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A Matching-Adjusted Indirect Comparison of the Efficacy of Bimekizumab and Secukinumab at 52 Weeks for the Treatment of Radiographic Axial Spondyloarthritis

Walter P. Maksymowych,[1] Howard Thom,[2,3] Michael F. Mørup,[4] Vanessa Taieb,[5] Damon Willems,[6] Karl Gaffney[7]

Objective

This matching-adjusted indirect comparison (MAIC) analysis assessed the relative efficacy of bimekizumab versus secukinumab in patients with radiographic axial spondyloarthritis (r-axSpA) at Week 52.

Background

- Bimekizumab, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated consistent and sustained efficacy to Week 52 across the full spectrum of axSpA.[1,2]
- A previous network meta-analysis established higher relative efficacy for Assessment of SpondyloArthritis international Society (ASAS) outcomes at Weeks 12–16 with subcutaneous bimekizumab 160 mg every four weeks (Q4W), versus subcutaneous secukinumab 150 mg Q4W, an IL-17A-only inhibitor, in patients with r-axSpA (i.e. ankylosing spondylitis[3]).[4]
- Here, we assessed the relative efficacy at Week 52 of bimekizumab versus secukinumab 150 mg and the secukinumab 300 mg dose escalation approved for patients with an inadequate response to the 150 mg dose.[5]

Methods

- Individual patient data from BE MOBILE 2 (bimekizumab 160 mg; NCT03928743; n=220) were matched to MEASURE 1/2/3/4 pooled summary data (secukinumab 150 mg; NCT01358175, NCT01649375, NCT02008916, NCT02159053; n=504) and MEASURE 3 (secukinumab 300 mg; n=76) (**Table 1**). MEASURE 5 was excluded from the analysis due to heterogeneity in the patient population.
- To adjust for cross-trial differences, BE MOBILE 2 patients were reweighted to match baseline characteristics in the secukinumab trials (MEASURE 1/2/3/4).
- Weights, determined by propensity score, were based on age, sex, ethnicity, previous TNFi exposure, weight, time from diagnosis and baseline BASDAI.
- These were identified as important effect modifiers and prognostic factors by clinician consensus and literature review, but are limited to those characteristics reported by the MEASURE trials.
- BMI, symptom duration and baseline ASDAS and BASFI were reported for BE MOBILE 2 but not all the MEASURE 1/2/3/4 trials, therefore matching these variables in the MAIC was not possible.
- 52-week outcomes were recalculated for ASAS20, ASAS40 and BASDAI change from baseline as pre-specified outcomes for this MAIC.
- Odds ratios (OR) or mean differences (MD) were estimated alongside 95% confidence intervals (CI) based on robust sandwich estimates of the standard error. Effective sample size (ESS) was estimated to assess the overlap between BE MOBILE 2 and MEASURE 1/2/3/4 trial populations.
- These analyses followed the MAIC methodology described by Signorovitch et al.,[6] in accordance with the NICE Decision Support Unit Technical Support Document 18.[7]

Results

- With bimekizumab, patients had a higher likelihood of achieving ASAS20 (p=0.056; ESS=176), significantly higher likelihood of achieving ASAS40 (p=0.025; ESS=176) and significantly higher likelihood of achieving greater reductions from baseline in BASDAI (p=0.013; ESS=181) than with secukinumab 150 mg at Week 52 (**Figure 1** and **Figure 2**).
- Dose escalation with secukinumab 300 mg showed similar likelihood of achieving ASAS20 (p=0.940) and ASAS40 (p=0.802) to bimekizumab (ESS=112; **Figure 2** and **Figure 3**).

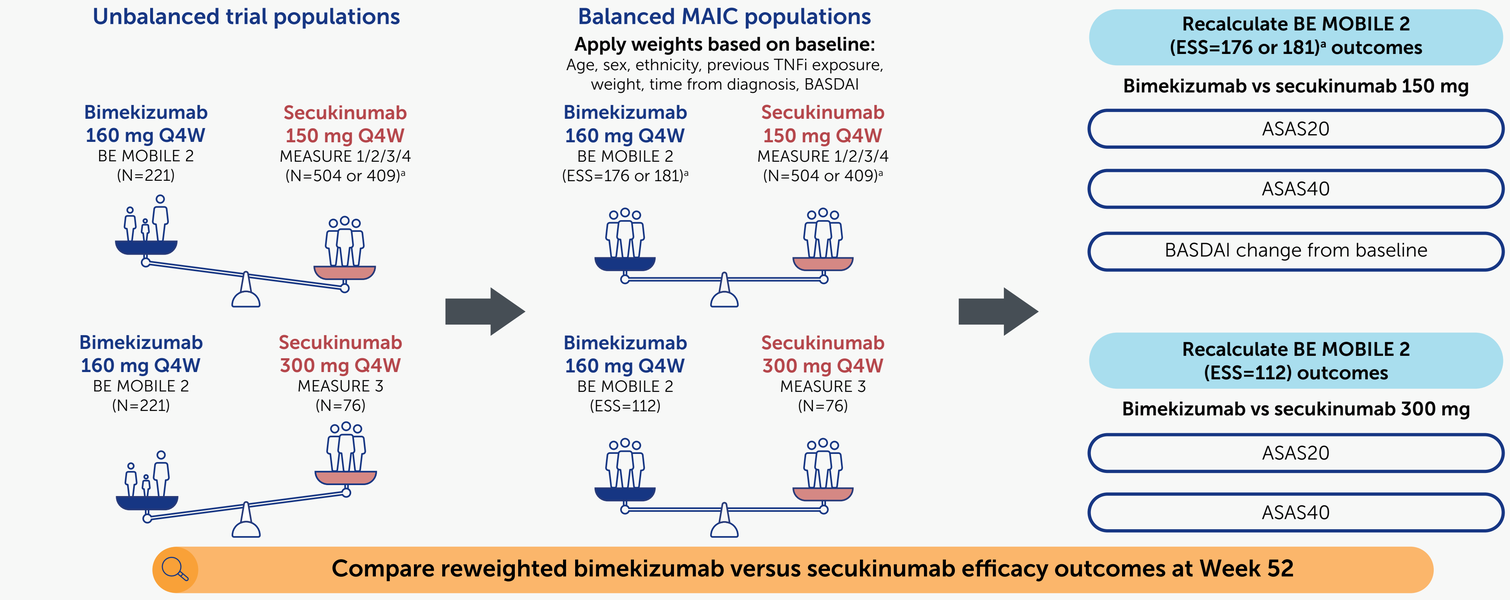
Limitations

- Unlicensed intravenous loading of secukinumab was used in MEASURE 3, which may overestimate the efficacy of licensed subcutaneous secukinumab 300 mg dosing.
- An unanchored MAIC analysis does not utilise a common control arm or randomisation to balance effect modifiers and prognostic factors, and bias can result from unreported but important characteristics.

Conclusions

Patients with r-axSpA treated with bimekizumab 160 mg Q4W may have a significantly greater likelihood of long-term ASAS40 and BASDAI responses versus secukinumab 150 mg at Week 52, and similar likelihood of achieving ASAS20 and ASAS40 versus the escalated secukinumab 300 mg dose (with intravenous loading).

Methodology Summary



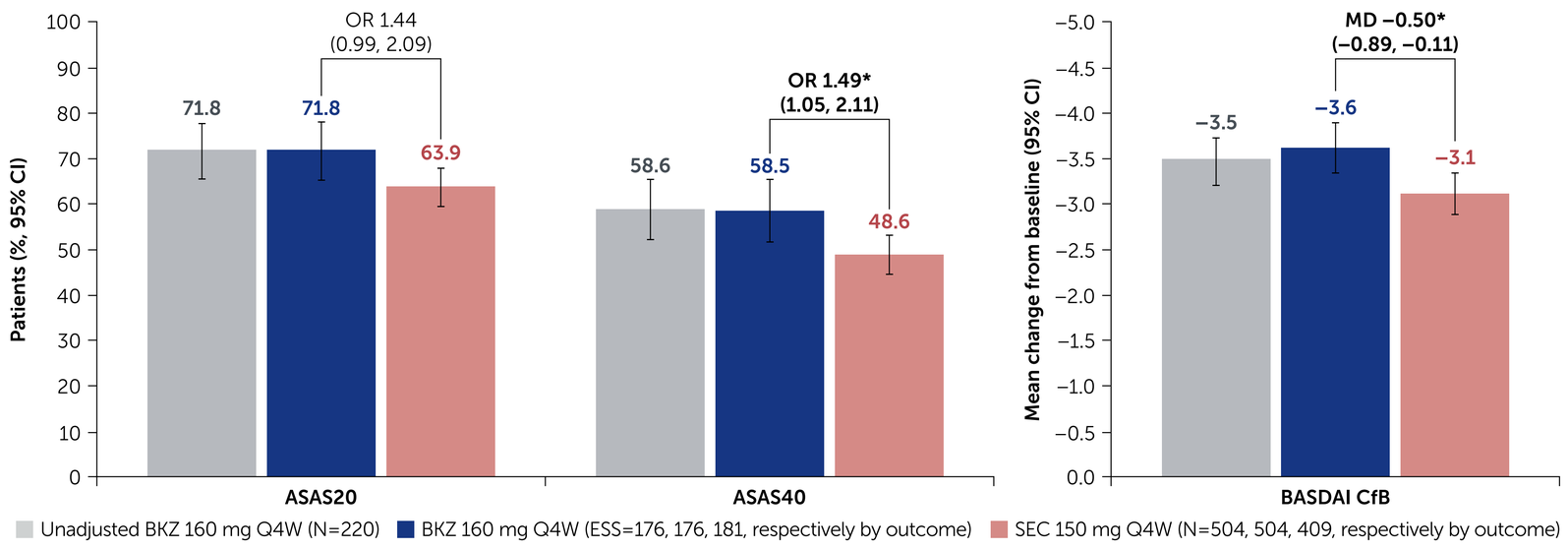
[a]Dependent on efficacy outcome assessed; not all MEASURE trials reported all outcomes.

Table 1 Baseline characteristics of patients with r-axSpA in relevant BKZ and SEC randomised controlled trials

Trial	Unadjusted BE MOBILE 2	Adjusted BE MOBILE 2[a]	Adjusted BE MOBILE 2[b]	Unadjusted MEASURE 1	Unadjusted MEASURE 2	Unadjusted MEASURE 3	Unadjusted MEASURE 3	Unadjusted MEASURE 4	Unadjusted MEASURE 4
Treatment	BKZ 160 mg Q4W	BKZ 160 mg Q4W	BKZ 160 mg Q4W	SEC 150 mg Q4W[c]	SEC 150 mg Q4W[c]	SEC 150 mg Q4W[c]	SEC 300 mg Q4W[c]	SEC 150 mg (No Loading)	SEC 150 mg (Loading)
N	221	176	112	125	72	74	76	117	116
Age, years, mean (SD)	41.0 (12.1)	42.0 (11.6)	42.1 (11.8)	40.1 (11.6)	41.9 (12.5)	42.9 (11.1)	42.1 (11.8)	41.2 (11.1)	44.5 (11.6)
Male, %	72.4	67.4	65.8	67	64	62.2	65.8	70.9	69.8
White, %	80.1	83.7	68.4	55	96	73.0	68.4	100	97.4
Previous TNFi exposure, %	16.7	27.9	25.0	26	39	23.0	25.0	27.4	26.7
Weight, kg, mean (SD)	80.0 (19.1)	79.9 (18.4)	82.7 (16.9)	74.7 (16.2)	82.3 (18.0)	80.3 (19.2)	82.7 (16.9)	80.3 (18.2)	83.4 (20.4)
Time from diagnosis, years, mean (SD)	6.7 (8.3)	6.9 (8.3)	5.3 (7.3)	6.5 (6.9)	7.0 (8.2)	6.0 (7.2)	5.3 (7.3)	6.5 (7.6)	8.4 (10.8)
BASDAI, mean (SD)	6.5 (1.3)	6.8 (1.4)	7.0 (1.4)	6.4 (1.6)	6.6 (1.5)	7.0 (1.4)	7.0 (1.4)	7.0 (1.3)	7.0 (1.2)

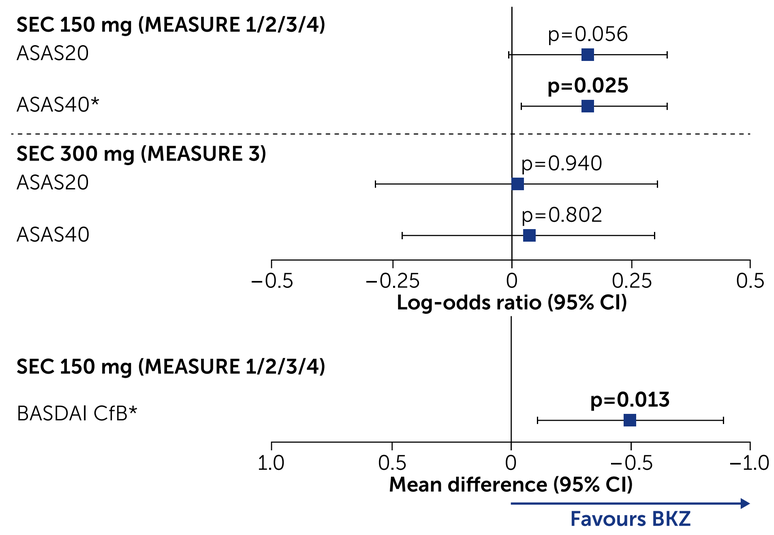
[a]For ASAS40 vs SEC 150 mg; [b]For ASAS40 vs SEC 300 mg; [c]With intravenous loading. Only matching variables are reported. Unadjusted values reported as presented in the published trial manuscripts. Values reported to a higher level of precision are presented to 1 decimal place.

Figure 1 Adjusted outcomes for BKZ (BE MOBILE 2) vs SEC 150 mg (MEASURE 1/2/3/4) at Week 52



*Statistically significant difference (p<0.05 between BKZ and SEC). Error bars represent 95% CI. Differences in N and ESS numbers are due to these outcomes not being reported in all the MEASURE 1/2/3/4 trials.

Figure 2 Odds ratios for relevant outcomes for BKZ vs SEC 150 mg and BKZ vs SEC 300 mg at Week 52



*Statistically significant difference (p<0.05 between BKZ and SEC). Vertical lines show log-odds ratio of 0 (i.e. identical effects of SEC) for ASAS20 and ASAS40 outcomes and a mean difference of 0 for BASDAI CfB. Error bars represent 95% CI.

Figure 3 Adjusted response rates for BKZ (BE MOBILE 2) vs SEC 300 mg (MEASURE 3) at Week 52

Error bars represent 95% CI.

ASAS: Assessment of SpondyloArthritis international Society; **ASAS20/40:** ASAS ≥20/40% improvement; **ASDAS:** Ankylosing Spondylitis Disease Activity Score; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BASFI:** Bath Ankylosing Spondylitis Functional Index; **BKZ:** bimekizumab; **BMI:** body mass index; **CfB:** change from baseline; **CI:** confidence interval; **ESS:** effective sample size; **IL:** interleukin; **MAIC:** matching-adjusted indirect comparison; **MD:** mean difference; **NICE:** National Institute of Health and Care Excellence; **OR:** odds ratio; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **SEC:** secukinumab; **TNFi:** tumour necrosis factor inhibitor.

Institutions: [1]University of Alberta, Edmonton, Alberta, Canada; [2]University of Bristol, Bristol, UK; [3]Clifton Insight, Bristol, UK; [4]UCB Pharma, Copenhagen, Denmark; [5]UCB Pharma, Colombes, France; [6]UCB Pharma, Brussels, Belgium; [7]Norfolk and Norwich University Hospital NHS Trust, Norfolk, UK.

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