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Bimekizumab treatment history and quality of life outcomes in patients with moderate to severe plaque psoriasis in routine clinical practice: Results from the second interim analysis of ELEVATE

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Objective

To present patient-reported outcomes (PROs) in adults with moderate to severe psoriasis receiving bimekizumab (BKZ) in routine clinical practice in Germany, stratified by systemic treatment history.

Introduction

- Psoriasis negatively impacts the health-related quality of life (HRQoL) of patients as a result of physical symptoms, psychological strain, and stigmatisation.[1]
  - BKZ, a humanised monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[2] is authorised in multiple countries for the treatment of moderate to severe plaque psoriasis.[3]
- By taking a patient-centered approach, ELEVATE describes the impact of BKZ treatment in key areas of HRQoL, treatment satisfaction, and psoriasis signs and symptoms in routine clinical practice, as reported by patients themselves.
- Here, results from the second interim analysis (IA2) of ELEVATE are presented for patients enrolled in Germany, stratified by systemic treatment (ST) history.

Methods

- ELEVATE is a multicentre, prospective, observational study ongoing in five European countries.
  - Eligible patients are aged ≥18 years with moderate to severe plaque psoriasis who are newly initiating BKZ treatment, as per the local label.
- Patients are followed up for around 12 months after starting BKZ treatment electronically completing PRO measures (Dermatology Life Quality Index [DLQI], Psoriasis Symptoms and Impacts Measure [P-SIM], and Treatment Satisfaction Questionnaire for Medications version 9 [TSQM-9]) at eight observational periods (OPs): Week 0 (baseline) and approximately Weeks 2, 4, 8, 12, 26, 39, and 52 (**Figure 1**).
- The co-primary objectives are to describe the systemic treatment history of patients with psoriasis prior to BKZ initiation and the proportion of patients reporting that their moderate to severe psoriasis has no impact on their life, as measured by DLQI 0/1 at Week 26 (OP6).[4]
- This interim analysis was performed once 300 patients completed 6 months of BKZ treatment in Germany (data lock: 25 October 2023).
- PROs are summarised in the full analysis set (FAS; patients with ≥1 baseline and post-baseline assessment), and results are reported for the overall group and by treatment subgroups: systemic naïve (no prior ST), biologic naïve (prior ST, but no prior biologic treatment [BT]), and biologic experienced (prior BT).
  - Analyses included only patients enrolled in Germany and were based on observed cases (OC).

Results

- At the data cut-off, 497 patients received ≥1 dose of BKZ (safety set) and 289 completed Week 26.
  - 453 patients were included in the FAS (66.9% male; mean [standard deviation, SD] age: 45.5 [14.6] years; mean [SD] disease duration: 16.8 [13.8] years).
  - DLQI scores at baseline were available for 413 patients (mean [SD]: 14.3 [7.7]).
  - History of any systemic therapy was reported in 342 (75.5%) patients, with 163 (47.7%) having received a biologic.
- At Week 26 (OP6), 55.9% (104/186) of patients with available DLQI data achieved a DLQI of 0/1 (**Figure 2**).
  - DLQI 0/1 achievement was comparable across patient subgroups stratified by treatment history.
- The proportion of patients with no or small impact on HRQoL, defined by DLQI severity categories, increased from baseline through Week 26 (OP6), with a corresponding decrease in those with a very/extremely large impact on their HRQoL (**Figure 2**).
  - This was similar across patient subgroups stratified by treatment history, with the greatest improvement seen in the biologic naïve group.
- The proportion of patients with P-SIM item scores of 0 (indicating no symptoms), including for skin itching, scaling, redness, and pain, rapidly increased from baseline to Week 2 (OP2) and continued to increase through Week 26 (OP6) across all treatment history subgroups (**Figure 3**).
- At Week 26 (OP6), patients reported high treatment satisfaction according to mean (SD) TSQM-9 domain scores (scored 0–100), including convenience (82.3 [18.6]; **Table 1**).

Conclusions

Overall, more than half of patients in this interim analysis self-reported no impact of skin disease on their HRQoL after 26 weeks of bimekizumab treatment, with symptom improvements observed as early as Week 2.

Bimekizumab resulted in consistent and rapid improvements in HRQoL and symptoms and is an option for patients with psoriasis in routine clinical practice, regardless of systemic treatment history.

Summary

55.9% of patients achieved a **DLQI of 0/1** at Week 26; this was consistent independent of treatment history

Mean TSQM-9 domain scores in all patients at Week 26 (0–100)

Effectiveness: 74.2

Convenience: 82.3

Global satisfaction: 82.1

Proportion of patients reporting P-SIM scores of 0 (no symptoms) at Week 26

Bimekizumab resulted in **consistent and rapid improvements** in HRQoL and symptoms, independent of treatment history

Table 1 TSQM-9 domain scores at Week 26 (OP6) by treatment history (OC)

Mean (SD)	Treatment History: Systemic naïve (No prior ST) N=111	Biologic naïve (Prior ST/ no prior BT) N=179	Biologic experienced (Prior BT) N=163	Total N=453
n	43	81	66	190
Effectiveness score	65.1 (36.7)	83.0 (28.5)	69.4 (30.9)	74.2 (32.1)
Convenience score	80.1 (19.0)	82.1 (19.2)	84.0 (17.6)	82.3 (18.6)
Global satisfaction score	81.1 (23.2)	87.1 (16.6)	76.6 (23.3)	82.1 (21.1)

Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy.

Figure 1 Study design

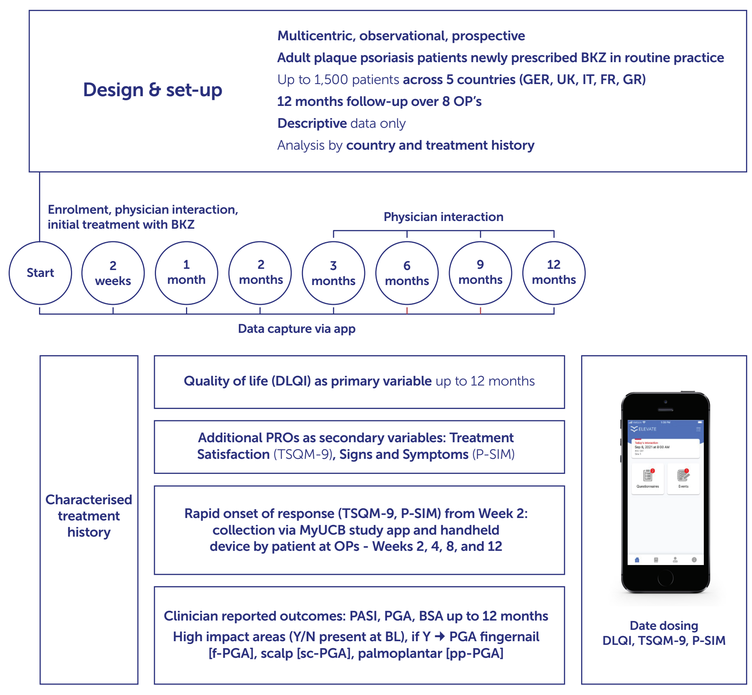
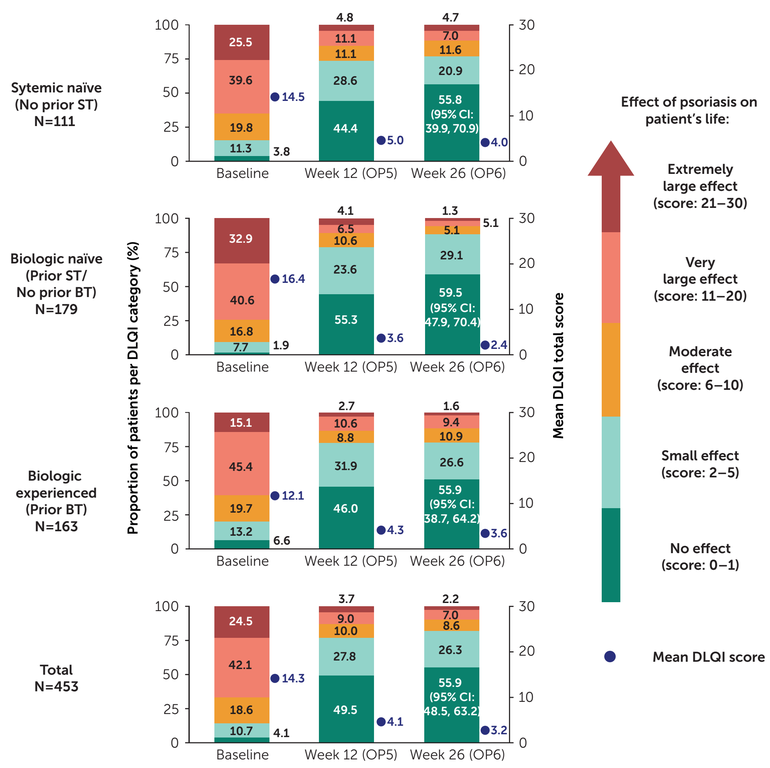


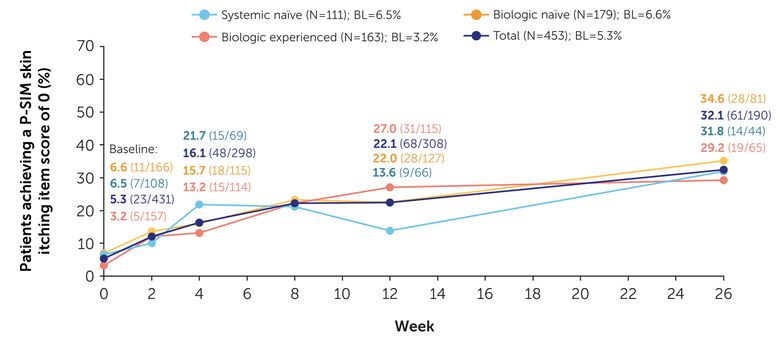
Figure 2 Proportion of patients per DLQI category from baseline through Week 26 (OP6) by treatment history (OC)



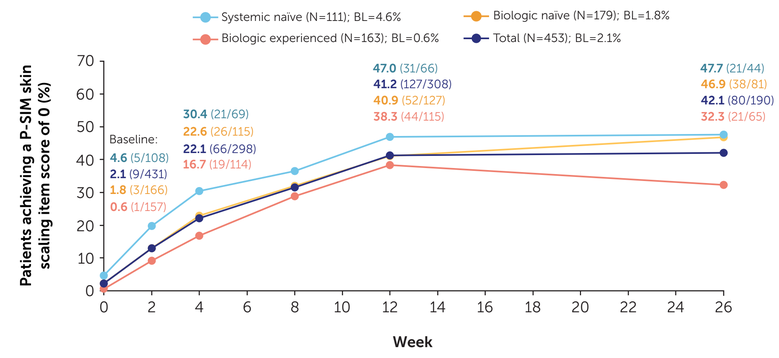
Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy. Data were missing for 40 patients at baseline, 154 patients at Week 12, and 267 patients at Week 26.

Figure 3 Proportions of patients reporting P-SIM item scores of 0 (no symptom) from baseline through Week 26 (OP6) by treatment history (OC)

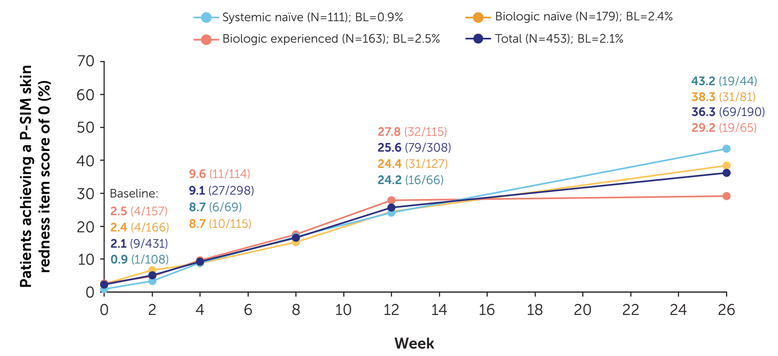
A) Skin itching



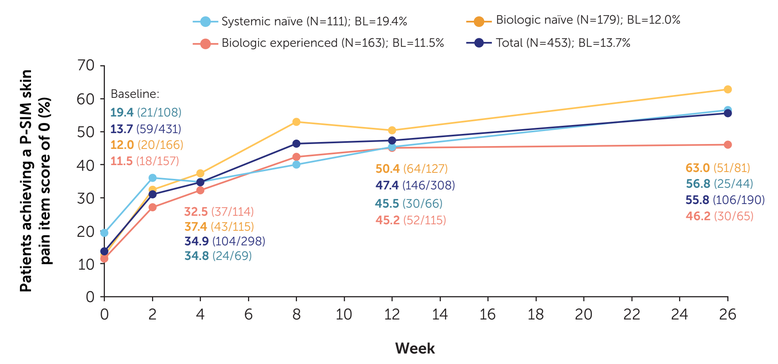
B) Skin scaling



C) Skin redness



D) Skin pain



Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy. P-SIM items were scored from 0 (no signs/symptoms/impacts) to 10 (very severe signs/symptoms/impacts).

BKZ: bimekizumab; **BL:** baseline; **BSA:** body surface area; **BT:** biological treatment; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **FAS:** full analysis set; **f-PGA**: finger nail-specific Physician's Global Assessment; **HRQoL:** health-related quality of life; **IA2:** interim analysis 2; **IL:** interleukin; **OC:** observed case; **OP:** observational period; **PASI:** Psoriasis Area Severity Index; **PGA:** Physician's Global Assessment; **pp-PGA:** palmoplantar-specific Physician's Global Assessment; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **sc-PGA**: scalp-specific Physician's Global Assessment; **ST:** systemic treatment; **TSQM-9:** Treatment Satisfaction Questionnaire for Medications 9; **Y/N:** yes/no.

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