P3366

Bimekizumab in routine clinical practice: Baseline characteristics and treatment history of patients with moderate to severe plaque psoriasis from the second interim analysis of ELEVATE

Ralph von Kiedrowski,[1] Diamant Thaçi,[2] Thomas Stavermann,[3] Sven Quist,[4,5] Tanja Heidbrede,[6] Frederik Fierens,[7] Kathrin Schlüter,[8] Leonor Avó,[9] Maria Forbes,[10] Priyanka Deep,[11] Bernhard Korge[12]

Objective

To present the baseline characteristics and treatment history (TxH) for patients with moderate to severe psoriasis initiating bimekizumab (BKZ) therapy in Germany and enrolled in ELEVATE.

Introduction

- BKZ, a humanised monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,[1,2] is authorised in multiple regions for the treatment of moderate to severe plaque psoriasis.[3]
- ELEVATE is a multicentre, prospective, observational study aiming to describe patient-reported outcomes (PROs) in adult patients with psoriasis receiving BKZ in routine practice, stratified by TxH.
- A first interim analysis (IA1) described baseline characteristics and TxH of 196 patients newly initiating BKZ in the first year of use in German routine practice.[4]
- Here, results from the second interim analysis (IA2) of ELEVATE are presented for patients enrolled in Germany during the first 2 years of BKZ use in routine practice.

Methods

- Eligible patients for ELEVATE, enrolled from November 2021 to October 2023, are adults with moderate to severe plaque psoriasis who are newly initiating BKZ, as per the locally approved label, in five European countries.
- PROs captured at baseline surveyed via a specific myUCB study app include:
  - Dermatology Life Quality Index (DLQI; scored 0–1: no effect; 2–5: small effect; 6–10: moderate effect; 11–20: very large effect; 21–30: extremely large effect).
  - Psoriasis Symptoms and Impacts Measure (P-SIM; scored from 0 [no symptom/impact] to 10 [very severe symptom/impact]).
- Clinical assessments at baseline include:
  - Psoriasis Area and Severity Index (PASI).
  - Overall Physician's Global Assessment (PGA; scored 0: clear; 1: almost clear; 2: mild; 3: moderate; 4: severe) and PGA for high-impact areas (fingernails: f-PGA; scalp: sc-PGA; and palmoplantar: pp-PGA).
  - Affected body surface area (BSA); scored 0–100%.
- IA2 was performed once 300 patients completed 6 months of BKZ treatment in Germany (data lock: 25 October 2023). Here, baseline characteristics and TxH are presented for patients enrolled in Germany in the safety set (consists of all consenting patients who received ≥1 BKZ dose).
- Results are reported for the overall group and by treatment subgroups: systemic naïve (no prior systemic treatment [ST]), biologic naïve (prior ST, but no prior biologic treatment [BT]), and biologic experienced (prior BT).

Results

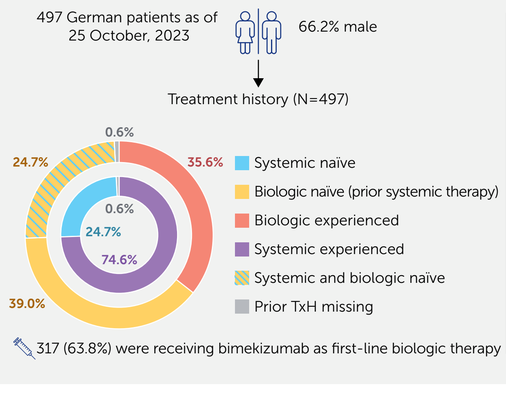
- At the data lock, 505 patients in Germany had consented to participate; the safety set included 497 patients.
- Baseline demographics and disease severity for patients in the safety set are presented in **Table 1**.
  - Disease duration and sex distribution at baseline varied by TxH.
  - Mean (SD) PASI and DLQI scores were 13.6 (8.7) and 14.5 (7.7), respectively (**Table 1**; **Figures 1 and 2**).
  - Mean P-SIM scores were >5 for 13 of 14 items and ≥7 for skin redness, scaling, and dryness (**Table 1**; **Figure 3**).
  - 92.2% of patients had presence of psoriasis in ≥1 high-impact psoriasis area (nail, scalp, and palmoplantar) and 41.9%, 71.4%, and 33.2% were mild to severely impacted (score of ≥2) for the nail (f-PGA), scalp (sc-PGA), and palmoplantar (pp-PGA) regions, respectively (**Table 1**).
- A summary of patients' recent (≤12 months before BKZ first dose) and past (>12 months before BKZ first dose) systemic TxH is presented in **Figure 4**.
  - Most patients (N=371; 74.6%) had TxH of any systemic therapy, of which 177 (47.7%) had received biologic therapy; 123 (24.7%) patients were naïve for any systemic therapy.
  - Overall BKZ was the first line biologic therapy for 317 (63.8%) patients.
- Among the 177 patients with prior biologic TxH, 34 (19.2%) had two prior biologic treatment and 46 (26.0%) had more than two.
  - The most recent biologic treatment mode of action before BKZ were tumour necrosis factor-alpha inhibition (N=54; 30.5%), IL-23p19 inhibition (N=51; 28.8%) and IL-17A inhibition (N=47; 26.6%).

Conclusions

In patients newly initiating bimekizumab in German routine practice in ELEVATE, baseline scores measuring disease severity and quality of life confirmed moderate to severe psoriasis disease state. Almost all patients had presence of psoriasis in ≥1 high-impact area.

Most patients had a systemic therapy TxH and for 63.8% of patients, bimekizumab was their first biologic therapy for psoriasis (including both systemic experienced and systemic naïve patients). The profile of patients enrolled remained consistent with IA1.[4]

Summary



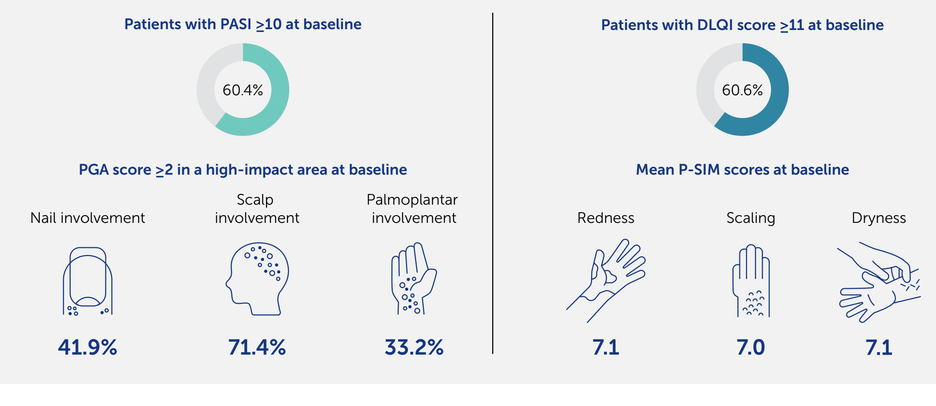
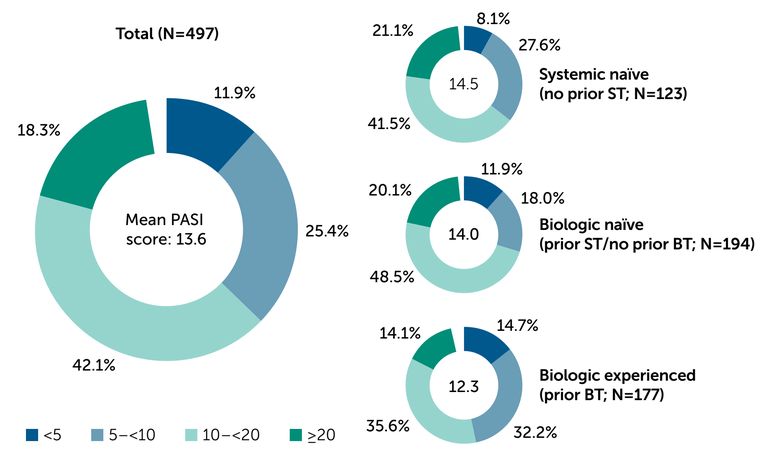


Table 1 Baseline characteristics

	Systemic naïve (No prior ST)[a] N=123	Biologic naïve (Prior ST/ no prior BT[b]) N=194	Biologic experienced (Prior BT) N=177	Total[c] N=497
Age (years), mean ± SD	43.3 ± 14.8	44.2 ± 13.9	47.6 ± 14.6	45.2 ± 14.4
Sex, male, n (%)	75 (61.0)	134 (69.1)	117 (66.1)	329 (66.2)
BMI (kg/m²), mean (SD)	28.1 (5.6)	28.6 (6.2)	30.4 (6.7)	29.2 (6.3)
Disease duration (years), mean (SD)	12.3 (11.9)	14.9 (11.7)	22.1 (15.2)	16.8 (13.7)
BSA ≥30%, n (%)	51 (41.5)	81 (41.8)	54 (30.5)	187 (37.6)
PASI score, mean (SD)	14.5 (9.6)	14.0 (8.1)	12.3 (8.7)	13.6 (8.7)
PASI score ≥10, n (%)	77 (62.6)	133 (68.6)	88 (49.7)	300 (60.4)
DLQI total score, mean (SD)	14.9 (7.9)	16.2 (7.6)	12.3 (7.2)	14.5 (7.7)
DLQI score ≥11, n (%)	77 (62.6)	122 (62.9)	99 (55.9)	301 (60.6)
Missing, n (%)	7 (5.7)	27 (13.9)	12 (6.8)	46 (9.3)
Comorbidities, n (%)[d]				
Suspected/confirmed PsA and/or spondyloarthritis	3 (2.4)	6 (3.1)	29 (16.4)	38 (7.6)
Anxiety and depression	10 (8.1)	9 (4.6)	16 (9.0)	35 (7.0)
Major adverse cardiac event	8 (6.5)	13 (6.7)	9 (5.1)	30 (6.0)
Metabolic syndrome	6 (4.9)	9 (4.6)	11 (6.2)	26 (5.2)
P-SIM score, mean (SD)[e]				
Skin redness	7.3 (2.3)	7.4 (2.6)	6.5 (2.7)	7.1 (2.6)
Skin scaling	7.1 (2.8)	7.3 (2.6)	6.6 (2.6)	7.0 (2.7)
Skin dryness	7.1 (2.6)	7.2 (2.5)	6.9 (2.4)	7.1 (2.5)
Missing, n (%)	5 (4.1)	14 (7.2)	8 (4.5)	27 (5.4)
PGA score, n (%)				
3: moderate	82 (66.7)	122 (62.9)	106 (59.9)	312 (62.8)
4: severe	29 (23.6)	48 (24.7)	36 (20.3)	114 (22.9)
PGA score ≥2, n (%)[f]				
f-PGA	60 (48.8)	85 (43.8)	62 (35.0)	208 (41.9)
sc-PGA	99 (80.5)	140 (72.2)	115 (65.0)	355 (71.4)
pp-PGA	44 (35.8)	66 (34.0)	55 (31.1)	165 (33.2)

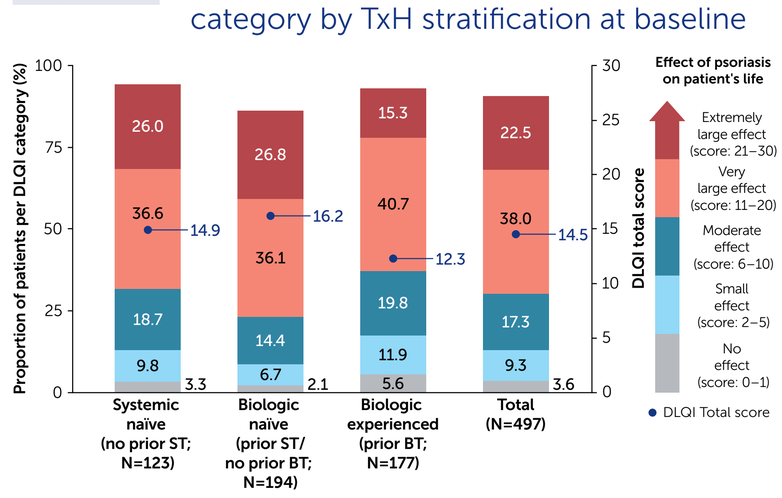
Safety set (patients who received ≥1 BKZ dose). **[a]** Systemic naïve patients had no prior systemic or biologic therapy; **[b]** Biologic naïve patients had prior systemic therapy but no prior biologic therapy; **[c]** Data on treatment history were missing for 3 patients; **[d]** MedDRA-based terms; **[e]** Only P-SIM items with a total mean score ≥7 are included in this table; **[f]** PGA score ≥2 indicates patients were mildly to severely impacted in the relevant area.

Figure 1 Proportion of patients within each PASI category by TxH stratification at baseline



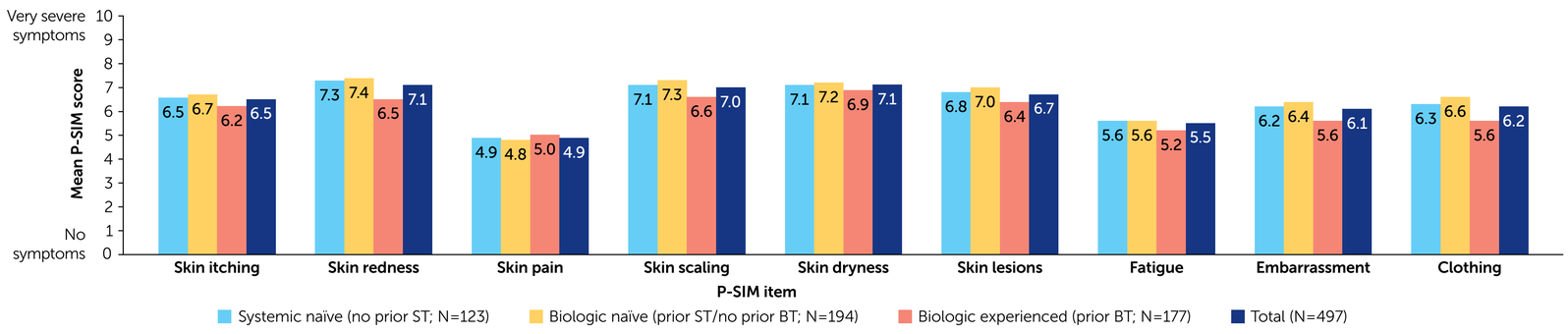
Safety set (patients who received ≥1 BKZ dose). Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy. Data were missing for 12 patients at baseline in the total group (2 systemic naïve; 3 biologic naïve; 6 biologic experienced).

Figure 2 Proportion of patients within each DLQI category by TxH stratification at baseline



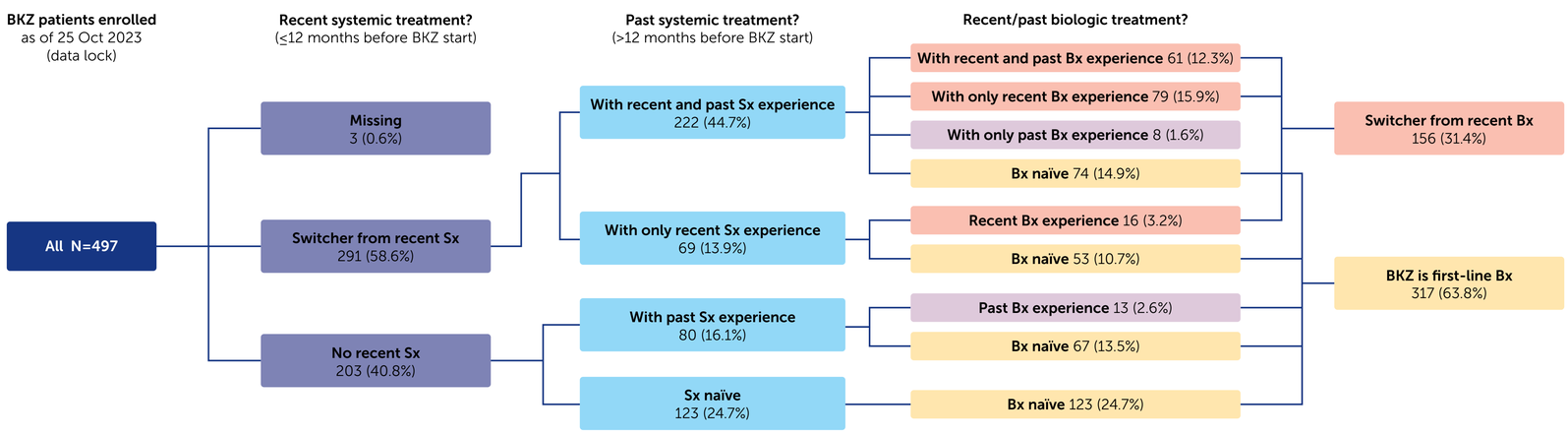
Safety set (patients who received ≥1 BKZ dose). Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy. Data were missing for 46 patients at baseline in the total group (7 systemic naïve; 27 biologic naïve; 12 biologic experienced).

Figure 3 P-SIM score by TxH stratification at baseline



Safety set (patients who received ≥1 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 4 Patient stratification based on treatment history for patients enrolled at the IA2 data lock in Germany



Safety set. Percentages are calculated as a proportion of all patients who had received ≥1 BKZ dose at the data lock (N=497). Recent systemic therapy is defined as previous systemic therapy received in ≤12 months before the first BKZ dose. Past systemic therapy is defined as previous systemic therapy received >12 months before the first BKZ dose.

BKZ: bimekizumab; **BMI:** body mass index; **BSA:** body surface area; **BT:** biologic treatment; **DLQI:** Dermatology Life Quality Index; **f-PGA:** fingernail-Physician's Global Assessment; **IA1:** first interim analysis; **IA2:** second interim analysis; **IL:** interleukin; **MedDRA:** Medical Dictionary for Regulatory Activities; **PASI:** Psoriasis Area and Severity Index; **PGA:** Physician's Global Assessment; **pp-PGA:** palmoplantar-Physician's Global Assessment; **PRO:** patient-reported outcome; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **ST:** systemic treatment; **sc-PGA:** scalp-Physician's Global Assessment; **PsA:** psoriatic arthritis; **SD:** standard deviation; **Sx:** systemic therapy; **TxH:** treatment history.

Institutions: [1]Company for Medical Study & Service Selters GmbH, Rheinland-Pfalz, Germany; [2]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [3]MVZ Hautzentrum Gropiuspas. GmbH, Berlin, Germany; [4]University of Magdeburg, Magdeburg, Germany; [5]Clinic of Dermatology, Helix Medical Excellence Center Mainz, Mainz, Germany; [6]UCB BioSciences GmbH, Monheim am Rhein, Germany; [7]UCB, Brussels, Belgium; [8]UCB, Monheim am Rhein, Germany; [9]UCB, Lisbon, Portugal; [10]UCB, Slough, UK; [11]UCB, Oakville, Ontario, Canada; [12]Hautarztpraxis, Düren, Germany.

References: [1]Glatt S et al. Ann Rheum Dis. 2018;77:523–32; [2]Adams R et al. Front Immunol. 2020;11:1894; [3]EMA: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed September 2024]; [4]Asadullah K et al. Presented at EADV 2023;P2594. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **RvK**, **DT**, **TS**, **SQ**, **TH**, **FF**, **KS**, **LA**, **MF**, **PD**, **BK**; Drafting of the publication, or reviewing it critically for important intellectual content: **RvK**, **DT**, **TS**, **SQ**, **TH**, **FF**, **KS**, **LA**, **MF**, **PD**, **BK**; Final approval of the publication: **RvK**, **DT**, **TS**, **SQ**, **TH**, **FF**, **KS**, **LA**, **MF**, **PD**, **BK**. **Author Disclosures:** **RvK:** Dr. von Kiedrowski, with his service company CMS3 GmbH, provides consulting services, registry research, activities as an investigator in interventional and non-interventional studies, other services and scientific lectures for AbbVie, ALK Scherax, Almirall Hermal, Amgen, Beiersdorf Dermo Medical, Biofrontera, Biogen, BMS, Boehringer Ingelheim, Celgene, Celltrion HC, DermaPharm, Eli Lilly, Foamix, Galderma, Gilead, Heine Optotechnik, Hexal, Janssen-Cilag, LEO Pharma, Meda, Medac, Menlo, MSD, Novartis, Dr. R. Pfleger, Pfizer, Regeneron, Sanofi, Stallergens, Stiefel GSK, Tigercut, and UCB. **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **TS:** Received honorary for talks from Abbvie, Incyte, Janssen, and UCB. **SQ:** Received funds for scientific advice and clinical trials from UCB. **TH:** Employee of UCB BioSciences GmbH and shareholder of UCB. **FF**, **KS**, **LA:** Employees and shareholders of UCB. **MF:** Employee of UCB. **PD:** Cytel contracted statistician of UCB. **BK:** Conducted clinical trials, participated in advisory boards and was a speaker for AbbVie, Almirall Hermal, Amgen, Beiersdorf Dermo Medical, Biogen, Bristol Myers Squibb, Celgene, Dr. Pfleger, Galderma, Janssen-Cilag, LEO Pharma, Eli Lilly, Novartis, Pierre Fabre, and UCB. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors acknowledge Frederik Fierens, PhD, and Isabelle Fovel, UCB, Brussels, Belgium for publication coordination, Ria Gill, BSc, Costello Medical, Manchester, England for medical writing and editorial assistance and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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