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SAT0396

IMPROVEMENT IN THE SIGNS AND SYMPTOMS OF PSORIATIC ARTHRITIS WITH IXEKIZUMAB COMPARED TO PLACEBO IN PATIENT SUBGROUPS DEFINED BY BASELINE DISEASE CHARACTERISTICS

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Background: Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, was superior to placebo (PBO) in two randomized Phase 3 studies in patients (pts) with active psoriatic arthritis (PsA).^{1,2}

Objectives: To assess the consistency of response of IXE across subgroups of pts defined by specific baseline disease characteristics.

Methods: Data were analyzed from an integrated database of 2 randomized, double-blind, Phase 3 studies in pts who were either biologic Disease Modifying Anti-Rheumatic Drug (bDMARD)-naïve (SPIRIT-P1) or who had prior inadequate response or intolerance to TNF inhibitors (SPIRIT-P2). Analyses included pts randomly assigned to the approved dosing regimen of IXE (80 mg IXE every 4 wks [IXE Q4W]) with a starting dose of 160 mg IXE) or to PBO through Wk 24. Efficacy was measured as the percentage of pts achieving $\geq 20\%$, 50%, or 70% improvement from baseline in the American College of Rheumatology criteria (ACR20/50/70) or minimal disease activity (MDA) in subgroups of pts defined by baseline presence of enthesitis, dactylitis, psoriasis body surface area (BSA) involvement ($<3\%$ or $\geq 3\%$), and c-reactive protein (CRP) >6 or ≤ 6 mg/L. Missing data were imputed by nonresponder imputation.

Results: Clinical response rates at Wk 24 in each subgroup are summarized (Table). Significantly ($p < 0.05$) more patients achieved ACR20, ACR50, ACR70, and MDA with IXE compared to placebo across patient subgroups defined by presence of enthesitis, presence of dactylitis, percentage of psoriasis BSA involvement, and by CRP levels at baseline.

Conclusion: At Wk 24, IXE was superior to placebo for the treatment of PsA signs and symptoms regardless of baseline presence of dactylitis or enthesitis, BSA involvement, or CRP levels.

REFERENCES

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SAT0397

DESCRIPTIVE COMPARISONS OF THE IMPACT OF APREMILAST AND METHOTREXATE MONOTHERAPY ON PATIENTS WITH OLIGOARTICULAR PSORIATIC ARTHRITIS IN THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS REGISTRY

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Background: Therapeutic effectiveness has rarely been studied in a sub-population of patients with oligoarticular PsA.

Objectives: To examine baseline characteristics and 6-month clinical assessments of PsA patients with oligoarthritis (≤ 4 swollen joints) who initiated apremilast (APR) or methotrexate (MTX) monotherapy in the Corrona PsA/SpA Registry, a prospective, US-based, observational cohort study. Patients initiating bDMARD monotherapy were also examined as a point of reference.

Methods: Patients ≥ 18 years of age with PsA and oligoarthritis in the registry who initiated APR, MTX or a bDMARD (reference group) monotherapy and had a 6-month follow-up visit between June 2014 and March 2018 were included. Descriptive statistics were calculated for patients' clinical characteristics and disease assessments at treatment initiation and at the 6-month follow-up visit.

Results: The analysis included 150 patients initiating therapy (APR: n=34; MTX: n=15; bDMARD: n=101). Among APR and MTX initiators, 79% and 20% received at least 1 prior bDMARD, respectively. APR initiators, compared with MTX initiators, were younger (mean [SD]: 55.7 [12.6] vs. 61.5 [16.6] years), had longer disease duration (mean [SD]: 8.0 [6.7] vs. 5.4 [7.8] years), and had higher levels of disease activity

Clinical responses at Week 24 in subgroups defined by baseline disease characteristics (NRI)

	ACR20		ACR50		ACR70		MDA	
	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)	PBO (N=224)	IXE Q4W (N=229)
Enthesitis Present	29/142 (20)	88/159 (55)†	12/142 (9)	58/159 (37)†	2/142 (1)	31/159 (20)†	6/142 (4)	41/159 (26)†
Enthesitis Absent	26/81 (32)	39/70 (56)‡	10/81 (12)	28/70 (40)†	4/81 (5)	21/70 (30)†	14/81 (17)	25/70 (36)*
Dactylitis Present	12/59 (20)	55/92 (60)†	6/59 (10)	38/92 (41)†	2/59 (3)	24/92 (26)†	5/59 (9)	33/92 (36)†
Dactylitis Absent	43/164 (26)	72/137 (53)†	16/164 (10)	48/137 (35)†	4/164 (2)	28/137 (20)†	15/164 (9)	33/137 (24)†
BSA $<3\%$	20/85 (24)	44/80 (55)†	8/85 (9)	29/80 (36)†	2/85 (2)	17/80 (21)†	6/85 (7)	21/80 (26)‡
BSA $\geq 3\%$	35/134 (26)	77/141 (55)†	14/134 (10)	55/141 (39)†	4/134 (3)	34/141 (24)†	13/134 (10)	42/141 (30)†
CRP ≤ 6 mg/L	29/100 (29)	45/97 (46)*	11/100 (11)	31/97 (32)†	2/100 (2)	16/97 (17)†	11/100 (11)	25/97 (26)‡
CRP >6 mg/L	26/122 (21)	80/129 (62)†	11/122 (9)	54/129 (42)†	4/122 (3)	36/129 (28)†	9/122 (7)	41/129 (32)†

Data are provided as n/Ns (%) where n=number of responders and Ns=number of patients in each subgroup p-values from Fisher's exact test; *= $p < 0.05$, ‡= $p < 0.01$, †= $p < 0.001$

ACR20/50/70 = $\geq 20\%$, 50%, or 70% improvement from baseline in the American College of Rheumatology criteria; BSA = body surface area; CRP = c-reactive protein; IXE Q4W = 80 mg IXE every 4 weeks; MDA = minimal disease activity; PBO = placebo