Bimekizumab response maintenance to 48 weeks in patients with moderate to severe hidradenitis suppurativa: Pooled responder analysis from the phase 3, double-blind, placebo-controlled, randomized clinical trials BE HEARD I & II

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Objective

To report maintenance of response over 48 weeks in patients with moderate to severe hidradenitis suppurativa (HS) who achieved clinical responses after 16 weeks of bimekizumab (BKZ) treatment from the phase 3 BE HEARD I & II studies.

Introduction

- HS is a chronic, relapsing, and painful inflammatory skin disease associated with significant comorbidities and poor quality of life.[1]
- However, treatment options are limited.[2]
- BKZ, a monoclonal immunoglobulin G1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated efficacy in patients with moderate to severe HS.[2]
- Here, we report maintenance of response through Week 48 from BE HEARD I & II.[3,4]

Methods

- Data were pooled from BE HEARD I & II.[3,4] These randomized, double-blinded, placebo (PBO)-controlled phase 3 studies were comprised of an initial (Weeks 0–16) and a maintenance (Weeks 16–48) treatment period (**Figure 1**).
- Maintenance of response is reported respectively as a) the percentage of BKZ-treated patients who achieved 50/75/90% HS Clinical Response (HiSCR50/75/90) or b) an abscess and inflammatory nodule (AN) count of 0, 1, or 2 at both Week 16 and Week 48.
- Data are reported as observed cases (OC) throughout; last observation carried forward (LOCF) data are provided in **Table 2**.

Results

Baseline characteristics

- Baseline demographics were comparable across treatment arms (**Table 1**).

Week 48 responders

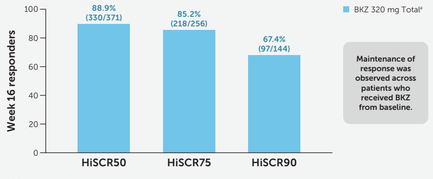
- Among Week 16 HiSCR50 responders, 88.5–89.6% of patients maintained this response through Week 48, across treatment regimens (**Table 2**; **Figure 2**).
- Among Week 16 HiSCR75 responders, 80.9–88.3% of patients maintained this response through Week 48, across treatment regimens (**Table 2**; **Figure 3**).
- Among Week 16 HiSCR90 responders, 65.2–69.2% of patients maintained this response through Week 48, across treatment regimens (**Table 2**; **Figure 4**).
- Among patients with an AN count of 0, 1, or 2 at Week 16, 82.1%–88.0% of patients maintained this response through Week 48, across treatment regimens (**Table 2**; **Figure 5**).

Conclusions

Maintenance of response among Week 16 responders was high across the primary endpoint (HiSCR50) and more stringent clinical outcome measures for bimekizumab-randomized patients.

Summary

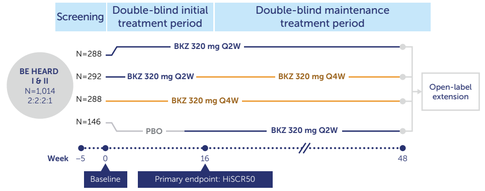
Maintenance of response through Week 48 in Week 16 responders (OC)



Maintenance of response was observed across patients who received BKZ from baseline.

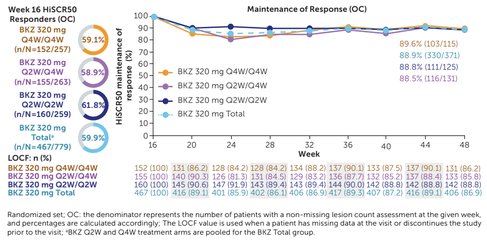
OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

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.

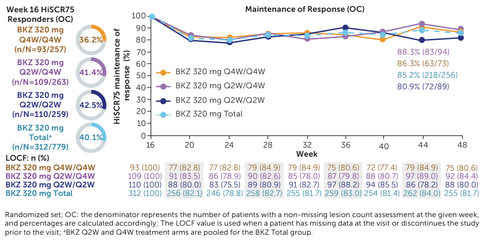
Figure 2 HiSCR50 maintenance of response (OC, LOCF)



LOCF: n (%)	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48
BKZ 320 mg Q4W/Q4W	152 (100)	131 (86.2)	128 (84.2)	128 (84.2)	134 (88.2)	137 (90.1)	133 (87.5)	137 (90.1)	131 (86.2)
BKZ 320 mg Q2W/Q4W	155 (100)	140 (90.3)	126 (81.3)	131 (84.5)	129 (83.2)	136 (87.7)	132 (85.2)	137 (88.4)	133 (85.8)
BKZ 320 mg Q2W/Q2W	160 (100)	145 (90.6)	147 (91.9)	143 (89.4)	143 (89.4)	144 (90.0)	142 (88.8)	142 (88.8)	142 (88.8)
BKZ 320 mg Total	467 (100)	416 (89.1)	401 (85.9)	402 (86.1)	406 (86.9)	417 (89.3)	407 (87.2)	416 (89.1)	406 (86.9)

Randomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

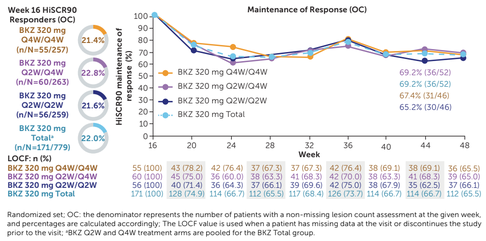
Figure 3 HiSCR75 maintenance of response (OC, LOCF)



LOCF: n (%)	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48
BKZ 320 mg Q4W/Q4W	93 (100)	77 (82.8)	77 (82.8)	79 (84.9)	79 (84.9)	75 (80.6)	72 (77.4)	79 (84.9)	75 (80.6)
BKZ 320 mg Q2W/Q4W	109 (100)	91 (83.5)	86 (78.9)	90 (82.6)	85 (78.0)	87 (79.8)	88 (80.7)	97 (89.0)	92 (84.4)
BKZ 320 mg Q2W/Q2W	110 (100)	88 (80.0)	83 (75.5)	89 (80.9)	91 (82.7)	97 (88.2)	94 (85.5)	86 (78.2)	88 (80.0)
BKZ 320 mg Total	312 (100)	256 (82.1)	246 (78.8)	258 (82.7)	255 (81.7)	259 (83.0)	254 (81.4)	262 (84.0)	255 (81.7)

Randomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

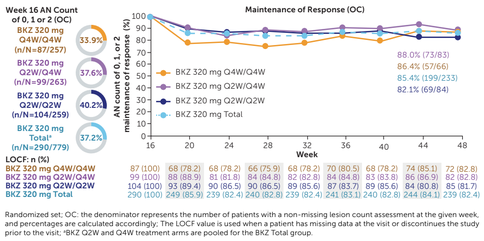
Figure 4 HiSCR90 maintenance of response (OC, LOCF)



LOCF: n (%)	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48
BKZ 320 mg Q4W/Q4W	55 (100)	43 (78.2)	42 (76.4)	37 (67.3)	37 (67.3)	42 (76.4)	38 (69.1)	38 (69.1)	36 (65.5)
BKZ 320 mg Q2W/Q4W	60 (100)	45 (75.0)	36 (60.0)	38 (63.3)	41 (68.3)	42 (70.0)	38 (63.3)	41 (68.3)	39 (65.0)
BKZ 320 mg Q2W/Q2W	56 (100)	40 (71.4)	36 (64.3)	37 (66.1)	39 (69.6)	42 (75.0)	38 (67.9)	35 (62.5)	37 (66.1)
BKZ 320 mg Total	171 (100)	128 (74.9)	114 (66.7)	112 (65.5)	117 (68.4)	126 (73.7)	114 (66.7)	114 (66.7)	112 (65.5)

Randomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

Figure 5 AN count of 0, 1, or 2 maintenance of response (OC, LOCF)



LOCF: n (%)	Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48
BKZ 320 mg Q4W/Q4W	87 (100)	68 (78.2)	68 (78.2)	68 (78.2)	66 (75.9)	68 (78.2)	70 (80.5)	68 (78.2)	74 (85.1)	72 (82.8)
BKZ 320 mg Q2W/Q4W	99 (100)	88 (88.9)	81 (81.8)	84 (84.8)	82 (82.8)	84 (84.8)	83 (83.8)	86 (86.9)	82 (82.8)
BKZ 320 mg Q2W/Q2W	104 (100)	93 (89.4)	90 (86.5)	90 (86.5)	89 (85.6)	87 (83.7)	89 (85.6)	84 (80.8)	85 (81.7)
BKZ 320 mg Total	290 (100)	249 (85.9)	239 (82.4)	240 (82.8)	239 (82.4)	241 (83.1)	240 (82.8)	244 (84.1)	239 (82.4)

Randomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

Table 1 Baseline characteristics

	PBO/BKZ 320 mg Q2W (N=146)	BKZ 320 mg Q4W/Q4W (N=288)	BKZ 320 mg Q2W/Q4W (N=292)	BKZ 320 mg Q2W/Q2W (N=288)	BKZ 320 mg Total[a] (N=868)
			Overall		
Age, years, mean (SD)	37.3 (12.8)	35.8 (11.6)	37.0 (12.4)	36.8 (12.4)	36.5 (12.1)
Sex, female, n (%)	75 (51.4)	175 (60.8)	174 (59.6)	152 (52.8)	501 (57.7)
BMI, kg/m², mean (SD)	33.1 (8.3)	33.8 (7.9)	32.7 (7.9)	32.7 (8.6)	33.1 (8.1)
Duration of HS, years, mean (SD)	9.8 (9.4)	7.3 (7.3)	8.3 (7.7)	7.6 (7.4)	7.7 (7.4)
Baseline AN count, mean (SD)	14.4 (10.0)	17.7 (20.9)	17.2 (16.8)	14.7 (11.6)	16.6 (16.9)
Hurley stage, n (%)					
II	79 (54.1)	160 (55.6)	160 (54.8)	166 (57.6)	486 (56.0)
III	67 (45.9)	128 (44.4)	132 (45.2)	122 (42.4)	382 (44.0)
DLQI total score, mean (SD)	12.2 (7.1)	11.7 (7.4)	10.8 (6.7)	11.2 (6.5)	11.2 (6.9)
Prior biologic use, n (%)	29 (19.9)	47 (16.3)	57 (19.5)	60 (20.8)	164 (18.9)
Baseline antibiotic use, n (%)	11 (7.5)	18 (6.3)	28 (9.6)	29 (10.1)	75 (8.6)
			Week 16 HiSCR50 Responders		
	PBO/BKZ 320 mg Q2W (n=48)	BKZ 320 mg Q4W/Q4W (n=152)	BKZ 320 mg Q2W/Q4W (n=155)	BKZ 320 mg Q2W/Q2W (n=160)	BKZ 320 mg Total[a] (n=467)
Age, years, mean (SD)	36.4 (11.9)	34.8 (11.8)	36.7 (12.2)	36.2 (12.8)	35.9 (12.3)
Sex, female, n (%)	27 (56.3)	93 (61.2)	91 (58.7)	89 (55.6)	273 (58.5)
BMI, kg/m², mean (SD)	32.7 (9.0)	34.2 (8.4)	31.9 (7.0)	31.9 (8.3)	32.7 (8.0)
Duration of HS, years, mean (SD)	8.8 (9.3)	6.4 (6.3)	7.8 (6.8)	6.9 (7.1)	7.0 (6.7)
Baseline AN count, mean (SD)	13.1 (8.0)	18.6 (24.9)	15.5 (13.3)	14.5 (10.5)	16.2 (17.3)
Hurley stage, n (%)					
II	25 (52.1)	86 (56.6)	95 (61.3)	99 (61.9)	280 (60.0)
III	23 (47.9)	66 (43.4)	60 (38.7)	61 (38.1)	187 (40.0)
DLQI total score, mean (SD)	10.7 (6.6)	10.4 (6.6)	10.6 (6.6)	10.9 (6.2)	10.6 (6.5)
Prior biologic use, n (%)	8 (16.7)	23 (15.1)	28 (18.1)	35 (21.9)	86 (18.4)
Baseline antibiotic use, n (%)	1 (2.1)	7 (4.6)	10 (6.5)	18 (11.3)	35 (7.5)
			Week 16 AN Count of 0, 1, or 2		
	PBO/BKZ 320 mg Q2W (n=30)	BKZ 320 mg Q4W/Q4W (n=87)	BKZ 320 mg Q2W/Q4W (n=99)	BKZ 320 mg Q2W/Q2W (n=104)	BKZ 320 mg Total[a] (n=290)
Age, years, mean (SD)	34.1 (10.2)	34.6 (11.8)	38.1 (12.4)	36.5 (12.9)	36.5 (12.5)
Sex, female, n (%)	16 (53.3)	56 (64.4)	55 (55.6)	52 (50.0)	163 (56.2)
BMI, kg/m², mean (SD)	31.8 (9.3)	33.8 (8.6)	32.2 (6.9)	31.6 (8.1)	32.4 (7.9)
Duration of HS, years, mean (SD)	9.0 (8.6)	6.4 (6.7)	7.7 (6.9)	6.4 (7.0)	6.8 (6.9)
Baseline AN count, mean (SD)	9.2 (4.6)	11.1 (10.0)	9.8 (6.4)	9.7 (5.5)	10.2 (7.4)
Hurley stage, n (%)					
II	17 (56.7)	55 (63.2)	72 (72.7)	72 (69.2)	199 (68.6)
III	13 (43.3)	32 (36.8)	27 (27.3)	32 (30.8)	91 (31.4)
DLQI total score, mean (SD)	9.1 (5.5)	9.5 (6.6)	9.5 (6.4)	10.4 (6.2)	9.8 (6.4)
Prior biologic use, n (%)	3 (10.0)	13 (14.9)	15 (15.2)	20 (19.2)	48 (16.6)
Baseline antibiotic use, n (%)	0	4 (4.6)	8 (8.1)	13 (12.5)	25 (8.6)

Pooled set; baseline characteristics evaluated at Week 0; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

Table 2 Maintenance of response through Week 48 (OC, LOCF)

		BKZ 320 mg Q4W/Q4W		BKZ 320 mg Q2W/Q4W		BKZ 320 mg Q2W/Q2W		BKZ 320 mg Total[a]	
		OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)
Week 16 HiSCR50 responders	Week 32	116/131 (88.5)	134 (88.2)	120/141 (85.1)	129 (83.2)	121/135 (89.6)	143 (89.4)	357/407 (87.7)	406 (86.9)
	Week 48	103/115 (89.6)	131 (86.2)	116/131 (88.5)	133 (85.8)	111/125 (88.8)	142 (88.8)	330/371 (88.9)	406 (86.9)
Week 16 HiSCR75 responders	Week 32	70/82 (85.4)	79 (84.9)	79/99 (79.8)	85 (78.0)	77/92 (83.7)	91 (82.7)	226/273 (82.8)	255 (81.7)
	Week 48	63/73 (86.3)	75 (80.6)	83/94 (88.3)	92 (84.4)	72/89 (80.9)	88 (80.0)	218/256 (85.2)	255 (81.7)
Week 16 HiSCR90 responders	Week 32	32/49 (65.3)	37 (67.3)	39/55 (70.9)	41 (68.3)	32/45 (71.1)	39 (69.6)	103/149 (69.1)	117 (68.4)
	Week 48	31/46 (67.4)	36 (65.5)	36/52 (69.2)	39 (65.0)	30/46 (65.2)	37 (66.1)	97/144 (67.4)	112 (65.5)
		BKZ 320 mg Q4W/Q4W		BKZ 320 mg Q2W/Q4W		BKZ 320 mg Q2W/Q2W		BKZ 320 mg Total[a]	
		OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)	OC n/N (%)	LOCF n (%)
Week 16 AN count of 0, 1, or 2	Week 32	58/75 (77.3)	68 (78.2)	75/87 (86.2)	82 (82.8)	75/88 (85.2)	89 (85.6)	208/250 (83.2)	239 (82.4)
	Week 48	57/66 (86.4)	72 (82.8)	73/83 (88.0)	82 (82.8)	69/84 (82.1)	85 (81.7)	199/233 (85.4)	239 (82.4)

Randomized set; OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly; The LOCF value is used when a patient has missing data at the visit or discontinues the study prior to the visit; [a]BKZ Q2W and Q4W treatment arms are pooled for the BKZ Total group.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **HiSCR:** HS clinical response; **HiSCR50/75/90:** ≥50/75/90% 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; **LOCF:** last observation carried forward; **OC:** observed case; **PBO:** placebo; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **SD:** standard deviation.

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References: [1]Dufour DN, et al. Postgrad Med J 2014;90:216–21; [2]Glatt S, et al. JAMA Dermatol 2021;157:1279–88; [3]BE HEARD I: https://clinicaltrials.gov/ct2/show/NCT04242446; [4]BE HEARD II: https://clinicaltrials.gov/ct2/show/NCT04242498. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JRI**, **MP**, **RC**, **EJBG**, **FGB**, **HF**, **WG**, **EM**, **MB**, **RR**, **RB**, **JSK**; Drafting of the publication, or reviewing it critically for important intellectual content: **JRI**, **MP**, **RC**, **EJBG**, **FGB**, **HF**, **WG**, **EM**, **MB**, **RR**, **RB**, **JSK**; Final approval of the publication: **JRI**; **MP**, **RC**, **EJBG**, **FGB**, **HF**, **WG**, **EM**, **MB**, **RR**, **RB**, **JSK**. **Author Disclosures: JRI:** Receives a stipend as Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Boehringer Ingelheim, ChemoCentryx, Citryll, MoonLake Immunotherapeutics, Novartis, UCB Pharma, and Union Therapeutics and has served on advisory boards for Insmed, Kymera Therapeutics, and Viela Bio; co-copyright holder of HiSQOL® and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments. **MP:** Consultant and investigator for AbbVie, Anaptys Bio, Aristea, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonomabio, and UCB Pharma; consultant for Alumis, FIDE, and Trifecta Clinical; investigator for Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals; received royalties from Beth Israel Deaconess Medical Center. **RC:** Served as an advisory board member, consultant, and/or investigator for AbbVie, Apogee, Arcutis, Argenx, Aslan, Beiersdorf, Bristol Myers Squibb, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Galderma, Genentech, Incyte, L'Oréal, LEO Pharma, Novan, Pfizer, Regeneron, Sanofi, and UCB Pharma; speaker for AbbVie, Arcutis, Beiersdorf, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Incyte, LEO Pharma, Novan, Pfizer, Regeneron, Sanofi, and UCB Pharma. **EJGB:** Received honoraria from Abbott CH, bioMérieux, Brahms GmbH, GSK, InflaRx GmbH, Sobi, and XBiotech; independent educational grants from Abbott CH, AxisShield, bioMérieux, InflaRx GmbH, Johnson & Johnson, MSD, Novartis, Sobi, and XBiotech; funding from the Horizon2020 Marie Sktodowska-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 (granted to the Hellenic Institute for the Study of Sepsis). **FGB:** Received honoraria for consulting and/or presentations and/or sponsoring for scientific projects and/or clinical studies from AbbVie, AbbVie Deutschland, Acelyrin, Beiersdorf, Boehringer Ingelheim, Celltrion, Dr. Wolff, Incyte, Janssen-Cilag, Merck, Mölnlycke, MoonLake Immunotherapeutics, Novartis, and UCB Pharma. **HF:** Received honoraria or fees for serving on advisory boards, as a speaker and as a consultant, as well as grants as an investigator from AbbVie; Amgen; Boehringer Ingelheim, Bristol Myers Squibb, Daichi Sankyo, Eisai, Eli Lilly and Company, Janssen, Japan Blood Products Organization, JMEC, Kaken Pharmaceutical, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe, Nihon Pharmaceutical, Novartis, Otsuka Pharmaceutical, Sanofi, Sato Pharmaceutical, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB Pharma, and Ushio. **WG:** Received grants/research support from AbbVie, Amgen, Eli Lilly and Company, Novartis, and Pfizer; received honoraria for advisory boards/invited talks/consultation from AbbVie; Actelion, Amgen, Arylide, Bausch Health, Boehringer, Celgene, Cipher, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, PeerVoice, Pfizer, Sanofi-Genzyme, Sun Pharma, Tribute, UCB Pharma, and Valeant; received clinical trial study fees from AbbVie; Asana Biosciences, Astellas, Boehringer-Ingleheim, Celgene, Corrona/National Psoriasis Foundation, Devonian, Eli Lilly and Company, Galapagos, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sun Pharma, and UCB Pharma. **EM, RR, RB:** Employee and shareholder of UCB Pharma. **MB:** Employee of UCB Pharma. **JSK:** Reports personal fees from AbbVie, ChemoCentryx, CSL Behring, DermTech, Incyte, Insmed, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB Pharma; personal fees and grants from Incyte; co-copyright holder of HiSQOL®; consultant for and received honoraria from AbbVie, Alumis, DermTech, Incyte, Insmed, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB Pharma; and has been a speaker for AbbVie, Janssen, Novartis, and UCB Pharma. **Acknowledgments:** This study was funded by UCB Pharma. 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 Pharma, Monheim, Germany for publication coordination, Isabel Katz, BA, Costello Medical, London, UK for medical writing and editorial assistance, and the Creative team at Costello Medical for graphic design assistance. All costs associated with development of this poster were funded by UCB Pharma.

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