Bimekizumab safety and sustained long-term efficacy in patients with active psoriatic arthritis and baseline psoriasis: Up to 3-year results from two phase 3 studies

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Presentation Number: 73636

Objective

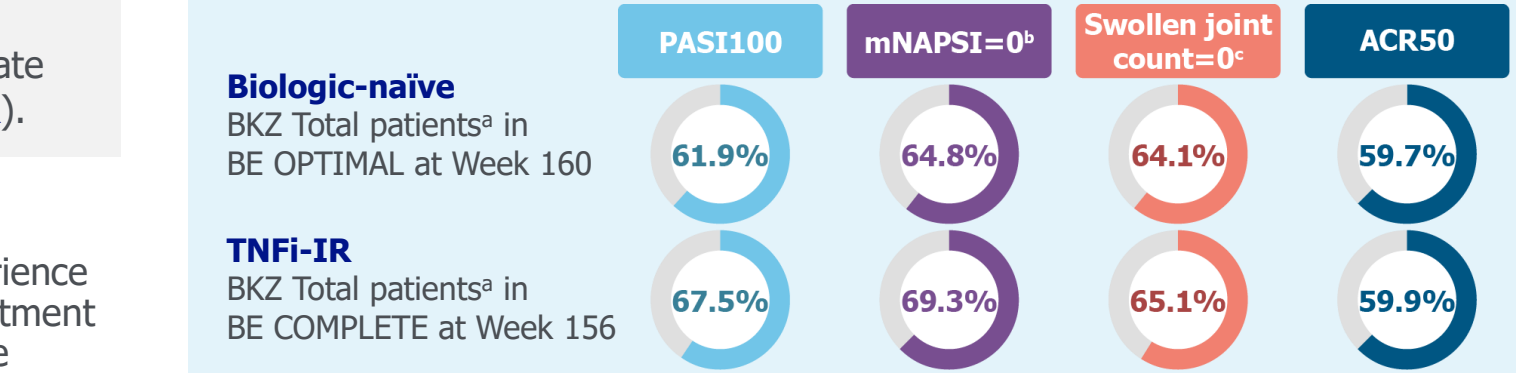
- To evaluate the **long-term efficacy** and **safety** of **bimekizumab** (BKZ) up to **3 years** in patients with active **psoriatic arthritis** (PsA) and **baseline psoriasis** (≥3% body surface area [BSA]), who were either biologic disease-modifying antirheumatic drug-naïve (**biologic-naïve**) or had prior intolerance or inadequate response to tumor necrosis factor inhibitors (**TNFi-IR**).

Background

- Patients with PsA and coexisting psoriasis often experience more severe disease manifestations and reduced treatment durability.[1,2] There is a need for therapies that provide sustained, long-term control across multiple disease domains.
- Assessing long-term treatment with BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, is therefore clinically important.

Summary

Bimekizumab resulted in **sustained clinical efficacy** up to **3 years** in patients with **PsA** who also had baseline **psoriasis**, with **high proportions** of biologic-naïve and TNFi-IR patients **achieving efficacy outcomes** across the **domains of joints, skin, and nails** (mNRI)



Bimekizumab was **well tolerated** to 3 years in patients with **PsA** and baseline **psoriasis**, with **no new safety signals** identified

[a] BKZ Total includes BKZ patients and placebo patients who switched to BKZ at Week 16; **[b]** In patients with nail involvement (mNAPSI >0) at baseline (BE OPTIMAL: BKZ Total n=221; BE COMPLETE: BKZ Total=159); **[c]** Assessed in 66 joints. **1.** Walsh JA et al. Joint Bone Spine 2023;90:105534; **2.** Boehncke WH et al. Am J Clin Dermatol 2013;14:377–88.
ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ**: bimekizumab; **BSA**: body surface area; **IL**: interleukin; **mNAPSI**: modified Nail Psoriasis Severity Index; **mNRI**: modified non-responder imputation; **PASI100**: 100% improvement from baseline in Psoriasis Area and Severity Index; **PsA**: psoriatic arthritis; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

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Methods

- Post hoc analysis of patients with PsA and baseline psoriasis (≥3% BSA) in BE OPTIMAL (biologic-naïve) and BE COMPLETE (TNFi-IR).[1,2] Both studies assessed subcutaneous BKZ 160 mg every four weeks (Q4W) and were placebo-controlled to Week 16.
- BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W).[a] BE OPTIMAL Week 52/BE COMPLETE Week 16 completers could enter the BE VITAL open-label extension, where all patients received BKZ 160 mg Q4W.[1–3]
- Efficacy outcomes reported to Week 160 (BE OPTIMAL) and Week 156 (BE COMPLETE) for placebo patients who switched to BKZ at Week 16 (placebo/BKZ), BKZ-randomized patients, and the BKZ Total group (placebo/BKZ and BKZ-randomized):

PASI100 **mNAPSI=0** **Swollen joint count=0** **ACR50**

- Data reported using modified non-responder imputation (mNRI)[b] or observed case.
- Safety data are reported to Week 156 for all patients treated with BKZ.

Results

- Overall, 357/712 (50.1%) biologic-naïve and 264/400 (66.0%) TNFi-IR BKZ Total group patients had PsA and baseline psoriasis. Of these, 288/357 (80.7%) biologic-naïve and 206/400 (78.0%) TNFi-IR patients completed Week 160/156.

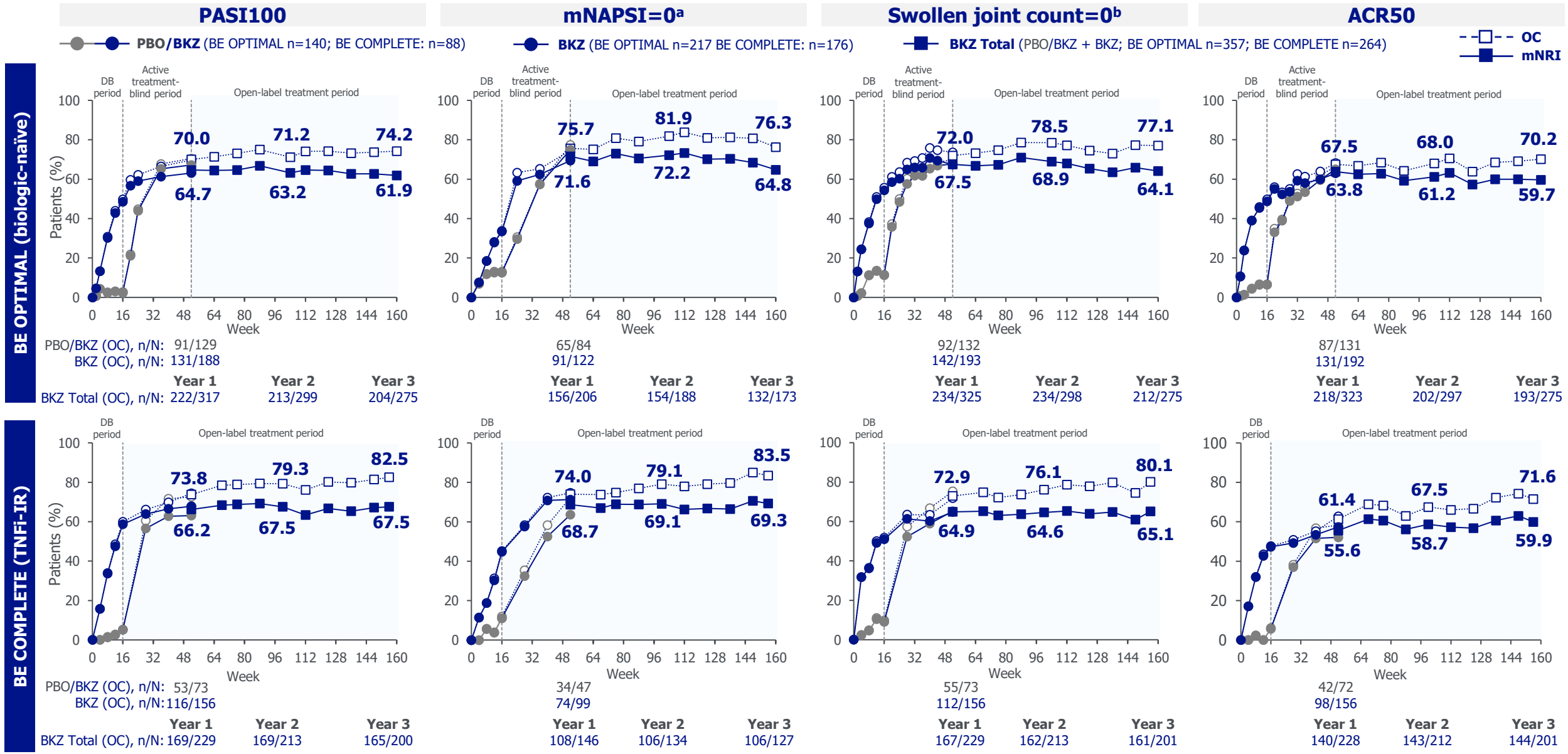
Baseline Characteristics

In patients with PsA and baseline psoriasis (≥3% BSA)

	BE OPTIMAL (biologic-naïve)	BE COMPLETE (TNFi-IR)
	BKZ 160 mg Q4W Total n=357	**BKZ 160 mg Q4W Total n=264**
Age (years), mean (SD)	47.2 (11.9)	49.2 (12.6)
Male, n (%)	173 (48.5)	129 (48.9)
BMI (kg/m²), mean (SD)	29.9 (6.6)	29.5 (6.2)
Duration of disease, PsA (years), mean (SD)	6.8 (8.0)[c]	9.8 (9.9)[d]
Duration of disease, psoriasis (years), mean (SD)	16.4 (12.4)	18.9 (12.9)[e]
≥3% BSA affected by psoriasis, n (%)		
≥3–≤10%	236 (66.1)	172 (65.2)
>10%	121 (33.9)	92 (34.8)
PASI score, mean (SD)	8.1 (6.4)	9.6 (8.4)
Nail psoriasis (mNAPSI>0), n (%)	221 (61.9)	159 (60.2)
Tender joint count (of 68 joints), mean (SD)	17.3 (12.1)	18.7 (13.4)
Swollen joint count (of 66 joints), mean (SD)	9.7 (6.8)	10.3 (8.1)
Pain VAS score,[f] mean (SD)	57.4 (23.4)[g]	61.3 (24.2)

[a] Adalimumab patients switched to BKZ at Week 52; no washout between treatments; **[b]** mNRI considered all visits following discontinuation due to adverse event or lack of efficacy as non-response; all other missing data imputed with multiple imputation and the response derived from the imputed values; **[c]** n=353; **[d]** n=262; **[e]** n=263; **[f]** Pain measured using Patient's Assessment of Arthritis Pain (range: 0 ["no pain"] to 100 ["most severe pain"]); **[g]** n=356. **1.** McInnes IB et al. Lancet 2023;401:25–37 (BE OPTIMAL: NCT03895203); **2.** Merola JF et al. Lancet 2023;401:38–48 (BE COMPLETE: NCT03896581); **3.** Mease PJ et al. Rheumatol Ther 2024;11:1363–82 (BE VITAL: NCT04009499). **ACR50**: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ**: bimekizumab; **BMI**: body mass index; **BSA**: body surface area; **mNAPSI**: modified Nail Psoriasis Severity Index; **mNRI**: modified non-responder imputation; **PASI**: Psoriasis Area and Severity Index; **PASI100**: 100% improvement from baseline in PASI; **PsA**: psoriatic arthritis; Q2W: every 2 weeks; **Q4W**: every 4 weeks; **SD**: standard deviation; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors; **VAS**: visual analog scale.

Efficacy Responses to 3 Years in Patients With PsA and Baseline Psoriasis (≥3% BSA; mNRI, OC)



Randomized set. **[a]** In patients with nail involvement (mNAPSI >0) at baseline (BE OPTIMAL: PBO n=88, BKZ n=133, BKZ Total n=221; BE COMPLETE: PBO n=54, BKZ n=105, BKZ Total=159); **[b]** Assessed in 66 joints. **ACR50**: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ**: bimekizumab; **BSA**: body surface area; **DB**: double-blind; **mNAPSI**: modified Nail Psoriasis Severity Index; **mNRI**: modified non-responder imputation; **OC**: observed case; **PASI100**: 100% improvement from baseline in Psoriasis Area and Severity Index; **PBO**: placebo; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

Safety to 3 Years in Patients with PsA and Baseline Psoriasis (≥3% BSA)

n (%) [EAIR/100 PY]	BE OPTIMAL (biologic-naïve) BKZ 160 mg Q4W Treated[a] n=416; 1,036.6 PY	BE COMPLETE (TNFi-IR) BKZ 160 mg Q4W Treated[a] n=255; 659.7 PY
Any TEAE	376 (90.4) [142.7]	196 (76.9) [72.8]
Serious TEAEs	49 (11.8) [5.0]	29 (11.4) [4.6]
Discontinuation due to TEAEs	27 (6.5) [2.6]	17 (6.7) [2.6]
Drug-related TEAEs[b]	157 (37.7) [20.8]	78 (30.6) [15.0]
Severe TEAEs	32 (7.7) [3.2]	24 (9.4) [3.8]
Deaths[c]	2 (0.5) [0.2]	1 (0.4) [0.2]
Most frequent TEAEs[d]		
SARS-CoV-2 (COVID-19)	94 (22.6) [10.2]	40 (15.7) [6.7]
Nasopharyngitis	76 (18.3) [8.5]	30 (11.8) [4.9]
Upper respiratory tract infection	44 (10.6) [4.5]	19 (7.5) [3.0]
Urinary tract infection	37 (8.9) [3.8]	23 (9.0) [3.7]
Serious infections	12 (2.9) [1.2]	9 (3.5) [1.4]
Opportunistic infections	9 (2.2) [0.9][e]	3 (1.2) [0.5][f]
Active tuberculosis	0	0
Fungal infections	66 (15.9) [7.1]	24 (9.4) [3.9]
Candida infections	43 (10.3) [4.5]	12 (4.7) [1.9]
Oral candidiasis	32 (7.7) [3.2]	10 (3.9) [1.6]
Fungal infections NEC	32 (7.7) [3.2]	14 (5.5) [2.2]
Neutropenia	11 (2.6) [1.1]	12 (4.7) [1.9]
Serious hypersensitivity reaction	0	1 (0.4) [0.2][g]
Administration/injection site reaction	12 (2.9) [1.2]	5 (2.0) [0.8]
Elevated liver enzymes	49 (11.8) [5.1]	28 (11.0) [4.5]
>3x ULN ALT or AST	26 (6.3) [2.6]	13 (5.1) [2.0]
Adjudicated MACE	3 (0.7) [0.3]	2 (0.8) [0.3]
Malignancies, excluding non-melanoma skin cancer	4 (1.0) [0.4]	5 (2.0) [0.8]
Adjudicated suicidal ideation and behavior	2 (0.5) [0.2]	0
Definite or probable adjudicated IBD	2 (0.5) [0.2]	1 (0.4) [0.2]
Uveitis	3 (0.7) [0.3]	0

Safety set. **[a]** Safety events reported whilst receiving BKZ for the 3-year duration (1,095 days after baseline dose). For patients who switched to BKZ from placebo (Week 16) or adalimumab (BE OPTIMAL Week 52), includes events after switch only; **[b]** Per study investigator assessment; **[c]** Deaths were considered unrelated to treatment; **[d]** Most frequent TEAEs are the top four adverse events occurring in all BKZ-treated patients with PsA and baseline psoriasis (≥3% BSA); **[e]** Includes three esophageal candidiasis, one oropharyngeal candidiasis, two fungal esophagitis, one fungal laryngitis, one herpes ophthalmic, and one herpes zoster; **[f]** Includes two esophageal candidiasis and one herpes zoster; **[g]** One case of dermatitis classed as serious due to the patient requiring hospitalization. **ALT**: alanine aminotransferase; **AST**: aspartate aminotransferase; **BKZ**: bimekizumab; **BSA:** body surface area; **EAIR**: exposure-adjusted incidence rate; **IBD**: inflammatory bowel disease; **MACE**: major adverse cardiovascular event; **NEC**: not elsewhere classified; **PY**: patient-years; **Q4W**: every four weeks; **TEAE**: treatment-emergent adverse event; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors; **ULN**: upper limit of normal.

Conclusions

Bimekizumab demonstrated sustained efficacy in patients with PsA and baseline psoriasis to 3 years across the domains of joints, skin, and nails.

Responses were consistent across both biologic-naïve and TNFi-IR patients, suggesting bimekizumab was effective regardless of prior biologic treatment history.

Bimekizumab was well tolerated, with no new safety signals identified.[1,2]

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ML, AA, ABG, SK, AP, RBW, BI, RB, JC, AD**; Drafting of the publication, or reviewing it critically for important intellectual content: **ML, AA, ABG, SK, AP, RBW, BI, RB, JC, AD**; Final approval of the publication: **ML, AA, ABG, SK, AP, RBW, BI, RB, JC, AD**.

Disclosures: ML: Employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly and Company, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; consultant for Aikium, Almirall, AltruBio Inc., Amgen, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, BMS, Boehringer Ingelheim, Castle Biosciences, Celltrion, CorEvitas (formerly Corrona), Dermavant Sciences, Dermsquared, Evommune Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera, Mirum Pharmaceuticals, Oruka, Pfizer, Revolo, Sanofi-Regeneron, Seanergy, Strata, Sun Pharma, Takeda, Trevi, and Verrica. **AA:** Honoraria and/or research grants from AbbVie, Amgen, BMS, Boehringer Ingelheim, Eisai, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Novartis, Pfizer, Sun Pharma, Taiho Pharma, Torii Pharmaceutical Co., and UCB. **ABG:** Research/educational grants from BMS, 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; honoraria as an advisory board member and consultant for AbbVie, Amgen, BMS, Eli Lilly, Janssen, Novartis, Oruka, Sanofi, Sun Pharma, Takeda, Teva, and UCB. **SK:** Research grants from AbbVie, Acelyrin, BMS, and Incyte; consulting, advisory board, and speakers bureau roles for AbbVie, Eli Lilly, Janssen, LEO Pharma, Regeneron, and UCB. **AP:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, UCB, and Zuellig Pharma. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, BMS, Boehringer Ingelheim, Celgene, DICE Therapeutics, Eli Lilly, Galderma, GSK, Immunocore, Janssen, LEO Pharma, Meiji Pharma, Nektar Therapeutics, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, BMS, Eli Lilly and Company, Galderma, Janssen, and Novartis. **BI:** Employee of UCB; shareholder of AbbVie, GSK, and UCB. **RB and JC:** Employees and shareholders of UCB. **AD:** Consultant for AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly, LEO Pharma, and UCB; speaker for Amgen, Janssen, and UCB.

Acknowledgements: 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 Heather Edens, PhD, UCB, Smyrna, GA, USA and Lyes Derouiche, PhD, UCB, Anderlecht, Belgium, for publication coordination. The authors acknowledge Lyes Derouiche, PhD, UCB, Anderlecht, Belgium, for publication coordination, and Zahraa Omran, MSci, Costello Medical, Bristol, UK, for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB.

Abbreviations: **PsA**: psoriatic arthritis; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

References: **1**. Mease PJ et al. Rheumatol Ther 2024;11:1363–82; **2**. Blauvelt A et al. J Am Acad Dermatol 2025;S0190-9622(25)00668-1.