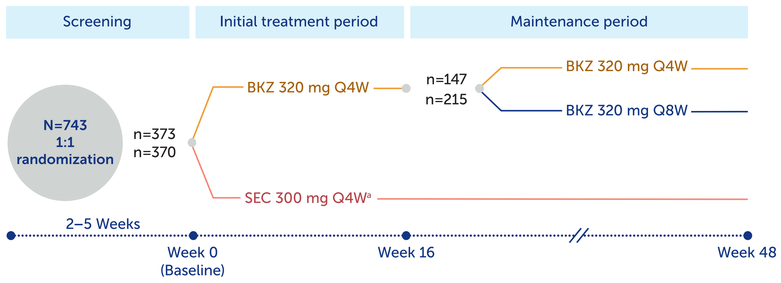


**Table 1** Baseline characteristics

| | BKZ Week 16 PASI 90 responders N=319 | SEC Week 16 PASI 90 responders N=273 |
|---|---|---|
| **Age (years)**, mean ± SD | 45.2 ± 14.0 | 43.0 ± 14.4 |
| **Male**, n (%) | 213 (66.8) | 171 (62.6) |
| **White**, n (%) | 298 (93.4) | 259 (94.9) |
| **Weight (kg)**, mean ± SD | 89.0 ± 21.1 | 87.4 ± 19.6 |
| **Duration of psoriasis (years)**, mean ± SD | 18.0 ± 12.7 | 17.0 ± 12.1 |
| **PASI**, mean ± SD | 20.2 ± 7.5 | 19.7 ± 6.3 |
| **BSA (%)**, mean ± SD | 24.9 ± 15.7 | 23.6 ± 13.6 |
| **IGA**, n (%) | | |
| 3: moderate | 208 (65.2) | 205 (75.1) |
| 4: severe | 110 (34.5) | 68 (24.9) |
| **DLQI**, mean ± SD | 11.0 ± 6.6 | 11.2 ± 7.1 |
| **Any prior systemic therapy**, n (%) | 228 (71.5) | 202 (74.0) |
| **Any prior biologic therapy**, n (%) | 107 (33.5) | 87 (31.9) |

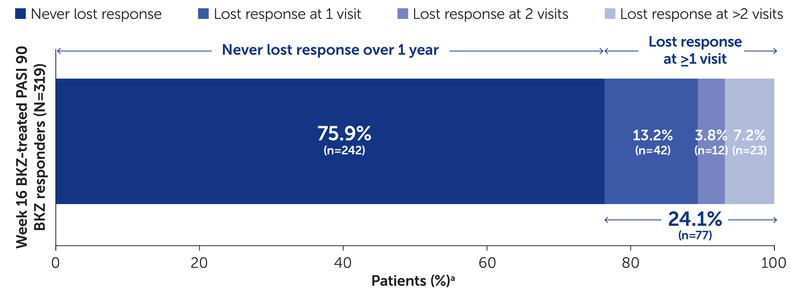
Data are reported by initial dosing regimen (i.e., BKZ 320 mg Q4W or SEC 300 mg Q4W). The BKZ treatment group consists of patients re-randomized to receive BKZ 320 mg Q4W or BKZ 320 mg Q8W at Week 16.

**Figure 1** Study design




At Week 48, patients entered the open-label extension, or entered the safety follow-up period. [a] SEC 300 mg was administered at baseline, Weeks 1, 2, 3 and 4, then Q4W for the remainder of the double-blinded treatment period.

**Figure 2** Week 16 BKZ-treated PASI 90 responders who either never lost response or lost response at ≥1 visit through Week 48 (NRI)




[a] Proportional values for each category of PASI 90 response maintenance total to 100.1% when rounded to 1 decimal place.

**Figure 3** Heat map of the 24.1% of BKZ-treated patients without an observed PASI 90 response at every subsequent visit from Week 16

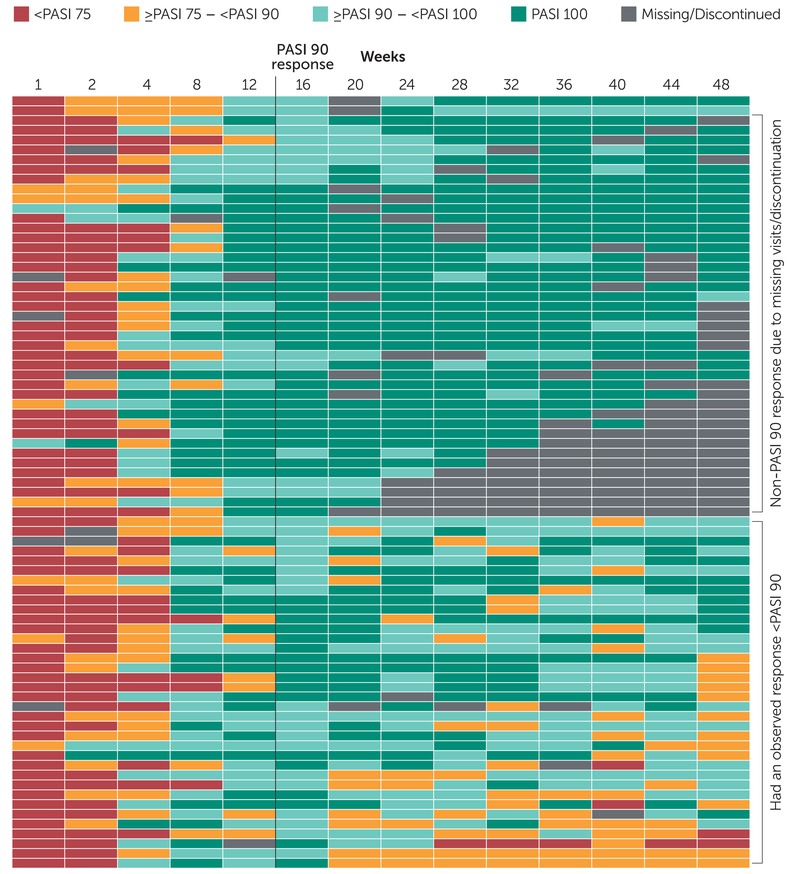



**Table 2** Proportion of Week 16 responders maintaining responses at every single visit through Week 48

| | BKZ-randomized patients | | | SEC-randomized patients | | |
|---|---|---|---|---|---|---|
| | NRI, % (n/N) | mNRI, % (95% CI) | OC, % (n/N) | NRI, % (n/N) | mNRI, % (95% CI) | OC, % (n/N) |
| **Week 16 PASI 90 responders maintaining:** | | | | | | |
| PASI 90 | 75.9 (242/319) | 87.6 (83.9, 91.3) | 81.2 (242/298) | 64.8 (177/273) | 79.2 (74.2, 84.2) | 71.1 (177/249) |
| **Week 16 PASI 100 responders maintaining:** | | | | | | |
| PASI 90 | 80.9 (186/230) | 92.0 (88.4, 95.6) | 86.9 (186/214) | 73.3 (132/180) | 88.3 (83.2, 93.3) | 79.0 (132/167) |
| PASI 100 | 60.4 (139/230) | 64.0 (57.5, 70.4) | 65.0 (139/214) | 51.7 (93/180) | 54.5 (47.0, 61.9) | 55.7 (93/167) |

**BKZ:** bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **MI:** multiple imputation; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in PASI. **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SEC:** secukinumab.

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**References:** [1]Papp KA et al. J Am Acad Dermatol 2018;79:277–86; [2]Reich K et al. N Engl J Med 2021;385:142–52; [3]Tada Y et al. J Dermatol 2021;48:1665–74; [4]Rasmussen MK et al. Acta Derm Venereol 2019;99:158–63. **Author contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM**, **CC**, **PF**, **LI**, **RGL**, **GK**, **LD**, **BH**, **JD**, **RBW**. Drafting of the publication, or reviewing it critically for important intellectual content: **JFM**, **CC**, **PF**, **LI**, **RGL**, **GK**, **LD**, **BH**, **JD**, **RBW**. Final approval of the publication: **JFM**, **CC**, **PF**, **LI**, **RGL**, **GK**, **LD**, **BH**, **JD**, **RBW**. **Disclosures: JFM:** Consultant and/or investigator for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Therapeutics, Novartis, Pfizer, Regeneron, Sanofi-Regeneron, Sun Pharma, and UCB Pharma. **CC:** Consultant and/or principal investigator in clinical trials for AbbVie, Actelion, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Samsung, Sanofi, and UCB Pharma. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; an investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Celtaxsys, CSL, Cutanea, Dermira, Eli Lilly and Company, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Hexima, Incyte, Janssen, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Takeda, Teva, UCB Pharma, and Valeant; served on the advisory board for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute; received travel grants from AbbVie, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, and Sun Pharma; served as a speaker for or received honoraria from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant. **LI:** Consultant and/or paid speaker for and/or participated in clinical trials sponsored by AbbVie, Almirall, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Regranion, Samsung-Bioepis, UCB Pharma, and Union Therapeutics. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, and Pfizer. **GK:** Received travel grants or honoraria, or has been a consultant member of advisory boards and speakers bureaus or has served as investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Hexal-Sandoz, Janssen, LEO Pharma, Eli Lilly and Company, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB Pharma. **LD, BH:** Employees and shareholders of UCB Pharma. **JD:** Employee of UCB Pharma. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; research grants to institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; honoraria from Astellas, DiCE, GSK, and Union Therapeutics. **Acknowledgements:** This study was funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, Isabel Raynaud, MBBS, Costello Medical, Cambridge, UK, for medical writing and editorial assistance and the Creative team, Costello Medical, UK, for graphic design assistance.

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