Bimekizumab efficacy by patient subgroups in moderate to severe hidradenitis suppurativa: 2-year phase 3 results from BE HEARD EXT

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Presentation Number: 63285

OBJECTIVE

- To report bimekizumab (BKZ) efficacy outcomes across different subgroups of patients with moderate to severe hidradenitis suppurativa (HS) over 2 years.

Background

- **BKZ** is a humanized monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[1]
- HS **disease characteristics vary** between individuals based on age, disease duration, Hurley Stage, and sex.[2]
- Biological therapies which provide **consistent efficacy**, regardless of patient characteristics, are needed.

Methods

- Data were pooled from **phase 3 BE HEARD I&II** and their open-label extension, BE HEARD EXT.[3,4]
- We report the proportions of patients achieving **≥50%/75% HS Clinical Response** (HiSCR50/75) for patient subgroups at Week 48 and Week 96.
- Data are reported 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**).
- Data are reported as observed case (OC).

Patient subgroups

- **Age**:[a] </≥ median
- **Sex**: Male or Female
- **Weight**:[b] ≤/>100 kg
- **BMI**:[b] <30/30–<35/≥35 kg/m^2
- **Duration of HS**:[a] </≥ median
- **Hurley Stage**: II or III
- **Prior biologic use**: Yes or No
- **IHS4**: Moderate or Severe

[a] Median years calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Baseline value for BKZ Total. **1.** Adams R. et al. Front Immunol 2020;11:1894; **2.** Schrader AMR. et al. J Am Acad Dermatol 2014;71:460–7; **3.** Kimball AB. et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **4.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; BMI: body mass index; HS: hidradenitis suppurativa; IHS4: International Hidradenitis Suppurativa Severity Score System; IL: interleukin; OC: observed case.

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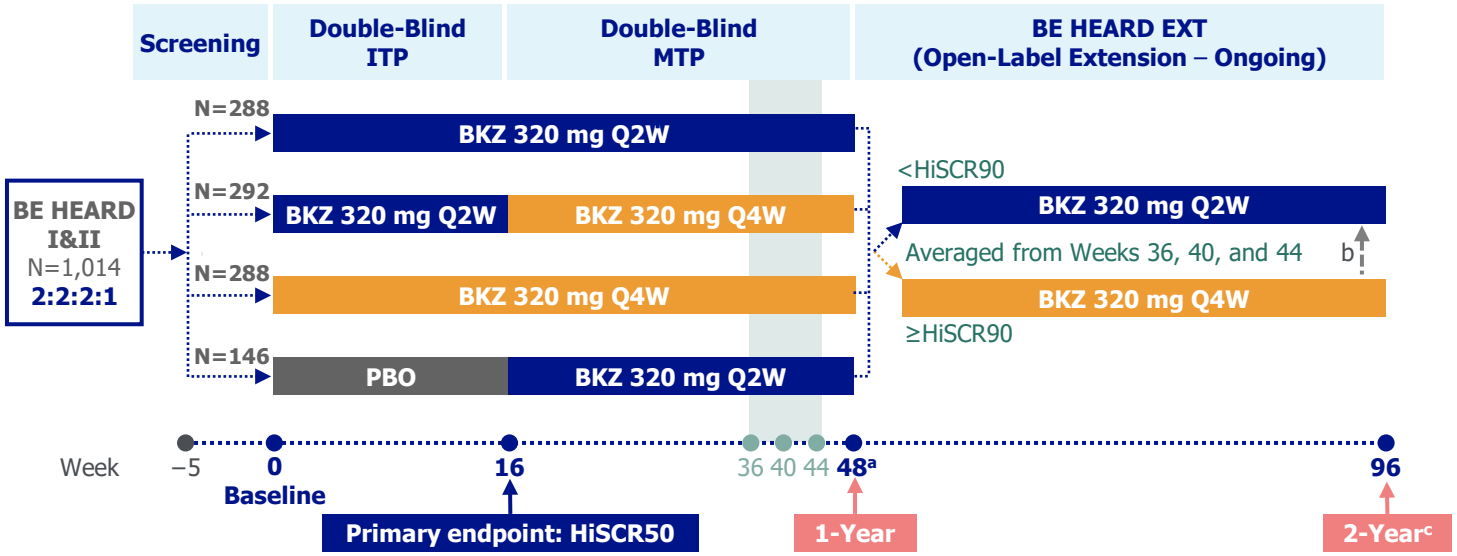
Study Design



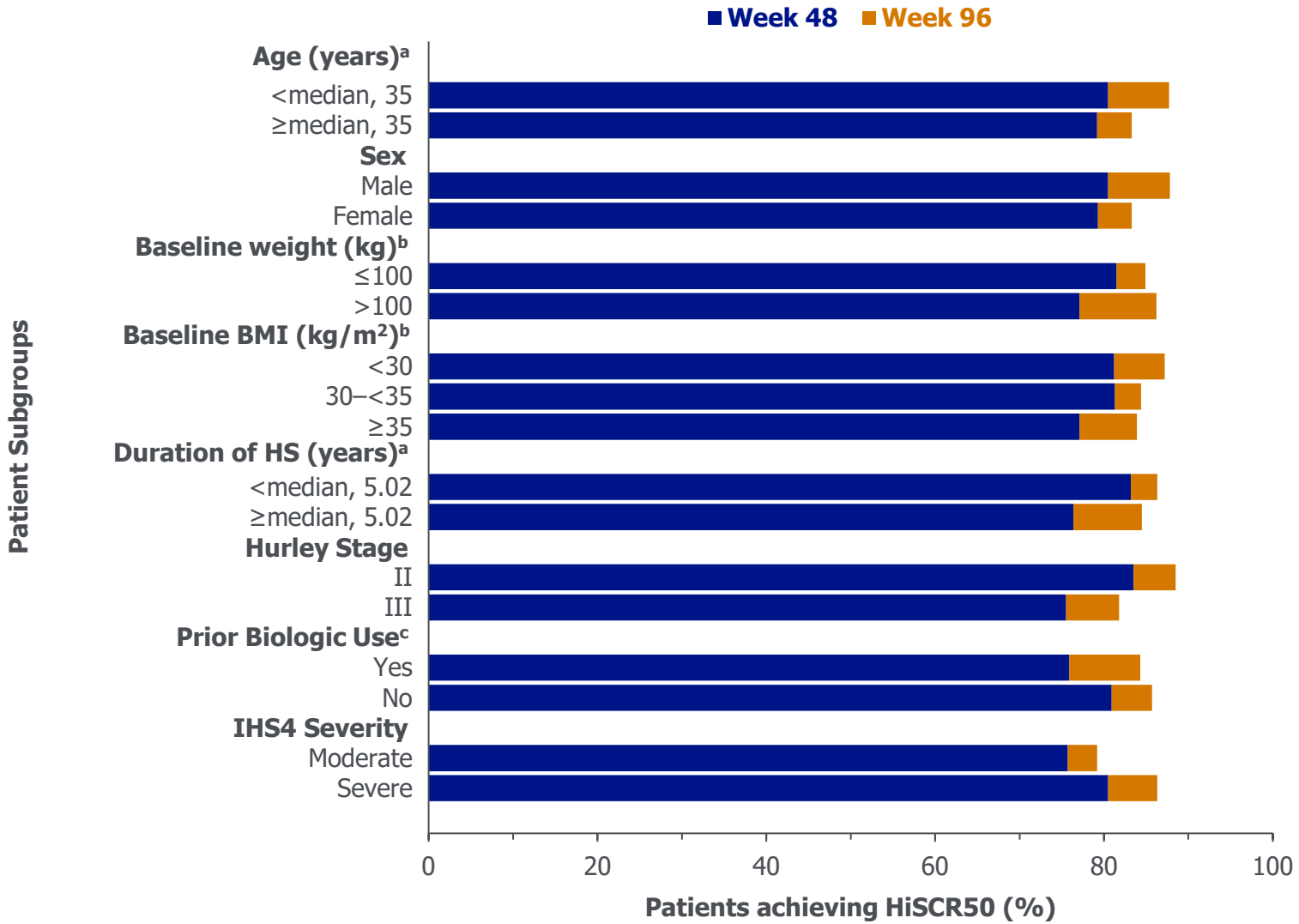
- Patients completing the 48-week BE HEARD I&II studies could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on HiSCR90 response, averaged from Weeks 36, 40, and 44.[1,2]

Baseline Characteristics

	BKZ 320 mg Total N=556
Age (years), mean ± SD	36.3 ± 12.2
Sex, female, n (%)	299 (53.8)
Racial group, n (%)	
White	448 (80.6)
Black	55 (9.9)
Weight (kg), mean ± SD	96.2 ± 23.5
BMI (kg/m²), 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,[d] n (%)	112 (20.1)
IHS4 severity, n (%)	
Mild, ≤3	0
Moderate, 4–10	70 (12.6)
Severe, ≥11	486 (87.4)

OLE set; 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. **[a]** Patients who completed Week 48 of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT); **[d]** Patients received prior biologic therapy for any indication. **1.** Kimball AB. et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **2.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. AN: abscess and inflammatory nodule; BMI: body mass index; DT: draining tunnel; HiSCR50/90: ≥50%/90% reduction in the total AN count from baseline with no increase from baseline in abscess or DT count; IHS4: international HS severity score system; ITP: initial treatment period; MTP: maintenance treatment period; OLE: open-label extension; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation.

Achievement of HiSCR50 by Subgroups for BKZ Total (OC)

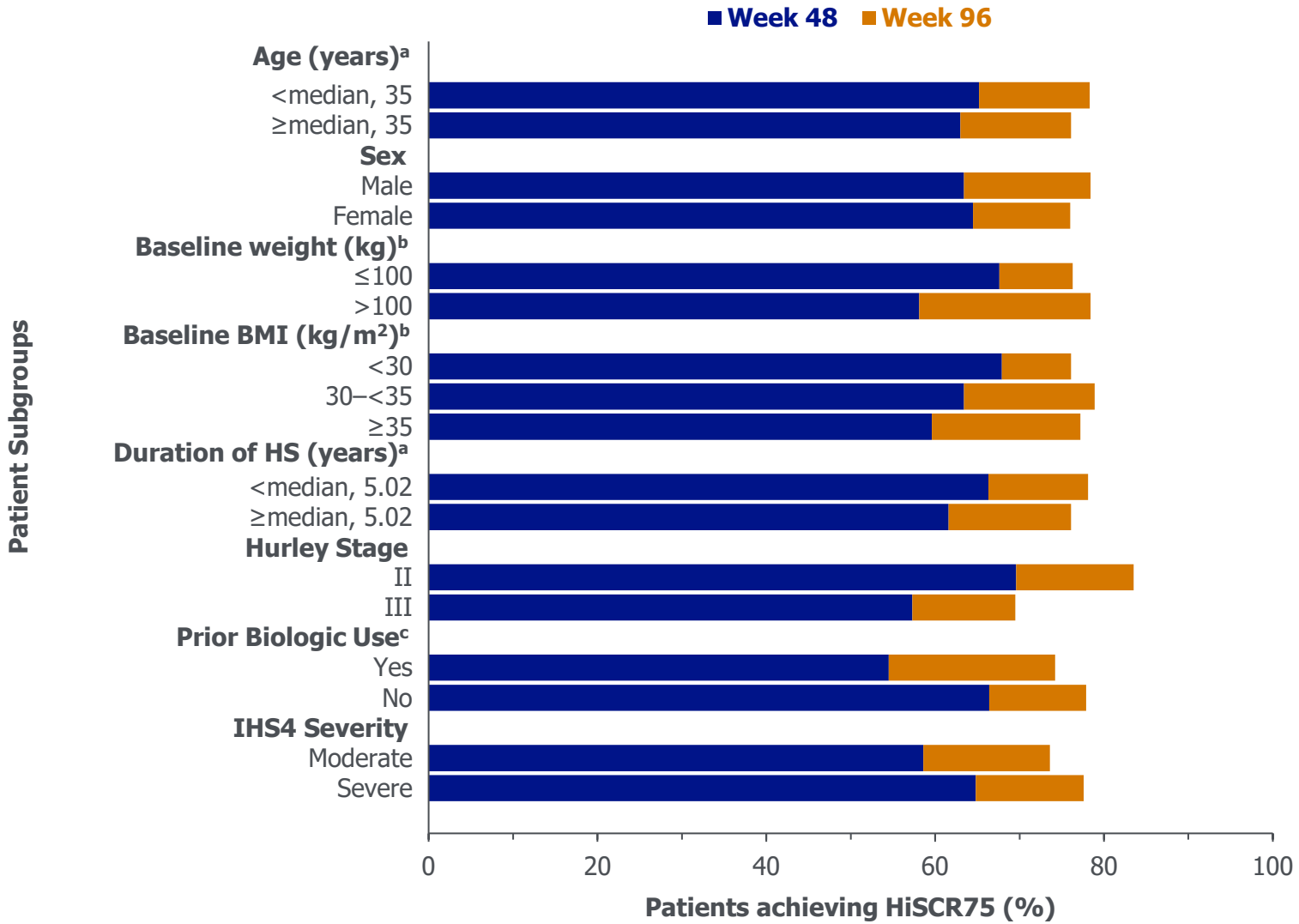


	Week 48 (N=556)		Week 96 (N=446)	
	HiSCR50, %	n/N	HiSCR50, %	n/N
Age (years)[a]				
<median, 35	80.5	215/267	87.7	186/212
≥median, 35	79.2	229/289	83.3	195/234
Sex				
Male	80.5	207/257	87.8	187/213
Female	79.3	237/299	83.3	194/233
Baseline weight (kg)[b]				
≤100	81.5	282/346	84.9	237/279
>100	77.1	162/210	86.2	144/167
Baseline BMI (kg/m²)[b]				
<30	81.2	190/234	87.2	164/188
30–<35	81.3	109/134	84.4	92/109
≥35	77.1	145/188	83.9	125/149
Duration of HS (years)[a]				
<median, 5.02	83.2	237/285	86.3	201/233
≥median, 5.02	76.4	207/271	84.5	180/213
Hurley Stage				
II	83.5	253/303	88.5	215/243
III	75.5	191/253	81.8	166/203
Prior Biologic Use[c]				
Yes	75.9	85/112	84.3	75/89
No	80.9	359/444	85.7	306/357
IHS4 Severity				
Moderate	75.7	53/70	79.2	42/53
Severe	80.5	391/486	86.3	339/393

Overall HiSCR50:
Week 48: 79.9% (444/556)
Week 96: 85.4% (381/446)

OLE set; 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. OC, 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]** Baseline value for BKZ Total; **[c]** Patients received prior biologic therapy for any indication. BKZ: bimekizumab; BMI: body mass index; HiSCR50: ≥50% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; IHS4: international hidradenitis suppurativa severity score system; OC: observed case; OLE: open-label extension.

Achievement of HiSCR75 by Subgroups for BKZ Total (OC)



	Week 48 (N=556)		Week 96 (N=446)	
	HiSCR75, %	n/N	HiSCR75, %	n/N
Age (years)[a]				
<median, 35	65.2	174/267	78.3	166/212
≥median, 35	63.0	182/289	76.1	178/234
Sex				
Male	63.4	163/257	78.4	167/213
Female	64.5	193/299	76.0	177/233
Baseline weight (kg)[b]				
≤100	67.6	234/346	76.3	213/279
>100	58.1	122/210	78.4	131/167
Baseline BMI (kg/m²)[b]				
<30	67.9	159/234	76.1	143/188
30–<35	63.4	85/134	78.9	86/109
≥35	59.6	112/188	77.2	115/149
Duration of HS (years)[a]				
<median, 5.02	66.3	189/285	78.1	182/233
≥median, 5.02	61.6	167/271	76.1	162/213
Hurley Stage				
II	69.6	211/303	83.5	203/243
III	57.3	145/253	69.5	141/203
Prior Biologic Use[c]				
Yes	54.5	61/112	74.2	66/89
No	66.4	295/444	77.9	278/357
IHS4 Severity				
Moderate	58.6	41/70	73.6	39/53
Severe	64.8	315/486	77.6	305/393

Overall HiSCR75:
Week 48: 64.0% (356/556)
Week 96: 77.1% (344/446)

OLE set; 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. OC, 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]** Baseline value for BKZ Total; **[c]** Patients received prior biologic therapy for any indication. BKZ: bimekizumab; BMI: body mass index; HiSCR75: ≥75% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; IHS4: international hidradenitis suppurativa severity score system; OC: observed case; OLE: open-label extension.

CONCLUSIONS

Patients treated with bimekizumab demonstrated high clinical response rates across subgroups at 1 year, with responses maintained or increased through to 2 years.

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

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **CJS**, **MLP, GK, PG, JCS, VP, SY, BL, RR, SK, AM**; Drafting of the publication, or reviewing it critically for important intellectual content: **CJS, MLP, GK, PG, JCS, VP, SY, BL, RR, SK, AM**; Final approval of the publication: **CJS, MLP, GK, PG, JCS, VP, SY, BL, RR, SK, AM**.

Disclosures: CJS: Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis. **MLP:** Consultant and investigator for AbbVie, Avalo Therapeutics, Aristea Therapeutics, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG, and ZuraBio; investigator for Anaptys Bio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals, and Regeneron; received royalties from Beth Israel Deaconess Medical Center. **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. **PG:** Received honoraria for consulting from AbbVie, Novartis, and UCB. **JCS:** Consultant and advisory board member ofAbbVie, 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 Therapeutics, Boehringer Ingelheim, Biocom, Bio Thera, Bristol Myers Squibb, Celltrion, CuraTeQ Biologics, DICE Therapeutics, Eli Lilly and Company, Helm AG, Galapagos, Galderma, Janssen, Incyte, InflaRx, 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. **VP:** Consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly and Company, Janssen, MedImmune, Novartis, Pfizer, Sun Pharma, UCB, and Valeant. **SY**: Consulting for Kaken Pharmaceutical; received travel grants or honoraria from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Maruho, Sanofi, TAIYO Pharma, and UCB; department participated in trials for AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin Corporation, Novartis, Sanofi, and UCB. **BL, RR:** Employees and shareholders of UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Autobahn Therapeutics, Cognition Therapeutics, Colorado Prevention Center, Karuna Therapeutics, Kisbee Therapeutics, LB Pharmaceuticals, Nesos, Novartis, Onward Medical, PharPoint Research, Summit Analytical, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **AM:** Received honoraria and/or travel grants and/or acted as an advisory board member for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, L'Oréal, Novartis, Sanofi, Legit Health, and UCB; worked as a principal investigator in clinical trials supported by AbbVie, Bristol Myers Squibb, Galderma, Janssen, Eli Lilly and Company, Novartis, Sanofi, and UCB.

Acknowledgments: These studies were funded by UCB. 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, and May-Li MacKinnon, Costello Medical, Manchester, UK for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB.