CO10

A Matching-Adjusted Indirect Comparison of the Efficacy of Bimekizumab and Secukinumab at 52 Weeks for the Treatment of Psoriatic Arthritis

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Objectives

To assess the 52-week comparative efficacy of bimekizumab (BKZ) 160 mg every 4 weeks (Q4W) vs secukinumab (SEC) 150 or 300 mg Q4W in patients with psoriatic arthritis (PsA) who are either biologic disease-modifying anti-rheumatic drug-naïve (bio-n) or tumour necrosis factor inhibitor-experienced (TNFi-exp).

Background

- Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has shown efficacy and tolerability in patients with active PsA for 52 weeks in two Phase 3 trials: BE OPTIMAL (NCT03895203)[1] and BE COMPLETE (NCT03896581)[2].
- Secukinumab (SEC), an IL-17A inhibitor, has also demonstrated efficacy and safety in patients with PsA for 52 weeks in the FUTURE 2 (NCT01752634)[3] Phase 3 trial.
- Due to the absence of direct comparison trials or control arms to compare the efficacy of BKZ and SEC in PsA, a matching-adjusted indirect comparison (MAIC) was conducted to evaluate the relative efficacy of BKZ 160 mg Q4W compared to SEC 150 or 300 mg Q4W at 52 weeks in bio-n and TNFi-exp patients with PsA.

Methods

- Relevant trials were identified as part of a systematic literature review.[4] Specifically, FUTURE 2 randomized controlled trial for SEC was identified as most relevant for this MAIC analysis as it was the pivotal trial used for regulatory and HTA assessment in Europe.[3]
- The MAIC method was followed in accordance with Signorovitch et al.[5] and the National Institute for Health and Care Excellence Decision Support Unit Technical Support Document 18 (NICE DSU TSD 18).[6]
- **Figure 1** shows how individual patient data (IPD) from BKZ trials were matched to SEC trials.
- To adjust for cross-trial differences, patients from the BKZ trials were reweighted to match the baseline characteristics (**Table 1**) of the SEC trial patients; weights were determined using a logistic regression based on sex, age, methotrexate use, Health Assessment Questionnaire-Disability Index, percentage with psoriasis affecting ≥3% body surface area, swollen and tender joint counts, and disease duration. The adjustment variables were selected based on expert consensus (n=5).
- Recalculated BKZ 52-week outcomes for American College of Rheumatology (ACR) 20/50/70 and minimal disease activity (MDA) index (non-responder imputation [NRI]) were compared to SEC outcomes via non-placebo-adjusted comparisons and were reported as odds ratios (ORs). The likelihood of outcome (e.g., greater or worse) was determined by the exclusion of value 1 from the 95% CIs. All analyses were conducted with R version 3.6.2 using the program provided in the NICE DSU TSD 18.

Results

- **In bio-n patients,** the post-matching effective sample size (ESS) for BKZ was 236 [55% of original sample size (OSS)] for the comparison to both SEC 150 and 300 mg (**Figure 2 A/B and Figure 3 A/B**)
  - BKZ had a greater likelihood of achieving ACR70 response at 52 weeks compared to SEC 150 mg and SEC 300 mg.
- **In TNFi-exp patients,** the post-matching ESS for BKZ was 146 (55% of OSS) for comparison to both SEC 150 and 300 mg (**Figure 2 C/D and Figure 3 C/D**)
  - BKZ had a greater likelihood of response than SEC 150 mg for ACR20, ACR50, ACR70, and MDA outcomes at 52 weeks.
  - BKZ had a greater likelihood of achieving ACR50 and MDA outcomes at 52 weeks compared to SEC 300 mg.
- The MAIC-adjusted ORs did not differ greatly from the unadjusted ORs for any outcome.

Conclusions

Using MAIC methodology, bio-n patients treated with BKZ had a higher probability of achieving ACR70 response at 52 weeks compared to patients who received SEC 150 mg and 300 mg.

TNFi-exp patients treated with BKZ had a higher probability of achieving all ACR response levels compared to those who received SEC 150 mg, and a higher probability of achieving ACR50 and MDA responses compared to those who received SEC 300 mg at 52 weeks.

These findings align with a recently published NMA where BKZ showed improvements over SEC in terms of efficacy for most joint outcomes at 16 to 24 weeks.

Figure 1 Summary of MAIC method

- MAICs use IPD from trials of one treatment to match baseline aggregate statistics reported from trials of another treatment.
- By using an approach similar to propensity score weighting, treatment outcomes can be compared across balanced trial populations after matching.

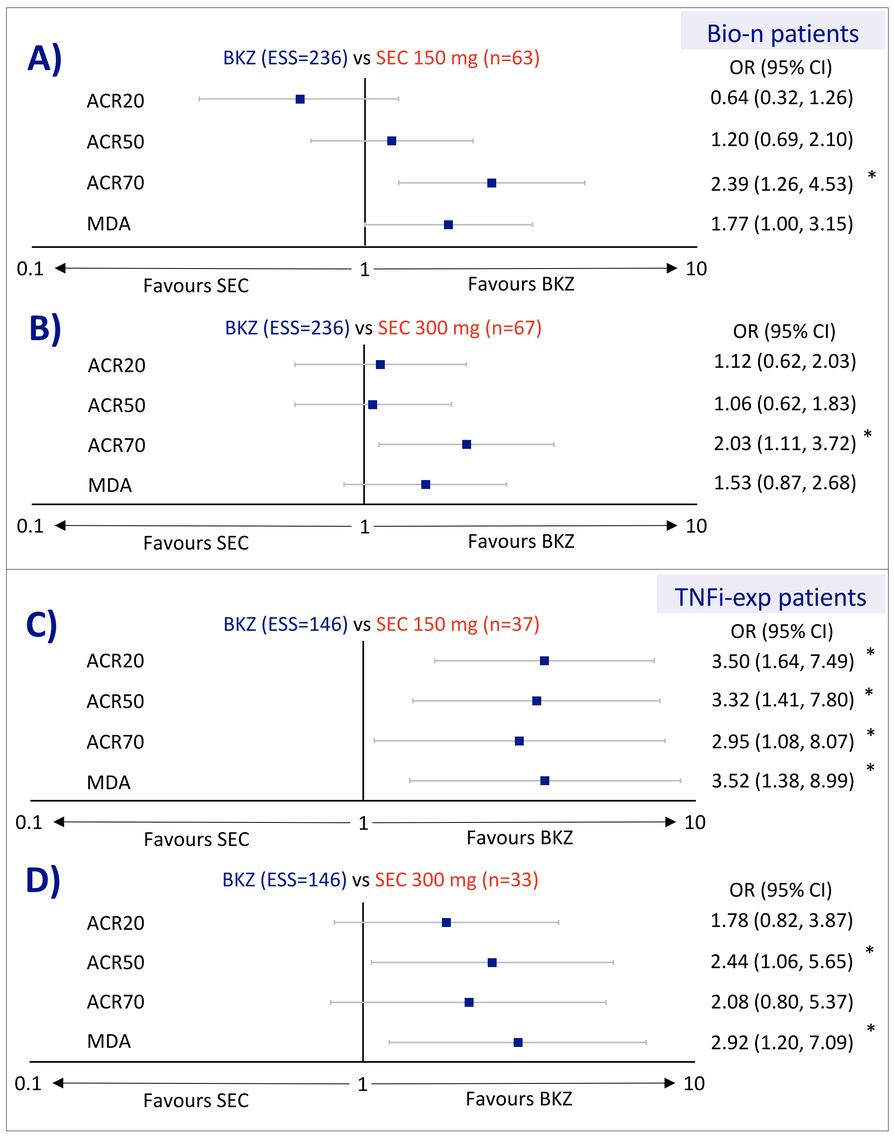
Bio-n patients	**BKZ BE OPTIMAL (n=431)** (individual patient data)	Match with	**SEC FUTURE 2 Bio-n (150 mg, n=63; 300 mg, n=67)** (published aggregated data)
TNFi-exp patients	**BKZ BE COMPLETE (n=267)** (individual patient data)	Match with	**SEC FUTURE 2 TNFi-exp (150 mg, n=37; 300 mg, n=33)** (published aggregated data)

Table 1 Patient baseline characteristics before matching

Mean (SD) unless stated	Bio-n: BE OPTIMAL N=431	Bio-n: FUTURE2* Bio-n N=63 (150mg) N=67 (300mg)	TNFi-exp: BE COMPLETE N=267	TNFi-exp: FUTURE2* TNFi-exp N=37 (150mg) N=33 (300mg)
Age, years	49 (13)	47 (12)	50 (12)	48 (12)
Male, %	47	51	49	52
Time since diagnosis, years	6.0 (7.3)	NA	9.6 (9.9)	NA
MTX use, %	59	49	45	40
SJC (of 66 joints)	9.0 (6.2)	10.8 (8.6)	9.7 (7.5)	12.4 (9.7)
TJC (of 68 joints)	16.8 (11.8)	20.3 (14.7)	18.4 (13.5)	25.6 (19.1)
HAQ-DI score	0.82 (0.59)	1.2 (0.6)	0.97 (0.59)	1.3 (0.6)
Psoriasis BSA ≥3%, %	50	51	66	48

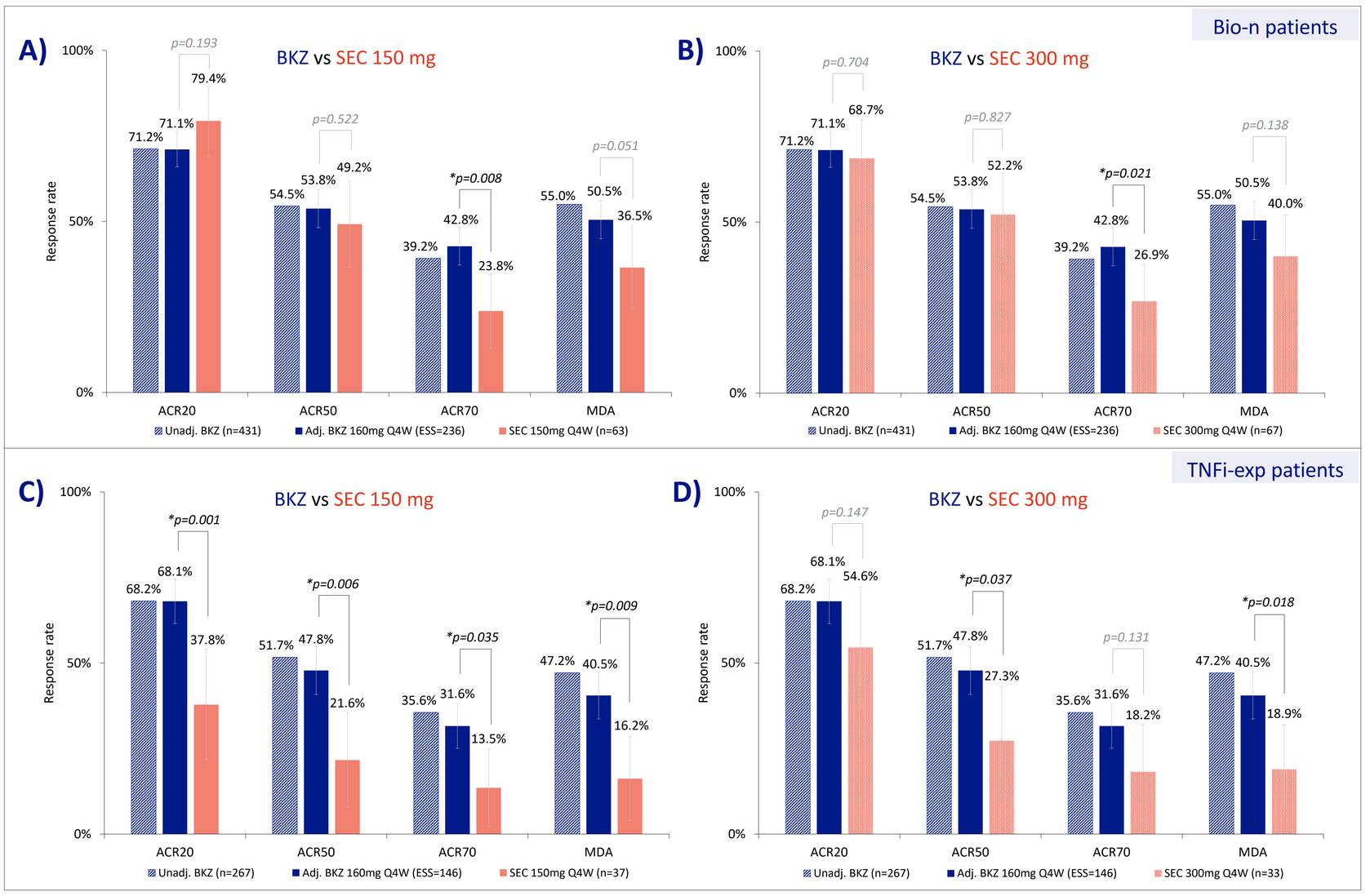
*For the FUTURE 2 trial, patient baseline characteristics were assumed to be similar among bDMARD-naïve patients and TNFi-experienced patients randomised to either SEC 150 mg or 300 mg doses.

Figure 2 Matching-adjusted odds ratio comparison of BKZ vs SEC at Week 52 (NRI)



A) BKZ 160 mg Q4W vs SEC 150 mg Q4W in bio-n patients with PsA, B) BKZ 160 mg Q4W vs SEC 300 mg Q4W in bio-n patients with PsA, C) BKZ 160 mg Q4W vs SEC 150 mg Q4W in TNFi-exp patients with PsA, D) BKZ 160 mg Q4W vs SEC 300 mg Q4W in TNFi-exp patients with PsA
*indicates statistical significance. Figures show a logarithmic scale

Figure 3 Matching-adjusted response rates of BKZ vs SEC in patients with active PsA at Week 52 (NRI)



A) BKZ 160 mg Q4W vs SEC 150 mg Q4W in bio-n patients with PsA, B) BKZ 160 mg Q4W vs SEC 300 mg Q4W in bio-n patients with PsA, C) BKZ 160 mg Q4W vs SEC 150 mg Q4W in TNFi-exp patients with PsA, D) BKZ 160 mg Q4W vs SEC 300 mg Q4W in TNFi-exp patients with PsA
*indicates statistical significance

ACR: American College of Rheumatology; **ACR20/50/70:** at least a 20/50/70% improvement in ACR response; **bio-n:** biologic disease-modifying anti-rheumatic drug-naïve; **BMI:** body mass index; **BKZ:** bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **csDMARD:** conventional synthetic disease-modifying anti-rheumatic drug; **ESS:** effective sample size; **HAQ-DI:** Health Assessment Questionnaire–Disability Index; **IL:** interleukin; **IPD:** individual patient data; **MAIC:** matching adjusted indirect comparison; **MDA:** minimal disease activity; **MTX:** methotrexate; **NA:** not applicable; **NICE DSU TSD 18:** National Institute for Health and Care Excellence Decision Support Unit Technical Support Document 18; **NMA:** network meta-analysis; **NRI:** non-responder imputation; **OR:** odds ratio; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **SD:** standard deviation; **SEC:** secukinumab; **SJC:** swollen joint count; **TJC:** tender joint count; **TNFi-exp:** tumour necrosis factor inhibitor-experienced; **VAS:** visual analogue score; **Unadj:** unadjusted.

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Presented at the International Society for Pharmacoeconomics and Outcomes Research European Congress 2023 | Copenhagen, Denmark | 12–15 November 2023