Bimekizumab safety and tolerability in patients with moderate to severe hidradenitis suppurativa: 2-year results from BE HEARD EXT

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OBJECTIVES

- To evaluate the safety profile of bimekizumab (BKZ) in patients with moderate to severe hidradenitis suppurativa (HS) over 2 years.
- To assess whether there are changes in exposure-adjusted incidence rates (EAIRs; per 100 participant-years [PY]) of treatment-emergent adverse events (TEAEs) with each year of BKZ treatment.

Background

- **HS** is a chronic, systemic, **inflammatory skin disease** characterized by painful lesions.[1]
- **BKZ** is a humanized monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Methods

- Pooled data are reported for patients who received ≥1 BKZ 320 mg dose across BE HEARD I&II and BE HEARD EXT (data cut-off November 2023).[3,4]
- Patients switching from placebo to BKZ at Week 16 are also included following switch to BKZ, from Week 16 onwards.
- **TEAEs** are reported as EAIRs (per 100 PY) **over 2 years** of BKZ treatment (Weeks 0–96 from start of BKZ or Weeks 16–96 for placebo to BKZ switchers).
- TEAEs are also reported separately for Year 1 (Weeks 0–48) and Year 2 (Weeks 48–96) of BKZ treatment.

1. Zouboulis CC et al. Dermatology 2015;231:184–90; **2.** Adams R et al. Front Immunol 2020;11:1894; **3.** Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **4.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; EAIRs: exposure-adjusted incidence rates; HS: hidradenitis suppurativa; IgG: immunoglobulin; IL: interleukin; PY: participant-years; TEAEs: treatment-emergent adverse events.

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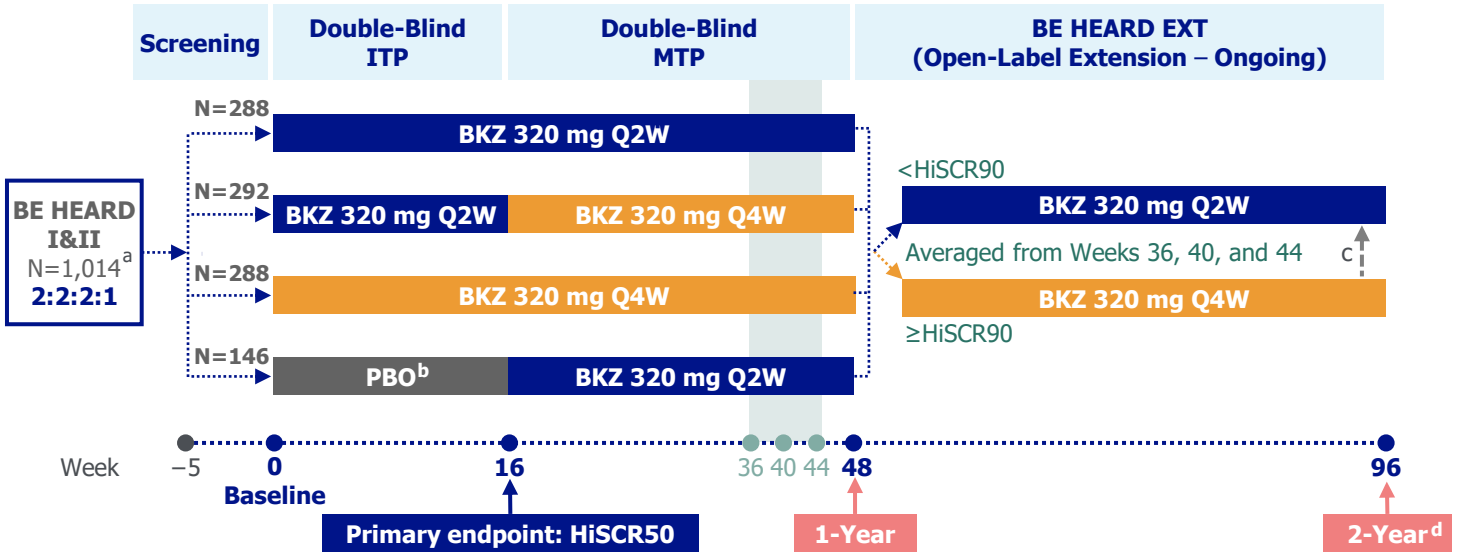
Study Design



- Patients completing the 48-week **BE HEARD I&II trials** could enroll in the open-label extension, **BE HEARD EXT**, and receive open-label BKZ every 2 weeks (Q2W) or BKZ every 4 weeks (Q4W) based on HiSCR90 responder status using the average lesion counts from Week 36, 40, and 44 of BE HEARD I&II.[1,2]

Baseline Characteristics

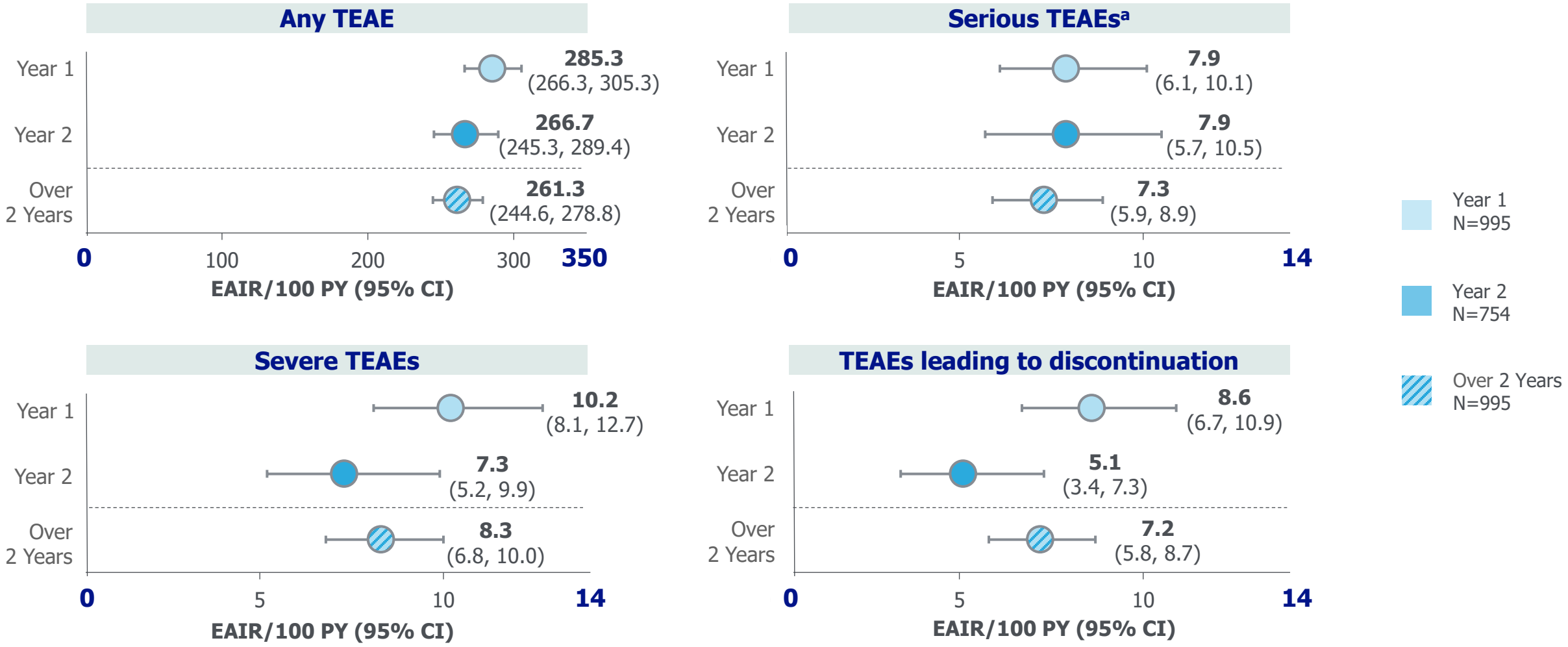
	Patients who received ≥1 BKZ 320 mg dose (N=995)
Age (years), mean (SD)	36.7 (12.2)
Sex, Female, n (%)	564 (56.7)
Racial group, White, n (%) **Racial group,** Black, n (%)	796 (80.0) 106 (10.7)
Weight (kg), mean (SD)	97.2 (24.5)
BMI (kg/m²), mean (SD)	33.0 (8.1)
Disease duration (years), mean (SD)	8.0 (7.8)
Hurley Stage II, n (%) **Hurley Stage III,** n (%)	553 (55.6) 442 (44.4)
DLQI total score, mean (SD)	11.2 (6.9)
Prior biologic use, n (%)	192 (19.3)
Baseline antibiotic use, n (%)	83 (8.3)
Total AN count, mean (SD)	16.1 (16.0)
Total DT count, mean (SD)	3.6 (4.3)

BKZ Exposure

	Year 1 N=995	Year 2 N=754	Over 2 years N=995
Weeks	0–48	>48–96	0–96
Total exposure (time at risk), PY	817.7	576.6	1,394.3
Median exposure (range), days	336.0 (1–336)	336.0 (1–336)	672.0 (1–672)

[a] N represents the number of randomized patients; **[b]** Patients switching from placebo to BKZ at Week 16 were also included following switch to BKZ; **[c]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[d]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). **1.** Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **2.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnel; DLQI: Dermatology Life Quality Index; HiSCR50/90: ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; ITP: initial treatment period; MTP: maintenance treatment period; PBO: placebo; PY: participant-years; Q2W: every two weeks; Q4W: every four weeks; SD: standard deviation.

Incidence of TEAEs Over 2 Years (Patients Who Received ≥1 BKZ 320 mg Dose)



Overall, the EAIR of TEAEs **did not increase with longer BKZ exposure** over 2 years[b]

TEAEs were coded using MedDRA v19.0 and are reported as EAIRs; error bars represent 95% CI. Data are presented for patients who received ≥1 BKZ dose for the full pooled trial period (over 2 years), and separately for Years 1 (Weeks 0–48), and 2 (Weeks 48–96). Pooled data are reported for patients who received ≥1 BKZ dose across BE HEARD I&II or BE HEARD EXT (data cut-off: November 2023); patients switching from placebo to BKZ at Week 16 were also included following switch to BKZ. **[a]** TEAEs leading to death were reported in 2 patients over 2 years (one patient with significant cardiovascular history died due to congestive heart failure; one patient died due to possible central nervous system infection in the context of deteriorating HS); **[b]** The rates of some TEAEs over 2 years may be lower than the rates observed in an individual year due to the adjustment for exposure time at risk for adverse events, which for an individual participant can be up to 2 years in the over 2 years analysis and up to 1 year in the individual year analysis. BKZ: bimekizumab; CI: confidence intervals; EAIR: exposure-adjusted incidence rate; HS: hidradenitis suppurativa; PY: participant-years; TEAE: treatment-emergent adverse event.

Most Common TEAEs and TEAEs of Interest (Patients Who Received ≥1 BKZ 320 mg Dose)

	Year 1 (N=995)	Year 2 (N=754)	Over 2 years (N=995)
Most Common TEAEs,[a] EAIR/100 PY (95% CI)			
Hidradenitis	25.2 (21.7, 29.1)	27.1 (22.7, 32.0)	23.0 (20.4, 25.9)
Corona virus infection	14.6 (12.0, 17.5)	21.3 (17.5, 25.6)	17.3 (15.1, 19.8)
Oral candidiasis	15.4 (12.7, 18.4)	12.1 (9.4, 15.4)	12.0 (10.1, 14.0)
TEAEs of Interest, EAIR/100 PY (95% CI)			
Serious infections	1.8 (1.0, 3.0)	1.7 (0.8, 3.2)	1.7 (1.1, 2.5)
Active tuberculosis	0	0	0
Fungal infections	35.3 (31.0, 40.0)	25.4 (21.3, 30.2)	27.7 (24.7, 31.0)
Candida infections	21.6 (18.4, 25.2)	17.3 (13.9, 21.2)	17.1 (14.8, 19.6)
Oral candidiasis Vulvovaginal candidiasis	15.4 (12.7, 18.4) 3.6 (2.4, 5.2)	12.1 (9.4, 15.4) 2.1 (1.1, 3.7)	12.0 (10.1, 14.0) 2.9 (2.0, 3.9)
Neutropenia	0.1 (0.0, 0.7)	0.2 (0.0, 1.0)	0.1 (0.0, 0.5)
Definite or probable adjudicated inflammatory bowel disease	0.9 (0.3, 1.8)	0.5 (0.1, 1.5)	0.7 (0.3, 1.3)
With history of IBD[b]	0	40.6 (4.9, 146.5)	17.3 (2.1, 62.4)[c]
No history of IBD[b]	0.9 (0.3, 1.8)	0.2 (0.0, 1.0)	0.6 (0.3, 1.1)
Adjudicated major adverse cardiac event	0.4 (0.1, 1.1)	0.2 (0.0, 1.0)	0.3 (0.1, 0.7)
Adjudicated suicidal ideation and behavior[d]	0.7 (0.3, 1.6)	0.9 (0.3, 2.0)	0.8 (0.4, 1.4)
Hepatic events	5.7 (4.1, 7.6)	6.1 (4.2, 8.5)	5.4 (4.2, 6.8)
ALT or AST elevations >3x ULN	20.4 (13.4, 29.6)	21.8 (12.7, 34.9)	10.7 (7.8, 14.4)
ALT or AST elevations >5x ULN[e]	6.3 (2.7, 12.5)	7.7 (2.8, 16.9)	3.5 (1.9, 5.9)
Serious hypersensitivity reactions[f]	0.1 (0.0, 0.7)	0	0.1 (0.0, 0.4)
Injection site reactions	8.5 (6.6, 10.8)	2.3 (1.2, 3.9)	5.9 (4.6, 7.3)
Malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.3)	0.7 (0.3, 1.3)
Any malignancies excluding non-melanoma skin cancer	0.2 (0.0, 0.9)	1.0 (0.4, 2.3)	0.6 (0.2, 1.1)

TEAEs were coded using MedDRA v19.0. Data are presented for patients who received ≥1 BKZ dose for the full pooled trial period (over 2 years), and separately for Years 1 (Weeks 0–48), and 2 (Weeks 48–96). Pooled data are reported for patients who received ≥1 BKZ dose across BE HEARD I&II or BE HEARD EXT (data cut-off: November 2023); patients switching from placebo to BKZ at Week 16 were also included following switch to BKZ. **[a]** Most common as measured over 2 years; **[b]** Number of patients with history of IBD: Year 1: n=8, Year 2: n=7, over 2 years: n=8; number of patients with no history of IBD: Year 1: n=987, Year 2: n=747, over 2 years: n=987; **[c]** Of the 8 patients with history of IBD, 2 experienced TEAEs of IBD over 2 years; **[d]** No cases of completed suicide reported; **[e]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN; **[f]** All cases due to rash pustular; no anaphylaxis associated with BKZ reported over 2 years. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; PY: participant-years; TEAE: treatment-emergent adverse event, ULN: upper limit of normal.

CONCLUSIONS

Bimekizumab was well-tolerated and demonstrated a safety profile that was consistent over 2 years in patients with moderate to severe hidradenitis suppurativa.

Overall, the EAIRs of TEAEs did not increase with longer bimekizumab exposure over 2 years.

No new safety signals were observed for bimekizumab.

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