Identification of Responder and Disease Activity Thresholds for the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) Questionnaire Using Pooled Data from Two Phase 3 Trials of Bimekizumab in Patients with Psoriatic Arthritis

Objective
To determine clinically meaningful within-patient improvement thresholds to be used as responder thresholds, and to explore preliminary disease activity/impact bands for the Psoriatic Arthritis Impact of Disease-12 total and single-item domain scores for patients with active psoriatic arthritis.

Background
The Psoriatic Arthritis (PsA) Impact of Disease-12 (PsAID-12) questionnaire is a 12-item patient-reported outcome measure developed to assess the impact of PsA on physical, social, and psychological domains.

Methods

Blinded pooled data were analysed from two double-blind, placebo-controlled phase 3 trials (BE OPTIMAL [NC1793320102 and BE COMPLETE [NC1793318161]), of subcutaneous bimekizumab (160 mg every 4 weeks in patients with PsA). BE OPTIMAL included an adalimumab reference arm. Analyses were conducted on observed scores for all randomised patients with ≥1 non-missing PsAID-12 single-item domain between baseline and Week 16. The method for within-patient improvement was used to determine thresholds for each single-item domain score.

Week 16 clinically meaningful within-patient improvement thresholds:

• Total score (0–10 scale): 2-point decrease
• Single-item domain scores (0–10 scale): 1-point decrease

Figure 1: CDF curves of changes in PsAID-12 total score from baseline to Week 16 by ACR response category

Clinical meaningful within-patient improvements and disease activity thresholds were determined using the PsAID-12 total score and single-item domain scores, including pain, fatigue and skin problems, to assess treatment efficacy and disease impact in patients.

Table 1: Baseline patient demographics and disease characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>50.8 (12.4)</td>
</tr>
<tr>
<td>BMI</td>
<td>26.9 (5.2)</td>
</tr>
<tr>
<td>TJC (of 68 joints)</td>
<td>6.1 (5.0)</td>
</tr>
<tr>
<td>SJC (of 66 joints)</td>
<td>1.9 (1.7)</td>
</tr>
<tr>
<td>PsAID-12 total score</td>
<td>5.4 (2.9)</td>
</tr>
<tr>
<td>PsAID-12 total score</td>
<td>4.4 (2.9)</td>
</tr>
<tr>
<td>PsAID-12 total score</td>
<td>6.2 (3.6)</td>
</tr>
<tr>
<td>PsAID-12 total score</td>
<td>5.4 (2.9)</td>
</tr>
<tr>
<td>PsAID-12 total score</td>
<td>5.9 (2.7)</td>
</tr>
</tbody>
</table>

Results
Patient characteristics at baseline are presented in Table 1.

- Mean PsAID-12 total and single-item domain scores at baseline and Week 30 are presented in Figure 2.
- Anchor-based and distribution-based approaches supported the use of 2-point reduction in the PsAID-12 total score to represent a marked CMWP improvement.
- For eight PsAID-12 single-item domain scores, CMWP improvement thresholds were set at a 1-point reduction in scores.
- CMWP improvement thresholds could not be determined for four single-item domain scores due to low proportions of patients scoring 0 (no symptoms) at baseline: anxiety, fear and uncertainty; embarrassment and/or shame; and depression.
- Findings from the aROC curves supported the use of the above CMWP estimates (Figure 4).

The ROC curves used to determine disease impact/activity thresholds for the PsAID-12 total score using PASI43 disease activity categories are shown in Figure 3.

Conclusion

- Clinically meaningful within-patient improvement thresholds across single-and total-item domain scores for the PsAID-12 were determined.
- Disease activity thresholds were identified for the PsAID-12.

Figure 2: ROC curves for determination of disease activity thresholds for the PsAID-12 total score using PASDAS-based disease activity categories

Figure 3: EULAR 2023 POS0590-HPR

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 messing with the patient's call to action. This may impact the user's experience and understanding of the information provided. Is there a way to improve this?