Bimekizumab efficacy in patients with moderate to severe plaque psoriasis: Psoriasis Symptoms and Impacts Measure (P-SIM) results across 14 items through Week 16 of three pivotal phase 3 trials

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Objective

To assess signs, symptoms and life impacts in patients with moderate to severe plaque psoriasis using the 14-item Psoriasis Symptoms and Impacts Measure (P-SIM) in the BE VIVID, BE SURE and BE READY phase 3 trials.

Background

- The P-SIM is a novel, reliable, well-defined, and validated 14-item patient-reported outcome tool developed to capture key signs, symptoms and life impacts of psoriasis.[1]
- Its items include: itching, redness, skin pain, burning, scaling, cracking, dryness, irritation, sensitivity, lesions, thickening, fatigue, embarrassment, and choice of clothing. P-SIM items are scored on an 11-point numeric rating scale ranging from 0 (no sign/symptom/impact) to 10 (very severe sign/symptom/impact).
- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[2] has demonstrated rapid and superior efficacy in the treatment of patients with moderate to severe plaque psoriasis in head-to-head studies versus ustekinumab (UST), adalimumab (ADA) and secukinumab, with established long-term durability of response.[3–7]
- BKZ has also previously demonstrated efficacy in improving itching, skin pain and scaling in patients with moderate to severe plaque psoriasis.[8–10]

Methods

- **Pooled** data are reported for **BKZ** from the first 16 weeks of the BE VIVID,[3] BE SURE[4] and BE READY[5] phase 3 trials; these patients were randomised to BKZ dosed 320 mg every 4 weeks (Q4W) to Week 16.
- **Study-level** data are also reported for **BKZ vs comparators** from the first 16 weeks of BE VIVID, BE SURE and BE READY, with patients assigned to treatment as shown in **Figure 1**.
- During the first 16 weeks of each study, P-SIM items were scored daily and averaged weekly.
- Here, the proportions of patients achieving a marked clinically meaningful improvement (defined as a ≥4-point reduction; patients with baseline item scores ≥4 only; pooled BKZ),[1] and the proportions achieving scores of 0 (patients with baseline item scores >0 only; pooled and study-level data), are reported for each P-SIM item at Week 16.
- Weekly P-SIM scores were set as missing if there were less than 4 recordings in a week; missing data were imputed using non-responder imputation (NRI).

Results

- Pooled across trials, 989 patients were initially randomised to BKZ (**Figure 1**).
- Baseline scores for each P-SIM item were similar across all treatment arms (**Table 1**).
- Baseline characteristics have been reported previously for both pooled BKZ and each treatment arm in each trial.[3–5, 11]

Pooled BKZ

- At Week 16, for each P-SIM item, the majority of patients randomised to BKZ achieved ≥4-point reductions from baseline, ranging from 62.1% for fatigue to 73.0% for scaling (**Figure 2A**).
- Across items, a substantial proportion of patients randomised to BKZ achieved P-SIM=0 at Week 16 (P-SIM score of 0 at every recording in the week leading up to the Week 16 study visit), ranging from 26.8% for dryness to 52.5% for skin pain (**Figure 2B**).

Study-level

- At study level, numerically higher proportions of patients achieved resolution of signs, symptoms or impacts (P-SIM=0) at Week 16 for each P-SIM item with BKZ versus UST, ADA and placebo (PBO) (**Figure 3**).

Conclusions

BKZ treatment was associated with marked clinically meaningful improvements in, or resolution of, psoriasis-related signs, symptoms and impacts at Week 16. Numerically higher proportions of patients achieved the stringent outcome of complete symptom resolution with BKZ compared with UST, ADA and PBO at the individual study level.

About the 14-item P-SIM

The P-SIM is a reliable, validated, **patient-reported outcome (PRO)** tool capturing **key signs, symptoms and impacts** of plaque psoriasis.[1]

A **≥4-point reduction from baseline** is considered to indicate a **marked clinically meaningful improvement** in P-SIM items.[1] A score of **0 indicates no sign/symptom/impact**.

Here, the **14 P-SIM items** were scored daily by patients and averaged weekly during the first 16 weeks of BE VIVID, BE SURE and BE READY using an electronic **PRO tablet**.

1. Itching
2. Redness
3. Skin pain
4. Burning
5. Scaling
6. Cracking
7. Dryness
8. Irritation
9. Sensitivity
10. Lesions
11. Thickening
12. Fatigue
13. Embarrassment
14. Choice of clothing

0 No signs/ symptoms/impacts

10 Very severe signs/ symptoms/impacts[a]

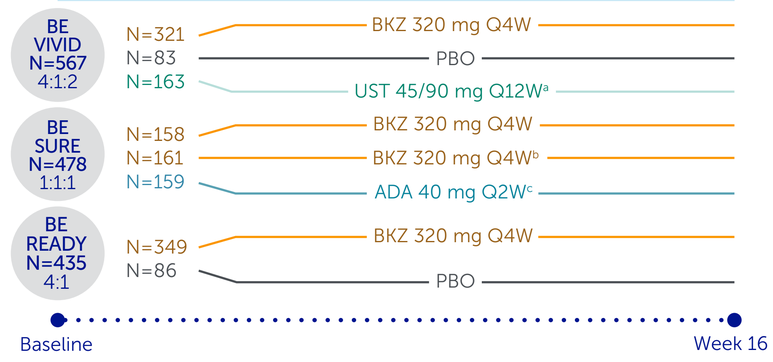
[a]For fatigue and embarrassment, 10 indicated 'worst possible fatigue/feelings of embarrassment'; for choice of clothing, 10 indicated 'completely impacted choice of clothing'.

Table 1 Baseline P-SIM scores

P-SIM Item	Mean baseline P-SIM item score ± SD							
	Pooled across studies (n/N)[a]	BE VIVID (n/N)[a]			BE SURE (n/N)[a]		BE READY (n/N)[a]	
	Pooled BKZ n=837/989	BKZ n=260/321	UST n=124/163	PBO n=67/83	BKZ n=271/319	ADA n=125/159	BKZ n=306/349	PBO n=74/86
Itching	6.6 ± 2.4	6.6 ± 2.4	6.6 ± 2.4	6.1 ± 2.5	7.1 ± 2.1	6.6 ± 2.5	6.3 ± 2.5	6.4 ± 2.4
Redness	6.7 ± 2.2	6.6 ± 2.3	6.6 ± 2.3	6.3 ± 2.4	7.1 ± 2.0	6.5 ± 2.4	6.5 ± 2.3	6.5 ± 2.4
Skin pain	5.8 ± 2.8	5.7 ± 2.9	5.7 ± 2.9	5.1 ± 2.9	6.3 ± 2.6	5.7 ± 2.9	5.4 ± 2.9	5.6 ± 2.9
Burning	5.9 ± 2.7	5.9 ± 2.7	5.9 ± 2.9	5.3 ± 2.8	6.3 ± 2.5	5.8 ± 2.8	5.6 ± 2.9	5.8 ± 2.9
Scaling	6.8 ± 2.2	6.7 ± 2.3	6.8 ± 2.4	6.6 ± 2.3	7.3 ± 2.1	6.7 ± 2.3	6.6 ± 2.3	6.6 ± 2.3
Cracking	6.0 ± 2.7	5.9 ± 2.8	6.1 ± 2.8	5.6 ± 2.8	6.4 ± 2.5	5.8 ± 2.9	5.7 ± 2.8	5.8 ± 2.7
Dryness	7.0 ± 2.3	6.7 ± 2.5	6.9 ± 2.3	6.5 ± 2.5	7.5 ± 1.9	6.9 ± 2.3	6.8 ± 2.3	6.8 ± 2.3
Irritation	6.5 ± 2.5	6.2 ± 2.6	6.3 ± 2.6	5.8 ± 2.8	7.0 ± 2.2	6.3 ± 2.5	6.3 ± 2.5	6.3 ± 2.6
Sensitivity	6.2 ± 2.6	6.0 ± 2.7	6.2 ± 2.6	5.7 ± 2.9	6.7 ± 2.2	6.1 ± 2.6	6.0 ± 2.7	6.1 ± 2.7
Lesions	6.7 ± 2.3	6.5 ± 2.4	6.7 ± 2.4	6.3 ± 2.5	7.2 ± 2.1	6.5 ± 2.4	6.5 ± 2.4	6.7 ± 2.6
Thickening	6.5 ± 2.4	6.2 ± 2.5	6.5 ± 2.5	6.1 ± 2.7	6.9 ± 2.4	6.3 ± 2.5	6.3 ± 2.4	6.4 ± 2.4
Fatigue	5.2 ± 3.1	5.1 ± 3.1	5.3 ± 3.0	4.9 ± 3.1	5.5 ± 3.0	5.0 ± 3.1	5.1 ± 3.3	5.5 ± 3.2
Embarrassment	6.3 ± 3.2	5.8 ± 3.3	6.2 ± 3.0	5.3 ± 3.5	6.8 ± 3.0	5.9 ± 3.1	6.2 ± 3.2	6.1 ± 3.4
Choice of clothing	6.5 ± 3.3	6.0 ± 3.5	6.5 ± 3.2	5.7 ± 3.6	6.9 ± 3.0	6.3 ± 3.3	6.7 ± 3.3	6.1 ± 3.4

[a]N, number of patients randomised to that treatment; n, number of patients with non-missing baseline P-SIM data.

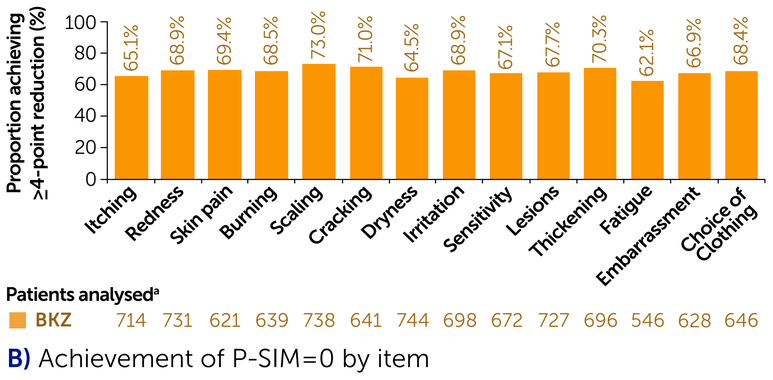
Figure 1 BE VIVID, BE SURE and BE READY study designs



Here, P-SIM scores are reported from Week 0–16 of these trials. [a]UST 45/90 mg (by weight) was administered at baseline and then Q12W from Week 4; [b]These patients were randomised to receive BKZ 320 mg Q4W from Week 0–16, then Q8W from Week 16; [c]ADA was administered 80 mg at Week 0 and 40 mg at Week 1 then Q2W.

Figure 2 Pooled BKZ P-SIM response rates at Week 16 (NRI)

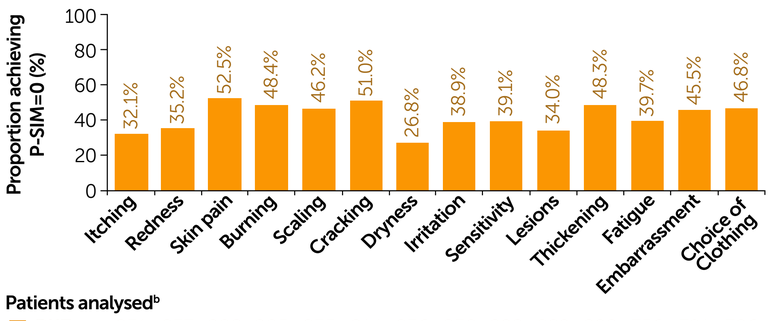
A) Achievement of ≥4-point reduction from baseline in P-SIM by item



Patients analysed[a]

BKZ	714	731	621	639	738	641	744	698	672	727	696	546	628	646

B) Achievement of P-SIM=0 by item



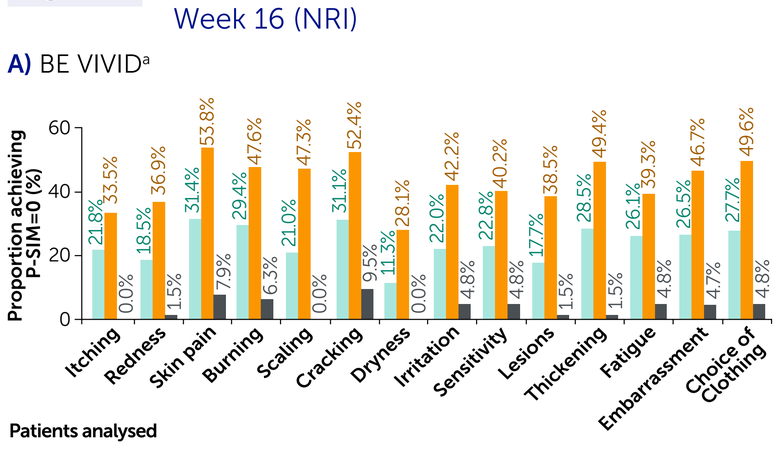
Patients analysed[b]

BKZ	831	837	808	805	835	814	836	830	828	829	828	756	791	786

Data were pooled for all patients randomised to BKZ at BE VIVID, BE SURE and BE READY trial baselines. Data are reported in patients with a baseline P-SIM score ≥4 (A) or a baseline P-SIM score >0 (B) for the item of interest. [a]Table under the graph indicates the number of patients with P-SIM score ≥4 at baseline for each item. [b]Table under the graph indicates the number of patients with P-SIM score >0 at baseline for each item.

Figure 3 Study-level achievement of P-SIM=0 at Week 16 (NRI)

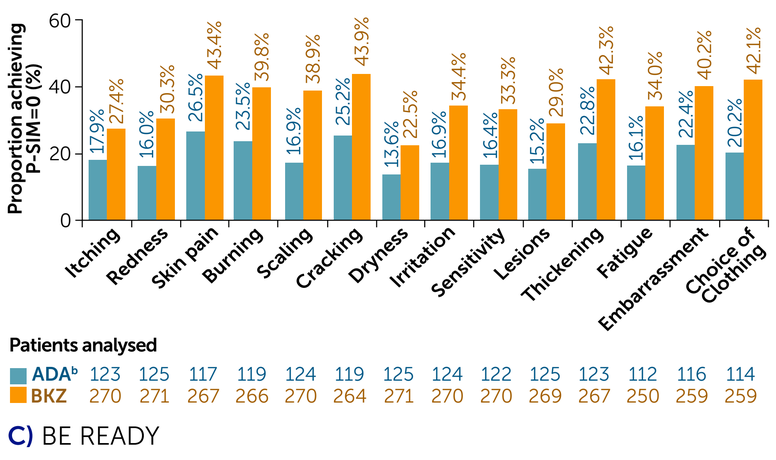
A) BE VIVID[a]



Patients analysed

UST[a]	124	124	118	119	124	122	124	123	123	124	123	115	117	119
BKZ	257	260	249	252	260	252	260	258	256	257	259	234	242	240
PBO	66	67	63	64	67	63	66	63	63	66	65	62	64	62

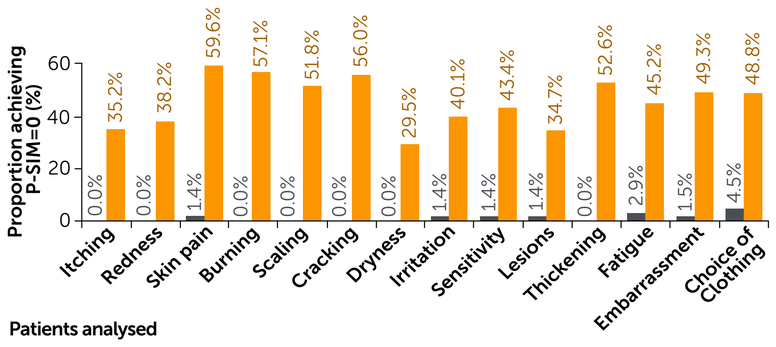
B) BE SURE[b]



Patients analysed

ADA[b]	123	125	117	119	124	119	125	124	122	125	123	112	116	114
BKZ	270	271	267	266	270	264	271	270	270	269	267	250	259	259

C) BE READY



Patients analysed

PBO	74	74	72	71	74	72	74	74	73	74	74	68	68	67
BKZ	304	306	292	287	305	298	305	302	302	303	302	272	290	287

Data are reported in patients with a baseline P-SIM score >0. Tables under each graph indicate the number of patients with P-SIM score >0 at baseline for each item. [a]UST 45/90 mg (by weight) was administered at baseline and then Q12W from Week 4; [b]ADA was administered 80 mg at Week 0 and 40 mg at Week 1 then Q2W.

ADA: adalimumab; **BKZ:** bimekizumab; **IL:** interleukin; **NRI:** non-responder imputation; **PBO:** placebo; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **Q12W:** every 12 weeks; **SD:** standard deviation; **UST:** ustekinumab.

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