P3369

Bimekizumab treatment history and clinical 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 investigate clinical outcomes in adults with moderate to severe psoriasis receiving bimekizumab (BKZ) in routine clinical practice in Germany, stratified by systemic treatment history.

Introduction

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, is authorised in multiple countries for the treatment of moderate to severe plaque psoriasis.[1,2]
- Efficacy data from routine clinical practice adds valuable, and more diverse insights to that of data collected in randomised controlled trials.[3,4]
- Here, results from the second interim analysis (IA2) of ELEVATE on the clinical outcomes of patients with psoriasis who initiated BKZ treatment in Germany are presented.

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 newly initiating BKZ treatment.
- Patients are observed for ~12 months following initiation of BKZ treatment. Clinical assessments, including Psoriasis Area and Severity Index (PASI), Physician's Global Assessment (PGA), and Dermatology Life Quality Index (DLQI) occur at five observational periods (OP): Week 0 (baseline) and approximately Weeks 12, 26, 39, and 52 (**Figure 1**).
  - The co-primary objectives to describe systemic treatment history and the proportion of patients reaching DLQI 0/1 at Week 26 are described elsewhere (Posters P3366 and P3368).
- Secondary outcomes include the proportion of patients with PASI ≤2, and a PGA score of 0/1 (clear/almost clear) for high-impact areas (nails: f-PGA; scalp: sc-PGA; and palmoplantar: pp-PGA).
- Treatment-emergent adverse events (TEAEs) are recorded via passive pharmacovigilance surveillance, summarised using the Medical Dictionary for Regulatory Activities, version 26.0.
- TEAEs are summarised in the safety set and patient demographics and clinical outcomes in the full analysis set (FAS).
- This interim analysis was performed once 300 patients had completed 6 months of BKZ treatment in Germany (data lock: 25 October 2023).
- Results are reported for the overall patient group and by treatment history subgroups: systemic naïve (no prior systemic treatment [ST] or biologic treatment [BT]), biologic naïve (prior ST, but no prior BT), and biologic experienced (prior BT).
  - Analyses include only patients enrolled in Germany and were descriptive and based on observed cases (OC).

Results

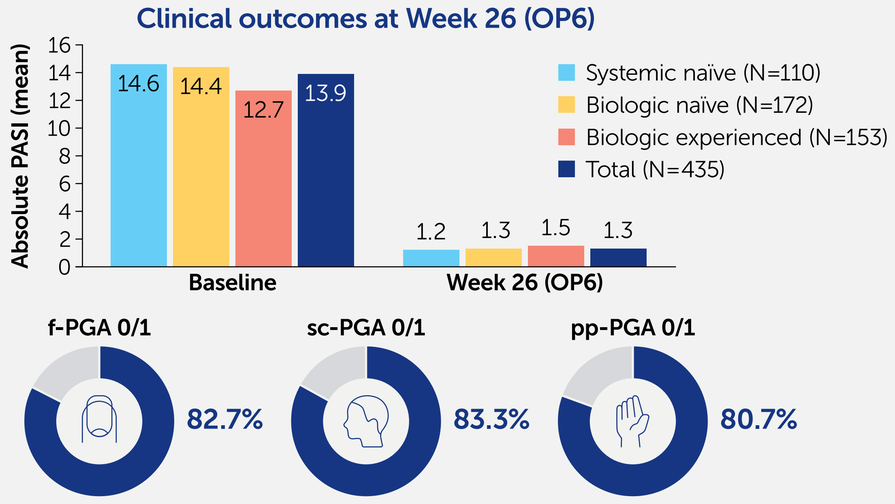
- At the data cut-off, 497 patients had received ≥1 dose of BKZ and 289 completed Week 26.
- In total, 453 patients (FAS) had ≥1 baseline and post-baseline assessment:
  - 66.9% of patients were male; mean (standard deviation [SD]) age was 45.5 (14.6); mean (SD) PASI was 13.6 (8.7); mean (SD) DLQI was 14.3 (7.7), and 86.3% of patients had PGA ≥3. Full baseline characteristics are reported elsewhere (Poster 3366).
  - 342 (75.5%) patients reported treatment history of any systemic therapy, of which 163 (47.7%) had treatment history of any biological therapy.
- In patients with PASI >1 at baseline (N=435), mean (SD) PASI decreased from 13.9 (8.6) at baseline to 1.6 (2.9) at Week 12 (OP5), and 1.3 (2.7) at Week 26 (OP6).
  - Decreases in mean PASI observed by Week 26 (OP6) were generally similar across treatment history subgroups (**Figure 2**).
  - Absolute PASI ≤2 was achieved by 82.0% of patients at Week 26 (OP6) (**Figure 3**).
- At Week 26 (OP6), >80% of patients achieved PGA 0/1 in high-impact areas of the fingernail, scalp, or palmoplantar area, with similar responses observed irrespective of previous treatment (**Figure 4**).
- TEAEs by treatment history are summarised in **Table 1**.
  - Common TEAEs reported up to the data lock by preferred term included: oral candidiasis (28/497; 5.6%), nasopharyngitis (12/497; 2.4%), COVID-19 (10/497; 2.0%), and eczema (8/497; 1.6%).

Conclusions

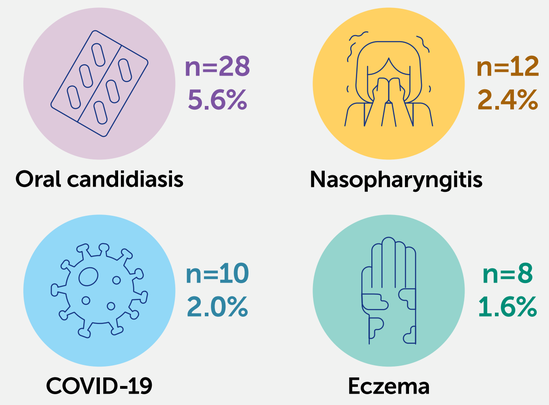
This second interim analysis demonstrated substantial improvement in clinical outcomes following 26 weeks of bimekizumab treatment in patients with psoriasis, including in high-impact areas. Response rates were generally consistently high across systemic treatment history subgroups.

Summary

Clinical outcomes at Week 26 (OP6)



Safety up to data lock



Bimekizumab resulted in **substantial improvement in clinical outcomes**, and was well-tolerated, **independent of systemic treatment history**.

Figure 1 Study design

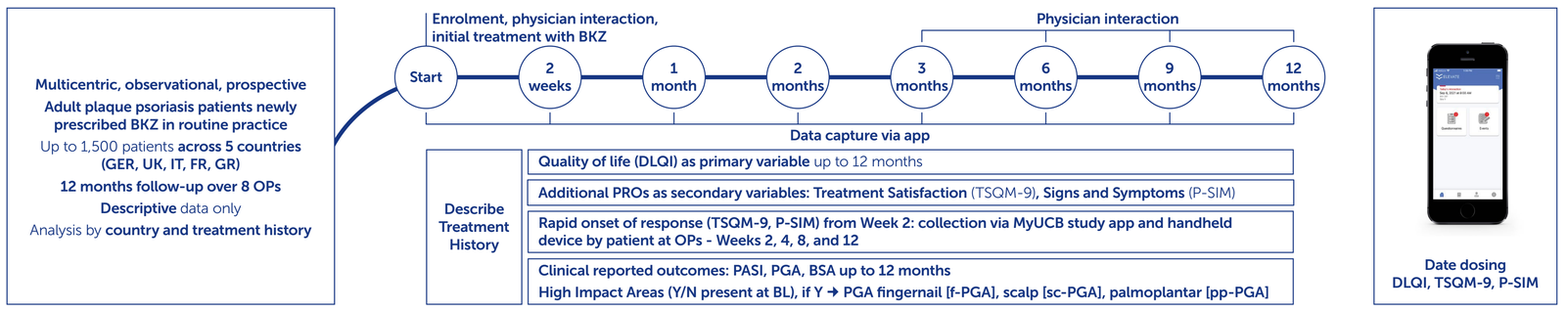
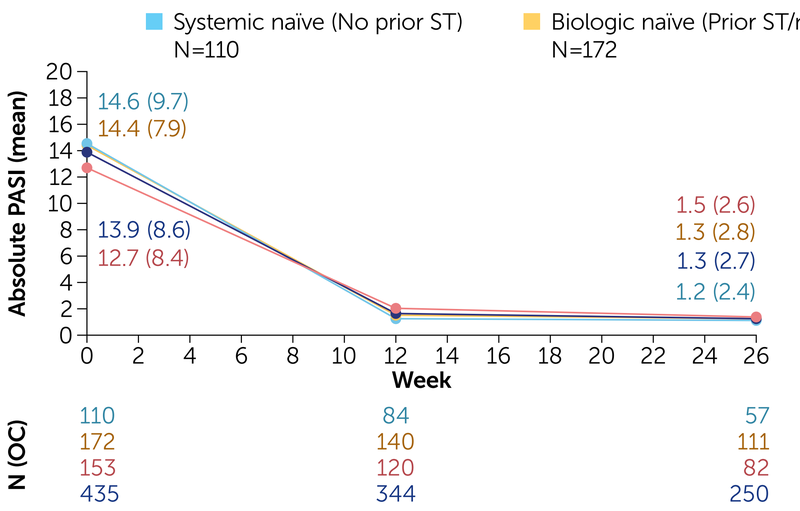


Table 1 TEAEs by systemic treatment history reported up to the data lock

Category, n (%)	Treatment history: Systemic naïve (No prior ST) N=123 Exposure=96 PY	Biologic naïve (Prior ST/no prior BT) N=194 Exposure=172 PY	Biologic experienced (Prior BT) N=177 Exposure=144 PY	Total N=497 Exposure=413 PY
Any TEAEs	26 (21.1)	65 (33.5)	55 (31.1)	146 (29.4)
Severe TEAEs	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.2)
Serious TEAEs	6 (4.9)	14 (7.2)	19 (10.7)	39 (7.8)
ADRs	13 (10.6)	36 (18.6)	25 (14.1)	74 (14.9)
Serious ADRs	2 (1.6)	5 (2.6)	8 (4.5)	15 (3.0)

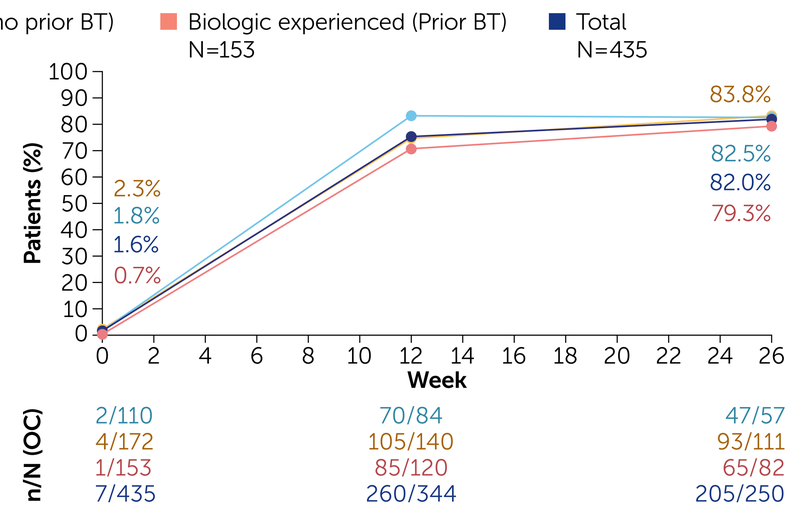
Safety set: patients who received ≥1 dose of study treatment. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy.

Figure 2 Mean absolute PASI through Week 26 (OP6) by treatment history (OC)



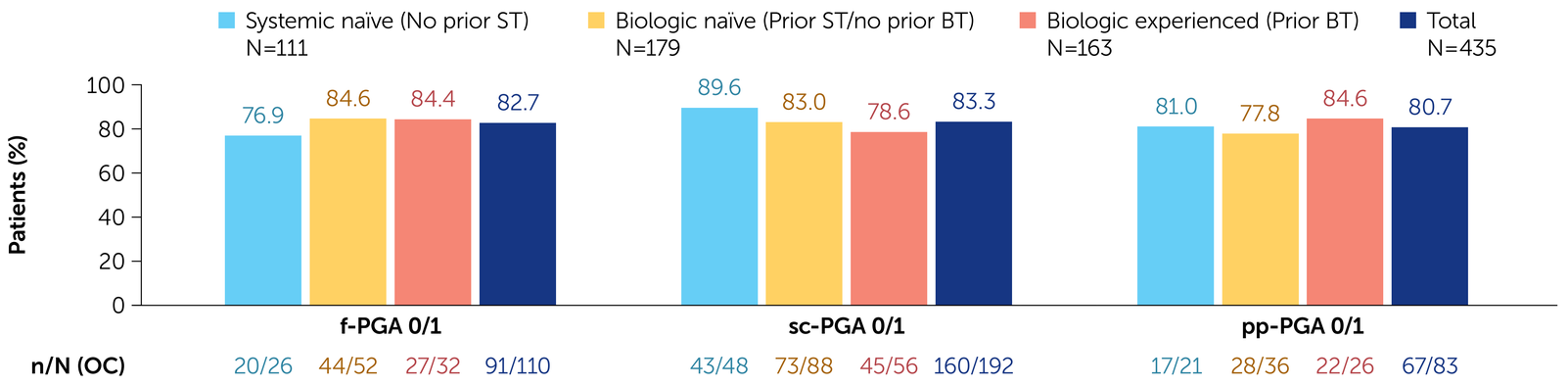
Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. Only patients with baseline PASI >1 were included. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy. Standard deviation (SD) are in brackets.

Figure 3 Proportion of patients achieving PASI ≤2 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. Only patients with baseline PASI >1 were included. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy.

Figure 4 Proportion of patients with PGA 0/1 in high impact areas at 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. Only patients with PGA ≥2 at baseline were included. OC: N represents the number of patients with a non-missing measurement for the given responder variable at Week 26, with percentages calculated accordingly. Systemic naïve patients had no prior systemic or biologic therapy. Biologic naïve patients had prior systemic therapy but no prior biologic therapy.

ADR: adverse drug reaction; **BKZ:** bimekizumab; **BSA:** body surface area; **BT:** biological treatment; **DLQI:** Dermatology Life Quality Index; **FAS:** full analysis set; **f-PGA:** finger nail-specific Physician's Global Assessment; **FR:** France; **GER:** Germany; **GR:** Greece; **IA2:** second interim analysis; **IL:** interleukin; **IT:** Italy; **OC:** observed case; **OP:** observational period; **PASI:** Psoriasis Area and Severity Index; **PGA:** Physician's Global Assessment; **pp-PGA:** palmoplantar-specific Physician's Global Assessment; **P-SIM:** Psoriasis Symptoms and Impacts Measure; **PRO:** patient-reported outcome; **PY:** patient-years; **sc-PGA:** scalp-specific Physician's Global Assessment; **SD:** standard deviation; **ST:** systemic treatment; **TEAE:** treatment-emergent adverse event; **TSQM-9:** Treatment Satisfaction Questionnaire for Medications - 9 items; **UK:** United Kingdom.

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References: [1]Glatt S et al. Ann Rheum Dis. 2018;77:523–32; [2]EMA: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed September 2024]; [3]Kim HS et al. J Korean Med Sci. 2018;33:e213; [4]Blonde L et al. Adv Ther. 2018;35:1763–74. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DT**, **KA**, **RvK**, **AS**, **PD**, **LA**, **FF**, **NC**, **YM**, **MA**; Drafting of the publication, or reviewing it critically for important intellectual content: **DT**, **KA**, **RvK**, **AS**, **PD**, **LA**, **FF**, **NC**, **YM**, **MA**; Final approval of the publication: **DT**, **KA**, **RvK**, **AS**, **PD**, **LA**, **FF**, **NC**, **YM**, **MA**. **Author Disclosures: DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, and UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **KA:** Received honoraria for participation in advisory boards, consultation, clinical trials or as speaker from AbbVie, Almirall, Antabio, Bayer, Brand Murray Fuller, Bristol Myers Squibb, Emeritipharma, Emphasis, Euroimmune, Galderma, Janssen, La Roche-Posay, LEO Pharma, L'Oréal, Novartis, Parexel International, Pierre Fabre, RG Pharma, Roxall, Sanofi Genzyme, TFS Trial Form Support, and UCB. **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 and Company, 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. **AS**, **LA**, **FF**, **NC**, **YM:** Employees and shareholders of UCB. **PD:** Employee of Cytel Canada Health Inc. and contracted Real-World Evidence Statistician of UCB. **MA:** Received consulting fees and/or speaker fees and/or institutional research support from the following pharmaceutical companies manufacturing drugs for psoriasis: AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Centocor, Eli Lilly and Company, Fresenius, GSK, Hexal, Janssen, Klinge, LEO Pharma, MC2, Medac, Merck, MSD, Novartis, Pfizer, Sandoz, Sun Pharma, UCB, and Viatris. **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, Laura Morillo, BSc Neuroscience, Costello Medical, London, UK 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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