Bimekizumab Efficacy and Safety Through 3 Years in Patients with Hidradenitis Suppurativa: Results from the Phase 3 BE HEARD I&II Trials and Their Open-Label Extension BE HEARD EXT

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Objective

To report efficacy and safety of bimekizumab (BKZ) in patients with moderate to severe hidradenitis suppurativa (HS) up to 3 years (148 weeks) for the pooled phase 3 BE HEARD I&II trials and the open-label extension (OLE) BE HEARD EXT.[1,2]

Introduction

- HS is a chronic, relapsing, inflammatory skin disease, characterized by painful lesions which cause disability and diminish patients' health-related quality of life (HRQoL).[3–5]
- Long-term disease control is essential to prevent irreversible damage and disease progression.[6]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, and has demonstrated clinically meaningful improvements in patients with moderate to severe HS for up to 2 years of treatment.[1,7,8]

Methods

- Data were pooled from BE HEARD I&II (NCT04242446 and NCT04242498) and BE HEARD EXT (NCT04901195).
- For efficacy outcomes, we report data for patients who were randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total group). For safety outcomes, we report data for patients who received ≥1 dose of BKZ across BE HEARD I&II/BE HEARD EXT.
- Data reported over time to Year 3:
  - HS Clinical Response (HiSCR)50/75/90/100 rates;
  - Absolute change from baseline (CfB) in draining tunnel (DT) count;
  - Dermatology Life Quality Index (DLQI) 0/1 response rates.
- Exposure-adjusted incidence rates (EAIR) for any treatment-emergent adverse event (TEAE) reported up to 3 years of BKZ treatment.
- Data are reported as observed case (OC) and modified non-responder imputation (mNRI) for HiSCR and DLQI outcomes.
  - OC: patients who discontinued for any reason–left as missing;
  - mNRI: patients who discontinued due to adverse events or lack of efficacy–imputed as non-response.

Results

- Of the 1,014 patients in BE HEARD I&II, 556 randomized to BKZ at baseline completed Year 1 (Week 48) and entered BE HEARD EXT (BKZ Total).
- Baseline demographics and clinical characteristics of patients are presented in **Table 1**.
- Up to 3 years, the EAIR for any TEAE was 226.8 patient-years, showing a decrease with longer exposure to BKZ (**Table 2**).
- At Week 48, HiSCR50/75/90/100 responses were 79.9%/64.0%/42.3%/30.2% (OC); responses were maintained to Week 148 at 90.2%/81.2%/64.3%/50.1% (OC) (**Figure 1**).
- Patients had DLQI 0/1 response rates of 38.1% (OC) and 31.9% (mNRI) at Week 148 (**Figure 2**).
- At Week 96, mean absolute CfB in DT count was –2.9, which was maintained through Week 148 (OC) (**Figure 3**).

Conclusions

Clinical improvements observed at Year 1 in the bimekizumab hidradenitis suppurativa phase 3 trials were maintained or further improved through 3 years of treatment. Draining tunnel and health-related quality of life improvements were also maintained through 3 years.

Bimekizumab was well-tolerated and no new safety signals were identified up to 3 years of treatment.

These data highlight the depth and durability of response to bimekizumab treatment in patients with moderate to severe hidradenitis suppurativa.

Plain Language Summary

Why was this study needed?

Hidradenitis suppurativa (HS) is a long-lasting skin condition. It can cause painful lumps and draining tunnels under the skin. These signs of progressive disease cause irreversible damage and reduce quality of life.

What did this study show?

After 1 year of treatment with bimekizumab, patients with HS had several improvements, including better quality of life and fewer draining tunnels. These improvements were maintained through 3 years of treatment.

No new safety concerns were identified.

Why is this important?

Treatment with bimekizumab reduces lasting symptoms of HS to improve patients' daily lives.

Table 1 Baseline characteristics

	BKZ Total[a] (Efficacy set) N=556	Patients with ≥1 dose BKZ (Safety set) N=995
Age, years, mean (SD)	36.3 (12.2)	36.7 (12.2)
Sex, female, n (%)	299 (53.8)	564 (56.7)
Racial group, White, n (%)	448 (80.6)	796 (80.0)
BMI, kg/m², mean (SD)	32.5 (7.8)	33.0 (8.1)
Duration of disease, years, mean (SD)	7.4 (7.1)	8.0 (7.8)
Hurley stage, n (%)		
I	303 (54.5)	553 (55.6)
II	253 (45.5)	442 (44.4)
DLQI total score, mean (SD)	11.0 (6.8)	11.2 (6.9)
Prior biologic use[b], n (%)	112 (20.1)	192 (19.3)
Baseline antibiotic use, n (%)	54 (9.7)	83 (8.3)

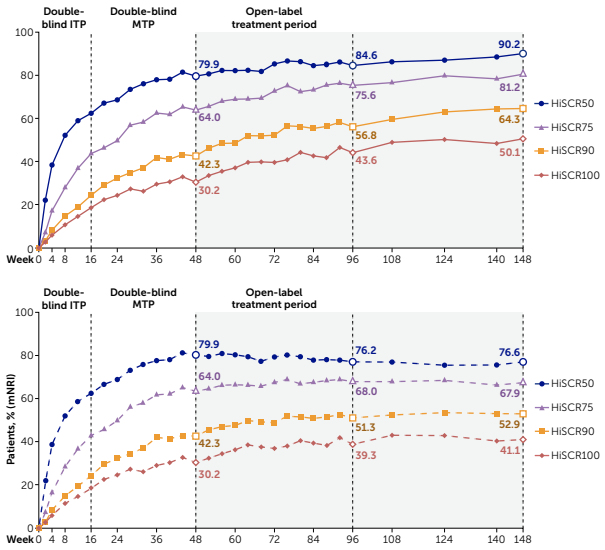
OLE set for efficacy set; Pool S3 for safety set. **[a]** BKZ Total comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT. **[b]** Patients received prior biologic therapy for any indication.

Table 2 Incidence of TEAEs per 100 patient-years

EAIR/100 PY (95% CI)	Patients with ≥1 dose BKZ N=995			
	Year 1 (Week 0–48) Total exposure: 7.8 per 100 PY	Year 2 (Week >48–96) Total exposure: 5.9 per 100 PY	Year 3 (Week >96–144) Total exposure: 4.7 per 100 PY	Up to 3 Years (Week 0–144) Total exposure: 18.4 per 100 PY
Any TEAE	261.9 (244.5, 280.3)	237.2 (218.3, 257.2)	168.3 (152.2, 185.6)	226.8 (212.4, 242.0)
Serious TEAEs	8.2 (6.3, 10.5)	7.9 (5.7, 10.5)	7.9 (5.5, 10.9)	7.2 (6.0, 8.6)
Severe TEAEs	10.4 (8.2, 12.9)	7.2 (5.2, 9.8)	7.0 (4.8, 9.9)	7.7 (6.4, 9.1)
TEAEs leading to discontinuation	8.7 (6.8, 11.1)	4.8 (3.2, 7.0)	3.0 (1.7, 5.1)	6.0 (5.0, 7.3)
Any TEAE leading to death[a]	0.1 (0.0, 0.7)	0.3 (0.0, 1.2)	0.0	0.2 (0.0, 0.5)
Most common TEAEs[b]				
Hidradenitis	25.5 (21.9, 29.5)	27.4 (23.1, 32.2)	18.2 (14.4, 22.7)	20.7 (18.5, 23.2)
Coronavirus infection	13.6 (11.1, 16.5)	23.7 (19.7, 28.2)	7.5 (5.2, 10.5)	15.3 (13.4, 17.4)
Oral candidiasis	15.2 (12.5, 18.2)	12.3 (9.5, 15.6)	10.3 (7.5, 13.8)	10.4 (8.9, 12.1)
Serious infections	1.9 (1.1, 3.2)	1.7 (0.8, 3.2)	3.2 (1.8, 5.3)	2.0 (1.4, 2.8)
Fungal infections	34.8 (30.5, 39.6)	25.0 (20.9, 29.7)	22.3 (18.0, 27.2)	24.4 (21.9, 27.1)
Any malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.2)	0.6 (0.1, 1.9)	0.7 (0.4, 1.2)
Any hepatic events	6.0 (4.4, 8.0)	5.8 (4.0, 8.2)	4.6 (2.8, 7.0)	4.7 (3.8, 5.9)
Adjudicated suicidal ideation and behavior[c]	0.8 (0.3, 1.7)	0.9 (0.3, 2.0)	0.4 (0.1, 1.6)	0.7 (0.4, 1.2)
Definite or probable adjudicated IBD[d]	0.9 (0.4, 1.8)	0.5 (0.1, 1.5)	0.2 (0.0, 1.2)	0.5 (0.3, 1.0)

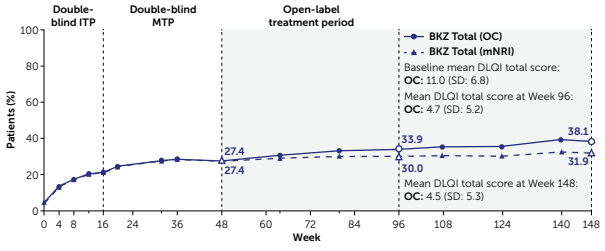
Data presented relates to the initial treatment and maintenance periods of BE HEARD I&II, and the open-label extension BE HEARD EXT (total of 3 years). TEAEs were coded using MedDRA v19.0 and reported for up to 3 years of BKZ treatment using EAIRs per 100 patient-years. **[a]** Up to 3 years, three patients died; 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, and one patient with history of gynecological cancer died of leiomyosarcoma. **[b]** The three most common TEAEs are organized in descending order based on the Up to 3 Years data. **[c]** There were no events of completed suicide. **[d]** Among the eight patients with a history of IBD, two patients experienced flares up to 3 years.

Figure 1 HiSCR in BKZ Total



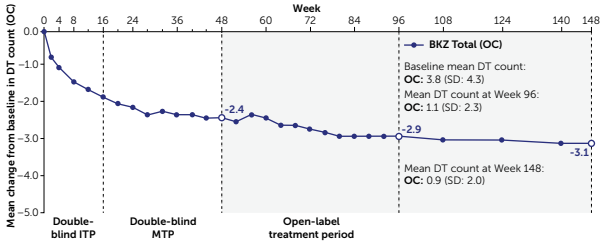
OC, n/N: denominator represents number of patients with a lesion assessment in the given week, and percentages are calculated accordingly. Week 48 n/N: HiSCR50, 444/556; HiSCR75, 356/556; HiSCR90, 235/556; HiSCR100, 168/556; Week 96 n/N: HiSCR50, 378/447; HiSCR75, 338/447; HiSCR90, 254/447; HiSCR100, 195/447; Week 148 n/N: HiSCR50, 331/367; HiSCR75, 298/367; HiSCR90, 236/367; HiSCR100, 184/367. Of the 146 patients who were randomized to placebo at baseline in BE HEARD I&II, the proportions achieving Week 16 HiSCR thresholds were: HiSCR50: 48/135; HiSCR75: 25/135; HiSCR90: 13/135; HiSCR100: 8/135. For mNRI, discontinuation due to adverse event or lack of efficacy constituted an intercurrent event. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event.

Figure 2 DLQI 0/1 response rates[a] in BKZ Total



Week 48 n/N: 151/551, Week 96 n/N: 151/445, Week 148 n/N: 137/360. OC, n/N: denominator represents number of patients with a DLQI assessment in the given week, and percentages are calculated accordingly. For mNRI, discontinuation due to adverse event or lack of efficacy constituted an intercurrent event. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. **[a]** DLQI 0/1 response defined as total score of 0 or 1 (no effect at all on patients' life); DLQI score ranges 0–30.

Figure 3 Mean absolute change from baseline in DT count in BKZ Total



Week 48 n: 556, Week 96 n: 447, Week 148 n: 367. OC, n: represents number of patients with a non-missing lesion count assessment in the given week and a non-zero baseline lesion count assessment. Baseline mean total abscess and inflammatory nodule count (SD): 16.9 (18.5).

BKZ: bimekizumab; **BMI:** body mass index; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **EAIR:** exposure-adjusted incidence rate; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/75/90/100:** ≥50%/75%/90%/100% reduction from baseline in total abscess and inflammatory nodules with no increase from baseline in abscess or draining tunnel count; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **IBD:** inflammatory bowel disease; **IL:** interleukin; **ITP:** initial treatment period; **MedDRA:** Medical Dictionary for Regulatory Activities; **mNRI:** modified non-responder imputation; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension; **PY:** patient-years; **SD:** standard deviation; **SE:** standard error; **TEAEs:** treatment-emergent adverse events.

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EADV 2024; Presentation 7925. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JRI**, **ABK**, **AG**, **FGB**, **BK**, **AM**, **WG**, **BL**, **DD**, **JL**, **CC**, **TV**, **CJS**; Drafting of the publication, or reviewing it critically for important intellectual content: **JRI**, **ABK**, **AG**, **FGB**, **BK**, **AM**, **WG**, **BL**, **DD**, **JL**, **CC**, **TV**, **CJS**; Final approval of the publication: **JRI**, **ABK**, **AG**, **FGB**, **BK**, **AM**, **WG**, **BL**, **DD**, **JL**, **CC**, **TV**, **CJS**. **Author Disclosures: JRI:** Received a stipend as recent Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Boehringer Ingelheim, Cantargia, ChemoCentryx, Cityrll, Elasmogen, Engitix, Incyte, Indero, Insmed, Kymera Therapeutics, MoonLake Immunotherapeutics, Novartis, UCB, UNION Therapeutics, and Viela Bio; co-copyright holder of HiSQOL®, HS Patient global assessment, and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **ABK:** Institution received grants from AbbVie, Admirx, AnaptysBio, Aristea, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sonoma Biotherapeutics, and UCB; received consulting fees from AbbVie, Alumis, Avalo, Bayer, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sanofi, Sonoma Biotherapeutics, Target RWE, UCB, UNION Therapeutics, and Ventyx; serves on the board of directors of Almirall. **AG:** Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, UNION Therapeutics, and Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB. **FGB:** Received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie, Acelyrin, Beiersdorf, Boehringer Ingelheim, Cellirion, Dr. Wolff, Incyte, Janssen, Johnson & Johnson, Merck, Mölnlycke, MoonLake Immunotherapeutics, Novartis, Sanofi, Sitala, and UCB. **BK:** Received research support from or has been a principal investigator (clinical trials) for AbbVie, Almirall, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; has been a consultant for AbbVie, Almirall, Janssen, Merck, MC2 Therapeutics, MoonLake Immunotherapeutics, Novartis, Pfizer, UNION Therapeutics, and UCB; has received honoraria from AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MC2 Therapeutics, MoonLake Immunotherapeutics, Novartis, Pfizer, UNION Therapeutics, and UCB; and has been on scientific advisory boards for AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB. **AM:** Research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio. **WG:** Grants and research support from AbbVie, Amgen, Eli Lilly and Company, Novartis, and Pfizer; honoraria for advisory boards/invited talks/consultation: AbbVie, Actelion, Amgen, Ayrlide, Bausch Health, Boehringer Ingelheim, Celgene, Cipher, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, PeerVoice, Pfizer, Sanofi, Sun Pharma, Tribute, UCB, and Valeant; clinical trials (study fees): AbbVie, Asana Biosciences, Astellas, Boehringer Ingelheim, Celgene, CorEvitas/Psoriasis Patient Foundation, Devonian, Eli Lilly and Company, Galapagos, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB. **BL**, **DD**, **JL**, **CC**, **TV:** Employees and shareholders of UCB. **CJS:** Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis. **Acknowledgments:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. 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