

Achieving Early Clinical Response was Associated with Cumulative Benefits on Disease Impact up to 2 Years in Patients with Active Psoriatic Arthritis Treated with Bimekizumab

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Objective

To examine the association between clinical responses at Week 16 with bimekizumab treatment and the subsequent cumulative benefit on patient-reported disease impact in patients with psoriatic arthritis (PsA) up to 2 years.

Background

- PsA negatively impacts health-related quality of life.¹ The PsA Impact of Disease-12 (PsAID-12) questionnaire assesses physical, social, and psychological impacts of PsA.²
- Achieving high treatment targets and reducing long-term disease impact are important treatment goals for the management of patients with PsA.³
- Bimekizumab, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained reductions in disease impact in patients with active PsA up to 2 years.⁴

Methods

- Post hoc analysis of BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve) and BE COMPLETE (NCT03896581; tumor necrosis factor inhibitor [TNFi]-IR), which assessed subcutaneous bimekizumab 160 mg every 4 weeks in patients with PsA.⁴
- BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers could enter BE VITAL (NCT04009499; open-label extension), in which all patients received bimekizumab.⁴
- Only bimekizumab-randomized patients were included in this analysis; patients were grouped into responders vs non-responders, based on achievement at Week 16 of $\geq 50\%$ improvement from baseline in American College of Rheumatology (ACR) criteria (ACR50), minimal disease activity (MDA), or swollen joint count (SJC) resolution (SJC=0), a clinical measure of reduced inflammation.
- Cumulative benefit on disease impact, assessed using time in PsAID-12 remission/low disease activity (REM/LDA; total score ≤ 1.95), was estimated using area under the curve (AUC) to Week 104 (728 days) in BE OPTIMAL and Week 88 (616 days) in BE COMPLETE (Figure 1).
- Missing data were imputed using non-responder imputation (NRI).

Results

- Overall, 359/431 (83.3%) bDMARD-naïve and 221/267 (82.8%) TNFi-IR bimekizumab-randomized patients completed Week 104/88.
- For bDMARD-naïve and TNFi-IR patients respectively, 189/431 (43.9%) and 115/267 (43.1%) achieved ACR50, 194/431 (45.0%) and 117/267 (43.8%) achieved MDA, and 206/431 (47.8%) and 122/267 (45.7%) achieved SJC=0 at Week 16.
- At Week 16, a greater proportion of patients who achieved stringent response criteria (ACR50, MDA, or SJC=0) also achieved PsAID-12 REM/LDA vs patients who were non-responders at Week 16 (Figure 2).
- PsAID-12 REM/LDA achievement rates were sustained up to 2 years in Week 16 responders, and were higher than in non-responders.
- Week 16 responders spent a greater number of days in a favorable disease state, as estimated by a higher total AUC_{0-104/88} for PsAID-12 REM/LDA response, compared with non-responders.
- bDMARD-naïve/TNFi-IR patients who achieved ACR50, MDA, or SJC=0 at Week 16 with bimekizumab treatment experienced approximately 9.6/7.3, 10.4/9.6, or 3.5/5.2 more cumulative months in PsAID-12 REM/LDA than those who did not achieve treatment response, out of a total 24/20-month period.

Conclusions

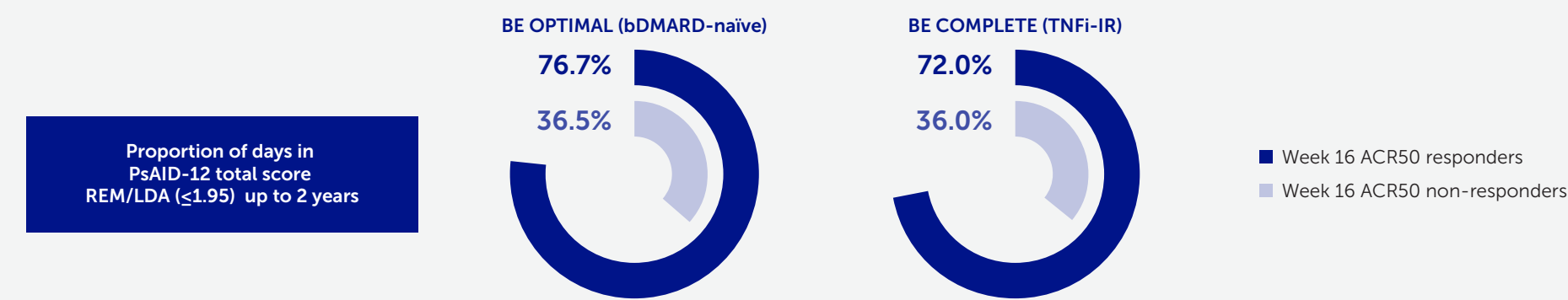
In bDMARD-naïve and TNFi-IR patients with PsA treated with bimekizumab, achieving a stringent clinical response at Week 16 was associated with numerically greater cumulative benefits on patient-reported disease impact over 2 years.

Summary

Control of inflammation to reduce symptoms and disease impact is an important treatment goal for patients with PsA.

Cumulative days of reduced disease impact up to 2 years were assessed in patients with PsA at baseline using PsAID-12 and AUC analyses.

Patients who achieved ACR50 at Week 16 had a greater proportion of days in REM/LDA for PsAID-12 total score (≤ 1.95) up to 2 years of bimekizumab treatment vs non-responders.^a

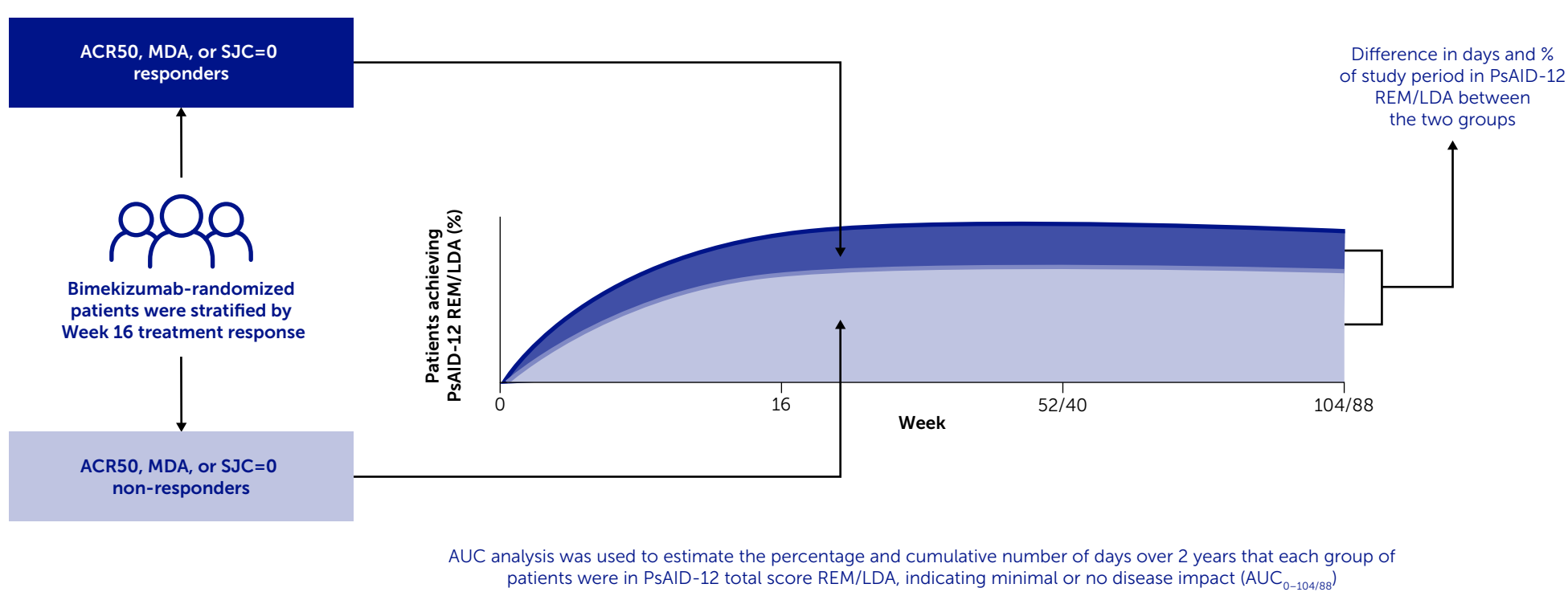


Similar trends were observed in patients who achieved MDA or resolution of SJC (SJC=0), a clinical measure of reduced inflammation, at Week 16.

Achievement of ACR50, MDA, or SJC=0 with bimekizumab treatment at Week 16 was associated with numerically greater cumulative benefits on patient-reported disease impact up to 2 years in patients with PsA.

[a] Values reported using NRI; estimated percentage and cumulative number of days in PsAID-12 REM/LDA out of the total number of days in the study period were manually calculated based on AUC_{0-104/88} data.

Figure 1 Method for estimating cumulative disease impact based on treatment response

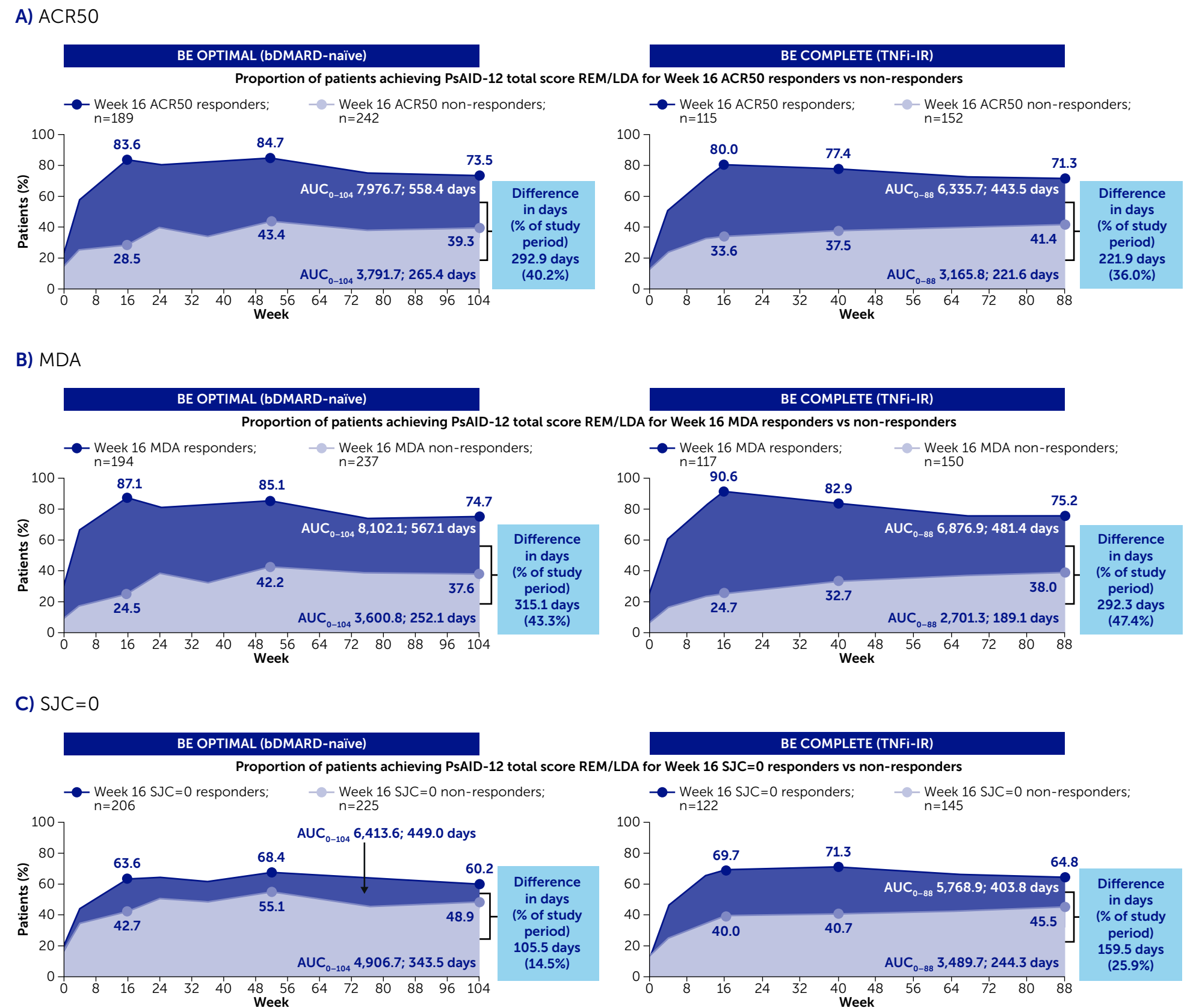


Week 16 treatment responders (ACR50, MDA, or SJC=0) imputed using NRI. AUC analysis was used to calculate the cumulative number of days in PsAID-12 REM/LDA (total score ≤ 1.95); the cumulative number of days was used to calculate the percentage of study period based on the total study duration in days.

ACR: American College of Rheumatology; ACR50: $\geq 50\%$ improvement from baseline in ACR response criteria; AUC: area under the curve; bDMARD: biologic disease-modifying antirheumatic drug; IL: interleukin; LDA: low disease activity; MDA: minimal disease activity; NRI: non-responder imputation; PsA: psoriatic arthritis; PsAID-12: PsA Impact of Disease-12; REM: remission; SJC: swollen joint count; TNF: tumor necrosis factor; TNFi-IR: prior inadequate response or intolerance to TNF inhibitors.

References: ¹Ogdie A, et al. RMD Open 2020;6:e001321. ²Coates LC, et al. Nat Rev Rheumatol 2022;18:465-79. ³Orbai A-M, et al. J Rheumatol 2019;46:990-5. ⁴Mease PJ, et al. Rheumatol Ther 2024;11:1363-82. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **WT, JFM, IBM, KBG, RBW, PH, JL, HE, BI, PV, LG.** Drafting of the publication, or reviewing it critically for important intellectual content: **WT, JFM, IBM, KBG, RBW, PH, JL, HE, BI, PV, LG.** Final approval of the publication: **WT, JFM, IBM, KBG, RBW, PH, JL, HE, BI, PV, LG.** Publication coordination: **HE.** **Author Disclosures:** Research grants, consulting fees, speaking fees and/or honoraria from AbbVie, Amgen, BMS, Celgene, Eli Lilly and Company, GSK, Janssen, MSD, Novartis, Ono Pharma, Pfizer, Takeda, and UCB. **JFM:** Consultant and/or investigator for AbbVie, Amgen, AstraZeneca, Biogen, BMS, Boehringer Ingelheim, Dermavant, Eli Lilly and Company, Incyte, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. **IBM:** Consulting fees and honoraria from AbbVie, AstraZeneca, BMS, Boehringer Ingelheim, Caballero, Causeway Therapeutics, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, and UCB; research support from Boehringer Ingelheim, BMS, Celgene, Janssen, Novartis, and UCB. **KBG:** Consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, BMS, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, BMS, Celgene, Eli Lilly and Company, Janssen, Novartis, and UCB. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, BMS, Celgene, DICE Therapeutics, Eli Lilly and Company, Galderma, GSK, Immunocore, Janssen, LEO Pharma, Meiji Pharma, 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. **PH, JL:** Employee and shareholder of UCB. **HE:** Employee of UCB; shareholder of Abbott and UCB. **BI:** Employee of UCB; shareholder of AbbVie, GSK, and UCB. **PV:** Speaking fees from AbbVie, Boehringer Ingelheim, J&J, Pfizer, and UCB. **LG:** Research grants from AbbVie, Eli Lilly and Company, Novartis, and UCB; consulting fees from AbbVie, AltiSigma, Amgen, BMS, Celltrion, J&J, Eli Lilly and Company, MoonLake Immunotherapeutics, Nordic Pharma, Novartis, Oruka, Pfizer, Stada, Takeda, and UCB; non-financial support from AbbVie, Amgen, Biogen, BMS, Celltrion, J&J, Eli Lilly and Company, Pfizer, and UCB. **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 Sona Popat, BA, Costello Medical, London, UK for medical writing and editorial assistance and the Costello Medical Creative team for design support. These studies were funded by UCB. All costs associated with development of this presentation were funded by UCB.

Figure 2 Achievement of stringent response criteria at Week 16 was associated with a greater percentage and cumulative number of days in PsAID-12 REM/LDA up to 2 years vs non-responders (NRI)



Patients who did not achieve ACR50, MDA, or SJC=0 at Week 16 were classified as non-responders. Estimated percentage (%) and cumulative number of days in PsAID-12 REM/LDA (total score ≤ 1.95) out of the total number of days in the study period were manually calculated based on AUC_{0-104/88} data.

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