Resolution of Enthesitis and Peripheral Arthritis with Bimekizumab in Patients with Axial Spondyloarthritis: Week 52 Results from the BE MOBILE 1 and BE MOBILE 2 Phase 3 Studies

Objective
To evaluate the impact of bimekizumab treatment on the main peripheral and axial manifestations of spondyloarthritis, including enthesitis and peripheral arthritis, in patients with axial spondyloarthritis trials.

Background
• Peripheral manifestations such as enthesitis and peripheral arthritis are common in patients with spondyloarthritis (sSpA) contributing to disease activity and poor quality of life.
• Bimekizumab (BKZ) is a monoclonal IgG4 antibody that selectively inhibits interleukin (IL)-23, with a demonstrated efficacy in patients with non-radiographic sSpA (nr-sSpA) and radiographic sSpA (r-sSpA), i.e. sSpA with axial manifestations (spinal stenosis and radiographic sacroiliitis).

Materials and Methods
• The patients in MOBILE 1 (n=431) and 2 (n=423), NCT03867673 and NCT03867574, respectively, were randomized to receive bimekizumab or placebo (PBO) in a double-blind period followed by a maintenance period.

• This post-hoc analysis reports the following outcomes in a subset of patients with the corresponding peripheral manifestations of arthritis:
  - Mean change from baseline in Maastricht ankylosing spondylitis enthesitis score (MASES), swollen joint count (SJC) and tender joint count (TJC), multiple imputation (MI).
  - Complete resolution of enthesitis (MASES=0) or peripheral arthritis (SJC=0 at Week 52).

Results
Baseline Characteristics
• Patients with peripheral manifestations of sSpA at baseline:
  - nr-sSpA: 72.4% (n=310), nr-axSpA: 60.9% (n=263), r-axSpA: 27.6% (n=127).

• This post-hoc analysis reports the following outcomes in a subset of patients with peripheral manifestations of arthritis:
  - Mean change from baseline in Maastricht ankylosing spondylitis enthesitis score (MASES), swollen joint count (SJC) and tender joint count (TJC), multiple imputation (MI).
  - Complete resolution of enthesitis (MASES=0) or peripheral arthritis (SJC=0 at Week 52).

Improvements in Peripheral Manifestations of axSpA
Enthesitis
• Across the full disease spectrum of axSpA, mean change from baseline in MASES was larger in patients receiving BKZ compared with those in the placebo group at all time points.

• At the same time point, a greater proportion of patients achieved complete resolution of enthesitis (MASES=0) with BKZ vs placebo (Figure 2).

Peripheral arthritis
• At Week 16, a larger mean change from baseline in SJC or TJC was achieved in patients with axSpA receiving BKZ compared with those in the placebo group (Table 1).

• By Week 52, over 50% of BKZ treated patients achieved complete resolution of peripheral arthritis according to SJC=0 or TJC=0 achieved by Week 52.

Conclusions
Bimekizumab treatment resulted in sustained improvements in peripheral manifestations. Week 52 analysis of the BE MOBILE 1 and BE MOBILE 2 trials demonstrate the potential for bimekizumab to improve peripheral manifestations of axSpA, with a significant impact on enthesitis and peripheral arthritis.

Table 1
<table>
<thead>
<tr>
<th>Treatment</th>
<th>n Baseline</th>
<th>Change from baseline</th>
<th>SJC=0</th>
<th>TJC=0</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBO</td>
<td>111</td>
<td>28.9</td>
<td>0.9%</td>
<td>8.1%</td>
</tr>
<tr>
<td>BKZ 160 mg Q4W</td>
<td>128</td>
<td>56.8</td>
<td>25.8%</td>
<td>43.8%</td>
</tr>
</tbody>
</table>

Figure 2
Distribution of A) enthesitis by tendons and B) swollen joints at baseline in patients with nr-axSpA and r-axSpA (OJC)