Bimekizumab efficacy in moderate to severe plaque psoriasis: Improvements in symptom severity assessed using Psoriasis Symptoms and Impacts Measure (P-SIM) thresholds in BE VIVID and BE SURE

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OBJECTIVE:

- To evaluate and compare improvements in psoriasis symptom severity at Weeks 16 (BE VIVID) and 24 (BE SURE) of bimekizumab (BKZ) treatment vs ustekinumab (UST) and adalimumab (ADA), respectively, by measuring changes in severity categories in P-SIM items.

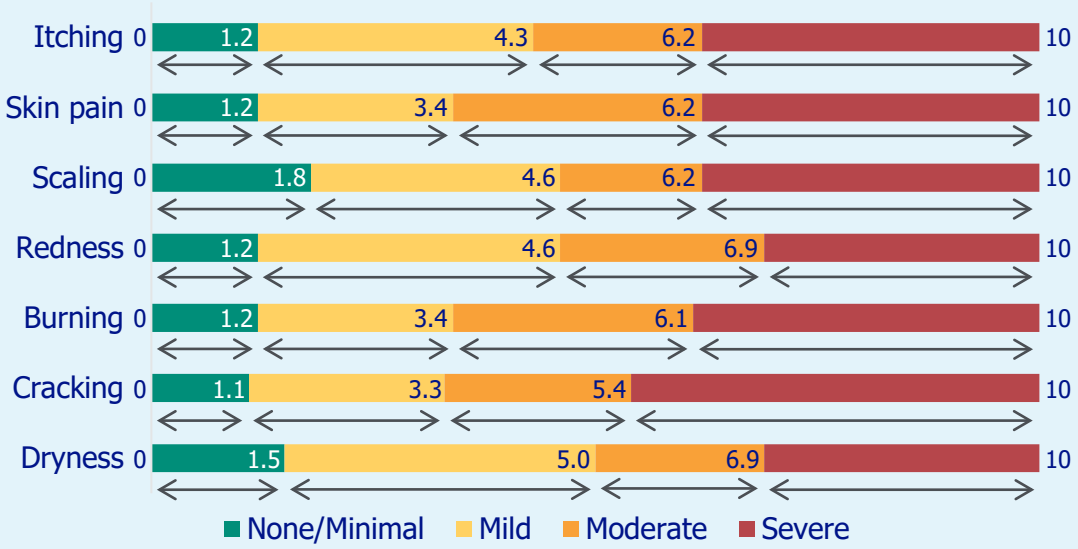
Background:

- Psoriasis negatively impacts the health-related quality of life of patients, as a result of physical symptoms, psychological strain, and stigmatization.[1]
- BKZ has previously shown superior clinical responses vs UST and ADA in the BE VIVID and BE SURE phase 3 trials.[2,3]

P-SIM Items and Thresholds[4]

The P-SIM is a valid and reliable patient-reported outcome tool which captures key symptoms and life impacts of plaque psoriasis as perceived by patients.[5]

Seven P-SIM items have been identified as reflecting core symptoms experienced by patients with psoriasis:[6]



1. Augustin M & Radtke MA. Expert Rev Pharmacoecon Outcomes Res 2014;14:559–68; **2.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **3.** Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; **4.** Augustin M et al. Presented at ISPOR EU 2023, MSR52; **5.** Warren RB et al. Dermatol Ther (Heidelb) 2021;11:1551–69; **6.** Warren RB et al. Presented at ISPOR EU 2023, MSR85. ADA: adalimumab; BKZ: bimekizumab; P-SIM: Psoriasis Symptoms and Impacts Measure; UST: ustekinumab.

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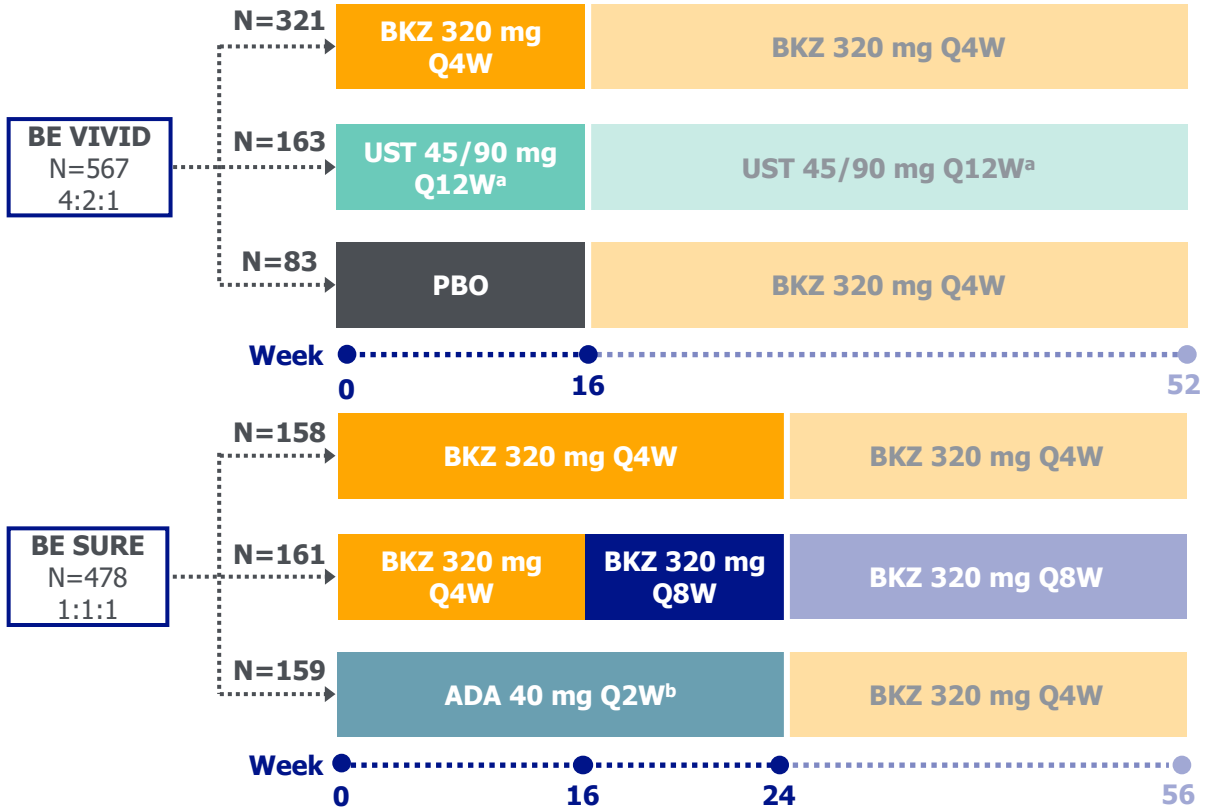
Methods and Study Designs

- P-SIM items were scored daily on a numeric rating scale from 0–10 and averaged weekly to Week 16 of BE VIVID (BKZ vs UST) and Week 24 of BE SURE (BKZ vs ADA).
- Improvements in severity of seven representative symptom items were analyzed; missing data were imputed using non-responder imputation (NRI).



Baseline Characteristics

	BE VIVID		BE SURE	
	BKZ 320 mg Q4W N=321	**UST** N=163	**BKZ Total[c]** N=319	**ADA** N=159
Age (years), mean ± SD	45.2 ± 14.0	46.0 ± 13.6	44.6 ± 13.3	45.5 ± 14.3
Male, n (%)	229 (71.3)	117 (71.8)	214 (67.1)	114 (71.7)
White, n (%)	237 (73.8)	120 (73.6)	280 (87.8)	141 (88.7)
Weight (kg), mean ± SD	88.7 ± 23.1	87.2 ± 21.1	91.4 ± 23.0	90.5 ± 22.1
Duration of psoriasis (years), mean ± SD	16.0 ± 11.6	17.8 ± 11.6	18.8 ± 12.2	16.2 ± 11.9
PASI, mean ± SD	22.0 ± 8.6	21.3 ± 8.3	20.2 ± 6.5	19.0 ± 5.9
BSA (%), mean ± SD	29.0 ± 17.1	27.3 ± 16.7	25.9 ± 14.2	25.0 ± 14.4
IGA, n (%)				
3: moderate	201 (62.6)	96 (58.9)	213 (66.8)	114 (71.7)
4: severe	119 (37.1)	66 (40.5)	106 (33.2)	45 (28.3)
DLQI total score, mean ± SD	9.9 ± 6.3	11.0 ± 6.9	10.9 ± 6.3	10.5 ± 7.4
Any prior systemic therapy, n (%)	267 (83.2)	132 (81.0)	228 (71.5)	110 (69.2)
Any prior biologic therapy, n (%)	125 (38.9)	63 (38.7)	100 (31.3)	53 (33.3)

[a] UST was dosed 45 mg/90 mg (by weight) at baseline and Week 4, then Q12W; **[b]** ADA was dosed 80 mg at Week 0 and 40 mg at Week 1, then Q2W until Week 23; **[c]** For BE SURE, BKZ Total includes patients who were randomized to BKZ Q4W throughout, and patients who were randomized to BKZ Q4W to Week 16 then Q8W from Week 16 onwards. ADA: adalimumab; BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Assessment; PBO: placebo; P-SIM: Psoriasis Symptoms and Impacts Measure; Q2W: every 2 weeks; Q4W: every 4 weeks; Q8W: every 8 weeks; Q12W: every 12 weeks; SD: standard deviation; UST: ustekinumab.

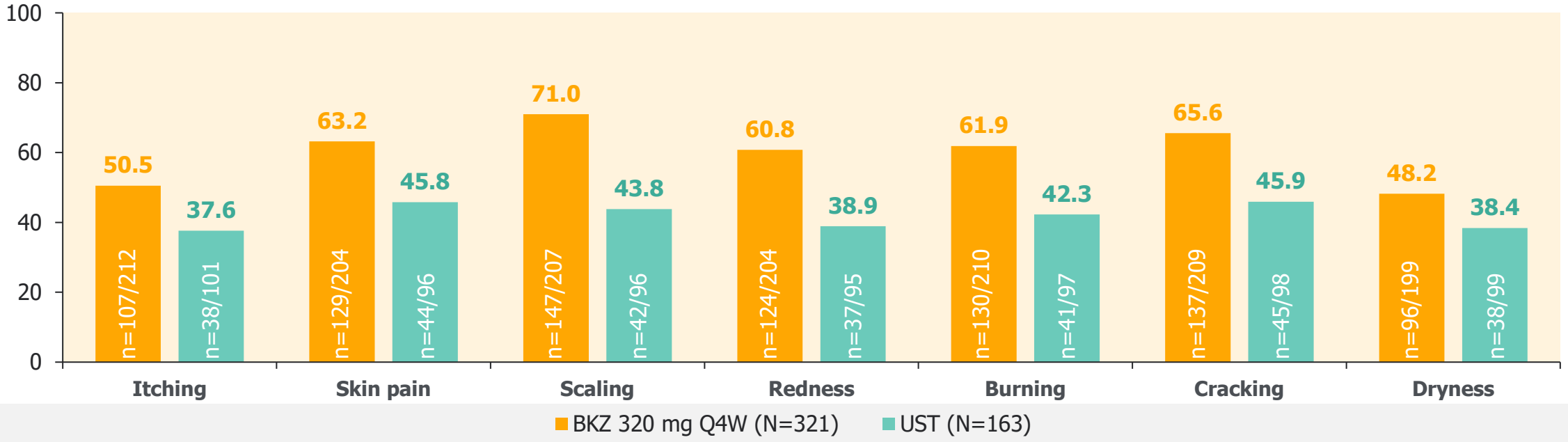
Results from BE VIVID: BKZ- vs UST-Treated Patients

Proportion of patients with moderate/severe symptoms at baseline who achieved no/minimal symptoms at Week 16 (NRI)

Baseline
P-SIM severity categories, n (%)

	Itching		Skin pain		Scaling		Redness		Burning		Cracking		Dryness	
	BKZ	UST	BKZ	UST	BKZ	UST	BKZ	UST	BKZ	UST	BKZ	UST	BKZ	UST
None/ Minimal	4 (1.2)	3 (1.8)	27 (8.4)	16 (9.8)	4 (1.2)	4 (2.5)	3 (0.9)	1 (0.6)	15 (4.7)	14 (8.6)	18 (5.6)	6 (3.7)	5 (1.6)	2 (1.2)
Mild	44 (13.7)	20 (12.3)	29 (9.0)	12 (7.4)	49 (15.3)	24 (14.7)	53 (16.5)	28 (17.2)	35 (10.9)	13 (8.0)	33 (10.3)	20 (12.3)	56 (17.4)	23 (14.1)
Moderate	57 (17.8)	25 (15.3)	83 (25.9)	30 (18.4)	60 (18.7)	14 (8.6)	80 (24.9)	27 (16.6)	84 (26.2)	26 (16.0)	51 (15.9)	16 (9.8)	66 (20.6)	30 (18.4)
Severe	155 (48.3)	76 (46.6)	121 (37.7)	66 (40.5)	147 (45.8)	82 (50.3)	124 (38.6)	68 (41.7)	126 (39.3)	71 (43.6)	158 (49.2)	82 (50.3)	133 (41.4)	69 (42.3)
Missing	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)	61 (19.0)	39 (23.9)

Week 16
Proportions improving from moderate/severe symptoms to no/minimal symptoms, %



Analysis was restricted to all patients randomized to BKZ and UST who had moderate to severe symptom item scores at baseline (denominators show the number of patients with moderate/severe symptom item scores at baseline). Severity categories were defined as shown on the first slide. BKZ: bimekizumab; NRI: non-responder imputation; Q4W: every 4 weeks; UST: ustekinumab.

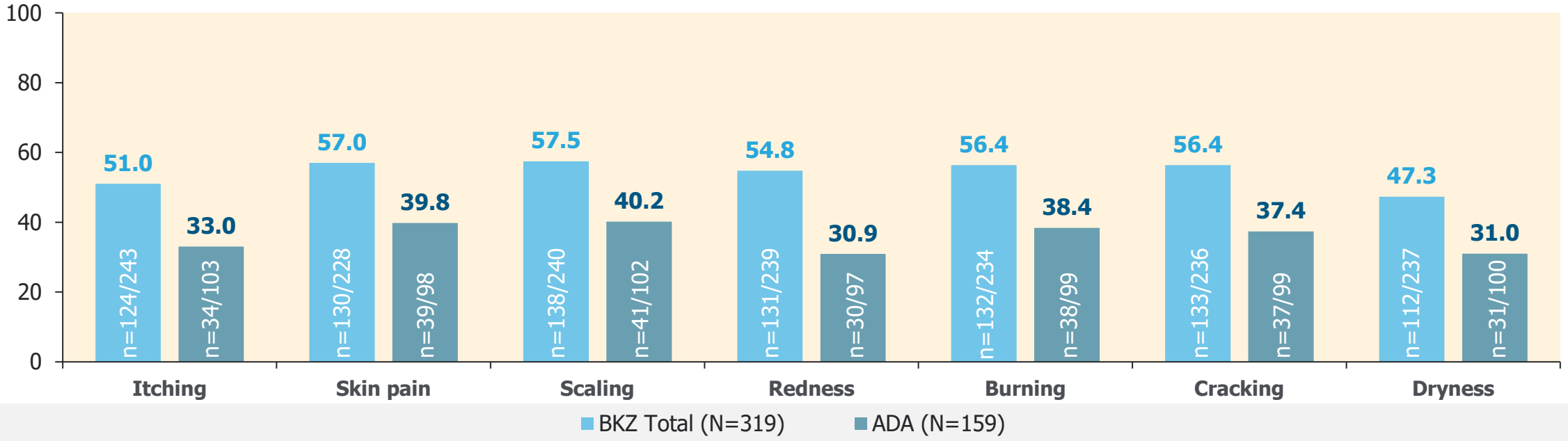
Results from BE SURE: BKZ- vs ADA-Treated Patients

Proportion of patients with moderate/severe symptoms at baseline who achieved no/minimal symptoms at Week 24 (NRI)

Baseline
P-SIM severity categories, n (%)

	Itching		Skin pain		Scaling		Redness		Burning		Cracking		Dryness	
	BKZ	ADA	BKZ	ADA	BKZ	ADA	BKZ	ADA	BKZ	ADA	BKZ	ADA	BKZ	ADA
None/ Minimal	5 (1.6)	5 (3.1)	16 (5.0)	13 (8.2)	5 (1.6)	5 (3.1)	2 (0.6)	3 (1.9)	13 (4.1)	11 (6.9)	12 (3.8)	14 (8.8)	1 (0.3)	3 (1.9)
Mild	23 (7.2)	17 (10.7)	27 (8.5)	14 (8.8)	26 (8.2)	18 (11.3)	30 (9.4)	25 (15.7)	24 (7.5)	15 (9.4)	23 (7.2)	12 (7.5)	33 (10.3)	22 (13.8)
Moderate	52 (16.3)	29 (18.2)	76 (23.8)	38 (23.9)	39 (12.2)	23 (14.5)	82 (25.7)	38 (23.9)	79 (24.8)	36 (22.6)	51 (16.0)	22 (13.8)	58 (18.2)	31 (19.5)
Severe	191 (59.9)	74 (46.5)	152 (47.6)	60 (37.7)	201 (63.0)	79 (49.7)	157 (49.2)	59 (37.1)	155 (48.6)	63 (39.6)	185 (58.0)	77 (48.4)	179 (56.1)	69 (43.4)
Missing	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)	48 (15.0)	34 (21.4)

Week 24
Proportions improving from moderate/severe symptoms to no/minimal symptoms, %



Analysis was restricted to all patients randomized to BKZ and ADA who had moderate to severe symptom item scores at baseline (denominators show the number of patients with moderate/severe symptom item scores at baseline); BKZ Total includes patients who were randomized to BKZ Q4W throughout, and patients who were randomized to BKZ Q4W to Week 16 then Q8W from Week 16 onwards. Severity categories were defined as shown on the first slide. ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; Q4W: every 4 weeks; Q8W: every 8 weeks.

CONCLUSIONS:

- We assessed changes in previously-defined symptom severity categories for a subset of seven items from the P-SIM which reflect core symptoms experienced by patients with plaque psoriasis.[1]
- Numerically greater proportions of bimekizumab-treated patients improved from moderate/severe to no/minimal symptoms versus ustekinumab and adalimumab in these seven items.

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1. Warren RB et al. Presented at ISPOR EU 2023, MSR85. P-SIM: Psoriasis Symptoms and Impacts Measure.