Bimekizumab Lesion Resolution Over 3 Years in HS: Results from BE HEARD I&II and BE HEARD EXT

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Objective

Here, we report lesion resolution with bimekizumab (BKZ) over 3 years from the BE HEARD I&II and BE HEARD EXT trials, in patients with moderate to severe hidradenitis suppurativa (HS).

Background

- HS is a chronic, inflammatory skin disease characterized by lesions that can progress if untreated, causing irreversible damage and sequelae.[1]
- Bimekizumab (BKZ), a humanized IgG1 monoclonal antibody, selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Methods

- Data were pooled from the phase 3 BE HEARD I&II trials (NCT04242446/NCT04242498) and the open-label extension, BE HEARD EXT (NCT04901195), for patients with moderate to severe HS.[3,4]
- Data are reported for patients who were randomized to BKZ 320 mg at baseline in BE HEARD I&II and entered BE HEARD EXT (BKZ Total).
- Proportions of patients with ≥1 lesions of the specified type at baseline who achieved complete lesion resolution (lesion-type100) are reported to Week 148 (Year 3). This includes: draining tunnels (DT100), total tunnels (TT100), abscesses (A100), abscesses and inflammatory nodules (AN100), inflammatory nodules (IN100), and abscesses and DTs (A+DT100).
- Achievement of 100% reduction from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4-100) is reported to Year 3 (all patients in BE HEARD I&II had abscess and inflammatory nodule counts ≥1 at baseline).
- Patients discontinuing treatment due to lack of efficacy/treatment-related adverse events were considered non-responders (modified non-responder imputation; mNRI); multiple imputation was used for other missing data.
- Data are reported as observed case (OC) and mNRI (reported in figure footnotes).

Results

- Of the 1,014 patients in BE HEARD I&II, 556 randomized to BKZ at baseline completed Week 48 (Year 1) and entered BE HEARD EXT (BKZ Total).
- Baseline demographics and clinical characteristics of patients are presented in **Table 1**.
- Among patients randomized to BKZ, 425 had ≥1 DT, 492 had ≥1 TT, 381 had ≥1 abscesses, 556 had ≥1 AN, 550 had ≥1 IN, and 502 had ≥1 A+DT at baseline.
- The proportions of patients achieving complete DT (48.2%) and TT (24.6%) resolution at Year 1 further increased by Year 3 (62.9% and 31.5%, respectively; **Figure 1**).
- At Year 1, 75.3% of patients achieved A100, and 31.7% achieved AN100. By Year 3, these proportions increased to 83.5% and 51.5%, respectively (**Figure 2** and **Figure 3**).
- At Year 1/Year 3, 35.1% (193/550) and 54.8% (199/363) of patients achieved IN100.
  - For mNRI, 35.1% and 46.3% of patients achieved IN100 at Year 1 and Year 3, respectively.
- Similarly, at Year 1, 48.2% of patients achieved A+DT100 and 25.2% achieved IHS4-100, with improvements to 60.8% and 40.1% at Year 3, respectively (**Figure 4** and **Figure 5**).
- Generally, similar trends were observed across both OC and mNRI data (**Figure 1–5**).

Conclusions

Bimekizumab demonstrated clinically meaningful resolution across HS lesions at Year 1, with numerical increases to Year 3. Further analyses of total tunnel resolution would be valuable to better understand the clinical implications of these data.

Notable proportions of patients with moderate to severe HS achieved total inflammatory lesion resolution, as measured by IHS4-100.

Plain Language Summary

Why was this study needed?

Hidradenitis suppurativa (HS) is a long-term skin condition that causes painful sores and abscesses, as well as lumps ('nodules') and connecting channels under the skin ('tunnels'). These lesions can ooze or drain pus.

HS lesions can cause lasting damage to the skin, if left untreated.

What did this study show?

Bimekizumab is a drug used to treat patients with HS.

Over 3 years, treatment with bimekizumab led to more patients experiencing complete disappearance of various types of skin lesions.

Why is this important?

Bimekizumab reduces lesions and may help ease symptoms.

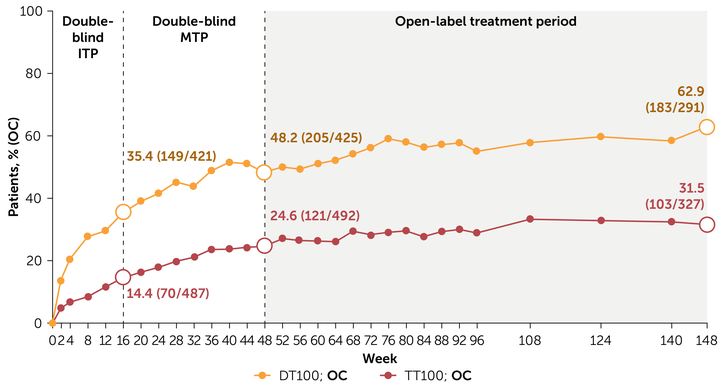
The symptoms caused by HS lesions can greatly impact the lives of patients with HS. Therefore, treatments that can help patients to achieve lesion clearance are needed.

Table 1 Baseline characteristics

	Week 148 responders (BKZ Total)						
	DT100 N=183	TT100 N=103	A100 N=203	AN100 N=189	IN100 N=199	A+DT100 N=202	IHS4-100 N=147
Age, years, mean (SD)	36.9 (12.8)	37.6 (14.0)	37.0 (12.8)	37.5 (13.1)	37.2 (13.0)	36.7 (12.7)	37.1 (13.3)
Sex, female, n (%)	96 (52.5)	63 (61.2)	107 (52.7)	96 (50.8)	98 (49.2)	111 (55.0)	81 (55.1)
Racial group, white, n (%)	151 (82.5)	82 (79.6)	175 (86.2)	158 (83.6)	166 (83.4)	168 (83.2)	120 (81.6)
BMI, kg/m², mean (SD)	31.5 (7.4)	31.5 (8.0)	32.2 (7.6)	31.4 (7.9)	31.3 (8.0)	32.2 (7.9)	32.0 (8.3)
Duration of HS, years, mean (SD)	6.9 (7.1)	7.1 (8.3)	6.9 (7.2)	6.5 (7.0)	6.6 (6.9)	7.0 (7.5)	6.5 (7.2)
AN count, mean (SD)	14.9 (12.6)	17.3 (15.9)	17.2 (12.3)	14.6 (11.6)	14.8 (11.7)	15.4 (13.2)	14.1 (11.0)
DT count, mean (SD)	3.9 (3.4)	2.9 (2.9)	4.4 (4.6)	3.8 (4.1)	3.8 (4.0)	3.3 (3.5)	3.0 (3.1)
Abscess count, mean (SD)	2.8 (3.2)	3.2 (3.8)	4.5 (4.3)	3.0 (4.2)	3.1 (4.3)	3.0 (4.1)	2.9 (4.2)
IN count, mean (SD)	12.1 (11.9)	14.1 (16.0)	12.7 (10.9)	11.6 (10.8)	11.7 (10.8)	12.5 (11.9)	11.2 (9.8)
Total tunnel count, mean (SD)	7.0 (7.1)	5.4 (5.9)	7.9 (8.0)	6.8 (7.2)	6.8 (7.3)	6.2 (7.0)	5.4 (5.7)

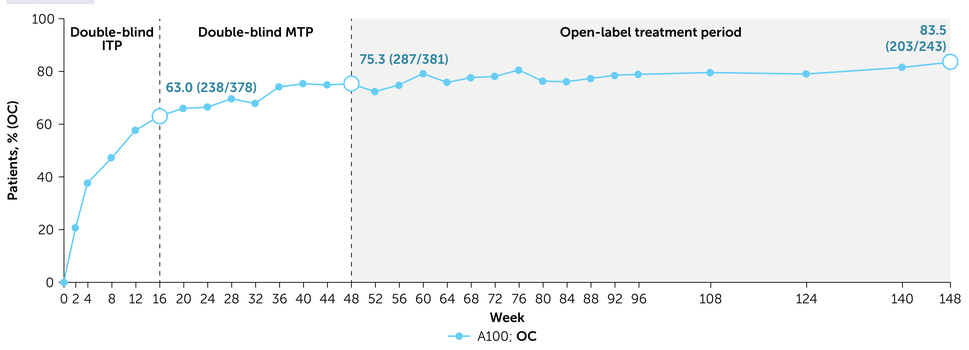
Baseline characteristics are stratified by achievement of lesion resolution at Week 148.

Figure 1 Proportions of patients achieving DT100 and TT100 over 3 years



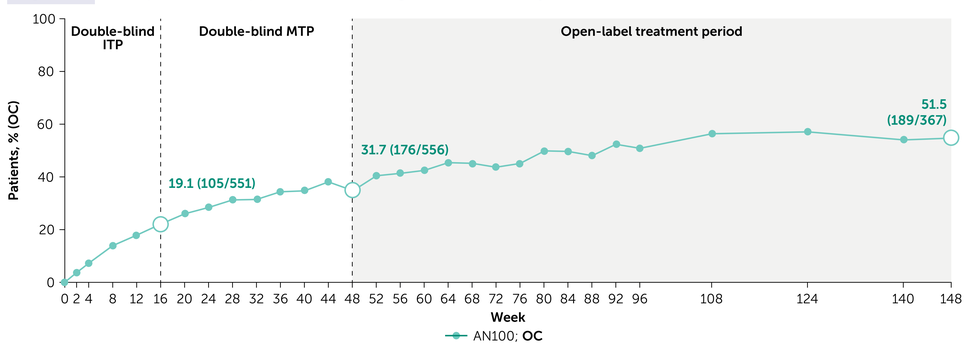
OC; n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Data reported for patients with ≥1 DT (DT100 data) and ≥1 TT (TT100 data) at baseline. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. DT100 mNRI at Week 16/48/148: 35.4%/48.2%/52.8%. TT100 mNRI at Week 16/48/148: 14.5%/24.6%/26.0%.

Figure 2 Proportions of patients achieving A100 over 3 years



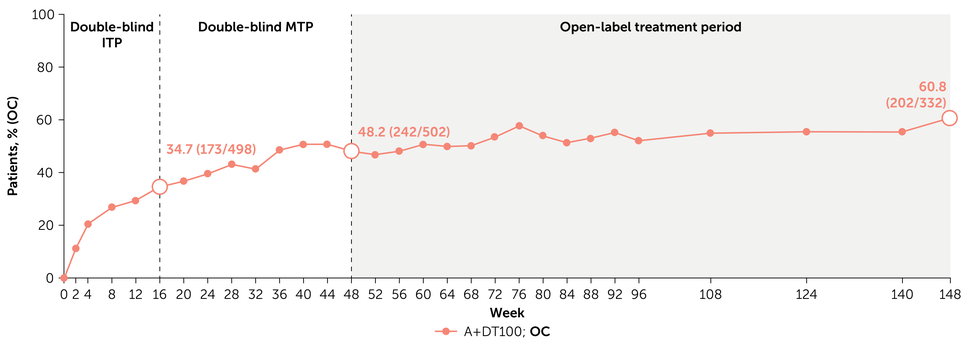
OC; n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Data reported for patients with ≥1 abscess at baseline. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. A100 mNRI at Week 16/48/148: 62.8%/75.3%/68.1%.

Figure 3 Proportions of patients achieving AN100 over 3 years



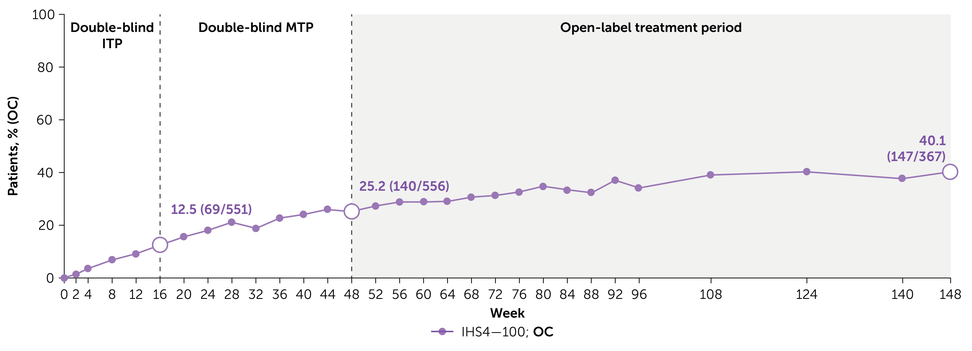
OC; n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Data reported for patients with ≥1 abscess and inflammatory nodule at baseline. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. AN100 mNRI at Week 16/48/148: 19.0%/31.7%/43.6%.

Figure 4 Proportions of patients achieving A+DT100 over 3 years



OC; n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Data reported for patients with ≥1 abscess and draining tunnel at baseline. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. A+DT100 mNRI at Week 16/48/148: 34.8%/48.2%/49.8%.

Figure 5 Proportions of patients achieving IHS4-100 over 3 years



OC; n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. The requirement of a visit at Week 48 to enter the OLE resulted in an increase in N number at Week 48. IHS4-100 mNRI at Week 16/48/148: 12.5%/25.2%/33.2%.

A+DT100: total resolution of abscesses and draining tunnels; **A100:** total resolution of abscesses; **AN:** abscesses and inflammatory nodules; **AN100:** total resolution of abscesses and inflammatory nodules; **BKZ:** bimekizumab; **BMI:** body mass index; **DT:** draining tunnels; **DT100:** total resolution of draining tunnels; **IHS4-100:** 100% reduction from baseline in the International Hidradenitis Suppurativa Severity Score System; **IL:** interleukin; **IN:** inflammatory nodules; **IN100:** total resolution of inflammatory nodules; **ITP:** initial treatment phase; **mNRI:** modified non-responder imputation; **MTP:** maintenance treatment phase; **OC:** observed case; **SD:** standard deviation; **TT100:** total resolution of total tunnels.

References: [1]Van Straalen KR et al. J Allergy Clin Immunol. 2022;149:1150–61; [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. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AG**, **MLP**, **SD**, **TT**, **WG**, **KH**, **BL**, **CC**, **NT**, **GK**; Drafting of the publication, or reviewing it critically for important intellectual content: **AG**, **MLP**, **SD**, **TT**, **WG**, **KH**, **BL**, **CC**, **NT**, **GK**; Final approval of the publication: **AG**, **MLP**, **SD**, **TT**, **WG**, **KH**, **BL**, **CC**, **NT**, **GK**. **Author Disclosures: AG:** Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Englitix, 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. **MLP:** Consultant and investigator for AbbVie, Aristea Therapeutics, Avalo Therapeutics, Eli Lilly and Company, Incyte, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG, and ZuraBio; 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. **SD:** Speaker for AbbVie, Novartis, and UCB; consultant for AbbVie, Novartis, and UCB; research grants from AbbVie, Incyte, Insmed, MoonLake Immunotherapeutics, Pfizer, Regeneron, Sanofi, and UCB. **TT:** Consultancy/advisory boards/speaker fees from AbbVie, Boehringer Ingelheim, Novartis, and UCB; treasurer of the European Hidradenitis Suppurativa Foundation e.V. **WG:** Grants and research support from AbbVie, Amgen, Eli Lilly and Company, Novartis and Pfizer. Honoraria for advisory boards/invited talks/consultation from AbbVie, Actelion, Amgen, Arylide, 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; received study fees for clinical trials from 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. **KH:** Principal investigator for and member of consultancy/advisory boards for AbbVie, Boehringer Ingelheim, Novartis, Sanofi, and UCB; recipient of speaker fees and/or research grants from AbbVie, Boehringer Ingelheim, Eisai, Maruho, Novartis, and UCB. **BL**, **CC**, **NT:** 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, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB. **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, Kate Metcalfe, BSc (Hons), Costello Medical, London, United Kingdom 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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