Bimekizumab Treatment in Patients with Active Axial
Spondyloarthritis: 52-Week Efficacy and Safety From the
Randomised Parallel Phase 3 BE MOBILE 1 and BE MOBILE
2 Studies

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SUPPLEMENTARY METHODS

Study design
Randomisation was performed using interactive response technology, stratified by region (Asia, Eastern Europe, Western Europe, and North America), MRI/CRP classification (BE MOBILE 1 only) and TNFi exposure (BE MOBILE 2 only).

Patient and public involvement
Patients with axSpA were consulted during development of the BKZ in axSpA clinical trial programme to understand treatment needs and recommend ways to facilitate trial participation while minimising burden of trial visits. Most efficacy endpoints were derived from existing patient-reported outcome measures which were originally developed with patient input to capture the experience of patients with axSpA. Trial participants were recruited by the trial sites and provided written consent to participate.

MRI scoring
Inflammation of the SIJ was measured using the MRI SPARCC SIJ scoring method due to its favourable inter-reader reliability and sensitivity compared with other scoring methods. Inflammation of the spine was measured using a modified MRI Berlin spine method as this method is widely used in clinical studies of axSpA.

MRI endpoints are presented for the subset of patients in the MRI sub studies. MRIs were assessed using central reading by two independent expert readers, with a third adjudicator in cases of disagreement. MRIs from all time points were read in a single reading campaign with readers blinded to time point and treatment arm.
Safety endpoint definitions

TEAEs were defined as adverse events with an onset date on or after the first dose of the study drug and within 20 weeks of the final dose. Treatment-emergent SAEs were defined as any TEAE meeting ≥1 of the following: death, life-threatening illness, medically significant or persistent disability or incapacity, congenital anomaly, or birth defect (including that occurring in a foetus), important medical event, and initial inpatient hospitalisation or prolongation of hospitalisation.

Statistical analysis

Sample size calculations and statistical analyses were performed as described previously. For continuous ranked endpoints reported at Week 16, missing data to Week 16 were imputed with reference-based multiple imputation (RBMI), with the MI model based on PBO group data only. Missing data for non-ranked continuous endpoints and continuous ranked endpoints before and after Week 16 were handled with MI using data from both BKZ and PBO groups. OC data are reported for MRI SPARCC SIJ and Berlin spine inflammation scores, as only a subset of patients underwent MRI.

For binary endpoints, an intercurrent event (IE) was defined as discontinuation of study treatment prior to Week 16 due to any reason. Study participants with missing data at Week 16 preceded by an intercurrent event were counted as non-responders, as well as study participants with missing data at Week 16 that were not preceded by an intercurrent event. For continuous endpoints, an IE was defined as discontinuation due to lack of efficacy or AE. Continuous ranked endpoints with missing data at Week 16 and non-missing data after IE (which are reset to missing),
were imputed using MI based on a reference-based approach, in which the MI model
is based on data from the PBO group. For non-ranked continuous endpoints and
continuous ranked endpoints, missing data at Week 16 were imputed using MI based
on Markov Chain Monte Carlo followed by monotone regression.

**SUPPLEMENTARY RESULTS**

Patients were screened for both studies from 25 April 2019. The last Week 52 visits
were 1 July 2022 (BE MOBILE 1) and 31 May 2022 (BE MOBILE 2).

**Covid-19 impact**

COVID-19 had minimal impact on the trials despite both trials being conducted
during the COVID-19 pandemic. Across all study participants (both BKZ and PBO/BKZ
groups), only 8 (3.1%) patients in BE MOBILE 1 and 17 (5.1%) patients in BE
MOBILE 2 had visits classed as ‘not done’ to Week 52; visits classed as not done
were deemed related to COVID-19 and could include discontinuation of treatment or
termination of study participation. To Week 52, only 13 (5.1%) doses in BE MOBILE
1 and 22 doses (6.6%) were missed in BE MOBILE 2 (either BKZ or PBO) due to
COVID-19.

The number of confirmed corona virus infections in both trials during the DBTP have
been reported previously. During the overall period (Weeks 0–52), there were 17
(8.3/100 PY) and 7 cases (2.4/100 PY) in BE MOBILE 1 and BE MOBILE 2,
respectively. All corona virus cases were mild to moderate and none were serious.
Supportive analyses demonstrated that the pandemic had a negligible impact on the
results of the BE MOBILE trials and the treatment effect for ASAS40 in the COVID-19
free set aligned with that of the overall population (data not reported).
Enthesitis and peripheral arthritis

Among patients with enthesitis at baseline (MASES >0), mean MASES at baseline was 4.8 (BKZ) and 4.9 (PBO/BKZ) for patients with nr-axSpA and 4.2 (BKZ) and 4.4 (PBO/BKZ) for patients with r-axSpA. Reductions (mean CfB) in MASES observed at Week 16 were sustained to Week 52 for patients initially randomised to BKZ (nr-axSpA: −3.6; r-axSpA: −2.9 [MI]); to Week 52, reductions in MASES were also observed in patients switching from PBO at Week 16 (nr-axSpA: −2.9; r-axSpA: −3.2 [MI]; Table S4). It should be noted that MASES is measure of enthesal tenderness and therefore may overestimate the proportion of patients with active enthesitis at baseline.

Among patients with SJC >0 or TJC >0 at baseline, reductions in SJC and TJC score were observed to Week 52 both for patients originally randomised to BKZ (CfB [baseline mean]: SJC: nr-axSpA: −2.5 [4.2]; r-axSpA: −4.2 [4.7]; TJC: nr-axSpA: −4.0 [6.0]; r-axSpA: −4.0 [5.3]; MI) and patients switching from PBO to BKZ at Week 16 (SJC: nr-axSpA: −2.9 [3.8]; r-axSpA: −3.6 [3.9]; TJC: nr-axSpA: −3.5 [6.3]; r-axSpA: −4.5 [5.4]; MI; Table S4).
**SUPPLEMENTARY TABLES AND FIGURES**

**Table S1. Individual ASAS components of the primary endpoint at Week 16 and Week 52**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Change from baseline</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week 16</td>
<td>Week 52</td>
</tr>
<tr>
<td></td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>PBO</td>
<td>BKZ vs PBO difference,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mean (95% CI)</td>
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<tr>
<td></td>
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</tr>
<tr>
<td>nr-axSpA (BE MOBILE 1)</td>
<td>n=126</td>
<td>n=128</td>
<td>n=126</td>
<td>n=128</td>
</tr>
<tr>
<td>r-axSpA (BE MOBILE 2)</td>
<td>n=111</td>
<td>n=221</td>
<td>n=126</td>
<td>n=221</td>
</tr>
<tr>
<td><strong>PtGADA [RBMI/MI], mean (SE)</strong></td>
<td></td>
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<tr>
<td>nr-axSpA</td>
<td>6.9 (0.2)</td>
<td>7.1 (0.2)</td>
<td>-1.4 (0.2)</td>
<td>-3.2 (0.2)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>6.7 (0.2)</td>
<td>6.6 (0.1)</td>
<td>-1.6 (0.2)</td>
<td>-2.7 (0.2)</td>
</tr>
<tr>
<td><strong>Total spinal pain [RBMI/MI], mean (SE)</strong></td>
<td></td>
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</tr>
<tr>
<td>nr-axSpA</td>
<td>7.1 (0.1)</td>
<td>7.3 (0.1)</td>
<td>-1.7 (0.2)</td>
<td>-3.4 (0.2)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>7.2 (0.1)</td>
<td>7.1 (0.1)</td>
<td>-1.9 (0.2)</td>
<td>-3.3 (0.2)</td>
</tr>
<tr>
<td><strong>BASFI [RBMI/MI], mean (SE)</strong></td>
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<tr>
<td>nr-axSpA</td>
<td>5.3 (0.2)</td>
<td>5.5 (0.2)</td>
<td>-1.0 (0.2)</td>
<td>-2.5 (0.2)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>5.2 (0.2)</td>
<td>5.3 (0.2)</td>
<td>-1.1 (0.2)</td>
<td>-2.2 (0.1)</td>
</tr>
<tr>
<td><strong>BASDAI Q5&amp;6 mean score (morning stiffness) [RBMI/MI], mean (SE)</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>nr-axSpA</td>
<td>6.9 (0.1)</td>
<td>7.0 (0.2)</td>
<td>-1.9 (0.2)</td>
<td>-3.6 (0.3)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>6.8 (0.2)</td>
<td>6.7 (0.1)</td>
<td>-2.1 (0.2)</td>
<td>-3.2 (0.2)</td>
</tr>
</tbody>
</table>

Randomised set. Least squares mean differences between BKZ and PBO are reported from the ANCOVA model in which treatment, MRI/CRP classification and region (BE MOBILE 1) or treatment, prior TNFi exposure and region (BE MOBILE 2) were included as fixed effects, and baseline values as covariates. *Missing data were imputed using MI; †Missing data were imputed using RBMI. ANCOVA: analysis of covariance; ASAS: Assessment of SpondyloArthritis international Society; BKZ: bimekizumab; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; CI: confidence interval; CRP: C-reactive protein; MI: multiple imputation; MI: multiple imputation; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; PtGADA: Patient’s Global Assessment of Disease Activity; Q: question; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis; RBMI: reference-based multiple imputation; SE: standard error; TNFi: tumour necrosis factor inhibitor.
### Table S2. ASAS40 responses in TNF-naïve and –IR patients at Week 16 and Week 52

<table>
<thead>
<tr>
<th></th>
<th>Week 16</th>
<th></th>
<th>P value</th>
<th>Week 52</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td></td>
<td>PBO→BKZ</td>
<td>BKZ 160 mg Q4W</td>
</tr>
<tr>
<td>nr-axSpA (BE MOBILE 1)</td>
<td>n=109</td>
<td>n=118</td>
<td></td>
<td>n=109</td>
<td>n=118</td>
</tr>
<tr>
<td>r-axSpA (BE MOBILE 2)</td>
<td>n=94</td>
<td>n=184</td>
<td></td>
<td>n=94</td>
<td>n=184</td>
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<tr>
<td><strong>ASAS40 in TNFi-naïve</strong></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>nr-axSpA</td>
<td>25 (22.9)</td>
<td>55 (46.6)</td>
<td></td>
<td>58 (53.2)</td>
<td>73 (61.9)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>22 (23.4)</td>
<td>84 (45.7)</td>
<td></td>
<td>67 (71.3)</td>
<td>108 (58.7)</td>
</tr>
<tr>
<td><strong>ASAS40 in TNFi-IR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>nr-axSpA</td>
<td>2 (11.8)</td>
<td>6 (60.0)</td>
<td>-</td>
<td>6 (35.3)</td>
<td>5 (50.0)</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>3 (17.6)</td>
<td>15 (40.5)</td>
<td>-</td>
<td>9 (52.9)</td>
<td>21 (56.8)</td>
</tr>
</tbody>
</table>

- Randomised set.
- Ranked secondary endpoint in BE MOBILE 2 only; outcome was not part of the statistical hierarchy, therefore p values are nominal (no multiplicity adjustment) and should not be used as an indicator of statistical significance;
Table S3. Change from baseline in BASDAI Q1 (fatigue) scores at Week 16 and Week 52

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Change from baseline</th>
<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Week 16</td>
<td>Week 52</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>PBO→BKZ 160 mg Q4W</td>
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<tr>
<td>nr-axSpA (BE MOBILE 1)</td>
<td>n=126</td>
<td>n=128</td>
<td>n=126</td>
<td>n=128</td>
<td>n=126</td>
<td>n=128</td>
</tr>
<tr>
<td>r-axSpA (BE MOBILE 2)</td>
<td>n=111</td>
<td>n=221</td>
<td>n=111</td>
<td>n=221</td>
<td>n=111</td>
<td>n=221</td>
</tr>
<tr>
<td>BASDAI Q1, mean (SE)</td>
<td>6.4 (0.2)</td>
<td>6.7 (0.1)</td>
<td>−1.1 (0.2)</td>
<td>−2.6 (0.2)</td>
<td>−2.7 (0.2)</td>
<td>−3.2 (0.2)</td>
</tr>
<tr>
<td></td>
<td>6.4 (0.1)</td>
<td>6.4 (0.1)</td>
<td>−1.7 (0.2)</td>
<td>−2.5 (0.2)</td>
<td>−3.4 (0.2)</td>
<td>−3.1 (0.2)</td>
</tr>
</tbody>
</table>

Randomised set. Data reported are MI. BKZ: bimekizumab; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; MI: multiple imputation; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; Q: question; r-axSpA: radiographic axial spondyloarthritis; Q4W: every 4 weeks; SE: standard error.
**Table S4. Change from baseline in enthesitis (MASES) and peripheral arthritis (SJC and TJC) score at Week 16 and Week 52**

<table>
<thead>
<tr>
<th></th>
<th>Mean (SE)</th>
<th>Baseline</th>
<th>Week 16</th>
<th>Change from baseline</th>
<th>Baseline</th>
<th>Week 52</th>
<th>Nominal p value</th>
<th>PBO→BKZ 160 mg Q4W</th>
<th>BKZ 160 mg Q4W</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>Nominal p value</td>
<td>PBO→BKZ 160 mg Q4W</td>
<td>BKZ 160 mg Q4W</td>
<td></td>
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<tr>
<td><strong>MASES</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
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<td></td>
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<tr>
<td>nr-axSpA&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4.9 (0.4)</td>
<td>4.8 (0.3)</td>
<td>−1.3 (0.3)</td>
<td>−2.4 (0.3)</td>
<td>0.013</td>
<td>−2.9 (0.4)</td>
<td>−3.6 (0.3)</td>
<td></td>
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<tr>
<td>r-axSpA&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4.4 (0.3)</td>
<td>4.2 (0.3)</td>
<td>−1.5 (0.3)</td>
<td>−2.4 (0.3)</td>
<td>0.003</td>
<td>−3.2 (0.3)</td>
<td>−2.9 (0.3)</td>
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<tr>
<td><strong>SJC</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
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<td></td>
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<tr>
<td>nr-axSpA&lt;sup&gt;c&lt;/sup&gt;</td>
<td>3.8 (0.5)</td>
<td>4.2 (0.8)</td>
<td>−1.3 (0.6)</td>
<td>−3.1 (0.7)</td>
<td>0.007</td>
<td>−2.9 (0.4)</td>
<td>−4.2 (0.8)</td>
<td></td>
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</tr>
<tr>
<td>r-axSpA&lt;sup&gt;c&lt;/sup&gt;</td>
<td>3.9 (0.7)</td>
<td>4.7 (0.6)</td>
<td>−2.1 (0.5)</td>
<td>−3.6 (0.5)</td>
<td>0.074</td>
<td>−3.6 (0.8)</td>
<td>−4.2 (0.6)</td>
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<tr>
<td><strong>TJC</strong>&lt;sup&gt;g&lt;/sup&gt;</td>
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<tr>
<td>nr-axSpA&lt;sup&gt;d&lt;/sup&gt;</td>
<td>6.3 (0.6)</td>
<td>6.0 (0.8)</td>
<td>−1.1 (0.5)</td>
<td>−3.0 (0.7)</td>
<td>0.008</td>
<td>−3.5 (0.6)</td>
<td>−4.0 (0.8)</td>
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<tr>
<td>r-axSpA&lt;sup&gt;d&lt;/sup&gt;</td>
<td>5.4 (0.6)</td>
<td>5.3 (0.6)</td>
<td>−2.9 (0.5)</td>
<td>−2.5 (0.4)</td>
<td>0.401</td>
<td>−4.5 (0.6)</td>
<td>−4.0 (0.5)</td>
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</tbody>
</table>

Randomised set. Data reported are MI. Assessed in pts with:

- MASES >0 at BL: PBO n=92; BKZ n=94; BKZ 160 mg Q4W n=94.
- SJC >0 at BL: PBO n=67; BKZ n=132.
- TJC >0 at BL: PBO n=43; BKZ n=45; BKZ 160 mg Q4W n=44.

p values without any multiplicity adjustment are indicated as nominal p values and should not be used as an indicator of statistical significance. p values for the comparison of BKZ to PBO (LS mean difference) were calculated using ANCOVA with treatment, region, MRI/CRP classification (BE MOBILE 1 only), prior TNFi exposure (BE MOBILE 2 only) as fixed effects, and baseline scores as covariate. ANCOVA: analysis of covariance; BKZ: bimekizumab; BL: baseline; CRP: C-reactive protein; LS: least squares; MASES: Maastricht ankylosing spondylitis enthesitis score; MI: multiple imputation; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; r-axSpA: radiographic axial spondyloarthritis; Q4W: every 4 weeks; SE: standard error; SJC: swollen joint count; TJC: tender joint count; TNFi: tumour necrosis factor inhibitor.
## Table S5. TEAEs leading to discontinuation of study drug by preferred term

<table>
<thead>
<tr>
<th>n (%)</th>
<th>Double-blind treatment period</th>
<th>Overall</th>
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<tbody>
<tr>
<td></td>
<td>Weeks 0–16</td>
<td>Weeks 0–52</td>
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<tr>
<td></td>
<td>PBO</td>
<td>BKZ 160 mg Q4W</td>
<td>BKZ 160 mg Q4W Total²</td>
</tr>
<tr>
<td></td>
<td>nr-axSpA (BE MOBILE 1) n=126 (38.1 PYAR)</td>
<td>n=128 (40.4 PYAR)</td>
<td>n=244 (208.2 PYAR)</td>
</tr>
<tr>
<td></td>
<td>r-axSpA (BE MOBILE 2) n=111 (34.6 PYAR)</td>
<td>n=221 (68.3 PYAR)</td>
<td>n=330 (290.9 PYAR)</td>
</tr>
<tr>
<td>Any TEAE leading to discontinuation of study drug</td>
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<td></td>
</tr>
<tr>
<td>nr-axSpA</td>
<td>5 (4.0)</td>
<td>2 (1.6)</td>
<td>8 (3.3) [3.9]</td>
</tr>
<tr>
<td>r-axSpA</td>
<td>0</td>
<td>7 (3.2)</td>
<td>16 (4.8) [5.6]</td>
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<td>Iridocyclitis</td>
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<tr>
<td>nr-axSpA</td>
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<td>0</td>
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<tr>
<td>r-axSpA</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Uveitis</td>
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<tr>
<td>nr-axSpA</td>
<td>2 (1.6)</td>
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<tr>
<td>r-axSpA</td>
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<td>Colitis ulcerative</td>
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<tr>
<td>nr-axSpA</td>
<td>1 (0.8)</td>
<td>0</td>
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</tr>
<tr>
<td>r-axSpA</td>
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2. n (%), overall period: [EAIR/100 PY]

3. PBO

4. BKZ 160 mg Q4W

5. BKZ 160 mg Q4W Total²

6. Ann Rheum Dis


n (%) overall period: [EAIR/100 PY]

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1 Safety set. MedDRA (Version 19.0), preferred terms reported. \(^a\)Includes patients who switched from PBO to BKZ (events after switch only); \(^b\)Assessed as related to study medication by the investigator; ‘Lymphoid tissue hyperplasia was a TEAE related to gastrointestinal disorders and not related to lymphoid blood cells – the TEAE was diagnosed and reported as ‘lymphoid nodular hyperplasia’. BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; MedDRA: medical dictionary for regulatory activities; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; PY: patient-years; PYAR: patient-years at risk; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis; TEAE: treatment-emergent adverse event.
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Safety set. MedDRA (Version 19.0), preferred terms reported. \(^a\)Includes patients who switched from PBO to BKZ (events after switch only); \(^b\)One event in one patient assessed as related to study medication by the investigator; \(^c\)Assessed as related to study medication by the investigator; \(^d\)One event assessed as related to study medication by the investigator; \(^e\)SAE occurred 132 days after treatment initiation. BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; MedDRA: medical dictionary for regulatory activities; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; PY: patient-years; PYAR: patient-years at risk; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis; SAE: treatment-emergent serious adverse event.
### Table S7. Fungal infections

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<sup>a</sup> Total number of patients = n=244; Total number of PYAR = 208.2

<sup>b</sup> Includes candidal esophagitis and candidal laryngitis.
### Double-blind treatment period

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1 Safety Set. MedDRA (Version 19.0), preferred terms reported. Overall period includes all data available up to the last Week 52 visit, including data for patients treated beyond Week 24. aIncludes patients who switched from PBO to BKZ (events after switch only); bFor BE MOBILE 1, 1 oropharyngeal candidiasis event in the Weeks 0–16 period and 4 oropharyngeal candidiasis events and 1 oropharyngitis fungal event in the Weeks 0–52 period were reported as opportunistic infections. For BE MOBILE 2, 1 oesophageal candidiasis, 1 oropharyngeal candidiasis and 1 fungal oesophagitis event in the Weeks 0–52 period was reported as an opportunistic infection. BKZ: bimekizumab; EAIR: exposure-adjusted incidence rate; NEC: not elsewhere classified; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; PY: patient-years; PYAR: patient-years at risk; Q4W: every four weeks; r-axSpA: radiographic axial spondyloarthritis.
## Table S8. Supportive observed case data for binary and continuous endpoints

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<td>BKZ 160 mg Q4W</td>
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<td>n=128</td>
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### Binary endpoints

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<td>25/109 (22.9)</td>
<td>61/127 (48.0)</td>
<td>99/210 (47.1)</td>
<td>64/108 (59.3)</td>
<td>76/102 (74.5)</td>
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<td>ASAS40 in TNFi-naive patientsc, n/N (%)</td>
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<td>55/117 (47.0)</td>
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### Continuous endpoints

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1 Randomised set. 2 Primary endpoint; 3 Secondary endpoints; 4 Ranked secondary endpoint in BE MOBILE 2; 5 Exploratory endpoints; 6 In patients with MASES >0 at baseline; 7 In patients with SJC >0 at baseline. 8 ASAS20/40/PR: Assessment of Spondyloarthritis international Society 20%/40% response/partial remission; ASDAS-ID/MI: Ankylosing Spondylitis Disease Activity Score inactive disease/major improvement; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASDAI50: BASDAI 50% response; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; BKZ: bimekizumab; CfB: change from baseline; CI: confidence interval; CV: coefficient of variation; hs-CRP: CRP: high sensitivity C-reactive protein; LDA: low disease activity; MASES: Maastricht ankylosing spondylitis enthesitis score; MI: multiple imputation; N: number of participants with a non-missing measurement for that timepoint; nr-axSpA: non-radiographic axial spondyloarthritis; NRI: non-responder imputation; OC: observed case; PBO: placebo; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis; TNFi: tumour necrosis factor inhibitor; SD: standard deviation; SE: standard error; SF-36 PCS: Short-Form 36-item Health Survey Physical Component Summary; SJC: swollen joint count; TJC: tender joint count; TNFi: tumour necrosis factor inhibitor.
Figure S1. Study design

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14–35 days

Weeks:

Baseline

Primary endpoint: ASAS40

Week 16

52

Week 52 analysis

Extension study, BE MOVING (NCT04436640), to evaluate long-term response to treatment and safety

Safety follow-up visit 20 weeks after last dose for patients not enrolling in the extension study

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Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator while continuing to receive BKZ. aIncluded patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacroiliitis on MRI and/or elevated CRP [≥6 mg/L]); bIncluded patients had radiographic evidence of nr-axSpA fulfilling modified New York criteria. ASAS: Assessment of SpondyloArthritis international Society; ASAS40: ASAS 40% response; BKZ: bimekizumab; CRP: C-reactive protein; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis.
1  Figure S2. Enrollment, randomisation and treatment

**BE MOBILE 1**
(nr-axSpA)

- 781 patients were assessed for eligibility
- 92 patients negative for mNY radiographic criteria cross-screened
- 537 were ineligible, reasons included:
  - 499 did not meet entry criteria
  - 10 withdrew consent
  - 2 had an adverse event
  - 11 had other reasons

- 254 underwent randomisation

- 120 were assigned to receive placebo Q4W
  - 8 discontinued from the study
  - 3 had an adverse event
  - 1 had lack of efficacy

- 118 (98.3%) completed double-blind period to Week 16
- 2 did not enter 36-week maintenance period

**BE MOBILE 2**
(r-axSpA)

- 610 patients were assessed for eligibility
- 71 patients positive for mNY radiographic criteria cross-screened
- 260 were ineligible, reasons included:
  - 256 did not meet entry criteria
  - 9 withdrew consent
  - 1 was lost to follow-up
  - 1 had an adverse event
  - 11 had other reasons

- 332 underwent randomisation

- 221 were assigned to receive bremizumab 160 mg Q4W
  - 8 discontinued from the study
  - 3 had an adverse event
  - 1 had lack of efficacy
  - 1 had another reason

- 213 (95.4%) completed double-blind period to Week 16
- 3 did not enter 36-week maintenance period

- 14 discontinued from the study
- 7 had an adverse event
- 2 had lack of efficacy
- 2 were lost to follow-up
- 1 had another reason

**Notes:**
- Patients who failed screening in both studies could not be re-screened; ‘Screen failure reasons noted as ‘other’ mainly related to the COVID-19 pandemic (e.g. hospital closures or the halt in enrolment early in the pandemic). mNY: modified New York; nr-axSpA: non-radiographic axial spondyloarthritis; Q4W: every 4 weeks; r-axSpA: radiographic axial spondyloarthritis.
REFERENCES

