Bimekizumab efficacy over two years in patients with moderate to severe plaque psoriasis with scalp and nail involvement who switched from adalimumab, ustekinumab, or secukinumab: Results from the BE SURE, BE VIVID, BE BRIGHT, and BE RADIANT phase 3/3b trials

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Objectives

To evaluate scalp and nail outcomes over two years in patients with moderate to severe plaque psoriasis who switched to bimekizumab (BKZ) from adalimumab (ADA), ustekinumab (UST), or secukinumab (SEC).

Introduction

- Patients with moderate to severe plaque psoriasis may choose to switch biologics due to an inadequate response to their current biologic therapy.[1]
- For patients and clinicians to make informed treatment decisions, it is important to determine the efficacy of switching biologics.
- Psoriatic lesions in highly visible areas, such as the scalp and nails, disproportionately impair patients' health-related quality of life.[2]

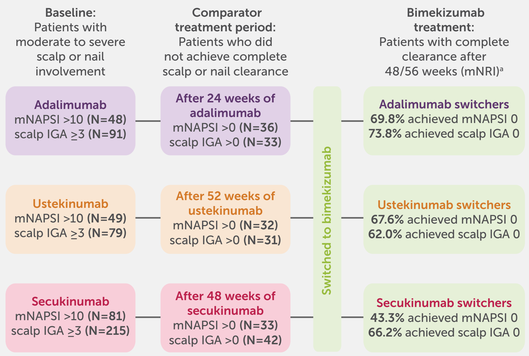
Materials and Methods

- Patients in these analyses switched to BKZ from ADA after 24 weeks, UST after 52 weeks or SEC after 48 weeks as shown in **Figure 1**.[3–6]
- Regional involvement was analysed using the modified Nail Psoriasis Severity Index (mNAPSI; total fingernail score on a 0–130 scale) and the scalp Investigator's Global Assessment (IGA; 5-point scale [0–4]):
  - mNAPSI 0 and scalp IGA 0 responses are reported for patients with moderate to severe regional involvement at baseline (mNAPSI >10; scalp IGA ≥3) who had not achieved complete clearance (mNAPSI 0; scalp IGA 0) at time of switch to BKZ.
- Data are reported using modified non-responder imputation (mNRI), NRI, and as the observed case (OC).
  - For mNRI, patients who discontinued due to lack of efficacy were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results

- Baseline demographics for all patients with baseline mNAPSI >10 and scalp IGA ≥3 are shown in **Table 1**.
- In patients with baseline mNAPSI >10 who switched to BKZ from ADA (N=48), UST (N=49) or SEC (N=81), mean (range) mNAPSI at switch was 8.0 (0.0–45.0), 8.2 (0.0–35.0), and 4.1 (0.0–40.0).
- In these patients, 36 on ADA, 32 on UST, and 33 on SEC had not achieved mNAPSI 0 at switch to BKZ (**Figure 2**). At switch, mean (range) mNAPSI in these non-responders was 10.6 (1.0–45.0), 12.6 (2.0–35.0), and 10.0 (1.0–40.0).
  - Improvements in mNAPSI 0 response rates were observed 24 weeks after switching to BKZ, and responses were maintained or improved with BKZ for up to 80 weeks (Year Two; mNRI; **Figure 2**).
- In patients with baseline scalp IGA ≥3 who switched to BKZ from ADA (N=91), UST (N=79) or SEC (N=215), mean (range) scalp IGA at switch was 0.7 (0.0–4.0), 0.7 (0.0–4.0), and 0.3 (0.0–3.0).
- In these patients, 33 on ADA, 31 on UST, and 42 on SEC had not achieved scalp IGA 0 at switch to BKZ (**Figure 2**). At switch, mean (range) scalp IGA in these non-responders was 1.9 (1.0–4.0), 1.7 (1.0–4.0), and 1.4 (1.0–3.0).
  - A high proportion of these patients achieved scalp IGA 0 24 weeks after switching to BKZ. Patients who switched to BKZ from ADA and SEC maintained their responses for at least 48 weeks and up to 80 weeks (Year Two; mNRI; **Figure 2**).
- Rates of complete regional clearance of scalp and nail psoriasis after switching to BKZ are shown using mNRI, NRI, and OC in **Table 2**.

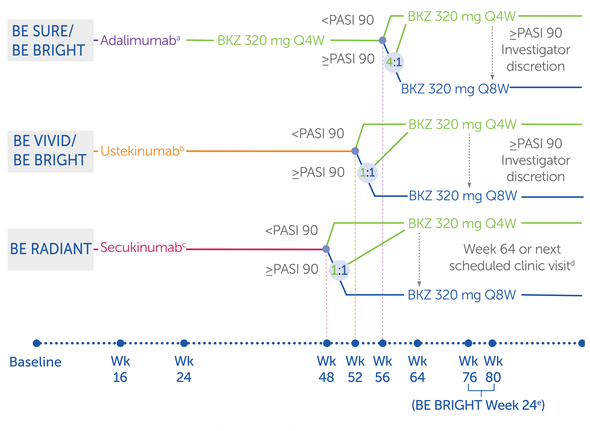
Summary



[a]Data presented are 56 weeks after switch to BKZ for ADA, and 48 weeks after switch to BKZ for UST and SEC.

High proportions of patients who did not achieve mNAPSI 0 or scalp IGA 0 with ADA, UST, or SEC achieved complete clearance after switching to BKZ.

Figure 1 Study design



Only active-comparator treatment groups in BE SURE, BE VIVID, and BE RADIANT are shown. Patients who completed BE SURE or BE VIVID could enroll in the BE BRIGHT OLE and received BKZ Q4W or Q8W, depending on PASI response on completion of the feeder trial. Patients who completed the 48-week double-blinded treatment period of BE RADIANT could enter the BE RADIANT OLE and received BKZ Q4W or Q8W, depending on Week 48 PASI response. In these analyses, BKZ Q4W and Q8W treatment arms for each trial are pooled. [a]Dosed 80 mg at baseline, 40 mg at Week 1, then 40 mg Q2W; [b]Dosing based on bodyweight at baseline: 45 mg for patients weighing ≤100 kg, and 90 mg patients weighing >100 kg, received at baseline; Week 4, then Q12W; [c]Dosed 300 mg weekly to Week 4, then Q4W; [d]At Week 64, or the next scheduled clinic visit, patients switched from BKZ 320 mg Q4W to Q8W after the implementation of a protocol amendment; [e]At BE BRIGHT Week 24 patients receiving BKZ 320 mg Q4W who achieved PASI 90 could switch to Q8W, at the investigator's discretion.

Table 1 Baseline characteristics

	mNAPSI >10 at baseline			Scalp IGA ≥3 at baseline		
	ADA/BKZ N=48	UST/BKZ N=49	SEC/BKZ N=81	ADA/BKZ N=91	UST/BKZ N=79	SEC/BKZ N=215
Age (years), mean ± SD	44.0 ± 12.9	46.5 ± 12.0	44.6 ± 12.8	43.6 ± 14.6	46.3 ± 13.0	42.9 ± 14.0
Male, n (%)	37 (77.1)	41 (83.7)	67 (82.7)	61 (67.0)	54 (68.4)	132 (61.4)
Caucasian, n (%)	43 (89.6)	41 (83.7)	80 (98.8)	78 (85.7)	59 (74.7)	204 (94.9)
Weight (kg), mean ± SD	90.6 ± 19.0	94.8 ± 20.3	91.7 ± 18.5	88.5 ± 20.3	87.8 ± 20.0	89.0 ± 20.1
Duration of psoriasis (years), mean ± SD	14.9 ± 8.9	19.0 ± 10.5	18.1 ± 11.2	16.5 ± 11.4	18.8 ± 12.1	16.4 ± 11.8
PASI, mean ± SD	20.5 ± 6.2	21.1 ± 9.0	20.6 ± 6.5	19.5 ± 6.3	21.1 ± 8.7	20.1 ± 6.5
BSA (%), mean ± SD	27.8 ± 16.7	26.4 ± 16.7	23.9 ± 13.0	25.2 ± 16.1	26.9 ± 18.4	23.4 ± 13.8
Scalp IGA, n (%)						
0: clear	2 (4.2)	3 (6.1)	5 (6.2)	-	-	-
1: almost clear	2 (4.2)	3 (6.1)	1 (1.2)	-	-	-
2: mild	11 (22.9)	11 (22.4)	11 (13.6)	-	-	-
3: moderate	26 (54.2)	24 (49.0)	46 (56.8)	74 (81.3)	60 (75.9)	174 (80.9)
4: severe	7 (14.6)	8 (16.3)	18 (22.2)	17 (18.7)	19 (24.1)	41 (19.1)
mNAPSI total, mean ± SD[a]	28.8 ± 19.5	32.4 ± 19.0	28.3 ± 15.8	20.0 ± 18.9[b]	22.6 ± 21.1[c]	18.4 ± 17.6[d]
Any prior systemic therapy, n (%)	36 (75.0)	42 (85.7)	68 (84.0)	69 (75.8)	67 (84.8)	162 (75.3)
Prior biologic therapy, n (%)	19 (39.6)	20 (40.8)	35 (43.2)	33 (36.3)	29 (36.7)	75 (34.9)

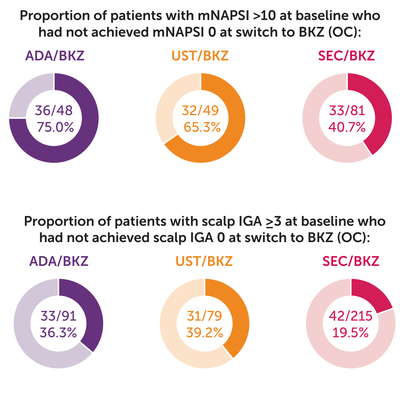
Baseline data reported for all patients with mNAPSI >10 or scalp IGA ≥3 at baseline. [a]In patients with mNAPSI >0; [b]n=53; [c]n=54; [d]n=112.

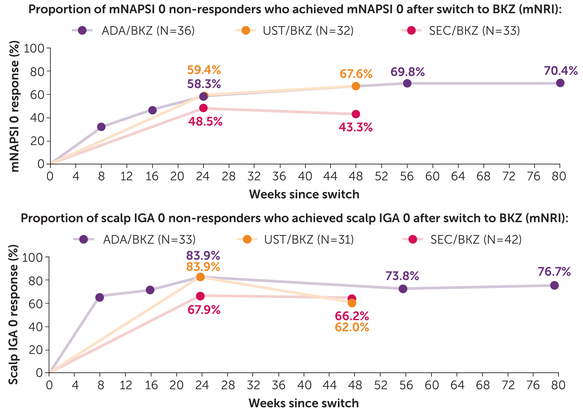
Table 2 Summary of mNAPSI 0 and scalp IGA 0 responses after switch to BKZ

	BE SURE/BE BRIGHT ADA/BKZ			BE VIVID/BE BRIGHT UST/BKZ			BE RADIANT SEC/BKZ		
mNAPSI 0	**N=36**			**N=32**			**N=33**		
Weeks since switch	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**
Week 24	58.3	58.3	21/36 (58.3)	59.4	59.4	19/32 (59.4)	48.5	48.5	16/32 (50.0)
Week 48/56[b]	69.8	61.1	22/29 (75.9)	67.6	65.6	21/30 (70.0)	43.3	39.4	13/28 (46.4)
Week 80[c]	70.4	66.7	24/32 (75.0)	-	-	-	-	-	-
Scalp IGA 0	**N=33**			**N=31**			**N=42**		
Weeks since switch	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**	**mNRI (%)**	**NRI (%)**	**OC n/N (%)[a]**
Week 24	83.9	81.8	27/32 (84.4)	83.9	83.9	26/31 (83.9)	67.9	66.7	28/40 (70.0)
Week 48/56[b]	73.8	63.6	21/29 (72.4)	62.0	54.8	17/28 (60.7)	66.2	61.9	26/37 (70.3)
Week 80[c]	76.7	69.7	23/30 (76.7)	-	-	-	-	-	-

Data reported for patients with baseline mNAPSI >10 or scalp IGA ≥3 (moderate to severe regional involvement) who had not achieved mNAPSI 0 or scalp IGA 0 at time of switch to BKZ. [a]N represents the number of patients with a non-missing measurement, and percentages were calculated accordingly. [b]Due to differences in scheduling, assessments were performed 48 weeks after switch in BE RADIANT and BE VIVID/BE BRIGHT, and 56 weeks after switch in BE SURE/BE BRIGHT; [c]Long-term data up to 80 weeks after switch from UST and SEC to BKZ are still pending.

Figure 2 Complete regional clearance of nail and scalp psoriasis after switch to BKZ





Data reported for patients with baseline mNAPSI >10 or scalp IGA ≥3 (moderate to severe regional involvement) who had not achieved mNAPSI 0 or scalp IGA 0 at time of switch to BKZ. Due to differences in scheduling, assessments were performed at different timepoints after switch from ADA, UST, and SEC to BKZ. Long-term data up to 80 weeks after switch from UST and SEC to BKZ are still pending.

ADA: adalimumab; **BKZ:** bimekizumab; **IGA:** Investigator's Global Assessment; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **PASI:** Psoriasis Area and Severity Index; **PASI 90:** ≥90% reduction from baseline in Psoriasis Area and Severity Index; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **Q12W:** every 12 weeks; **SEC:** secukinumab; **UST:** ustekinumab; **Wk:** Week.

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References: [1]Honda H et al. J Dermatol 2017;44:1015–19; [2]Augustin M et al. Br J Dermatol 2019;181:358–65; [3]Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; [4]Reich K et al. Lancet 2021;397:487–98, NCT03370133; [5]Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884; [6]BE BRIGHT: NCT03598790. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RBW, BS, AP, AB, MS, LD, VV, SW, MG;** Drafting of the publication, or revising it critically for important intellectual content: **RBW, BS, AP, AB, MS, LD, VV, SW, MG;** Final approval of the publication: **RBW, BS, AP, AB, MS, LD, VV, SW, MG.** **Author Disclosures: RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; honoraria from Astellas, DiCE, GSK, and Union. **BS:** Consultant (honoraria) from AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, EPI Health, Evelo Biosciences, Immunic Therapeutics, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Ono, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB Pharma, Union Therapeutics, Ventyxbio, and ViTv Therapeutics; stock options for Connect Biopharma and Mindera Health; speaker for AbbVie, Eli Lilly, Janssen, Regeneron, and Sanofi Genzyme; scientific co-director (consulting fee) for CorEvitas (formerly Corrona) Psoriasis Registry; investigator for AbbVie, Cara, CorEvitas Psoriasis Registry, Dermavant, Dermira, and Novartis; Editor-in-Chief (honorarium) of Journal of Psoriasis and Psoriatic Arthritis. **AP:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2, Medac, Merck Serono, Mitsubishi Pharma, MSD, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, and UCB Pharma. **AB:** Has served as a speaker/received honoraria from AbbVie, Eli Lilly, and UCB; served as a scientific adviser/received honoraria from AbbVie, Abcentra, Affibody, Aligos, Almirall, Alumis, Amgen, Anaptysbio, Arcutis, Arena, Aslan, Athenex, Boehringer Ingelheim, Bristol-Myers Squibb, Cara Therapeutics, Dermavant, EcoR1, Eli Lilly and Company, Escient, Evelo, Evommune, Forte, Galderma, HighlightII Pharma, Incyte, Janssen, Landos, LEO Pharma, Merck, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Spherix Global Insights, Sun Pharma, TLL Pharmaceutical, TrialSpark, UCB Pharma, Viblixome, and Xencor; acted as a clinical study investigator/institution has received clinical study funds from AbbVie, Acelyrin, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Evelo, Galderma, Incyte, Janssen, Leo, Merck, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB Pharma. **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, Galderma, Genentech, GSK, Incythe, Janssen, LEO Pharma, MedImmune, MSD, Mundipharma, Novartis, Pfizer, Regeneron, and UCB Pharma. **LD, VV, SW:** Employees and shareholders of UCB Pharma. **MG:** Investigator, speaker, consultant or advisory board member for AbbVie, Amgen, Akros, AnaptysBio, Arcutis, Bausch Health, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly, Galderma, GSK, Janssen, Kyowa Kirin, MedImmune, Meiji, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma. **Acknowledgements:** These studies were 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 Natalie Nunez Gomez, MD, former employee of UCB Pharma, for critical review, Robert Jones, PhD, Costello Medical, Manchester, UK, for medical writing and editorial assistance and the Design team at Costello Medical for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma. RBW is supported by the NIHR Manchester Biomedical Centre.

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Conclusions

High proportions of patients who did not achieve mNAPSI 0 or scalp IGA 0 with ADA, UST or SEC, demonstrated substantial improvements in complete clearance 24 weeks after switching to BKZ.

Results were generally maintained across a BKZ treatment period of up to 80 weeks.