Bimekizumab Time to Meaningful Improvements in Clinical and Patient-Reported Outcomes in Patients with Psoriatic Arthritis: Results from a Post Hoc Analysis of Two Pooled Phase 3 Studies

POS0486

Alen Zabotti,[1] Laura C. Coates,[2] Alice B. Gottlieb,[3] Peter Nash,[4] Philipp Sewerin,[5] Andrew Jordan,[6] Masato Okada,[7] Renaud Felten,[8] Jérémy Lambert,[9] Nadine Goldammer,[10] Patrick Healy,[11] Joseph F. Merola[12]

[1]University of Udine, University Hospital Santa Maria della Misericordia, Department of Medicine (DMED), Rheumatology Division, Udine, Italy; [2]Oxford University Hospitals NHS Trust, University of Oxford and Oxford Biomedical Research Centre, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Diseases, Oxford, UK; [3]UT Southwestern Medical Center, Department of Dermatology, Dallas, USA; [4]Griffith University, School of Medicine, Brisbane, Australia; [5]University Hospital of the Ruhr University Bochum, Rheumazentrum Ruhrgebiet, Herne, Germany; [6]BJC Health, Parramatta, Australia; [7]St. Luke's International Hospital, Immuno-Rheumatology Center, Tokyo, Japan; [8]Strasbourg University Hospitals, Hautepierre Hospital, Clinical Investigation Center, Rheumatology Department and National Reference Center for Rare Systemic Autoimmune Diseases, Strasbourg, France; [9]UCB, Courbevoie, France; [10]UCB, Monheim am Rhein, Germany; [11]UCB, Morrisville, USA; [12]UT Southwestern Medical Center, Department of Dermatology and Department of Medicine, Division of Rheumatology, Dallas, USA.

Objective

To report the median time to clinically meaningful improvement in clinical composite endpoints and patient-reported outcomes (PROs) in patients with psoriatic arthritis (PsA) who were treated with bimekizumab (BKZ), using pooled data from two phase 3 studies.

Background

- PsA is a chronic, inflammatory disease that manifests across multiple domains and substantially impacts patient quality of life.[1,2]
- BKZ, which selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated sustained and consistent efficacy and safety up to 3 years in patients with active PsA who were biological disease-modifying antirheumatic drug (bDMARD)-naïve or had prior inadequate response or intolerance to tumour necrosis factor inhibitors (TNFi-IR).[3,4]

Methods

Trials reported

- The BE OPTIMAL (NCT03895203; bDMARD-naïve) and BE COMPLETE (NCT03896581; TNFi-IR) phase 3 trials assessed BKZ 160 mg every 4 weeks (Q4W) in patients with PsA.
- Placebo-randomised patients switched to BKZ (PBO/BKZ) at Week 16. BE OPTIMAL reference arm (adalimumab 40 mg Q2W) data not reported here. BKZ Total group reported as PBO/BKZ and BKZ groups combined.
- Eligible completers had the option to enter BE VITAL (NCT04009499; open-label extension); all patients received BKZ.

Time to median response analyses

- Study data were pooled and reported as BKZ Total to Year 3 (pooled Week 160/156 BE OPTIMAL/BE COMPLETE data) as observed case.
- The Kaplan-Meier method was used to estimate median time to achievement and the probability of achieving minimal clinically important differences (MCIDs) or improvements (MCIIs) or higher treatment targets (HTTs) in clinical outcomes and PROs by Year 3.
- Time to response was calculated from first BKZ treatment (Week 0 for BKZ-randomised patients and Week 16 for PBO-randomised patients).
- Patients not meeting thresholds for outcomes from time of first BKZ treatment were included.
- Efficacy in achieving MCIDs, MCIIs and HTTs for clinical outcomes and PROs were reported; the list of outcomes can be found in **Figure 1**.

Results

- 1,112 BKZ Total patients were included.
- The BKZ Total group demonstrated rapid achievement of MCIDs or MCIIs across clinical and PRO measures (**Figure 1**); the median times to achievement of MCID in PROs ranged from 8.1 weeks for Pain30 to 25.0 weeks for PsAID-12.
- The median times to achieve the HTTs of ACR50, SJC=0, PASI100 and MDA were 12.3–20.1 weeks in the BKZ Total group (**Figure 1**).
- PsAID-12 REM/LDA, defined as PsAID-12 total score ≤1.95, was achieved at 24.1 weeks.
- Kaplan-Meier plots support a consistent pattern of rapid and sustained response across objective signs of inflammation, overall clinical disease control and quality of life with BKZ intervention (**Figure 2**).

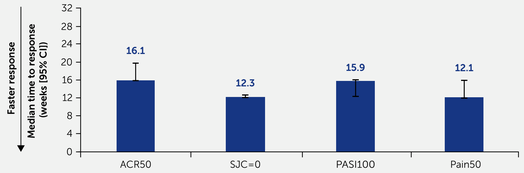
Conclusions

- **Bimekizumab treatment was associated with rapid, clinically meaningful improvements across joint, skin and PRO measures.**
- **Median time to response for many measures was within 8–16 weeks in patients with active PsA who were bDMARD-naïve or TNFi-IR, though interpretation should consider the post hoc design and potential confounding factors.**
- **Notably, patients receiving bimekizumab treatment reported meeting improvements for pain (Pain30) and physical function (HAQ-DI MCID) within approximately 8–12 weeks on average, highlighting the potential benefit of bimekizumab for prompt patient well-being enhancement.**

Summary

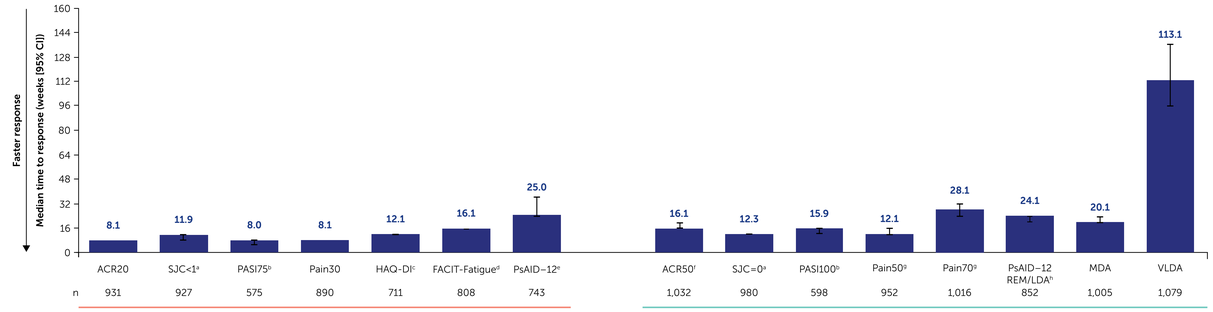
This analysis examined the **median time to response for clinical and patient-reported outcomes** through 3 years of treatment with **bimekizumab** in patients with **PsA** using pooled data from two phase 3 trials

The median time to response for **BKZ-randomised patients** for the following clinical and patient-reported outcomes were:



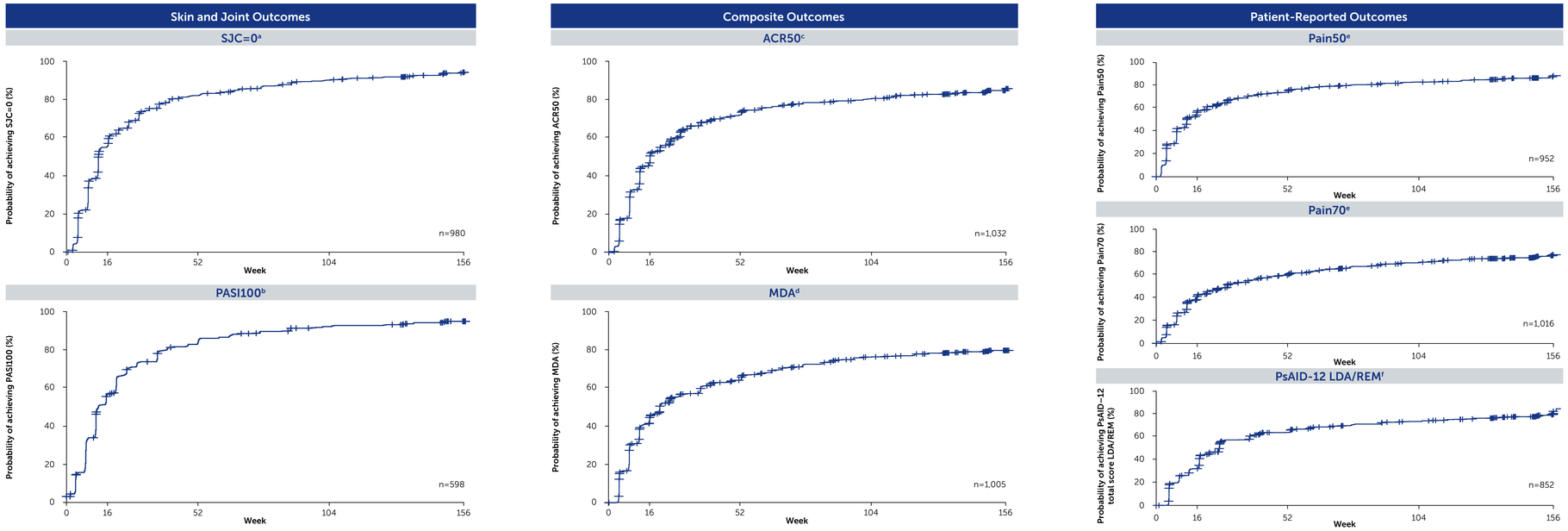
BKZ treatment was associated with **rapid, clinically meaningful improvements**, with many outcomes achieved within **8–16 weeks**.

Figure 1 Median time to the achievement of MCIDs/MCIIs or HTTs in joint, skin, composite and patient-reported outcomes in BKZ Total group



Randomised set from BE OPTIMAL and BE COMPLETE (including data from BE VITAL), pooled for all BKZ Total group patients who were bDMARD-naive or TNFi-IR. BKZ Total group includes BKZ-randomised patients and PBO patients who switched to BKZ at Week 16. Time to response presented as median weeks to response with 95% CIs (95% CIs were not estimable for ACR20 and Pain30). Time to achievement = date of first achievement of threshold − date of first administration of BKZ + 1, calculated from time of first BKZ treatment regardless of treatment group (Week 0 for BKZ-randomised patients and Week 16 for PBO-randomised patients). Patients achieving target threshold prior to or at first administration of BKZ were not included. **[a]** SJC≤1 and SJC=0 were assessed in 66 joints; **[b]** In patients with psoriasis affecting ≥3% BSA at baseline; **[c]** HAQ-DI MCID defined as decrease from baseline ≥0.35, in patients scoring ≥0.35 at baseline; **[d]** FACIT-Fatigue MCID defined as score increase from baseline ≥4 in patients scoring ≤48 at baseline; **[e]** Defined as PsAID-12 total score decrease of ≥3 in patients scoring ≥3 at baseline; PsAID-12 total scores range from 0–10; higher scores indicate worse status; **[f]** ACR50 at Week 16 was the primary endpoint of BE OPTIMAL and BE COMPLETE;[3,4] **[g]** Pain VAS ≥50% and ≥70% improvement represent substantial improvements in patient-reported pain;[5] **[h]** Defined as PsAID-12 total score ≤1.95.

Figure 2 Kaplan-Meier time curves showing the probability of achieving response for signs of inflammation, composite outcomes and PROs to Year 3 in BKZ Total group



Randomised set from BE OPTIMAL and BE COMPLETE (including data from BE VITAL). Data from BE OPTIMAL and BE COMPLETE were pooled to Year 3 for all PBO-randomised patients. BKZ-randomised patients or BKZ Total patients who were bDMARD-naïve or TNFi-IR (BKZ 160mg Q4W Total). All patients were censored at last visit if response was not achieved. Time to achievement = date of first achievement of threshold − date of first administration of BKZ + 1, calculated from time of first BKZ treatment regardless of treatment group (Week 0 for BKZ-randomised patients and Week 16 for PBO-randomised patients). Patients achieving target threshold prior to or at first administration of BKZ were not included. Plus symbols (+) indicate censored patients. **[a]** SJC=0 was assessed in 66 joints; **[b]** In patients with psoriasis affecting ≥3% BSA at baseline; **[c]** ACR50 at Week 16 was the primary endpoint of BE OPTIMAL and BE COMPLETE;[3,4] **[d]** In patients who did not achieve MDA prior or at baseline; **[e]** Pain VAS ≥50% and ≥70% improvement represents substantial improvements in patient-reported pain;[5] **[f]** Defined as PsAID-12 total score ≤1.95.

ACR20/50: ≥20%/50% improvement from baseline in American College of Rheumatology response criteria; **bDMARD:** biological disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **FACIT:** Functional Assessment of Chronic Illness Therapy; **HAQ-DI:** Health Assessment Questionnaire-Disability Index; **HTT:** higher treatment target; **IL:** interleukin; **LDA:** low disease activity; **MCID:** minimal clinically important difference; **MCII:** minimal clinically important improvement; **MDA:** minimal disease activity; **Pain30/50/70:** ≥30%/50%/70% improvement on the Pain VAS scale; **PASI75/100:** ≥75%/100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **PRO:** patient-reported outcome; **PsA:** psoriatic arthritis; **PsAID-12:** Psoriatic Arthritis Impact of Disease-12; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **REM:** remission; **SJC:** swollen joint count; **TNFi-IR:** inadequate response or intolerance to tumour necrosis factor inhibitors; **VAS:** visual analogue scale; **VLDA:** very low disease activity.

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