Bimekizumab treatment resulted in sustained improvements in nail psoriasis and signs and symptoms of psoriatic arthritis in patients with baseline nail disease: 1-year pooled results from two phase 3 studies

Joseph F. Merola,[1,2] Diamant Thaçi,[3] Barbara Ink,[4] Rajan Bajracharya,[4] Jérémy Lambert,[5] Jason Coarse,[6] Alice B. Gottlieb[7]

[1]Department of Dermatology, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; [2]Division of Rheumatology, Department of Medicine, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; [3]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; [4]UCB Pharma, Slough, UK; [5]UCB Pharma, Colombes, France; [6]UCB Pharma, Morrisville, NC, USA; [7]Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, NY, USA

Presentation Number: 51569

OBJECTIVES:

- To report the efficacy of **bimekizumab (BKZ)** up to 1 year in the **clearance of nail psoriasis** in patients with active **psoriatic arthritis** (PsA) who had **nail involvement at baseline**, using data from two phase 3 studies.
- To demonstrate **sustained improvements** in **musculoskeletal and skin symptoms** and **health-related quality of life** (HRQoL) up to 1 year in patients with PsA with nail psoriasis at baseline treated with BKZ.

Background:

- Nail psoriasis is associated with increased risk of PsA in patients with psoriasis, as well as poorer PsA prognosis and decreased HRQoL.[1,2]
- We report 1-year efficacy of BKZ, a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A, in patients with PsA and baseline nail psoriasis.

Methods:

- Nail disease was assessed using the modified Nail Psoriasis Severity Index (mNAPSI) on the most affected nail identified at baseline; the chosen nail was observed throughout.

Scoring:

0–3 for:
- Onycholysis/oil drop dyschromia
- Nail plate crumbling
- Pitting

0 (no) or 1 (yes) for:
- Leukonychia
- Nail bed hyperkeratosis
- Splinter hemorrhages
- Reds spots in lunula

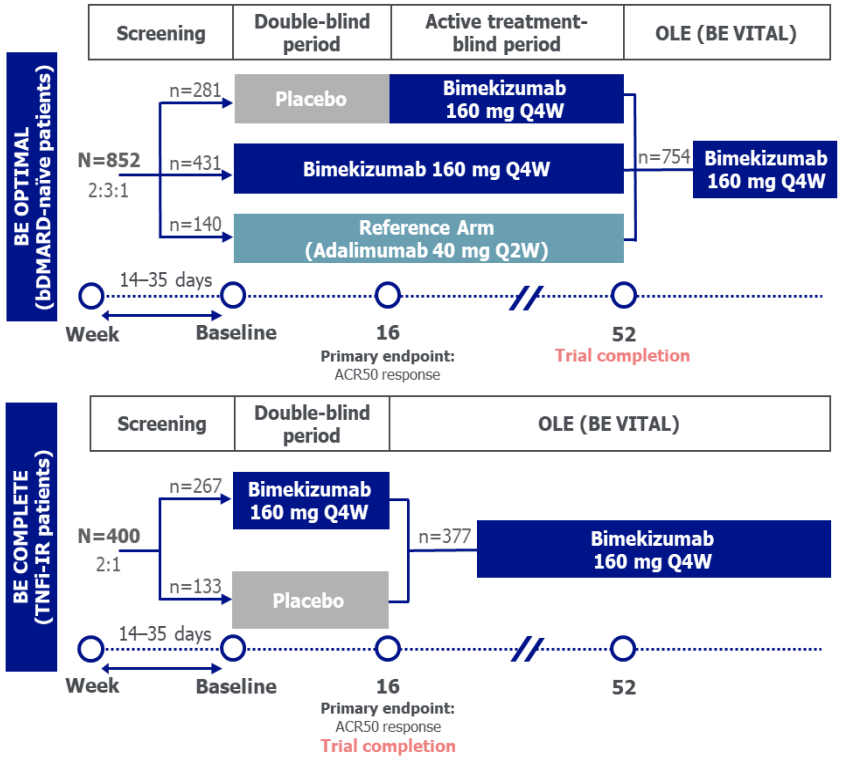
mNAPSI is the sum of the scores (0 indicates clear nails)

- HRQoL, joint and skin symptoms were assessed using measures including PASI, swollen and tender joint count, Health Assessment Questionnaire-Disability Index (HAQ-DI), pain, and Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores.
- Data reported for patients randomized to BKZ or placebo (PBO) with nail disease at baseline (mNAPSI >0).
- Missing data imputed using non-responder imputation (NRI; binary) or multiple imputation (MI; continuous).

Data reported from BE OPTIMAL (NCT03895203)[3] and BE COMPLETE (NCT03896581)[4]/BE VITAL (NCT04009499). **1.** Zabotti A. Ann Rheum Dis 2023;82:1162–70; **2.** Cengiz G. Int J Rheum Dis 2023;26:43–50; **3.** McInnes IB. Lancet 2023;401:25–37; **4.** Merola JF. Lancet 2023;401:38–48. BKZ: bimekizumab; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; HRQoL: health-related quality of life; IL: interleukin; MI: multiple imputation; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis.

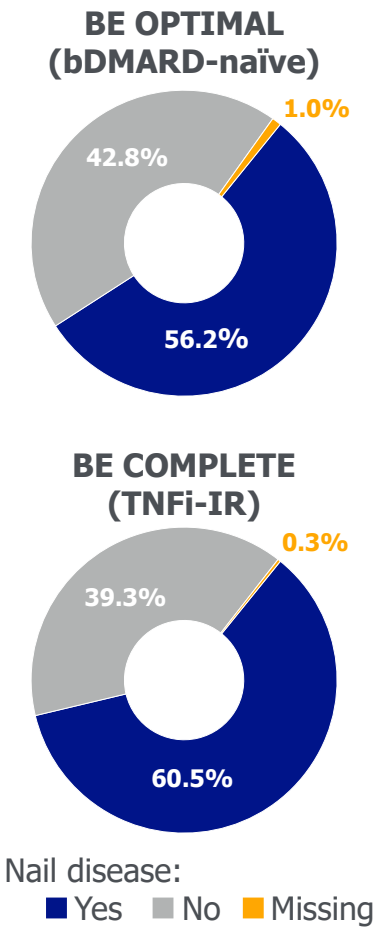
To receive a copy of this poster, scan the QR code or visit UCBposters.com/AAD2024
Poster ID: 51569; Link expiration: June 10, 2024

BE OPTIMAL, BE COMPLETE, and BE VITAL (OLE) Study Designs



BKZ dose of 160 mg Q4W used in BE OPTIMAL and BE COMPLETE differs from the plaque psoriasis dose of 320 mg Q4W/Q8W[1,2]

Proportion of Patients with Nail Disease at Baseline (mNAPSI >0)



Baseline Characteristics of Patients with Nail Disease at Baseline (mNAPSI >0)

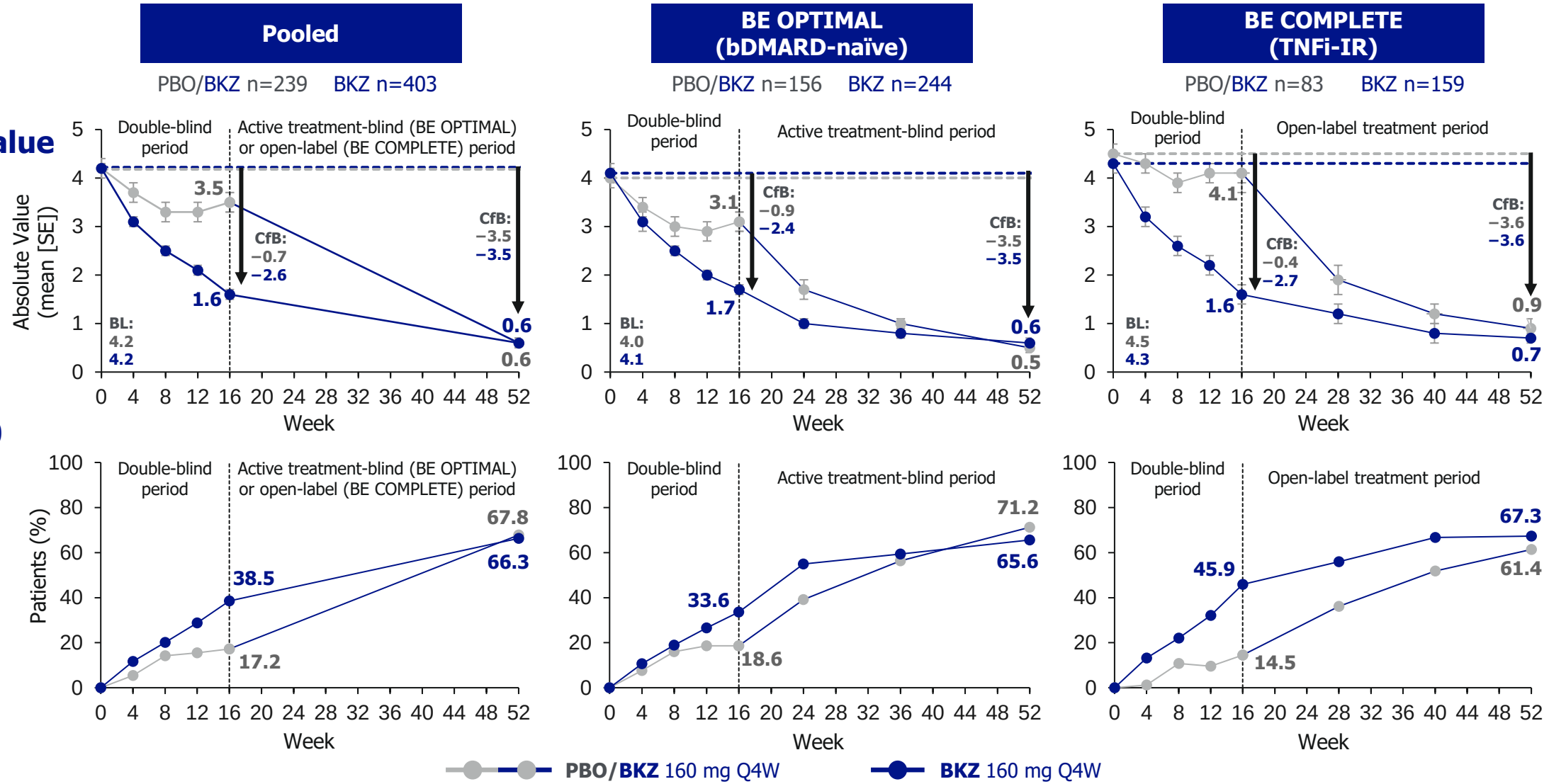
	BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	PBO (n=156)	BKZ 160 mg Q4W (n=244)	PBO (n=83)	BKZ 160 mg Q4W (n=159)
Age (years), mean ± SD	49.5 ± 10.8	47.9 ± 11.8	50.4 ± 13.3	50.3 ± 12.3
Male, n (%)	80 (51.3)	116 (47.5)	44 (53.0)	89 (56.0)
BMI (kg/m^2), mean ± SD	29.1 ± 5.8	29.0 ± 5.9	28.6 ± 5.2	29.9 ± 5.4
Time since PsA diagnosis (years), mean ± SD	6.1 ± 6.6	6.2 ± 8.0[a]	8.8 ± 7.1[b]	9.6 ± 9.2
Concomitant methotrexate, n (%)	91 (58.3)	146 (59.8)	38 (45.8)	72 (45.3)
Psoriasis BSA ≥3%, n (%)	88 (56.4)	133 (54.5)	54 (65.1)	105 (66.0)
Psoriasis BSA >10%, n (%)	34 (21.8)	53 (21.7)	18 (21.7)	47 (29.6)
PASI score,[c] mean ± SD	9.0 ± 6.0[d]	9.2 ± 7.8[e]	9.3 ± 7.4[f]	11.8 ± 10.2[g]
TJC (of 68 joints), mean ± SD	16.6 ± 11.9	17.6 ± 12.4	19.2 ± 14.2	19.2 ± 14.5
SJC (of 66 joints), mean ± SD	9.6 ± 8.0	9.5 ± 6.7	10.9 ± 9.1	10.8 ± 8.9
Enthesitis (LEI >0), n (%)	43 (27.6)	84 (34.4)	25 (30.1)	64 (40.3)
mNAPSI, mean ± SD	4.0 ± 2.1	4.1 ± 2.5	4.5 ± 2.8	4.3 ± 2.8
HAQ-DI, mean ± SD	0.90 ± 0.62	0.82 ± 0.59	0.97 ± 0.70	0.99 ± 0.58
PsAID-12 total score, mean ± SD	4.3 ± 2.0	4.1 ± 1.9	4.3 ± 2.0	4.5 ± 2.1
FACIT-Fatigue, mean ± SD	36.0 ± 9.8	37.4 ± 9.5	36.4 ± 9.4	35.1 ± 11.0

Study design: The adalimumab arm was included in BE OPTIMAL for reference versus standard of care for safety to Week 52; data not reported. **Table:** Randomized set, in patients with nail disease at baseline (mNAPSI >0). **1.** European Medicines Agency (EMA). Bimekizumab Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [accessed: January 3, 2024]; **2.** United States Food and Drug Administration (FDA). Bimekizumab Prescribing Information Leaflet. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf [accessed: January 3, 2024]. **[a]** n=239; **[b]** n=82; **[c]** In patients with psoriasis involving at least 3% of BSA at baseline; **[d]** n=88; **[e]** n=133; **[f]** n=54; **[g]** n=105. ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; LEI: Leeds Enthesitis Index; MI: multiple imputation; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; PsAID-12: PsA Impact of Disease-12 questionnaire; Q2W: every 2 weeks; Q4W: every 4 weeks; Q4W: every 8 weeks; SD: standard deviation; SJC: swollen joint count; TJC: tender joint count; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors.

mNAPSI Change from Baseline (MI) and Resolution (NRI) to 1 Year in Patients with Nail Disease at Baseline (mNAPSI >0)

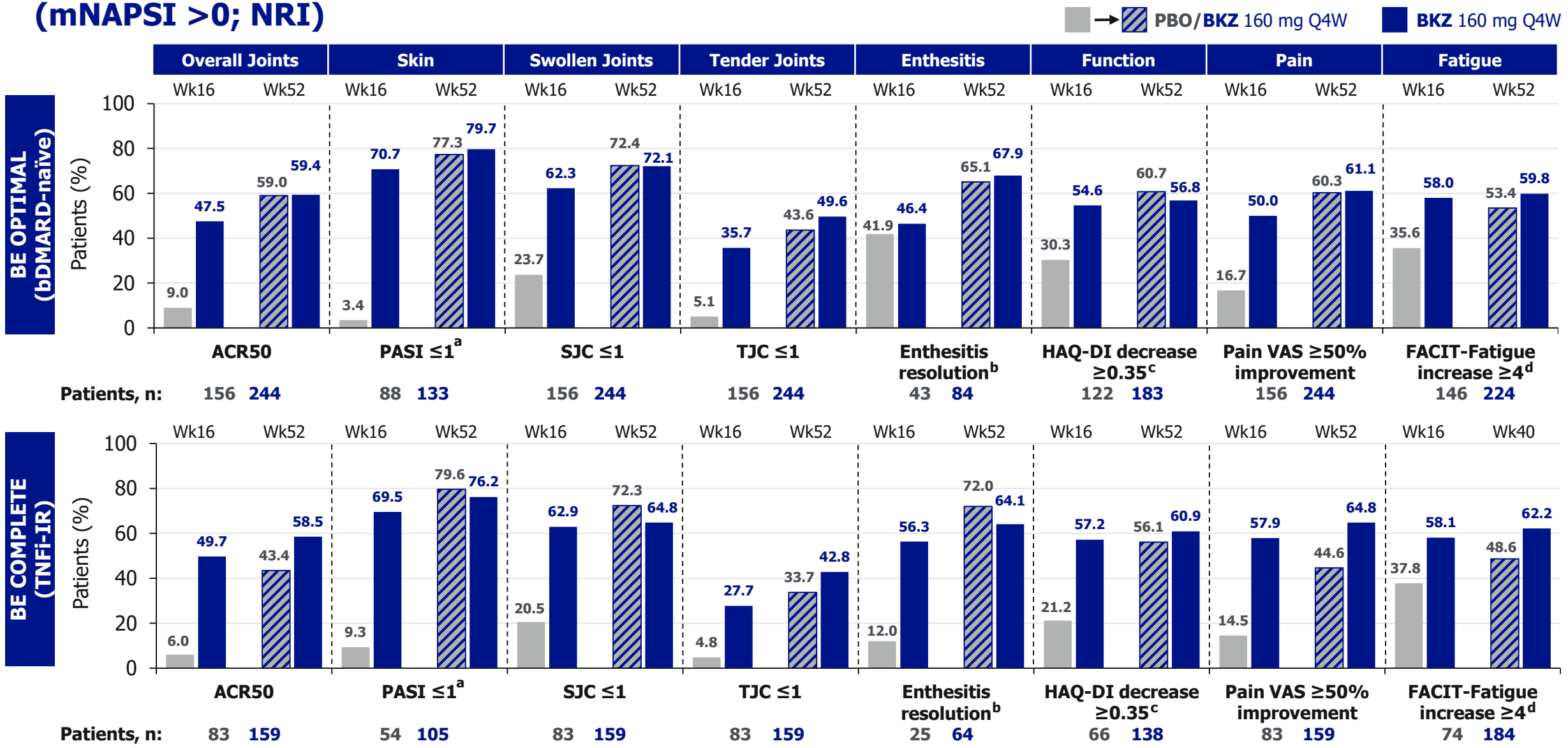
mNAPSI absolute value and CfB

mNAPSI=0



Randomized set, in patients with nail disease at baseline (mNAPSI >0). PBO patients switched to BKZ 160 mg Q4W at Week 16. bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; CfB: change from baseline; MI: multiple imputation; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PBO: placebo; Q4W: every 4 weeks; SE: standard error; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors.

Clinically Meaningful Responses in Patients with PsA and Nail Disease at Baseline (mNAPSI >0; NRI)



Randomized set, in patients with nail disease at baseline (mNAPSI >0). PBO patients switched to BKZ 160 mg Q4W at Week 16. **[a]** In patients with psoriasis involving at least 3% of BSA at baseline; **[b]** In patients with LEI >0 at baseline; **[c]** In patients with HAQ-DI ≥0.35 at baseline; **[d]** In patients with FACIT-Fatigue subscale score ≤48 at baseline. ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; LEI: Leeds Enthesitis Index; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; SJC: swollen joint count; TJC: tender joint count; TNFi-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analog scale; Wk: Week.

CONCLUSIONS:

- Bimekizumab demonstrated sustained improvements in nail psoriasis to 1 year in patients with PsA who were bDMARD-naïve or had inadequate response or intolerance to TNFi.
- Most patients with PsA and nail psoriasis at baseline achieved complete nail clearance over 1 year of bimekizumab treatment.
- Bimekizumab-treated patients with PsA and nail psoriasis at baseline demonstrated clinically meaningful improvements across all outcomes, including joint and skin symptoms and HRQoL measures.

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

Disclosures: JFM: Affiliated with Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA at time of analysis; currently affiliated with UT Southwestern Medical Center, Dallas, TX, USA; consultant and/or investigator for AbbVie, Amgen, Biogen, Boehringer Ingelheim, BMS, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB Pharma. **DT:** Served as an investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly and Company, Galderma, Janssen-Cilag, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Target-RWE, and UCB Pharma; received grants from AbbVie, LEO Pharma, and Novartis. **BI:** Employee of UCB Pharma. Shareholder of AbbVie, GSK, and UCB Pharma. **RB, JL, and JC:** Employees and shareholders of UCB Pharma. **ABG:** Received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres Therapeutics, BMS, Boehringer Ingelheim, Dice Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, UCB Pharma, and Xbiotech; received research/educational grants from AnaptysBio, BMS, Highlights Therapeutics, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB Pharma; all paid to Mount Sinai School of Medicine.

This study was funded by UCB Pharma. 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 Heather Edens, PhD, UCB Pharma, Smyrna, GA, USA, for publication coordination, and Orla Woodward, PhD, Costello Medical, London, UK, for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

bDMARD: biologic disease-modifying antirheumatic drug; HRQoL: health-related quality of life; PsA: psoriatic arthritis; TNFi: tumor necrosis factor inhibitors.