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Ixekizumab provides high PASI response for both shorter and longer psoriasis disease durations: results from six randomized clinical trials

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Introduction & Objectives:

Ixekizumab (IXE) is a high-affinity, monoclonal antibody targeting IL-17A approved for the treatment of moderate-to-severe psoriasis (PsO). Clinical response to biologic treatment can vary according to patient demographics and disease characteristics. Although studies indicate that longer disease duration does not impact the response to IXE treatment1,2, these analyses have not examined the response of patients with a shorter disease duration. This study aims to assess the efficacy of IXE in different disease duration subgroups.

Materials & Methods:

An integrated post hoc analysis consisting of patients treated with on-label IXE from the intent to treat populations of six pooled randomised clinical trials (UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-S, IXORA-R and SPIRIT-H2H) was used to assess the efficacy of IXE in disease duration subgroups (<2 or ≥2 years and <5 or ≥5 years). The response rates of patients in each subgroup achieving 90% and 100% improvement from baseline in Psoriasis Area and Severity Index (PASI90 and PASI100) through week 12 was evaluated. Another outcome evaluated was the mean PASI percent improvement from baseline through week 12. For missing data, non-responder imputation was applied for categorical responses and modified baseline observation carried forward was applied for continuous results. PASI response rates with 95% confidence intervals (CI) and mean PASI percent improvement with 95% CI were summarized. Descriptive data compared the baseline disease and demographics characteristics across subgroups.

Results:

Baseline demographics and disease characteristics were similar among most of the selected patient subgroups (Table 1). A higher proportion of patients had nail psoriasis in the longer disease subgroups (≥2 years: 60.3%; ≥5 years: 61.1 %) compared to patients in the shorter disease subgroups (<2 years: 36.7 %; <5 years: 46.6 %); a similar trend was observed for psoriatic arthritis (PsA) (Table 1). All subgroups of patients treated with IXE showed rapid skin clearance with PASI90 and PASI100 response rates increasing over time (Figure 1). Overall, PASI response rates and treatment efficacy at week 12 were similar across the subgroups (Figure 1). Mean percentage improvements in PASI scores were similar for the shorter and longer disease duration subgroups (Figure 2).

Conclusion:

The response rates and mean PASI percent improvement were similar for the shorter and longer disease duration

subgroups (<2, ≥2 years and <5, ≥5 years). IXE consistently showed high efficacy at 12 weeks, and early onset of skin clearance at 4 weeks, for patients with moderate-to-severe PsO irrespective of disease duration in these subgroup analysis from 6 clinical studies through week 12.

References:

1. Lynde, C., et al. Comparative Effectiveness of Biologics Across Subgroups of Patients with Moderate-to-Severe Plaque Psoriasis: Results at Week 12 from the PSoHO Study in a Real-World Setting. Adv Ther. 2023; 40(3):869-886.
2. Torres, T., et al. Drug survival of IL-12/23, IL-17 and IL-23 inhibitors for psoriasis treatment: a retrospective multi-country, multicentric cohort study. Am J Clin Dermatol. 2021; 22:567–579.

Data are mean (standard deviation) unless otherwise stated.

Abbreviations: Body surface area (BSA); Dermatology Life Quality Index (DLQI); Psoriasis Area and Severity Index (PASI); Psoriatic arthritis (PsA); Psoriasis (PsO); Static Physician Global Assessment (sPGA).

*Pooled data from 6 clinical trials: UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-R, IXORA-S and SPIRIT-H2H (PsO population).

[a]Nail psoriasis is summarized as collected for each study: Baseline Fingernail Involvement (UNCOVER-1, UNCOVER-2, UNCOVER-3, IXORA-S), Physician's Global Assessment of Fingernails score>0 (IXORA-R), Nail Psoriasis Severity Index score>0 (SPIRIT-H2H).

[b]Pooled data from 5 studies (IXORA-S excluded, as no PsA data collected at baseline).

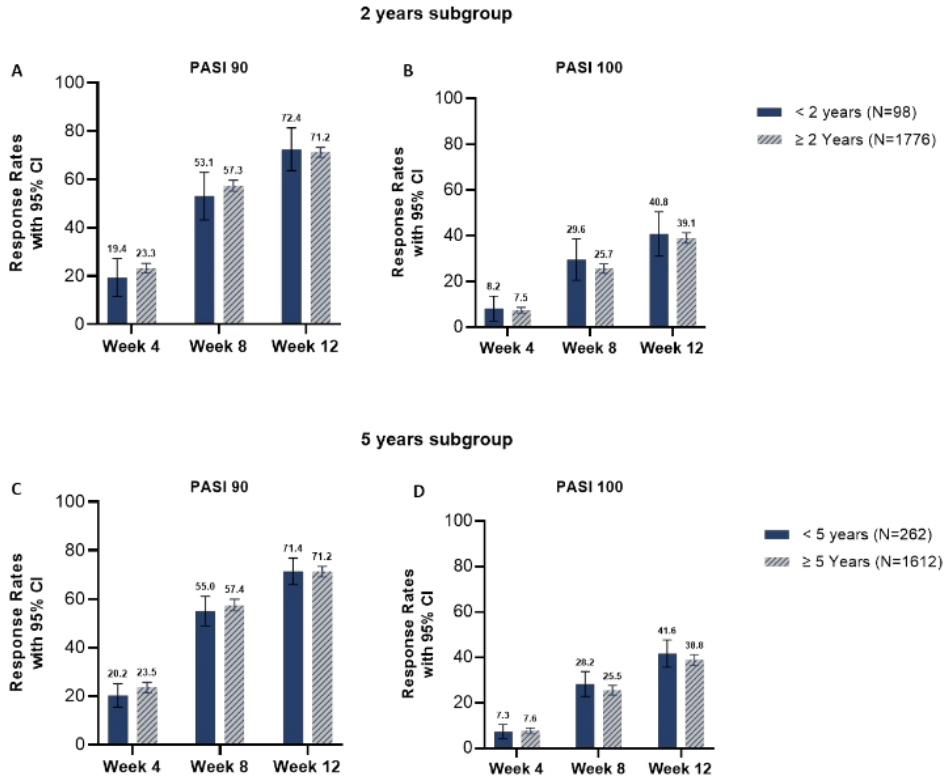
[c]Pooled data from 4 studies (SPIRIT-H2H and IXORA-R excluded, as no scalp PsO data collected at baseline).

	Duration of PsO symptoms (N=1874)			
	2 years subgroup		**5 years subgroup**	
	< 2 years (N=98)	**≥ 2 years (N=1776)**	**< 5 years (N=262)**	**≥ 5 years (N=1612)**
Age, years	44.4 (16.1)	46.1 (13.1)	43 (15.3)	46.5 (12.9)
Male, n (%)	54 (55.1)	1170 (65.9)	162 (61.8)	1062 (65.9)
Weight, kg	89 (23.4)	92 (23.4)	93.2 (27.2)	91.6 (22.7)
Duration of psoriasis (PsO), years	1.2 (0.4)	19.1 (12.2)	2.6 (1.3)	20.7 (11.7)
Percentage of Body surface area (BSA)	26.4 (16.8)	26.7 (17.2)	25.1 (16)	26.9 (17.4)
PASI score	19.6 (7.2)	20 (8)	19.8 (7.9)	20 (8)
sPGA	3.4 (0.5)	3.6 (0.6)	3.5 (0.6)	3.6 (0.6)
Nail Psoriasis[a], n (%)	36 (36.7)	1071 (60.3)	122 (46.6)	985 (61.1)
PsA[b], n (%)	12 (13.2)	442 (26.9)	49 (20.2)	405 (27.1)
Scalp Psoriasis[c]	45 (86.5)	1137 (90.7)	134 (89.3)	1048 (90.7)
DLQI score	14.1 (6.4)	12.7 (7)	13.8 (6.8)	12.6 (7)

Tables and Figures

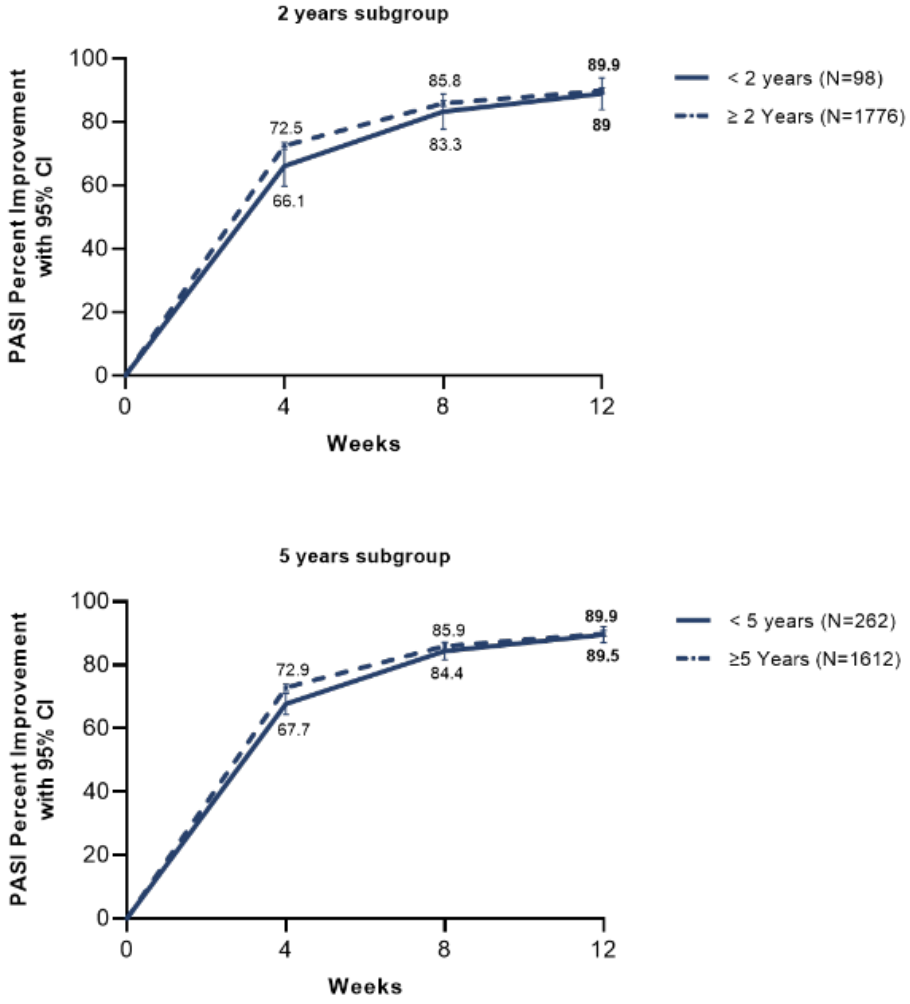
Table 1. Baseline demographics and disease characteristics of pooled data from six clinical trials* by PsO disease duration subgroups

Figure 1. PASI90 and PASI100 response rates of patients treated with IXE by duration of PsO



Abbreviations: Confidence intervals (CI); IXE (Ixekizumab); Psoriasis Area and Severity Index (PASI); Psoriasis (PsO).

Figure 2. PASI percent improvement (%) from baseline of patients treated with IXE by duration of PsO



CI for weeks 4, 8 and 12 are smaller than the width of the line for the ≥ 2 and ≥ 5 years subgroups.

Mean values represented (above line: the ≥ 2 and ≥ 5 years subgroups; below line: the < 2 and < 5 years subgroups).

Abbreviations: Confidence intervals (CI); IXE (Ixekizumab); Psoriasis Area and Severity Index (PASI); Psoriasis (PsO).