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Figure 2. Clinically Meaningful Improvement (≥ 5 Points) in PROMIS-29 T-Scores at Week 24

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AB0814

SUSTAINED IMPROVEMENTS IN PHYSICAL FUNCTION, QUALITY OF LIFE, AND WORK PRODUCTIVITY WITH IXEKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND PREVIOUS INADEQUATE RESPONSE TO TUMOUR NECROSIS FACTOR-INHIBITORS: 3-YEAR RESULTS FROM SPIRIT-P2 TRIAL

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Background: Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets IL-17A, has shown improvements compared to placebo (PBO) not only in disease activity but also in various patient-reported outcomes (PROs) assessing physical function, quality of life (QoL), and work productivity in PsA patients treated for 24 weeks and sustained up to 52 weeks.^{1,2}

Objectives: To report the effects of treatment with IXE on these PROs after up to 3 years of treatment.

Methods: In SPIRIT-P2 (NCT02349295), a Phase 3 trial, 363 adult patients with active PsA and prior inadequate response or intolerance to 1 or 2 TNF inhibitors (TNFis) were randomized 1:1:1 to IXE 80 mg every 4 weeks (IXEQ4W; N=122) or every 2 weeks (IXEQ2W; N=123), or PBO (N=118) in the double-blind treatment period (Weeks 0-24). Both IXE regimens had a starting dose of 160 mg. Results are reported from a subset of the intent-to-treat population who were randomized to IXE at baseline (Week 0). The following PROs were assessed during Weeks 0-156: HAQ-DI (minimally clinically important difference [MCID] an improvement ≥ 0.35), medical outcomes survey Short Form-36 (SF-36) Physical and Mental Component Summary (PCS and MCS), European Quality of Life 5 Dimensions Visual Analog Scale (EQ-5D VAS), and Work Productivity and Activity Impairment Questionnaire-Specific Health Problem (WPAI-SHP; absenteeism, presenteeism, work productivity, and activity impairment). Missing values were imputed by observed analysis and modified baseline observation carried forward (mBOCF) for continuous data or by modified non-responder imputation (mNRI) for categorical data.

Results: Mean baseline scores for SF-36 (PCS and MCS), EQ-5D VAS, and WPAI-SHP (Figure 1) and HAQ-DI (mean [SD]: IXEQ4W=1.2 [0.6]; IXEQ2W=1.2 [0.6]), indicated impaired physical function and QoL. The percentage of patients of who completed 156 weeks of the study in IXEQ4W and IXEQ2W arms were 57.4% (n=70) and 44.7% (n=55), respectively. Patients receiving IXE treatment up to 3 years reported sustained improvements in SF-36 (PCS and MCS), EQ-5D VAS, and WPAI-SHP (presenteeism, work productivity, and activity impairment) (Figure 1). Observed HAQ-DI mean change from baseline in IXEQ4W: -0.46 (0.62) and IXEQ2W: -0.48 (0.55). The percentage of IXE treated patients achieving MCID for HAQ-DI (improvement ≥ 0.35) was sustained at 3 years (Figure 2).

SF-36 scores include range from 0-100, with higher scores indicating better levels of function and/or better health. EQ-5D is measured on a 0-100 mm VAS. WPAI is assessed by 4 scores: percentage of absenteeism, percentage of presenteeism (reduced productivity while at work), an overall work impairment score that combines absenteeism and presenteeism, and percentage of impairment in activities performed outside of work. Greater scores indicate greater impairment. Abbreviations: EQ-5D=European Quality of Life 5 Dimension Questionnaire; IXE=ixekizumab; mBOCF=modified baseline observation carried forward; MCID=minimally clinically important difference; MCS=Mental Component Summary; mNRI=modified nonresponder imputation; n=number of patients with nonmissing data; N=number of patients in the analysis population; PCS=Physical Component Summary; Q4W/Q2W=40 mg ixekizumab once every 4 or 2 weeks; SD=standard deviation; SF-36=Short Form (36 Items) Health Survey; VAS=visual analog scale; WPAI=Work Productivity and Activity Impairment Questionnaire.

Figure 1. Summary of Patient-Reported Outcomes presented as change from baseline at Week 156 (Observed and mBOCF): Intent-to-Treat Population (Patients Randomized to IXE at Baseline)

Figure 2. Patients achieving HAQ-DI MCID Response up to Week 156 (Observed) and at Week 156 (mNRI) among patients with HAQ-DI ≥ 0.35 at baseline: Intent-to-Treat Population (Patients Randomized to IXE at Baseline)

Conclusion: Improvements in PROs, measuring physical and mental function, quality of life, and work productivity are maintained up to 3 years with IXE treatment in patients with active PsA who have had an inadequate response or intolerance to 1 or 2 TNFis.

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AB0815

CHANGES IN BODY COMPOSITION, BONE MINERAL DENSITY AND BONE REMODELING MARKERS DURING INTERLEUKIN 12/23 INHIBITION IN PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease characterized by multiple comorbid conditions including cardiovascular comorbidities, diabetes, obesity and osteoporosis. Little is known about body composition in patients with PsA and no data are available regarding body composition changes under DMARDs.

Objectives: We investigated the effects of ustekinumab (UST), a humanized anti-interleukin 12/23 antibody, on body composition, bone mineral density (BMD) and bone remodeling markers in patients treated for PsA.

Methods: Thirty patients with active PsA treated with UST were included in a 6 months open follow-up study. Body mass index, DAS28-CRP, bone remodeling markers, serum levels of leptin, BMD and body composition (dual-energy X-ray absorptiometry) were measured at baseline and 6 months of treatment. At baseline, PsA patients were compared with 60 non-PsA controls matched for age, sex and body mass index.

Results: Compared with controls, we observed lower total and appendicular lean mass (53.1 ± 13.1 vs. 56.7 ± 11.9 kg, $p=0.013$ and 21.6 ± 6.3 vs. 23.4 ± 5.0 kg,

$p=0.010$ respectively) and greater fat mass in PsA (32.5 ± 10.8 vs. 25.2 ± 8.9 kg, $p<0.001$). Among PsA patients, 30% had a skeletal muscle mass index below the cut-off point for sarcopenia (Baumgartner's criteria: men 7.26 kg/m², women 5.5 kg/m²) whereas no case was observed in the control group. After 6 months of treatment with UST, there was not a significant change of BMI, while there was a tendency for reaching the significant level for fat mass ($+1.75 \pm 3.60$ kg, $p=0.054$), and fat mass index ($+0.59 \pm 1.25$ kg/m², $p=0.061$). In contrast, a decrease in total lean mass was observed (-1.57 ± 3.10 kg, $p=0.046$) without a significant change in appendicular lean mass and skeletal muscle mass index. No changes for bone remodeling markers, leptin and BMD were observed at 6 months.

Conclusion: Patients with active PsA required biologic therapy had increased fat mass and decreased lean mass. Moreover, ustekinumab might worsen the decrease in lean mass with no significant change in fat mass.

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AB0816

CARDIOVASCULAR COMORBIDITIES IN PSORIATIC ARTHRITIS: A CASE CONTROL STUDY.

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Background: Psoriatic Arthritis (PsA) is an inflammatory arthritis associated with psoriasis. It occurs in approximately 8% –30% of patients diagnosed with psoriasis. In addition to joint and skin manifestations, patients with PsA have an increased prevalence of traditional cardiovascular (CV) risk factors that has been associated with a higher severity of PsA and increased cardiovascular disease (CVD). However, this increased risk has been attributed not only to increased traditional risk factors but also to chronic systemic inflammation.

Objectives: To compare the most relevant CV comorbidities in patients with PsA and controls.

Methods: A cross-sectional observational study was designed, 94 patients between 45-75 years who fulfilled the CASPAR classification criteria for PsA and 94 age-matched controls were included. The clinical characteristics compared between groups were: age, BMI, waist/hip index, gender, diabetes mellitus, hypertension, dyslipidemia, overweight, obesity, smoking history and prior cardiovascular event. Student-t test, Mann-Whitney U, Chi² test and Fisher's exact test were used to compare data and odds ratio were calculated. $p \leq 0.05$ was considered statistically significant. Logistic regression analysis was used to test association between significant clinical risk factors for PsA. The data were analyzed using the SPSS version 25 software.

Results: 94 PsA patients and 94 controls were included. The majority of the patients were women (57.4% in the PsA group and 80.9% in the control group) ($p < 0.001$). Body mass index and waist/hip index were higher in PsA group ($p < 0.002$) ($p < 0.001$) respectively.

PsA patients had more hypertension than controls ($p < 0.022$), more overweight ($p < 0.005$), and a higher smoking history ($p < 0.001$) than the control group. There was a trend in higher hyperlipidemia prevalence in PsA patients (Table 1).

Table 1. Clinical comorbidities and risk factors for PsA.

Variable	PsA	Control	p	OR (95% CI)
Age*	53.23 $\pm$ 11.31	53 $\pm$ 10	0.790	
BMI*	29.37 $\pm$ 5.32	27.21 $\pm$ 4.17	0.002	
Waist/Hip Index**	0.94 (0.88-1.03)	0.90 (0.85-0.92)	<0.001	
Gender			0.001	
Female	54 (57.4%)	76 (80.9%)		
Male	40 (42.6%)	18 (19.1%)		
Diabetes	18 (19.1%)	14 (14.9%)	0.438	1.35 (0.62-2.91)
Hypertension	33 (35.1%)	19 (20.2%)	0.022	2.13 (1.10-4.12)
Dyslipidemia	36 (38.3%)	24 (25.5%)	0.06	1.81 (0.97-3.37)
Overweight	77 (81.9%)	60 (63.8%)	0.005	2.56 (1.31-5.03)
Obesity	36 (37.6%)	26 (27.7%)	0.146	1.57 (0.85-2.92)
Smoking history	36 (38.3%)	78 (83%)	<0.001	0.127 (0.06-0.25)
History of CVD	68 (72.3%)	8 (53.3%)	0.137	2.28 (0.75-6.94)

*Data are reported in mean $\pm$ SD

**Data are reported in median (IQR)