Bimekizumab treatment resulted in long-term maintenance of complete clinical resolution across skin, joint, and nail domains in patients with active psoriatic arthritis: 3-year results from two phase 3 studies

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Objective

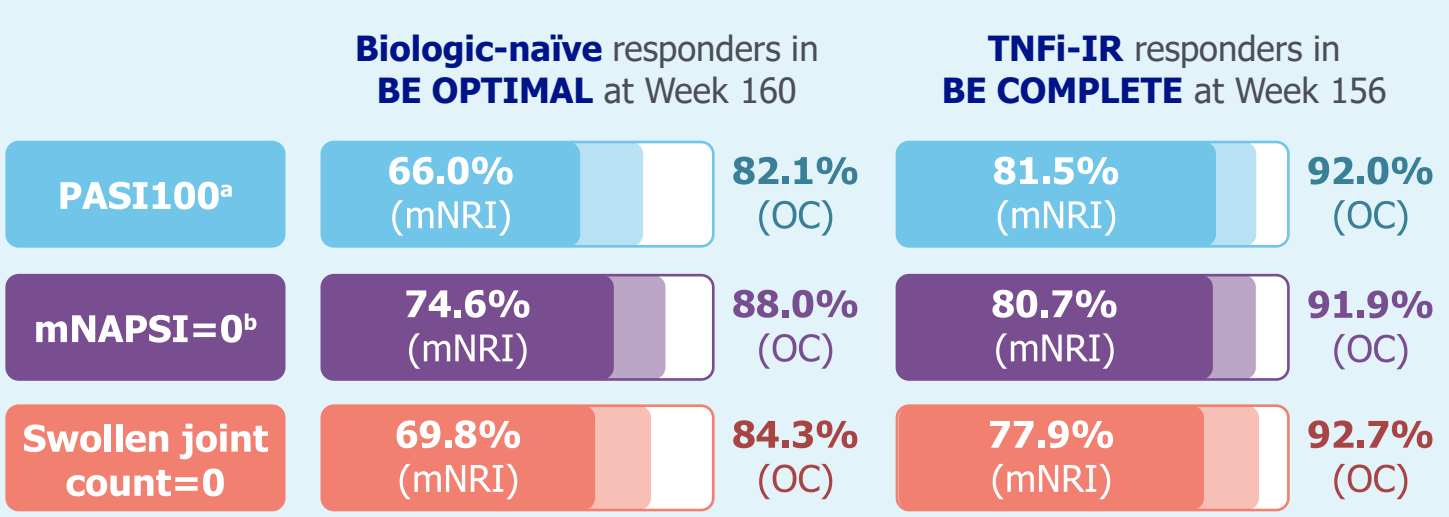
- To assess the **long-term maintenance** of clinically relevant, **complete resolution responses** across different disease domains to **3 years** in **bimekizumab**-treated patients with **psoriatic arthritis** (PsA) who were either biologic disease-modifying antirheumatic drug-naïve (**biologic-naïve**) or had prior intolerance/inadequate response to tumor necrosis factor inhibitors (**TNFi-IR**).

Background

- Achieving complete resolution across the domains of PsA, including skin, nails, and joints, is a stringent treatment goal.[1,2]
- Therefore, it is important to assess the impact of treatment on long-term clinical resolution.
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.

Summary

High proportions of **patients with PsA** who **responded to BKZ at Week 16/24/28** demonstrated **maintenance of complete resolution at 3 years across skin**, **nail**, **and joint domains**. These proportions were generally **consistent across biologic-naïve and TNFi-IR patients** (mNRI; OC).



[a] In patients with baseline psoriasis affecting ≥3% body surface area; **[b]** In patients with nail involvement (mNAPSI >0) at baseline. **1.** Coates LC et al. Nat Rev Rheumatol 2022;18:465–79; **2.** Gossec L et al. Ann Rheum Dis 2024;83:706–19. **ACR50**: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ**: bimekizumab; **IL**: interleukin; **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; **PsA**: psoriatic arthritis; **SJC:** swollen joint count; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

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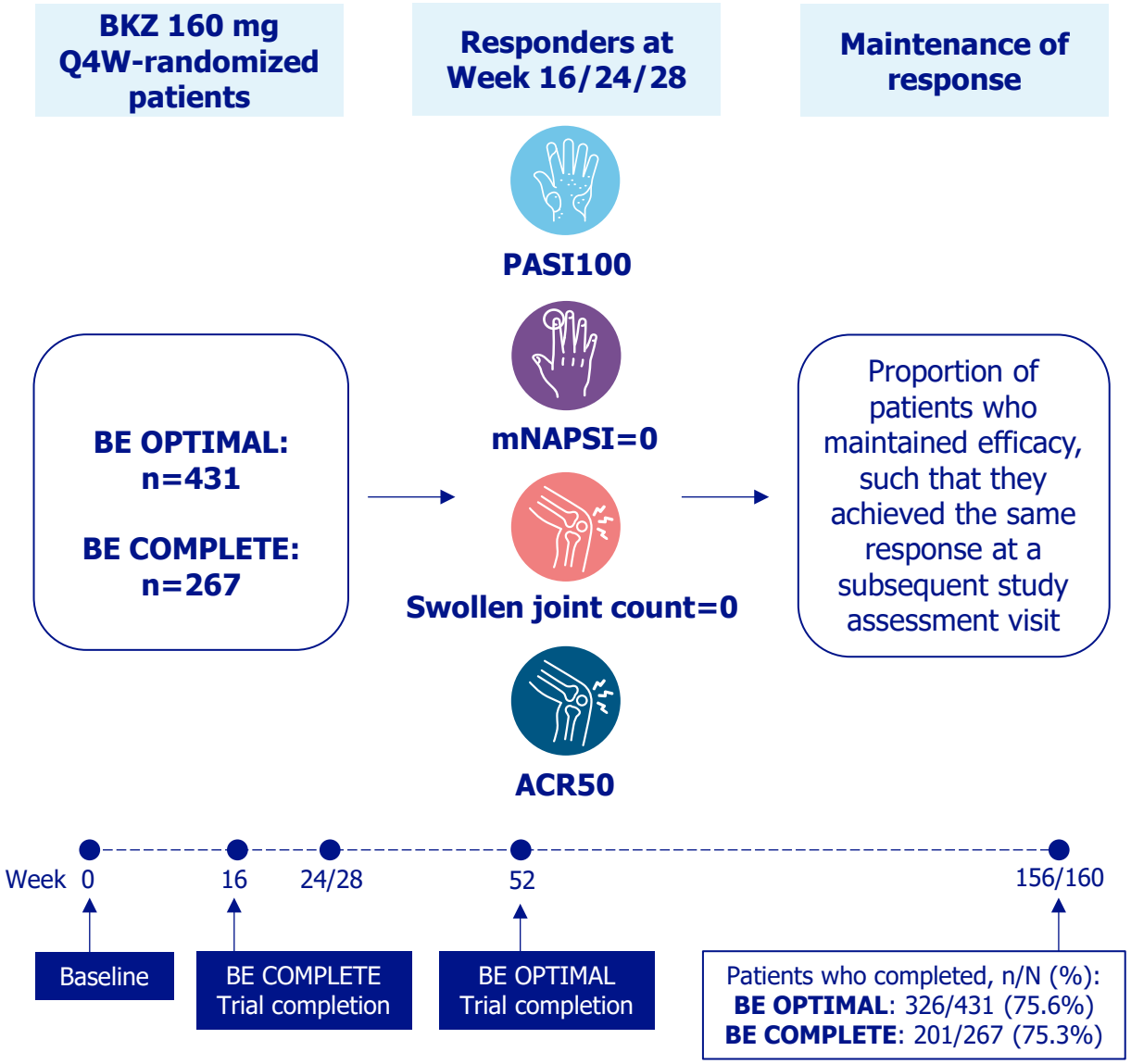
Maintenance of Response Analysis Design



Methods

- Post hoc analysis of BE OPTIMAL (biologic-naïve) and BE COMPLETE (TNFi-IR), which assessed BKZ 160 mg Q4W in patients with PsA; patients randomized to placebo switched to BKZ at Week 16.[1–3] BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W; data not shown).
- BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers could enter BE VITAL (open-label extension) where all patients received BKZ.[3]
- **Maintenance of complete clinical resolution** is reported to Week 160 in BE OPTIMAL and Week 156 in BE COMPLETE for BKZ-randomized patients who achieved one of the following outcomes at Week 16 or Week 24/28:
  - **PASI100** (Week 16), in patients with psoriasis (≥3% body surface area) at baseline
  - Resolution of nail psoriasis, **mNAPSI=0** (Week 24/28), in patients with nail involvement (mNAPSI >0) at baseline
  - **Swollen joint count=0** (Week 16)
  - **ACR50** (Week 16); ACR50 was the primary endpoint of BE OPTIMAL and BE COMPLETE and is used as a measure of clinically meaningful improvement in disease activity
- The later timepoint of Week 24/28 was used for mNAPSI=0 due to the longer time required to show a response in nail psoriasis.
- When assessing maintenance of response, only Week 16/24/28 and the second timepoint are considered (i.e., response, or lack thereof, at intermediate visits is not considered).
- Data are reported using modified non-responder imputation (mNRI)[a] or as observed case (OC).

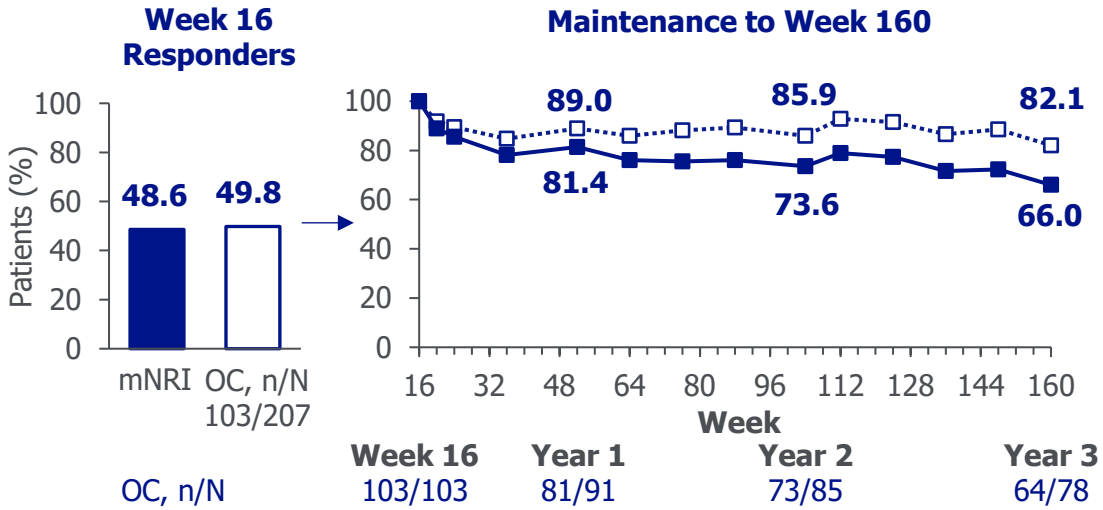
Completion rates are reported to Week 160 in BE OPTIMAL and Week 156 in BE COMPLETE. **[a]** mNRI considered all visits following discontinuation due to adverse events or lack of efficacy as non-response; all other missing data were imputed with MI and the response derived from the imputed values. **1.** 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; **MI**: multiple imputation; **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; **PsA:** psoriatic arthritis; **Q2W**: every 2 weeks; **Q4W**: every four weeks; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

Maintenance of Skin and Nail Efficacy Responses to 3 Years in Week 16/24/28 Responders (mNRI, OC)

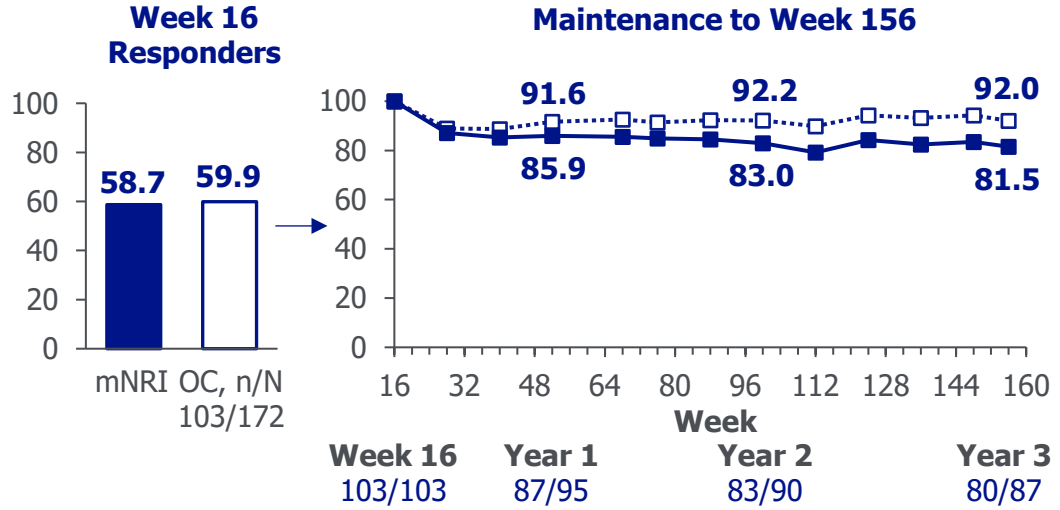
BE OPTIMAL (biologic-naïve)
BKZ 160 mg Q4W (n=431)

BE COMPLETE (TNFi-IR)
BKZ 160 mg Q4W (n=267)

PASI100[a]

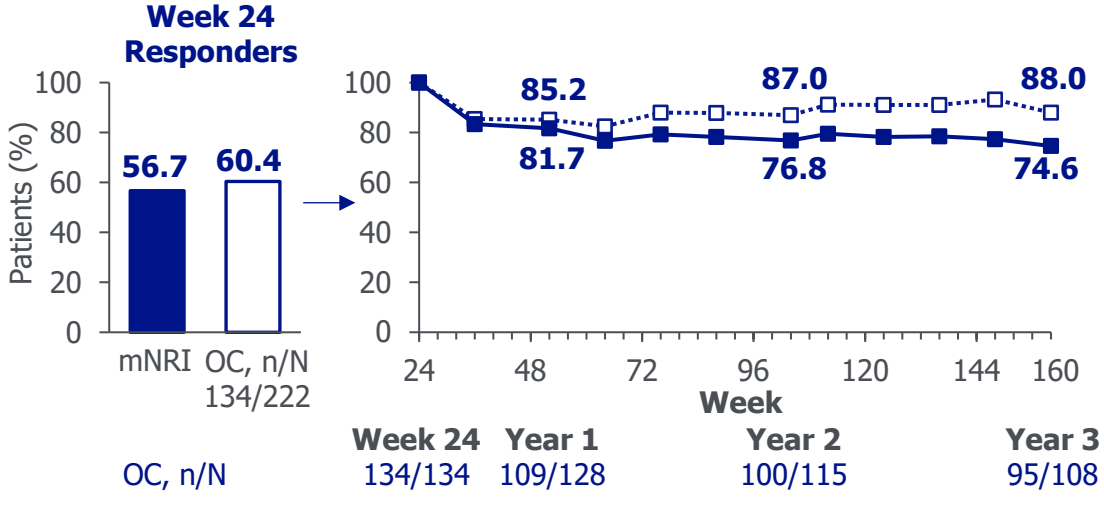


OC, n/N	Week 16	Year 1	Year 2	Year 3
	103/103	81/91	73/85	64/78

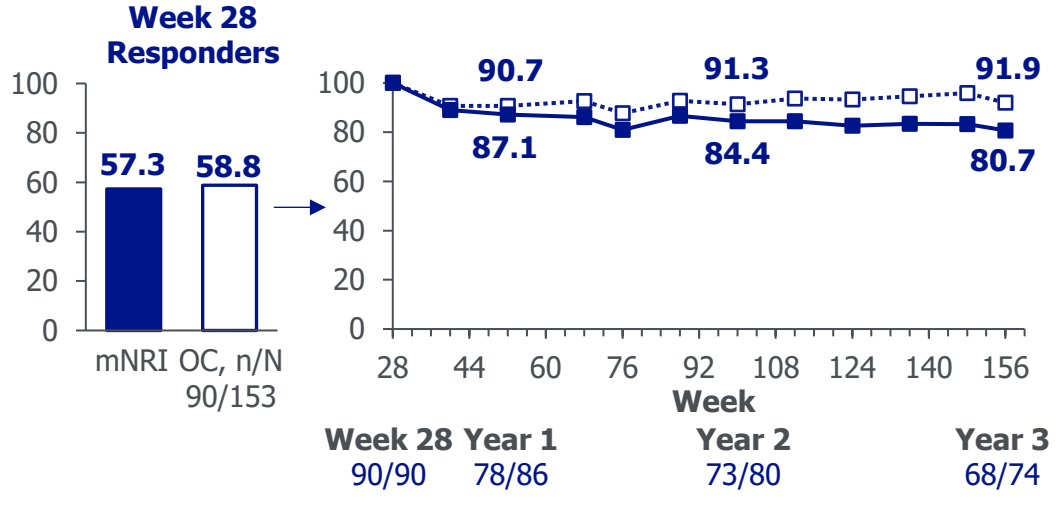


	Week 16	Year 1	Year 2	Year 3
	103/103	87/95	83/90	80/87

mNAPSI=0[b]



OC, n/N	Week 24	Year 1	Year 2	Year 3
	134/134	109/128	100/115	95/108



	Week 28	Year 1	Year 2	Year 3
	90/90	78/86	73/80	68/74

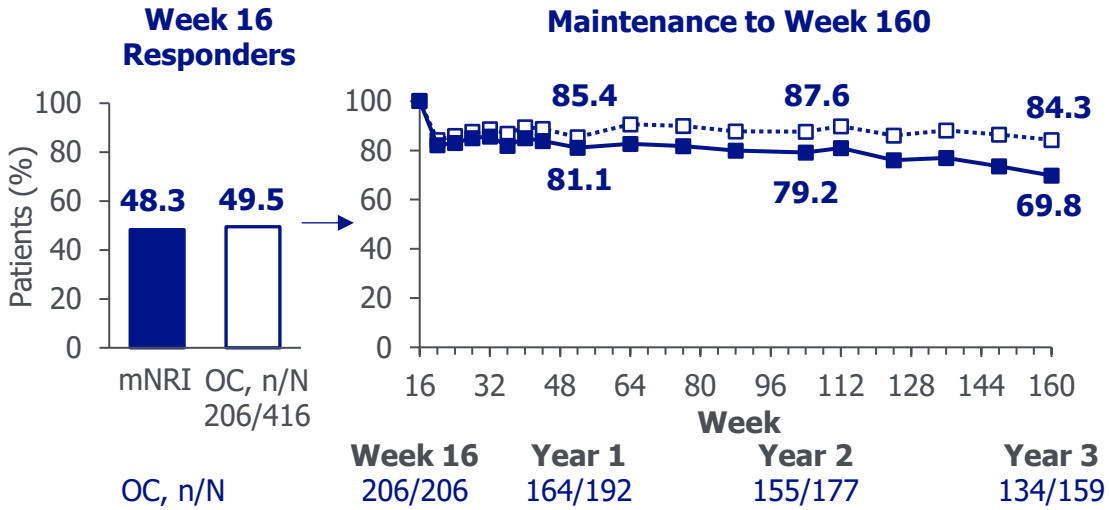
mNRI OC

Randomized set. Data reported using mNRI do not have an associated n (number of responders) value because the statistic is a pooled mean proportion across the multiple imputations. **[a]** In patients with psoriasis (≥3% body surface area) at baseline (BE OPTIMAL: n=217; BE COMPLETE: n=176); **[b]** In patients with nail involvement (mNAPSI >0) at baseline (BE OPTIMAL: n=244; BE COMPLETE: n=159). **BKZ**: bimekizumab; **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; **Q4W**: every four weeks; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

Maintenance of Joint and Clinical Efficacy Responses to 3 Years in Week 16 Responders (mNRI, OC)

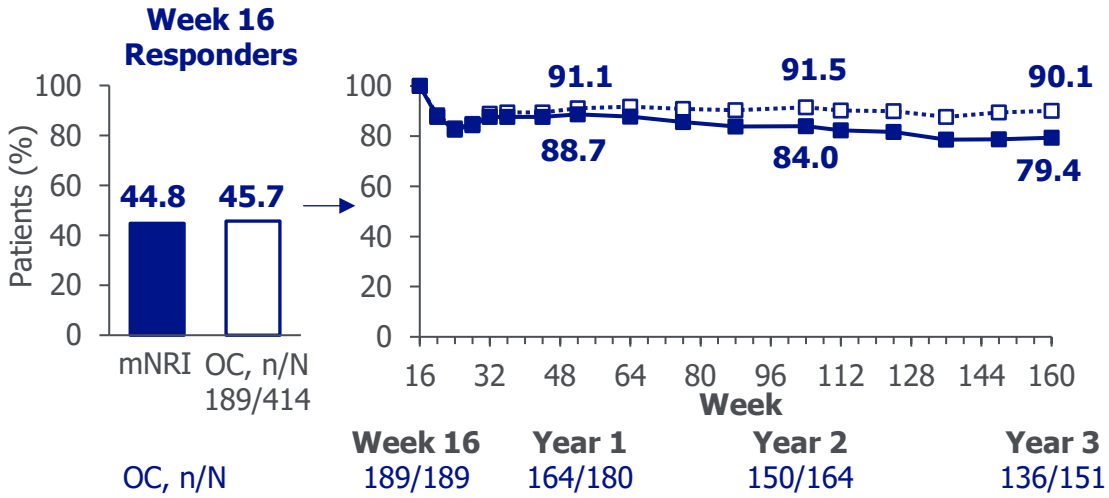
BE OPTIMAL (biologic-naïve)
BKZ 160 mg Q4W (n=431)

Swollen joint count=0[a]



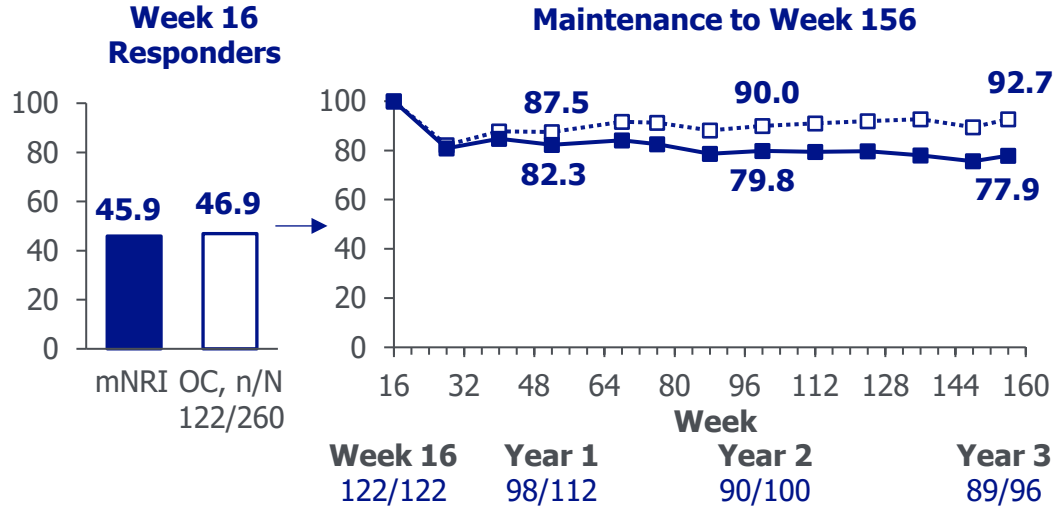
OC, n/N	Week 16	Year 1	Year 2	Year 3
	206/206	164/192	155/177	134/159

ACR50

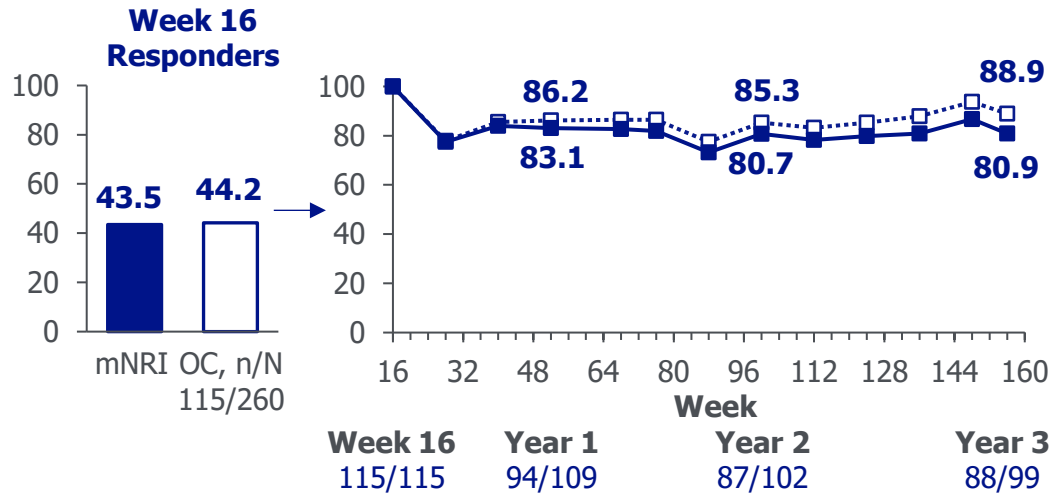


OC, n/N	Week 16	Year 1	Year 2	Year 3
	189/189	164/180	150/164	136/151

BE COMPLETE (TNFi-IR)
BKZ 160 mg Q4W (n=267)



Week 16	Year 1	Year 2	Year 3
122/122	98/112	90/100	89/96



Week 16	Year 1	Year 2	Year 3
115/115	94/109	87/102	88/99

mNRI OC

Randomized set. Data reported using mNRI do not have an associated n (number of responders) value because the statistic is a pooled mean proportion across the multiple imputations. **[a]** Resolution of swollen joint count (SJC=0) is assessed in 66 joints.
ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; **BKZ**: bimekizumab; **mNRI**: modified non-responder imputation; **OC**: observed case; **Q4W**: every four weeks; **TNFi-IR**: prior inadequate response or intolerance to tumor necrosis factor inhibitors.

Conclusions

Bimekizumab resulted in high rates of maintenance of clinical resolution across skin, nail, and joint domains at 3 years, in patients with PsA who achieved resolution at Week 16/24/28.

Findings were generally consistent across biologic-naïve and TNFi-IR patients up to 3 years.

These findings support bimekizumab as a valuable treatment option for patients with PsA, reinforcing its sustained, high-level efficacy regardless of prior treatment experience.

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