# Effect of Bimekizumab on Symptoms and Impact of Disease in Patients with Psoriatic Arthritis over 3 Years: Results from BE ACTIVE

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RHEUMATOLOGY

Rheumatology 2023;62:617–628
https://doi.org/10.1093/rheumatology/keac353
Advance access publication 5 July 2022

Original article

# Effect of bimekizumab on symptoms and impact of disease in patients with psoriatic arthritis over 3 years: results from BE ACTIVE

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## Abstract

**Objectives.** Evaluate effects of long-term bimekizumab treatment on patient-reported outcome (PRO) measures, symptoms and the impact of PsA on patients.

**Methods.** Patients with active PsA were enrolled into BE ACTIVE, a 48-week randomised controlled trial (NCT02969525). After Week 48, patients could enter a 104-week open-label extension (NCT03347110), receiving bimekizumab 160 mg every four weeks. PRO measures assessed included arthritis pain visual analogue scale (VAS), PsA Impact of Disease (PsAID)-9, 36-Item Short Form Survey (SF-36) and HAQ-Disability Index (HAQ-DI). Results were analysed as mean (S.E.M.) changes from baseline (CfB) from Week 0 to the end of the open-label extension (3 years) and as percentage of patients reaching patient-acceptable symptom state (PASS) for global impact (PsAID-9 total score $\leq$4) and normal function (HAQ-DI total score $<$0.5). Non-responder imputation was applied to missing binary outcomes.

**Results.** In 206 patients (mean age 49.3 years, 51.0% male), completion rate was high; 161 (78.2%) patients completed Week 152. Bimekizumab treatment was associated with long-term sustained improvements in pain [arthritis pain VAS CfB; Week 48: −29.9 (1.9); Week 152: −32.0 (1.9)] and fatigue [PsAID-9 fatigue CfB; −2.4 (0.2); −2.7 (0.2)]. High percentages of patients achieved acceptable symptom state (PsAID-9 PASS: 75.2%; 65.0%) and normalised function (HAQ-DI $<$0.5: 49.0%; 46.1%). Improvements in patient global assessment and SF-36 Physical Component Summary were also sustained.

**Conclusions.** Bimekizumab treatment was associated with long-term sustained improvements in pain and fatigue, reducing overall impact of PsA on patients. Physical function and quality of life improved up to 3 years.

**Trial registration.** ClinicalTrials.gov, https://clinicaltrials.gov, NCT02969525, NCT03347110.

CLINICAL SCIENCE

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Submitted 22 March 2022; accepted 14 June 2022

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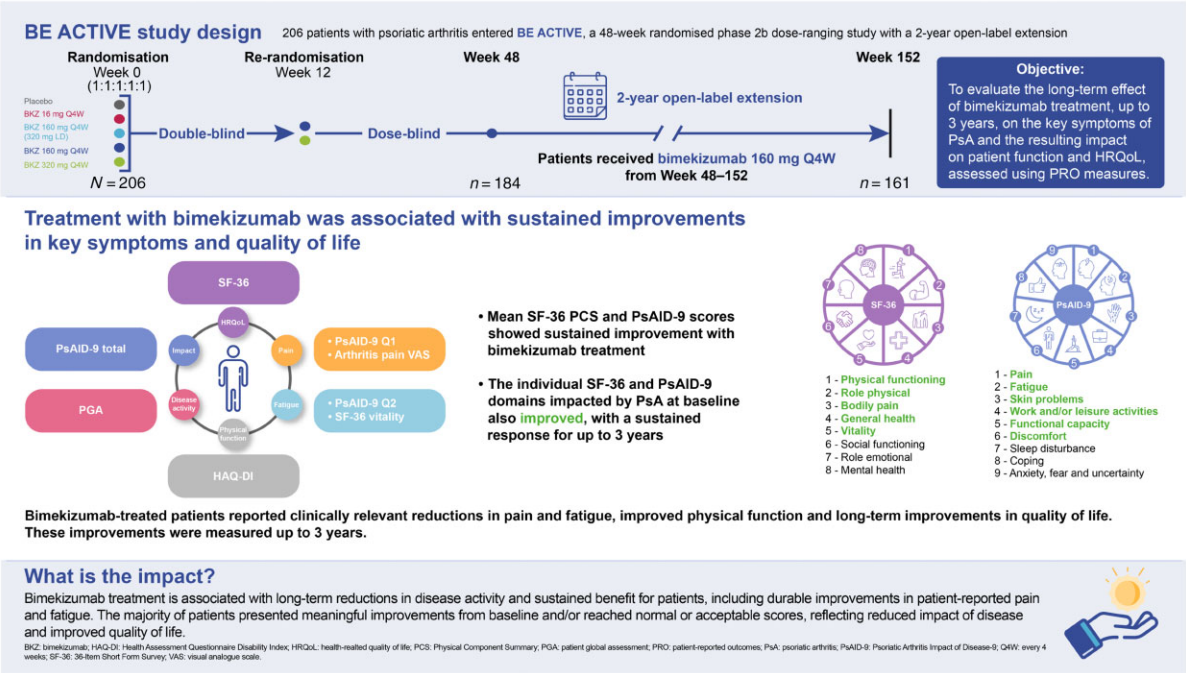
## Graphical Abstract




**Key words:** psoriatic arthritis, bimekizumab, patient-reported outcome measures, physical function, fatigue, pain

**Rheumatology key messages**

- Bimekizumab treatment resulted in sustained reductions in PsAID-9 pain and fatigue of 2–3 points.
- High percentages of patients had acceptable symptom states and normalised function over 3 years.
- Long-term bimekizumab treatment improved the symptoms of PsA, resulting in sustained improvements in HRQoL.

## Introduction

PsA is associated with both short- and long-term impacts on a patient's quality of life, particularly when compared with general populations [1–6]. Several patient-reported outcome (PRO) measures, including generic and PsA-specific assessments, have been used to evaluate the negative impact in terms of symptom severity and the resulting change in patient function, and overall health-related quality of life (HRQoL) [1, 7, 8]. These measures are often used in clinical trials, providing patients with a means of assessing their disease state, as well as the effectiveness of their treatment [8], and providing clinicians with valuable information for monitoring a patient's disease burden [9].

Pain and fatigue are frequently reported to significantly impact patients and both contribute to reduced physical function and HRQoL [3–5, 10–14]. However, these concepts are complex: there are several types of pain and discomfort that present in various locations, as well as different aspects of fatigue such as tiredness, lack of energy, and mental fatigue, which may be a direct result of the disease or due to indirect factors such as a lack of sleep [15]. Furthermore, patients often experience skin itchiness, redness or scaling that increases their pain burden and the psychological impact of PsA [2, 15, 16]. As a result of this complexity, a single, unidimensional score may underrepresent the true burden of PsA on patients [9, 15]. Therefore, multiple PRO measures are required to assess these symptoms and the impact of PsA on patient function and HRQoL. This holistic approach enables a detailed and comprehensive understanding of treatment efficacy from a patient perspective, accounting for the most burdensome aspects of the disease.

The introduction of multiple biologic and targeted synthetic therapies has greatly improved clinical outcomes

and HRQoL for patients with PsA [6, 17]. Despite this, there may be a lack or loss of response from current treatments in some patients, leading to continued pain and fatigue, reduced function and diminished HRQoL [6, 10–12]. Therefore, there is a need for long-term data that allow evaluation of sustained responses. These data should capture the primary treatment goal of maximising HRQoL via reduction of symptoms such as pain and fatigue, as well as improvement in physical function [17, 18].

Bimekizumab is a humanised monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A. Treatment with bimekizumab has resulted in rapid and sustained improvements in joint and skin outcomes in patients with PsA; furthermore, bimekizumab is well tolerated in patients with PsA for up to 3 years [19, 20]. Previously, we reported improvements in specific PRO measures of disease impact, particularly related to physical function and overall HRQoL, up to Week 48 [19]. The objective of this analysis was to evaluate the long-term effect of bimekizumab treatment, up to 3 years, on the key symptoms of PsA and the resulting impact on patient function and HRQoL, assessed using PRO measures.

## Methods

### Study design and participants

The study design for BE ACTIVE (NCT02969525) and its open-label extension (NCT03347110) have been reported previously and are shown in Supplementary Fig. S1, available at *Rheumatology* online [19, 20]. In brief, the 48-week randomised phase 2b dose-ranging study assessed bimekizumab treatment in a double-blind, placebo-controlled manner to Week 12, followed by a dose-blind period to Week 48 (Supplementary Fig. S1, available at *Rheumatology* online). Patients who completed 48 weeks of treatment and provided separate informed consent were eligible to enter the 104-week open-label extension. These patients received subcutaneous bimekizumab 160 mg every 4 weeks (Q4W) up to Week 148, regardless of prior treatment assignment and with a final efficacy assessment at Week 152. A safety follow-up visit was carried out 20 weeks after the final dose.

Key inclusion and exclusion criteria have been reported previously [19]. Eligible patients were ≥18 years of age and had a clinical diagnosis of active adult-onset PsA [categorised by Classification Criteria for Psoriatic Arthritis (CASPAR) criteria] with symptom duration of ≥6 months, baseline tender joint count (TJC) of ≥3/78 and swollen joint count (SJC) of ≥3/76. Patients with prior exposure to one biologic treatment (specifically, a tumour necrosis factor inhibitor) were eligible.

### Patient-reported outcome measures

Pain was assessed using the arthritis pain visual analogue scale (VAS) and the PsA pain numerical rating scale [NRS; question 1 of the PsA Impact of Disease (PsAID)-9 questionnaire]. Reductions in the arthritis pain VAS of ≥30% ('much improved') and ≥50% ('very much improved') from baseline were considered as clinically important improvements and assessed post hoc, as per the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials recommendations [21, 22]. Fatigue was assessed using the PsAID-9 fatigue NRS (question 2 of the PsAID-9 questionnaire) and vitality by the 36-Item Short Form Survey (SF-36) vitality dimension score.

Other PRO measures reported in this analysis included patient global assessment (PGA) of disease activity [23], the PsAID-9 questionnaire assessing the impact of PsA [7], the HAQ-Disability Index (HAQ-DI) as a measure of function [24], and the SF-36 [25], a measure of HRQoL.

Post hoc analyses using response definition thresholds relating to PsAID-9 and HAQ-DI were performed. For PsAID-9, meaningful response thresholds included patients reaching a score of ≤4 [considered a patient acceptable symptom state (PASS) in previous research [7]] and patients with a reduction in PsAID-9 score of ≥3 points (in those having had a PsAID-9 total score of ≥3 at baseline), corresponding to the minimal clinically important improvement (MCII) [7]. Thresholds for HAQ-DI included the percentage of patients reaching a score of <0.5, indicating normal function [26], and patients with a reduction in score of ≥0.35 points (in those with a score of ≥0.35 at baseline), corresponding to a minimally important difference (MID) [27]. Additional details of all PRO measures are provided in Supplementary Table S1, available at *Rheumatology* online.

During Weeks 0–48, the abovementioned PRO assessments were completed by patients at baseline (Week 0) and at Weeks 4, 12, 16, 24, 36 and 48. In addition, PsAID-9 was assessed at Week 8. The HAQ-DI was also completed at Weeks 2, 8 and 20 with PGA and the arthritis pain VAS (both of which were also assessed at Week 1). During the open-label extension, all measures were completed every 12 weeks from Week 48 to Week 144, and at Weeks 148 and 152. Mean scores and change from baseline (CfB) in all PRO scale scores are included; for multi-dimensional scores, both the summary and individual dimension scores are reported.

Results from a post hoc analysis of the association between mean PsAID-9 total score and disease activity [assessed using minimal disease activity (MDA), very low disease activity (VLDA) and Disease Activity Index for PSoriatic Arthritis (DAPSA) disease states] are also reported for Weeks 48 and 152.

### Statistical analysis

Data from Weeks 0–152 are presented using the full analysis set of the phase 2b study ($N = 206$), consisting of all randomised patients who received at least one dose of bimekizumab or placebo and who had a valid measurement of the primary efficacy variable at study baseline (Week 0). Observed case (OC) data are presented alongside results with non-responder imputation (NRI) for discrete variables, or multiple imputation (MI; based on the missing at random assumption) for continuous variables.

Endpoints using OC data are presented with S.D. to show the variation in the data. For endpoints using the MI method, the S.E.M. was used to summarise the variation in the data, rather than S.D., as this accounts for the variation between imputations in the MI process. CfB and responder analyses were calculated from study baseline. All computations and generation of outputs were done in SAS (version 9.3 or later).

### Ethics approval

BE ACTIVE and its open-label extension were conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonisation Guidance for Good Clinical Practice. Ethical approval was obtained from the relevant institutional review boards at all participating sites. All patients provided written informed consent in accordance with local requirements.

## Results

### Patient disposition and baseline characteristics

A total of 206 patients were randomised at baseline (Week 0). In total, 189 (91.7%) completed Week 48, of whom five did not consent to enter the open-label extension study; a further patient discontinued before receiving bimekizumab. A total of 161 (78.2%) completed 152 weeks (Supplementary Figs S1 and S2, available at *Rheumatology* online). Patient demographics and characteristics at study baseline are presented in Table 1 and indicate a patient population with moderate to severe PsA [mean (S.D.) age: 49.3 (12.4) years; 51.0% male; mean TJC: 21.6 (15.0); mean SJC: 11.5 (8.4)].

The mean (S.D.) PsAID-9, HAQ-DI, arthritis pain VAS and PGA scores at study baseline were 4.6 (1.9), 0.97 (0.59), 52.2 (23.0) and 50.2 (23.4), respectively. A mean SF-36 Physical Component Summary (PCS) score of 36.6 (9.1) was indicative of impaired physical function at baseline, while the Mental Component Summary (MCS) score of 55.8 (8.7) indicated normal psychological function at baseline (compared with the US general population mean value of 50) [3]. PsAID-9 PASS and HAQ-DI score of $<0.5$ were reported by 71/206 (34.5%) and 44/206 (21.4%) patients at baseline, respectively.

### Pain

For bimekizumab-treated patients, improvements in pain seen at Week 48 were sustained to Week 152. This included the arthritis pain VAS and PsAID-9 pain NRS (Fig. 1A and B). Decreases from baseline were observed at Weeks 48 and 152 for both measures. Mean scores for these measures at Weeks 0, 48 and 152 are provided in Supplementary Table S2, available at *Rheumatology* online. The percentage of patients with $\geq$30% or $\geq$50% reduction in pain from baseline showed rapid improvements up to Week 48 [142/206 (68.9%) and 116/206 (56.3%), respectively], which remained high at Week 152 [124/206 (60.2%) and 111/206 (53.9%); Fig. 1C and D].

**Table 1** Patient demographics and baseline characteristics

| | Total BKZ ($N = 206$) |
|---|---|
| Age, years, mean (S.D.) | 49.3 (12.4) |
| Male, *n* (%) | 105 (51.0) |
| Weight, kg, mean (S.D.) | 85.7 (18.5) |
| BMI, kg/m$^2$, mean (S.D.) | 29.6 (6.0) |
| Time since diagnosis, years, mean (S.D.) | 7.1 (8.2) |
| Prior TNFi therapy, *n* (%) | 39 (18.9) |
| Concomitant therapies, *n* (%) | |
| NSAIDs | 133 (64.6) |
| Methotrexate | 131 (63.6) |
| TJC, mean (S.D.) | 21.6 (15.0) |
| SJC, mean (S.D.) | 11.5 (8.4) |
| hs-CRP, mg/L, median (range) | 5.9 (0.1–99.9) |
| Psoriasis BSA $\geq$3%, *n* (%) | 137 (66.5) |
| Dactylitis, *n* (%) | 59 (28.6) |
| Enthesitis, *n* (%) | 107 (51.9) |
| Baseline PRO scores, mean (S.D.) | |
| Arthritis pain VAS | 52.2 (23.0) |
| PGA | 50.2 (23.4) |
| PsAID-9 total | 4.6 (1.9) |
| HAQ-DI | 0.97 (0.59) |
| SF-36 PCS | 36.6 (9.1) |
| SF-36 MCS | 55.8 (8.7) |
| Baseline PsAID-9 PASS,[a] *n* (%) | 71 (34.5) |
| HAQ-DI $<0.5$, *n* (%) | 44 (21.4) |

Baseline characteristics reported from the start of the double-blind period for the full analysis set. [a]PsAID-9 total score of $\leq$4; BKZ: bimekizumab; BSA: body surface area; HAQ-DI: HAQ-Disability Index; hs-CRP: high sensitivity CRP; MCS: Mental Component Summary; PCS: Physical Component Summary; PGA: patient global assessment; SF-36: 36-Item Short Form Survey; SJC: swollen joint count; TJC: tender joint count; TNFi: TNF inhibitor; VAS: visual analogue scale.

Improvement in the SF-36 bodily pain dimension supported these results (Supplementary Fig. S3, available at *Rheumatology* online).

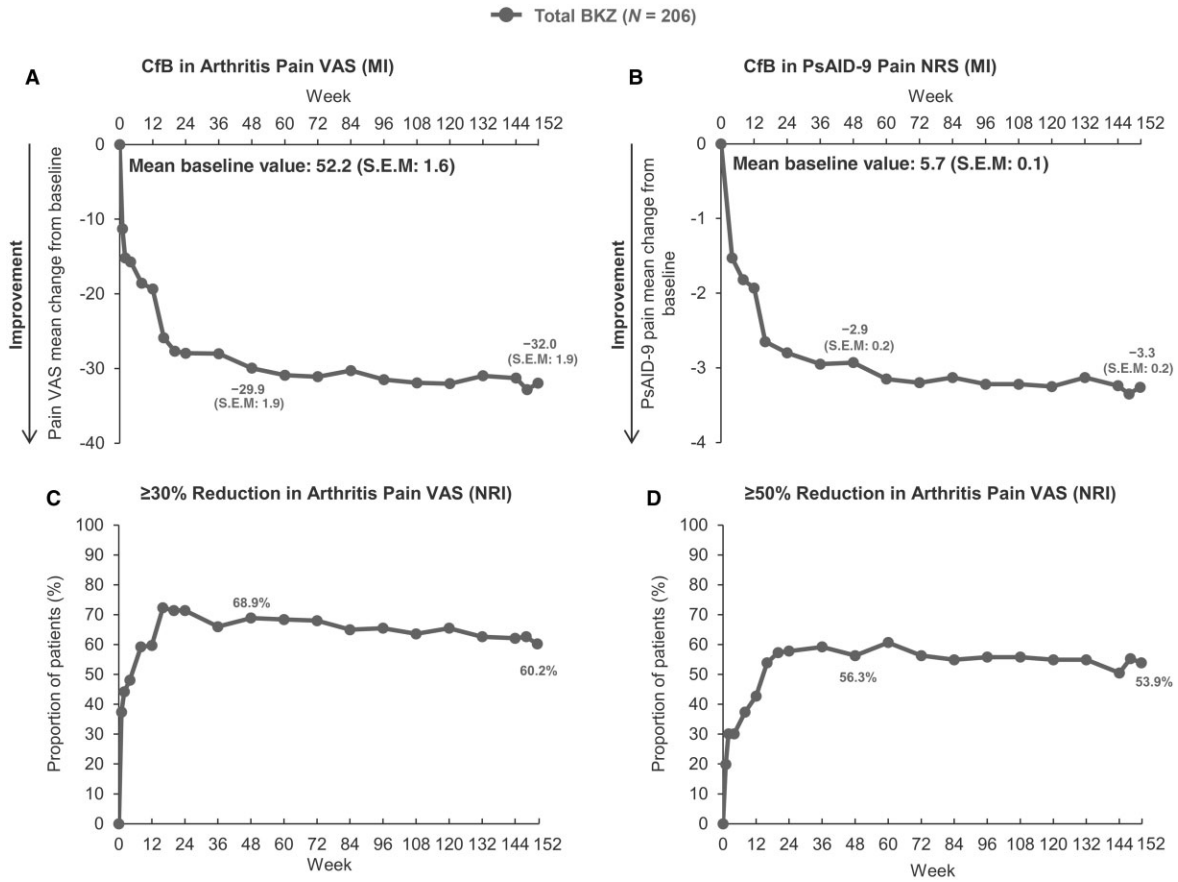
### Fatigue and vitality

An improvement of 2–3 points (on a 0–10 scale) in the mean PsAID-9 fatigue score at Week 48 was sustained through Week 152 for bimekizumab-treated patients (Fig. 2A). The mean (S.E.M.) value of 49.7 (0.7) at baseline for SF-36 vitality was not impaired compared with the general US general population mean value of 50 [3]; however, vitality improved and the response at Week 48 was sustained through Week 152 (Fig. 2B). Mean scores for these measures are provided in Supplementary Table S2, available at *Rheumatology* online.

### Patient global assessment

Patient-reported disease activity had decreased by Week 48 and this improvement was sustained to Week 152. The mean (S.E.M.) CfB in PGA score was –27.6 (1.9) at Week 48 and –30.8 (1.9) at Week 152,

**Fig. 1** Sustained improvements in pain for patients treated with bimekizumab




Full analysis set. Patient-reported pain was measured by the CfB in arthritis pain VAS score (**A**) and PsAID-9 pain NRS (**B**) as well as the percentage of patients achieving ≥30% (**C**) and ≥50% (**D**) improvement in the arthritis pain VAS. Week 48 and Week 152 values shown. BKZ: bimekizumab; CfB: change from baseline; MI: multiple imputation; NRI: non-responder imputation; NRS: numerical rating scale; PsAID-9: PsA Impact of Disease-9; VAS: visual analogue scale.

indicative of an improvement in patients' perception of disease (Supplementary Fig. S4, available at *Rheumatology* online).

## Assessment of disease impact and patient function

High percentages of patients achieved PASS and clinically meaningful responses throughout the open-label extension, suggesting long-term reductions in disease impact (Fig. 3A and C). At Week 48, 75.2% of patients achieved PsAID-9 PASS and this remained high at Week 152 (65.0%). PsAID-9 MCII was achieved by 42.6% of patients at Week 48 and 43.2% at Week 152. CfB in the mean PsAID-9 total score at Week 48 was also sustained to Week 152 (Fig. 3E).

The improvement in patient function at Week 48 was also sustained to Week 152, indicated by the percentage of patients reaching HAQ-DI <0.5 and MID (Fig. 3B and D). A total of 49.0% of patients had HAQ-DI <0.5 at Week 48, sustained to Week 152 (46.1%). HAQ-DI MID was achieved by 59.2% of patients at Week 48 and remained high at Week 152 (51.7%). The mean CfB in HAQ-DI score at Week 48 was also sustained to Week 152 (Fig. 3F).

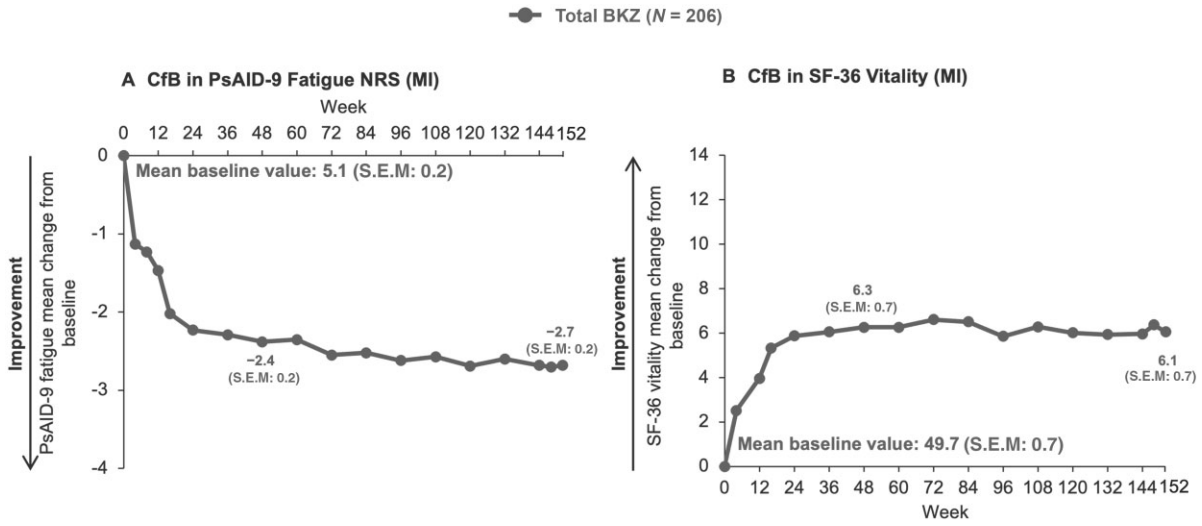
## Association of PsAID-9 and disease activity

Reduced disease activity was associated with a lower mean PsAID-9 score at Weeks 48 and 152 (Fig. 4). Patients treated with bimekizumab who reached the lowest levels of disease activity [very low disease activity (VLDA) and DAPSA remission (REM)] achieved the lowest mean PsAID-9 scores. Achievement of VLDA and DAPSA REM was associated with much lower scores at both Week 48 and 152, even as compared with those achieving MDA and DAPSA LDA, respectively.

## HRQoL

Relative to baseline, the mean SF-36 PCS score was increased at Week 48 and sustained to Week 152 (Supplementary Fig. S5A, available at *Rheumatology* online). The CfB in mean (S.E.M.) PCS score at Week

Fig. 2 Sustained improvements in fatigue for patients treated with bimekizumab




Full analysis set. Patient-reported fatigue was measured by the PsAID-9 fatigue NRS (**A**) and SF-36 vitality dimension (**B**). Scores obtained using MI with Week 48 and Week 152 values shown. BKZ: bimekizumab; CfB: change from baseline; MI: multiple imputation; NRS: numerical rating scale; PsAID-9: PsA Impact of Disease-9; SF-36: 36-Item Short Form Survey.

48 [9.1 (0.6)] was sustained to Week 152 [CfB: 9.1 (0.7)] and was superior to the responder threshold generally considered to interpret change in PCS score (2.5–5.0 points) [28].

The mean SF-36 MCS score remained close to the normal reference value of 50 (based on the US general population) throughout the study (Supplementary Fig. S5B, available at *Rheumatology* online) [3]. The mean (S.E.M.) baseline score was 55.8 (0.6) with a CfB of 1.7 (0.6) and 0.9 (0.6) at Weeks 48 and 152, respectively.

### PsAID-9 and SF-36 dimension scores

Improvements were seen in all components of the PsAID-9 questionnaire at Week 152. The most pronounced improvements were observed in the dimensions that were most impacted at baseline, such as pain [mean (S.E.M.) CfB: −3.3 (0.2)], fatigue [CfB: −2.7 (0.2)] and skin problems [CfB: −2.8 (0.2)], as well as the impact on work/leisure [CfB: −2.8 (0.2)], functional capacity [CfB: −2.7 (0.2)] and discomfort [CfB: −2.6 (0.2)] (Fig. 5).

The physical components of the SF-36 measure showed substantial improvements at Week 152. Mean (S.E.M.) CfB values indicated that all dimensions were improved including physical functioning [CfB: 7.4 (0.7)], role physical [CfB: 6.2 (0.7)], bodily pain [CfB: 11.2 (0.8)] and general health [CfB: 3.7 (0.7)]; the most notable improvement was observed in bodily pain [CfB: 11.2 (0.8)]. Except for vitality, the mental components remained within the normal range at Week 152, as reflected in the MCS score. The mean CfB (S.E.M.) values at Week 152 were: vitality 6.1 (0.7), social functioning 4.3 (0.7), role emotional 1.3 (0.5) and mental health 2.8 (0.7).

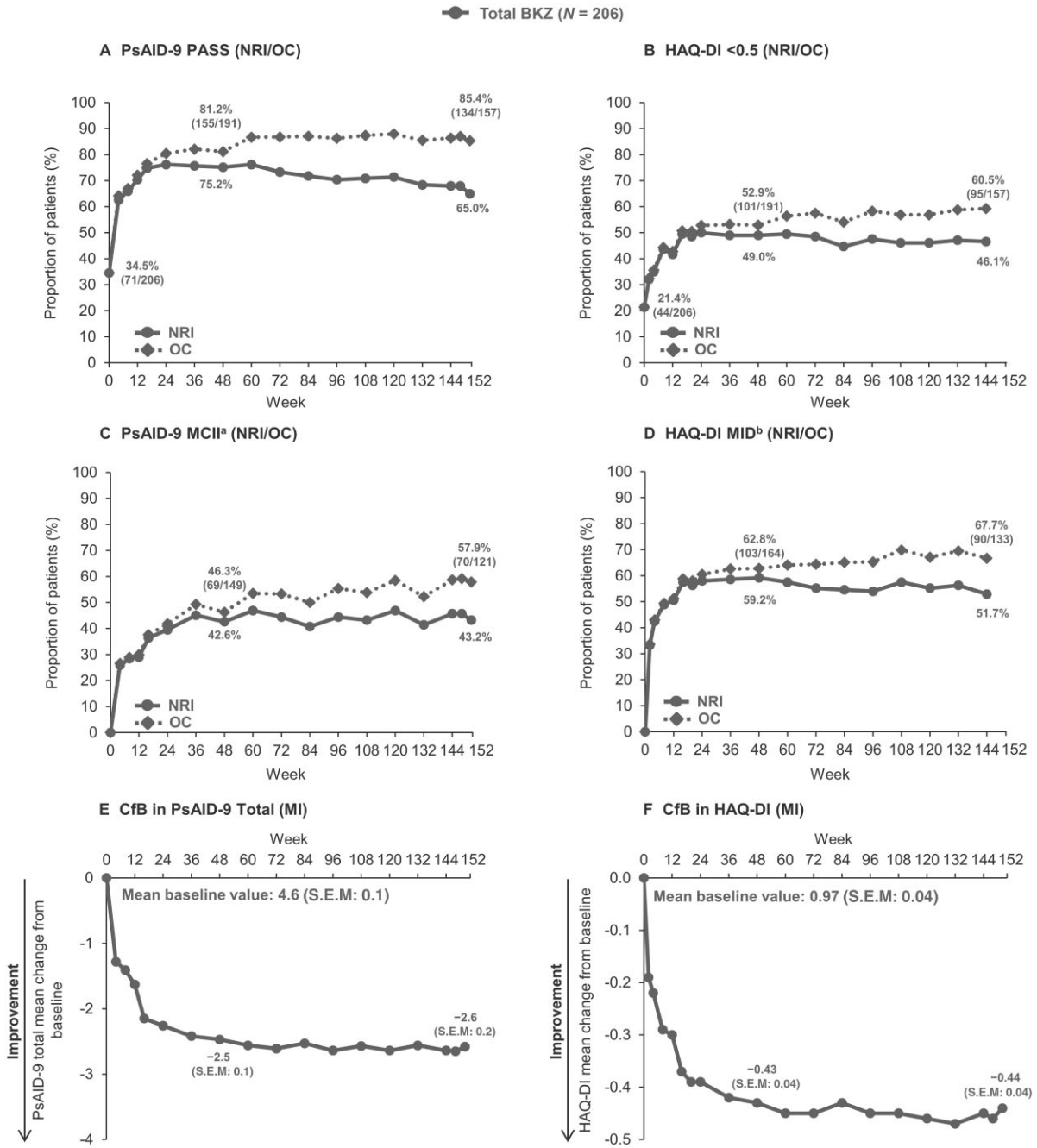
## Discussion

Patients with PsA, treated with bimekizumab for up to three years in this phase 2b study, showed notable and durable improvements in all PRO measures evaluated. The data presented for PRO measures align closely with the improvements reported in clinical measures of PsA joint and skin manifestations [19, 20]. This long-term improvement was reflected in patient function and overall HRQoL, resulting in a positive impact on patients with PsA.

Pain and fatigue are commonly reported as the most impactful and disturbing symptoms and were assessed using the PsA-specific PsAID-9 questionnaire and arthritis pain VAS [10–12, 14, 15]. Reductions in pain and fatigue were demonstrated by all measures and were sustained from Week 48 through Week 152. Post hoc analyses indicated a high percentage of patients reporting a clinically meaningful reduction in arthritis pain (≥50% reduction) at Week 48, sustained to Week 152. The results presented here provide evidence for the long-term efficacy of bimekizumab in reducing the severity of pain and fatigue up to 3 years.

Impaired physical function has a significant impact on patients with PsA [15, 27, 29], and was assessed with the widely used HAQ-DI measure. Sustained improvements were observed in all scores and thresholds reported for patients receiving bimekizumab. The HAQ-DI, originally developed for rheumatoid arthritis, has been validated for PsA, as has the PsA-specific PsAID, which includes a functional capacity score [29]. The HAQ-DI assesses a range of different functions such as dressing, arising, eating, walking, hygiene, grip and usual activities [24], while the PsAID functional capacity score is a

**Fig. 3** Improvements in PsAID-9 and HAQ-DI thresholds and CfB in total scores for bimekizumab-treated patients

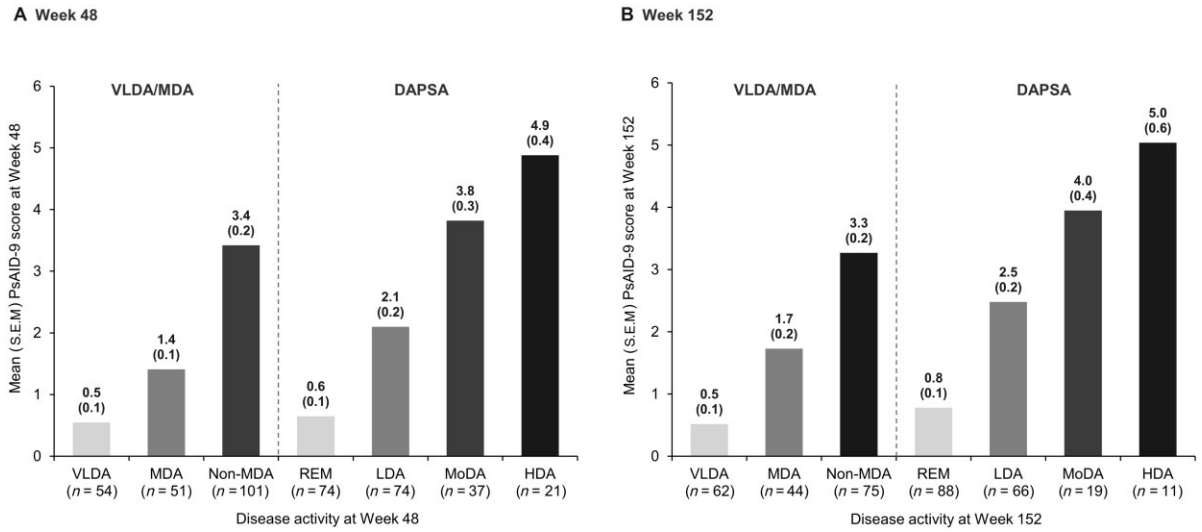



The percentage of patients achieving PsAID-9 PASS (PsAID-9 total score $\leq 4$) (**A**) and HAQ-DI $<0.5$ (**B**), clinically meaningful thresholds (PsAID-9 MCII (**C**) and HAQ-DI MID (**D**) and CfB in PsAID-9 (**E**) and HAQ-DI (**F**) score; full analysis set. [a]Patients with a PsAID-9 total score $\geq 3$ at baseline ($n = 162$); [b]Patients with HAQ-DI $\geq 0.35$ at baseline ($n = 174$). BKZ: bimekizumab; CfB: change from baseline; HAQ-DI: HAQ-Disability Index; MCII: minimal clinically important improvement; MI: multiple imputation; MID: minimally important difference; NRI: non-responder imputation; OC: observed case; PASS: Patient Acceptable Symptom State; PsAID-9: PsA Impact of Disease-9.

single question. Overall, improvements measured by HAQ-DI aligned with those in the PsAID-9 functional capacity dimension, indicating improved function for bimekizumab-treated patients.

The PsA-specific PsAID-9 questionnaire assessed the wider impact of PsA on patients' lives. The results suggest that PsA had a reduced impact on patients receiving bimekizumab, for up to 3 years; however, the

FIG. 4 Association of PsAID-9 total score with disease activity at Weeks 48 and 152




Full analysis set. MI was used for PsAID-9 total scores. This analysis is based on observed disease status at Weeks 48 (**A**) and 152 (**B**). Disease activity was categorised by VLDA, MDA and DAPSA disease states. BKZ: bimekizumab; DAPSA: Disease Activity Index for PsA; HDA: high disease activity; LDA: low disease activity; MDA: minimal disease activity; MI: multiple imputation; MoDA: moderate disease activity; PsAID-9: PsA Impact of Disease-9; REM: remission; VLDA: very low disease activity.

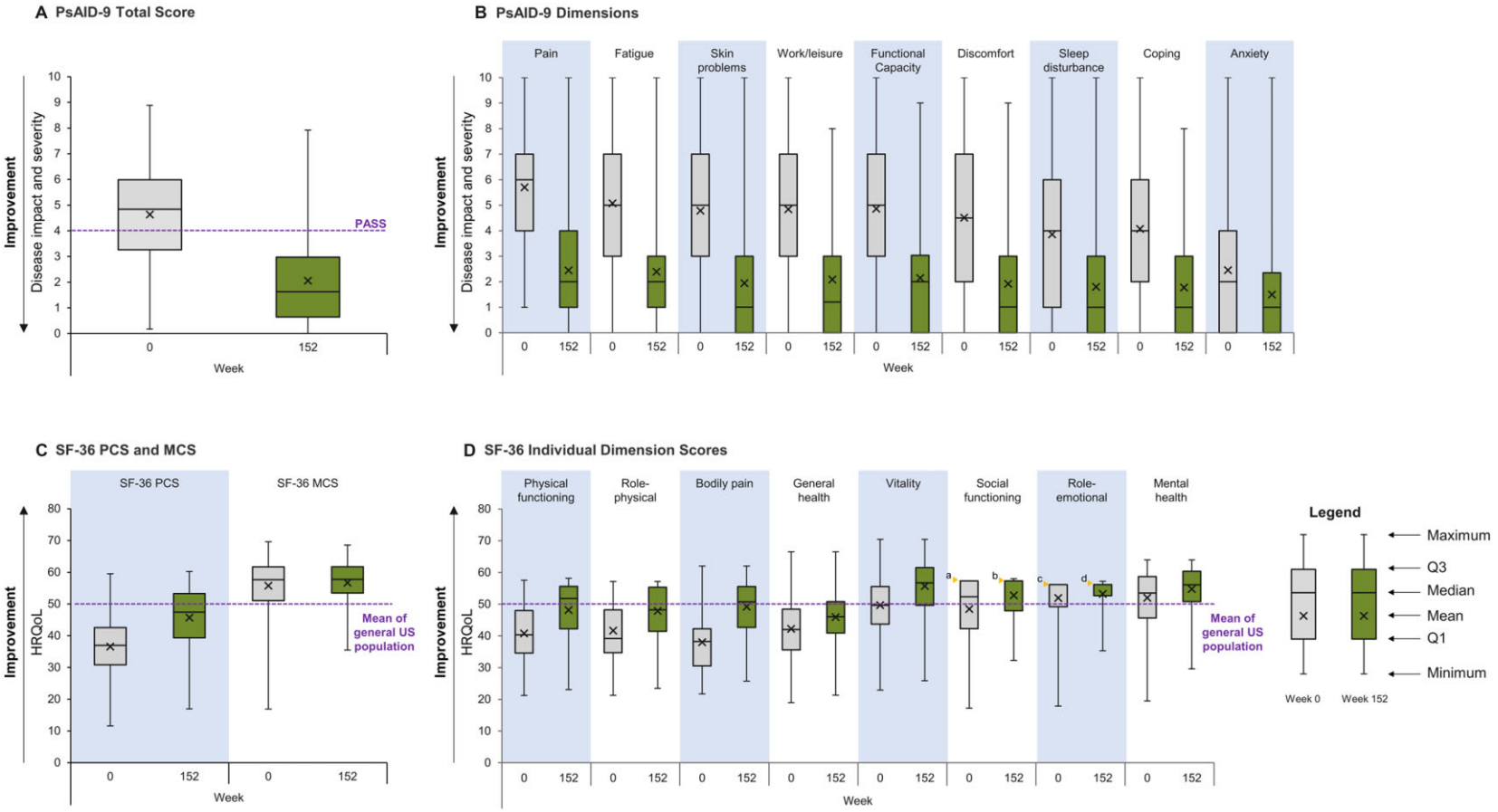
relatively high percentage of patients reporting PASS at baseline (34.5%) may suggest that this threshold is too high for PsAID-9. Evaluation of the individual dimensions of the PsAID-9 questionnaire provided an insight into the contributors of this improved score; pain, fatigue, physical function, skin problems, and discomfort, all of which negatively affect patients with PsA [2–5, 15], were improved, as was the work/leisure dimension score. The SF-36 dimensions related to the symptoms of PsA (bodily pain, physical functioning, role physical) also improved and approached the normative mean value at Week 152. Additionally, a post hoc analysis of the association between disease activity and disease impact suggested a consistent pattern of reduced disease impact being associated with reduced disease activity for up to 3 years. This aligns with previous reports for Week 12 associations and adds to previous studies reporting the relationship between increased disease activity and decreased HRQoL [10, 13, 15, 30].

Previous work has shown the correlation between individual dimensions of the PsAID-9 questionnaire and specific PRO measures, such as a correlation between the PsAID-9 work/leisure dimension and the Work Productivity and Activity Impairment Questionnaire: Specific Health Problem [31]. These correlations suggest that the evaluation of individual PsAID-9 dimensions is reliable, particularly as a PsA-specific PRO measure; this also illustrates that bimekizumab reduces the severity of a range of symptoms and improves overall patient HRQoL up to 3 years.

A descriptive analysis of the results shows that bimekizumab treatment reduces PsA symptom severity, accompanied by long-term improvements in patient function and overall HRQoL, up to 3 years. The sustained reduction in pain and fatigue, along with improved function and HRQoL, is consistent with recently reported long-term results for other biologic and oral treatments for PsA [32–34]. However, increased longevity of this effect was observed in this study given the 3-year duration. Furthermore, improvements across all measures indicate that bimekizumab treatment may address the complex and varied manifestations of both pain and fatigue, as reported by Ogdie *et al.* [15].

This study provides the most extensive evidence for the sustained efficacy of bimekizumab to date, assessed using PRO measures. The results are of importance and highlight the durability of bimekizumab treatment, in particular reducing both pain and fatigue up to 3 years. Evaluation of the validated, PsA-specific PsAID-9 questionnaire through 3 years represents a strength of this study, particularly as the improvements in the total score and individual dimensions were consistent with those reported for more widely used PRO measures. Key limitations of this phase 2b study include the inherently limited sample size ($N = 206$), use of post hoc data and lack of placebo control beyond Week 12. Furthermore, patients participating in long-term extension studies are highly likely to be responders in the earlier part of the study and hence pre-selected to succeed; thus, the results should be interpreted within this context. Ongoing phase 3 studies of bimekizumab in patients with PsA should allow more in-depth evaluation of bimekizumab on these patient-reported measures in a larger study setting.

**Fig. 5** Box and whisker plots of PsAID-9 and SF-36 measures at Weeks 0 and 152




Full analysis set. PsAID-9 total (**A**) and individual dimension (**B**) scores and SF-36 PCS, MCS (**C**) and individual dimension (**D**) scores reported using MI. [a]Q3 and maximum values were equal (57.3); [b]Median and Q3, values were equal (57.3); [c]Median, Q3 and maximum values were equal (56.2); [d]Median and Q3 values were equal (56.2). BKZ: bimekizumab; CfB: change from baseline; MCS: Mental Component Summary; MI: multiple imputation; PASS: patient acceptable symptom state; PCS: Physical Component Summary; PsAID-9: PsA Impact of Disease-9; Q1: lower quartile; Q3: upper quartile; SF-36: 36-Item Short Form Survey.

Overall, bimekizumab is associated with long-term reductions in disease activity and impact on patients with PsA. This manifests as rapid and sustained improvements in patient-reported pain, fatigue, physical function and HRQoL up to 3 years. These long-term improvements could help to improve the treatment landscape for patients with PsA, addressing an unmet need in those who continue to be affected by the burdensome and impactful symptoms of pain and fatigue.

## Acknowledgements

The authors thank the patients, the investigators and their teams who took part in this study. The authors also acknowledge Heather Edens, PhD, UCB Pharma, Smyrna, GA, USA, for publication coordination and editorial support and Luke Green, PhD, Costello Medical, Cambridge, UK, for medical writing and editorial assistance based on the authors' input and direction. The authors would also like to thank Professor Alexis Ogdie for data interpretation and discussion of manuscript content. This study was funded by UCB Pharma.

Substantial contributions to study conception and design: P.J.M., A.A., D.D.G., Y.T., W.T., B.I., D.A., J.C., J.E.; substantial contributions to analysis and interpretation of the data: P.J.M., A.A., D.D.G., Y.T., W.T., B.I., D.A., C.dlL., J.C., J.E., L.G.; drafting the article or revising it critically for important intellectual content: P.J.M., A.A., D.D.G., Y.T., W.T., B.I., D.A., C.dlL., J.C., J.E., L.G.; final approval of the version of the article to be published: P.J.M., A.A., D.D.G., Y.T., W.T., B.I., D.A., C.dlL., J.C., J.E., L.G.

*Funding:* This work was supported by UCB Pharma. This article was based on the original study BE ACTIVE (NCT02969525) and its open-label extension (NCT03347110), sponsored by UCB Pharma. Support for third-party writing assistance for this article, provided by Luke Green, PhD, Costello Medical, UK, was funded by UCB Pharma in accordance with Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).

*Disclosure statement:* P.J.M.: Speakers' bureau from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma; consultancy fees from AbbVie, Amgen, BMS, Boehringer Ingelheim, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Novartis, Pfizer, Sun Pharma and UCB Pharma; research grants from AbbVie, Amgen, BMS, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Sun Pharma and UCB Pharma. A.A.: Honoraria and/or research grants from AbbVie, Celgene, Eisai, Eli Lilly, Janssen, Kyowa Kirin, LEO Pharma, Maruho, Mitsubishi Pharma, Sun Pharma, Taiho Pharma, Torii Pharmaceutical and UCB Pharma. D.D.G.: Received grants from AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma; consulting fees from AbbVie, Amgen, BMS, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, Pfizer and UCB Pharma. Y.T.: Speakers bureau for Abbvie, Amgen, Astellas, AstraZeneca, BMS, Boehringer-Ingelheim, Chugai, Eisai, Eli Lilly, Gilead, Mitsubishi-Tanabe and YL Biologics; research grants for AbbVie, Asahi-Kasei, Boehringer-Ingelheim, Chugai, Corrona, Daiichi-Sankyo, Eisai, Kowa Mitsubishi-Tanabe and Takeda; consultant fee for AbbVie, Ayumi, Daiichi-Sankyo, Eli Lilly, GSK, Sanofi and Taisho. W.T.: Research grants, consulting fees, speaking fees, and/or honoraria from AbbVie, Amgen, Celgene, Eli Lilly, Janssen, MSD, Novartis, Pfizer and UCB Pharma. B.I.: Shareholder of GSK and UCB Pharma; employee of UCB Pharma. D.A.: Stockholder and employee of UCB Pharma. C.dlL.: Consultant for UCB Pharma. J.C.: Stockholder and employee of UCB Pharma. J.E.: Stockholder and employee of UCB Pharma. L.G.: Research grants from Amgen, Galapagos, Lilly, Pfizer and Sandoz; consulting fees from AbbVie, Amgen, BMS, Galapagos, Gilead, Janssen, Lilly, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis and UCB Pharma.

*Consent for publication:* All the results presented in this article are in aggregate form, and no personally identifiable information was used for this study.

## Data availability statement

Underlying data from this manuscript may be requested by qualified researchers six months after product approval in the US and/or Europe, or global development is discontinued, and 18 months after trial completion. Investigators may request access to anonymised individual patient-level data and redacted trial documents which may include: analysis-ready datasets, study protocol, annotated case report form, statistical analysis plan, dataset specifications and clinical study report. Prior to use of the data, proposals need to be approved by an independent review panel at www.vivli.org and a signed data sharing agreement will need to be executed. All documents are available in English only, for a prespecified time, typically 12 months, on a password protected portal.

## Supplementary data

Supplementary data are available at *Rheumatology* online.

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