Bimekizumab Improves Physical Function and Health-Related Quality of Life in Patients with Axial Spondyloarthritis: Results from Two Phase 3 Studies

Presented at ACR Convergence 2022 | Philadelphia, Pennsylvania, USA | November 10–14

1280939

Maureen Dubreuil1, Karl Gaffney1, Lianne S. Gensler3, Jonathan Kay1, Victoria Navarro-Copnin1, Christine de la Loge1, Alicia M. Ellis1, Carmen Fleurinck2, Marga Dortgensen3, Vanessa Taib3, Ali Dechel1

Objective
To report the impact of bimekizumab (BKZ) versus placebo (PBO) on physical function and health-related quality of life (HRQoL) in patients with non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS, i.e. radiographic axSpA).

Background
The clinical symptoms of axSpA severely impact patients’ physical function and HRQoL.1

- BKZ is a monoclonal IgG antibody that selectively inhibits interleukin (IL)-17 in addition to IL-17A, has demonstrated sustained efficacy and was well tolerated up to 24 weeks in patients across the axSpA disease spectrum active nr-axSpA and AS in the phase 3 studies BE MOBILE 1 and 2.2,3

In both studies, all primary and ranked secondary endpoints at Week 16 were met, including change from baseline (CfB) in physical function (BASFI), SF-36 PCS and HRQoL (ASQoL) measures. Here, results are reported to Week 24.

Methods
- BE MOBILE 1 (TACTIC3001): nr-axSpA and BE MOBILE 2 (TACTIC3002): AS (n=254 patients in each study). All patients were randomized in parallel and completed a 24-week double-blind period followed by a 52-week maintenance period (Figures 1A–1C).

Outcomes
- Here we report, for the Week 24 interim analysis for both studies, the proportion of patients achieving the following outcomes using non-responder imputation (NRI)

- Low BASFI scores (<5.0/10) at Week 18
- Clinically relevant improvements in SF-36 Physical Component Summary (PCS); ≥5-point increase from baseline to Week 24
- Clinically relevant improvements in HRQoL: ASQoL, ≥4-point reduction from baseline to Week 24.

- Mean CfB in BASFI, SF-36 PCS and ASQoL are also reported to Week 24, using multiple imputation (MI).

Results
Patients
- 504 patients with nr-axSpA (BKZ: 252; PBO: 252) and 332 with AS (BKZ: 168; PBO: 164) were randomized. 94.5% and 94.3% completed to Week 16 respectively.

- Mean baseline BASFI, SF-36 PCS scores, and ASQoL scores indicated impaired physical function and HRQoL across nr-axSpA and AS (Table I).

- Mean baseline SF-36 Mental Component Summary (MCS) score indicated non-impaired mental function in both studies which was maintained to Week 24. Therefore the impact of BKZ on SF-36 MCS vs PBO was not reported.

Physical Function & Health-Related Quality of Life
- At Week 16, the majority of patients with nr-axSpA and AS treated with BKZ vs PBO achieved:
  - Low BASFI and ≥5-point improvement in SF-36 PCS scores
  - ≥4-point improvement in SF-36 PCS scores

- Greater mean CfB with BKZ vs PBO at Week 16 was also achieved in ASQoL, SF-36 PCS, and MCS scores (Figure 2), with separation from PBO at the first post-baseline assessment.

- Improvements continued with BKZ to Week 24 and, for patients who switched from PBO to BKZ at Week 16, responses at Week 24 approached or exceeded similar levels to those seen in BKZ-randomized patients (Figure 2–3).

Conclusions
Inhibition of IL-17F in addition to IL-17A with BKZ resulted in rapid and significant improvements in physical function and HRQoL in patients across the spectrum of axSpA, with rapid separation from PBO from first post-baseline assessment. Greater proportions of BKZ- vs PBO-treated patients at Week 16 also reached multiple thresholds for improvement in BASFI and clinically relevant thresholds for improvement in SF-36 PCS and ASQoL. These results emphasize the benefit of BKZ for physical function and HRQoL in axSpA patients.

Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>BE MOBILE 1 (nr-axSpA)</th>
<th>BE MOBILE 2 (AS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), median (IQR)</td>
<td>38 (35–41)</td>
<td>48 (44–52)</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td>59 (23.5)</td>
<td>53 (21.6)</td>
</tr>
<tr>
<td>Sex</td>
<td>10 (7.3)</td>
<td>10 (6.7)</td>
</tr>
<tr>
<td>ESR, median (IQR)</td>
<td>5.7 (3.8–10.0)</td>
<td>2.9 (2.0–4.4)</td>
</tr>
<tr>
<td>CRP, median (IQR)</td>
<td>5.0 (3.3–11.0)</td>
<td>2.8 (1.9–4.7)</td>
</tr>
<tr>
<td>ASAS-ESR CRP, mean</td>
<td>4.3 (2.1)</td>
<td>2.8 (1.9)</td>
</tr>
<tr>
<td>Total spinal pain, mean</td>
<td>79.6 (17.4)</td>
<td>78.2 (17.3)</td>
</tr>
<tr>
<td>Bath Ankylosing Spondylitis Disease Activity Index, mean</td>
<td>47.8 (12.5)</td>
<td>47.8 (12.5)</td>
</tr>
<tr>
<td>BASFI, mean</td>
<td>4.5 (2.3)</td>
<td>5.7 (2.8)</td>
</tr>
<tr>
<td>SF-36 PCS, mean</td>
<td>44.6 (9.6)</td>
<td>46.0 (10.0)</td>
</tr>
<tr>
<td>SF-36 PCS, mean</td>
<td>41.7 (9.2)</td>
<td>41.7 (9.2)</td>
</tr>
<tr>
<td>SF-36 MCS, mean</td>
<td>45.4 (4.3)</td>
<td>45.4 (4.3)</td>
</tr>
<tr>
<td>SF-36 MCS, mean</td>
<td>45.4 (4.3)</td>
<td>45.4 (4.3)</td>
</tr>
</tbody>
</table>

Author Disclosures:
- Maureen Dubreuil, Karl Gaffney, Lianne S. Gensler, Jonathan Kay, Victoria Navarro-Copnin, Christine de la Loge, Alicia M. Ellis, Carmen Fleurinck, Marga Dortgensen, Vanessa Taib, Ali Dechel. All authors have declared no conflicts of interest. The 2 studies were sponsored by UCB Pharma. The authors are grateful for the support of all investigators, patients, and their caregivers in addition to all the investigators and their teams who contributed to this study.}

Notes

Citation