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Title: Effects of Risankizumab on Nail Psoriasis in Patients with Active Psoriatic Arthritis at Week 24: Results from KEEPSAKE 1

Lars E. Kristensen¹, Ahmed M. Soliman², Kim Papp³, Joseph F. Merola⁴, Lisa Barcomb², Wenjing Lu², Ann Eldred², Frank Behrens⁵

¹ The Parker Institute, Copenhagen University Hospital, Bispebjerg, Denmark, ² Abbvie Inc., United States, ³ K Papp Clinical Research, Probit Medical Research, Canada, ⁴ Brigham And Women's Hospital, Harvard Medical School, United States, ⁵ Goethe University, Germany

Introduction

Risankizumab (RZB), a humanized monoclonal antibody that inhibits interleukin-23, is being developed for the treatment of psoriatic arthritis (PsA). The objective of this study was to determine the effect of RZB on nail psoriasis among patients with active PsA.

Material and Methods

Data were obtained from adult patients with active PsA who had inadequate response or intolerance to at least 1 conventional synthetic disease-modifying antirheumatic drug (csDMARD) and were enrolled in the KEEPSAKE 1 trial (NCT03675308). Patients were randomized 1:1 to receive RZB (150 mg) or placebo (PBO) by subcutaneous injection at Weeks 0, 4, and 16. Nail psoriasis was assessed as the change from baseline in the modified Nail Psoriasis Severity Index (mNAPSI, 0–140 for all fingernails) and the Physician's Global Assessment of Fingernail Psoriasis (PGA-F, 0–4) at Week 24 in patients with nail psoriasis present at baseline; both measures were ranked secondary endpoints in the study. On both scales, higher scores denote more severe nail psoriasis. Data are presented as least square mean change from baseline compared with PBO at Week 24. Results are based on mixed-effect model repeated measurement analysis. Proportion of patients reporting 'clear' or 'minimal' (PGA-F = 0 or 1) with at least a 2-grade improvement in PGA-F were also compared between RZB and placebo arms using the Cochran-Mantel-Haenszel test adjusting for stratification factors of current use of csDMARD (0 or ≥ 1), presence of dactylitis (yes/no) or enthesitis (yes/no), and extent of psoriasis ($\geq 3\%$ BSA or $< 3\%$ BSA) at baseline. Analysis was limited to patients who had nail psoriasis at baseline (defined having mNAPSI > 0 and PGA-F score > 0).

Results

A total of 964 (RZB: 481; PBO: 483) patients (49.6% female) were enrolled. Mean duration of PsA was 7.12 ± 7.35 years and all patients had received at least 1 prior csDMARD. At baseline, 647 patients (67.3%; PBO: n=338, RZB: n=309) presented with nail psoriasis. At Week 24, patients treated with RZB experienced a significantly greater reduction in mNAPSI from baseline, indicating significant improvement in nail psoriasis, as compared with PBO (Table 1). Similarly, PGA-F scores were also significantly reduced from baseline at Week 24 as compared with PBO (Table 1). Of patients for whom PGA-F scores were graded as 'mild', 'moderate', or 'severe' (PGA-F > 1) at baseline, 37.8% (71/188) of patients receiving RZB, and 15.9% (30/190) of patients receiving PBO reported a PGA-F score of 'clear' or 'minimal' after 24 weeks of treatment (nominal $P < 0.001$).

Discussion

RZB treatment, as compared with PBO, results in significantly greater improvements in nail psoriasis in patients with PsA who had inadequate response or intolerance to csDMARD therapy.

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