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Bimekizumab maintenance of response from the end of pivotal trials through 4 years: Results in patients with moderate to severe plaque psoriasis from BE BRIGHT

Kenneth B. Gordon,[1] Jennifer Cather,[2] David Pariser,[3] Michael Sebastian,[4] Peter Foley,[5] Masahiro Kamata,[6] Owen Davies,[7] Sarah Kavanagh,[8] Krista Wixted,[8] Richard B. Warren[9,10]

Objective

To investigate maintenance of response in patients who achieved key clinical and patient-reported outcomes after 1 year (end of pivotal trials) of bimekizumab (BKZ) treatment, through 4 years (196 weeks).

Introduction

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F and 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.[2–4]
- Notably, BKZ has shown an established long-term durability of response,[5] a crucial factor given the chronic nature of psoriasis.[6]
- Maintenance of high response rates with BKZ treatment have been reported previously through 4 years in patients with moderate to severe plaque psoriasis who achieved clinical responses at Week 16.[7]

Methods

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY pivotal phase 3 trials, and their open-label extension (OLE), BE BRIGHT.[2–5,8]
- Included patients were randomised to BKZ 320 mg every 4 weeks (Q4W) at baseline to Week 16, then received BKZ Q4W or every 8 weeks (Q8W) until OLE entry (Week 52/56; Year 1). In the OLE, patients received BKZ Q4W or Q8W based on Psoriasis Area and Severity Index (PASI) response and prior maintenance dose.[6]
- Data are reported for the combined BKZ dose groups (BKZ Total) and for the subset of patients receiving BKZ Q4W to Week 16 then Q8W continuously into the OLE (BKZ Q4W/Q8W), the approved dosing regimen for most patients with psoriasis.[9]
- Maintenance of ≥90% and 100% improvement from baseline in PASI (PASI 90 and PASI 100), Investigator's Global Assessment (IGA) 0/1 response, and Dermatology Life Quality Index (DLQI) 0/1 response through Year 4 (Week 196) are reported in Year 1 PASI 90, PASI 100, IGA 0/1, and DLQI 0/1 responders, respectively.
- Responses are reported using modified non-responder imputation (mNRI), NRI, and observed case (OC). For 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, 771 patients were randomised to BKZ at baseline and received BKZ in the maintenance period and on OLE entry (**Table 1**).
- Of the 771 patients in the BKZ Total group, 699 (90.7%), 583 (75.6%), 685 (88.8%), and 621 (80.5%) patients were PASI 90, PASI 100, IGA 0/1, and DLQI 0/1 responders at Year 1, respectively (NRI; **Figure 1A–D**).
  - Of the 197 patients in the BKZ Q4W/Q8W group, 192 (97.5%), 167 (84.8%), 193 (98.0%), and 168 (85.3%) patients were PASI 90, PASI 100, IGA 0/1, and DLQI 0/1 responders at Year 1, respectively.
- PASI 90 responses were maintained by the vast majority of Year 1 responders through Year 2 and Year 3, and 87.9% maintained PASI 90 to Year 4 (Week 196; mNRI; **Figure 1A**).
- Among Year 1 PASI 100 responders, a large proportion of responses were maintained through Year 2 and Year 3, and 74.3% to Year 4 (mNRI; **Figure 1B**).
- Among IGA 0/1 and DLQI 0/1 Year 1 responders, 89.5% and 82.9% maintained their respective responses at Year 4 (mNRI; **Figure 1C–D**).
- Similarly high maintenance of PASI 90, PASI 100, IGA 0/1, and DLQI 0/1 responses over 4 years was observed in Year 1 responders who received BKZ Q4W/Q8W (**Figure 1A–D**).

Conclusions

The majority of patients who achieved complete or near-complete skin clearance, or reported no impact of skin disease on their life after 1 year of bimekizumab treatment (end of pivotal trials), maintained these responses through 4 years. Maintenance of response in patients receiving BKZ Q4W/Q8W was consistent with the overall population, where all dose groups were combined.

Summary

Maintenance of 1-year responses through 4 years of BKZ treatment

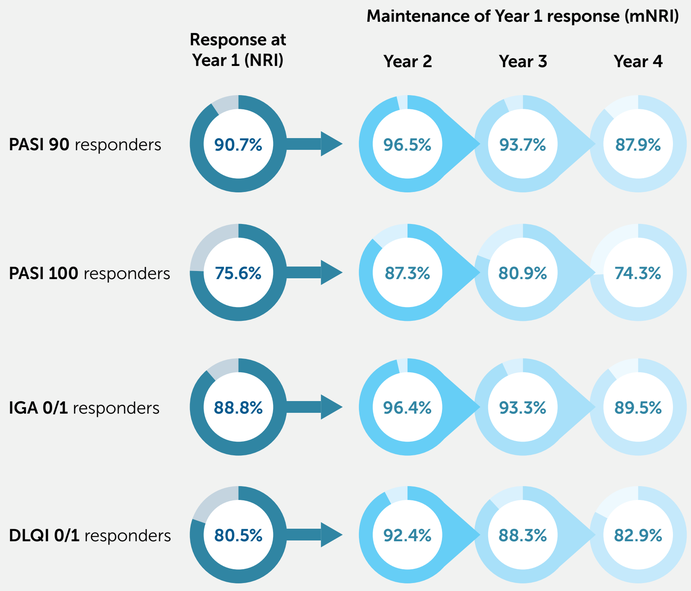


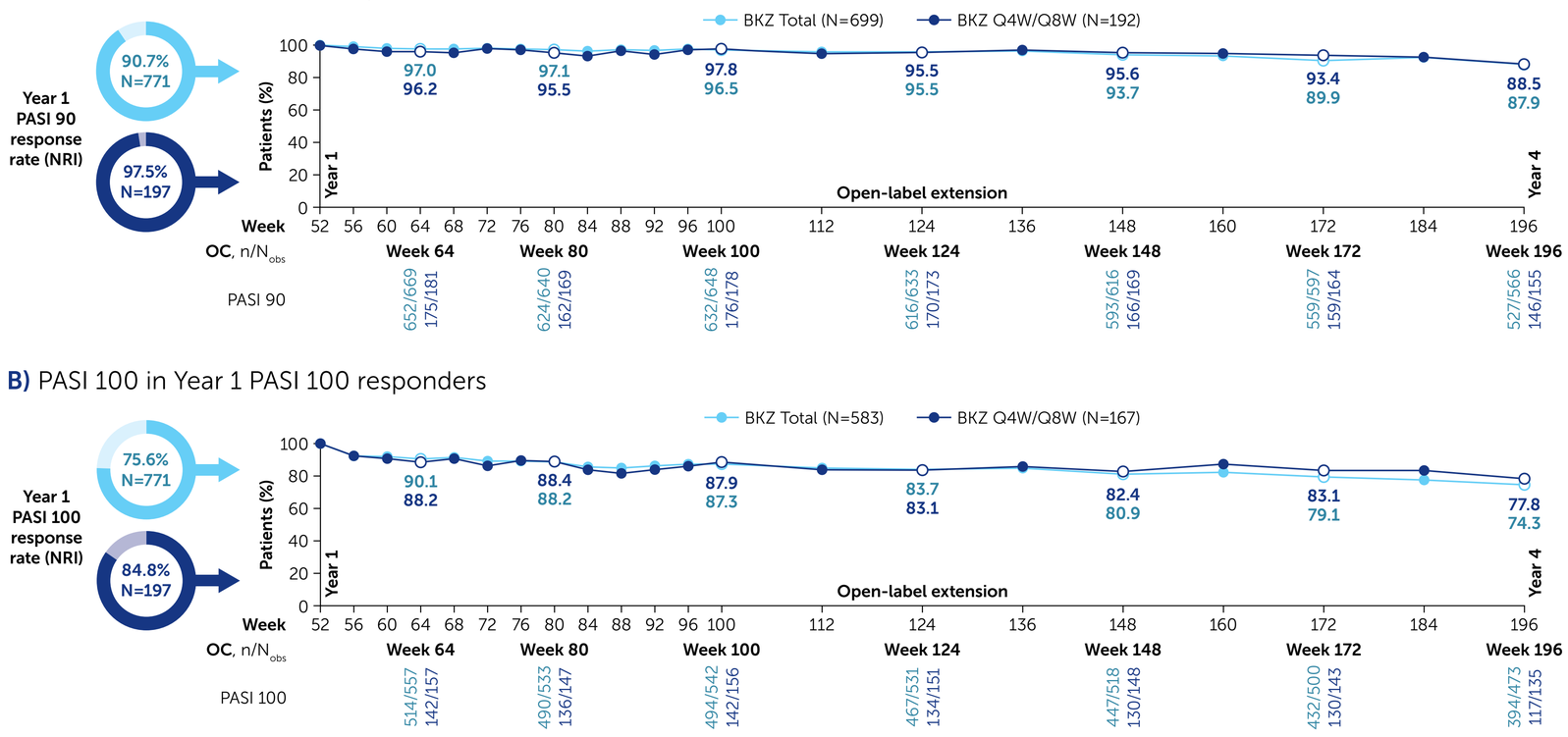
Table 1 Baseline characteristics

	Year 1 PASI 90 responders	Year 1 PASI 100 responders	Year 1 IGA 0/1 responders	Year 1 DLQI 0/1 responders
	BKZ Total N=699	BKZ Total N=583	BKZ Total N=685	BKZ Total N=621
Age (years), mean ± SD	45.3 ± 13.6	44.2 ± 13.4	45.0 ± 13.5	45.3 ± 13.5
Sex, **male**, n (%)	493 (70.5)	408 (70.0)	483 (70.5)	441 (71.0)
Racial group, **white**, n (%)	601 (86.0)	511 (87.7)	592 (86.4)	543 (87.4)
Weight (kg), mean ± SD	88.8 ± 20.9	88.8 ± 20.2	88.8 ± 20.7	89.0 ± 20.9
Disease duration (years), mean ± SD	18.3 ± 12.4	18.1 ± 12.2	18.2 ± 12.3	18.5 ± 12.3
PASI, mean ± SD	21.4 ± 7.7	21.1 ± 7.3	21.3 ± 7.6	21.3 ± 7.6
BSA (%), mean ± SD	27.5 ± 15.8	27.0 ± 15.3	27.4 ± 15.7	27.3 ± 15.7
IGA, n (%)				
3: moderate	463 (66.2)	394 (67.6)	457 (66.7)	420 (67.6)
4: severe	235 (33.6)	189 (32.4)	228 (33.3)	200 (32.2)
DLQI total, mean ± SD	10.6 ± 6.3	10.6 ± 6.2	10.5 ± 6.2	10.2 ± 6.1
Any prior systemic therapy, n (%)	563 (80.5)	471 (80.8)	547 (79.9)	505 (81.3)
Any prior biologic therapy, n (%)	278 (39.8)	231 (39.6)	269 (39.3)	252 (40.6)
Anti-TNF	95 (13.6)	74 (12.7)	89 (13.0)	90 (14.5)
Anti-IL-17	175 (25.0)	145 (24.9)	170 (24.8)	155 (25.0)
Anti-IL-12/23	36 (5.2)	31 (5.3)	35 (5.1)	34 (5.5)
Anti-IL-23	35 (5.0)	28 (4.8)	33 (4.8)	30 (4.8)

Only patients who entered the OLE are included.

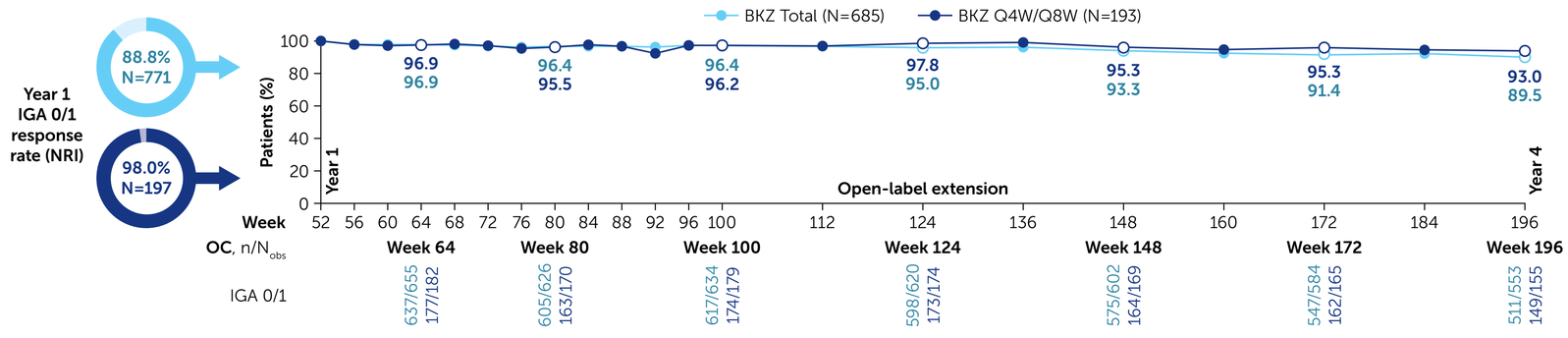
Figure 1 Maintenance of PASI 90, PASI 100, IGA 0/1, and DLQI 0/1 in Year 1 responders who entered the BE BRIGHT OLE through Year 4 (mNRI, OC)

A) PASI 90 in Year 1 PASI 90 responders

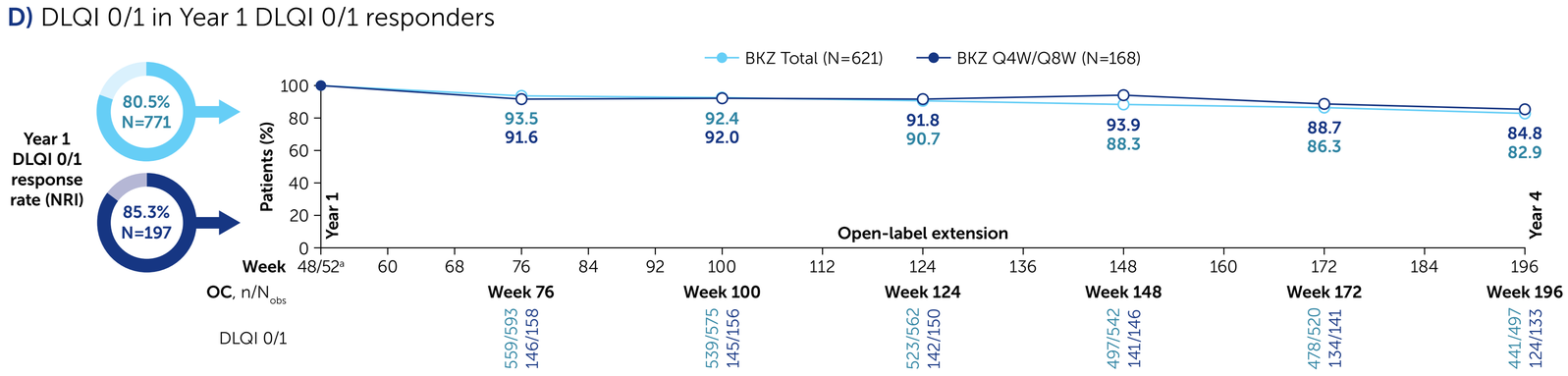


B) PASI 100 in Year 1 PASI 100 responders

C) IGA 0/1 in Year 1 IGA 0/1 responders



D) DLQI 0/1 in Year 1 DLQI 0/1 responders



Response rates for efficacy outcomes are reported among patients who achieved PASI 90, PASI 100, IGA 0/1, or DLQI 0/1 at Year 1 and entered the OLE. 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. 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. **[a]** Due to lack of common timepoints at which the DLQI was assessed, Week 48 (BE SURE and BE READY)/52 (BE VIVID) was used as a composite last timepoint before OLE entry (Year 1) when pooling the studies.

BKZ: bimekizumab; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **N_{obs}:** observed N; **OC:** observed case; **OLE:** open-label extension; **PASI 90/100:** ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TNF:** tumour necrosis factor.

Institutions: [1]Department of Dermatology, Medical College of Wisconsin, Milwaukee, Wisconsin, USA; [2]Mindful Dermatology and Modern Research Associates, Dallas, Texas, USA; [3]Eastern Virginia Medical School Department of Dermatology and Virginia Clinical Research, Inc, Norfolk, Virginia, USA; [4]Dermatologie Mahlow Practice Dr. med. Michael Sebastian, Mahlow, Germany; [5]The University of Melbourne, St. Vincent's Hospital Melbourne, Skin Health Institute, Carlton, Victoria, Australia; [6]Department of Dermatology, Teikyo University School of Medicine, Tokyo, Japan; [7]UCB, Slough, UK; [8]UCB, Morrisville, North Carolina, USA; [9]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, UK; [10]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, UK.

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Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed September 2024]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **KBG**, **JC**, **DP**, **MS**, **PF**, **MK**, **OD**, **SK**, **KW**, **RBW**; Drafting of the publication, or reviewing it critically for important intellectual content: **KBG**, **JC**, **DP**, **MS**, **PF**, **MK**, **OD**, **SK**, **KW**, **RBW**; Final approval of the publication: **KBG**, **JC**, **DP**, **MS**, **PF**, **MK**, **OD**, **SK**, **KW**, **RBW**. **Author Disclosures:** **KBG:** Consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis, and UCB. **JC:** Advisor for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, and Eli Lilly and Company; speaker for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, and Pfizer; clinical trials performed for AbbVie, Amgen, Bristol Myers Squibb, Celgene, ChemoCentryx, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Menlo Therapeutics, Sun Pharma, and UCB. **DP:** Honoraria for participation on advisory boards, data safety monitoring boards, consultancy, or as an investigator from Atacama Therapeutics, Bickel Biotechnology, Biofrontera AG, Bristol Myers Squibb, Celgene, Dermira, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, TheraVida, and Valeant; grants/research funding from Almirall, Amgen, AOBiome, Asana Biosciences, Bickel Biotechnology, Celgene, Dermavant, Dermira, Eli Lilly and Company, LEO Pharma, Menlo Therapeutics, Merck, Novartis, Novo Nordisk, Ortho Dermatologics, Pfizer, and Regeneron. **MS:** Received honoraria as an investigator, or received grants and has been an advisor/consultant for AbbVie, Affibody, Almirall, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Dr. August Wolff, Dr. Reddy's Laboratories, Eli Lilly and Company, Galderma, Genentech, GSK, Incyte, Janssen, LEO Pharma, MedImmune, MSD, Mundipharma, Novartis, Pfizer, Regeneron, and UCB. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; 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, and Valeant; advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB, and Valeant; consultant for Aslan, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GenesisCare, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB, and Wintermute; received travel grants from AbbVie, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sun Pharma, and Sanofi; 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, and Valeant. **MK:** Honoraria for lectures from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Kyowa Kirin, Maruho, Taiho Pharmaceutical, Torii Pharmaceutical, and UCB. **OD**, **KW:** Employees and shareholders 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, Tonix, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis. **Acknowledgements:** This study was funded by UCB. 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