Bimekizumab versus Ustekinumab in Plaque Psoriasis: Efficacy Translates to Sustained Improvements in Quality of Life in the BE VIVID Multicenter, Randomized, Double-Blinded Phase 3 Trial

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Objectives

To examine how improvements in skin clearance translate to health-related quality of life benefit for patients with moderate to severe plaque psoriasis who received BKZ or UST in the BE VIVID phase 3 trial.

Introduction

- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F.[1]
- In the BE VIVID phase 3 clinical trial, BKZ demonstrated superior rates of skin clearance versus the IL-12/IL-23 inhibitor ustekinumab (UST) and placebo.[2]
- Given that psoriasis can place a significant burden on patients' daily lives,[3] it is important to understand the impact of treatment and skin clearance on health-related quality of life.

Methods

- In BE VIVID (NCT03370133), patients were randomized 4:1:2 to BKZ 320 mg every four weeks (Q4W) to Week 52, placebo to Week 16 followed by BKZ 320 mg Q4W to Week 52, or UST 45/90 mg (by weight) Q4W to Week 4, then every 12 weeks (Q12W) to Week 52.
- The Dermatology Life Quality Index (DLQI) questionnaire was completed through Week 52; a DLQI score of 0 or 1 (DLQI 0/1) indicated no impact of skin disease on a patient's quality of life.
- Achievement of ≥90% improvement in Psoriasis Area and Severity Index (PASI 90), PASI 100, and DLQI 0/1 are reported for patients who received BKZ or UST through 52 weeks. Simultaneous achievement of PASI 90 and DLQI 0/1 and PASI 100 and DLQI 0/1 are also reported.
- Missing data were imputed as non-response (NRI). Observed case (OC) data are also reported.

Results

- Patient demographics and disease characteristics at baseline are reported in **Table 1**.
- At all timepoints, a higher proportion of patients receiving BKZ versus UST achieved PASI 90 response, with response rates peaking earlier in BKZ- versus UST-treated patients **(Figure 2A)**.
- Similarly, at all timepoints, a higher proportion of patients receiving BKZ versus UST achieved PASI 100 response **(Figure 2B)**.
- The proportion of patients achieving DLQI 0/1 increased through Week 52 in both BKZ- and UST-treated patients, with higher rates at all timepoints among BKZ-treated patients **(Figure 2C)**.
- Greater proportions of BKZ- versus UST-treated patients achieved both PASI 90 and DLQI 0/1 through 52 weeks; similar trends were observed for simultaneous achievement of PASI 100 and DLQI 0/1 **(Figure 3)**.

Summary

Patients with moderate to severe plaque psoriasis were assessed for achievement of PASI 90, PASI 100, and DLQI 0/1 at Weeks 16 and 52 of treatment with bimekizumab; data shown are observed case

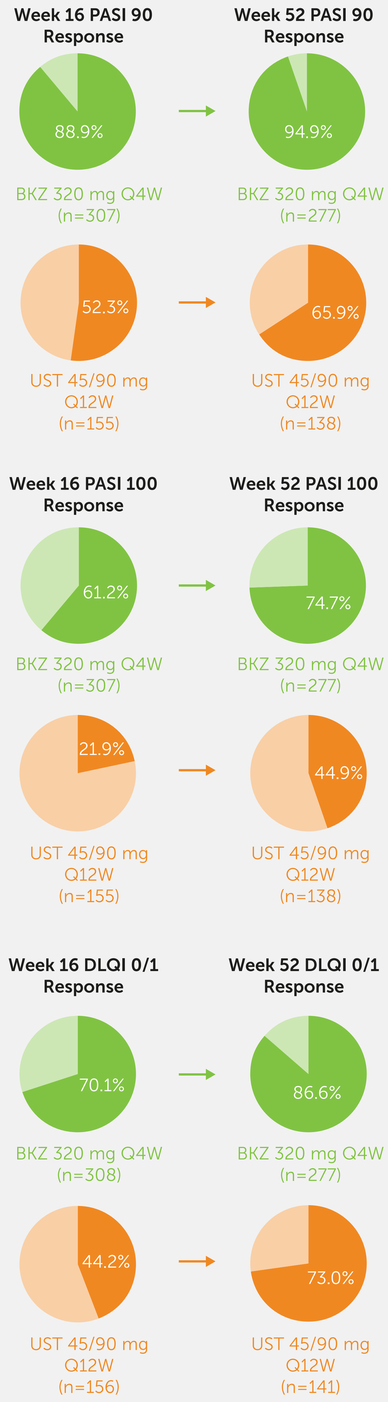
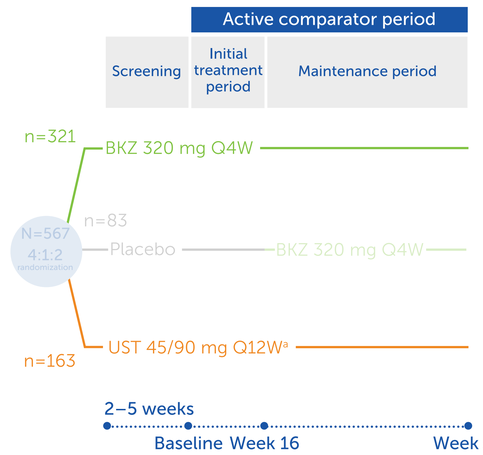


Table 1 Patient demographics and disease characteristics at baseline[2]

	BKZ 320 mg Q4W (n=321)	UST[a] (n=163)
Age (years), mean ± SD	45.2 ± 14.0	46.0 ± 13.6
Weight (kg), mean ± SD	88.7 ± 23.1	87.2 ± 21.1
Male, n (%)	229 (71.3)	117 (71.8)
Caucasian, n (%)	237 (73.8)	120 (73.6)
Duration of psoriasis (years), mean ± SD	16.0 ± 11.6	17.8 ± 11.6
PASI, mean ± SD	22.0 ± 8.6	21.3 ± 8.3
BSA (%), mean ± SD	29.0 ± 17.1	27.3 ± 16.7
IGA, n (%)		
3: moderate	201 (62.6)	96 (58.9)
4: severe	119 (37.1)	66 (40.5)
DLQI		
mean ± SD	9.9 ± 6.3	11.0 ± 6.9
median (min, max)	9.0 (0.0, 29.0)	10.0 (0.0, 30.0)
Any prior systemic therapy, n (%)	267 (83.2)	132 (81.0)
Prior biologic therapy, n (%)[b]	125 (38.9)	63 (38.7)
anti-TNF	51 (15.9)	24 (14.7)
anti-IL-17	76 (23.7)	38 (23.3)
anti-IL-23	16 (5.0)	6 (3.7)
anti-IL-12/23	1 (0.3)	0 (0.0)

[a]Patients received UST at baseline and Week 4, then every 12 weeks thereafter: UST dosing was based on weight: patients ≤100 kg at baseline received one UST 45 mg injection and one placebo injection, patients >100 kg at baseline received two UST 45 mg injections; [b]includes patients with multiple prior biologic use.

Figure 1 BE VIVID study design



[a]Patients received UST at baseline and Week 4, then every 12 weeks thereafter; UST dosing was based on weight: patients ≤100 kg at baseline received one UST 45 mg injection and one placebo injection, patients >100 kg at baseline received two UST 45 mg injections.

Figure 2 Achievement through 52 weeks (OC, NRI)

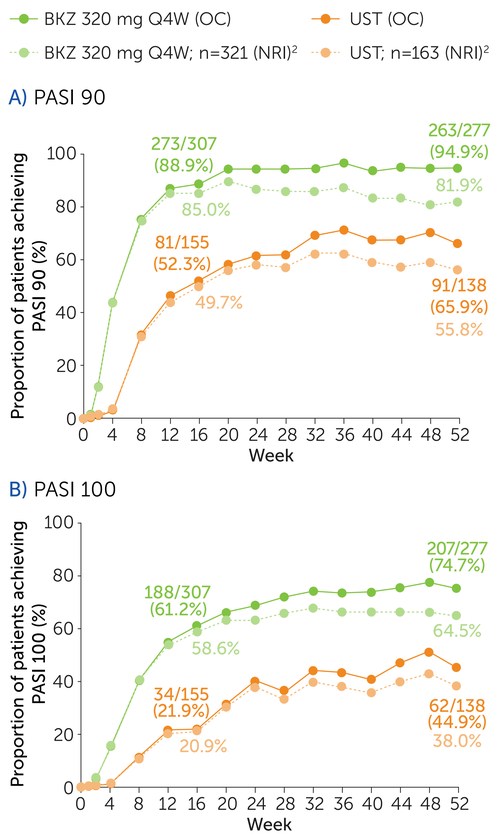
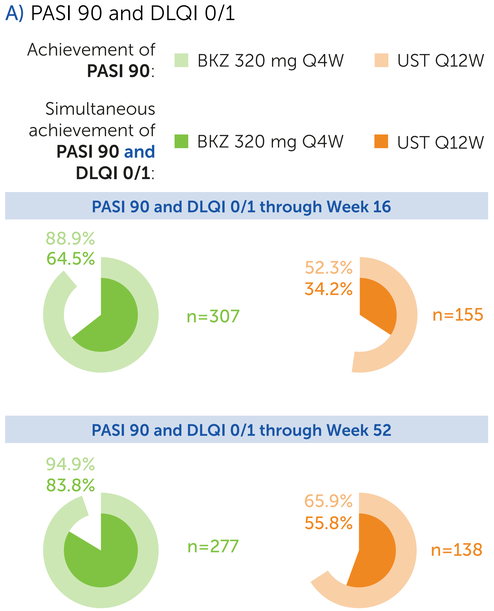


Figure 3 Simultaneous achievement (OC)



N represents the number of patients with both a PASI and DLQI assessment at each timepoint.

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; max: maximum; min: minimum; NRI: non-responder imputation; OC: observed case; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; TNF: tumor necrosis factor; UST: ustekinumab.

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References: [1]Adams R *et al.* Front Immunol 2020;11:1894; [2]Reich K *et al.* Lancet 2021;397:487–98; [3]Bhosle MJ *et al.* Health Qual Life Outcomes 2006;4:35. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **PF, KBG, SI, JFM, KW, VV, FS, VC, MO**; Drafting of the publication, or revising it critically for important intellectual content: **PF, KBG, SI, JFM, KW, VV, FS, VC, MO**; Final approval of the publication: **PF, KBG, SI, JFM, KW, VV, FS, VC, MO**. **Author Disclosures: PF**: Grant support from AbbVie, Amgen, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; served as an investigator for AbbVie, Akaal, Amgen, Arcutis, Aslan, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Bolanix, Celgene, Celtaxsys, CSL, Cutanea, Dermira Inc., Galderma, Genentech, GSK, Hexima, Janssen, LEO Pharma, Lilly, MedImmune, Merck, Novartis, Pfizer, Regeneron Pharmaceuticals Inc, Reistone, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant; served on advisory boards for AbbVie, Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma and Valeant; consultant for Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute; travel grants from AbbVie, Eli Lilly, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sun Pharma and Sanofi; speaker for or received honoraria from AbbVie, Amgen, Celgene, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, and Valeant. **KBG**: Received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira Inc., Eli Lilly, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, and UCB Pharma. **SI**: Received grants from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Kyowa Kirin, LEO Pharma, Pfizer, and UCB Pharma; speaker fees from AbbVie, Daiichi Sankyo, Eisai, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi-Tanabe, Novartis, Sun Pharma, and Taiho Pharma. **JFM**: Consultant for AbbVie, Amgen, Bayer, Biogen, Bristol Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi-Regeneron, UCB Pharma; principal investigator for Dermavant, LEO Pharma, and UCB Pharma. **KW, VV, FS, VC**: Employee and shareholder of UCB Pharma. **MO**: Honoraria and/or research grants from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly, Janssen Pharma, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, and UCB Pharma. **Acknowledgements**: This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, Natalie Nunez Gomez, MD, UCB Pharma, Brussels, Belgium for critical review and Claire Hews, PhD, Costello Medical, UK, for medical writing and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

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Conclusions

BKZ-treated patients achieved higher levels of disease control and lasting skin clearance through 52 weeks compared with UST.[2]

Greater levels of disease control observed with BKZ translated to greater quality of life benefit at Week 16, sustained to Week 52.