Bimekizumab Efficacy and Safety Over 4 Years in Patients with Moderate to Severe HS: Results from the BE HEARD EXT OLE2 in 4 Countries

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3000969

Objective

To report the long-term efficacy and safety of bimekizumab treatment over 4 years in patients with moderate to severe hidradenitis suppurativa (HS) who completed the phase 3 BE HEARD I&II trials, entered BE HEARD EXT, and were enrolled in the second open-label extension (OLE2) in four countries (OLE2 cohort).

Background

- HS is a chronic, progressive skin disease associated with substantial impairment in health-related quality of life (HRQoL), highlighting the need for effective and safe long-term control with treatment that may prevent disease progression.[1,2]
- Bimekizumab selectively inhibits interleukin (IL)-17F in addition to IL-17A and has demonstrated clinically meaningful improvements and a favorable safety profile in patients with moderate to severe HS over 3 years of treatment.[3–6]
- The BE HEARD OLE2 was conducted to provide continued access to bimekizumab in France, Germany, Japan, and the United States.

Methods

- Data across BE HEARD I&II (NCT04242446, NCT04242498)[4] and BE HEARD EXT (NCT04901195),[5] including the OLE2, were pooled and reported for patients with moderate to severe HS who enrolled in the OLE2 cohort at Year 3 (Week 148) in four countries (**Figure 1**).
- Efficacy outcomes are reported for patients randomized to bimekizumab at baseline in BE HEARD I&II who continued to receive bimekizumab during BE HEARD EXT and entered the OLE2 (efficacy set). The following outcomes are reported over 4 years (196 weeks):
  - ≥50%/≥75%/≥90%/100% HS Clinical Response (HiSCR50/75/90/100) rates;
  - Absolute change from baseline (CfB) in draining tunnel (DT) count;
  - Dermatology Life Quality Index (DLQI) 0/1 response rates.
- Safety data are reported for patients who entered the OLE2 and had ≥1 bimekizumab dose, including patients who were initially randomized to placebo (safety set).
  - Exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY) of the most common treatment-emergent adverse events (TEAEs) and safety topics of interest are reported over 4 years (192 weeks) of bimekizumab treatment;
  - EAIRs were calculated as the number of patients experiencing the event divided by the total PY at risk, providing a measure of event occurrence that accounts for patient-level differences in treatment exposure duration.
- Data are reported as observed case (OC).

Results

- The OLE2 efficacy set included 152 patients who were randomized to bimekizumab at baseline and continued to receive bimekizumab during BE HEARD EXT and the OLE2 to Year 4 (**Figure 1**).
- For the safety analyses, 184 patients received ≥1 bimekizumab dose to Year 4 and were included.
- Baseline demographics and clinical characteristics of patients are presented in **Table 1**.
- Results should be interpreted within the context of this selected population, which comprised OLE2-eligible patients from four countries and may therefore be subject to selection and regional bias.

Efficacy

- At Year 1, HiSCR50/75/90/100 responses were 74.3%/59.2%/40.8%/26.3%; responses were maintained or further improved to 81.9%/72.4%/54.3%/37.8% at Year 4 (**Figure 2**).
- Mean (standard deviation [SD]) DT count decreased from 3.5 (4.3) at baseline to 1.4 (2.5) at Year 1 (mean CfB: −2.1) and further reduced to 0.9 (1.8) at Year 4 (mean CfB: −2.9; **Figure 3**).
- The proportion of patients achieving DLQI 0/1 at Year 1 was 25.3% and numerically increased to 32.6% at Year 4 (**Figure 4**).

Safety

- Over 4 years, the EAIR for any TEAE was 169.9 per 100 PY (**Table 2**).
- No safety signals were observed, and safety data were generally consistent with previous observations in the global population.[4–6]

Conclusions

In patients included in the OLE2 cohort from four countries, efficacy and HRQoL outcome improvements observed with bimekizumab were maintained over 4 years.

Bimekizumab was well tolerated to Year 4 in the OLE2 cohort, with a safety profile consistent with previous analyses and overall study population.[4-6]

Although these results support the sustained long-term benefit of bimekizumab, the analyses are limited to patients who continued into the OLE2 from four countries, which may introduce selection and regional bias.

Plain Language Summary

Why was this study needed?

- Hidradenitis suppurativa (HS) is a long-term skin condition that can cause painful lumps and tunnels under the skin.
- HS can lead to permanent skin damage and scarring, making the condition difficult to manage and live with.

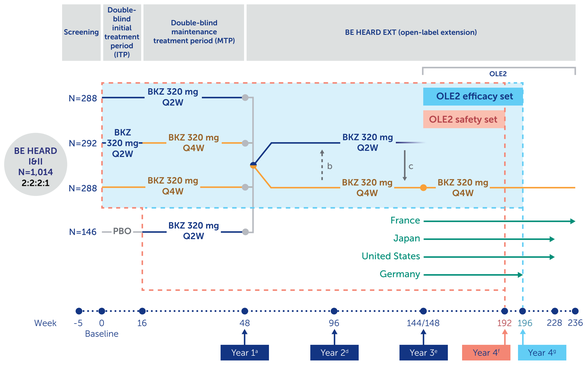
What did this study show?

- Bimekizumab is a medicine used to treat HS. This extended study investigated bimekizumab treatment over 4 years in patients living with HS in France, Germany, Japan, and the United States.
- Patients reported improvements with bimekizumab treatment, including better health-related quality of life and fewer tunnels, which were maintained over 4 years.
- Bimekizumab treatment over 4 years did not raise any new safety concerns.

Why is this important?

- HS causes pain and discomfort that affects patients' everyday lives and overall wellbeing.
- Long-term treatment with bimekizumab reduces these symptoms of HS, helping to improve patients' daily lives.

Figure 1 BE HEARD study design over 4 years



The OLE2 was conducted in France, Germany, Japan, and the United States only. **[a]** Patients who completed Week 48 (Year 1) of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label bimekizumab (BKZ) Q2W or BKZ Q4W based on HiSCR90 responder status (<HiSCR90: BKZ Q2W; ≥HiSCR90: BKZ Q4W) using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** Patients receiving BKZ 320 mg Q4W in BE HEARD EXT who could not sustain an average improvement from baseline in abscess and inflammatory nodule (AN) count of >90% over any 8-week period or achieve >75% improvement from baseline in AN count at any single visit, could have their dose increased to Q2W at investigator discretion; **[c]** Following approval of a protocol amendment in the third year, all BE HEARD EXT patients were to receive BKZ Q4W; **[d]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT); **[e]** Cumulative 3-year data (48 weeks in BE HEARD I&II and 96/100 weeks in BE HEARD EXT for safety/efficacy analyses, respectively); **[f]** Cumulative 4-year data (48 weeks in BE HEARD I&II and 144 weeks in BE HEARD EXT [including 44 weeks in OLE2]) for the safety set; **[g]** Cumulative 4-year data (48 weeks in BE HEARD I&II and 148 weeks in BE HEARD EXT [including 48 weeks in OLE2]) for the efficacy set.

Table 1 Baseline characteristics

	OLE2 efficacy set[a] N=152	OLE2 safety set[b] N=184
Age, **years**, mean (SD)	36.8 (11.4)	36.7 (11.6)
Sex, **female**, n (%)	90 (59.2)	108 (58.7)
Racial group, n (%)		
White	94 (61.8)	116 (63.0)
Black or African American	24 (15.8)	28 (15.2)
Asian	20 (13.2)	24 (13.0)
Other	10 (6.6)	12 (6.5)
Missing	4 (2.6)	4 (2.2)
BMI, **kg/m²**, mean (SD)	34.1 (9.1)	33.8 (9.0)
Country, n (%)		
France	38 (25.0)	42 (22.8)
Germany	20 (13.2)	28 (15.2)
Japan	20 (13.2)	24 (13.0)
United States	74 (48.7)	90 (48.9)
Duration of HS, **years**, mean (SD)	8.7 (7.9)	8.9 (7.9)
Hurley stage,[c] n (%)		
II	82 (53.9)	97 (52.7)
III	70 (46.1)	87 (47.3)
AN count, mean (SD)	18.3 (16.8)	17.3 (15.7)
DT count, mean (SD)	3.5 (4.3)	3.6 (4.3)
DLQI total score, mean (SD)	11.4 (7.3)	11.4 (7.3)
Prior biologic use,[d] n (%)	30 (19.7)	39 (21.2)
Baseline antibiotic use, n (%)	28 (18.4)	32 (17.4)

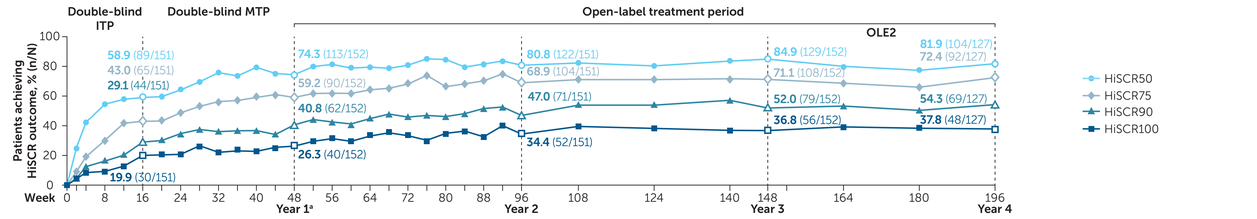
[a] OLE2 efficacy set comprised patients randomized to bimekizumab from baseline in BE HEARD I&II who continued to receive bimekizumab during BE HEARD EXT including OLE2; **[b]** OLE2 safety set comprised patients who received ≥1 bimekizumab dose, including patients who were initially randomized to placebo at baseline; **[c]** Hurley stage for each participant is the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions; **[d]** Patients received prior biologic therapy for any indication.

Table 2 Incidence of TEAEs per 100 PY over 4 years

EAIR per 100 PY (95% CI)	OLE2 safety set N=184; 100 PY=6.62
Any TEAE	169.9 (145.8, 196.8)
Serious TEAEs	4.4 (2.9, 6.4)
Severe TEAEs	3.7 (2.4, 5.6)
TEAEs leading to discontinuation in OLE2[a]	0.6 (0.2, 1.6)
Any TEAE leading to death in OLE2[a]	0
Most common TEAEs[b]	
Hidradenitis	19.9 (16.0, 24.4)
Corona virus infection	13.4 (10.4, 16.9)
Nasopharyngitis	9.8 (7.3, 12.8)
Hypersensitivity reactions[c]	19.9 (16.0, 24.5)
Serious hypersensitivity reactions	0
Serious infections	1.7 (0.9, 3.1)
Fungal infections	17.8 (14.2, 22.1)
Candida infections	7.8 (5.6, 10.4)
Oral candidiasis	5.4 (3.7, 7.6)
Any malignancies	0.2 (0.0, 0.8)
Any hepatic events	3.8 (2.4, 5.7)
Adjudicated definite or probable inflammatory bowel disease	0.3 (0.0, 1.1)
Adjudicated suicidal ideation and behavior events	0

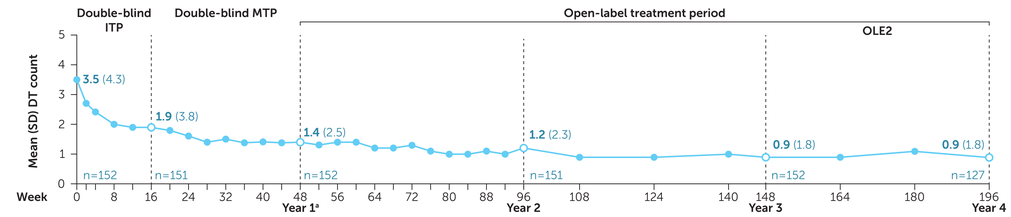
OLE2 safety set comprised patients who received ≥1 bimekizumab dose, including patients who were initially randomized to placebo at baseline. Over 4 years: Weeks 0–192. TEAEs were coded using MedDRA v19.0 and reported using EAIRs per 100 PY. **[a]** Only discontinuations and deaths that occurred due to TEAEs in OLE2 are shown; **[b]** The three TEAEs with the highest incidence over 4 years are presented, per the MedDRA Preferred Terms; **[c]** Hypersensitivity reactions are identified using the Standardised MedDRA Query (SMQ) 'Hypersensitivity' narrow terms.

Figure 2 HiSCR50/75/90/100 over 4 years in the OLE2 cohort



OC, n/N: denominator represents number of patients with a non-missing lesion assessment in the given week, and percentages are calculated accordingly. OLE2 efficacy set comprised patients randomized to bimekizumab from baseline in BE HEARD I&II who continued to receive bimekizumab during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Year 1 to enter the OLE resulted in an increase in n number at Year 1.

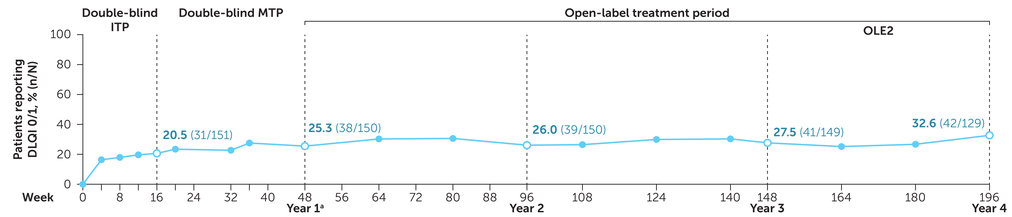
Figure 3 Mean (SD) DT count over 4 years in the OLE2 cohort



	Mean (SD) CfB in DT count
Year 1	−2.1 (3.6); n=152
Year 4	−2.9 (4.0); n=127

OC, n represents the number of patients with a non-missing lesion count assessment in the given week and percentages are calculated accordingly. OLE2 efficacy set comprised patients randomized to bimekizumab from baseline in BE HEARD I&II who continued to receive bimekizumab during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Week 48 to enter the OLE resulted in an increase in n number at Week 48.

Figure 4 DLQI 0/1 response rates over 4 years in the OLE2 cohort



	Mean (SD) DLQI total score
Baseline	11.4 (7.3); n=150
Year 4	4.9 (5.4); n=129

OC, n/N: denominator represents number of patients with a non-missing DLQI assessment in the given week, and percentages are calculated accordingly. DLQI 0/1 response was defined as total score of 0 or 1 (no effect at all of skin disease on patients' life); DLQI score ranges 0–30. OLE2 efficacy set comprised patients randomized to bimekizumab from baseline in BE HEARD I&II who continued to receive bimekizumab during BE HEARD EXT including OLE2. **[a]** The requirement of a visit at Year 1 to enter the OLE resulted in an increase in n number at Year 1.

Abbreviations: AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** Absolute change from baseline; **CI:** confidence interval; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **EAIR:** exposure-adjusted incidence rates; **HiSCR:** Hidradenitis Suppurativa Clinical Response; **HiSCR50/75/90/100:** ≥50%/≥75%/≥90%/100% reduction from baseline in the total AN count with no increase from baseline in abscess or DT count; **HRQoL:** health-related quality of life; **HS:** hidradenitis suppurativa; **IL:** interleukin; **ITP:** initial treatment period; **MedDRA:** Medical Dictionary for Regulatory Activities; **MTP:** maintenance treatment period; **OC:** observed case; **OLE:** open-label extension; **OLE2:** second OLE; **PBO:** placebo; **PY:** patient-years; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **TEAE:** treatment-emergent adverse event.

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Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**; Drafting of the publication, or reviewing it critically for important intellectual content: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**; Final approval of the publication: **FGB**, **CJS**, **AG**, **ZR**, **SSB**, **AP**, **SI**, **JMLP**, **DD**, **CC**, **TV**, **HBN**.

Author Disclosures: FGB: Received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie Inc., AbbVie Deutschland GmbH & Co. KG, Acelyrin, Almirall, Avalo, Beiersdorf, Boehringer Ingelheim Pharma GmbH & Co. KG, Celltrion, Cityrll, Eli Lilly and Company, Incyte Corporation, Inflax, JanssenCilag GmbH, Johnson & Johnson, Merck, Mölnlycke, MoonLake Immunotherapeutics, Navigator Medicines, Novartis Pharma GmbH, Sanofi, Sitala, Takeda, and UCB. **CJS:** Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, Arcutis, AstraZeneca, Incyte, InflaRx, Logical Images, MoonLake Immunotherapeutics, Oruka, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie, Novartis, and UCB. **AG:** Advisor for AbbVie, Almirall, Bluefin Biomedicine, Boehringer Ingelheim, Immunitas Therapeutics, Incyte, Insmed, Navigator Medicines, Novartis, Oruka Therapeutics, Otsuka Pharmaceutical, Pfizer, Provant, Sun Pharma, Takeda, UCB, and Zura Bio and receives honoraria; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB; co-copyright holder of the Hidradenitis suppurativa DrainageE (HIDE®), Hidradenitis Suppurativa Investigator Global Assessment (HS-IGA®), Hidradenitis Suppurativa Quality of Life (HiSGOL®) and the Hidradenitis Suppurativa Progression Outcome (HiSPRO®) instruments. **ZR:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Alumis, Amgen, Apogee, AstraZeneca, Avène, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, CeraVe, Eli Lilly and Company, Incyte, Johnson & Johnson, La Roche-Posay, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; personal fees for attending meetings or for travel from AbbVie, Almirall, Eli Lilly and Company, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. **SSB:** Received honoraria for participation in advisory boards, in clinical trials, and/or as speaker from AbbVie, Biogen, Boehringer Ingelheim, Hexal, MoonLake Immunotherapeutics, Novartis, Sanofi, and UCB. **AP:** Investigator, speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MoonLake Immunotherapeutics, MSD, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, UCB, and Zuellig Pharma. **SI:** Received grants from AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, Kyowa Kirin, LEO Pharma, Pfizer, SatoSeiyaku, Takeda, and UCB; speaker fees from AbbVie, Daiichi Sankyo, Eli Lilly and Company; GSK, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Novartis, Sun Pharma, and UCB. **JMLP, DD, CC, TV:** Employees and shareholders of UCB. **HBN:** Consulting fees from AbbVie, Incyte, Medscape, MoonLake Immunotherapeutics, Novartis, Sonoma Biotherapeutics, and UCB; received grants from Incyte and UCB; holds shares in Radera Inc.; editorial board member for JAMA Dermatology; President of the Hidradenitis Suppurativa Foundation.

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 also thank Susana Lobo Berastegui, MSci, of UCB, for editorial review during poster development and publication coordination. Rachel Grasmeder Allen, PhD, Costello Medical, 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.