Bimekizumab Mental Health Outcomes in Patients with HS: 2-Year Data from BE HEARD EXT

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Objective

To describe mental health outcomes up to 2 years in patients with moderate to severe hidradenitis suppurativa (HS) treated with bimekizumab (BKZ) in the BE HEARD I&II trials and their open-label extension, BE HEARD EXT.

Background

- The symptoms and social stigma of HS negatively impact quality of life through a range of psychosocial mechanisms.[1,2] Adults with HS are therefore at increased risk of psychiatric conditions, including anxiety, depression, and suicide, compared with the general population.[1,2]
  - In the BE HEARD I&II studies, inclusion and exclusion criteria during screening ensured that the study population was adequately representative of the HS population (**Table 1**).[1,3]
- BKZ, a humanized IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17F in addition to IL-17A.[4]

Methods

- Data were pooled from the phase 3 BE HEARD I&II studies (NCT04242446/ NCT04242498) and their open-label extension, BE HEARD EXT (NCT04901195).[3,5] At baseline in BE HEARD I&II, patients were randomised 6:1 to receive 320 mg BKZ or placebo.
- The Patient Health Questionnaire-9 (PHQ-9; higher scores indicate more severe depression) and the electronic Columbia-Suicide Severity Rating Scale (eC-SSRS) are patient-reported instruments used to assess mental health (**Figure 1**).
- As part of rigorous neuropsychiatric events monitoring, the PHQ-9 and eC-SSRS were assessed at screening/baseline, and then every 2 weeks (Q2W) for Weeks 0–4, Q4W through Week 96, and Q16W thereafter.
- Data are reported through Week 16 for patients randomized to placebo at baseline in BE HEARD I&II, and for up to 2 years for patients randomized to BKZ at baseline (BKZ Total), and patients who received ≥1 BKZ dose in BE HEARD.
- The following outcomes are reported:
  - PHQ-9 total score absolute mean change from baseline (CfB) and proportions of patients in each PHQ-9 severity category.
  - Overall positive and new-onset positive responses (a positive post-baseline response in a patient with no positive results during screening or at baseline) to eC-SSRS (to any question 1–9), eC-SSRS Q1 and PHQ-9 Q9. Proportions of patients with responses to both eC-SSRS Q1 and PHQ-9 Q9 are also shown to evaluate the agreement between patient responses.
  - Mental health treatment-emergent adverse events (TEAEs), including those adjudicated as suicidal by the external independent committee.
- Data are reported as observed case (OC).

Results

- In BE HEARD I&II, 1,007 patients were randomized and treated; 146 to placebo and 861 to BKZ Total. Patients were eligible to switch from placebo to BKZ at Week 16; N=995 patients received ≥1 BKZ dose up to 2 years (**Table 1**).
- At baseline, patients in the placebo and BKZ Total groups reported low PHQ-9 mean total scores of 3.7 (N=146) and 3.2 (N=861), respectively. From baseline to Week 16, patients in the BKZ Total group experienced numerically larger decreases from baseline in PHQ-9 compared with patients who received placebo (**Figure 2**). Patients in the BKZ Total group maintained these decreases from baseline to Week 48 and Week 96.
- At Week 16, the majority of patients with PHQ-9 assessments in the BKZ Total and placebo groups reported total scores that corresponded to no/minimal or mild depression; this majority was maintained at Week 48 and Week 96 for patients in the BKZ Total group (**Figure 3**).
- To Week 16, the proportions of patients in both the placebo and BKZ Total groups with overall and new-onset positive eC-SSRS responses were low, with a numerically higher number in the BKZ Total group than placebo, likely due to the 6:1 randomization. In patients with ≥1 BKZ dose, the proportion remained low to Week 96, although there was a numerical increase from Week 16. Due to the duration of the BKZ exposure arm, a cumulative numerical increase was expected (**Table 2**).
  - Most new-onset responses were to eC-SSRS Q1, representing passive suicidal ideation.
  - These eC-SSRS results were not unexpected considering the observed eC-SSRS positive responses at screening (**Table 1**).
- Mental health TEAEs were low to Week 16 in patients from both the placebo and BKZ Total groups (**Table 3**). Low rates were maintained to Week 96 for patients who received ≥1 BKZ dose.
  - There were no completed suicides to Week 96.

Conclusions

To Week 16, low PHQ-9 scores were observed for both placebo- and bimekizumab-treated patients.

Over 2 years of bimekizumab treatment, PHQ-9 scores, eC-SSRS positive responses, and incidence rates of mental health TEAEs remained low, considering the increased risk in the HS population.

Plain Language Summary

Why was this study needed?

Hidradenitis suppurativa (HS) is a long-term skin condition. Patients with HS have a higher risk of mental health conditions, such as anxiety, depression, and suicide.

What did this study show?

Bimekizumab is a drug used to treat HS. Up to 2 years of patients taking bimekizumab, there was no worsening of mental health conditions among patients.

Why is this important?

Mental health conditions can be a concern for patients with HS. This study shows that bimekizumab does not make mental health problems worse, which could address these concerns.

Figure 1 Tools used to assess mental health across phase 3 trials

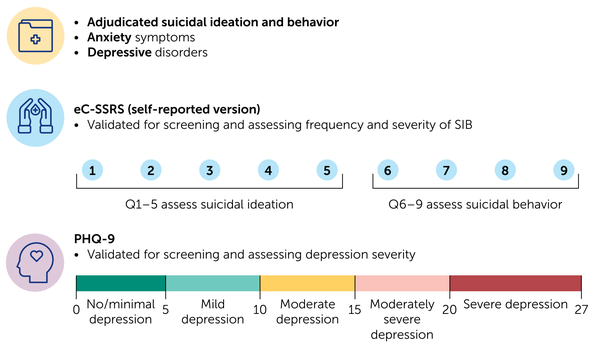
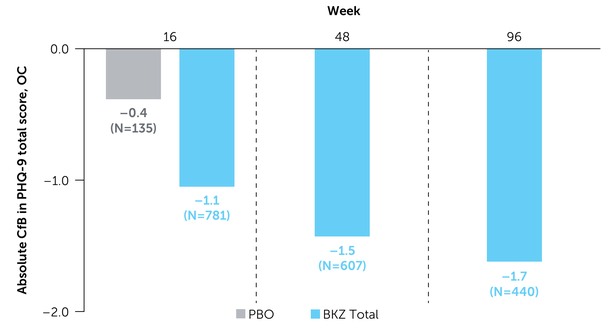


Figure 2 PHQ-9 total score absolute CfB to Week 96



Data are reported for patients with a non-missing assessment at baseline and in the given week, represented by N. Baseline mean is defined as the baseline (pre-dose) results for those subjects who were also assessed at the specified visit.

Table 1 Baseline characteristics

	Placebo N=146	BKZ 320mg Total N=861	≥1 BKZ dose N=995
Age, **years**, mean (SD)	37.3 (12.8)	36.5 (12.1)	36.7 (12.2)
Sex, **female**, n (%)	75 (51.4)	496 (57.6)	564 (56.7)
Racial group, **white**, n (%)	119 (81.5)	684 (79.4)	796 (80.0)
BMI, **kg/m²**, mean (SD)	33.1 (8.3)	33.0 (8.1)	33.0 (8.1)
Anxiety symptoms, n (%)	16 (11.0)	86 (10.0)	100 (10.1)
Depressive disorders, n (%)	23 (15.8)	121 (14.1)	146 (14.7)
Positive eC-SSRS response at screening[a,b], n (%)	18 (12.3)	113 (13.1)	127 (12.8)
PHQ-9 ≥5[c], n (%)	50 (34.2)	224 (26.0)	271 (27.2)
Duration of HS, **years**, mean (SD)	9.8 (9.4)	7.7 (7.4)	8.0 (7.8)
Hurley stage, n (%)			
II	79 (54.1)	481 (55.9)	553 (55.6)
III	67 (45.9)	380 (44.1)	442 (44.4)
DLQI total score, mean (SD)	12.2 (7.1)	11.2 (6.8)	11.2 (6.9)
HiSQOL total score, mean (SD)	26.4 (14.1)	24.9 (13.2)	25.0 (13.3)
Prior biologic use[d], n (%)	29 (19.9)	164 (19.0)	192 (19.3)
Baseline antibiotic use, n (%)	11 (7.5)	73 (8.5)	83 (8.3)

[a] The eC-SSRS questionnaire used at baseline was 'since [screening] visit', therefore eC-SSRS at screening is used to present pre-trial values. **[b]** Patients with positive responses to eC-SSRS Question 1, 2 and/or 3 were not excluded from study participation. **[c]** Patients with PHQ-9 total scores indicating mild to moderate depression at screening were not excluded from study participation. **[d]** Patients received prior biologic therapy for any indication.

Table 2 Overall positive and new-onset positive responses to eC-SSRS, eC-SSRS Q1 and PHQ-9 Q9 at least once during the respective period

	Week 0–16		Week 0–48	Week 0–96
n (%)	PBO N=146	BKZ Total N=861	≥1 BKZ dose N=995	
Positive eC-SSRS response[a]	1 (0.7)	16 (1.9)	22 (2.2)	31 (3.1)
New-onset positive eC-SSRS response[b]	0	8 (0.9)	20 (2.0)	30 (3.0)
New-onset positive eC-SSRS Q1 response[b] "Wish to be dead"	0	7 (0.8)	19 (1.9)	29 (2.9)
New-onset positive PHQ-9 Q9 response[b] "Thoughts that you would be better off dead or of hurting yourself"	2 (1.4)	16 (1.9)	32 (3.2)	48 (4.8)
New-onset positive response to both eC-SSRS Q1 and PHQ-9 Q9[b]	0	4 (0.5)	5 (0.5)	11 (1.1)

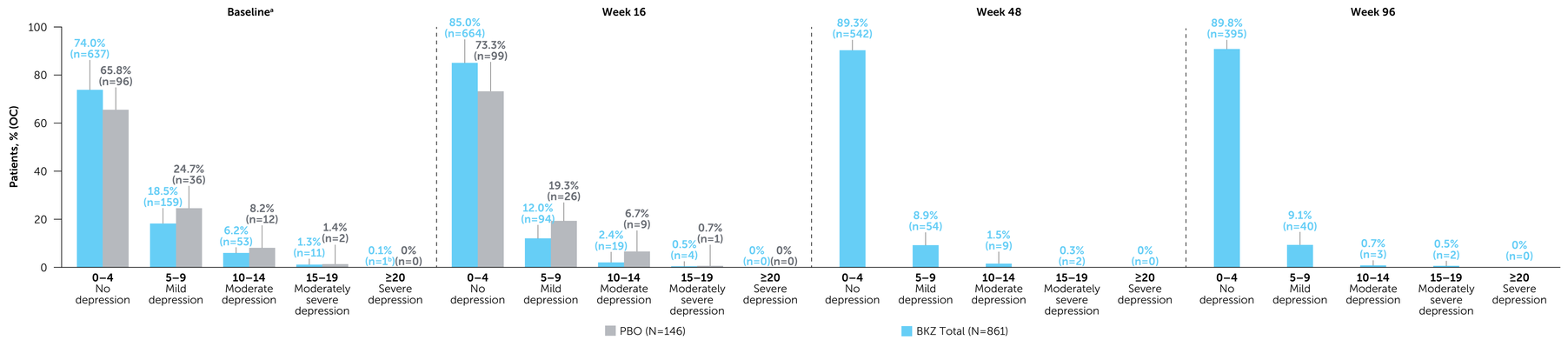
[a] Positive eC-SSRS response defined as positive response to any question (Q1–9), reported at least once during the respective period, assessed at every 2 weeks (Q2W) for Weeks 0–4, Q4W through Week 96, and Q16W thereafter. **[b]** New-onset responses were defined as a positive post-baseline result with no positive results during screening or at baseline.

Table 3 Mental health TEAEs

	Week 0–16		Up to 2 Years
Incidence (95% CI)	PBO 100 PY=0.5 N=146	BKZ Total 100 PY=2.6 N=861	≥1 BKZ dose 100 PY=13.7 N=995
Anxiety symptoms[a]	2.3 (0.1, 12.6)	3.8 (1.8, 7.1)	2.5 (1.7, 3.5)
Depressive disorders[b]	2.2 (0.1, 12.5)	4.2 (2.1, 7.6)	1.6 (1.0, 2.5)
Adjudicated SIB[c]	0	0.8 (0.1, 2.8)	0.8 (0.4, 1.4)

Incidence = incidence of new cases per 100 subject-years at risk. **[a]** Anxiety symptoms included the following preferred terms: anxiety, nervousness, stress and tension. **[b]** All events under the higher-level term 'depressive disorders' were coded as the preferred term 'depression'. **[c]** An independent Neuropsychiatric Adjudication Committee evaluated potential neuropsychiatric events and determined which events met criteria for SIB.

Figure 3 Incidence of PHQ-9 by depression category to Week 96



Incidences are based on observed data, including only participants with non-missing assessments at the respective study visit. When all randomized and treated patients are included in the denominator, 24.7% of patients in the placebo group versus 13.6% of patients in the BKZ Total group reported PHQ-9 total scores of ≥5 at Week 16. Missing data are not presented; participants were considered missing if they did not have an assessment at the applicable study visit (a majority due to study discontinuation). **[a]** PHQ-9 score at screening determined eligibility criteria in study. **[b]** Patient enrolled with a score of 6 at screening, presented a score of 20 at baseline visit and was discontinued from study in line with study protocol.

BKZ: bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **eC-SSRS:** electronic Columbia-Suicide Severity Rating Scale; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HS:** hidradenitis suppurativa; **IL:** interleukin; **OC:** observed case; **PBO:** placebo; **PHQ-9:** Patient Health Questionnaire-9; **PY:** patient years; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SIB:** suicidal ideation and behavior; **TEAE:** treatment-emergent adverse event.

References: [1]Thorlacius L et al. J Invest Dermatol 2018;138:52–57; [2]Wright S et al. J Am Acad Dermatol 2020;83:1360–1366; [3]Kimball AB et al. Lancet 2024;403:2504–19; [4]Adams R et al. Front Immunol 2020;11:1894; [5]BE HEARD EXT (NCT04901195). Available at: www.clinicaltrials.gov/study/NCT04901195 [Accessed August 2025]. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/ analysis/interpretation of data: **CJS**, **BS**, **HL-T**, **VYS**, **GBEJ**, **SY**, **VP**, **JLS**, **DD**, **CC**, **KW**, **ABK**; Drafting of the publication, or revising it critically for important intellectual content: **CJS**, **BS**, **HL-T**, **VYS**, **GBEJ**, **SY**, **VP**, **JLS**, **DD**, **CC**, **KW**, **ABK**; Final approval of the publication: **CJS**, **BS**, **HL-T**, **VYS**, **GBEJ**, **SY**, **VP**, **JLS**, **DD**, **CC**, **KW**, **ABK**. **Author Disclosures: 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. **BS:** Consultant (honorarial for AbbVie, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, PPD CorEvitas, LLC, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Novartis, Oruka, Pfizer, Protagonist, Rapt, Regeneron, Sanofi-Genzyme, Takeda, UCB, and Union Therapeutics; stock options from Connect Biopharma and Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi-Genzyme; Scientific Co-Director (consulting fee) CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; editor-in-chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **HL-T:** Consultant for Novartis and UCB. **VYS:** On the board of directors for the European Hidradenitis Suppurativa Foundation e.V., advisor for the National Eczema Association, shareholder of Learn Health and has served as an advisory board member, investigator, speaker, and/or received research funding from AbbVie, Altus Lab/cQuell, Alumis, Aristea Therapeutics, Boehringer Ingelheim, Burt's Bees, Dermira, Eli Lilly and Company, Galderma, Gerentech, GpSkin, Incyte, Kiniksa, LEO Pharma, Menlo Therapeutics, MYOR, Novartis, Pfizer, Polyfins Technology, Regeneron, Sanofi Genzyme, Skin Actives Scientific, Sun Pharma, Target-PharmaSolutions, and UCB. **GBEJ:** Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen, LEO Pharma, Novartis, and UCB for participation on advisory boards; investigator for AbbVie, CSL, InflaRx, Janssen, LEO Pharma, Novartis, Regeneron, Sanofi, and UCB; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis. **SY:** Consulting for Kaken Pharmaceutical, received travel grants or honoraria from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Maruho, Sanofi, TAIYO Pharma, and UCB; department participated in trials for AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin Corporation, Novartis, Sanofi, and UCB. **VP:** Consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly and Company, Janssen, MedImmune, Novartis, Pfizer, Sun Pharma, UCB, and Valeant. **JLS**, **DD**, **CC**, **KW:** Employees and shareholders of UCB. **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, Proviant, Sanofi, Sonoma Biotherapeutics, Target RWE, UCB, Union Therapeutics and Ventyx; serves on the board of directors of Almirall. **Acknowledgments:** These studies were 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 Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, George Seleiro, PhD, Costello Medical, Cambridge, UK for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.

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