Bimekizumab Efficacy by Patient Subgroups in Moderate to Severe Hidradenitis Suppurativa: 3-Year Phase 3 Results from BE HEARD EXT

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Objective

To report bimekizumab (BKZ) efficacy and maintenance of clinical response over 3 years across different subgroups of patients with moderate to severe hidradenitis suppurativa (HS) using phase 3 (BE HEARD I&II) and open label extension (BE HEARD EXT) data.

Synopsis

- HS disease varies between individuals based on patient and disease characteristics, such as sex and disease duration.[1]
- Biological therapies which provide consistent efficacy, regardless of patient characteristics, are needed.
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17A and IL-17F.[2]

Methods

- Data were pooled from the phase 3 BE HEARD I&II trials and their open-label extension, BE HEARD EXT.[3,4]
- Patients completing the 48-week BE HEARD I&II studies could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on HS Clinical Response (HiSCR)-90 response, averaged from Weeks 36, 40, and 44.
- We report the rates of patients achieving HiSCR50/90 for subgroups at Years 1, 2, and 3 (Weeks 48, 96, and 148).
- Data are reported as observed case (OC) for patients randomized to BKZ 320 mg from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ (BKZ Total).

Results

- 657 BE HEARD I&II completers entered BE HEARD EXT; 556 received BKZ from baseline.
- Baseline characteristics and clinical characteristics of patients are reported in the **Table**.
- Most patients across subgroups achieved HiSCR50, with responses maintained through to Year 3 (**Figure 1**).
- Similarly, most patients achieved HiSCR90 at Year 2, with responses maintained through to Year 3, indicating that deeper responses take longer to achieve (**Figure 2**).

Conclusions

Patients treated with bimekizumab demonstrated high clinical response rates across all subgroups at Year 1, with responses maintained through to Year 3.

These results emphasize the long-term benefit of bimekizumab as an effective treatment option for patients with hidradenitis suppurativa, regardless of patient demographics and disease characteristics.

Summary

Bimekizumab-treated patients achieved **high clinical response rates across** the following **subgroups** at **Year 1**, with **responses maintained** through to **Year 3**.

Age:[a]
<median, 35 years
≥median, 35 years

Sex:
Male
Female

Weight:
≤100 kg
>100 kg

BMI:
<30 kg/m^2,
30–35 kg/m^2,
≥35 kg/m^2

Duration of HS:[a]
<median, 5.02 years
≥median, 5.02 years

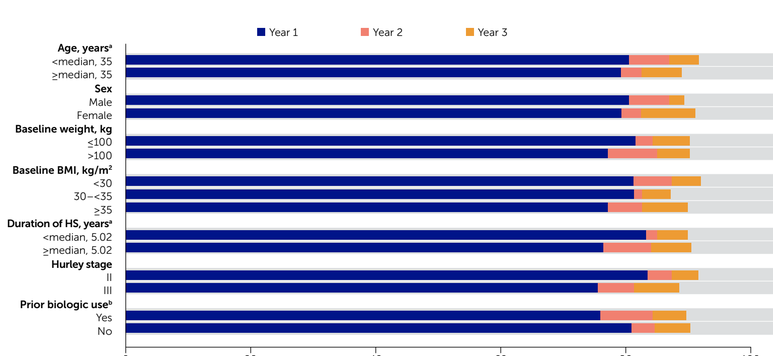
Hurley stage:
II
III

Prior biologic use:[b]
Yes
No

At Year 3 in all presented subgroups, **HiSCR50 achievement** was **≥87.2%**, while **HiSCR90 achievement** was **≥59.3%**.

[a] Median years calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication.

Figure 1 HiSCR50 achievement across patient subgroups to Year 3



	Year 1 (N=556)		Year 2 (N=447)		Year 3 (N=367)	
	HiSCR50, %	n/N	HiSCR50, %	n/N	HiSCR50, %	n/N
Age, years[a]						
<median, 35	80.5	215/267	86.9	185/213	91.7	155/169
≥median, 35	79.2	229/289	82.5	193/234	88.9	176/198
Sex						
Male	80.5	207/257	86.9	186/214	89.3	158/177
Female	79.3	237/299	82.4	192/233	91.1	173/190
Baseline weight, kg						
≤100	81.5	282/346	84.3	236/280	90.2	211/234
>100	77.1	162/210	85.0	142/167	90.2	120/133
Baseline BMI, kg/m^2						
<30	81.2	190/234	87.3	165/189	92.0	149/162
30–<35	81.3	109/134	82.6	90/109	87.2	75/86
≥35	77.1	145/188	82.6	123/149	89.9	107/119
Duration of HS, years[a]						
<median, 5.02	83.2	237/285	85.0	199/234	89.9	179/199
≥median, 5.02	76.4	207/271	84.0	179/213	90.5	152/168
Hurley stage						
II	83.5	253/303	87.3	214/244	91.6	185/202
III	75.5	191/253	81.3	165/203	88.5	146/165
Prior biologic use[b]						
Yes	75.9	85/112	84.3	75/89	89.7	70/78
No	80.9	359/444	84.6	303/358	90.3	261/289
				Overall HiSCR50		
	79.9% (444/556)		84.6% (378/447)		90.2% (331/367)	

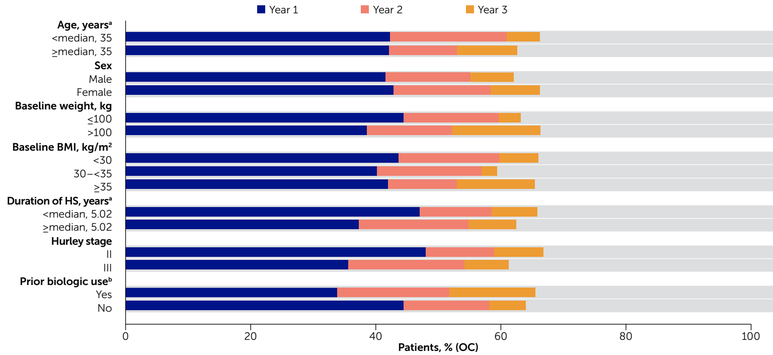
OLE set: N=657; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. **[a]** Median value calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication.

Table Baseline demographics

	BKZ Total[a] N=556
Age, years, mean (SD)	36.3 (12.2)
Sex, female, n (%)	299 (53.8)
Racial group, White, n (%)	448 (80.6)
Weight, kg, mean (SD)	96.2 (23.5)
BMI, kg/m^2, mean (SD)	32.5 (7.8)
Duration of HS, years, mean (SD)	7.4 (7.1)
Hurley stage, n (%)	
II	303 (54.5)
III	253 (45.5)
Prior biologic use[b], n (%)	112 (20.1)
IHS4 severity, n (%)	
Mild: ≤3	0
Moderate: 4–10	70 (12.6)
Severe: ≥11	486 (87.4)

OLE set: N=657; included only patients who entered BE HEARD EXT at Week 48. **[a]** BKZ Total comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ; **[b]** Patients received prior biologic therapy for any indication.

Figure 2 HiSCR90 achievement across patient subgroups to Year 3



	Year 1 (N=556)		Year 2 (N=447)		Year 3 (N=367)	
	HiSCR50, %	n/N	HiSCR50, %	n/N	HiSCR50, %	n/N
Age, years[a]						
<median, 35	42.3	113/267	61.0	130/213	66.3	112/169
≥median, 35	42.2	122/289	53.0	124/234	62.6	124/198
Sex						
Male	41.6	107/257	55.1	118/214	62.1	110/177
Female	42.8	128/299	58.4	136/233	66.3	126/190
Baseline weight, kg						
≤100	44.5	154/346	59.6	167/280	63.2	148/234
>100	38.6	81/210	52.1	87/167	66.2	88/133
Baseline BMI, kg/m^2						
<30	43.6	102/234	59.8	113/189	66.0	107/162
30–<35	40.3	54/134	56.9	62/109	59.3	51/86
≥35	42.0	79/188	53.0	79/149	65.5	78/119
Duration of HS, years[a]						
<median, 5.02	47.0	134/285	58.5	137/234	65.8	131/199
≥median, 5.02	37.3	101/271	54.9	117/213	62.5	105/168
Hurley stage						
II	47.9	145/303	59.0	144/244	66.8	135/202
III	35.6	90/253	54.2	110/203	61.2	101/165
Prior biologic use[b]						
Yes	33.9	38/112	51.7	46/89	65.4	51/78
No	44.4	197/444	58.1	208/358	64.0	185/289
				Overall HiSCR90		
	42.3% (235/556)		56.8% (254/447)		64.3% (236/367)	

OLE set: N=657; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. **[a]** Median value calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication.

BKZ: bimekizumab; **BMI:** body mass index; **HiSCR50/90:** ≥50/90% reduction from baseline in the total abscess and inflammatory nodule (AN) count, with no increase from baseline in abscess or draining tunnel (DT) count; **HS:** hidradenitis suppurativa; **IHS4:** International Hidradenitis Suppurativa Severity Score System; **IL:** Interleukin; **OC:** observed case; **OLE:** open-label extension; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

References: [1]Schrader AMR. et al. J Am Acad Dermatol 2014;71:460–7; [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 (NCT04901195): www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **CJS**, **MLP**, **AM-L**, **JCS**, **YI**, **EvR**, **CC**, **TV**, **GK**; Drafting of the publication, or reviewing it critically for important intellectual content: **CJS**, **MLP**, **AM-L**, **JCS**, **YI**, **EvR**, **CC**, **TV**, **GK**; Final approval of the publication: **CJS**, **MLP**, **AM-L**, **JCS**, **YI**, **EvR**, **CC**, **TV**, **GK**. **Author Disclosures: CJS:** Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, Arcutis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Oruka, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie, Novartis, and UCB. **MLP:** Consultant and investigator for AbbVie, Arcutis, Aristea Therapeutics, Avalo Therapeutics, Eli Lilly and Company, Incyte, Janssen, Merck, MoonLake Immunotherapeutics, Navigator Biosciences, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, UCB, Ventyx, and Zura Bio; consultant for Almirall, FIDE, Insmed, Oruka, Otsuka, Propeller Biosciences, Spyre, and Trifecta Clinical/WCG; investigator for AnaptysBio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals, and Regeneron; received royalties from Beth Israel Deaconess Medical Center; received fellowship funding to institution from AbbVie. **AM-L:** Received support for attending meetings, served as an advisory board member, and participated in clinical trials from AbbVie, Almirall, Incyte, MoonLake Immunotherapeutics, MSD, Novartis, Sanofi, and UCB. **JCS:** Consultant and advisory board member of AbbVie, Almirall, Boehringer Ingelheim, Galderma, LEO Pharma, Novartis, Pierre Fabre, Sandoz, Sanofi-Genzyme, and UCB; speaker for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi Genzyme, and UCB; investigator for AbbVie, Acelyrin, Almirall Hermal, Amgen, AnaptysBio, Argenx, Aslan, Boehringer Ingelheim, Biocom, Bio Thera, Bristol Myers Squibb, Celltrion, CuraTeQ Biologics, DICE Therapeutics, Eli Lilly and Company, Galapagos, Galderma, Helm AG, Incyte, InflaRx, Janssen, Kiniksa, Kymab Limited, LEO Pharma, MedImmune, Menlo Therapeutics, Merck, MoonLake Immunotherapeutics, Novartis, Pierre Fabre, Pfizer, Regeneron Pharmaceuticals, Takeda, Teva, Trevi Therapeutics, UCB, Uni Therapeutics, and Ventyx Bioscience. **YI:** Nothing to disclose. **EvR**, **CC**, **TV:** Employees and shareholders of UCB. **GK:** Received travel grants or honoraria, has been a consultant member of advisory boards and speaker bureaus, or has served as an investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Hexal-Sandoz, Janssen, LEO Pharma, L'Oréal, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB. **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. The authors acknowledge Susanne Wiegratz, UCB, Monheim am Rhein, Germany for publication coordination, Ujjawal Kumar MA MB BChir, Costello Medical, Cambridge, UK for medical writing support, Isabel Merrien, PgDip, for editorial assistance, and the Costello Medical Creative team for design support. This study was funded by UCB. All costs associated with development of this poster were funded by UCB.

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