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Descriptive effectiveness of b/tsDMARDs, including ixekizumab, at 12 months for patients with psoriatic arthritis in the German cohort of the PRO-SPIRIT observational study

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Introduction

PRO-SPIRIT is a multinational, 2-year observational study investigating real-world effectiveness and persistence of biologic/targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs), including ixekizumab (IXE), in the treatment of psoriatic arthritis (PsA).

Objectives: To describe baseline (BL) demographic/disease characteristics and the effectiveness of IXE and other b/tsDMARDs at 12 months (M) for patients (pts) with PsA from the PRO-SPIRIT German cohort.

Materials and Methods

Pts with PsA who initiated or switched to a new interleukin-17A inhibitor (IL-17Ai) (IXE or secukinumab [SEC]), tumour necrosis factor inhibitor (TNFi), IL-12/23i, IL-23i, Janus kinase inhibitor (JAKi), or phosphodiesterase-4 inhibitor (PDE4i) during December 2019-June 2022 were evaluated across Germany, Italy, Spain, France, UK, and Canada. Pt characteristics and clinical/pt-reported outcomes were collected at BL and 12M, including swollen-joint count, tender-joint count, change from baseline (CFB) in Clinical Disease Activity Index for PsA (cDAPSA) and PsA-affected body surface area (BSA), and proportion of pts achieving BSA <3%, cDAPSA remission (REM), and minimal disease activity (MDA). This post hoc analysis presents descriptive data for the German on-label population. Mixed models for repeated measures assessed CFB. Missing data were handled via multiple imputation.

Results

Of 1134 PRO-SPIRIT pts, 270 (23.8%) were enrolled in Germany.* Based on descriptive data only, pts taking IXE had longer disease duration (8.7 vs 6.9 years), more previous b/tsDMARD failures (69.8% vs 38.3%), more monotherapy use (72.9% vs 63.3%) and higher BSA ≥3% involvement (51.0% vs 46.7%) at BL than those taking TNFi (Table 1). At 12M, some IXE joint effectiveness measures were higher (unadjusted CFB in cDAPSA, –17.3 vs –11.5), more pts achieved cDAPSA REM (38.9% vs 27.0%) and MDA (46.9% vs 36.8%), and skin improvement was higher (BSA shift to <3%, 31.3% vs 25.0%) than what was observed with TNFi. At BL, pts with IXE had higher skin involvement (BSA ≥3%, 51.0% vs 42.5%) than pts with SEC. At 12M, IXE joint effectiveness was similar (unadjusted CFB in cDAPSA, –17.3 vs –16.8), more pts achieved cDAPSA REM/MDA (cDAPSA REM, 38.9% vs 11.5%; MDA, 46.9% vs 33.7%), and skin improvement was higher (BSA shift to <3%, 31.3% vs 25.0%) than what was observed with SEC. BL characteristics of pts taking IXE, IL-12/23i and IL-23i were similar, except for lower mean BSA (IXE 5.9% vs IL-12/23i 10.5% vs IL-23i 10.3%) and lower proportions of BSA ≥3% (IXE 51.0% vs IL-12/23i 66.7% vs IL-23i 71.4%) for IXE. At 12M, IXE joint effectiveness was similar (unadjusted CFB in cDAPSA, –

17 0 .3 vs –17.7), more pts achieved cDAPSA REM/MDA (cDAPSA REM, 38.9% vs 15.4%; MDA 46.9% vs 29.2%), and skin outcomes were similar (BSA shift to <3%, 31.3% vs 33.3%) to those observed with IL-23i. BL characteristics of pts taking IXE and JAKi were similar, except more pts taking IXE used monotherapy (72.9% vs 56.8%), had b/tsDMARD experience (69.8% vs 56.8%), or had BSA ≥3% (51.0% vs 34.1%). At 12M, IXE joint effectiveness was higher (unadjusted CFB in cDAPSA, –17.3 vs –12.9) and more pts achieved cDAPSA REM with IXE (38.9% vs 14.3%) while achievement of MDA (46.9% vs 44.2%) and skin outcomes (BSA shift to <3%, 31.3% vs 31.8%) were similar to what was observed with JAKi (Table 1).

*PDE4i group is not presented due to low pt numbers (32/1134 overall; 3/270 German pts).

Table 1: Baseline characteristics and effectiveness of IXE and other b/tsDMARDs in the German PRO-SPIRIT cohort at 12 months

Baseline	IXE	SEC total[a]	TNFi	IL-12/23i	IL-23i	JAKi	OVERALL[b]
n (%)	96 (35.6)	40 (14.8)	60 (22.2)	6 (2.2)	21 (7.8)	44 (16.3)	270 (100.0)
Age, years, mean (SD)	55.5 (12.1)	52.4 (11.1)	48.9 (13.9)	53.2 (14.8)	50.9 (11.4)	54.5 (12.4)	53.0 (12.5)
Female, n (%)	59 (61.5)	27 (67.5)	39 (65.0)	3 (50.0)	11 (52.4)	29 (65.9)	169 (62.6)
Time since PsA diagnosis, years, mean (SD)	8.7 (8.0)	7.6 (8.0)	6.9 (8.6)	8.8 (8.5)	6.1 (7.0)	7.1 (5.4)	7.6 (7.7)
b/tsDMARD experienced, n (%)	67 (69.8)	30 (75.0)	23 (38.3)	4 (66.7)	16 (76.2)	25 (56.8)	165 (61.1)
No csDMARD use (monotherapy)	70 (72.9)	28 (70.0)	38 (63.3)	6 (100)	15 (71.4)	25 (56.8)	185 (68.5)
SJC (0-66), mean (SD)	5.9 (6.5)	4.3 (4.5)	3.1 (5.3)	1.7 (2.7)	3.4 (3.2)	4.4 (4.9)	4.5 (5.5)
TJC (0-68), mean (SD)	9.5 (7.6)	9.6 (7.2)	5.5 (8.8)	6.0 (8.7)	11.0 (11.1)	8.8 (7.7)	8.5 (8.3)
cDAPSA, mean (SE)	27.5 (1.4)	26.4 (1.5)	19.7 (1.8)	15.8 (5.9)	26.6 (3.4)	24.9 (1.7)	24.8 (0.8)
BSA (%), mean (SD)	5.9 (9.6)	6.1 (13.4)	9.1 (16.6)	10.5 (14.8)	10.3 (11.8)	4.1 (9.5)	6.8 (12.3)
BSA ≥3%, n (%)	49 (51.0)	17 (42.5)	28 (46.7)	4 (66.7)	15 (71.4)	15 (34.1)	131 (48.5)
Effectiveness at 12M							
n (%) on-label	54	26	37	5	13	21	158
MDA[c], n/N[d] (%)	25 (46.9)	8 (33.7)	11 (36.8)	1 (25.0)	4 (29.2)	8 (44.2)	59 (40.1)
cDAPSA REM[c] (score ≤4), n/N[d] (%)	21 (38.9)	3 (11.5)	10 (27.0)	2 (40.0)	2 (15.4)	3 (14.3)	42 (26.6)
Unadjusted CFB in cDAPSA, mean (SE)	-17.3 (1.8)	-16.8 (2.3)	-11.5 (2.3)	-10.2 (4.3)	-17.7 (4.2)	-12.9 (2.8)	-15.2 (1.1)
12M cDAPSA, mean (SE)	9.2 (1.3)	11.1 (1.5)	8.8 (1.2)	8.4 (4.7)	9.9 (2.1)	9.7 (1.8)	9.4 (0.7)
Adjusted (MMRM) CFB in cDAPSA	-15.3 (1.1)	-13.7 (1.5)	-15.3 (1.3)	-15.7 (3.8)	-15.8 (2.2)	-14.5 (1.8)	-15.1 (0.7)
CFB in BSA (%), mean (SE)	-3.4 (1.0)	-3.8 (1.9)	-5.2 (1.4)	-5.5 (2.6)	-5.7 (1.9)	-3.2 (1.5)	-4.1 (0.6)
12M BSA (%), mean (SE)	2.5 (0.5)	2.3 (0.7)	3.9 (1.1)	5.0 (4.4)	4.6 (1.4)	0.9 (0.3)	2.7 (0.4)
Adjusted (MMRM) CFB in BSA, %	-3.9 (0.5)	-4.2 (0.7)	-3.4 (0.6)	-2.5 (2.0)	-2.9 (1.0)	-5.1 (0.7)	-3.9 (0.3)
12M shift from BSA ≥3% to <3%, n (%)	30 (31.3)	10 (25.0)	15 (25.0)	3 (50.0)	7 (33.3)	14 (31.8)	81 (30.0)

All data are presented as mean (SE) unless otherwise specified. [a]26 pts received SEC 150 mg and 14 pts received SEC 300 mg. [b]Includes data for 3 pts in the PDE4i group, which are not presented separately due to low pt numbers. [c]Pts who already met the criteria for MDA or cDAPSA REM at baseline were excluded from this analysis. [d]The percentage is not always equal to n/N due to the use of MI.

Abbreviations: **12M**, 12 months; **BSA**, body surface area; **b/ts DMARDs**, biologic or targeted synthetic disease-modifying anti-rheumatic drugs; **cDAPSA**, clinical Disease Activity index for Psoriatic Arthritis; **CFB**, change from baseline; **csDMARDs**, conventional synthetic disease-modifying anti-rheumatic drugs; **IL-12/23i**, Interleukin 12/23 inhibitors; **IL-23i**, Interleukin 23 inhibitors; IL-17Ai, interleukin 17A inhibitor; **IL-12/23i**, interleukin-12/23 inhibitors; **IXE**, ixekizumab; **JAKi**, Janus kinase inhibitors; **M,** month; **MDA**, minimal disease activity; **MI**, multiple imputation; **MMRM**, mixed models for repeated measures with least squares mean (SE); **PDE4i**, Phosphodiesterase-4 inhibitors; **REM**, remission; **SD**, standard deviation; **SE**, standard error; **SEC total**, the pooled group of pts who initiated secukinumab (an IL-17Ai) 150mg or 300mg; **SJC**, swollen joint count; **TJC**, tender joint count; **TNFi**, tumor necrosis factor inhibitors.

Treatment groups drugs: TNFi (adalimumab, etanercept, infliximab or biosimilar), IL-12/23i (ustekinumab), IL-23i (guselkumab, risankizumab), JAKi (tofacitinib, upadacitinib).

Conclusions

These real-world data suggest that IXE may provide similar joint effectiveness for some related measures but greater skin improvement than TNFi, despite longer disease duration, more prior b/tsDMARDs, and greater skin involvement at BL. IXE may lead to higher rates of cDAPSA REM than SEC, IL-23i and JAKi and similar skin improvement to IL-23i. In general, these descriptive trends in the German cohort align with findings from the overall PRO-SPIRIT population [1,2], supporting well-balanced joint and skin improvements with IXE in PsA.

References:

1. Kristensen LE, Ng KJ, Ngantcha M, et al. Comparative early effectiveness across 14 PsA drugs and 5 classes of PsA treatment: 3-month results from the PRO-SPIRIT study. RMD Open. 2024 Sep 20;10(3):e004318. 2. Marzo-Ortego M, Sewerin P, Selmi C, et al. Comparative effectiveness and persistence of ixekizumab and other b/tsDMARDs in patients with PsA from a real-world setting: 12-month results from PRO-SPIRIT study. Accepted for publication in RMD Open on 13 January 2026.