

FRI0345

HEAD-TO-HEAD STUDY EVALUATING THE COMBINED ACR50/PASI100 TREATMENT RESPONSE OF IXEKIZUMAB VERSUS ADALIMUMAB: INDIVIDUAL PATIENT DATA FROM A RANDOMIZED, OPEN-LABEL STUDY IN BIOLOGIC-NAÏVE PATIENTS WITH PSORIATIC ARTHRITIS THROUGH WEEK 52

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Background: Multiple biologic DMARDs (bDMARDs) are available for the treatment of psoriatic arthritis (PsA), but there are few direct comparisons of their efficacy and safety. In SPIRIT-H2H study, ixekizumab (IXE), a high-affinity monoclonal antibody selectively targeting IL-17A, was superior to adalimumab (ADA) at Week 24 for simultaneous achievement of ACR50 and 100% improvement from baseline in the Psoriasis Area and Severity Index (PASI 100) in patients (pts) with active PsA. Efficacy on other PsA domains was shown.¹

Objectives: To provide individual patient data demonstrating the simultaneous improvement in musculoskeletal and skin symptoms as assessed by American College of Rheumatology (ACR) response criteria and Psoriasis Area and Severity Index (PASI) percent improvement, respectively.

Methods: Pts with active PsA fulfilling Classification for Psoriatic Arthritis (CASPAR) criteria, $\geq 3/66$ tender and $\geq 3/68$ swollen joints, $\geq 3\%$ psoriasis body surface area (BSA) involvement, no prior treatment with bDMARDs, and prior inadequate response to ≥ 1 conventional synthetic DMARD (csDMARD), were randomized 1:1 to open-label IXE or ADA (label dosing according to presence/absence of moderate-to-severe psoriasis [baseline BSA $\geq 10\%$, PASI ≥ 12 , and static Physician's Global Assessment ≥ 3]) in Study 11F-MC-RHCF (NCT03151551). In this analysis, max ACRx was defined as the maximum ACRx response a patient can achieve where ACRx derivation follows the typical ACR response criteria: $\geq x\%$ improvement in both tender joint count (TJC) and swollen joint count (SJC) and $\geq x\%$ improvement in ≥ 3 of the 5 remaining components, Health Assessment Questionnaire-Disability Index total score (HAQ-DI), C-reactive protein (CRP), Patient Global Assessment (PatGA), Physician Global Assessment (PhyGA), and patient assessment of joint pain (patJP). Missing data were imputed using the last observation carried forward (LOCF) method.

Results: At baseline, demographic and disease characteristics were similar across treatment groups. Mean baseline values for the ACR core data set were 20.2 (TJC), 10.4 (SJC), 63.8 (PatGA), 10.2 (CRP), 59.2 (PhyGA), 1.2 (HAQ-DI), and 61.0 (patJP). Mean PASI total score was 7.8. Figures 1 and 2 show the maximum ACR response by PASI percent improvement at Weeks 24 and 52, respectively. Independent of joint improvement, more ixekizumab-treated patients compared to adalimumab-treated patients achieved \geq PASI 90 (76.6% vs. 57.5% at week 24 and 83.0% vs. 59.6% at Week 52). Evaluation of patient-level data shows that while very few patients had joint improvement but little skin improvement (max ACRx ≥ 50 and PASI < 50 ; Figures 1 and 2) in both treatment arms (IXE: 1.8%; ADA: 1.4%), fewer patients treated with IXE had no to little improvement in both joint and skin symptoms (PASI < 50 and max ACRx < 50) than those treated with ADA at Week 24 (IXE: 3.6%; ADA: 13.3%). A similar pattern was observed at Week 52 (Figure 2).

Conclusion: Ixekizumab treatment was superior to adalimumab when evaluating the combination of musculoskeletal and skin symptoms of PsA as measured by ACR response and PASI response.

References:

[1] Mease PJ, Smolen JS, Behrens F et al., Ann Rheum Dis 2019; 79(1):123-131.

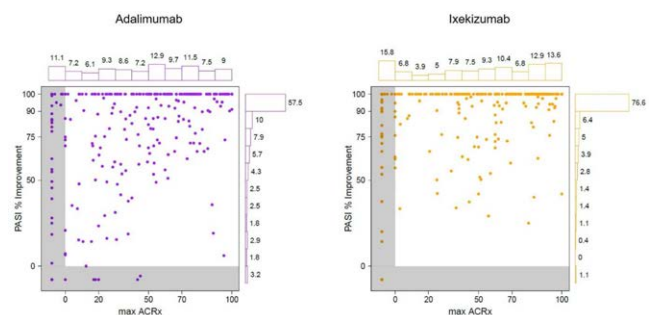


Figure 1. Maximum ACR response-by-PASI Percent Improvement at Week 24. Abbreviations: ACR, American College of Rheumatology; BSA, body surface area; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis. Please note: Nine patients with active PsA and BSA $\geq 3\%$ were assessed as PASI=0 at baseline, a medical inconsistency that was resolved using medical judgement. These patients were considered PASI100 responders if PASI=0 and BSA=0 at post baseline visits.

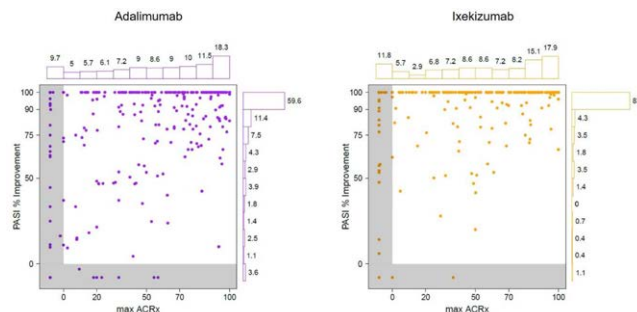


Figure 2. Maximum ACR response-by-PASI Percent Improvement at Week 52. Abbreviations: ACR, American College of Rheumatology; BSA, body surface area; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis. Please note: Nine patients with active PsA and BSA $\geq 3\%$ were assessed as PASI=0 at baseline, a medical inconsistency that was resolved using medical judgement. These patients were considered PASI100 responders if PASI=0 and BSA=0 at post baseline visits.

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FRI0346

EFFICACY OF NETAKIMAB IN THE TREATMENT OF AXIAL DISEASE IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS OF SUBANALYSIS FROM A DOUBLE-BLIND RANDOMIZED PHASE 3 TRIAL (PATERA)

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Background: The presence of axial involvement significantly impacts on psoriatic arthritis (PsA) activity, outcomes and patients (pts) quality of life. IL-17A inhibitors were previously shown to improve axial disease in PsA. Netakimab (NTK) is a humanized anti-interleukin 17A antibody approved for the treatment of moderate-to-severe plaque psoriasis.

Objectives: To evaluate the effects of NTK on axial symptoms in patients with PsA, based on data of 24-week (wk) observation from an ongoing phase 3 PATERA study (NCT03598751).

Methods: PATERA is a phase 3 international double-blind, placebo-controlled clinical study. After completion of screening 194 eligible adult patients with PsA fulfilling the CASPAR criteria, with inadequate response to csDMARD or one TNFI, were randomly assigned (1:1) to receive NTK 120mg or placebo (PBO) at Wks 0, 1, 2, 4, 6, 8, 10, 14, 18 and 22. 84 patients from PBO arm, failed to achieve ACR20 (20% improvement the American College of Rheumatology criteria) by Wk 16, were switched to NTK. A subset of pts with axial involvement (defined by presence of inflammatory back pain (IBP) according to ASAS IBP criteria, 2009) was evaluated with spondylitis-specific assessments: spinal pain (10-item numerical rating scale), nocturnal back pain (10-item numerical rating scale), BASDAI (Bath Ankylosing Spondylitis Disease Activity Index), ASDAS-CRP (Ankylosing Spondylitis Disease Activity Score with C-reactive protein).

Results: 104 PsA patients (NTK N=54, PBO N=50) with IBP at baseline (BL) were included in the analysis. Demographic and BL disease characteristics were comparable across the groups (Table 1). During the analyzed period, BASDAI and ASDAS-CRP scores significantly decreased in NTK-treated patients (Figure 1). Maximum decrease in axial disease activity developed by Wk 4-8