Treatment history and symptom severity in patients with moderate to severe plaque psoriasis being initiated on bimekizumab: Use during the 1st year of routine clinical practice

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Objective

To characterise the treatment history (TxH) of patients initiating bimekizumab (BKZ) therapy and describe the effect of plaque psoriasis on their life stratified by their TxH.

Introduction

- BKZ, a humanized monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A,[1,2] is authorized for the treatment of moderate to severe plaque psoriasis.[3]
- ELEVATE aims to describe patient-focused outcomes of effectiveness in adult patients with plaque psoriasis in routine clinical practice, contextualized with the TxH.

Materials and Methods

- ELEVATE is a multicentric, prospective observational study being conducted in France, Germany, Greece, Italy, and the United Kingdom (**Figure 1**).
- Eligible patients are adults with moderate to severe plaque psoriasis who are newly initiated on BKZ as per locally approved label, and previously naïve for BKZ treatment. Eligibility criteria are given in **Figure 1**.
- Patients are followed up for approximately 12 months across 8 observational points (OPs).
- The co-primary outcomes are to characterise the TxH of patients initiating BKZ, and to describe the proportion of patients reporting that their plaque psoriasis has no effect on their life (Dermatology Life Quality Index [DLQI 0/1]) after 26 weeks of treatment (OP6) with BKZ, stratified by the TxH.
- Here we present a first interim analysis (data lock [DL]: October 25, 2022) on TxH and disease severity in the patients enrolled in Germany during the first year of BKZ use in routine practice.
- Demographics and baseline (BL) characteristics as recorded at OP1 are summarised for patients in the safety set (consists of all consenting patients who received at least one dose of the prescribed study treatment).

Results

- At DL, 196 patients from 41 German centers consented to participate. Most patients (126; 64.3%) had a TxH of any systemic treatment, of which 54 had received a biologic (**Table 1**).
- Among patients with a TxH of systemic therapy, 104 switched from a recent therapy (≤12 months before BKZ 1st dose) of which 43 had a recent biologic treatment, 22 patients had a past (≥13 months before BKZ 1st dose) but no recent systemic TxH, 49 (25.0%) were naive for any systemic therapy, and overall BKZ was the 1st line biologic for 121 (61.7%) patients (**Figure 2** and **Table 1**).
- In patients with prior biologic use, adalimumab, secukinumab and ixekizumab were most commonly reported. **Table 2** summarises demographics and BL disease severity for patients with known TxH.
- Patients with past systemic TxH tended to be 5 to 7 years older, with 7 to 12 years longer disease duration (**Table 2**).
- At BL among patients with known TxH, 64.6% of patients had a Psoriasis Area and Severity Index (PASI) ≥10, 86.9% had ≥10% body surface area (BSA) and 57.2% patients reported a DLQI >10 (**Figure 3** and **4**). For 14.3% of patients DLQI was missing at DL.
- The Psoriasis Symptoms and Impacts Measure (P-SIM) mean score at BL was >5 for all 14 items and ≥7 for skin redness, scaling, dryness and irritation (**Figure 5**).

Distribution of high impact area assessed by Physician's Global Assessment (PGA) stratified by TxH

- Around 40% of the patients with known TxH were mild to severely impacted (score of ≥2 as per specific PGA) for the nail region, 80% for the scalp, and 33% for the palmoplantar (**Figure 6**).
- Most patients (91.4%) with known TxH were impacted mild to severely (score of ≥2 as per specific PGA) for at least one of the these assessed high impact area's (nail, scalp, palmoplantar).

Conclusions

- **In ELEVATE, baseline DLQI and PASI scores confirm a profile of plaque psoriasis patients suffering from moderate to severe plaque psoriasis.**
- **The variation in the prior TxH, as documented for patients enrolled in ELEVATE, suggests a broad profile of patients prescribed BKZ in German routine clinical practice, with a large proportion (~62%) of patients receiving BKZ as 1st line biologic for plaque psoriasis, consistent with other data.[4]**

Summary

At BL, most patients suffered from moderate to severe plaque psoriasis and had a history of systemic treatment

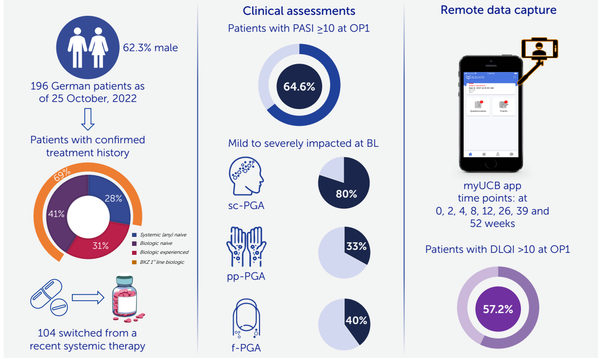


Table 1 TxH of patients screened from Germany

Variable, n (%)	Total N=196
No prior systemic therapy	49 (25.0)
Any prior systemic therapy	126 (64.3)
Any prior biologic therapy	54 (42.9)*
No prior biologic therapy	72 (57.1)*
Missing**	21 (10.7)

Recent systemic/biologic therapy is defined as previous systemic/biologic therapy in the 12 months before the first BKZ dose. Past systemic/biologic therapy is defined as previous systemic/biologic therapy in the 13+ months prior to the first BKZ dose.
*percentages are computed based on patients with confirmed systemic TxH.** missing or unavailable at DL

Table 2 Demographics and BL characteristics, for patients with known TxH – safety set

Variable	Recent & past systemic treatment N=83	Recent & no past systemic treatment N=21	No recent & past systemic treatment N=22	No recent & no past systemic treatment N=49	Total N=175*
Male, n (%)	55 (66.3)	12 (57.1)	14 (63.6)	28 (57.1)	109 (62.3)
Age, mean±SD	49.9±13.8	44.6±12.7	49.1±14.8	42.0±15.6	47.0±14.6
BMI (kg/m²), mean±SD	30.5±5.8	28.9±4.9	29.2±5.1	27.0±5.6	29.2±5.7
Disease duration (years), mean±SD	20.7±15.7	13.7±15.4	22.2±11.5	10.4±10.3	17.2±14.5
Presence of high-impact plaque psoriasis: Yes, n (%)	75 (90.4)	20 (95.2)	22 (100.0)	48 (98.0)	165 (94.3)
Presence of meaningful high-impact plaque psoriasis: Yes, n (%)	71 (85.5)	19 (90.5)	22 (100.0)	48 (98.0)	160 (91.4)
Infection history: Yes, n (%)	4 (4.8)	2 (9.5)	1 (4.5)	2 (4.1)	9 (5.1)
Treatment required for infection: Yes, n (%)	4 (100.0)	2 (100.0)	1 (100.0)	1 (50.0)	8 (88.9)
PASI, mean±SD	11.8±7.4	14.8±9.4	16.9±11.2	14.8±7.5	13.6±8.4
DLQI (treatment start), mean±SD	13.4±7.6	19.4±5.9	19.8±6.8	15.1±8.8	15.3±8.1

Recent systemic treatment is defined as previous systemic treatment in the 12 months before the first BKZ dose. Past systemic treatment is defined as previous systemic treatment in the 13+ months prior to the first BKZ dose.
*As of Oct 25th, 196 patients were enrolled, and 21 patients had missing information at the time of database lock.

Bx: biologic; **BKZ**: bimekizumab; **BL**: baseline; **BSA**: body surface area; **CRO**: clinician-reported outcomes; **DL**: data lock; **DLQI**: Dermatology Life Quality Index; **NIS**: non-interventional study; **OP**: observation period; **PASI**: Psoriasis Area and Severity Index; **PGA**: Physician's Global Assessment; **PRO**: patient-reported outcomes; **P-SIM**: Psoriasis Symptoms and Impacts Measure; **PST**: past systemic treatment; **RST**: recent systemic treatment; **SD**: standard deviation; **Sx**: systemic; **TSQM-9**: Treatment Satisfaction Questionnaire-version 9; **TxH**: treatment history.

Figure 1 ELEVATE study design

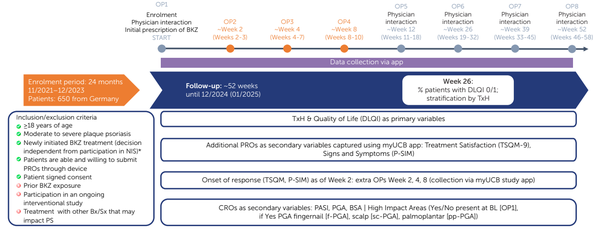


Figure 2 Patient stratification based on TxH

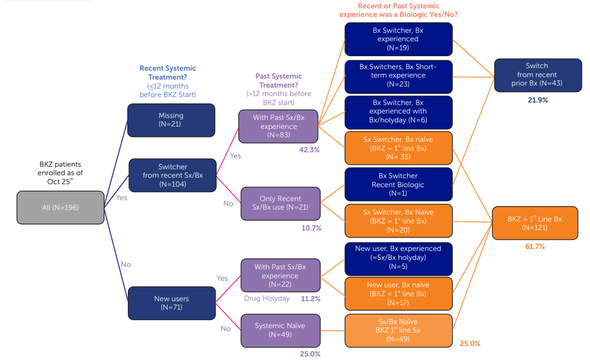


Figure 3 PASI categories by TxH stratification at BL

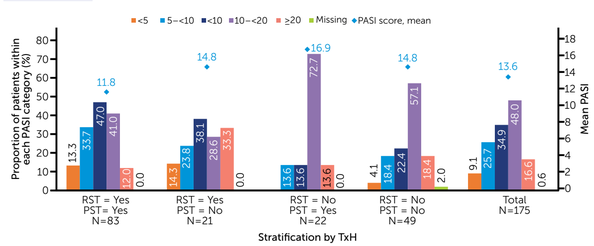


Figure 4 DLQI categories by TxH stratification at BL

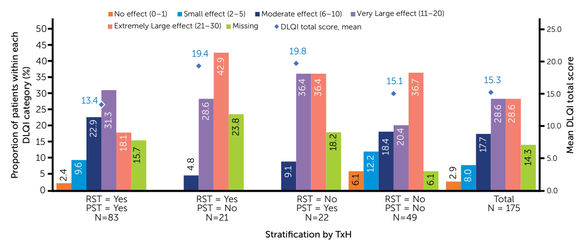


Figure 5 P-SIM score by TxH strata at BL

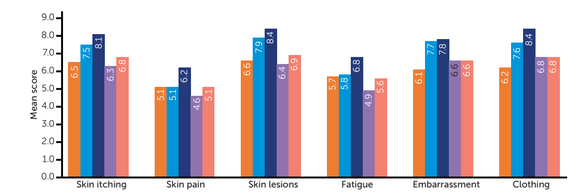
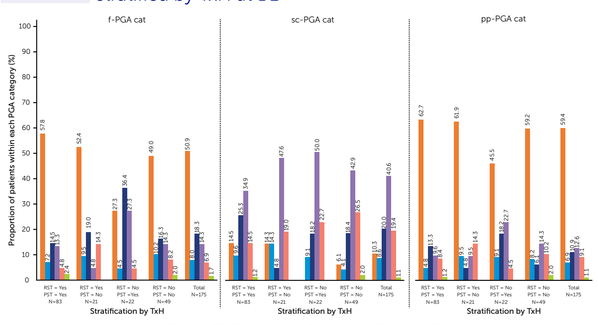


Figure 6 Distribution of high impact area assessed by PGA stratified by TxH at BL



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References: 1. Glatt et al. Ann Rheum Dis. 2018;77:523–532; 2. Adams et al. Front Immunol. 2020;11:1894; 3. EMA, Aug 2021, available at: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf. Last accessed March 2023; 4. Zinc et al. Poster P2533. Real-world patient characteristics and prior treatment history of bimekizumab patients in Germany. Presented at the 32nd EADV, 2023, Berlin, Germany.
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