Bimekizumab Demonstrates Sustained Improvements in Pain, Morning Stiffness, and Fatigue in Axial Spondyloarthritis: 3-Year Results from Two Phase 3 Studies

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Presentation Number: 75256

Objectives

- To present phase 3 data on **long-term impact** of bimekizumab (BKZ) treatment on **patient-reported symptoms** in axial spondyloarthritis (axSpA) such as **pain, morning stiffness, and fatigue.**
- To assess **changes over time** in these important symptoms, providing relevant insights for dermatologists managing patients with axial symptoms alongside other interleukin (IL)-17-mediated conditions such as psoriasis and hidradenitis suppurativa (HS).

Background

- axSpA causes disabling symptoms and can **co-occur** with other IL-17-mediated inflammatory diseases such as **psoriasis or HS**.[1–3]
- BKZ, a monoclonal IgG1 antibody that selectively inhibits **IL-17F in addition to IL-17A**, has demonstrated efficacy in axSpA, psoriatic arthritis, plaque psoriasis, and HS.[4–8]
- Here, we assess the impact of **3 years** of BKZ treatment on **total back pain, morning stiffness, and fatigue in axSpA** using long-term **phase 3 data** from the BE MOBILE 1 & 2 trials and their combined open-label extension (OLE).

Summary

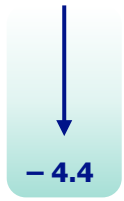
axSpA is a **chronic inflammatory disease** mainly affecting the sacroiliac joints and spine.[1]

Understanding axSpA is important for dermatologists, as **patients with psoriasis or HS may present with axial symptoms** due to **co-occurrence** of axSpA with other **IL-17-mediated inflammatory diseases.**[2,3]

In patients with axSpA in the phase 3 trials BE MOBILE 1 & 2 and their combined OLE, treatment with bimekizumab **over 3 years** led to **sustained improvements** from baseline in:

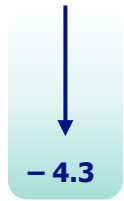
Total back pain
BASDAI Q2

Baseline 7.4



Morning stiffness
Mean BASDAI Q5+6

Baseline 6.8



Fatigue
BASDAI Q1

Baseline 6.5

1. Navarro-Compán V et al. Lancet 2025;405:159–72; **2**. Navarro-Compán V et al. Front Immunol 2023;14:1191782; **3.** Meier K et al. Ther Adv Musculoskelet Dis 2020;12:1759720X20975915; **4**. van der Heijde D et al. Ann Rheum Dis 2023;82:515–26; **5**. McInnes IB et al. Lancet 2023;401:25–37; **6**. Merola JF et al. Lancet 2023;401:38–48; **7**. Warren RB et al. Br J Dermatol 2025;193:44–55; **8**. Kimball AB et al. Lancet 2024;403:2504–19. axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; HS: hidradenitis suppurativa; Ig: immunoglobulin; IL: interleukin; OLE: open-label extension; Q: question; UK: United Kingdom; USA: United States of America.

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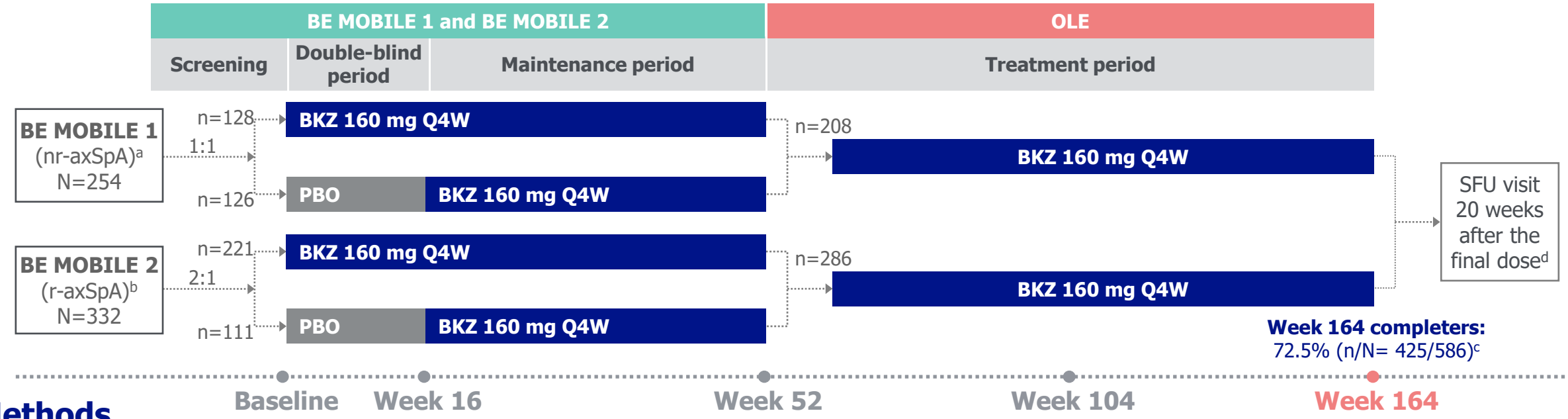
BE MOBILE 1, BE MOBILE 2, and OLE Study Design[1]



Methods

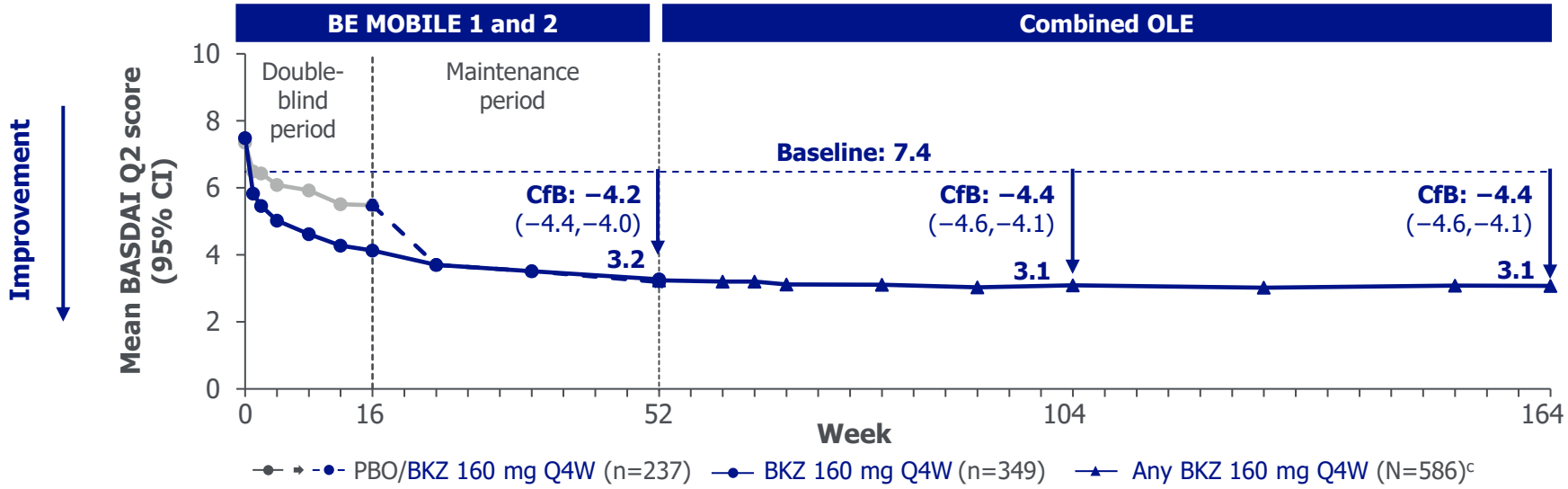
- **BE MOBILE 1** (non-radiographic [nr]-axSpA; NCT03928704) and **BE MOBILE 2** (radiographic [r]-axSpA; NCT03928743) each comprised a 16-week, double-blind, placebo (PBO)-controlled period and a 36-week maintenance period.[1]
  - All patients received subcutaneous **BKZ 160 mg every 4 weeks** (Q4W) from Week 16; eligible patients could enter the OLE (NCT04436640) at Week 52 and continue to receive BKZ to Week 164.
- Patient-reported outcome data for pain, morning stiffness, and fatigue are reported using Bath Ankylosing Spondylitis Disease Activity Index **(BASDAI) Q2 (total back pain), mean of BASDAI Q5+6 (morning stiffness),** and **BASDAI Q1 (fatigue)**. Each BASDAI question is scored on a 0–10 numeric rating scale, where higher scores indicate worse pain/morning stiffness/fatigue.
  - Data were pooled across all randomized patients treated with BKZ, including PBO-randomized patients who switched to BKZ at Week 16, and analyzed using multiple imputation (MI).
- We report mean absolute scores, and change from baseline (CfB) with associated 95% confidence intervals (CI), to Week 164.

1. Baraliakos X. et al. Ann Rheum Dis 2024;83:199–213. **[a]** Included patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP [≥6 mg/L]); **[b]** Included patients had radiographic evidence of r-axSpA fulfilling mNY criteria. All patients in BE MOBILE 2 also fulfilled ASAS criteria; **[c]** 10 patients were ongoing in the OLE prior to Week 164 at the time of the data-cut in September 2024; **[d]** Study participants will receive their final treatment dose at Week 160 (i.e., OLE Week 108); the SFU Visit will be conducted 20 weeks after the final treatment dose. ASAS: Assessment of SpondyloArthritis international Society; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CfB: change from baseline; CI: confidence interval; CRP: C-reactive protein; MI: multiple imputation; mNY; modified New York; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; OLE: open-label extension; PBO: placebo; Q: question; Q4W: every four weeks; r-axSpA: radiographic axial spondyloarthritis; SFU: safety follow-up.

Baseline Characteristics

Mean (SD) unless otherwise stated	**BE MOBILE 1 (nr-axSpA) N=254**	**BE MOBILE 2 (r-axSpA) N=332**
Age (years)	39.4 (11.5)	40.4 (12.3)
Sex, male, n (%)	138 (54.3)	240 (72.3)
BMI (kg/m²)	27.4 (5.8)	26.9 (5.8)
Symptom duration (years)	9.0 (8.8)	13.5 (10.3)
HLA-B27 positive, n (%)	197 (77.6)	284 (85.5)
ASDAS	3.7 (0.7)	3.7 (0.8)[a]
BASDAI	6.8 (1.3)	6.5 (1.3)
hs-CRP (mg/L), geometric mean (geometric CV, %)	4.8 (261.8)	6.6 (246.3)
Prior TNFi exposure,[b] n (%)	27 (10.6)	54 (16.3)

Total Back Pain to Week 164 (BASDAI Q2; MI)

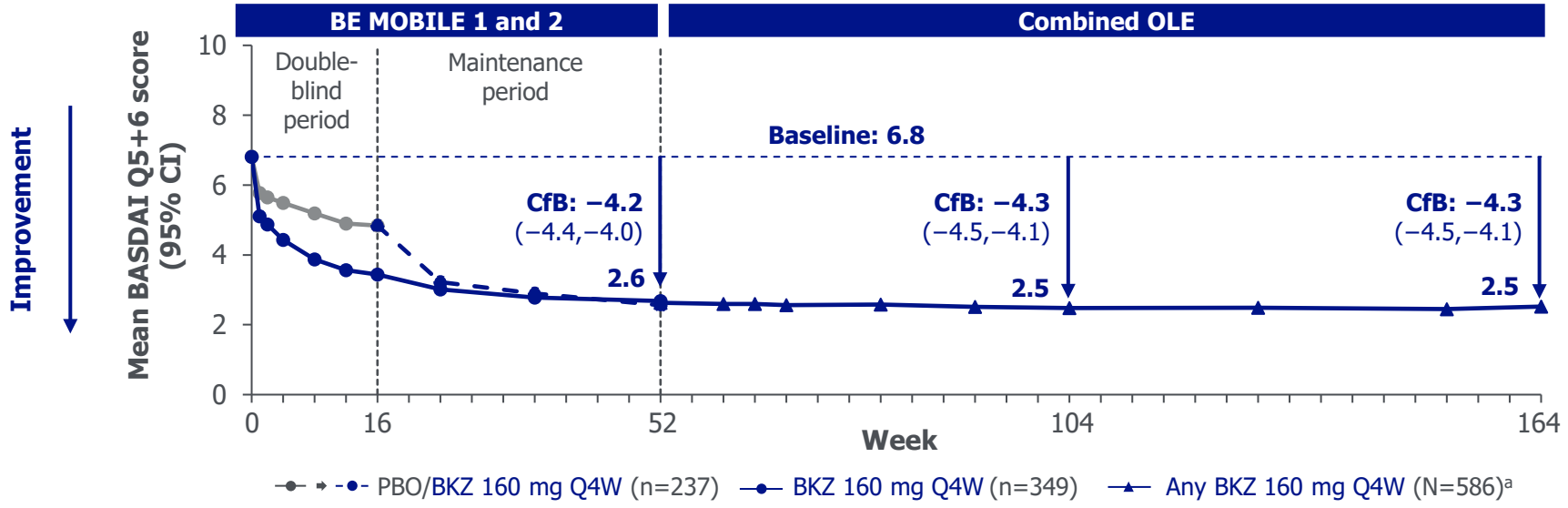


BASDAI Q2: Total Back Pain

Assesses the severity of **neck, back, or hip pain** experienced by patients over the past week, using a numeric rating scale from 0 (none) to 10 (very severe).

Randomized sets/pooled randomized set. **[a]** n=331; **[b]** Defined as patients who were intolerant or experienced an inadequate response to previous TNFi treatment given at an approved dose for at least 12 weeks; **[c]** Includes patients originally randomized to placebo who switched to bimekizumab at Week 16. ASDAS: Axial Spondyloarthritis Disease Activity Score; axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; BMI: body mass index; CfB: change from baseline; CI: confidence interval; CV: coefficient of variation; HLA-B27: human leukocyte antigen-B27; hs-CRP: high-sensitivity C-reactive protein; MI: multiple imputation; nr-axSpA: non-radiographic axSpA; Q: question; OLE: open-label extension; PBO: placebo; Q: question; Q4W: every four weeks; r-axSpA: radiographic axSpA; SD: standard deviation; TNFi: tumor necrosis factor inhibitor.

Morning Stiffness to Week 164 (Mean of BASDAI Q5+6; MI)



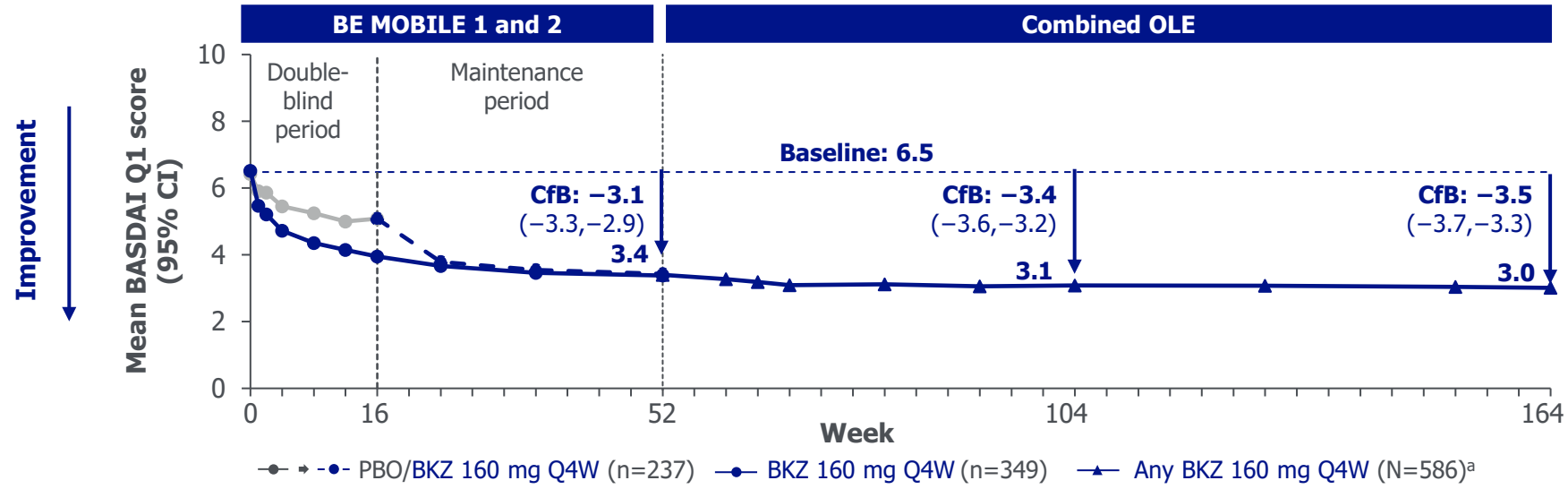
Mean BASDAI Q5+6: Morning Stiffness

Measures the severity and duration of **morning stiffness** using a numeric rating scale:

- Q5 assesses the intensity of morning stiffness on a scale from 0 (none) to 10 (very severe)
- Q6 measures duration of morning stiffness, from 0 (0 hours) to 10 (≥2 hours)

Mean BASDAI Q5+6 is the mean of these two scores, which provides an overall measure of morning stiffness.

Fatigue to Week 164 (BASDAI Q1; MI)



BASDAI Q1: Fatigue

Assesses the severity of **fatigue** experienced by patients over the past week, using a numeric rating scale from 0 (none) to 10 (very severe).

Pooled randomized set. **[a]** Includes patients originally randomized to placebo who switched to bimekizumab at Week 16. axSpA: axial spondyloarthritis; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CfB: change from baseline; CI: confidence interval; MI: multiple imputation; OLE: open-label extension; PBO: placebo; Q: question; Q4W: every four weeks.

Conclusions

Improvements in total back pain, morning stiffness, and fatigue were observed over 3 years of bimekizumab treatment across the full disease spectrum of axSpA.

Bimekizumab demonstrated sustained efficacy from Week 52 to Week 164, reflecting a long-term positive impact on symptom severity.

These findings indicate bimekizumab may provide a valuable long-term treatment option for achieving and maintaining treatment targets in axSpA.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ABG, VNC, UK, PJM, KG, AD, CdIL, SK, JC, HMO;** Drafting of the publication, or reviewing it critically for important intellectual content: **ABG, VNC, UK, PJM, KG, AD, CdIL, SK, JC, HMO;** Final approval of the publication: **ABG, VNC, UK, PJM, KG, AD, CdIL, SK, JC, HMO.**

Disclosures: ABG: Received research/educational grants from Bristol-Myers Squibb, Janssen, Moonlake Immunotherapeutics and UCB (all paid to Mount Sinai School of Medicine until May 1, 2025); at UTSW, ABG is Sub-Investigator on studies from BMS and Janssen; received honoraria as an advisory board member and consultant for AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Oruka, Sanofi, SunPharma, Takeda, Teva, and UCB. **VNC:** Speakers bureau for AbbVie, Alfasigma, Eli Lilly and Company, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer, and UCB; consultant for AbbVie, Alfasigma, Eli Lilly and Company, Galapagos, MoonLake, MSD, Novartis, Pfizer, and UCB; grant/research support from AbbVie and Novartis. **UK:** Grant and research support and consultancy fees from AbbVie, Amgen, Biocad, Biogen, BMS, Chugai, Eli Lilly, Fresenius, GBA, Gilead, Grünenthal, GSK, Hexal, Janssen, MSD, Novartis, onkowissen.de, Pfizer, Roche, UCB, and Viatris. **PJM:** Research grants from AbbVie, Acelyrin, Amgen, Bristol Myers Squibb, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer, Inc., Sana, and UCB; consulting fees from AbbVie, Acelyrin, Amgen, Bristol Myers Squibb, Century, Cullinan, Eli Lilly and Company, Inmagene, Johnson & Johnson Innovative Medicine, MoonLake Immunotherapeutics, Novartis, Pfizer, Inc., Spyre, Takeda, and UCB; speakers bureau fees from AbbVie, Amgen, Eli Lilly and Company, Johnson & Johnson Innovative Medicine, Novartis, Pfizer, Inc., and UCB. **KG:** Speakers bureau for AbbVie, Eli Lilly, Novartis, and UCB; consultant of AbbVie, Eli Lilly, Novartis, and UCB; grant/research support from: AbbVie, Gilead, Eli Lilly, Novartis, and UCB. **AD:** Speaker for Eli Lilly, J&J, Novartis, Pfizer, and UCB; consultant for BMS, Eli Lilly, J&J, MoonLake, Novartis, Pfizer, and UCB; grant/research support from BMS, Eli Lilly, J&J, Novartis, Pfizer, and UCB. **CdIL:** Consultant to UCB. **SK:** Consultant for Aclipse Therapeutics, Aliada Therapeutics, Allay Therapeutics, Autobahn Therapeutics, Biolacuna, Cognition Therapeutics, Colorado Prevention Center, Cytonics Corp, Karuna Therapeutics, Kisbee Therapeutics, LB Pharmaceuticals, Nesos, Novartis, Onward Medical, PharPoint Research, Summit Analytical, Therini Bio, Tonix Pharmaceuticals, Tornado Therapeutics, UCB, Whitsell Innovations, Worldwide Clinical Trials, and Zosano Pharma. **JC:** Employee and shareholder of UCB. **HMO:** Speaking honoraria and/or consultancy fees from AbbVie, Advanz Pharma, Amgen, Biogen, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Takeda, and UCB; research grants from Janssen, Novartis, Pfizer, and UCB.

Acknowledgments: This study was 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 this study.
The authors acknowledge Celia Menckeberg, UCB, Breda, The Netherlands, for publication coordination, and Sylvia Ang, MBI, and Sneha Krishnamurthy, MSc, Costello Medical, London, UK for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB.

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