Bimekizumab efficacy in moderate to severe plaque psoriasis: Improvements in fatigue observed in two phase 3 studies

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Objective

To assess the effect of bimekizumab (BKZ) on fatigue levels, using the Psoriasis Symptoms and Impacts Measure (P-SIM) fatigue item, vs adalimumab (ADA), ustekinumab (UST), and placebo (PBO) in patients with moderate to severe plaque psoriasis from two phase 3 studies.

Background

- Patients with psoriasis can experience significant fatigue,[1] which can have a major impact on physical and social functioning, and reduces the ability of patients to perform daily activities.[2,3]
- High levels of fatigue have been described as a symptom that predicts development of psoriatic arthritis.[4]
- Biologic agents have demonstrated benefits in reducing fatigue among patients with psoriasis.[2]
- BKZ is a monoclonal IgG1 antibody biologic therapy which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[5]
- BKZ has demonstrated long-term sustained improvements in fatigue in patients with psoriatic arthritis, as assessed using patient-reported outcome measures;[6] here, we assess the impact of BKZ on fatigue in patients with psoriasis using the single psoriasis-related fatigue item from the P-SIM, a 14-item patient-reported outcome tool which captures key symptoms and life impacts of psoriasis.[7]

Methods

- Study designs for BE VIVID and BE SURE have been published previously.[8,9]
- In BE VIVID, patients received BKZ 320 mg every 4 weeks (Q4W), UST at baseline and Week 4 then Q12W, or PBO for the 16-week active comparator-controlled initial treatment period.[8]
- In BE SURE, patients received BKZ Q4W to Week 16 then BKZ Q4W or Q8W thereafter (dosing groups combined; BKZ Total), or ADA Q2W for the 24-week active comparator-controlled period.[9]
- P-SIM data were collected until Week 16 of BE VIVID and Week 24 of BE SURE.
- The P-SIM fatigue item was scored daily on a numeric rating scale from 0–10 (no fatigue–worst possible fatigue) and averaged weekly. Mean P-SIM fatigue scores and mean change from baseline are reported using observed case (OC) data.
- Additionally, proportions of patients recording a P-SIM fatigue score of 0 are reported, alongside proportions with baseline P-SIM fatigue scores ≥4 who achieved a clinically meaningful improvement (≥4-point reduction from baseline),[7] using non-responder imputation (NRI).

Results

- In BE VIVID, 321 patients were randomised to BKZ, 163 to UST, and 83 to PBO.
- In BE SURE, 319 patients were randomised to BKZ and 159 to ADA.
- In both studies, observed mean P-SIM fatigue scores were similar across treatment groups at baseline and were numerically lower at Week 4 and Week 16/24 with BKZ vs comparators (**Table 1**).
- Proportions of patients recording a P-SIM fatigue score of 0 at baseline were low and similar across treatment groups; proportions increased by Week 4 and were numerically higher by Week 16/24 with BKZ vs comparators (**Figure 1**).
- In patients with baseline P-SIM fatigue scores ≥4, numerically greater proportions of BKZ-treated patients achieved a clinically meaningful ≥4-point reduction from baseline at Week 16/24 vs comparators (**Figure 2**).
  - Notably, numerically greater proportions of BKZ-treated patients demonstrated clinically meaningful improvement vs comparators as early as Week 4.

Conclusions

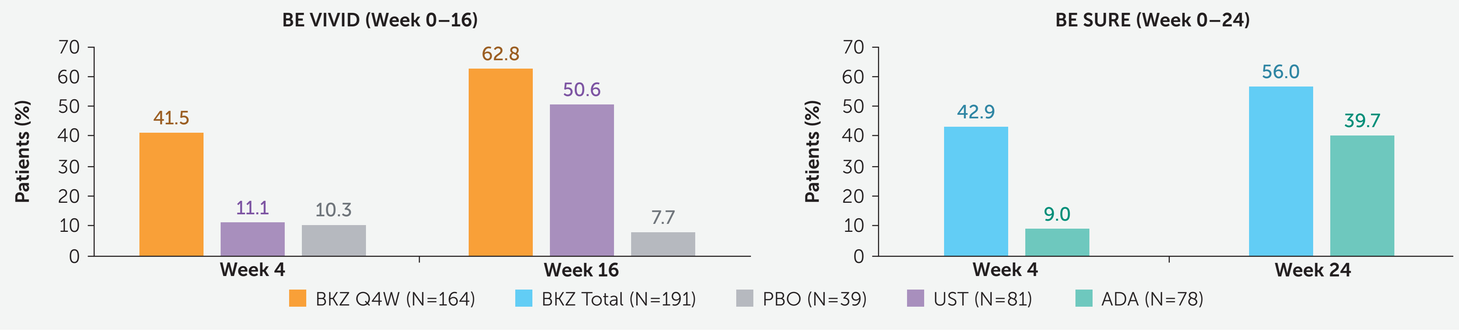
BKZ treatment resulted in faster improvements in fatigue vs ADA, UST, and PBO, with numerically greater proportions of BKZ patients achieving a clinically meaningful improvement as early as Week 4. These proportions further improved and were numerically greater with BKZ vs comparators through to Week 16/24.

Additionally, after 16/24 weeks, numerically greater proportions of BKZ-treated patients vs comparators reported having no fatigue, the presence of which has been reported as a predictor for progression to psoriatic arthritis.[4]

Summary

BKZ treatment resulted in numerically greater proportions of patients achieving a **clinically meaningful improvement** in fatigue, indicated by a ≥4-point reduction from baseline in the P-SIM fatigue score (0–10), as early as Week 4 and through to Week 16/24 vs comparators (NRI)

Patients achieving a clinically meaningful change from baseline in P-SIM fatigue scores:



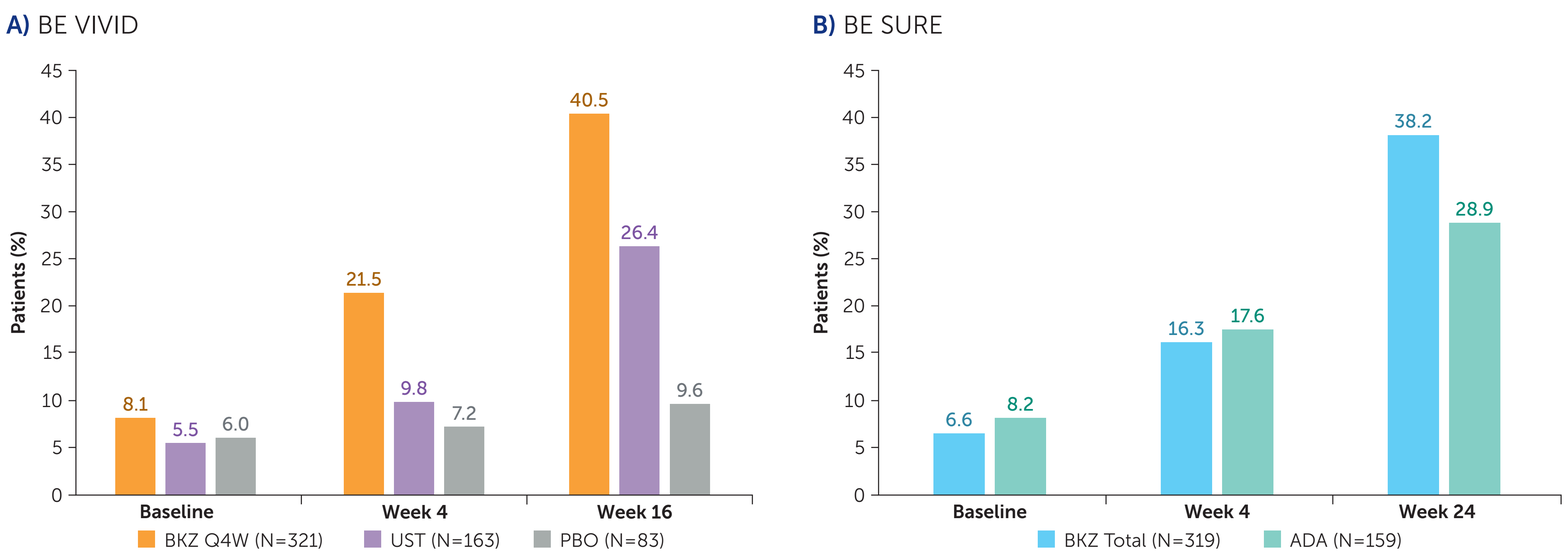
Patients included in this analysis had P-SIM fatigue scores of ≥4 at baseline. BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen.

Table 1 Mean P-SIM fatigue scores and mean change from baseline in BKZ- and comparator-treated patients from BE VIVID and BE SURE (OC)

BE VIVID	BKZ Q4W N=321	UST Q12W[a] N=163	PBO N=83
P-SIM fatigue score, mean ± SD (N_{obs})			
Baseline	5.1 ± 3.1 (260)	5.3 ± 3.0 (124)	4.9 ± 3.1 (67)
Week 4	2.4 ± 2.4 (291)	3.7 ± 2.9 (135)	4.8 ± 3.1 (72)
Week 16	1.2 ± 1.8 (258)	2.2 ± 2.6 (124)	4.7 ± 3.2 (59)
Change from baseline, mean ± SD (N_{obs})			
Week 4	−2.6 ± 2.5 (248)	−1.3 ± 1.7 (112)	−0.2 ± 2.1 (62)
Week 16	−3.8 ± 3.1 (225)	−3.1 ± 3.1 (106)	0.5 ± 2.7 (53)
BE SURE	**BKZ Total N=319**	**ADA Q2W[b] N=159**	
P-SIM fatigue score, mean ± SD (N_{obs})			
Baseline	5.5 ± 3.0 (271)	5.0 ± 3.1 (125)	
Week 4	2.5 ± 2.4 (249)	3.6 ± 2.8 (123)	
Week 24	1.3 ± 2.2 (224)	2.3 ± 2.9 (108)	
Change from baseline, mean ± SD (N_{obs})			
Week 4	−3.1 ± 2.7 (226)	−1.4 ± 1.8 (104)	
Week 24	−4.2 ± 3.2 (206)	−2.5 ± 3.0 (93)	

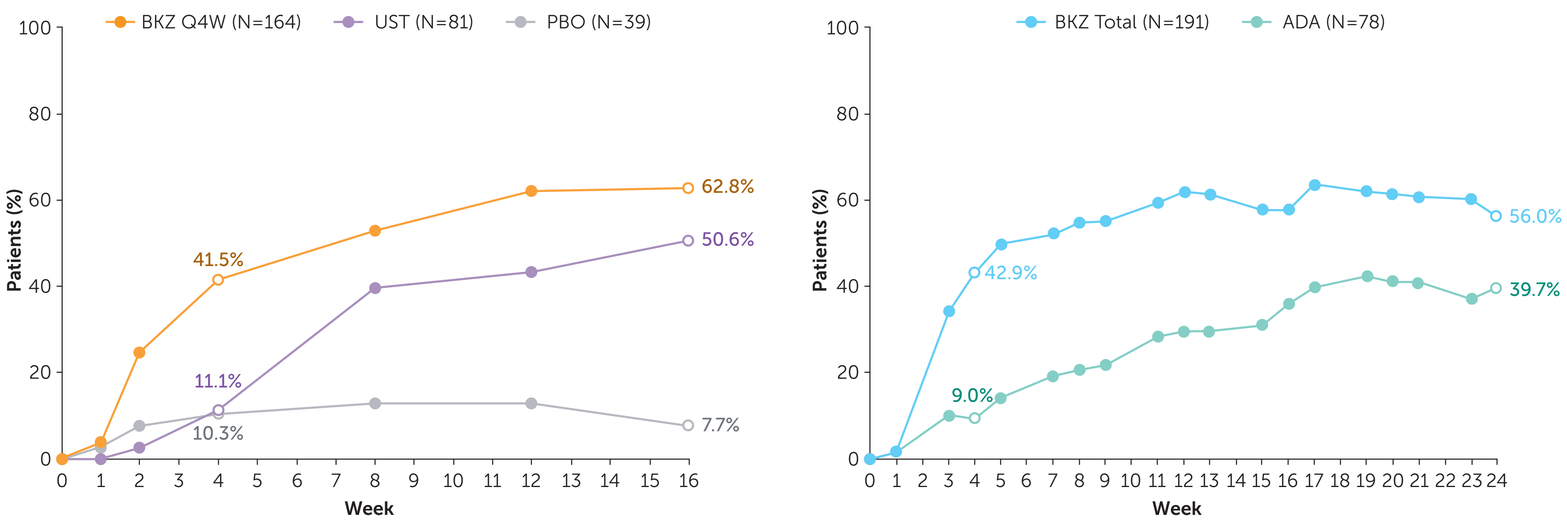
BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen. [a] Patients received UST at baseline, Week 4, then Q12W thereafter, per labelling recommendations (45 mg for patients weighing ≤100 kg and 90 mg for patients weighing >100 kg); [b] Patients received ADA 80 mg at baseline, then 40 mg Q2W from Week 1 until Week 24, per labelling recommendations.

Figure 1 Proportion of patients achieving P-SIM fatigue scores of 0 in BE VIVID and BE SURE (NRI)



BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen.

Figure 2 Clinically meaningful change from baseline in P-SIM fatigue scores (≥4-point reduction from baseline) in patients with scores of ≥4 at baseline in BE VIVID and BE SURE (NRI)



BKZ Total includes all BKZ-randomised patients, regardless of dosing regimen.

ADA: adalimumab; **BKZ:** bimekizumab; **IL:** interleukin; **N_{obs}:** N observed; **NRI:** non-responder imputation; **OC:** observed case; **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.

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N Engl J Med 2021;385:130–41, NCT03412747. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ABG**, **MA**, **JoL**, **AP**, **LJS**, **TFT**, **PF**, **CP**, **RW**, **JeL**, **SW**, **MS**; Drafting of the publication, or reviewing it critically for important intellectual content: **ABG**, **MA**, **JoL**, **AP**, **LJS**, **TFT**, **PF**, **CP**, **RW**, **JeL**, **SW**, **MS**; Final approval of the publication: **ABG**, **MA**, **JoL**, **AP**, **LJS**, **TFT**, **PF**, **CP**, **RW**, **JeL**, **SW**, **MS**. **Author Disclosures:** **ABG:** Received research/educational grants from Highlights Therapeutics, Bristol Myers Squibb, Janssen, and UCB Pharma (all paid to Mount Sinai School of Medicine); received honoraria/speaker fees as an advisory board member and consultant for Amgen, AnaptypsBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB Pharma, and Xbiotech (stock options for RA). **MA:** Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly and Company, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport. **JoL:** Advised AbbVie, Amgen, ArgenX, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Sanofi, and UCB Pharma. **AP:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, and UCB Pharma. **LJS:** Received grant/research support from Janssen and Pfizer; consultant for AbbVie, Almirall, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, and UCB Pharma; speaker for AbbVie, Almirall, Amgen, Aspire Pharma, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi-Genzyme, and UCB Pharma. **TFT:** Investigator, speaker and/or advisor for AbbVie, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, Kyowa Kirin, Merck Serono, MSD, Novartis, and Pfizer. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; served as an investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Celtaxsys, CSL, Cutanea, Dermira, Eli Lilly and Company, Evelo, Galderma, Genentech, Geneseq, GenesisCare, GSK, Heximа, Incyte, Janssen, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Takeda, Teva, UCB Pharma, and Valeant; served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and Valeant; served as a consultant for Aslan, Bristol Myers Squibb, Eli Lilly and Company, Galderma, GenesisCare, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute; received travel grants from AbbVie, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, and Sun Pharma; served as a speaker for or received honoraria from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant. **CP:** Consulting fees and/or grants from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, GSK, Janssen-Cilag, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi-Regeneron, and UCB Pharma. **RW:** Veramed statistical consultant for UCB Pharma. **JeL**, **SW:** Employees and shareholders of UCB Pharma. **MS:** Received honoraria for participating in advisory boards and has given lectures for AbbVie, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Lipidor, Novartis, Pfizer, and UCB Pharma. **Acknowledgements:** These studies were funded by UCB Pharma. 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