Psychometric Assessment of the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) Questionnaire using Pooled Data from the Phase 3 BE OPTIMAL and BE COMPLETE Trials of Bimekizumab in Patients with Psoriatic Arthritis

Laure Gossec,1 Laura C. Coates,2 Ana-Maria Orbaţi,3 Maarten de Wit,4 Christopher G. Pelligr5, Jérémy Lambert,6 Valérie Ciaravino,6 Barbara Ink,7 Vanessa Taïeb,6 Dafna D. Gladman8

Objective
To assess the psychometric properties of the Psoriatic Arthritis Impact of Disease-12 (PsAID-12) questionnaire total and single-domain scores using data from the phase 3 BE OPTIMAL and BE COMPLETE trials of bimekizumab in patients with PsA.

Background
- PsA can significantly impact multiple aspects of patients' quality of life due to symptoms including pain, fatigue, and reduced physical function.1
- The PsAID-12 questionnaire is a patient-reported outcome (PRO) measure designed to assess the impact of PsA on 12 physical, psychological, and social domains.2
- Clinical efficacy and improvements in PROs were demonstrated in patients with PsA.3
- The PsAID-12 questionnaire is a patient-reported outcome (PRO) measure developed to assess the impact of PsA on 12 physical, psychological, and social domains.2

Methods
- Pooled data were analysed from two double-blind, placebo-controlled, pivotal trials (BE OPTIMAL [NCT03895203] and BE COMPLETE [NCT04275657]) of bimekizumab in patients with PsA.4
- Psychometric analyses were conducted on observed scores for all patients who completed (PsAID-12) domain scores between baseline and Week 16 (n=1,252).
- Convergent validity was assessed at baseline and Week 16 between PsAID-12 and relevant PRO scores (PsA Quality of Life [PsAQoL]; Patient's Global Assessment of Psoriatic Arthritis [PGA-PsA]; Short-Form 36-item Health Survey [SF-36]; and relevant PRO scores).
- Responsiveness was assessed between baseline and post-baseline during 16 weeks of treatment using the mean change in PsAID-12 total and single-domain scores.

Results
- The PsAID-12 questionnaire demonstrated robust psychometric properties in patients with active PsA, supporting its use as a fit-for-purpose PRO measure for assessing treatment effects in this patient population.

Summary
- The PsAID-12 questionnaire is a PRO measure with 12 domains that assess the impact of PsA on patients.
- PsAID-12 total and single-domain score ranges from 0 (no symptom impact) to 10 (very severe impact).
- Psychometric analyses showed PsAID-12 total and single-domain scores to be valid, reliable, and responsive.

Psychometric properties
- Convergent validity was assessed at baseline and Week 16 between PsAID-12 and relevant PRO scores (PsAQoL; PGA-PsA; SF-36; and relevant PRO scores).
- Known-groups validity was evaluated by comparing PsAID-12 scores at baseline in patient subgroups based on the Department of Veterans Affairs disease activity index (VDAI).
- Test-retest reliability was evaluated using intraclass correlation coefficients (ICCs).

Responsiveness
- Responsiveness was assessed between baseline and post-baseline during 16 weeks of treatment using the mean change in PsAID-12 total and single-domain scores.

Responsiveness of the PsAID-12 total and single-domain scores

Table 1: Patient demographics and disease characteristics at baseline

Table 2: Internal consistency of the PsAID-12 total score

Table 3: Responsiveness of the PsAID-12 total and single-domain scores

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1. Sorbonne Université, and AP-HP, Pitié-Salpêtrière Hospital, Paris, France; 2. Nuffield Department of Orthopaedics, Rheumatology and Muscle Disease, John Radcliffe Hospital, University of Oxford, UK; 3. University of Texas Southwestern Medical Center, Dallas, TX, USA; 4. Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA; 5. Department of Medicine, University of Cincinnati, Cincinnati, OH, USA; 6. Clinique Ambroise Paré, Paris, France; 7. Patient Research Partner, Stichting Tools, Amsterdam, the Netherlands; 8. Division of Rheumatology, Department of Medicine, University of Toronto, Toronto, ON, Canada.

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