

Bimekizumab quality of life and treatment satisfaction outcomes in patients with moderate to severe plaque psoriasis in routine clinical practice in Germany: 1-year results from the ELEVATE observational study

P1190

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Objective

To evaluate patient-reported outcomes (PROs) through 52 weeks in patients receiving bimekizumab (BKZ) for moderate to severe plaque psoriasis who were enrolled in Germany in the ELEVATE observational study, stratified by previous treatment history.

Introduction

- BKZ, a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,¹ was approved in Europe and became available in Germany from September 2021 for the treatment of moderate to severe plaque psoriasis.^{2,3}
- Psoriasis can impose a significant burden on patients’ health-related quality of life (HRQoL) due to physical symptoms, psychological strain and stigmatisation.^{4,5}
- ELEVATE, a prospective, real-world study across France, Germany, Greece, Italy and the UK, describes treatment history, PROs (HRQoL, psoriasis signs/symptoms and treatment satisfaction) and clinical outcomes in adults receiving BKZ in routine clinical practice.
- Baseline characteristics of the total ELEVATE population (poster P1167) and 1-year clinical outcomes in the German population (poster P1186) are reported separately.

Methods

- ELEVATE is an ongoing multicentre, observational, non-interventional, primary data collection study.
- Eligible patients were aged ≥18 years with moderate to severe psoriasis newly initiating BKZ per local label requirements.
- Patients completed the following PRO measures via an app at Week 0 (baseline) and approximately Weeks 2, 4, 8, 12, 26, 39 and 52 (Figure 1):
 - Dermatology Life Quality Index (DLQI): 10-item questionnaire evaluating the effect of skin disease on patients’ lives; scored from 0 (no effect of skin disease on a patient’s life) to 30 (extremely large effect of skin disease on a patient’s life);⁶
 - Psoriasis Symptoms and Impacts Measure (P-SIM): 14-item questionnaire capturing patients’ experience of key signs, symptoms and impacts of psoriasis over the past 7 days on numerical rating scales from 0 (no sign/symptom/impact) to 10 (very severe sign/symptom/impact);⁷
 - Treatment Satisfaction Questionnaire for Medications-9 (TSQM-9): abbreviated 9-item version capturing patients’ satisfaction with treatment effectiveness, convenience and global satisfaction (scored 0–100).⁸
- Primary study objectives were to characterise the treatment history of patients initiating BKZ, and to assess the proportion of patients reporting no effect of skin disease on their lives (DLQI 0/1) at Week 26.
- This analysis was performed once all German patients completed approximately Week 52.
- Observed case (OC) results are reported for all patients with a baseline and ≥1 post-baseline assessment (full analysis set), stratified by treatment history subgroups (systemic-na  ve; systemic-experienced/biologic-na  ve; biologic-experienced).

Results

- Of the 1,337 patients enrolled in ELEVATE at the data cut-off who received ≥1 BKZ dose, 557 patients from Germany were included in this analysis (systemic-na  ve: N=140; systemic-experienced/biologic-na  ve: N=203; biologic-experienced: N=214).
 - Total German baseline characteristics are reported separately (poster P1167) and were representative of a moderate to severe psoriasis population.
- At Week 26, the DLQI 0/1 response rate (95% confidence intervals) in the total German population was 56.7% (50.6, 62.6), with >50% of patients in all subgroups reporting DLQI 0/1. Rates were maintained or numerically increased at Week 52 (Figure 2).
 - A clinically meaningful reduction (≥4-point within-patient improvement)^{9,10} was observed in the overall mean (standard deviation) DLQI score from baseline (14.1 [7.7]; N=502) to Week 52 (2.5 [4.1]; N=153), including all subgroups.
 - Mean DLQI scores at Week 52 were numerically lower for biologic-na  ve versus biologic-experienced patients.
- For all items (including skin itching, redness, pain and scaling shown here), the proportions of patients reporting no sign/symptom/impact (P-SIM=0) rapidly increased by Week 2 in all subgroups (Figure 3).
 - These proportions were generally maintained or numerically increased from Week 26 to Week 52.
- Mean TSQM-9 effectiveness scores increased from Week 2 to Week 52. Mean TSQM-9 convenience and global satisfaction scores remained high and numerically increased from Week 2 to Week 52 (Table 1).

Conclusions

In these PRO analyses of ELEVATE patients from Germany, bimekizumab resulted in rapid, meaningful symptom improvements and high treatment satisfaction as early as Week 2, which were maintained or further increased from Week 26 to Week 52.

This was associated with HRQoL improvements, with over half of patients reporting no effect of skin disease on their lives at Weeks 26 and 52; numerically higher responses were observed in biologic-na  ve patients.

These real-world data reflect the HRQoL results observed in clinical trials and support bimekizumab as a long-term treatment option for patients with moderate to severe psoriasis.

Summary

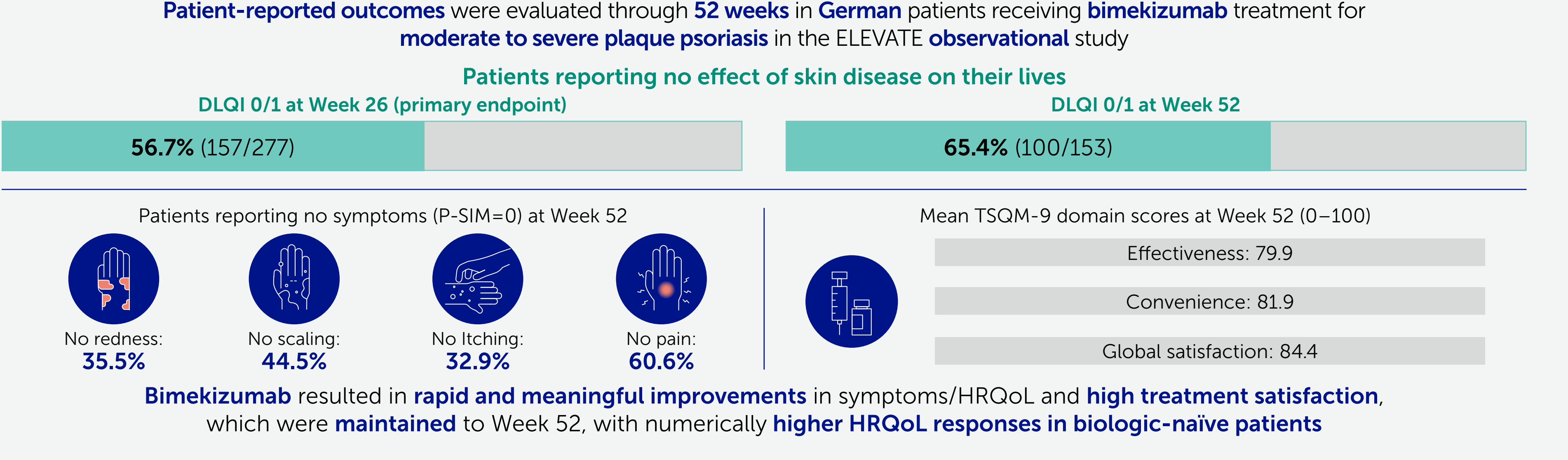


Figure 1 Study design

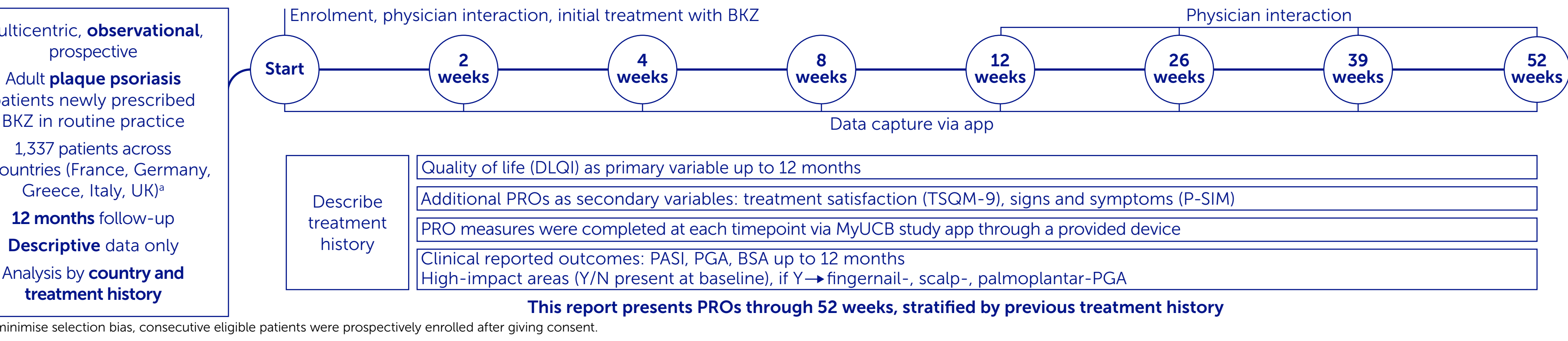


Figure 2 Proportion of patients per DLQI category through Week 52 by treatment history (OC)

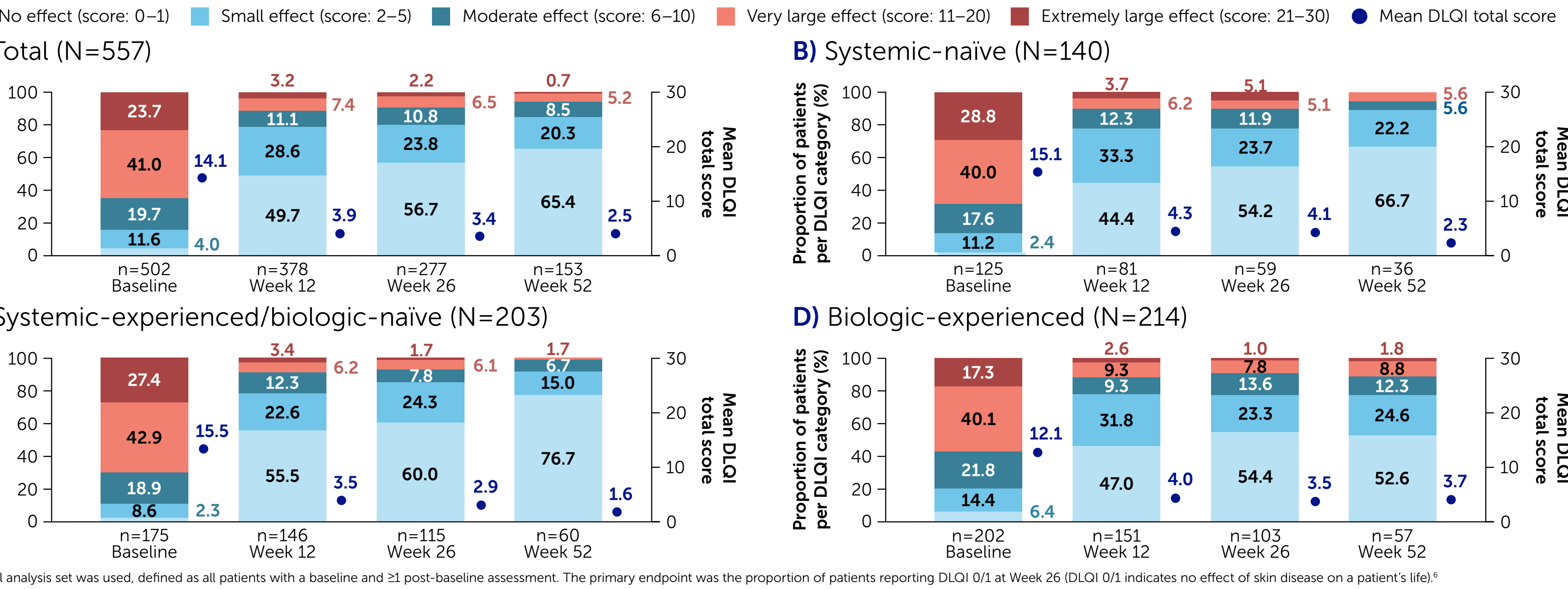


Figure 3 Proportions of patients reporting P-SIM=0 in skin itching, redness, pain and scaling through Week 52 by treatment history (OC)

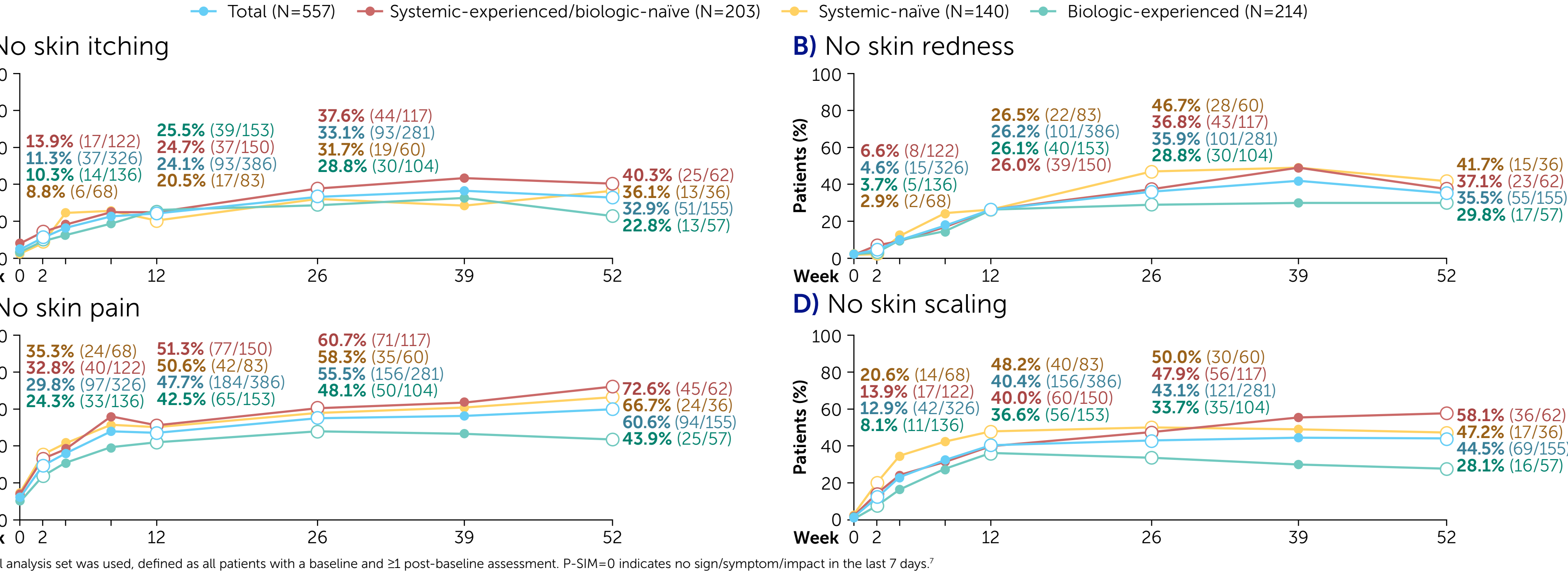


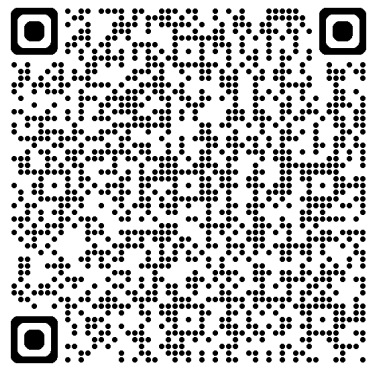
Table 1 TSQM-9 domain scores at Week 2 and Week 52 by treatment history (OC)

	Previous treatment history							
	Total N=557		Systemic-na��ve N=140		Systemic-experienced/ biologic-na��ve N=203		Biologic-experienced N=214	
Mean (SD)	Week 2 (n=325)	Week 52 (n=159)	Week 2 (n=69)	Week 52 (n=36)	Week 2 (n=120)	Week 52 (n=65)	Week 2 (n=136)	Week 52 (n=58)
Effectiveness score	69.3 (30.2)	79.9 (28.4)	68.6 (34.4)	70.5 (38.4)	70.5 (32.4)	89.6 (20.8)	68.6 (25.9)	74.9 (25.5)
Convenience score	76.8 (20.2)	81.9 (18.1)	76.5 (19.8)	84.3 (18.7)	74.1 (21.4)	80.6 (18.4)	79.4 (19.1)	81.8 (17.6)
Global satisfaction score	76.6 (19.6)	84.4 (19.5)	80.4 (17.9)	87.5 (17.5)	80.1 (19.0)	91.1 (12.6)	71.5 (19.9)	75.0 (23.3)

The full analysis set was used, defined as all patients with ≥1 baseline and post-baseline assessment. The TSQM-9 domain scores range from 0 to 100 with higher scores representing higher satisfaction.⁸

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; HRQoL: health-related quality of life; IL: interleukin; OC: observed case; PASI: Psoriasis Area and Severity Index; PGA: Physician’s Global Assessment; PRO: patient-reported outcome; P-SIM: Psoriasis Symptoms and Impacts Measure; SD: standard deviation; TSQM-9: Treatment Satisfaction Questionnaire for Medications-9; UK: United Kingdom.

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