Bimekizumab effect on the need for concomitant rescue interventions by HiSCR level in patients with moderate to severe hidradenitis suppurativa from BE HEARD I&II

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Synopsis

- Hidradenitis supurativa (HS) is a chronic, inflammatory skin disease characterized by painful lesions that negatively impact patients' quality of life.[1]
  - These lesions are difficult to treat and require a multifaceted treatment approach, including the need for rescue interventions alongside conventional therapy.[1]
- Bimekizumab (BKZ) is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Objective

To investigate the association between achievement of higher HS clinical response (HiSCR) levels with BKZ treatment and the need for concomitant rescue interventions in patients with moderate to severe HS.

Methods

- Data were pooled from the BE HEARD I&II phase 3 clinical trials.[3] Data are reported over the maintenance treatment period (Weeks 16–48). Here, patients randomized to receive BKZ from baseline are presented, with data also pooled across these treatment arms (BKZ Total) (**Figure 1**).
- Patients randomized to BKZ were grouped by achievement of mutually exclusive HiSCR bands at Week 16: <50% improvement from baseline (<HiSCR50); 50–<75% improvement (HiSCR50–<75); 75–100% improvement (HiSCR75–100).
- The incidence of patients not requiring **any concomitant rescue interventions** for HS during the maintenance treatment period are reported. Any concomitant rescue interventions are **further split into medical** (antibiotics, analgesics) and **procedural** (incision/drainage, intralesional triamcinolone injection) interventions.
- Data are reported as observed case (OC).

Results

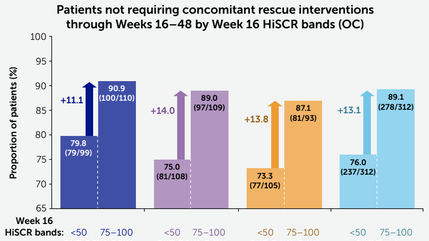
- Across the BE HEARD I&II clinical trials, patients were randomized to receive BKZ at baseline across 3 treatment arms (**Figure 1**).
- Baseline demographics across patients who did and did not receive concomitant rescue interventions and across treatment arms were mostly comparable, although some differences were observed, including the proportions of Hurley stage II and III at baseline (**Table 1**).
- Across BKZ-randomized treatment arms, a numerical increase in patients not receiving a rescue intervention in the maintenance treatment period was observed with increasing HiSCR band (**Figure 2**).
- The proportion of patients not requiring rescue interventions increased with higher HiSCR band over the same period in the BKZ Total group (**Figure 2**).
- Similar trends were also observed moving from the lowest to highest HiSCR bands when separating into any medical or procedural interventions (**Table 2**).

Conclusions

Overall, the majority of patients randomized to bimekizumab did not require any concomitant rescue medical or procedural interventions during the maintenance treatment period (Weeks 16–48). The proportion of patients not requiring concomitant rescue interventions increased as higher HiSCR bands were achieved.

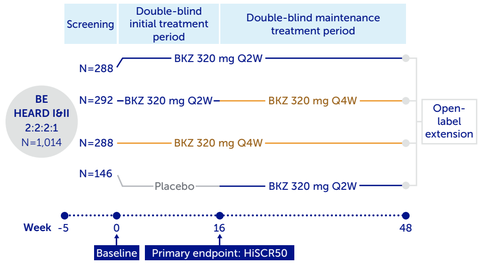
These data highlight the additional value to patients of a decreased need for concomitant rescue interventions when achieving higher levels of clinical response with bimekizumab treatment.

Summary



Reaching **higher HiSCR bands** with BKZ translated into a **reduced number of concomitant interventions**.

Figure 1 Study design



At baseline, 1,014 patients with moderate to severe HS were randomized 2:2:2:1 to BKZ 320 mg Q2W to Week 48, BKZ 320 mg Q4W to Week 48, BKZ 320 mg Q2W to Week 16 then BKZ 320 mg Q4W to Week 48, or PBO to Week 16 then BKZ 320 mg Q2W to Week 48.

Table 1 Baseline characteristics

Concomitant rescue intervention,[a] (Y/N):	BKZ 320 mg Q2W/Q2W N	BKZ 320 mg Q2W/Q2W Y	BKZ 320 mg Q2W/Q4W N	BKZ 320 mg Q2W/Q4W Y	BKZ 320 mg Q4W/Q4W N	BKZ 320 mg Q4W/Q4W Y	BKZ Total N	BKZ Total Y
	n=264	n=24	n=266	n=26	n=257	n=31	n=787	n=81
Age (years), mean ± SD	37.2 ± 12.3	32.7 ± 12.6	37.3 ± 12.3	33.8 ± 13.1	36.0 ± 11.7	33.7 ± 10.5	36.8 ± 12.1	33.4 ± 11.8
Sex, female, n (%)	140 (53.0)	12 (50.0)	159 (59.8)	15 (57.7)	157 (61.1)	18 (58.1)	456 (57.9)	45 (55.6)
Racial group, white, n (%)	217 (82.2)	15 (62.5)	211 (79.3)	22 (84.6)	208 (80.9)	16 (51.6)	636 (80.8)	53 (65.4)
BMI, kg/m², mean ± SD	32.7 ± 8.5	32.9 ± 9.6	32.7 ± 7.9	32.8 ± 7.3	33.6 ± 8.0	35.1 ± 7.3	33.0 ± 8.1	33.7 ± 8.0
Duration of HS (years), mean ± SD	7.7 ± 7.6	6.2 ± 4.3	8.3 ± 7.5	8.5 ± 9.2	7.1 ± 7.3	8.3 ± 7.0	7.7 ± 7.5	7.8 ± 7.2
AN count, mean ± SD	14.9 ± 11.7	12.4 ± 10.2	17.0 ± 16.6	19.5 ± 18.6	18.1 ± 21.9	14.6 ± 9.6	16.7 ± 17.2	15.5 ± 13.5
DT count, mean ± SD	3.9 ± 4.5	2.8 ± 3.3	3.7 ± 4.5	4.3 ± 3.9	3.3 ± 4.2	3.3 ± 3.8	3.7 ± 4.4	3.5 ± 3.7
Hurley Stage, n (%)								
II	151 (57.2)	15 (62.5)	151 (56.8)	9 (34.6)	145 (56.4)	15 (48.4)	447 (56.8)	39 (48.1)
III	113 (42.8)	9 (37.5)	115 (43.2)	17 (65.4)	112 (43.6)	16 (51.6)	340 (43.2)	42 (51.9)
DLQI Total score, mean ± SD	11.2 ± 6.3	12.0 ± 7.8	10.8 ± 6.7	11.2 ± 6.7	11.5 ± 7.2	13.5 ± 9.2	11.1 ± 6.7	12.3 ± 8.0
Prior biologic use,[b] n (%)	51 (19.3)	8 (33.3)	48 (18.0)	8 (30.8)	42 (16.3)	5 (16.1)	141 (17.9)	21 (25.9)
Baseline antibiotic use, n (%)	27 (10.2)	2 (8.3)	26 (9.8)	2 (7.7)	18 (7.0)	0 (0)	71 (9.0)	4 (4.9)

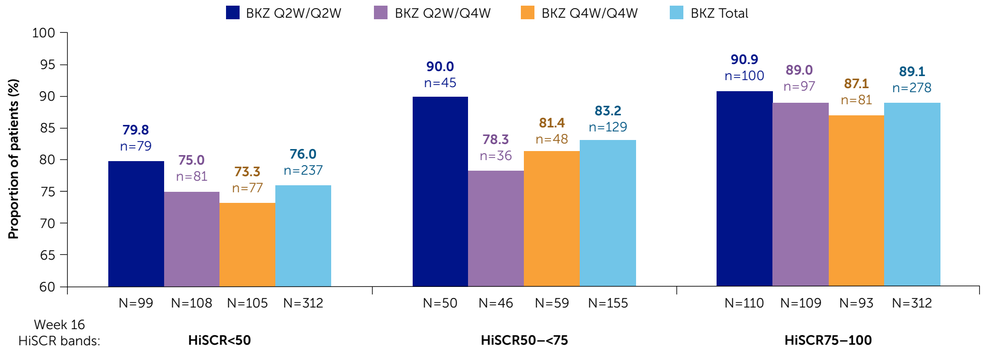
Patients randomized to BKZ (BKZ Total, N=868); baseline characteristics evaluated at Week 0. All patients randomized to receive BKZ at baseline (Week 0) are pooled in the BKZ Total group. **[a]** Patients receiving ≥1 concomitant rescue intervention during maintenance treatment period (Y/N: Yes/No); **[b]** Patients received prior biologic therapy for any indication.

Table 2 Patients not requiring any medical or procedural concomitant rescue interventions through Weeks 16–48 by achievement of different Week 16 HiSCR bands (OC)[a]

n/N (%)	BKZ 320 mg Q2W/Q2W N=288	BKZ 320 mg Q2W/Q4W N=292	BKZ 320 mg Q4W/Q4W N=288	BKZ Total N=868
No medical intervention				
HiSCR<50	83/99 (83.8)	86/108 (79.6)	81/105 (77.1)	250/312 (80.1)
HiSCR50–<75	47/50 (94.0)	39/46 (84.8)	50/59 (84.7)	136/155 (87.7)
HiSCR75–100	103/110 (93.6)	101/109 (92.7)	86/93 (92.5)	290/312 (92.9)
No procedural intervention				
HiSCR<50	88/99 (88.9)	95/108 (88.0)	93/105 (88.6)	276/312 (88.5)
HiSCR50–<75	47/50 (94.0)	40/46 (87.0)	54/59 (91.5)	141/155 (91.0)
HiSCR75–100	107/110 (97.3)	103/109 (94.5)	86/93 (92.5)	296/312 (94.9)

Patients randomized to BKZ (BKZ Total, N=868); all patients randomized to receive BKZ at baseline (Week 0) are pooled in the BKZ Total group. N represents the total number of patients achieving each HiSCR band and n represents the number of patients not requiring a concomitant rescue intervention within each HiSCR band. **[a]** Any concomitant rescue interventions are further split into medical and procedural interventions. Medical interventions include rescue systemic antiobiotics or rescue analgesics as determined by the principal investigator. Procedural interventions include incision/drainage and intralesional triamcinolone injection.

Figure 2 Patients not requiring any concomitant rescue interventions through Weeks 16–48 by achievement of different Week 16 HiSCR bands (OC)



Patients randomized to BKZ (BKZ Total, N=868); all patients randomized to receive BKZ at baseline (Week 0) are pooled in the BKZ Total group. N represents the total number of patients achieving each HiSCR band and n represents the number of patients not requiring a concomitant rescue intervention within each HiSCR band. Any intervention includes all patients who had ≥1 rescue intervention (both medical and procedural interventions) during the maintenance treatment period (Weeks 16–48).

AN: abscess and inflammatory nodule; **BMI:** body mass index; **BKZ:** bimekizumab; **DLQI**: Dermatology Life Quality Index; **DT:** draining tunnel; **HiSCR:** hidradenitis suppurativa clinical response; **HiSCR<50/50–<75/75–100:** <50/50–<75/75–100% reduction in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IL:** interleukin; **N:** no; **OC:** observed case; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation; **Y:** yes.

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References: [1]Zouboulis CC et al. J Eur Acad Dermatol Venereol 2015;29:619–44; [2]Adams R et al. Front Immunol 2020;11:1894; [3]Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498). **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **FGB**, **SF**, **AG**, **PG**, **HHZ**, **EJGB**, **AM**, **BL**, **RR**, **PD**, **NT**, **IH**; Drafting of the publication, or reviewing it critically for important intellectual content: **FGB**, **SF**, **AG**, **PG**, **HHZ**, **EJGB**, **AM**, **BL**, **RR**, **PD**, **NT**, **IH**; Final approval of the publication: **FGB**, **SF**, **AG**, **PG**, **HHZ**, **EJGB**, **AM**, **BL**, **RR**, **PD**, **NT**, **IH**. **Author Disclosures: FGB:** Received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie, Acelyrin, Boehringer Ingelheim, Celltrion, Dr. Wolff, Incyte Corporation, Janssen Cilag, Merck, Molnlycke, MoonLake Immunotherapeutics, Novartis, Sanofi Sitala, and UCB. **SF:** Investigator/consultant and/or advisor to AbbVie, Aclaris, Almirall, Arcutis, Aslan, BioHaven, Boehringer Ingelheim, Bristol Myers Squibb, Cali, Concert, Eli Lilly and Company, Evelo, Horizon Therapeutics, Incyte, Janssen, Merck, Pfizer, UCB, and Vertex. **AG:** Receives honoraria as an advisor for AbbVie, Boehringer Ingelheim, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, and Union Therapeutics; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB. **PG:** Received honoraria for consulting from AbbVie, Novartis, and UCB. **HHZ:** Consultant for AbbVie, Incyte, InflaRX, Insmed, Novartis, and UCB. **EJGB:** Received honoraria from Abbott Products Operations, bioMérieux, Brahms GmbH, GSK, InflaRx, Sobi, and XBiotech; independent educational grants from Abbott Products Operations, bioMérieux, InflaRx, Johnson & Johnson, MSD, Novartis, and Sobi; funding from the Horizon2020 Marie Skłodowska-Curie International Training Network "the European Sepsis Academy" (granted to the National and Kapodistrian University of Athens), the Horizon 2020 European Grants ImmunoSep and RISCinCOVID (granted to the Hellenic Institute for the Study of Sepsis) and the Horizon Health grant EPIC-CROWN-2, POIN and Homi-Lung (granted to the Hellenic Institute for the Study of Sepsis). **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. **BL**, **RR**, **PD**, **NT:** Employees and shareholders of UCB. **IH:** Consultant for AbbVie, Avita, Boehringer Ingelheim, Galderma, Incyte, Janssen, Novartis, Pfizer, Sonoma, UCB, and Union Therapeutics; investigator for Avita, Incyte, Lenicura, L'Oreal/La Roche-Posay, and Pfizer; board member and past-president of the HS Foundation and Global Vitiligo Foundation. **Acknowledgements:** These studies were funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, May-Li MacKinnon, PhD, Costello Medical, Manchester, United Kingdom for medical writing and editorial assistance and the Costello Medical Creative team for graphic design assistance. All costs associated with development of this poster were funded by UCB.

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