Bimekizumab treatment resulted in rapid and sustained improvement in total and individual Bath Ankylosing Spondylitis Disease Activity Index components in patients with psoriatic arthritis: 1-year results from two phase 3 studies

Joseph F. Merola,[1,2] Alice B. Gottlieb,[3] Barbara Ink,[4] Rajan Bajracharya,[4] Jérémy Lambert,[5] Jason Coarse,[6] Ennio G. Favalli[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]Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, NY, USA; [4]UCB Pharma, Slough, UK; [5]UCB Pharma, Colombes, France; [6]UCB Pharma, Morrisville, NC, USA; [7]Department of Rheumatology, ASST Gaetano Pini-CTO, University of Milan, Milan, Italy

Presentation Number: 51558

OBJECTIVES:

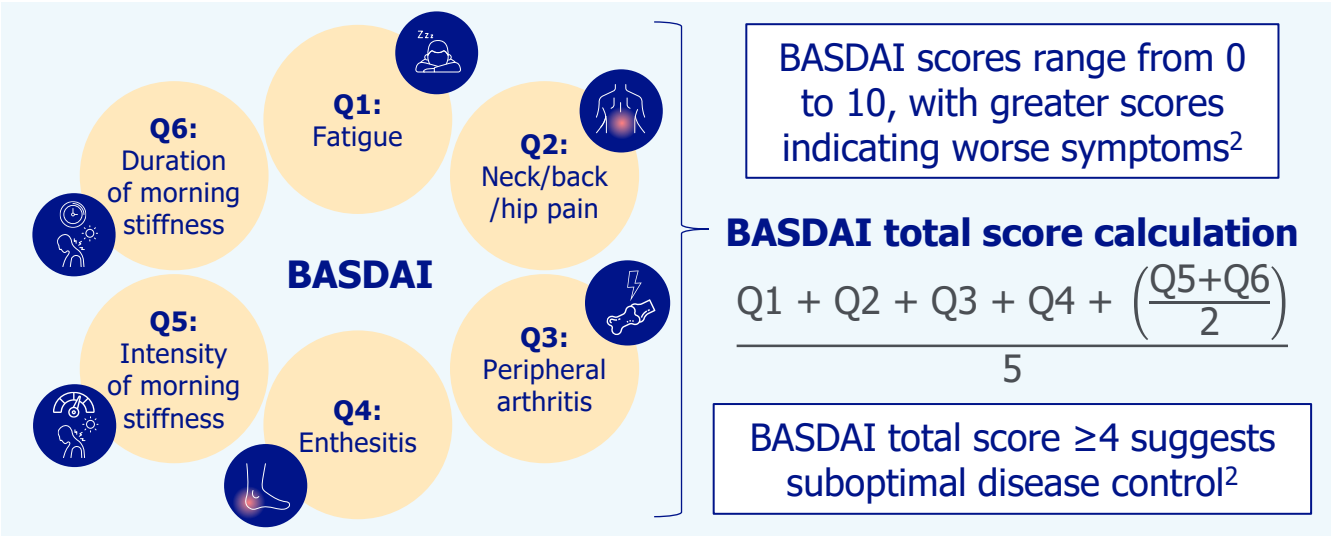
- To report the efficacy of **bimekizumab** (BKZ) in **improving symptoms** in patients with **psoriatic arthritis** (PsA) using the Bath Ankylosing Spondylitis Disease Activity Index **(BASDAI).**
- To use BASDAI scores and 50% response threshold to **demonstrate rapid and sustained improvements** in PsA symptoms with BKZ, **irrespective of** prior biologic disease-modifying antirheumatic drug **(bDMARD) use.**

Background:

- The patient-reported BASDAI questionnaire can assess symptom improvement in PsA;[1] the six items assess symptoms during the prior week on a 0–10 numeric rating scale.[2]
- We report BASDAI data from two phase 3 trials of BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, in patients with active PsA.[3,4]

Methods:

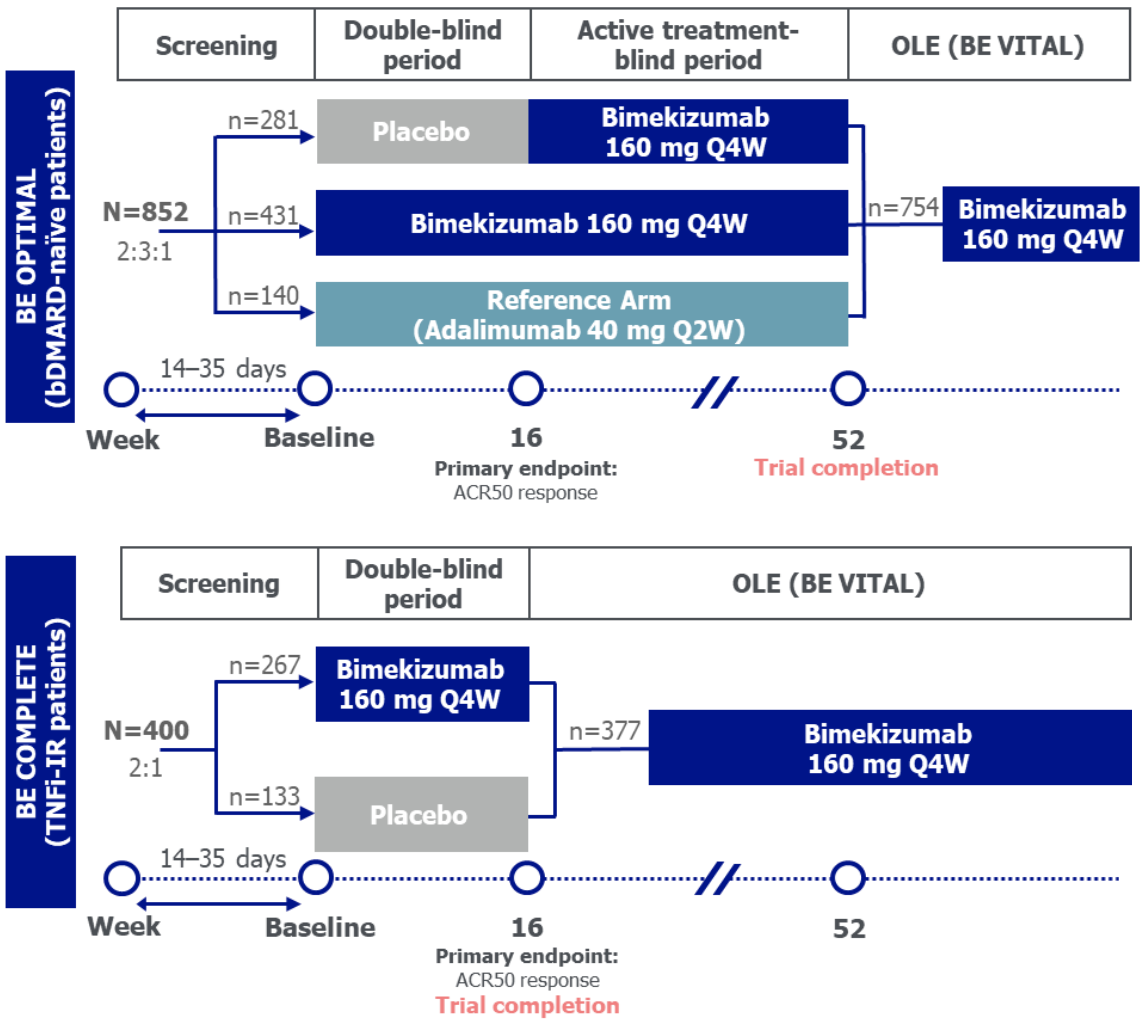
- BASDAI total scores (mean change from baseline [CfB]), mean component scores, and ≥50% improvement (BASDAI50) are reported for patients with BASDAI total score ≥4 at baseline.
- Missing data imputed using non-responder imputation (NRI; binary) and multiple imputation (MI; continuous).



Data are reported from BE OPTIMAL (NCT03895203)[3] and BE COMPLETE (NCT03896581)[4]/BE VITAL (NCT04009499). **1.** Ogdie A. Arthritis Care Res 2020;72 (Suppl 10):82–109; **2.** Landewé R. Curr Rheumatol Rep 2015; 17:47; **3.** McInnes IB. Lancet 2023;401:25–37; **4.** Merola JF. Lancet 2023;401:38–48.
BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASDAI50: ≥50% improvement in BASDAI total score; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; CfB: change from baseline; IL: interleukin; MI: multiple imputation; NRI: non-responder imputation; PsA: psoriatic arthritis; Q: question.

To receive a copy of this poster, scan the QR code or visit UCBposters.com/AAD2024
Poster ID: 51558; Link expiration: June 10, 2024

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



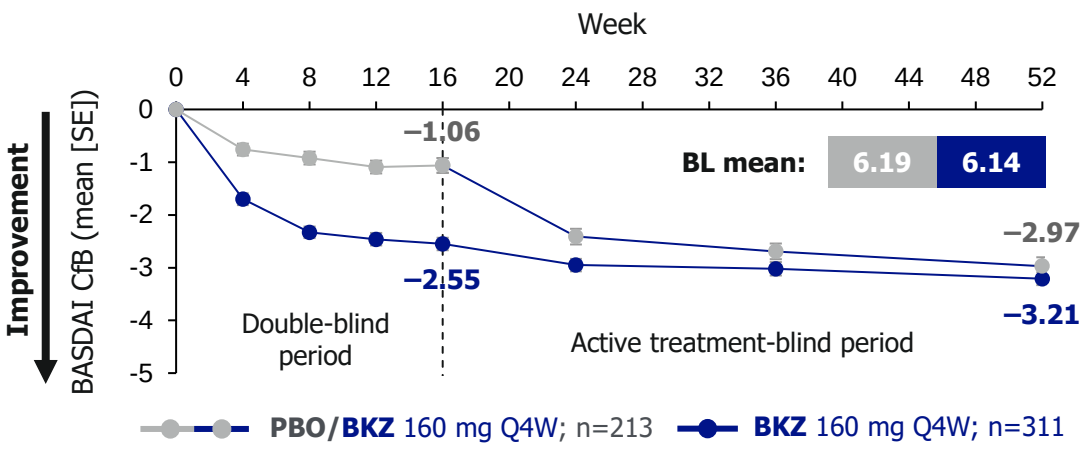
Baseline Characteristics

	BE OPTIMAL (bDMARD-naïve)		BE COMPLETE (TNFi-IR)	
	PBO (n=213)	BKZ 160 mg Q4W (n=311)	PBO (n=96)	BKZ 160 mg Q4W (n=204)
Age (years), mean ± SD	49.4 ± 11.1	49.0 ± 12.2	51.3 ± 13.5	49.6 ± 12.5
Male, n (%)	89 (41.8)	133 (42.8)	42 (43.8)	102 (50.0)
BMI (kg/m^2), mean ± SD	29.9 ± 6.1	29.7 ± 7.2	29.3 ± 5.4	30.6 ± 6.8
Time since first PsA diagnosis (years), mean ± SD	5.5 ± 6.0[a]	5.9 ± 7.5[b]	9.4 ± 8.5[c]	9.9 ± 10.2
Psoriasis BSA ≥3%, n (%)	107 (50.2)	164 (52.7)	70 (72.9)	134 (65.7)
PASI score,[d] mean ± SD	7.8 ± 5.7	8.3 ± 6.9	8.4 ± 6.6	10.3 ± 9.6
Enthesitis (LEI >0), n (%) LEI score,[f] mean ± SD	58 (27.2) 2.9 ± 1.6	117 (37.6)[e] 2.6 ± 1.5	18 (18.8)[c] 3.3 ± 1.7	82 (40.2) 2.6 ± 1.5
Dactylitis (LDI >0), n (%) LDI score,[g] mean ± SD	24 (11.3) 50.8 ± 44.7	49 (15.8)[e] 47.9 ± 56.9	11 (11.5)[c] 79.3 ± 142.6	28 (13.7) 55.0 ± 77.3
Nail psoriasis (mNAPSI >0), n (%) mNAPSI score,[h] mean ± SD	118 (55.4) 4.0 ± 2.2	183 (58.8)[i] 4.0 ± 2.5	55 (57.3)[c] 4.8 ± 2.9	122 (59.8) 4.1 ± 2.8
BASDAI scores, mean ± SD				
Total	6.2 ± 1.3	6.1 ± 1.3	6.5 ± 1.3	6.2 ± 1.3
Q1: Fatigue	5.8 ± 2.0	5.7 ± 2.2	5.9 ± 2.1	5.9 ± 2.1
Q2: Neck/back/hip pain[j]	6.1 ± 2.2	5.9 ± 2.3	6.4 ± 2.1	5.9 ± 2.2
Q3: Peripheral arthritis	6.5 ± 1.8	6.7 ± 1.6	7.2 ± 1.5	6.6 ± 1.7
Q4: Enthesitis	6.4 ± 1.9	6.3 ± 2.0	6.6 ± 2.0	6.4 ± 1.9
Q5: Intensity of morning stiffness	7.0 ± 1.8	6.9 ± 1.9	7.1 ± 1.8	7.0 ± 1.8
Q6: Duration of morning stiffness	5.3 ± 2.6	5.5 ± 2.6	5.8 ± 2.4	5.7 ± 2.6

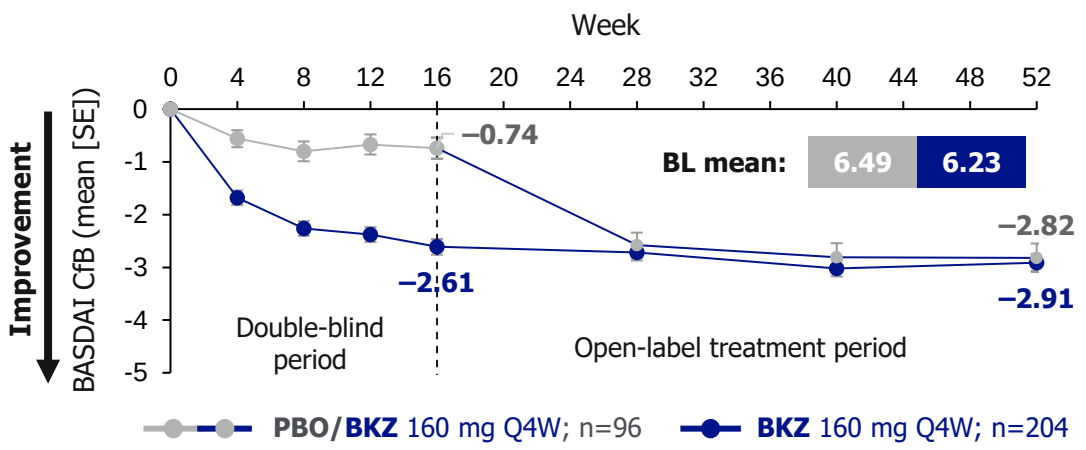
Study design: The adalimumab arm was included in BE OPTIMAL for reference versus standard of care for safety to Week 52; data not reported here. The study was not powered for statistical comparisons of adalimumab to BKZ or PBO. **Table**: In patients with BASDAI total score ≥4 at baseline. **[a]** Data missing for 2 patients; **[b]** Data missing for 7 patients; **[c]** Data missing for 1 patient; **[d]** In patients with psoriasis involving at least 3% of BSA at baseline; **[e]** Data missing for 4 patients; **[f]** In patients with enthesitis at baseline (LEI>0); **[g]** In patients with dactylitis at baseline (LDI>0); **[h]** In patients with nail psoriasis at baseline (mNAPSI>0); **[i]** Data missing for 5 patients; **[j]** Axial involvement was not identified by investigator-reporting, radiographic history or by alternative means. ACR50: ≥50% improvement in the American College of Rheumatology response criteria; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; LDI: Leeds Dactylitis Index; LEI: Leeds Enthesitis Index; mNAPSI: modified Nail Psoriasis Severity Index; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PBO: placebo; PsA: psoriatic arthritis; Q: question; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation; TNFi-IR: inadequate response/intolerance to tumor necrosis factor inhibitors.

Patients Demonstrated Improvement in BASDAI Total Score with BKZ Treatment through Week 52 (MI)

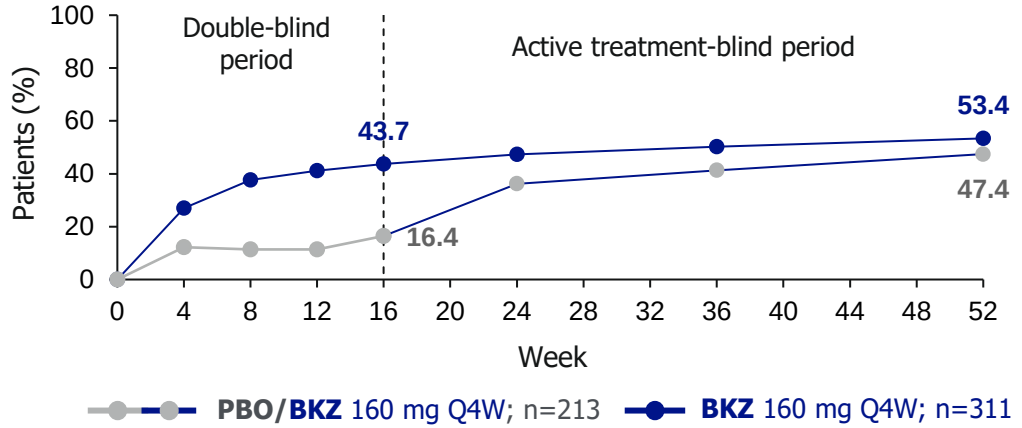
BE OPTIMAL (bDMARD-naïve)

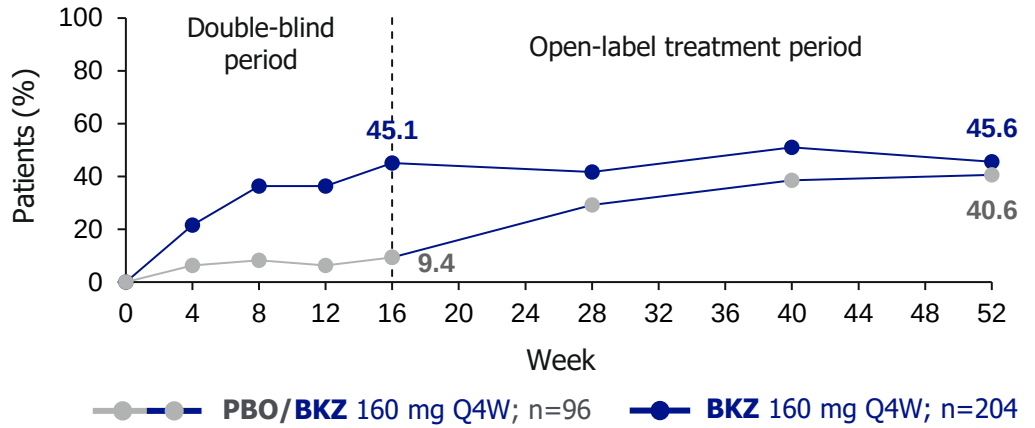


BE COMPLETE (TNFi-IR)



High Proportions of Patients Achieved BASDAI50 with BKZ Treatment through Week 52 (NRI)

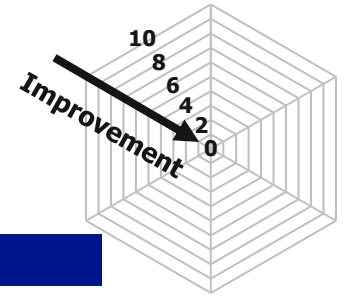




Results were generally similar in patients with psoriasis affecting <3% or ≥3% body surface area at baseline

Randomized set, in patients with BASDAI total score ≥4 at baseline. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASDAI50:≥50% improvement in BASDAI total score; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BL: baseline; CfB: change from baseline; MI: multiple imputation; NRI: non-responder imputation; PBO: placebo; Q4W: every 4 weeks; SE: standard error; TNFi-IR: inadequate response/intolerance to tumor necrosis factor inhibitors.

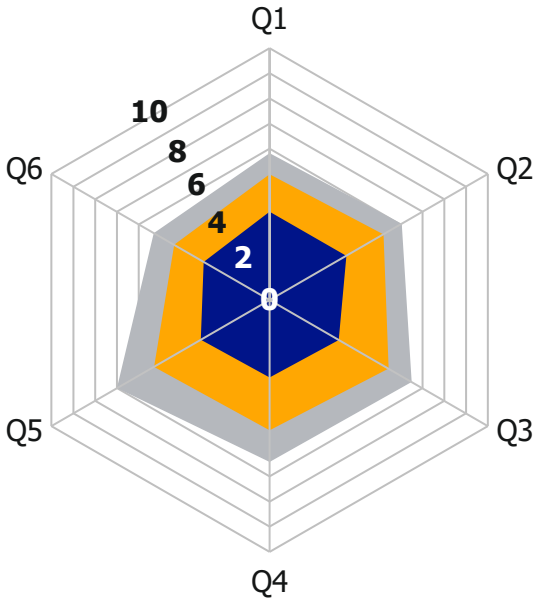
Mean BASDAI Component Scores for Patients through Week 52 (MI)



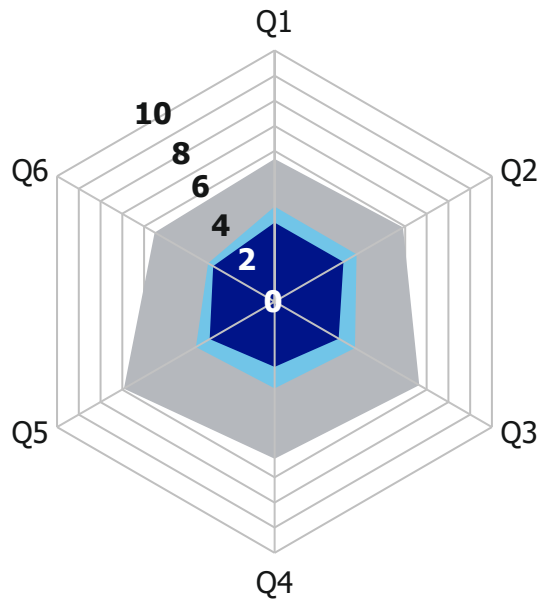
BKZ-treated patients demonstrated improvement in all BASDAI domains, including in neck/back/hip pain

BE OPTIMAL (bDMARD-naïve)

PBO/BKZ 160 mg Q4W
(n=213)

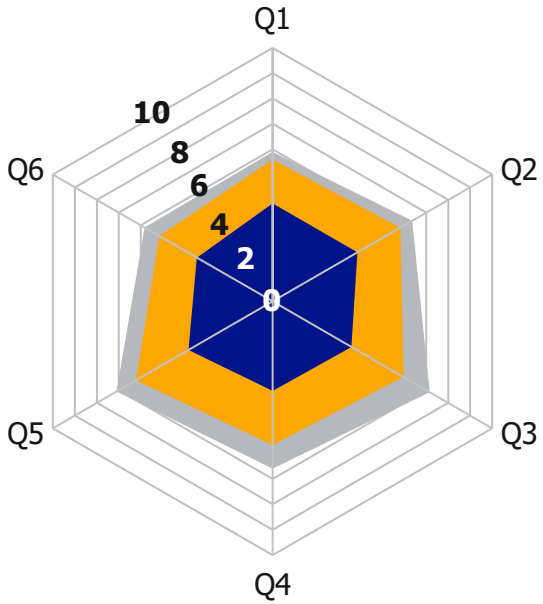


BKZ 160 mg Q4W
(n=311)

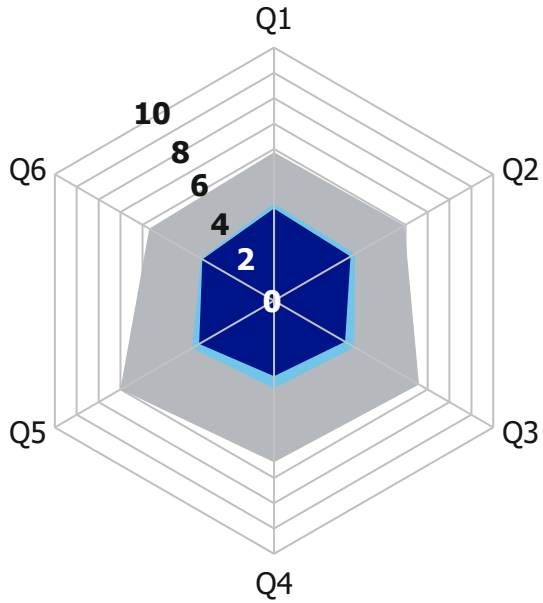


BE COMPLETE (TNFi-IR)

PBO/BKZ 160 mg Q4W
(n=96)



BKZ 160 mg Q4W
(n=204)



Baseline | Week 16 PBO | Week 16 BKZ 160 mg Q4W | Week 52 BKZ 160 mg Q4W

Q1: Fatigue; **Q2:** Neck/back/hip pain; **Q3**: Peripheral arthritis; **Q4:** Enthesitis; **Q5:** Intensity of morning stiffness; **Q6:** Duration of morning stiffness

Mean (SE) CfB in BASDAI Q2 score:	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
Week 16	–0.8 (0.2)	–2.1 (0.2)
Week 52	–2.5 (0.2)	–2.7 (0.2)

BL mean: 6.05 | 5.91

Mean (SE) CfB in BASDAI Q2 score:	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
Week 16	–0.6 (0.3)	–2.3 (0.2)
Week 52	–2.5 (0.3)	–2.5 (0.2)

BL mean: 6.36 | 5.94

Randomized set, in patients with BASDAI total score ≥4 at baseline. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BL: baseline; CfB: change from baseline; MI: multiple imputation; PBO: placebo; Q: question; Q4W: every 4 weeks; SE: standard error; TNFi-IR: inadequate response/intolerance to tumor necrosis factor inhibitors.

CONCLUSIONS:

- Bimekizumab-randomized patients demonstrated rapid improvement in BASDAI scores as early as Week 4.
- Improvement across all BASDAI domains, including neck/back/hip pain, were observed in bimekizumab-randomized patients versus placebo-randomized patients at Week 16, with sustained improvement to Week 52.
- Higher proportions of bimekizumab-randomized patients achieved BASDAI50 relative to placebo-randomized patients at Week 16, and responses were sustained to Week 52.
- Improvements were similar between the BE OPTIMAL and BE COMPLETE studies, demonstrating consistent responses in bDMARD-naïve and TNFi-IR patients.

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

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, BMS, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Incyte, Janssen, Leo Pharma, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB Pharma; **ABG:** Received research/educational grants from AnaptysBio, BMS, Highlights Therapeutics, MoonLake Immunotherapeutics, Novartis, and UCB Pharma (all paid to Mount Sinai School of Medicine); received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres, BMS, Boehringer Ingelheim, DICE Therapeutics, Eli Lilly and Company, Highlights Therapeutics, Janssen, Novartis, Sanofi, UCB Pharma, and Xbiotech; **BI:** Shareholder of AbbVie, GSK, and UCB Pharma; employee of UCB Pharma; **RB, JL, JC:** Employees and shareholders of UCB Pharma; **EGF:** Consultancy/speaker fees from AbbVie, BMS, Celltrion, Eli Lilly and Company, Galapagos, Janssen, MSD, Novartis, Pfizer, and UCB Pharma.

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 this study. The authors acknowledge Heather Edens, PhD, UCB Pharma, Smyrna, GA, USA, for publication coordination, and Aditi Mehta, MSc, Costello Medical, London, UK, for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASDAI50:≥50% improvement in BASDAI total score; bDMARD: biologic disease-modifying antirheumatic drug; TNFi-IR: inadequate response/intolerance to tumor necrosis factor inhibitors.