

Bimekizumab pharmacokinetics, safety and efficacy in adolescents with moderate to severe plaque psoriasis: Long-term data from the open-label BE CONNECTED phase 2 study

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Objective

To evaluate the long-term pharmacokinetics, safety and efficacy of bimekizumab (BKZ) for the total duration of the completed BE CONNECTED phase 2 study in adolescents with moderate to severe plaque psoriasis.

Background

- Approximately 30% of patients with psoriasis report symptoms before adulthood, of whom around 16% have moderate to severe disease.¹
- Given the chronic nature of paediatric psoriasis and the frequent requirement for prolonged treatment, the long-term evaluation of new treatments' safety and efficacy is crucial.²
- BKZ, a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,³ is approved for the treatment of moderate to severe plaque psoriasis in adults.^{4,5}
- During the 20-week initial treatment period (ITP) of BE CONNECTED, BKZ demonstrated similar pharmacokinetics, tolerability and high levels of efficacy to studies in adults.⁶

Methods

- BE CONNECTED (NCT04718896) enrolled adolescents aged ≥12 to <18 years with body weight ≥30 kg and body mass index for age percentile of ≥5 at baseline.^{6,7}
- Patients were stratified by baseline weight and randomised 1:1 to open-label BKZ **Dose A** (weight ≥65 kg: BKZ 320 mg every 4 weeks [Q4W]; weight <65 kg: BKZ 160 mg Q4W) or **Dose B** (weight ≥65 kg: BKZ 64 mg Q4W; weight <65 kg: BKZ 32 mg Q4W).
 - Dose A was predicted to achieve comparable systemic exposure to that of BKZ 320 mg Q4W in adults.
- After the 20-week ITP, patients who tolerated treatment and achieved Investigator's Global Assessment (IGA) ≤2 at Week 20 could continue the same dose in the 104-week open-label extension (OLE; total treatment duration 124 weeks; final BKZ dose at Week 120; **Figure 1**).
 - Patients completed a safety follow-up period of 20 weeks after the final BKZ dose.
- The primary endpoint was BKZ plasma concentration through Week 124 in patients who received ≥1 BKZ dose and provided ≥1 plasma concentration measurement.
- Treatment-emergent adverse events (TEAEs) were assessed from baseline through to the end of the safety follow-up period in patients who received ≥1 BKZ dose (safety set).
- Rates of 100%/≥90% improvement from baseline in the Psoriasis Area and Severity Index (PASI 100/90) and IGA 0/1 are reported from baseline through Week 124 in all patients who received ≥1 BKZ dose at or after Week 20 in the OLE (open-label set).
- Missing data were imputed as non-response; observed case data are also presented.

Results

- Overall, 41 patients received ≥1 BKZ dose in the ITP (safety set) and 39 patients entered the OLE and continued to receive BKZ (open-label set; Dose A: N=19; Dose B: N=20).
- Baseline characteristics were similar between patients receiving Dose A and Dose B (**Table 1**).
- Steady-state geometric mean BKZ plasma concentrations achieved between Weeks 16–20 were maintained to Week 124 (**Figure 2**).
 - Consistent with predictions, BKZ plasma concentrations were lower with Dose B than with Dose A.
- Over more than 2 years, 85.0%/81.0% of patients who received Dose A/Dose B had TEAEs (**Table 2**).
 - Two patients who received Dose A and three patients who received Dose B had serious TEAEs, though none were treatment related.
 - There were no serious, opportunistic or *Candida* infections, and no inflammatory bowel disease or adjudicated suicidal ideation/behaviour.
- In the open-label set, all patients receiving Dose A achieved complete skin clearance (PASI 100) at Week 20, and high rates of skin clearance were generally sustained, with 78.9%/89.5% achieving PASI 100/90 by Week 124 (**Figures 3A and 3B**).
 - In patients receiving Dose B, 70.0%/90.0% had PASI 100/90 at Week 20, respectively, with 65.0% of patients achieving both outcomes to Week 124.
- Rates of IGA 0/1 were similarly high compared with PASI 90 for both doses through Week 124 (**Figure 3C**).

Conclusions

Through more than 2 years of bimekizumab treatment in adolescents with moderate to severe psoriasis, pharmacokinetics remained within the expected range, aligning with the established pharmacokinetic profile in adults. Both bimekizumab doses were well tolerated, with no safety signals identified.

High levels of skin clearance were generally sustained during the open-label extension, consistent with adult studies,^{8,9} with higher rates of skin clearance and bimekizumab plasma concentrations observed for Dose A versus Dose B.

Summary

In adolescent patients with moderate to severe psoriasis randomised to receive one of two different doses of bimekizumab:



Steady-state BKZ plasma concentrations were maintained **to Week 124**, remaining within the expected range. BKZ plasma concentrations were higher with Dose A than with Dose B.

Both doses were **well tolerated**, with **no safety signals identified**

Serious TEAEs	Dose A 2 (10.0%)	Dose B 3 (14.3%)
TEAEs leading to study withdrawal/death	Dose A 0	Dose B 0
Fungal infections Both fungal infections were <i>Tinea pedis</i>	Dose A 2 (10.0%)	Dose B 0

These phase 2 findings provide initial evidence that bimekizumab may be an **effective treatment option for adolescents with psoriasis** and support the phase 3 evaluation of bimekizumab in **adolescents and children**.

High rates of skin clearance were generally sustained through Week 124

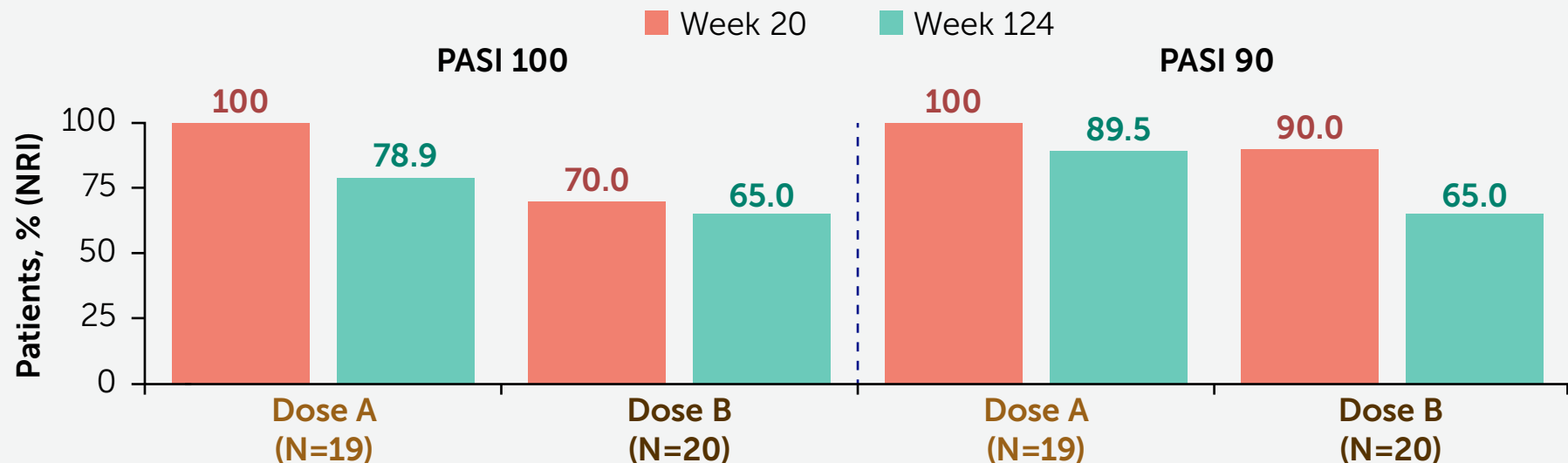
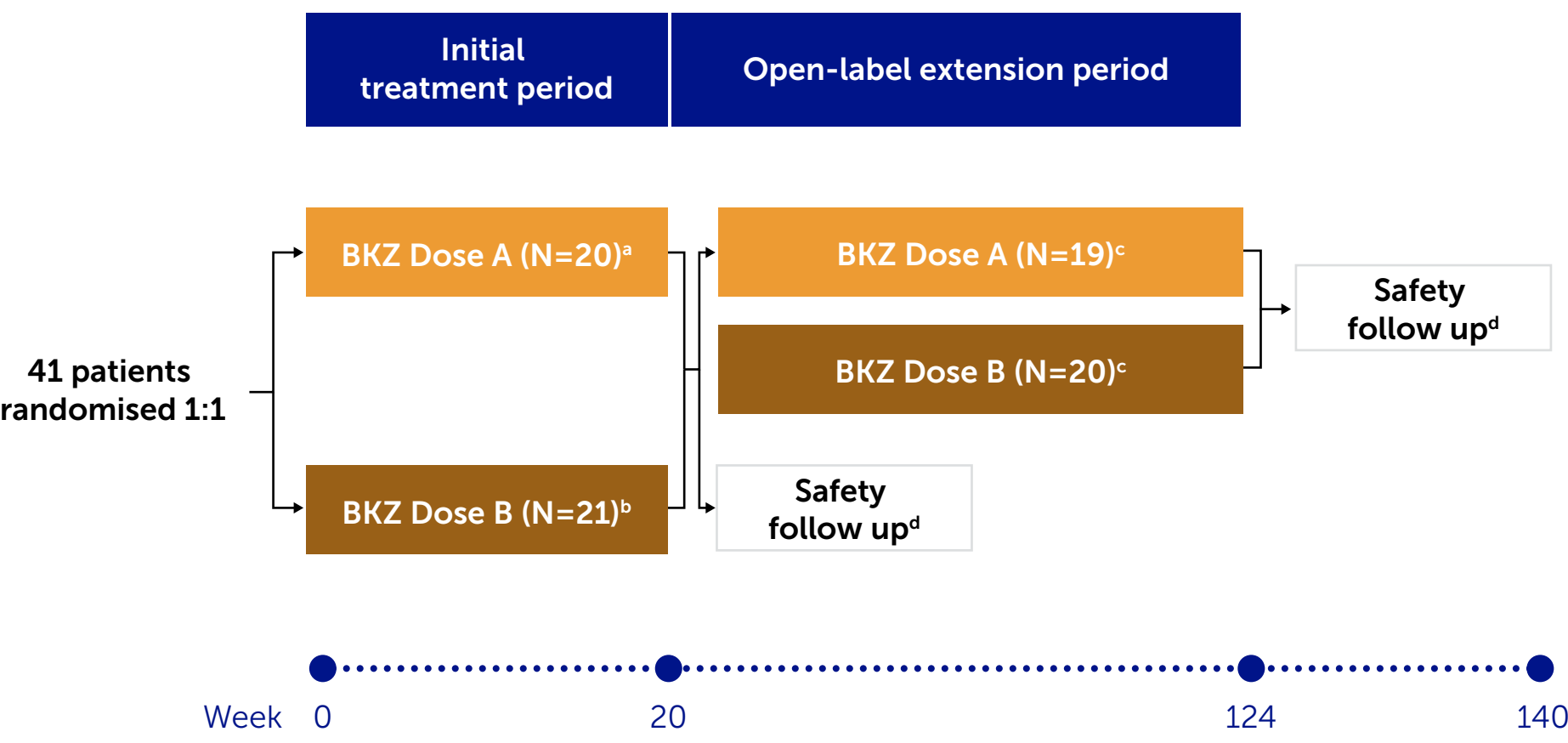


Figure 1 Study design



All enrolled patients had moderate to severe psoriasis, defined as: PASI ≥12 (or PASI ≥10 plus clinically relevant involvement in ≥1 of the following regions: face, genital, hand/foot); IGA score ≥3 and ≥10% BSA affected by psoriasis. **[a]** Dose A was predicted to achieve comparable systemic exposure to that of BKZ 320 mg Q4W in adults. **[b]** Dose B was predicted to achieve lower systemic exposure than Dose A. **[c]** Three patients discontinued during the OLE (Dose A: two lone withdrew consent, one moved abroad; Dose B: one [lack of efficacy]). **[d]** The safety follow up period was scheduled 20 weeks after the final dose of BKZ.

Figure 2 BKZ plasma concentration through Week 124

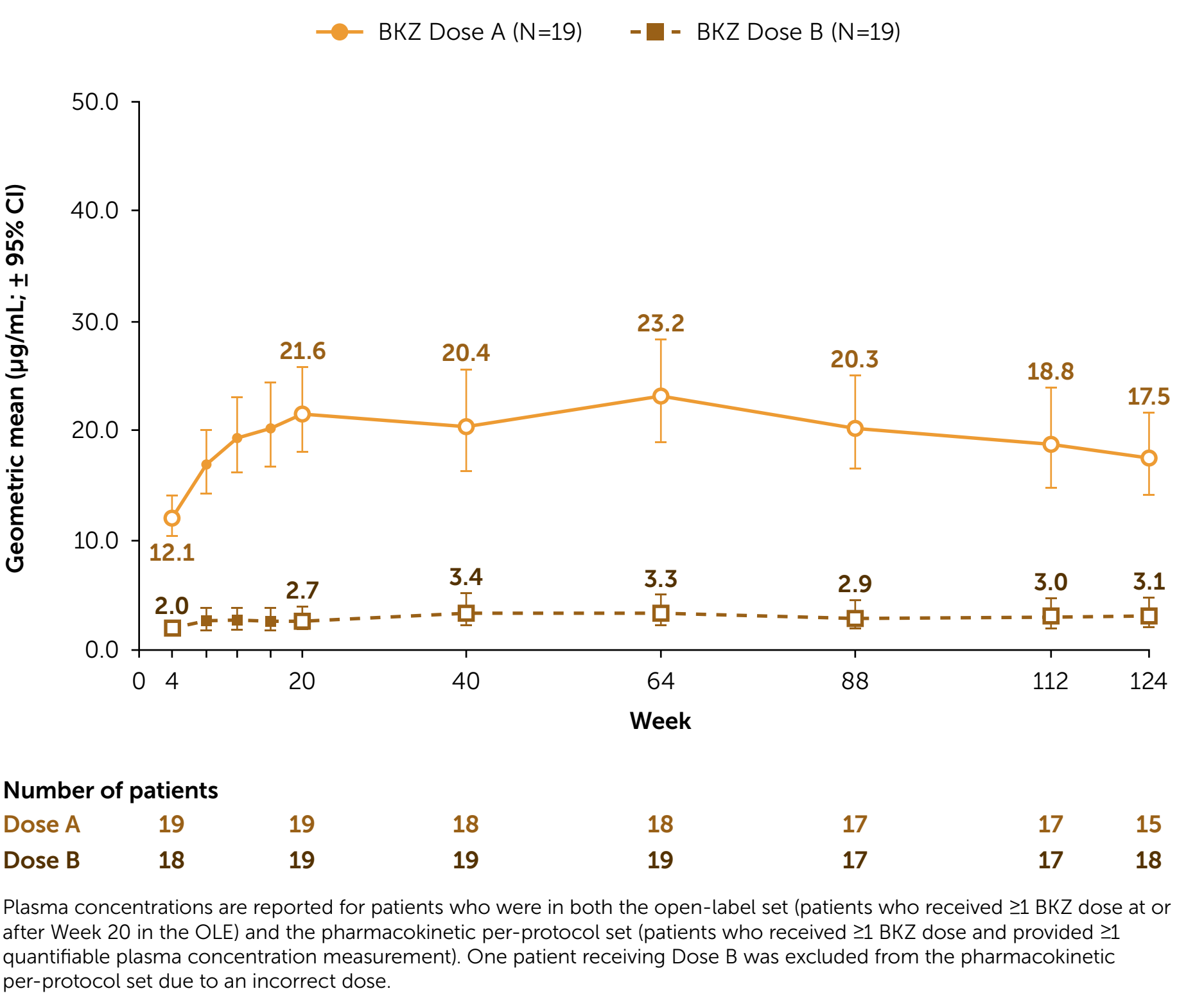
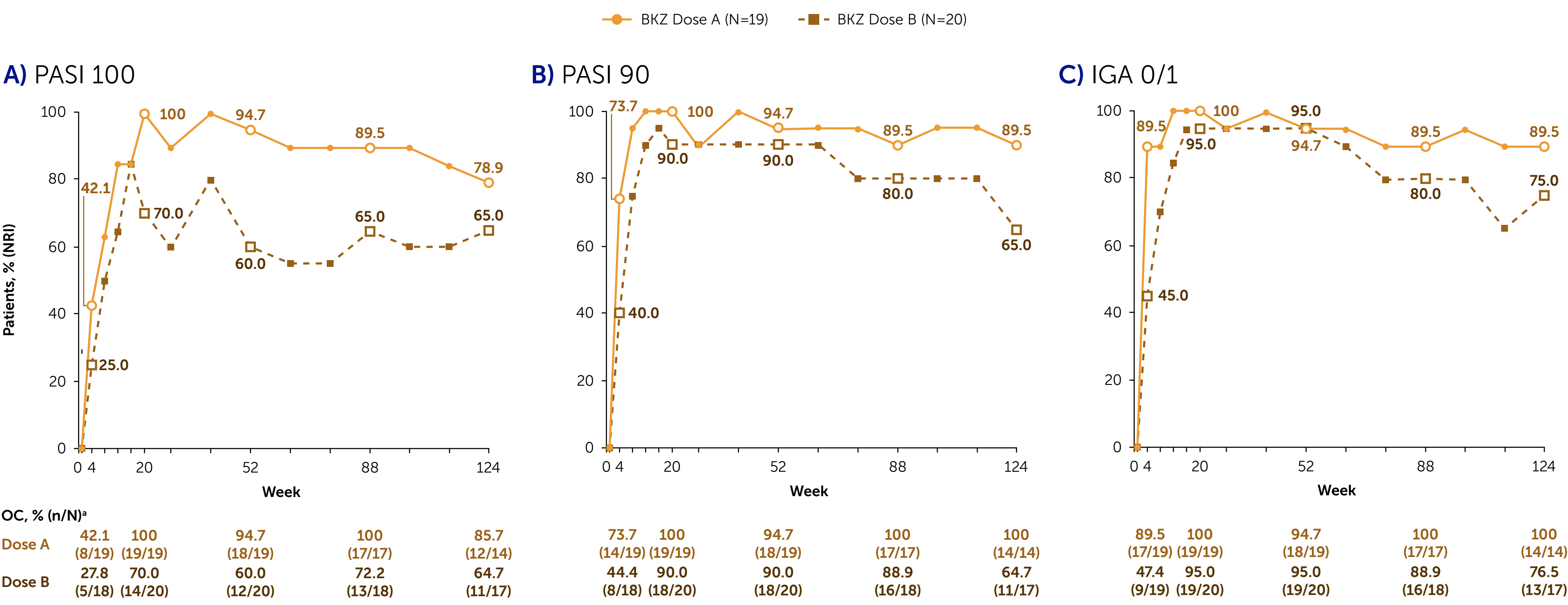


Figure 3 Clinical efficacy from baseline through Week 124 (NRI, OC)



Efficacy data are reported for the open-label set (all patients who received ≥1 BKZ dose at or after Week 20 in the OLE). **[a]** Data collected >5 days outside of the 4-week dosing interval were considered missing; therefore, any Week 124 data collected >5 days late (last BKZ dose at Week 120) were excluded from the OC analysis.

AE: adverse event; ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; BSA: body surface area; CDLQI: Children's Dermatology Life Quality Index; CI: confidence interval; IGA: Investigator's Global Assessment; ITP: initial treatment period; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; TB: tuberculosis; TEAE: treatment-emergent adverse event.

References: ¹Ramond A et al. *Dermatol Ther* (Heidelberg) 2025;15:3765–76; ²Hebert AA et al. *J Dermatol Treat* 2022;33:2433–42; ³Adams R et al. *Front Immunol* 2020;11:1894; ⁴European Medicines Agency. Available at: www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [Accessed September 2026]; ⁵FDA. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761151s0101b1.pdf [Accessed September 2026]; ⁶Paller et al. Presented at AAD 2026;P73380; ⁷BE CONNECTED. Available at: <https://clinicaltrials.gov/study/NCT04718896> [Accessed September 2026]; ⁸Blauvelt A et al. *J Am Acad Dermatol* 2025;93:644–53; ⁹Warren RB et al. *Br J Dermatol* 2025;193:44–5. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **API, JCS, AR, PC, FS, DD, MM, AD, APa**; Drafting of the publication, or reviewing it critically for important intellectual content: **API, JCS, AR, PC, FS, DD, MM, AD, APa**. **Final approval of the publication:** **API, JCS, AR, PC, FS, DD, MM, AD, APa**. **Author Disclosures:** **API:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Chema Rzeszów, Dermira, DICE Therapeutics, Galderma, Incyte, Inflix, Janssen, Kiniksa, Kymab, LEO Pharma, Medac, Novartis, Pfizer, Regeneron, Roche, Trevi Therapeutics and UCB. **PC, FS, DD, MM, AD:** Employees and shareholders of UCB. **APa:** Investigator, consultant and/or data and safety monitoring board member for AbbVie, Abeona Therapeutics, Arcutis, BioCryst, BioMedicines, Boehringer Ingelheim, Castle Creek Biosciences, Chiesi, Daiichi Sankyo, Dermavant, Eli Lilly and Company, Galderma, Incyte, Johnson & Johnson Innovative Medicine, Krystal Biotech, LEO Pharma, L'Oréal, MoonLake Immunotherapeutics, Pelthos, Quoin, Regeneron Pharmaceuticals and Sanofi. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors also thank Inés Duñas Pousa, PhD, of UCB for editorial review during poster development and publication coordination, Ujjawal Kumar, MA (Cantab.) MB BChir, Costello Medical, UK, for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.



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