Itching, skin pain and scaling in patients with plaque psoriasis: The relationship between improvements in Psoriasis Area and Severity Index and Psoriasis Symptoms and Impacts Measure responses

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Objective

To assess the impact of incremental improvements in Psoriasis Area and Severity Index (PASI) scores on the achievement of Psoriasis Symptoms and Impacts Measure (P-SIM) scores of 0 (indicating no symptom) for the itching, skin pain and scaling items.

Background

- Psoriasis can have a significant negative impact on patients' quality of life.[1]
- The P-SIM is a novel, reliable and well-defined patient-reported outcome tool capturing key symptoms of psoriasis in bimekizumab (BKZ) clinical trials (each symptom scored 0–10; 0=no symptom, 10=very severe symptom).[2]
- The association between skin clearance and Dermatology Life Quality Index (DLQI) has been reported previously; incremental PASI improvements translate to higher rates of achievement of DLQI 0/1 (no impact of skin disease on a patient's life).[3]

Methods

- These analyses used data pooled across all visits and treatment arms from the initial 16-week periods of the BE SURE, BE VIVID, BE READY and BE RADIANT BKZ in plaque psoriasis phase 3/3b trials (**Figure 1**).[4–7]
- A mixed-effects logistic regression model was used to assess the relationship between skin clearance and symptom absence for the itching, skin pain and scaling items of the P-SIM (observed case).
- Model-fitted estimates for P-SIM=0 response rates for each of the items at different levels of PASI response are reported with 95% confidence intervals (CI).

Results

- Analyses included 2,223 randomised patients, with mean baseline PASI=20.4 (n=2,222) and mean baseline P-SIM scores for itching=6.6, skin pain=5.3, and scaling=6.8 (n=1,970; **Table 1**).
- Model-estimated percentages of patients achieving P-SIM=0 for itching were 31.5% with PASI improvement=100%, 19.8% with PASI improvement=95%, 11.7% with PASI improvement=90% and 2.0% with PASI improvement=75% (**Figure 2A**).
- For P-SIM=0 in skin pain, estimated percentages were 81.8% with PASI improvement=100%, 73.1% with PASI improvement=95%, 62.1% with PASI improvement=90% and 26.6% with PASI improvement=75% (**Figure 2B**).
- For P-SIM=0 in scaling, estimated percentages were 63.0% with PASI improvement=100%, 44.8% with PASI improvement=95%, 27.9% with PASI improvement=90% and 4.0% with PASI improvement=75% (**Figure 2C**).

Conclusions

Incremental PASI improvements correspond with more patients achieving P-SIM=0 for itching, skin pain and scaling items, reflecting the importance of complete skin clearance as a treatment outcome.

Higher proportions of patients were estimated to achieve P-SIM=0 for skin pain and scaling, as compared with itching, for each PASI improvement level.

Both clinical and patient-reported outcome measures should be considered when investigating efficacy of psoriasis treatment.

Summary

Incremental **PASI improvements** correspond with more patients achieving **P-SIM=0** for the items: **itching, skin pain** and **scaling**

Relationship between different levels of skin clearance and symptom absence for the itching, skin pain and scaling items of the P-SIM

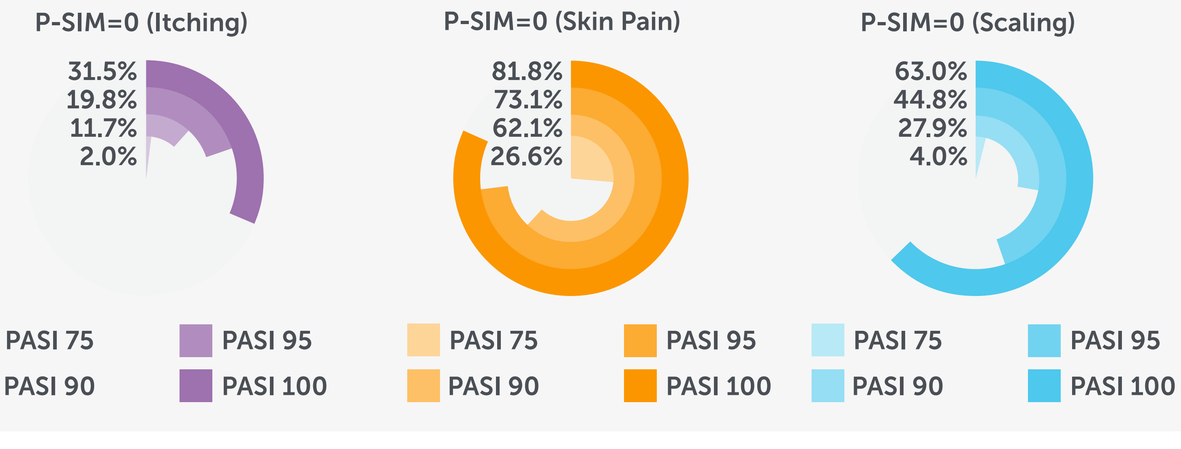
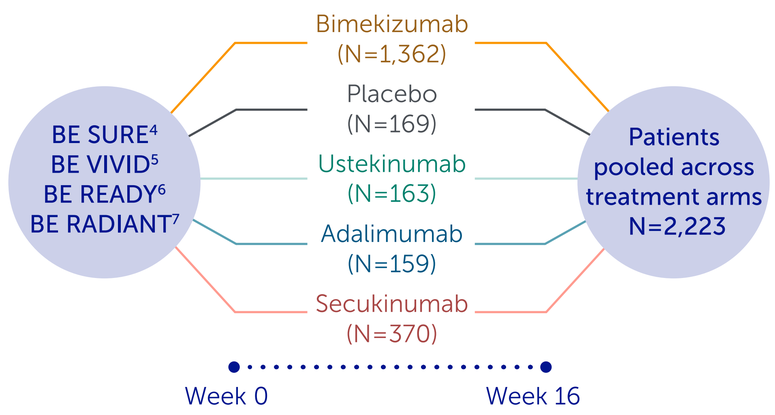


Figure 1 Included patients



P-SIM data were collected at study clinic visits only in BE RADIANT; P-SIM data were collected daily, and weekly averages calculated, in the other three trials (therefore making achievement of a score of 0 a more stringent outcome in these three trials). The number of patients who contributed to the models is 1,957; to be included in the models, patients were required to have non-missing baseline P-SIM and PASI scores, and at least one post-baseline visit at which both their P-SIM and PASI scores were not missing.

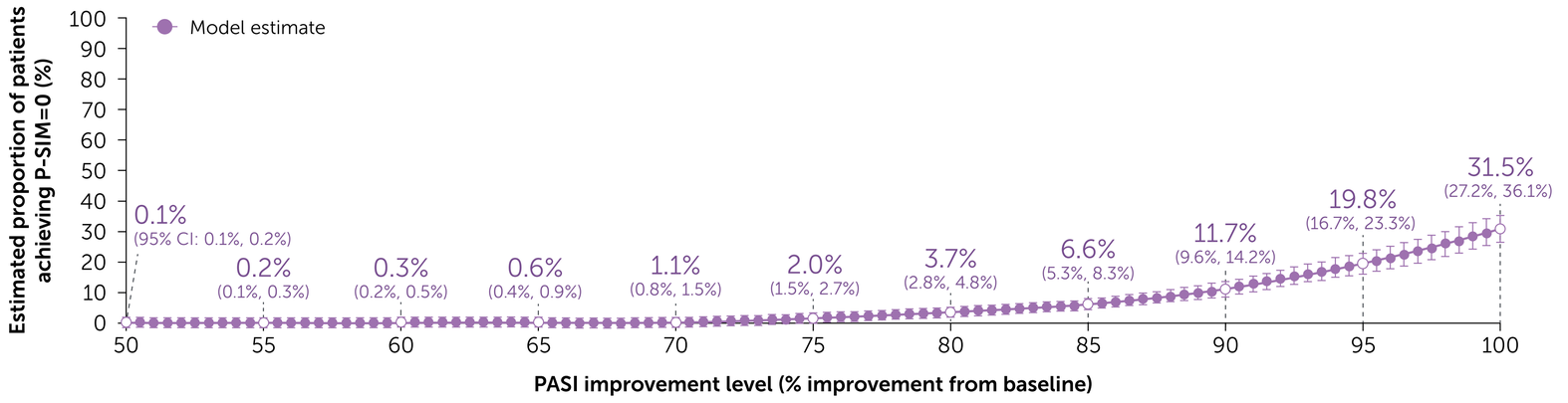
Table 1 Baseline characteristics

	Patients pooled across treatment arms N=2,223
Age (years), mean ± SD	45.1 ± 13.9
Male, n (%)	1,533 (69.0)
White, n (%)	1,939 (87.2)
Weight (kg), mean ± SD	89.5 ± 21.8
Duration of psoriasis (years), mean ± SD	18.0 ± 12.5
PASI,[a] mean ± SD	20.4 ± 7.4
P-SIM item score,[b] mean ± SD	
Itching	6.6 ± 2.5
Skin Pain	5.3 ± 3.0
Scaling	6.8 ± 2.3
DLQI total, mean ± SD	10.7 ± 6.7
Prior systemic therapy, n (%)	1,687 (75.9)
Prior biologic therapy, n (%)	810 (36.4)

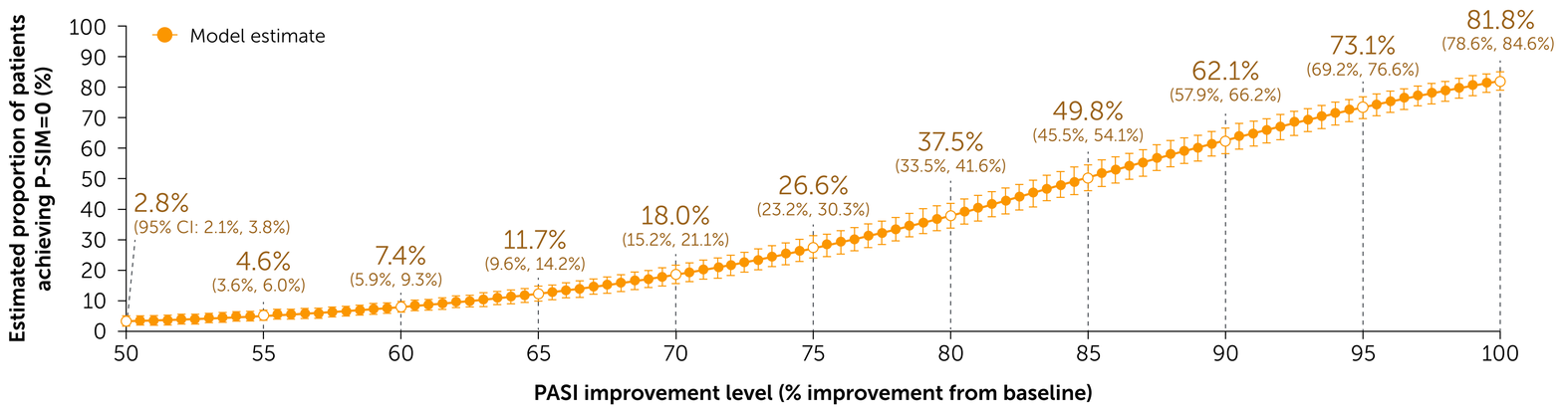
[a]n=2,222; [b]n=1,970.

Figure 2 Model-estimated proportions of patients achieving P-SIM=0 at different PASI improvement levels

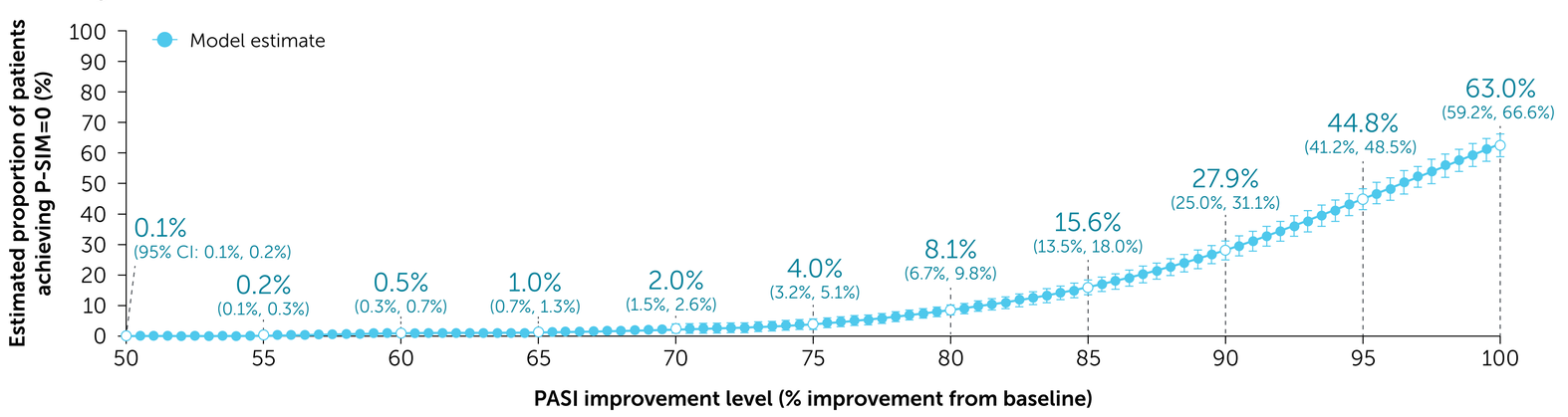
A) Itching



B) Skin Pain



C) Scaling



A mixed-effects logistic regression model used data pooled across all trial visits and treatments from the initial 16-week periods of BE SURE, BE VIVID, BE READY and BE RADIANT to estimate the proportions of patients achieving P-SIM=0 for the itching, skin pain and scaling items at specific PASI improvement levels. Models included PASI % change from baseline and baseline P-SIM score as covariates, with a patient-level random intercept to account for repeated observations at the patient level. The curves correspond to model estimates calculated with baseline P-SIM item scores equal to the baseline medians of 7.0, 5.8 and 7.0 for itching, skin pain and scaling, respectively. Error bars indicate 95% CIs.

BKZ: bimekizumab; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **PASI 75/90/95/100:** =75%/90%/95%/100% improvement in Psoriasis Area and Severity Index; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **SD:** standard deviation.

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References: [1]Blauvelt A *et al.* J Drugs Dermatol 2020;19:487–92; [2]Gottlieb AB *et al.* Dermatol Ther (Heidelb) 2020;10:1255–72; [3]Blauvelt A. *et al.* Presented at AAD 2022, Poster 33884; [4]Warren RB *et al.* N Engl J Med 2021;385:130–41, NCT03412747; [5]Reich K *et al.* Lancet 2021;397:487–98, NCT03370133; [6]Gordon KB *et al.* Lancet 2021;397:475–86, NCT03410992; [7]Reich K *et al.* N Engl J Med 2021;385:142–52, NCT03536884. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AP, MA, DP, PG, ALF, MH, RW, BS, SW, VC, ABG;** Drafting of the publication, or revising it critically for important intellectual content: **AP, MA, DP, PG, ALF, MH, RW, BS, SW, VC, ABG;** Final approval of the publication: **AP, MA, DP, PG, ALF, MH, RW, BS, SW, VC, ABG**. **Author Disclosures: AP:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma and UCB Pharma. **MA:** Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma and Xenoport. **DP:** Honoraria for participation on advisory boards, data safety monitoring boards, consultancy or as an investigator from: Atacama Therapeutics, Bickel Biotechnology, Biofrontera AG, Bristol Myers Squibb, Celgene, Dermira, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, TheraVida, and Valeant; grants/research funding: Almirall, Amgen, AOBiome, Asana Biosciences, Bickel Biotechnology, Celgene, Dermavant, Dermira, Eli Lilly, LEO Pharma, Menlo Therapeutics, Merck, Novartis, Novo Nordisk, Ortho Dermatologics, Pfizer and Regeneron. **PG:** Consultant for AbbVie, Abiogen, Almirall, Celgene, Eli Lilly, Janssen, LEO Pharma, Merck, MSD, Novartis, Otsuka, Pfizer, Pierre Fabre, Sanofi and UCB Pharma. **ALF:** Reports personal fees for participation as an advisory board member, consultant and/or speaker, and grants/research support for participation in clinical trials with AbbVie, Almirall, Amgen, Boehringer Ingelheim, Eli Lilly, Janssen, LEO Pharma, MSD, Novartis and UCB Pharma. **MH:** Advisor and/or received speakers' honoraria and/or received grants and/or participated in clinical trials of the following companies: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Eli Lilly, GSK, Janssen, LEO Pharma, MSD, Novartis, Pfizer and UCB Pharma. **RW:** Veramed statistical consultant for UCB Pharma. **BS, SW, VC:** Employees and shareholders of UCB Pharma. **ABG:** Received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres Therapeutics, Bristol Myers Squibb, Boehringer Ingelheim, Dice Therapeutics, Eli Lilly, Janssen, Novartis, Sanofi, UCB Pharma and Xbiotech; received research/educational grants from AnaptysBio, Bristol Myers Squibb, Moonlake Immunotherapeutics, Novartis and UCB Pharma; all funds paid to Mount Sinai School of Medicine. **Acknowledgements:** These studies were funded by UCB Pharma. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Yasha Najafi, MSc, Costello Medical, London, UK, for medical writing and editorial assistance and the Creative team, Costello Medical, UK for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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