

# Bimekizumab Impact on Core Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Domains for Patients with Psoriatic Arthritis: 52-Week Results from Four Phase 3 Studies

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## Objective

To report bimekizumab (BKZ) efficacy across the core Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) domains to Week 52 from two phase 3 trials in psoriatic arthritis (PsA), with axial domain outcomes from two phase 3 trials in axial spondyloarthritis (axSpA).

## Background

- The GRAPPA domain-based treatment recommendations for PsA focus on:<sup>1</sup>
  - Six key domains:** peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis, and nail psoriasis
  - PsA-related conditions:** uveitis and inflammatory bowel disease (IBD)
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated superior clinical efficacy versus placebo (PBO) to Week 16 in phase 3 clinical trials of patients with PsA.<sup>2,3</sup>
- In patients with psoriasis, superior skin domain efficacy has been demonstrated versus secukinumab (IL-17A inhibitor), ustekinumab (IL-12/23 inhibitor), and adalimumab (TNF inhibitor [TNFi]).<sup>4-6</sup>

## Methods

- Patients were randomized to receive subcutaneous BKZ 160 mg or PBO every 4 weeks (Q4W) in BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD] naïve patients with PsA), BE COMPLETE (NCT03896581; patients with PsA who had a prior inadequate response or intolerance to TNFi [TNFi-IR]), BE MOBILE 1 (NCT03928704; non-radiographic axSpA) and BE MOBILE 2 (NCT03928743; radiographic axSpA, i.e. ankylosing spondylitis). BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W) to Week 52; data not shown.<sup>2,3,7</sup>
- From Week 16, all PBO-randomized patients received BKZ 160 mg Q4W to Week 52 (PBO/BKZ). BE COMPLETE Week 16 and BE OPTIMAL Week 52 completers could enter BE VITAL (NCT04009499; open-label extension).
- For BE MOBILE 1 and 2, only outcomes related to axial disease are reported here.
- Outcomes are reported by GRAPPA domain. Missing data were imputed using non-responder imputation (NRI) for binary outcomes and multiple imputation (MI) for continuous outcomes, or reported using observed case (OC).

## Results

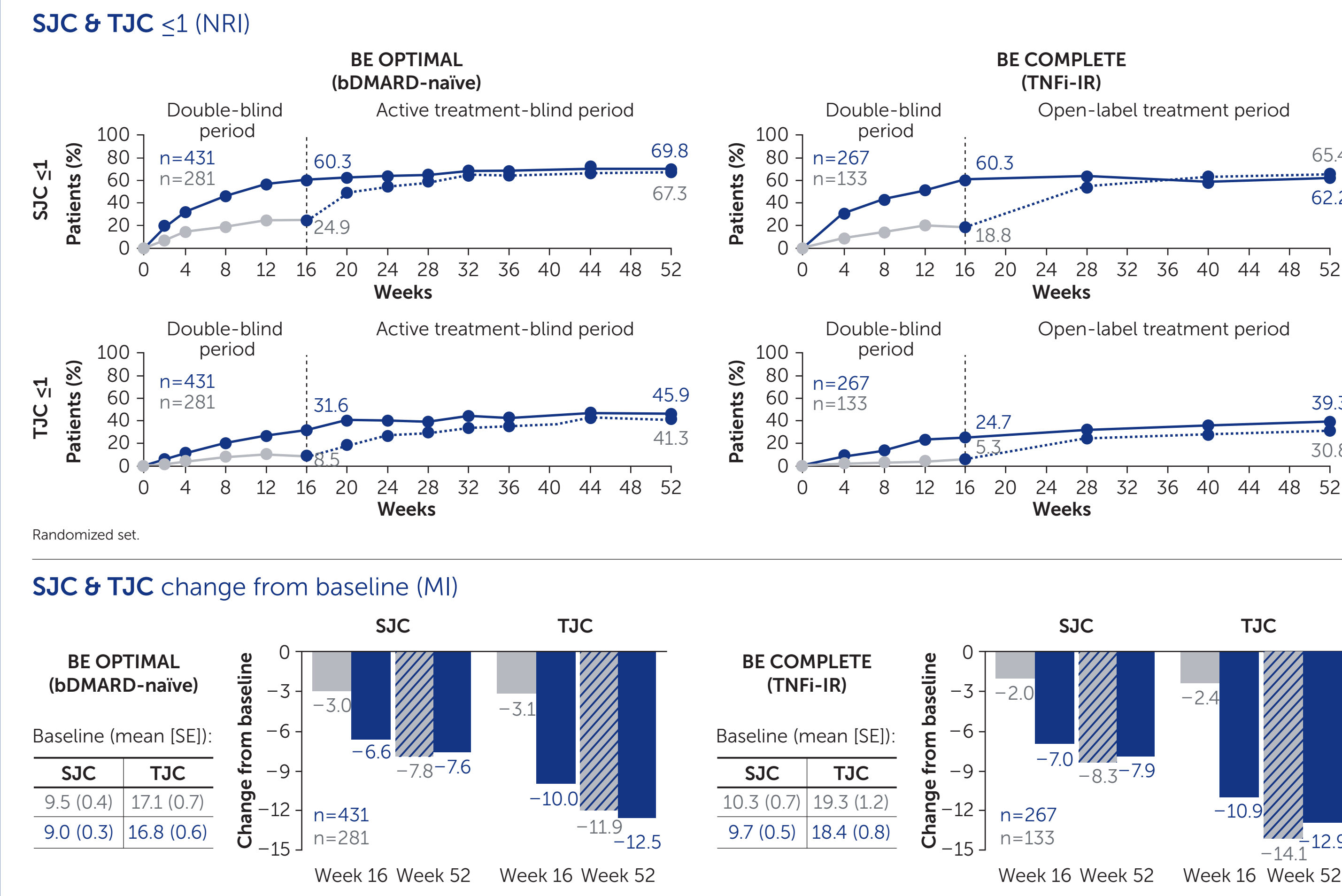
- Week 52 completion was high (BE OPTIMAL: 770/852 [90.4%], BE COMPLETE: 347/400 [86.8%], BE MOBILE 1: 220/254 [86.6%], BE MOBILE 2: 298/332 [89.8%]). Baseline demographics and disease characteristics have been previously reported.<sup>2,3,7</sup>
- Across all GRAPPA domains, improvements from Week 16 were sustained to Week 52 in BKZ-treated patients across all studies. Individual domain responses were generally consistent between bDMARD-naïve and TNFi-IR patients.
- Pooled results from **BE MOBILE 1 and 2** demonstrated BKZ efficacy in patients with axSpA and were suggestive of efficacy for axial disease in PsA.<sup>1</sup>
- Responses were generally consistent between BKZ and PBO/BKZ patients at Week 52. To Week 52, there were no instances of uveitis (BE OPTIMAL; BE COMPLETE). Four (0.5%) patients in BE OPTIMAL had probable or definite adjudicated IBD; no patients had adjudicated IBD in BE COMPLETE.

## Conclusions

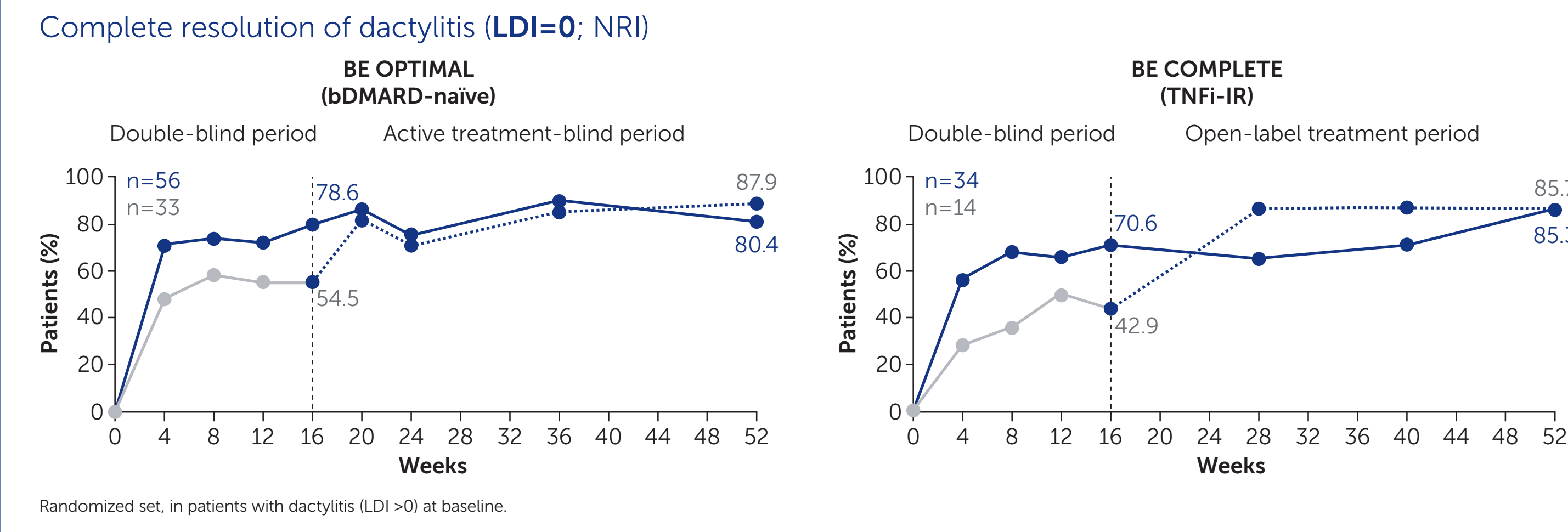
Treatment with bimekizumab resulted in robust and sustained improvements across GRAPPA domains with low rates of IBD and no uveitis to Week 52 for both bDMARD-naïve and TNFi-IR patients with PsA; results from patients with axSpA support efficacy in the axial domain.

PBO/BKZ 160 mg Q4W —●—→ —●—■ BKZ 160 mg Q4W —●—■

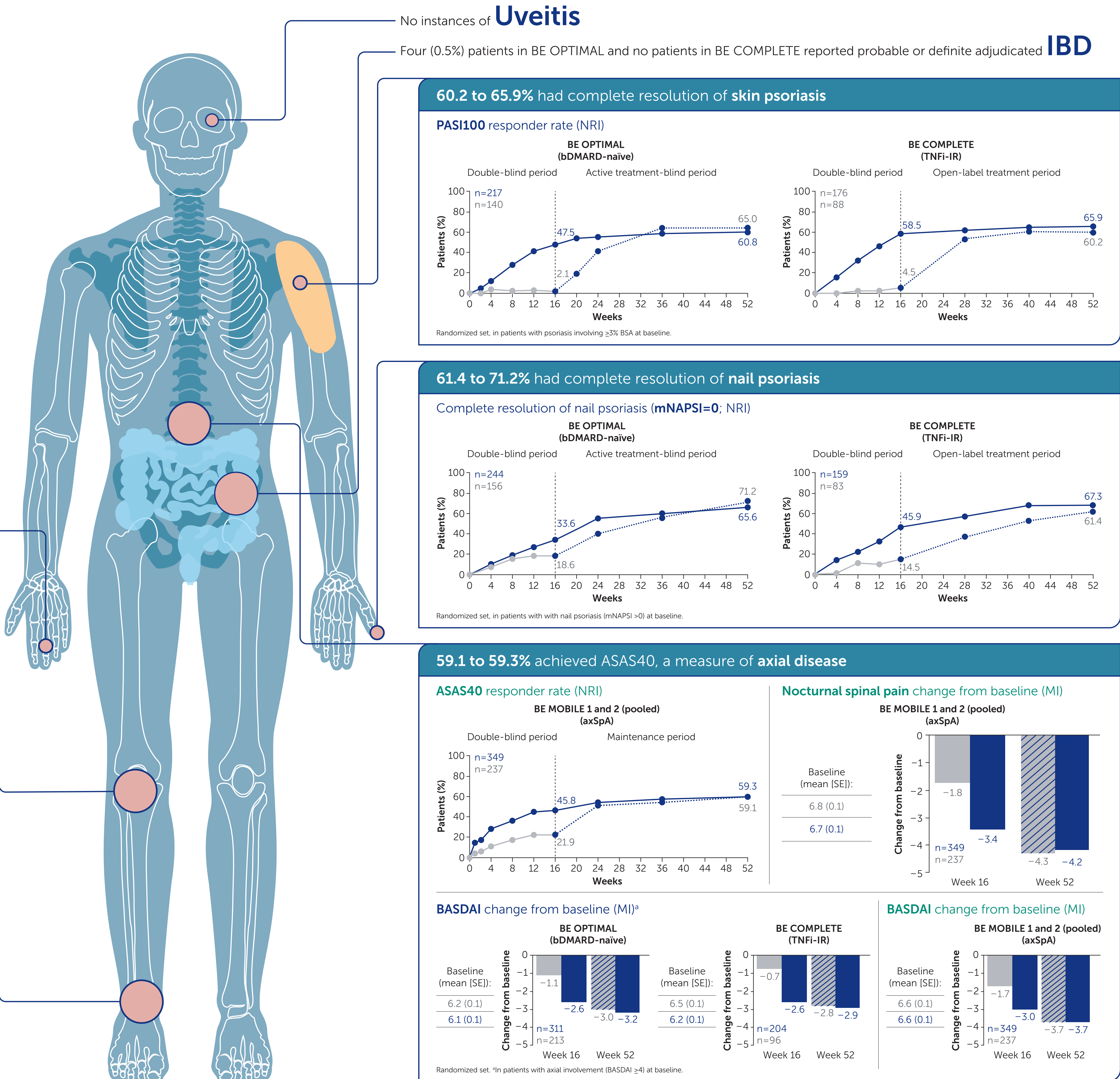
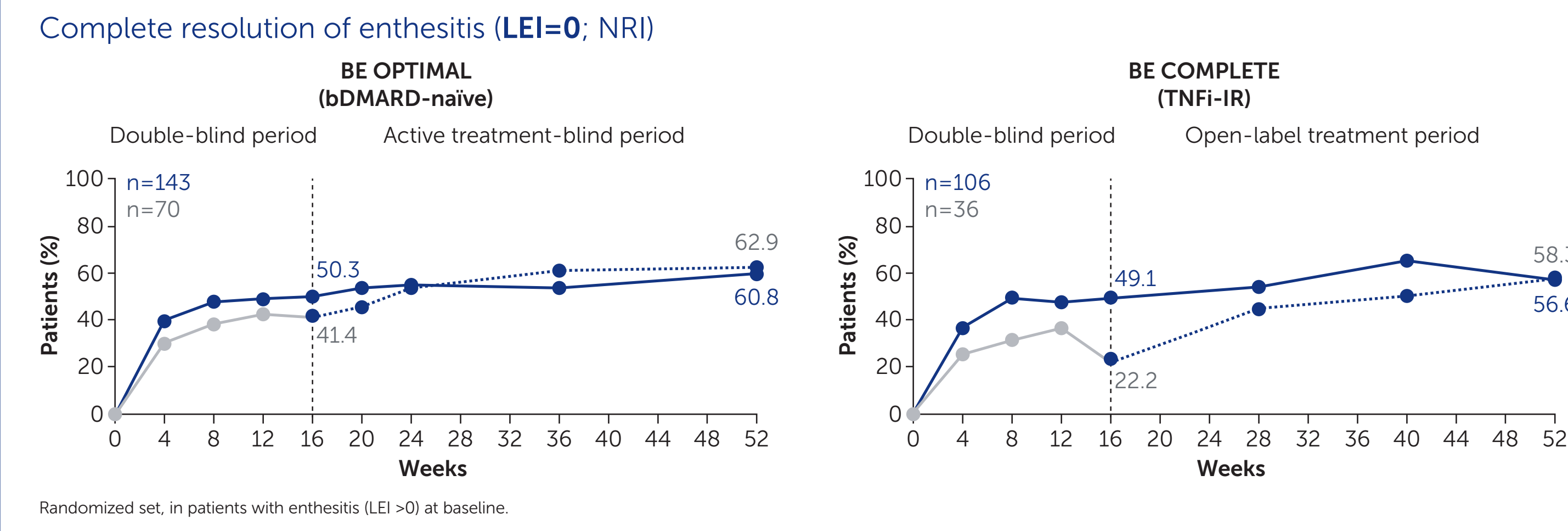
30.8 to 45.9% had TJC ≤1 and 62.2 to 69.8% had SJC ≤1, measures of peripheral arthritis



80.4 to 87.9% had complete resolution of dactylitis



56.6 to 62.9% had complete resolution of enthesitis



**ASAS40:** Assessment in Spondyloarthritis International Society 40% improvement; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **GRAPPA:** Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; **IBD:** inflammatory bowel disease; **IL:** interleukin; **LDI:** Leeds Dactylitis Index; **LEI:** Leeds Enthesitis Index; **MI:** multiple imputation; **mNAPSI:** modified Nail Psoriasis Severity Index; **NRI:** non-responder imputation; **OC:** observed case; **PASI100:** 100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PsA:** psoriatic arthritis; **Q2W:** every two weeks; **Q4W:** every four weeks; **SE:** standard error; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi:** tumor necrosis factor inhibitor; **TNFi-IR:** prior inadequate response or intolerance to TNFi.

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**References:** <sup>1</sup>Coates LC. Nat Rev Rheumatol 2022;18:465-79; <sup>2</sup>McInnes IB. Lancet 2023;401:25-37; <sup>3</sup>Merola JF. Lancet 2023;401:38-48; <sup>4</sup>Reich K. N Engl J Med 2021;385:142-52; <sup>5</sup>Reich K. Lancet 2021;397:487-98; <sup>6</sup>Warren RB. N Engl J Med 2021;385:130-41; <sup>7</sup>van der Heijde D. Ann Rheum Dis 2023;82:515-26. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **JFM, RJM, AD, BI, CF, RB, JC, LCC.** Drafting of the publication, or reviewing it critically for important intellectual content: **CF, JFM, RJM, AD, BI, CF, RB, JC, LCC.** Final approval of the publication: **CF, JFM, RJM, AD, BI, CF, RB, JC, LCC.** **Author Disclosures:** **CF:** Employee of UCB Pharma; **JFM:** Consultant and/or investigator for AbbVie, Amgen, Astra-Zeneca, Biogen, BMS, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen, Leo Pharma, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB Pharma; **RJM:** Research grants from AbbVie, Acelyrin, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Gilead, Janssen, Novartis, Pfizer, Sun Pharma, and UCB Pharma; consultancy fees from AbbVie, Acelyrin, Aclaris, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly and Company, Galapagos, Gilead, GSK, Janssen, Moonlake Pharma, Novartis, Pfizer, and UCB Pharma; **AD:** Speaker for Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma; **BI:** Speaker for Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma; **CF:** Employee and shareholder of UCB Pharma; **RB:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB Pharma; consultant for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Domain, Eli Lilly, Galapagos, Gilead, Janssen, Moonlake Pharma, Novartis, Pfizer, and UCB Pharma; speaking fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Medac, Novartis, Pfizer, and UCB Pharma; **JC:** Employee and shareholder of UCB Pharma; **LCC:** Grants/research support from AbbVie, Amgen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Medac, Novartis, Pfizer, and UCB Pharma; **BS:** Shareholder of AbbVie, GSK, and UCB Pharma. **Acknowledgments:** 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, UCB Publications Manager, PhD, UCB Pharma, Smyrna, Georgia, USA, for publication coordination, Jason Ellis, UCB Pharma, Slough, UK, and Natasha de Peyeracave, UCB Pharma, Brussels, Belgium for their contributions to abstract development, Laura Mawdsley, MSc, Costello Medical, Cambridge, UK for medical writing, Shimaila Siddiqui, MSc, MBA, Costello Medical, Manchester, UK for editorial assistance, and the Costello Medical Creative team for design support. These studies were funded by UCB Pharma. All costs associated with development of this presentation were funded by UCB Pharma.