Bimekizumab efficacy in high-impact areas for patients with moderate to severe plaque psoriasis: Pooled results through two years from the BE SURE and BE RADIANT phase 3 trials

Joseph F. Merola,[1] Alice B. Gottlieb,[2] Akimichi Morita,[3] Jose-Manuel Carrascosa,[4] Boni Elewski,[5] Nicola Tilt,[6] Susanne Wiegratz,[7] Krista Wixted,[8] Ulrich Mrowietz[9]

Presented at EADV 2022 | Milan, Italy | 7–10 September 2022 **P1467**

Objectives

To evaluate scalp, nail, and palmoplantar (pp) outcomes over 2 years in patients with moderate to severe plaque psoriasis treated with two different bimekizumab (BKZ) maintenance dosing regimens.

Introduction

- Plaque psoriasis affecting the scalp, nails, palms, and soles can cause significant physical impairment and negatively impact quality of life therefore, clearance of psoriasis in these high-impact areas is of substantial clinical interest.[1]
- High levels of complete clearance in high-impact areas after 1 year of BKZ treatment have been reported.[2]

Materials and Methods

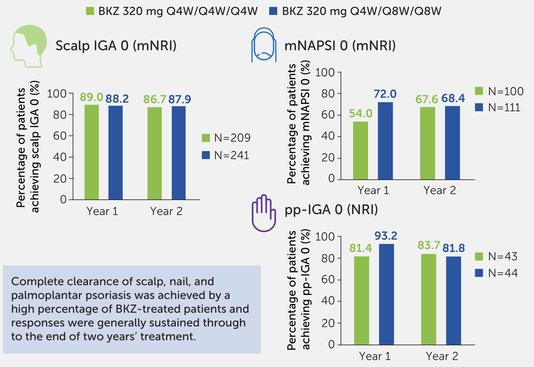
- Data were pooled over two years from the 1-year BE SURE phase 3 trial (NCT03412747) with the ongoing open-label extension (OLE), BE BRIGHT (NCT03598790), and the BE RADIANT phase 3b trial (NCT03536884), incorporating the first year of its ongoing OLE (**Figure 1**).[3,4]
- Patients included in these analyses had moderate to severe regional involvement at baseline (defined as scalp Investigator's Global Assessment [IGA] ≥3, modified Nail Psoriasis Severity Index [mNAPSI] >10, pp-IGA ≥3; [**Figure 2**]).
- Proportions of patients who achieved complete regional clearance (scalp IGA 0, mNAPSI 0, pp-IGA 0) are reported through Year 2 (OLE Week 48).
- Data are presented for patients who received BKZ every 4 weeks (Q4W) through Week 16 followed by continuous BKZ Q4W or every 8 weeks (Q8W) (Q4W/Q4W/Q4W or Q4W/Q8W/Q8W).
- Data are not presented for patients who received BKZ Q4W/Q4W/Q8W or Q4W/Q8W/Q4W due to low patient numbers.
- Data are reported using modified non-responder imputation (mNRI), NRI, and as the observed case (OC).
  - For mNRI (not reported for pp-IGA due to lack of convergence of the statistical model), 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 characteristics for patients included in this analysis are presented in **Table 1**.
- Among patients with scalp IGA ≥3 at baseline, complete clearance was achieved rapidly by a large proportion of patients; high levels of response were achieved through to the end of Year 2 (**Figure 3A**).
- Similar trends were observed in the proportions of patients achieving complete palmoplantar clearance among patients with pp-IGA ≥3 at baseline (**Figure 3B**).
- Among patients with mNAPSI >10 at baseline, levels of complete

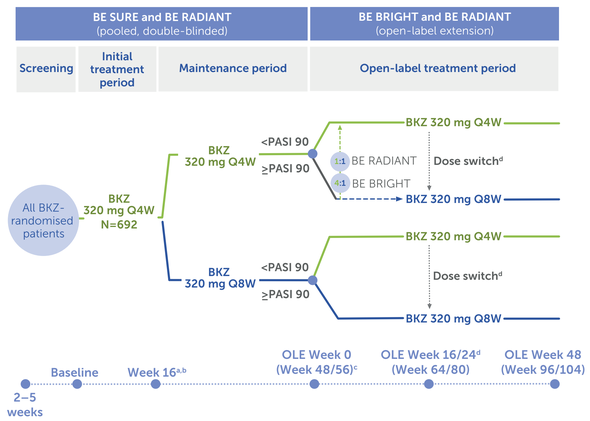
Summary

Complete regional clearance in high-impact areas to Year 2 (by maintenance/OLE dose)



Complete clearance of scalp, nail, and palmoplantar psoriasis was achieved by a high percentage of BKZ-treated patients and responses were generally sustained through to the end of two years' treatment.

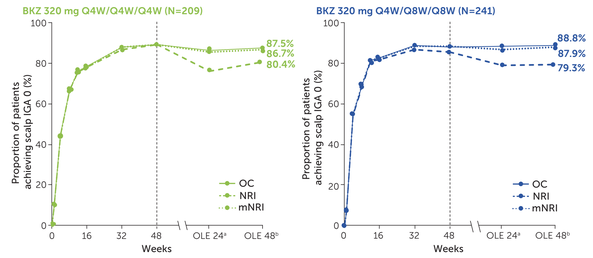
Figure 1 Study design (included patients)



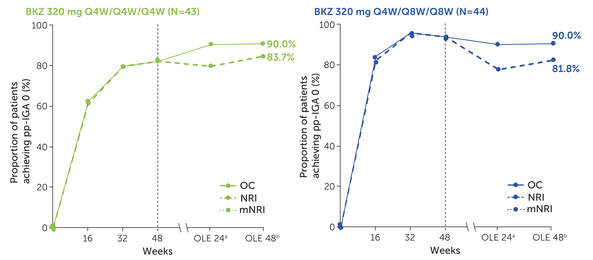
[a]In BE SURE, BKZ-randomised patients were allocated at baseline to either BKZ Q4W throughout the trial, or to switch from Q4W to Q8W at Week 16;[4] [b]At Week 16 in BE RADIANT, patients randomised to BKZ Q4W treatment were re-randomised to BKZ Q4W or Q8W (1:2 allocation ratio; re-randomisation was added via protocol amendment after 83 patients had already completed Week 16, roughly half of whom were initially randomised to BKZ and continued Q4W without re-randomisation);[3] [c]BE RADIANT ran for 48 weeks and BE SURE ran for 56 weeks; the last Week 48 visit for BE RADIANT was May 6th 2020 and the last Week 56 visit for BE SURE was February 26th 2020;[3,4] [d]Dose switch: BE RADIANT OLE Week 16 or next scheduled visit, dose switch added via protocol amendment; BE BRIGHT OLE Week 24, for patients achieving PASI 90 at investigator discretion.

Figure 3 Complete regional clearance of scalp, nail, or palmoplantar psoriasis over 2 years (mNRI, NRI, OC)

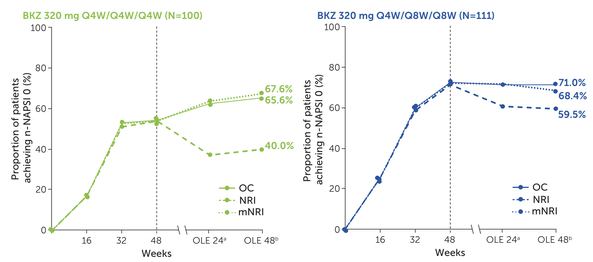
A) Scalp IGA 0 in patients with baseline scalp IGA ≥3



B) pp-IGA 0 in patients with baseline pp-IGA ≥3



C) mNAPSI 0 in patients with baseline mNAPSI >10



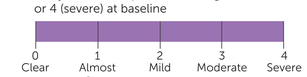
There are a high proportion of missing values that do not follow discontinuation due to lack of efficacy and are therefore not classified as non-responders for mNRI. [a]64 weeks' treatment for those entering the BE RADIANT OLE; 80 weeks' treatment for those entering the BE BRIGHT OLE from BE SURE; [b]96 weeks' treatment for those entering the BE RADIANT OLE; 104 weeks' treatment for those entering the BE BRIGHT OLE from BE SURE.

BKZ: bimekizumab; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **mNAPSI:** modified Nail Psoriasis Severity Index; **mNRI:** modified non-responder imputation; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **PASI 90:** >90% improvement in Psoriasis Area and Severity Index; **pp:** palmoplantar; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **TNF:** tumour necrosis factor.

Figure 2 Tools used to assess disease severity

mNAPSI
- Range 0 to 130 (0 to 13 per fingernail):
  - 0–3 for onycholysis, nail plate crumbling, and pitting
  - 0 or 1 for leukonychia, nail bed hyperkeratosis, splinter haemorrhages, and red spots in the lunula
- Score of 0 = clear nails
- Analysis includes patients scoring >10 (total across all nails) at baseline

pp-IGA
- Analysis includes patients scoring 3 (moderate) or 4 (severe) at baseline



Scalp IGA
- Analysis includes patients scoring 3 (moderate) or 4 (severe) at baseline

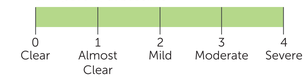


Table 1 Baseline characteristics

	BKZ 320 mg Q4W/Q4W/Q4W (N=303)	BKZ 320 mg Q4W/Q8W/Q8W (N=323)
Age (years), mean ± SD	45.6 ± 13.5	45.0 ± 14.3
Male, n (%)	210 (69.3)	225 (69.7)
Caucasian, n (%)	265 (87.5)	298 (92.3)
Weight (kg), mean ± SD	91.8 ± 21.0	90.0 ± 21.1
Duration of psoriasis (years), mean ± SD	18.4 ± 13.0	18.0 ± 12.2
PASI, mean ± SD	20.3 ± 7.1	20.3 ± 7.2
Scalp IGA ≥3, n (%)	209 (69.0)	241 (74.6)
mNAPSI >10, n (%)	100 (33.0)	111 (34.4)
pp-IGA ≥3, n (%)	43 (14.2)	44 (13.6)
Any prior systemic therapy, n (%)	220 (72.6)	240 (74.3)
Prior biologic therapy, n (%)	105 (34.7)	106 (32.8)
anti-TNF	33 (10.9)	44 (13.6)

Conclusions

Complete and sustained clearance of scalp and palmoplantar psoriasis was achieved in a high percentage of BKZ-treated patients over two years, regardless of dosing regimen.

Complete nail clearance increased through the first year of BKZ treatment, reflective of the longer timescale required for nail growth and repair, and was largely sustained through the second year, regardless of dosing regimen.

Institutions: [1]Harvard Medical School, Brigham and Women's Hospital, Boston, Massachusetts, USA; [2]Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, New York, USA; [3]Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; [4]Hospital Universitari Germans Trias I Pujol, UAB, IGTP, Badalona, Spain; [5]Department of Dermatology, University Hospitals of Cleveland, Case Western Reserve University, Cleveland, Ohio, USA; [6]UCB Pharma, Slough, UK; [7]UCB Pharma, Monheim, Germany; [8]UCB Pharma, Raleigh, North Carolina, USA; [9]Psoriasis Center, Department of Dermatology, University Medical Center Schleswig-Holstein, Campus Kiel, Germany.

References: [1]Merola JF et al. Dermatol Ther 2018;31:e12589; [2]Merola JF et al. Presented at EADV 2021; [3]Reich K et al. N Eng J Med 2021;385:142–52; [4]Warren RB et al. N Eng J Med 2021;385:130–41. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM, ABG, AM, JMC, BE, NT, SW, KW, UM**; Drafting of the publication, or revising it critically for important intellectual content: **JFM, ABG, AM, JMC, BE, NT, SW, KW, UM;** Final approval of the publication: **JFM, ABG, AM, JMC, BE, NT, SW, KW, UM.** **Author Disclosures: JFM:** Consultant and/or investigator for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Regeneron, Sanofi, Sun Pharma, and UCB Pharma. **ABG:** Honoraria as an advisory board member, non-promotional speaker or consultant for Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and XBiotech (only stock options); research/educational grants from AnaptysBio, Bristol Myers Squibb, Janssen, Novartis, Ortho Dermatologics, Sun Pharma, and UCB Pharma; all funds go to the Icahn School of Medicine at Mount Sinai. **AM:** Received research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharma, Torii Pharma, Ushio, and UCB Pharma. **JMC:** Participated as Principal/Senior Investigator and/or consultant and/or advisor for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, LEO Pharma, Novartis, Sandoz, and UCB Pharma. **BE:** Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Incyte, LEO Pharma, Eli Lilly, Merck, Menlo, Novartis, Pfizer, Regeneron, Sun Pharma, Valeant, and Vanda; Consultant (honoraria) from Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, LEO Pharma, Eli Lilly, Menlo, Novartis, Pfizer, Sun Pharma, UCB Pharma, Valeant, and Verrica. **NT:** Employee of UCB Pharma, stockholder of UCB Pharma. **SW, KW:** Employees and shareholders of UCB Pharma. **UM:** Served as advisor and/or clinical study investigator for, and/or received honoraria and/or grants from AbbVie, Almirall, Aristea, Boehringer Ingelheim, Celgene, Dr. Reddy's Laboratories, Eli Lilly, Foamix, Formycon, Forward Pharma, Janssen, LEO Pharma, Medac, Novartis, Phi-Stone, Pierre Fabre, Sanofi, and UCB Pharma. **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 Natalie Nunez Gomez, MD, former employee of UCB Pharma, Monheim, Germany, for critical review, Alexa Holland, MSc, 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.

To receive a copy of this poster, scan the QR code or visit the website below.

Website: UCBposters.com/EADV2022; Poster ID: P1467

Link expiration: 09 December 2022