Bimekizumab efficacy and safety in Japanese patients with generalized pustular psoriasis and erythrodermic psoriasis: 3-year results from BE BRIGHT, a multicenter, open-label, phase 3 study

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OBJECTIVE:

- To present the 3-year efficacy and safety of open-label bimekizumab (BKZ) treatment in **Japanese patients** with **generalized pustular psoriasis (GPP)** and **erythrodermic psoriasis (EP)**.

Background:

- GPP and EP are rare forms of psoriasis, which can be difficult to treat and are potentially life-threatening.[1,2]
- Clinical improvements in Japanese patients with GPP and EP, with no unexpected safety findings, have previously been reported with BKZ through to Week 48 of the BE BRIGHT phase 3 trial.[3]

Methods:

- Japanese patients with plaque psoriasis, GPP, and EP could directly enroll in BE BRIGHT (NCT03598790).[3]
- BKZ efficacy and safety were evaluated through Weeks 0–144.

Outcomes Summary

Efficacy

Outcomes evaluated:

IGA 0/1
DLQI 0/1
CGI-I improved/remission
PASI 90

Observed case (OC) data are reported

Safety

Treatment-emergent adverse events (TEAEs) were evaluated

Coded using MedDRA v19.0

1. Gooderham MJ et al. Expert Rev Clin Immunol 2019;15:907–19; **2.** Lo Y et al. Psoriasis (Auckl) 2021;11:59–73; **3.** Okubo Y et al. Presented at JSPR 2022, P89. BKZ: bimekizumab; CGI-I: Clinical Global Impressions - Improvement; DLQI: Dermatology Life Quality Index; EP: erythrodermic psoriasis; GPP: generalized pustular psoriasis; IGA: Investigator's Global Assessment; MedDRA: Medical Dictionary for Regulatory Activities; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; TEAEs: treatment-emergent adverse events.

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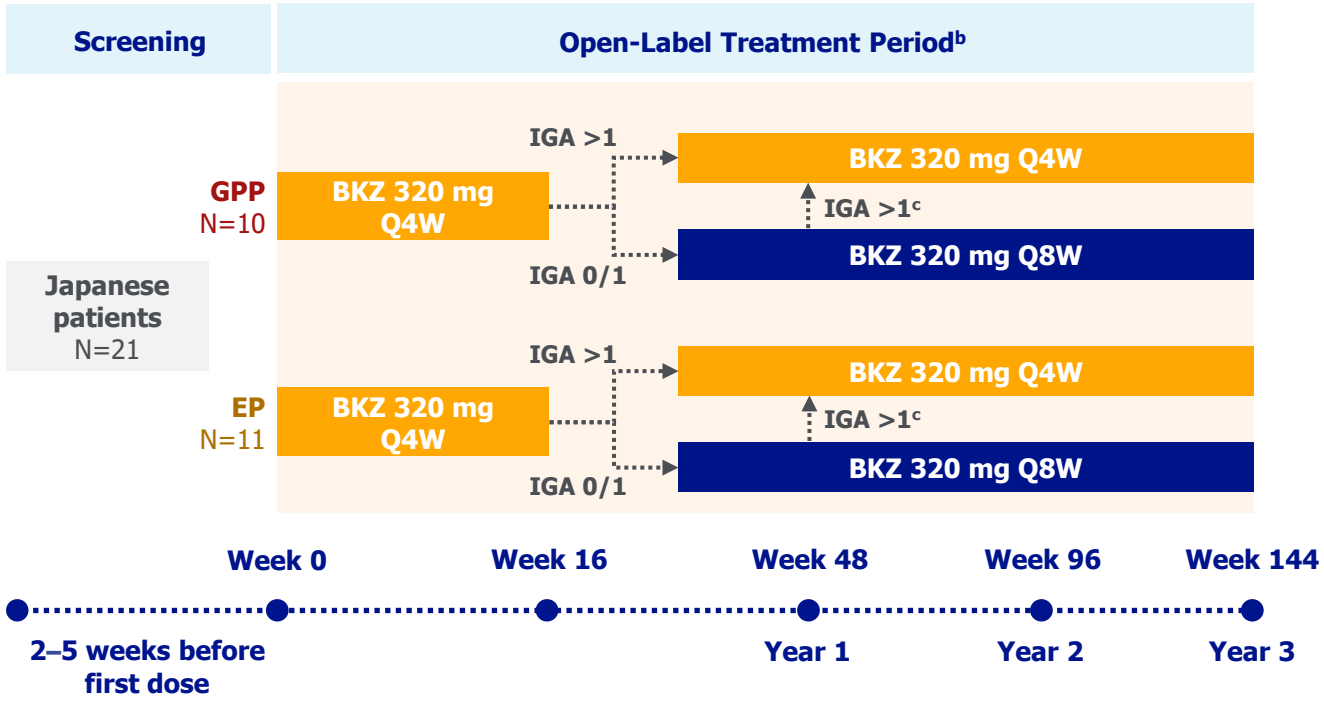
BE BRIGHT Cohort B Study Design[a]



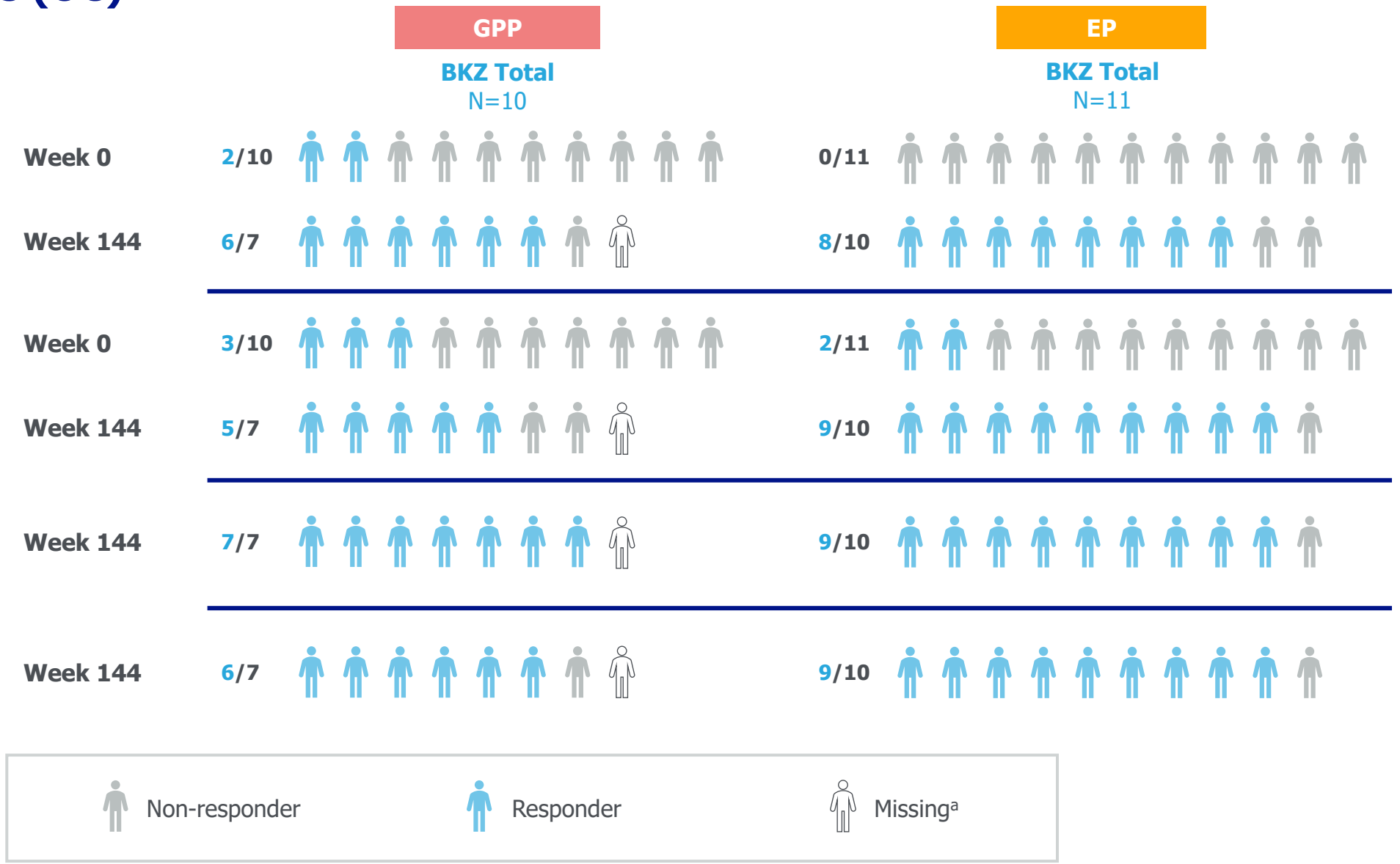
- The Investigator's Global Assessment (IGA) measures psoriasis severity on a 5-point scale with scores of clear (0), almost clear (1), mild (2), moderate (3), and severe (4).
- Efficacy results are pooled across all BKZ dosing regimens (**BKZ Total**).

Baseline Characteristics

	GPP BKZ Total N=10	**EP BKZ Total** N=11
Age (years), mean ± SD	46.0 ± 12.5	55.3 ± 11.9
Male, n (%)	6 (60.0)	11 (100.0)
Asian, n (%)	10 (100.0)	11 (100.0)
Weight (kg), mean ± SD	68.0 ± 18.0	76.7 ± 17.2
Duration of psoriasis (years), mean ± SD	9.4 ± 10.3	19.7 ± 12.1
PASI, mean ± SD	16.5 ± 13.9	45.4 ± 13.6
BSA (%), mean ± SD	28.0 ± 28.4	86.1 ± 2.7
IGA, n (%)		
3: moderate	5 (50.0)[d]	0
4: severe	2 (20.0)[d]	11 (100.0)
DLQI total score, mean ± SD	6.1 ± 6.2	7.1 ± 6.1
JDA Severity Index of GPP,[d] mean ± SD	3.3 ± 2.0	N/A
Any prior systemic therapy, n (%)	10 (100.0)	10 (90.9)
Any prior biologic therapy, n (%)	7 (70.0)	4 (36.4)

[a] BE BRIGHT Cohort B enrolled Japanese patients with moderate to severe plaque psoriasis, GPP, or EP. Results are reported for patients with GPP and EP only. BE BRIGHT Cohort B is distinct from the BE BRIGHT open-label extension that followed the BE SURE, BE VIVID, and BE READY phase 3 feeder studies; **[b]** At Week 28 and all following visits, patients on continuous treatment with BKZ for ≥12 weeks with a persistent IGA score ≥3 over at least a 4-week period were defined as non-responders and discontinued BKZ; **[c]** At Week 48, patients on BKZ Q8W with IGA >1 were switched to BKZ Q4W through to the end of the study (Week 144); **[d]** n=1 for each of the IGA 0, 1, and 2 categories, totaling 10 patients; **[e]** JDA Severity Index of GPP is only assessed for patients with GPP. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; EP: erythrodermic psoriasis; GPP: generalized pustular psoriasis; IGA: Investigator's Global Assessment; JDA: Japanese Dermatological Association; N/A: not applicable; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

Efficacy at 3 Years (OC)



Results for BKZ Total are pooled across both BKZ dose groups. **[a]** Patients who were still ongoing in the study but with missing measurements at the given week; patients who discontinued are not shown.
BKZ: bimekizumab; CGI-I: Clinical Global Impressions - Improvement; DLQI: Dermatology Life Quality Index; EP: erythrodermic psoriasis; GPP: generalized pustular psoriasis; IGA: Investigator's Global Assessment; OC: observed case; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index.

Incidence of TEAEs

	GPP BKZ Total N=10 Total exposure: 26.4 PY		EP BKZ Total N=11 Total exposure: 31.2 PY	
	n (%)	**EAIR/100 PY (95% CI)**	**n (%)**	**EAIR/100 PY (95% CI)**
Any TEAE	9 (90.0)	188.7 (86.3, 358.2)	11 (100.0)	328.3 (163.9, 587.3)
Serious TEAEs	2 (20.0)	7.6 (0.9, 27.3)	5 (45.5)	19.5 (6.3, 45.5)
Discontinuation due to TEAEs	2 (20.0)	7.7 (0.9, 27.7)	1 (9.1)	3.3 (0.1, 18.2)
Severe TEAEs	2 (20.0)	-	4 (36.4)	-
Deaths	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Most Common TEAEs (≥3 events in either group)				
Nasopharyngitis	2 (20.0)	9.4 (1.1, 33.9)	7 (63.6)	46.5 (18.7, 95.7)
Oral candidiasis	2 (20.0)	8.7 (1.1, 31.5)	4 (36.4)	18.2 (5.0, 46.6)
Eczema	0	0.0 (0.0, 0.0)	3 (27.3)	11.7 (2.4, 34.3)
Pyrexia	3[a] (30.0)	13.5 (2.8, 39.4)	1 (9.1)	3.3 (0.1, 18.4)
TEAEs of Interest				
Serious infections	0	0.0 (0.0, 0.0)	1 (9.1)	3.5 (0.1, 19.6)
Fungal infections[b]	3 (30.0)	14.0 (2.9, 40.9)	5 (45.5)	25.6 (8.3, 59.7)
Definite or probable adjudicated inflammatory bowel disease	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Adjudicated suicidal ideation and behavior	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Malignancies, including non-melanoma skin cancer	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Serious hypersensitivity reactions[c]	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Adjudicated major adverse cardiac event	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)
Hepatic events	4 (40.0)	18.0 (4.9, 46.1)	3 (27.3)	11.1 (2.3, 32.6)
AST or ALT elevations >3x upper limit of normal	2 (20.0)	-	2 (18.2)	-
AST or ALT elevations >5x upper limit of normal[d]	1 (10.0)	-	1 (9.1)	-
Injection site reactions	0	0.0 (0.0, 0.0)	0	0.0 (0.0, 0.0)

TEAEs were coded according to MedDRA v19.0. Data were pooled for all patients who received ≥1 BKZ dose (BKZ Total). EAIRs for cells marked '-' are unavailable. **[a]** In 2/3 participants, pyrexia was assessed as related to COVID-19 vaccines; **[b]** Includes the high-level terms *Candida* infections, and *Tinea* infections; **[c]** No anaphylactic reactions associated with BKZ were reported; **[d]** Patients with elevations >5x upper limit of normal were a subset of patients with elevations >3x upper limit of normal. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; EP: erythrodermic psoriasis; GPP: generalized pustular psoriasis; MedDRA: Medical Dictionary for Regulatory Activities; NEC: not elsewhere classified; PY: patient-years; TEAE: treatment-emergent adverse event.

CONCLUSIONS:

- Previously reported Week 48 responses to bimekizumab were sustained through Week 144, supporting bimekizumab use in patients with GPP and EP, despite the small population of patients with these forms of psoriasis.[1]
- Safety data were consistent with the safety profile of bimekizumab in moderate to severe plaque psoriasis, with no new safety signals identified.[2] Treatment with bimekizumab was well-tolerated, with a low overall incidence of TEAEs leading to study discontinuation.

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1. Okubo Y et al. Presented at JSPR 2022, P89; **2.** Gordon KB et al. JAMA Dermatol 2022;158:735–44. EP: erythrodermic psoriasis; GPP: generalized pustular psoriasis; TEAEs: treatment-emergent adverse events.