

Bimekizumab treatment in routine clinical care for psoriatic arthritis: Interim observational evidence of patient-reported outcome improvements from the European, multicentre SPEAK study

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Objective

To report interim data from the ongoing European observational SPEAK study, describing the characteristics of patients with psoriatic arthritis (PsA) at initiation of bimekizumab (BKZ) treatment, and patient-reported outcomes (PROs) and safety to 24 weeks, stratified by prior treatment history, in a real-world setting.

Background

- PsA is a chronic inflammatory disease with a significant burden on patients’ health-related quality of life (HRQoL).¹
- Biologic/targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) are used to treat PsA.
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained clinical efficacy, safety and improvements in PROs to 3 years in phase 3 clinical trials in patients with PsA.^{2,3}
- BKZ was approved for the treatment of PsA and axial spondyloarthritis (axSpA) in Europe in June 2023, and is also approved for moderate-to-severe plaque psoriasis and hidradenitis suppurativa.⁴
- SPEAK is the first prospective, observational, real-world study evaluating PROs, including HRQoL, and clinical outcomes with BKZ treatment in patients with active PsA or axSpA in routine clinical practice in Europe.

Methods

- SPEAK is an ongoing 52-week, multicentre, multi-country, European observational study (Figure 1).
 - Patient enrolment began in September 2023, 3 months after the approval of BKZ for the treatment of PsA and axSpA in Europe, and was staggered based on local launch.⁴
- Adults with a clinical diagnosis of active PsA or axSpA initiating BKZ treatment in routine clinical practice and consenting to participate in the SPEAK study were included.
- The primary outcome for patients with PsA was change from baseline (CfB) in HRQoL, measured by the PsA Impact of Disease 12-Item Questionnaire (PsAID-12) total score to Week 52.
- This planned interim analysis reports data to 2 April, 2025 (~50% of patients had completed Week 24) including baseline characteristics of BKZ-treated patients in the safety set (all patients with PsA who received at least one dose of BKZ), as well as the following PROs for patients in the full analysis set (includes all patients who had at least one valid baseline and post-baseline assessment) to 24 weeks:
 - PsAID-12 total score (range: 0–10; higher scores indicate higher disease impact) CfB and single-item domain mean scores.⁵
 - Patient Global Assessment of Disease Activity (PGADA) CfB.⁶
 - Short Form 36-item Health Survey (SF-36) Physical Component Summary (PCS) score CfB.⁷
- Adverse events (AEs) were reported in line with pharmacovigilance reporting guidelines.
- Outcomes are reported as observed case (OC) and stratified by prior b/tsDMARD exposure (b/tsDMARD-na  ve, 1 prior b/tsDMARD and   2 b/tsDMARDs).

Results

- By April 2025, baseline characteristics were available for 376 patients with PsA (Table).
 - Overall, 80 (21.3%) were b/tsDMARD-na  ve, 89 (23.7%) had 1 prior b/tsDMARD and 207 (55.1%) had received   2 prior b/tsDMARDs, of whom 22/207 (10.6%) had received   7 prior b/tsDMARDs;
 - 174 patients (46.3%) were previously treated with   2 b/tsDMARDs with distinct mechanisms of action; 118 patients (31.4%) received prior tumour necrosis factor inhibitor and IL-17A inhibitor therapy;
 - Patients previously treated with   2 b/tsDMARDs had longer disease duration at baseline, were older on average and a higher proportion were female.
- Patients with a greater number of prior treatment lines had worse baseline PROs (including poorer mental health), suggesting greater patient-reported impairment at baseline for patients starting BKZ as a later line therapy (Table).
 - Baseline SF-36 PCS and Mental Component Summary (MCS) scores increased with prior b/tsDMARD exposure; overall, 63.3% and 44.7% of patients reported SF-36 PCS and SF-36 MCS scores <45, respectively.
 - In total, 48 (12.8%) and 8 (2.1%) patients with PsA reported a medical history of depression or depressed mood, respectively; 2 patients (0.5%) reported a medical history of anxiety and 2 (0.5%) of anxiety disorder.
- Improvements in PsAID-12 total score and PGADA were observed from Week 2 after BKZ initiation, irrespective of prior treatment exposure, and continued through Week 24 (Figure 2). SF-36 PCS scores also improved to Week 24.
 - Across all outcomes, improvements were numerically greater in b/tsDMARD-na  ve patients than those who had experienced 1 or   2 prior b/tsDMARDs.
- Improvements from baseline across all PsAID-12 single-item domain scores were observed to 24 weeks, irrespective of prior treatment exposure (Figure 3).
- AEs were reported in 61.4% of patients; drug-related AEs in 34.8% of patients.
 - 79 patients discontinued treatment due to AEs;
 - Candida infections were reported by 43 patients (11.4%); 46 cases in total with 31 oral candidiasis cases;
 - Serious infections were reported by 15 patients (4.0%); 2 (0.5%) had serious Candida infections;
 - Major adverse cardiovascular events were reported by 1 patient (0.3%; myocardial infarction), deemed not drug-related;
 - Uveitis was reported by 1 patient (0.3%) with no prior uveitis history, deemed not drug-related;
 - Hepatic disorders were reported by 2 patients (0.5%);
 - No cases of venous thromboembolism, serious hypersensitivity, anaphylaxis, inflammatory bowel disease or suicidal ideation/behaviour were reported.

Conclusions

Patients with active PsA showed rapid improvements in PROs, including HRQoL, as early as Week 2 after BKZ treatment initiation, which were further improved through Week 24.

Improvements were seen across all prior treatment lines, with numerically greater changes observed in b/tsDMARD-na  ve patients, a group characterised by better baseline HRQoL and shorter disease duration.

These interim findings suggest that BKZ treatment, as part of routine clinical practice, may lead to improved PROs with no additional safety concerns, providing early evidence that the risk–benefit profile established in clinical trials is supported by data from the real-world setting.

Summary

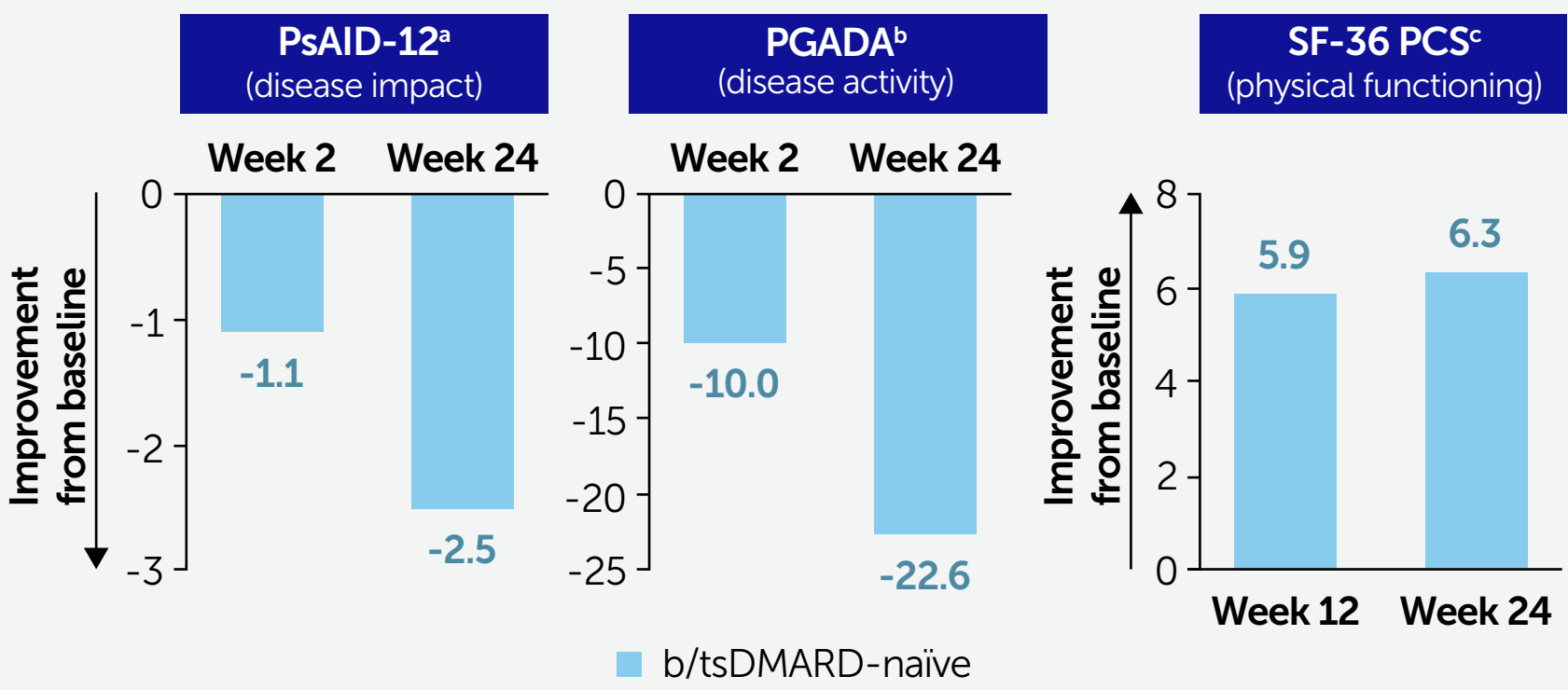
This analysis reports interim data from the ongoing SPEAK observational study describing patient-reported outcomes and safety with bimekizumab treatment to 24 weeks.

Lower baseline HRQoL in patients with prior b/tsDMARD exposure:

A greater number of prior treatment lines was associated with longer disease duration and worse patient-reported outcomes at baseline.

Improvements in patient-reported outcomes to Week 24:

Improvements in patient-reported outcomes were observed up to Week 24, regardless of prior b/tsDMARD exposure.



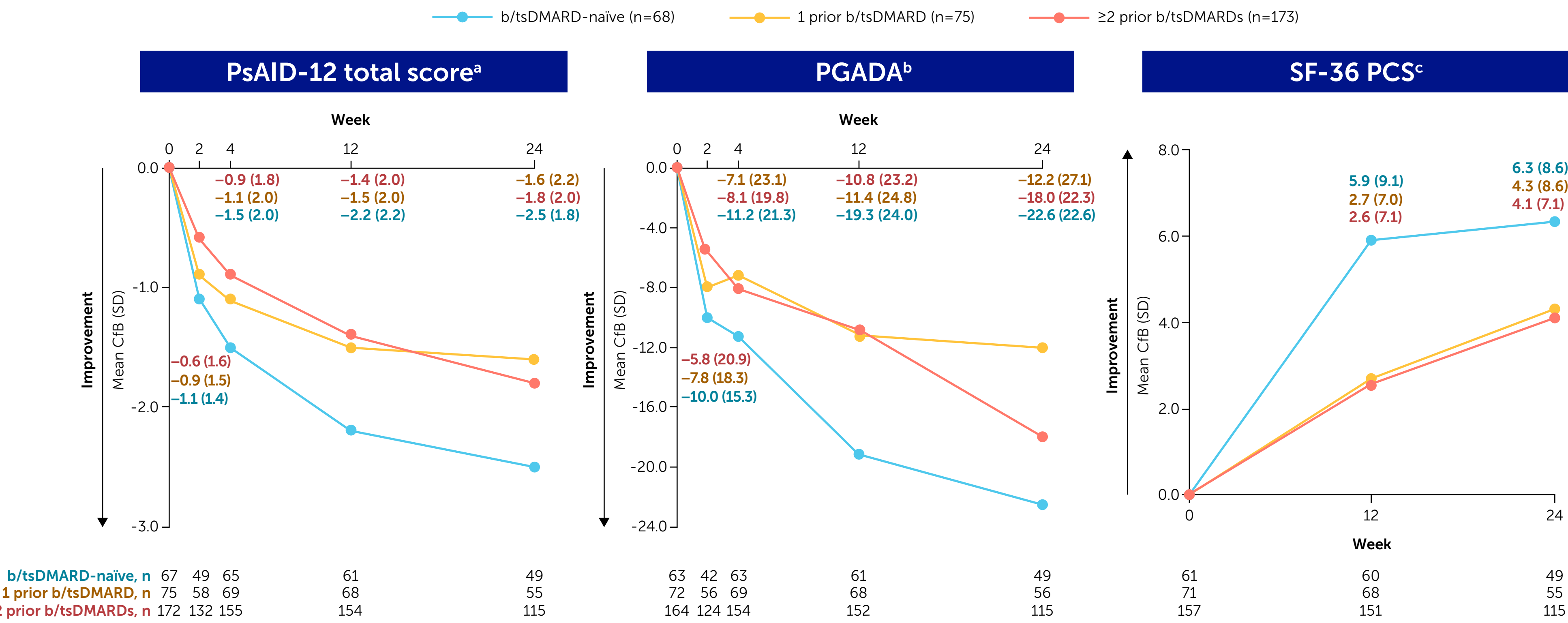
Similar rapid improvements were observed in patients with prior b/tsDMARD exposure across all outcomes, however, improvements were numerically greater in b/tsDMARD-na  ve patients, a patient population defined by shorter disease duration and better baseline patient-reported outcomes.

No new safety signals were reported.

Bimekizumab in routine clinical practice led to improved patient-reported outcomes with no new safety signals, providing early evidence that the risk–benefit profile observed in clinical trials is supported by findings in real-world settings.

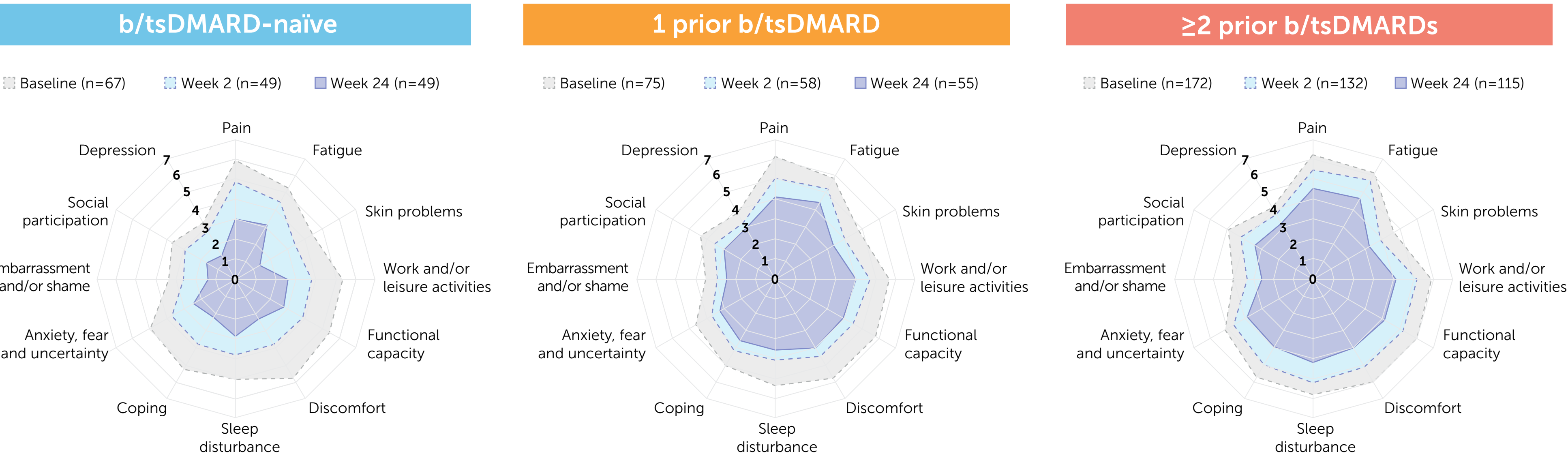
Full analysis set (includes all patients who had at least one valid baseline and post-baseline assessment). [a] PsAID-12 total score ranges from 0–10 (higher scores indicate higher disease impact). [b] PGADA in this study was assessed using a 0–100 VAS (higher scores indicate higher disease activity). [c] The SF-36 PCS is a norm-based T-score with mean (SD) of 50 (10), for the US general population, where higher scores reflects better HRQoL.⁷

Figure 2 Change from baseline in patient-reported outcomes in patients with PsA, stratified by prior treatment history, to Week 24 (OC)



Full analysis set (includes all patients who had at least one valid baseline and post-baseline assessment). Dates are approximate depending on how close to baseline the first dose was received. [a] PsAID-12 total score ranges from 0–10 (higher scores indicate higher disease impact). [b] PGADA in this study was assessed using a 0–100 VAS (higher scores indicate higher disease activity). [c] The SF-36 PCS is a norm-based T-score with mean (SD) of 50 (10), for the US general population, where higher scores reflects better HRQoL.⁷

Figure 3 Improvements across all PsAID-12 single-item domain scores in patients with PsA, stratified by prior treatment history, to Week 24 (OC)



Full analysis set (includes all patients who had at least one valid baseline and post-baseline assessment). PsAID-12 single-item domain scores range from 0–10; higher scores indicate higher disease impact.⁵

AE: adverse event; axSpA: axial spondyloarthritis; b/tsDMARD: biologic/targeted synthetic disease-modifying antirheumatic drug; BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; CfB: change from baseline; CRP: C-reactive protein; FPFV: first patient first visit; FPLV: first patient last visit; HAQ-DI: Health Assessment Questionnaire–Disability Index; HCP: healthcare professional; HRQoL: health-related quality of life; IBD: inflammatory bowel disease; IL: interleukin; LPFV: last patient first visit; LPLV: last patient last visit; OC: observed case; PGADA: Patient Global Assessment of Disease Activity; PRO: patient-reported outcome; PsA: psoriatic arthritis; PsAID-12: Psoriatic Arthritis Impact of Disease 12-Item Questionnaire; SD: standard deviation; SF-36 PCS/MCS: Short Form 36-Item Health Survey Physical Component Summary/Mental Component Summary; VAS: visual analogue scale.

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