P172 QUALITY OF LIFE IMPROVEMENTS IN PATIENTS WITH PSA WHO ACHIEVE REMISSION OR LOW DISEASE ACTIVITY TARGETS: RESULTS FROM TWO CLINICAL TRIALS OF IXEKIZUMAB AT THREE YEARS OF TREATMENT

Laura C. Coates[1], Julie Birt[2], Andris Kronbergs[2], Rebecca Bolce[2], Andrew J. Bradley[2], So Young Park[2] and Philip S. Helliwell[3]
[1]*Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UNITED KINGDOM,* [2]*Biomedicines, Eli Lilly and Company, Indianapolis, IN,* [3]*Leeds Insitute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UNITED KINGDOM*

Background/Aims
Treatment guidelines suggest a treat-to-target strategy using remission or low disease activity (LDA) targets in psoriatic arthritis (PsA). For patients with PsA, target achievement is associated with significantly improved quality of life (QoL). This analysis examined physical function and QoL improvements in PsA patients achieving remission or LDA targets at 3 years (156 weeks) of treatment with ixekizumab, a high-affinity monoclonal antibody selectively targeting interleukin-17A.

P172 TABLE 1: Association of Patients Achieving Remission or Low Disease Activity Targets with Incremental QoL Improvement at 3 Years.

	(1) Did not achieve MDA or VLDA	(2) MDA but not VLDA	(3) Achieved VLDA
HAQ-DI MCID RR			
Response, % (n/N)	16.3 (40/246)	83.1 (54/65)	94.4 (51/54)
Difference vs. (1), % (95% CI)	–	66.8 (56.6, 77.0) ‡	78.2 (70.5, 85.8) ‡
Difference vs. (2), % (95% CI)	–	–	11.4 (0.39, 22.3)
SF-36 PCS MCID RR			
Response, % (n/N)	27.2 (73/268)	80.3 (61/76)	86.4 (57/66)
Difference vs. (1), % (95% CI)	–	53.0 (42.6, 63.4) ‡	59.1 (49.3, 69.0) ‡
Difference vs. (2), % (95% CI)	–	–	6.1 (-6.1, 18.3)
EQ-5D-5L VAS CFB			
Nx	261	74	63
Mean (SD)	7.5 (21.1)	17.2 (22.7)	28.0 (22.1)
Mean Difference vs. (1), (95% CI)	–	9.7 (4.2, 15.3) ‡	20.5 (14.7, 26.4) ‡
Mean Difference vs. (2), (95% CI)	–	–	10.8 (3.3, 18.3)†
	(1) Did not achieve DAPSA LDA or DAPSA remission	(2) DAPSA LDA but not remission	(3) Achieved DAPSA remission
HAQ-DI MCID RR			
Response, % (n/N)	8.9 (17/191)	60.4 (55/91)	88.0 (73/83)
Difference vs. (1), % (95% CI)	–	51.5 (40.7, 62.4) ‡	79.1 (71.0, 87.1) ‡
Difference vs. (2), % (95% CI)	–	–	27.5 (15.3, 39.8) ‡
SF-36 PCS MCID RR			
Response, % (n/N)	15.2 (32/210)	72.1 (75/104)	87.5 (84/96)
Difference vs. (1), % (95% CI)	–	56.9 (47.0, 66.8) ‡	72.3 (64.1, 80.5) ‡
Difference vs. (2), % (95% CI)	–	–	15.4 (4.5, 26.3) †
EQ-5D-5L VAS CFB			
Nx	205	101	92
Mean (SD)	5.6 (20.8)	15.9 (21.1)	24.4 (23.5)
Mean Difference vs. (1), (95% CI)	–	10.4 (5.4, 15.3) ‡	18.8 (13.5, 24.1) ‡
Mean Difference vs. (2), (95% CI)	–	–	8.4 (2.1, 14.7)†
	(1) Did not achieve PASDAS LDA or VLDA	(2) PASDAS LDA but not VLDA	(3) Achieved PASDAS VLDA
HAQ-DI MCID RR			
Response, % (n/N)	15.3 (34/223)	63.2 (43/68)	91.9 (68/74)
Difference vs. (1), % (95% CI)	–	48.0 (35.6, 60.4) ‡	76.7 (68.8, 84.5) ‡
Difference vs. (2), % (95% CI)	–	–	29.7 (15.6, 41.7) ‡
SF-36 PCS MCID RR			
Response, % (n/N)	22.1 (54/244)	75.3 (61/81)	89.4 (76/85)
Difference vs. (1), % (95% CI)	–	53.2 (42.4, 63.9) ‡	67.3 (58.9, 75.6) ‡
Difference vs. (2), % (95% CI)	–	–	14.1 (2.7, 25.6)*
EQ-5D-5L VAS CFB			
Nx	238	78	82
Mean (SD)	6.2 (21.1)	15.8 (19.9)	27.7 (22.8
Mean Difference vs. (1), (95% CI)	–	9.5 (4.2, 14.9) ‡	21.5 (16.1, 26.9) ‡
Mean Difference vs. (2), (95% CI)	–	–	11.9 (5.3, 18.6) ‡

Negative changes from baseline indicate improvement in HAQ-DI. Positive changes from baseline indicate improvement in SF-36 PCS and EQ-5D-5L VAS. The MCID for HAQ-DI is defined as a CFB ≤-0.35. The MCID for SF-36 PCS is defined as a CFB ≥2.5. DAPSA LDA refers to a DAPSA score >4 but ≤14; DAPSA remission refers to a DAPSA score ≤4. PASDAS LDA refers to a PASDAS score >1.9 but ≤3.2; PASDAS VLDA refers to a PASDAS score ≤1.9.EQ-5D-5L VAS is measured on a scale of 1-100. Missing data were imputed by NRI for MCID (HAQ-DI and SF-36 PCS) and mBOCF for CFB (EQ-5D-5L VAS). P values were calculated by Fisher's exact test for MCID RR (HAQ-DI and SF-36) and one-way ANOVA for CFB (EQ-5D); *$p < 0.05$; †$p < 0.01$; ‡$p < 0.001$. ANOVA=analysis of variance; CFB= change from baseline; CI=confidence interval; DAPSA=Disease Activity in Psoriatic Arthritis; EQ-5D-5L VAS=5-Level EQ-5D Visual Analog Scale; HAQ-DI= Health Assessment Questionnaire-Disability Index; MCID RR=minimal clinically important difference response rate (%); LDA=low disease activity; mBOFC=modified baseline observation carried forward; MDA=minimal disease activity; n=number of patients achieving QoL measure; N=number of patients in subgroup; NRI=non-responder imputation; Nx=number of patients with non-missing data; PASDAS=Psoriatic Arthritis Disease Activity Score; QoL=quality of life; SD=standard deviation; SF-36 PCS=36-Item Short-Form Health Survey Physical Component Score; VLDA=very low disease activity.

Methods

This study used integrated data from 2 double-blind, randomized phase 3 clinical trials (SPIRIT-P1, NCT01695239; SPIRIT-P2, NCT02349295) of ixekizumab-treated PsA patients who entered the extension period (N = 410). QoL outcome measures included HAQ-Disability Index (HAQ-DI), 36-Item Short-Form Health Survey Physical Component Score (SF-36 PCS), and the 5-level EQ-5D Visual Analogue Scale (EQ-5D-5L VAS). Remission or LDA targets included minimal disease activity (MDA), very low disease activity (VLDA), Disease Activity in Psoriatic Arthritis (DAPSA) remission, DAPSA LDA, Psoriatic Arthritis Disease Activity Score (PASDAS) LDA, and PASDAS VLDA. The response rate (%) of patients achieving minimal clinically important differences (MCID RR) for measures with defined MCID and changes from baseline (CFB) for EQ-5D-5L VAS were observed. QoL improvements by remission or LDA target response status were assessed; significance was calculated by Fisher's exact test for MCID RR and one-way analysis of variance for CFB. Missing data were imputed by non-responder imputation and modified baseline observation carried forward for binary and continuous measures, respectively.

Results

At 3 years of treatment, the percentage of responders was 34.6% (n/N=142/410), 16.1% (n/N=66/410), 48.8% (n/N=200/410), 23.4% (n/N=96/410), 40.5% (n/N=166/410), and 20.7% (n/N=85/410) for MDA, VLDA, DAPSA LDA, DAPSA remission, PASDAS LDA, and PASDAS VLDA, respectively. Achievement of VLDA, DAPSA remission, and PASDAS VLDA were significantly associated with the most QoL improvement, more than achievement of MDA, DAPSA LDA, and PASDAS LDA, which were significantly associated with more QoL improvement than target nonachievement (Table).

Conclusion

Significant associations between remission or LDA target achievement and QoL improvements were present at 3 years of ixekizumab treatment. Numerical improvements in HAQ-DI and SF-36 PCS appear greater in patients achieving the lowest targets; achieving the lowest targets shows incremental QoL benefits compared to achieving LDA.

Disclosure

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