Bimekizumab efficacy and safety in Chinese patients with moderate to severe plaque psoriasis in the BE SHINING phase 3, multicentre, randomised, double-blinded, placebo-controlled study

P2763

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Objective

To evaluate the efficacy and safety of bimekizumab (BKZ) in Chinese patients with moderate to severe plaque psoriasis.

Introduction

- The prevalence of psoriasis is growing in China due to an ageing population, and lifestyle factors, including higher rates of smoking, obesity and co-morbid diseases.[1]
- BKZ, a dual interleukin (IL)-17A and IL-17F inhibitor,[2] was well tolerated and demonstrated significant, rapid and durable clinical improvements in global phase 3/3b clinical trials in moderate to severe plaque psoriasis.[3–6] However, these trials included limited numbers of Chinese patients.
- Due to the heterogeneity of psoriasis symptoms and pathophysiology observed among different populations,[7] it is important to understand the efficacy and safety of BKZ specifically in Chinese populations living with moderate to severe psoriasis.

Methods

- In the BE SHINING phase 3 trial (NCT06011733), Chinese adults with moderate to severe plaque psoriasis (Psoriasis Area and Severity Index [PASI] ≥12; body surface area [BSA] affected by psoriasis ≥10%; Investigator's Global Assessment [IGA] ≥3) were randomised in a 3:1 ratio to:
  - BKZ 320 mg every 4 weeks (Q4W) for 16 weeks followed by every 8 weeks (Q8W) through Weeks 16–32, or
  - Placebo (PBO) Q4W for 16 weeks followed by BKZ 320 mg Q4W through Weeks 16–32 (**Figure 1**).
- Co-primary efficacy endpoints were achievement of ≥90% improvement from baseline in PASI (PASI 90) and IGA of 0/1 (clear/almost clear) at Week 16.
  - Key secondary efficacy endpoints included achievement of PASI 75 at Week 4 and PASI 100 at Week 16; tertiary endpoints assessed efficacy responses over 32 weeks, including Dermatology Life Quality Index (DLQI) 0/1.
- Missing efficacy data were imputed as non-response (NRI), and p values were based on the Cochran–Mantel–Haenszel test.
- BKZ safety outcomes were assessed through Week 16 vs PBO, and throughout Weeks 0–32 (and up to 17 weeks after the final BKZ dose [safety follow-up visit]) in all patients who received ≥1 BKZ dose.

Results

- At baseline, 133 patients were randomised to BKZ Q4W/Q8W (N=100) or PBO/BKZ Q4W (N=33).
  - Baseline characteristics were largely similar between groups, with the exception of a higher male proportion in the PBO/BKZ Q4W group compared with the BKZ Q4W/Q8W group (**Table 1**).

Efficacy

- At Week 16, patients treated with BKZ had statistically superior clinical response rates compared with patients treated with PBO (PASI 90: 94.0% vs 3.0%, IGA 0/1: 92.0% vs 3.0%; p<0.001 for both comparisons; **Figure 2**).
  - In BKZ-treated patients, this level of response was sustained up to Week 32 (**Figure 2**).
  - Patients who switched from PBO to BKZ at Week 16 achieved similar response levels after 16 weeks of BKZ treatment (Week 32; **Figure 2**).
- Rapid clinical responses were seen in BKZ-treated patients after one dose, with 74.0% of patients achieving PASI 75 at Week 4 vs 3.0% of PBO patients (p<0.001; **Figure 3A**).
- Significantly higher rates of complete skin clearance (PASI 100) were observed in BKZ-treated patients than PBO-treated patients at Week 16 (65.0% vs 0.0%; p<0.001). BKZ PASI 100 rates were maintained to Week 32 (**Figure 3B**).
- BKZ treatment led to improvements in health-related quality of life, with 67.0% of BKZ Q4W/Q8W patients achieving DLQI 0/1 after 32 weeks.

Safety

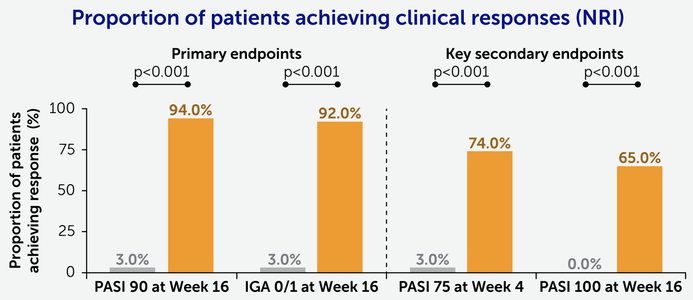
- Through to Week 16, rates of treatment-emergent adverse events (TEAEs), serious TEAEs and TEAEs leading to discontinuation were 62.0%, 1.0% and 1.0% in BKZ-treated patients, respectively, versus 51.5%, 9.1% and 3.0% with PBO (**Table 2**).
  - Through to Week 32, in all patients who received ≥1 BKZ dose, these rates were 73.8%, 6.2% and 5.4%, respectively (**Table 2**).
- There were no deaths in this study and no cases of inflammatory bowel disease or suicidal ideation and behaviour were reported. *Tinea* infections were the most frequent fungal infections; one *Candida* infection (mild) was reported. Other safety topics of interest are shown in **Table 2**.

Conclusions

Treatment with bimekizumab led to rapid and significantly improved clinical responses versus placebo in Chinese patients living with moderate to severe plaque psoriasis, consistent with responses in global populations.[3–6]

No new safety signals were identified and, apart from lower rates of candidiasis, observations were generally consistent with previous global studies.[3–6]

Summary



Through **Weeks 0–16** reported safety data were:

Serious TEAEs		TEAEs leading to discontinuation		Deaths	
BKZ 1 (1.0%)	PBO 3 (9.1%)	BKZ 1 (1.0%)	PBO 1 (3.0%)	BKZ 0	PBO 0

In Chinese patients living with moderate to severe psoriasis, bimekizumab treatment was **well tolerated** and led to **rapid and statistically superior responses versus placebo**, suggesting that bimekizumab is a suitable treatment option in these patients.

Figure 1 BE SHINING study design

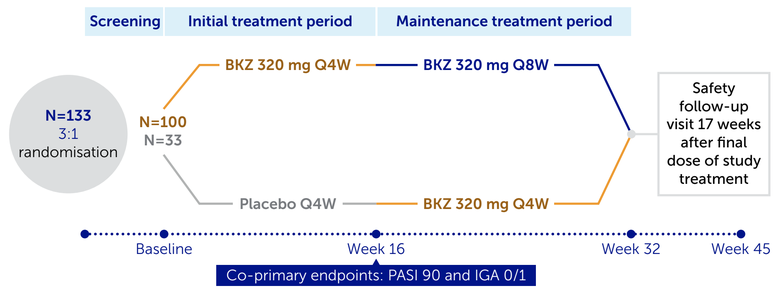


Table 1 Baseline characteristics

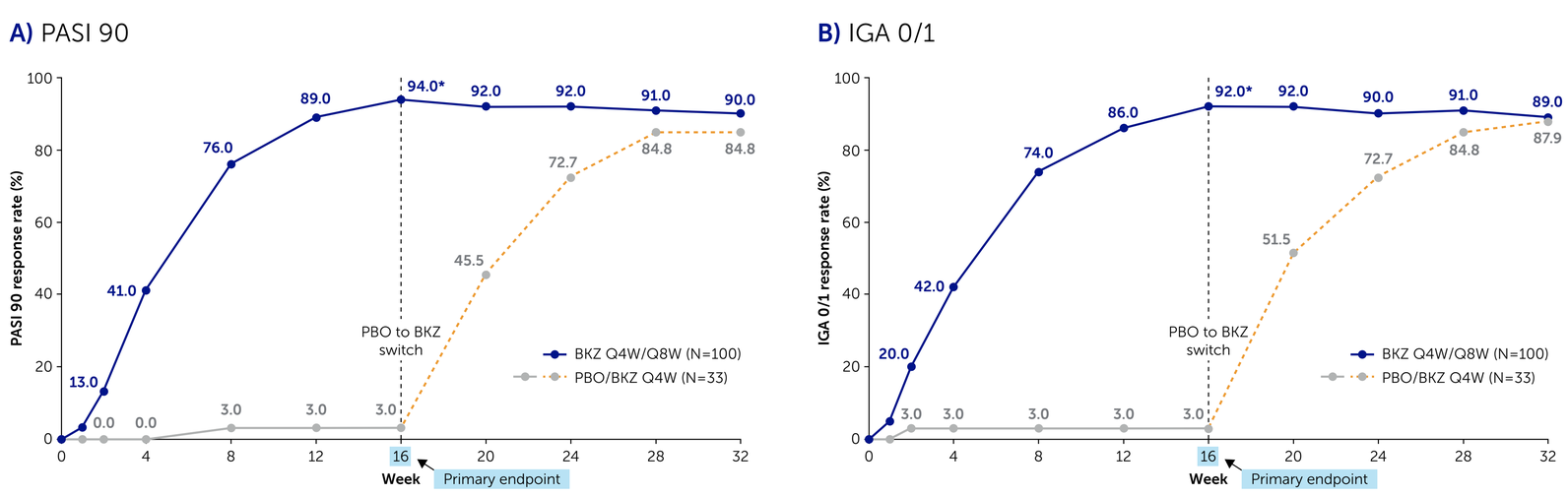
	Placebo/ BKZ 320 mg Q4W N=33	BKZ 320 mg Q4W/Q8W N=100	All patients N=133
Age (years), mean (SD)	39.9 (13.8)	39.8 (13.2)	39.8 (13.3)
Sex, **male**, n (%)	28 (84.8)	71 (71.0)	99 (74.4)
Weight (kg), mean (SD)	78.4 (19.1)	75.9 (17.0)	76.5 (17.5)
BMI ≥30 kg/m², n (%)	6 (18.2)	19 (19.0)	25 (18.8)
Duration of psoriasis (years), mean (SD)	11.6 (7.7)	9.7 (8.0)	10.2 (7.9)
PASI, mean (SD)	25.0 (12.6)	22.8 (9.2)	23.4 (10.2)
IGA, n (%)			
3: moderate	17 (51.5)	57 (57.0)	74 (55.6)
4: severe	16 (48.5)	43 (43.0)	59 (44.4)
BSA (%), mean (SD)	33.3 (20.6)	30.2 (17.0)	31.0 (17.9)
DLQI total, mean (SD)	15.9 (7.6)	16.5 (7.9)	16.3 (7.8)
Prior systemic therapy, n (%)	33 (100)	100 (100)	133 (100)
Prior biologic therapy, n (%)	11 (33.3)	28 (28.0)	39 (29.3)
Anti-TNF	2 (6.1)	5 (5.0)	7 (5.3)
Anti-IL-17	5 (15.2)	14 (14.0)	19 (14.3)

Table 2 Incidence of TEAEs – initial treatment period (Weeks 0–16) and initial and maintenance periods combined (Weeks 0–32)

Safety event	Weeks 0–16 PBO N=33 n[a] (%)	Weeks 0–16 BKZ 320 mg Q4W N=100 n[a] (%)	Weeks 0–32 ≥1 BKZ dose N=130 n[a] (%)
Any TEAE	17 (51.5)	62 (62.0)	96 (73.8)
Serious TEAEs	3 (9.1)	1 (1.0)	8 (6.2)
Discontinuation due to TEAEs	1 (3.0)	1 (1.0)	7 (5.4)
TEAEs leading to death	0	0	0
Most common TEAEs[b]			
Upper respiratory tract infection	2 (6.1)	21 (21.0)	25 (19.2)
Hepatic function abnormal	0	3 (3.0)	10 (7.7)
Injection site pain	1 (3.0)	5 (5.0)	9 (6.9)
TEAEs of interest			
Serious infections	0	0	1 (0.8)
Fungal infections	0	4 (4.0)	7 (5.4)
Candida infections	0	0	1 (0.8)
Tinea infections	0	3 (3.0)	5 (3.8)
Malignancies (excl. NMSC)	0	0	1 (0.8)
Hypersensitivity reactions	0	10 (10.0)[c]	20 (15.4)[c]
Serious hypersensitivity reactions	0	0	0
Suicidal ideation or behaviour	0	0	0
Inflammatory bowel disease	0	0	0
Cardiovascular events	0	0	3 (2.3)
Neutropenia events	0	2 (2.0)	5 (3.8)
Hepatic events[d]	3 (9.1)	9 (9.0)	22 (16.9)
AST/ALT elevations >3x ULN	0	4 (4.0)	8 (6.2)
AST/ALT elevations >5x ULN[e]	0	1 (1.0)	2 (1.5)[f]
Injection site reactions	1 (3.0)	8 (8.0)	11 (8.5)

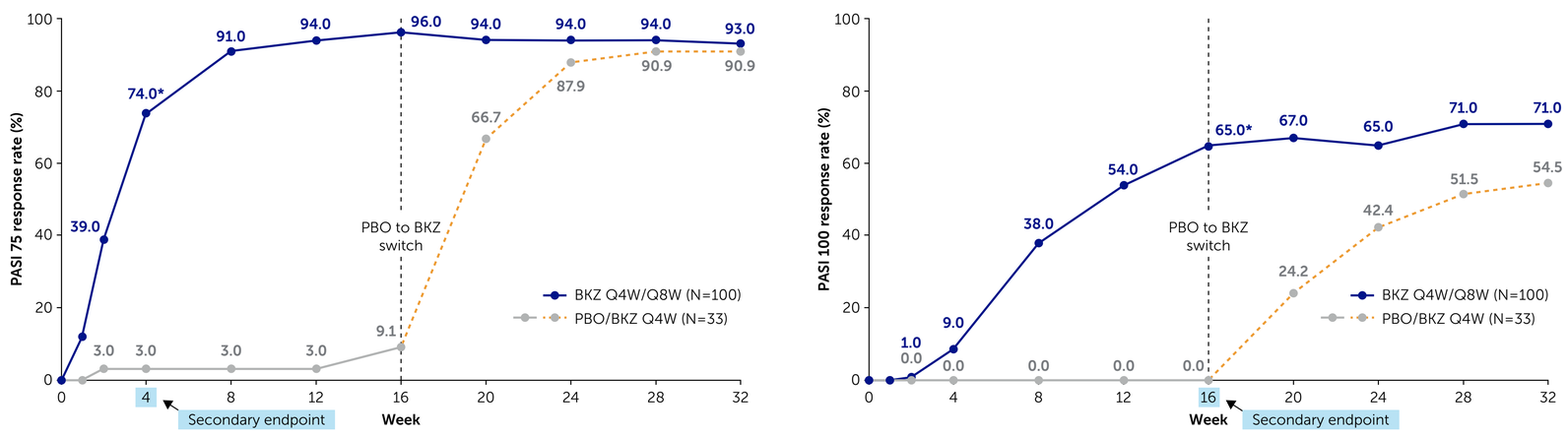
Safety set (Weeks 0–16: TEAEs in patients who received ≥1 dose of treatment; Weeks 0–32: TEAEs while on BKZ in patients who received ≥1 dose of BKZ but may have received PBO to Week 16). TEAEs were coded using MedDRA v19.0. **[a]** Number of patients reporting ≥1 TEAE. **[b]** Most commonly reported preferred terms through Weeks 0–32 (and up to 17 weeks after the final BKZ dose [safety follow-up visit]). **[c]** Driven by non-serious TEAEs falling under the high-level term 'dermatitis and eczema', BKZ 320 mg Q4W: n=9 (9.0%); ≥1 BKZ dose: n=15 (11.5%). **[d]** Also includes the 'hepatic function abnormal' TEAEs. **[e]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN. **[f]** One patient with hyperlipidaemia, alcohol use, elevated tumour marker and premature end of treatment due to epigastric discomfort; one overweight patient (BMI 29.4 kg/m²) lost to follow-up, where ALT/AST elevations tended to normalise.

Figure 2 PASI 90 and IGA 0/1 response rates through Week 32 (NRI)



Includes all patients randomised to treatment. *p<0.001. p values were used for comparisons based on the Cochran–Mantel–Haenszel test. Patients receiving PBO switched to BKZ Q4W from Week 16.

Figure 3 PASI 75 and PASI 100 response rates through Week 32 (NRI)



Includes all patients randomised to treatment. *p<0.001. p values were used for comparisons based on the Cochran-Mantel-Haenszel test. Patients receiving PBO switched to BKZ Q4W from Week 16.

ALT: alanine aminotransferase; **AST:** aspartate aminotransferase; **BKZ:** bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **DLQI:** Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **MedDRA:** Medical Dictionary for Regulatory Activities; **NMSC:** non-melanoma skin cancer; **NRI:** non-responder imputation; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in the Psoriasis Area and Severity Index; **PBO:** placebo; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event; **TNF:** tumour necrosis factor; **ULN:** upper limit of normal.

References: [1]Yu K et al. Front Public Health 2025;13:1541292; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Reich K et al. N Engl J Med 2021;385:142–52 (NCT03536884); [4]Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [5]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [6]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [7]Kim J et al. J Invest Dermatol 2016;136:161–72.
Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **LC**, **XM**, **JW**, **AW**, **YC**, **DD**, **JG**, **BH**, **WS**, **TL**, **JZ** Drafting of the publication, or reviewing it critically for important intellectual content: **LC**, **XM**, **JW**, **AW**, **YC**, **DD**, **JG**, **BH**, **WS**, **TL**, **JZ**; Final approval of the publication: **LC**, **XM**, **JW**, **AW**, **YC**, **DD**, **JG**, **BH**, **WS**, **TL**, **JZ**. **Author Disclosures:** **LC**, **XM**, **JW**, **AW**, **JZ:** None to disclose. **YC**, **DD**, **BH:** Employees and shareholders of UCB. **JG**, **TL**, **WS:** Employees of UCB. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Inés Dueñas Pousa, PhD, UCB, Madrid, Spain for publication coordination, Oscar Jenkyn-Jones, MSc, Costello Medical, London, UK, for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.

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