Bimekizumab safety and tolerability in moderate to severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials

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Disclosures

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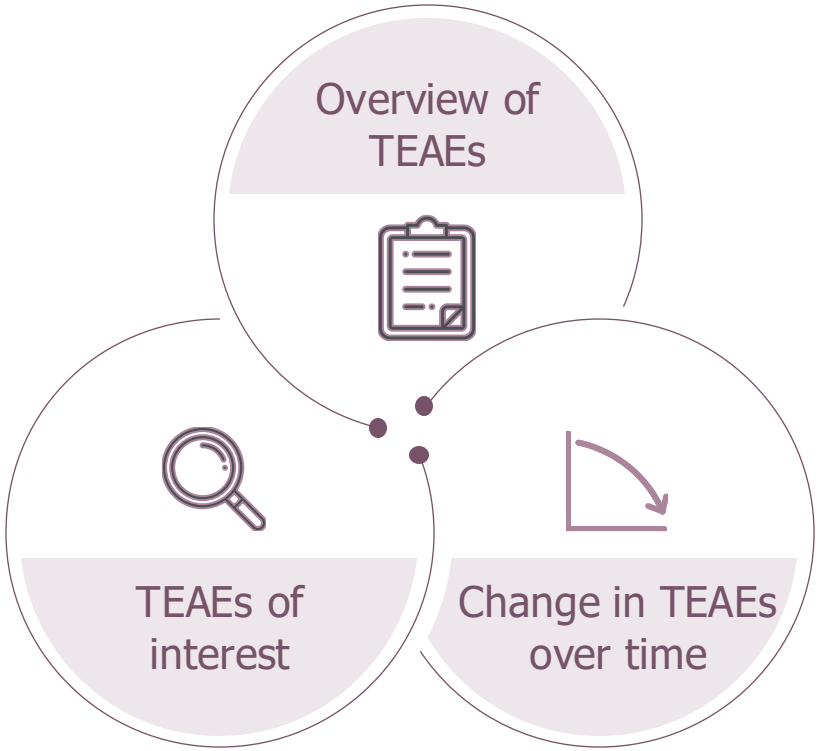
Introduction

- Bimekizumab (BKZ) is a monoclonal immunoglobulin G1 antibody which **selectively inhibits interleukin (IL)-17F in addition to IL-17A**.[1]
- Psoriasis is a **chronic condition** requiring long-term management. Therefore, evaluating **long-term safety** of treatments is essential for informing decision-making for clinicians, while managing risk for patients.[2]

This presentation reports



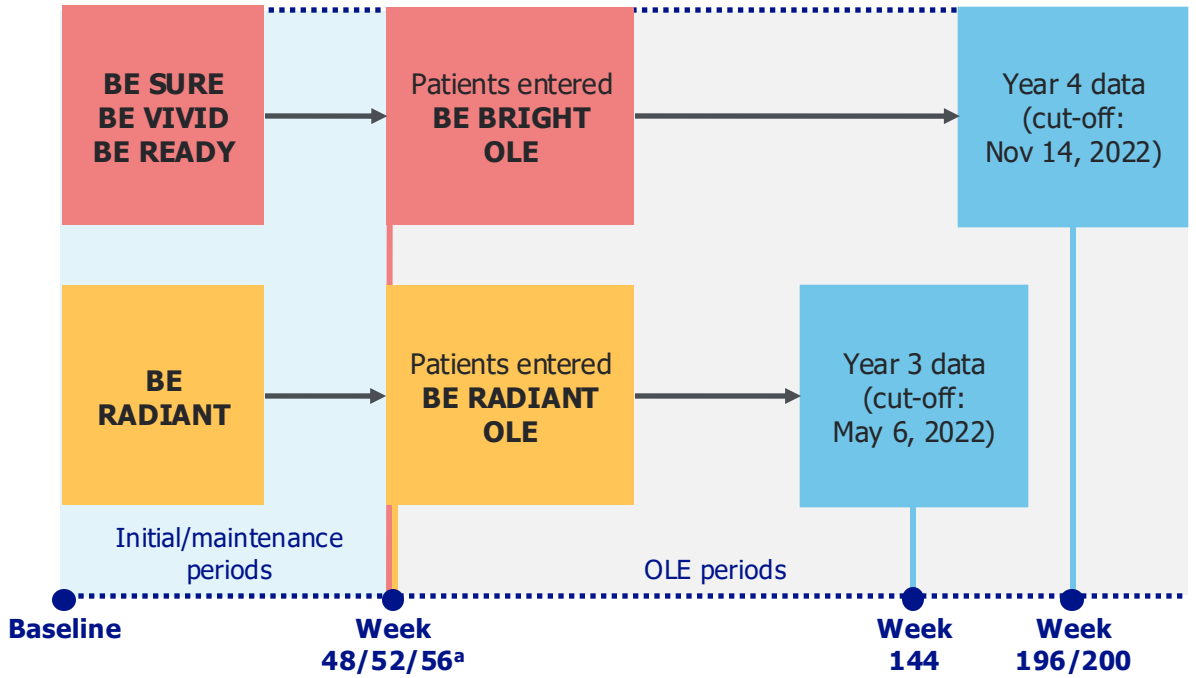
OBJECTIVE: To evaluate BKZ safety data up to 4 years in patients with moderate to severe plaque psoriasis.

1. Adams R et al. Front Immunol 2020;11:1894. **2.** Al-Janabi A & Yiu ZZN Psoriasis (Auckl) 2022;12:1–14. BKZ: bimekizumab; IL: interleukin; TEAE: treatment-emergent adverse event.

Methods

- Data were pooled from all patients who received ≥1 BKZ dose (**BKZ Total**) in:
  - The BE SURE, BE VIVID and BE READY phase 3 trials, their open-label extension (OLE) BE BRIGHT and the BE RADIANT phase 3b trial.[1–5]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W).
  - All patients received BKZ Q8W from Week 64 (BE RADIANT)/OLE Week 48 (BE BRIGHT) or the next scheduled clinic visit.
- Patients switching to BKZ from adalimumab, ustekinumab or secukinumab were also included.

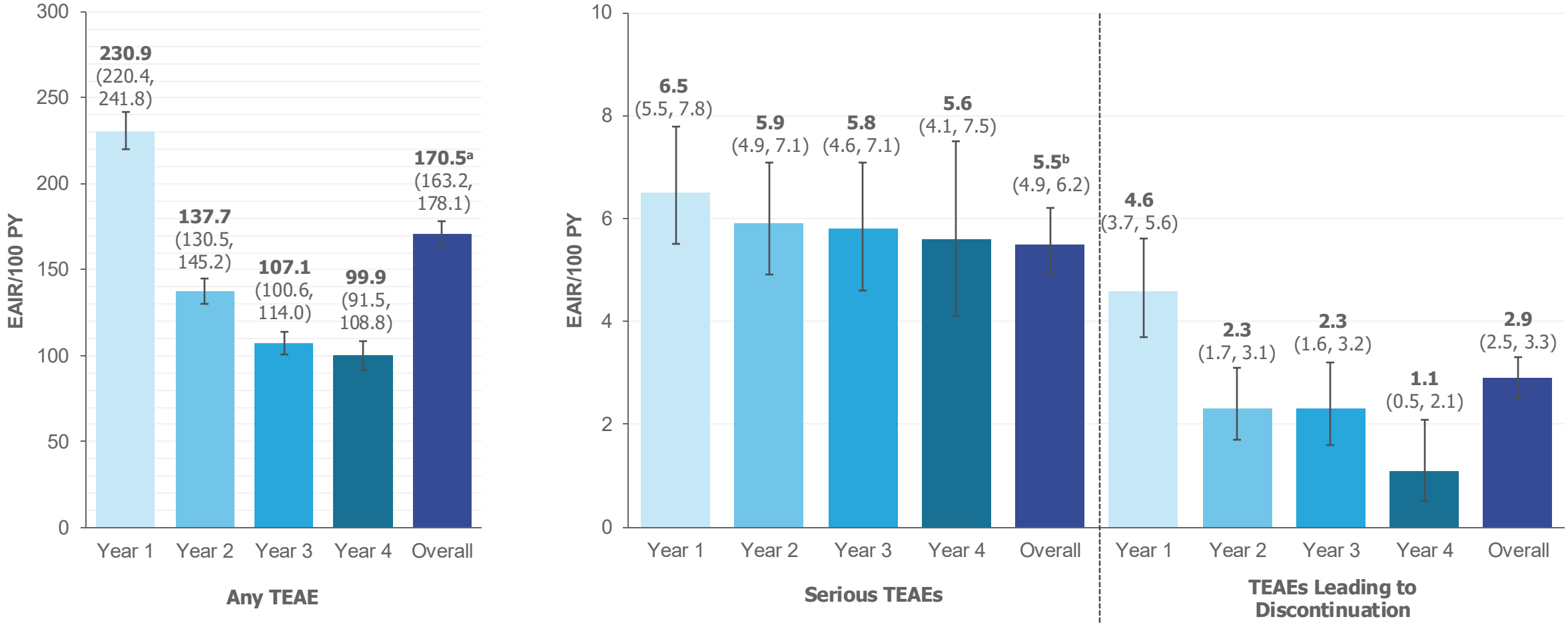
Included Studies



- **Treatment-emergent adverse events (TEAEs)** are reported here **over 4 years** using exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY).
- TEAEs were also evaluated **separately for Years 1, 2, 3** and **4** (Weeks 0–52, 52–104, 104–156 and 156–208) of BKZ treatment.

[a] Patients entered the BE BRIGHT OLE at Week 52 if they were enrolled in BE VIVID and Week 56 if they were enrolled in BE SURE or BE READY; patients in BE RADIANT entered the BE RADIANT OLE period at Week 48. **1.** Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; **2.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **3.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; **4.** Gordon KB et al. JAMA Dermatol 2022;158:735–44, NCT03598790; **5.** Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884. BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; OLE: open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event.

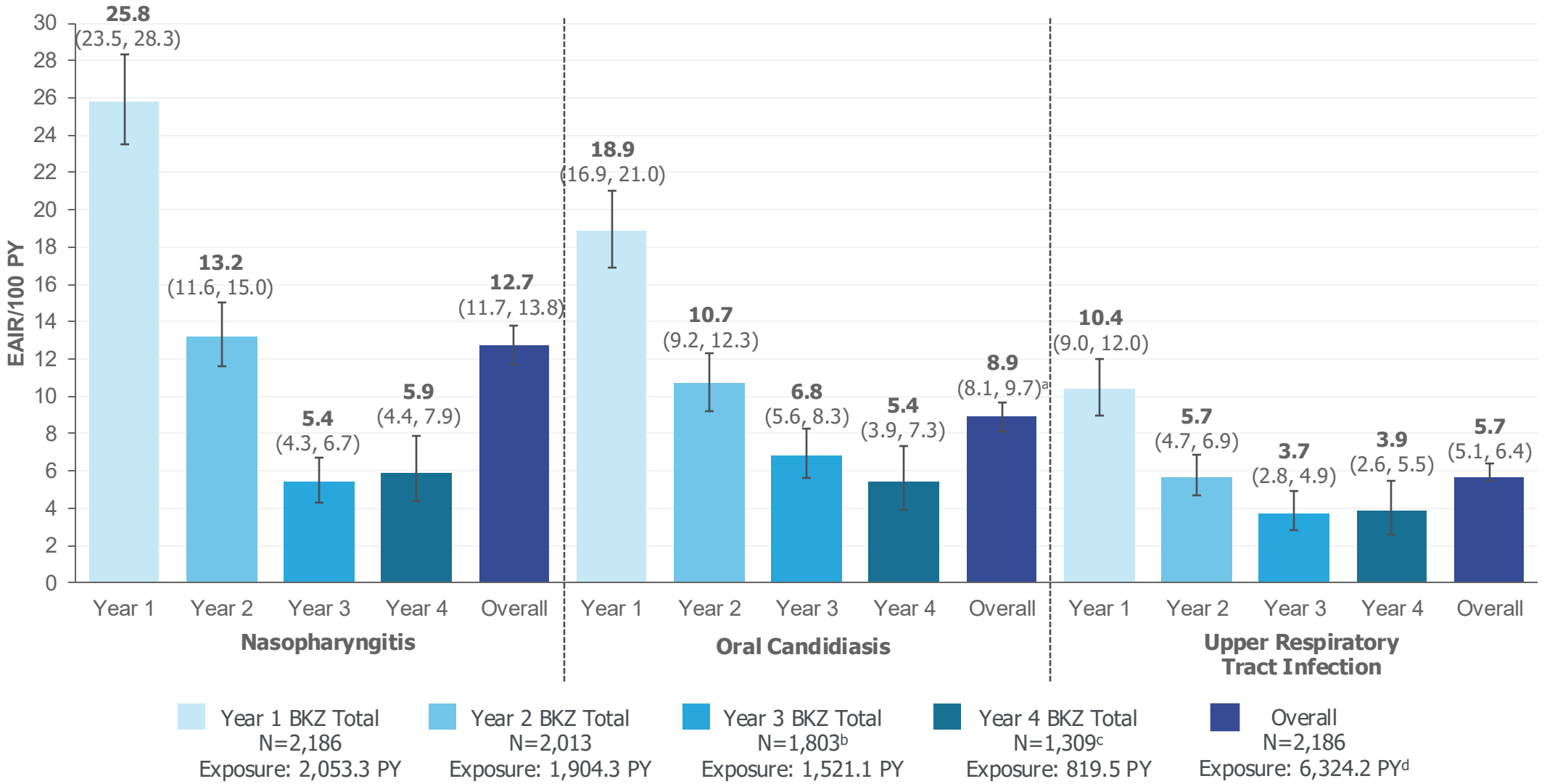
Incidence rates of TEAEs – Any, serious and discontinuations over time (BKZ Total)



Overall, the EAIR of TEAEs **decreased with longer BKZ exposure** over 4 years

Data are reported as EAIRs; error bars represent 95% CI. Data are presented for BKZ Total for the full pooled trial period, and separately for Years 1 (Weeks 0–52), 2 (Weeks 52–104), 3 (Weeks 104–156) and 4 (Weeks 156–208). Data were pooled for all patients who received ≥1 BKZ dose in each of the periods examined (BKZ Total). **[a]** The EAIR of TEAEs over 4 years was numerically lower in patients receiving BKZ Q8W vs Q4W (115.4/100 PY vs 224.4/100 PY); **[b]** The rate of serious TEAEs over 4 years is lower than the rate in any individual year due to time not accounted for in the individual year summaries; **[c]** BE RADIANT patients are not included after Year 3; **[d]** Total BKZ exposure over 4 years is greater than the sum of BKZ exposure in individual years, as data beyond Week 208 are included due to the use of a cut-off date. BKZ: bimekizumab; CI: confidence intervals; EAIR: exposure-adjusted incidence rate; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event.

Most common TEAEs (BKZ Total)



Data are reported as EAIRs; error bars represent 95% CI. Data are presented for BKZ Total for the full pooled trial period, and separately for Years 1 (Weeks 0–52), 2 (Weeks 52–104), 3 (Weeks 104–156) and 4 (Weeks 156–208). Data were pooled for all patients who received ≥1 BKZ dose in each of the periods examined (BKZ Total). **[a]** The EAIR for oral candidiasis over 4 years was numerically lower in patients receiving BKZ Q8W vs Q4W (6.5/100 PY vs 16.7/100 PY). The majority (99.1%) of oral candidiasis events were mild or moderate in severity; **[b]** Confounding factors linked to the COVID-19 pandemic, including social isolation, mask-wearing and lockdowns, may have impacted Year 3 and Year 4 data, particularly respiratory infection TEAEs such as nasopharyngitis; **[c]** BE RADIANT patients are not included after Year 3; **[d]** Total BKZ exposure over 4 years is greater than the sum of BKZ exposure in individual years, as data beyond Week 208 are included due to the use of a cut-off date. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; OLE: open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event.

TEAEs of interest (BKZ Total)

	Year 1 (N=2,186)	Year 2 (N=2,013)	Year 3 (N=1,803)[a]	Year 4 (N=1,309)[a]	Overall (N=2,186)
TEAEs of Interest, EAIR/100 PY (95% CI)					
Serious infections	1.7 (1.2, 2.3)	0.8 (0.5, 1.4)	1.4 (0.9, 2.1)	1.1 (0.5, 2.1)	1.3 (1.0, 1.6)
Active tuberculosis	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Fungal infections	30.6 (28.0, 33.3)	18.8 (16.8, 21.0)	11.9 (10.2, 13.8)	8.6 (6.6, 10.9)	15.7 (14.6, 16.9)
Candida infections	22.2 (20.1, 24.4)	12.8 (11.2, 14.6)	7.8 (6.5, 9.4)	5.7 (4.1, 7.6)	10.4 (9.5, 11.3)
Oral candidiasis	18.9 (16.9, 21.0)	10.7 (9.2, 12.3)	6.8 (5.6, 8.3)	5.4 (3.9, 7.3)	8.9 (8.1, 9.7)[b]
Adjudicated inflammatory bowel disease[b]	0.3 (0.1, 0.7)	0.2 (0.0, 0.5)	0.1 (0.0, 0.4)	0.1 (0.0, 0.7)	0.2 (0.1, 0.3)
Adjudicated major adverse cardiac event	0.5 (0.3, 1.0)	0.3 (0.1, 0.7)	0.6 (0.3, 1.1)	1.1 (0.5, 2.1)	0.6 (0.4, 0.8)
Malignancies	0.9 (0.6, 1.5)	1.1 (0.7, 1.7)	0.9 (0.5, 1.5)	1.0 (0.4, 1.9)	0.9 (0.6, 1.1)
Excluding non-melanoma skin cancer	0.4 (0.2, 0.8)	0.6 (0.3, 1.1)	0.7 (0.4, 1.3)	0.9 (0.3, 1.8)	0.6 (0.4, 0.8)
Adjudicated suicidal ideation and behaviour	0.1 (0.0, 0.4)	0.2 (0.0, 0.5)	0.1 (0.0, 0.5)	0.0 (0.0, 0.0)	0.1 (0.1, 0.2)
Neutropenia events	0.8 (0.5, 1.3)	0.5 (0.3, 1.0)	0.1 (0.0, 0.5)	0.2 (0.0, 0.9)	0.5 (0.3, 0.7)
ALT or AST elevations					
>3x ULN	2.6 (1.9, 3.4)	2.4 (1.7, 3.2)	1.9 (1.3, 2.8)	1.8 (1.0, 3.0)	1.9 (1.6, 2.3)
>5x ULN[c]	0.8 (0.5, 1.3)	0.3 (0.1, 0.7)	0.5 (0.2, 1.0)	0.6 (0.2, 1.4)	0.5 (0.4, 0.7)
Serious hypersensitivity reactions[d]	0.1 (0.0, 0.4)	0.1 (0.0, 0.4)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.1 (0.0, 0.2)
Injection site reactions	3.3 (2.5, 4.2)	1.1 (0.6, 1.6)	1.2 (0.7, 1.9)	0.4 (0.1, 1.1)	1.7 (1.4, 2.0)

Data are presented for BKZ Total for the full pooled trial period, and separately for Years 1 (Weeks 0–52), 2 (Weeks 52–104), 3 (Weeks 104–156) and 4 (Weeks 156–208). Data were pooled for all patients who received ≥1 BKZ dose in each of the periods examined (BKZ Total). **[a]** Confounding factors linked to the COVID-19 pandemic, including social isolation, mask-wearing and lockdowns, may have impacted Year 3 and Year 4 data, particularly respiratory infection TEAEs such as nasopharyngitis; **[b]** Includes any TEAE adjudicated as definite or probable inflammatory bowel disease; **[c]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN; **[d]** No anaphylactic reactions associated with BKZ were reported. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; OLE: open-label extension; PY: patient-years; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

Conclusions

Bimekizumab demonstrated **good tolerability** and a **comparable safety profile over 4 years** in patients with moderate to severe plaque psoriasis

The **most common treatment-emergent adverse events** were nasopharyngitis, oral candidiasis and upper respiratory tract infection

The exposure-adjusted incidence rate of treatment-emergent adverse events remained **consistent or decreased** with longer bimekizumab exposure, with **no new safety signals** observed

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