Bimekizumab PASI response levels in Week 16 PASI responders with moderate to severe plaque psoriasis through 4 years: Results from BE BRIGHT

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Objective

To evaluate the maintenance of 100%/≥90%/≥75% improvements from baseline in Psoriasis Area Severity Index (PASI) over 4 years in patients who achieved complete skin clearance after 16 weeks of bimekizumab (BKZ) treatment.

Introduction

- Patients with psoriasis treated with biologic therapies often lose their response to treatment over time. Therefore, it is important to study the durability of treatment efficacy to determine if responses are maintained throughout long-term management of the disease.
- Treatment with BKZ, a monoclonal IgG1 antibody that inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated rapid and high levels of complete skin clearance through 4 years in patients with moderate to severe plaque psoriasis, with low reduction in response rates over time.[1,2]
- Here, patients who achieved the most stringent outcome (PASI 100) after 4 months (16 weeks) of BKZ treatment were followed through 4 years.
  - We report the proportion of patients maintaining PASI 100, alongside the proportions of patients maintaining PASI 90 and PASI 75, to help understand the magnitude of any fluctuations in their symptoms over time.

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension (OLE), BE BRIGHT (**Figure 1**).[3–6]
  - Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ Q4W or every 8 weeks (Q4W) in the maintenance period and OLE.
  - All patients received BKZ Q8W from OLE Week 48 or the next scheduled clinic visit.
- PASI 100/90/75 responses are reported in Week 16 PASI 100 responders over 4 years.
- Data are reported regardless of dosing regimen (BKZ Total), and for the subset of patients who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).[7]
- Responses are reported using modified non-responder imputation (mNRI):
  - Patients who discontinued due to lack of efficacy/ treatment-related adverse events were considered non-responders at subsequent timepoints.
  - Multiple imputation was used for all other missing data.
- Observed case (OC) data are also reported.

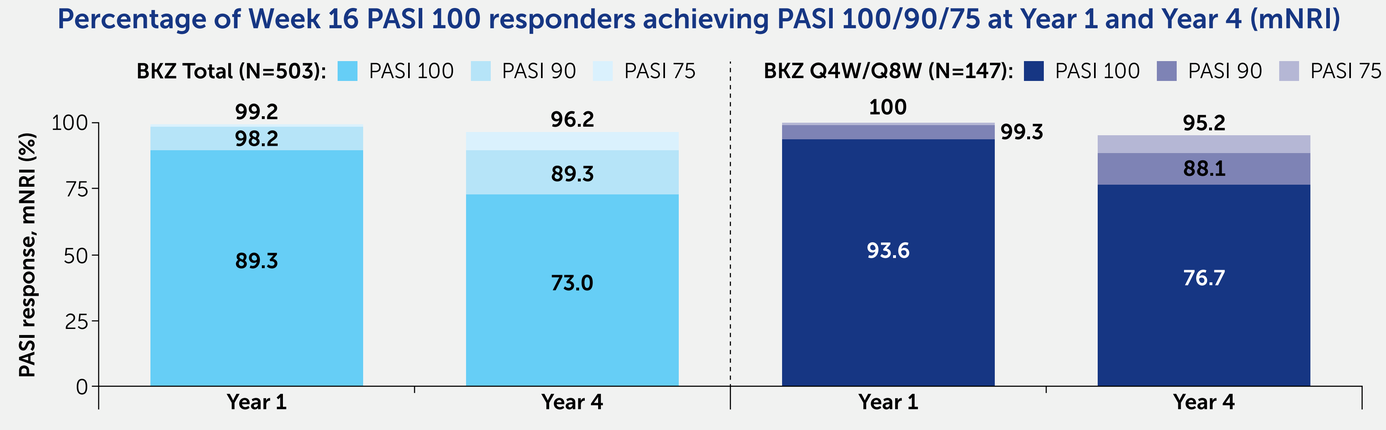
Results

- At Week 16, 620 BKZ patients achieved PASI 100 (NRI); 503 (81.1%) of these patients entered the OLE, receiving BKZ continuously up to 4 years (BKZ Total).
  - 147 of these patients received BKZ Q4W/Q8W.
- Of the Week 16 PASI 100 responders that entered the OLE, 84.9% of BKZ Total patients completed Year 4 (85.7% of BKZ Q4W/Q8W patients).
- For the BKZ Total group, 89.3% (95% confidence intervals [CIs]: 86.5%, 92.0%) of Week 16 PASI 100 responders maintained PASI 100 to Year 1; 73.0% (95% CIs: 68.7%, 77.4%) maintained PASI 100 to Year 4 (**Figure 2**).
  - PASI 90 was maintained by 98.2% (95% CIs: not estimable [NE]) at Year 1 and 89.3% (95% CIs: 86.2%, 92.3%) at Year 4.
  - PASI 75 was maintained by 99.2% (95% CIs: NE) at Year 1 and 96.2% (95% CIs: 94.5%, 98.0%) at Year 4.
- In the subgroup who received BKZ Q4W/Q8W, PASI 100/90/75 responses were similarly high through 4 years.

Conclusions

High proportions of bimekizumab-treated patients who achieved complete skin clearance (PASI 100) after 4 months maintained this response through 4 years. A large majority of patients who did not maintain PASI 100 sustained PASI 90, and almost all maintained at least PASI 75 over 4 years.

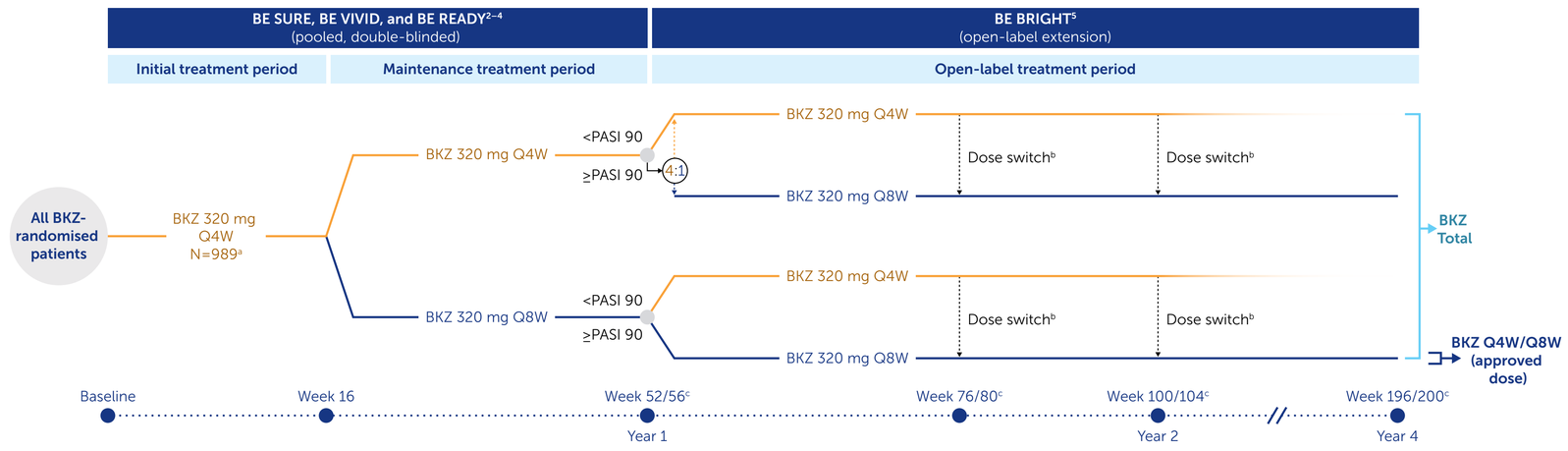
Summary



Around **three-quarters** of patients who achieved **complete skin clearance** (PASI 100) at Week 16 maintained this response over 4 years.

Nearly 90% maintained PASI 90 and **over 95%** maintained at least PASI 75 over 4 years.

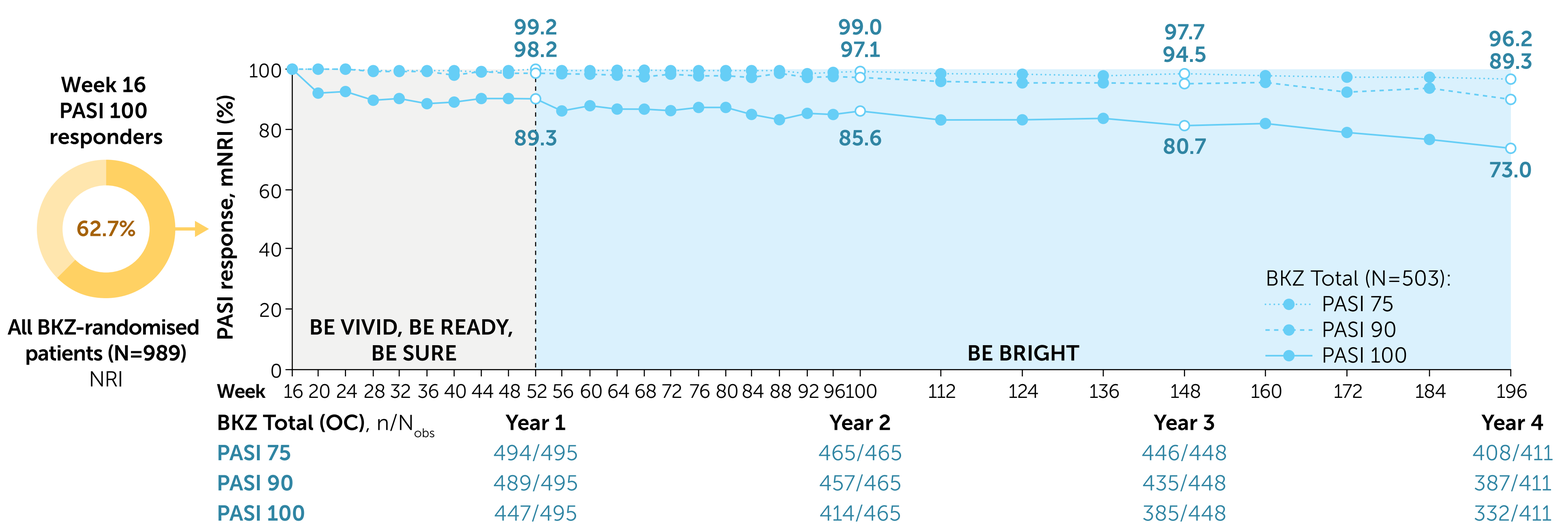
Figure 1 BE BRIGHT study design



[a] In BE READY, some BKZ-randomised patients were re-randomised to placebo at Week 16. These patients were excluded from this analysis; **[b]** At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[c]** Different week numbers are presented due to different feeder study lengths; for example Week 52/56 refers to Year 1/start of OLE, and corresponds to Week 52 in BE VIVID and Week 56 in BE SURE and BE READY.

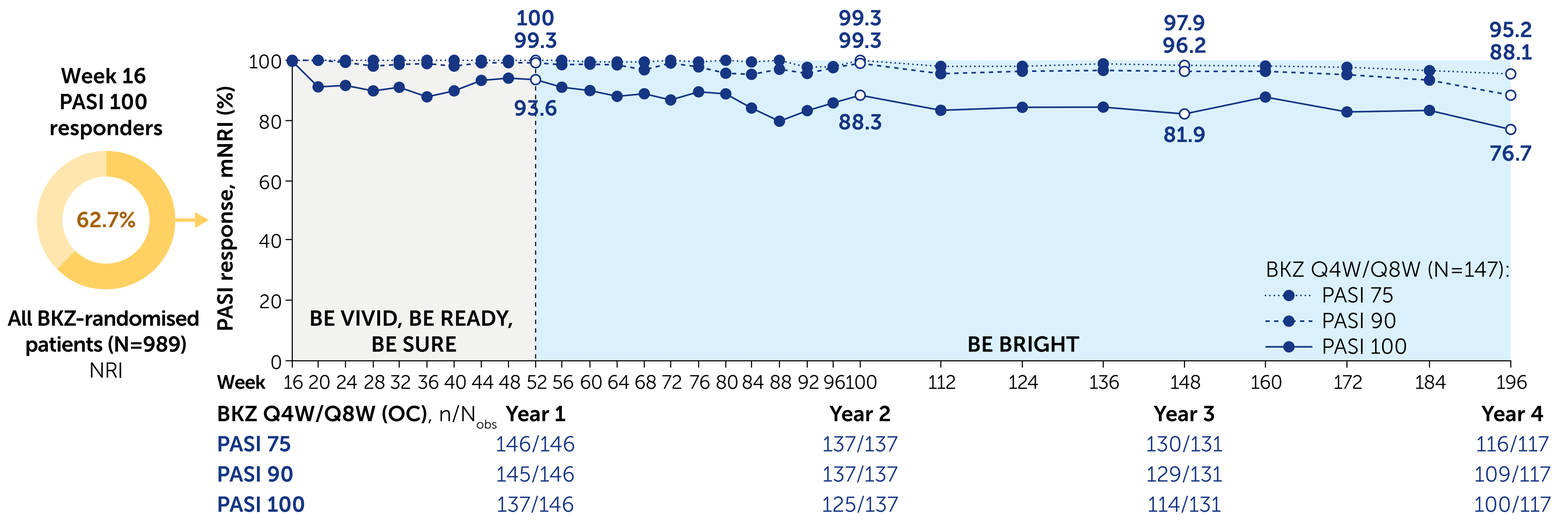
Figure 2 PASI response in Week 16 PASI 100 responders to Year 4 (mNRI and OC)

A) BKZ Total group



BKZ Total (OC), n/N_{obs}	Year 1	Year 2	Year 3	Year 4
PASI 75	494/495	465/465	446/448	408/411
PASI 90	489/495	457/465	435/448	387/411
PASI 100	447/495	414/465	385/448	332/411

B) BKZ Q4W/Q8W group



BKZ Q4W/Q8W (OC), n/N_{obs}	Year 1	Year 2	Year 3	Year 4
PASI 75	146/146	137/137	130/131	116/117
PASI 90	145/146	137/137	129/131	109/117
PASI 100	137/146	125/137	114/131	100/117

For mNRI, patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.[4] BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE.

BKZ: bimekizumab; **CI:** confidence interval; **IL:** interleukin; **mNRI:** modified non-responder imputation; **NE:** not estimable; **N_{obs}:** observed N; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI:** Psoriasis Area and Severity Index; **PASI 100/90/75:** 100%/≥90%/≥75% improvement from baseline in PASI; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks.

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Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed April 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DT**, **DR**, **JC**, **CC**, **SP**, **KAP**, **JMLP**, **SK**, **MK**, **BS**; Drafting of the publication, or reviewing it critically for important intellectual content: **DT**, **DR**, **JC**, **CC**, **SP**, **KAP**, **JMLP**, **SK**, **MK**, **BS**; Final approval of the publication: **DT**, **DR**, **JC**, **CC**, **SP**, **KAP**, **JMLP**, **SK**, **MK**, **BS**. **Author Disclosures:** **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **DR:** Received honoraria as a consultant for AbbVie, Abcuro, AltruBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Dermavant, Dermira, Eli Lilly and Company, Incyte, Janssen, Kyowa Kirin, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB, and VielaBio; has received research support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Galderma, Incyte, Janssen, Merck, Novartis, Pfizer, and Regeneron; and has served as a paid speaker for AbbVie, Amgen, Celgene, Eli Lilly and Company, Janssen, Novartis, Pfizer, Regeneron, and Sanofi. **JC:** Received research/grant support from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MC2 Therapeutics, Merck, Novartis, Pfizer, Regeneron, Sandoz, Sanofi, Sun Pharma, UCB, and Verrica Pharmaceuticals; has served as consultant for AbbVie, Amgen, Celgene, Dermira Inc., Eli Lilly and Company, Novartis, Sun Pharma and UCB; has worked on speakers bureau for AbbVie, Eli Lilly and Company, Janssen, Novartis, Regeneron, Sanofi, and UCB. **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, Merck, Novartis, Pfizer, Samsung, Sanofi, and UCB. **SP:** Served as consultant and/or speaker for AbbVie, Almirall, Celgene, Janssen, LEO Pharma, Eli Lilly and Company, Merck, Novartis, Pfizer, Sandoz, and UCB. **KAP:** Received honoraria and/or grants from AbbVie, Acelyrin, Akros, Alamar, Almirall, Alumis, Amgen, Arcutis, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite Biopharma, Celltrion, Concert Pharmaceuticals, Dermavant, Dermira, DiCE Pharmaceuticals, DiCE Therapeutics, Eli Lilly and Company, Evelo Biosciences, Forbion, Galderma, Horizon Therapeutics, Incyte, Janssen, Kymab, Kyowa Hakko Kirin, LEO Pharma, Meiji Seika Pharma, Mitsubishi Pharma, Nimbus Therapeutics, Novartis, Pfizer, Reistone, Sanofi-Aventis/Genzyme, Sandoz, Sun Pharma, Takeda, Tarsus Pharmaceuticals, UCB, and Zai Lab. **JMLP:** Employee and shareholder of UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharma, Nesos, Novartis, Onward, PharPoint Research, Summit Analytical, Tonix, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano. **MK:** Employee of UCB. **BS:** Consultant (honoraria): AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas (formerly Corrona), Dermavant, Eli Lilly and Company, Imagenebio, Janssen, Kangpu Pharmaceuticals, LEO Pharma, Maruho, Meiji Seika Pharma, Monte Carlo, Novartis, Pfizer, Protagonist, Rapt, Regeneron, Sanofi Genzyme, SG Cowen, Sun Pharma, Takeda, UCB, Union Therapeutics, Ventyxbio, and vTv Therapeutics; stock options from Connect Biopharma, Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi Genzyme; Scientific Co Director (consulting fee): CorEvitas (formerly Corrona) Psoriasis Registry; investigator for CorEvitas (formerly Corrona) Psoriasis Registry; editor-in-chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **Acknowledgements:** These studies were funded by UCB. 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