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

A. Kavanaugh¹, E. Lubrano², T. Muram³, C. Y. Lin³, S. Liu Leage⁴, F. Van den Bosch^{5,6}, L. E. Kristensen⁷. ¹University of California, San Diego, United States of America; ²Università degli Studi del Molise, Campobasso, Italy; ³Eli Lilly and Company, Indianapolis, United States of America; ⁴Lilly France, Fegersheim, France; ⁵Ghent University Hospital, Ghent, Belgium; ⁶VIB Center for Inflammation Research, Ghent, Belgium; ⁷The Parker Institute, Frederiksberg, Denmark

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:

- 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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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)

T. Korotkova¹, I. Gaydukova², V. Mazurov³, A. Samtsov³, V. Khayrutdinov³, A. Bakulev⁴, M. Kokhan⁵, A. Kundzer⁶, N. Soroka⁷, E. Dokukina⁸, A. Ereemeeva⁸. ¹Nasonova Research Institute of Rheumatology, Moscow, Russian Federation; ²Mechnikov North-Western State Medical University, St-Petersburg, Russian Federation; ³Kirov Military Medical Academy, St-Petersburg, Russian Federation; ⁴Razumovsky Saratov State Medical University, Saratov, Russian Federation; ⁵Ural Research Institute of Dermatovenereology and Immunopathology, Ekaterinburg, Russian Federation; ⁶Healthcare Institution Municipal Clinical Hospital No. 1, Minsk, Belarus; ⁷Scientific and Practical Center of Surgery, Transplantology and Hematology, Minsk, Belarus; ⁸JSC BIOCAD, St-Petersburg, Russian Federation

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 120 mg 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

depending on index of assessment. The achieved values maintained throughout the entire analyzed period (Table 2). At Wk 24, mean changes in ASDAS-CRP and BASDAI were -1.57 and -2.83 in NTK arm vs -0.11 and -0.19 in PBO arm respectively ($p<0.0001$).

Table 1. Baseline demographics and mean composite endpoint scores

Arm	NTK (N=54)	PBO (N=50)
Age (years)	43.5 (12.16)	42.7 (10.76)
Male, n (%)	27 (50)	26 (52)
PsA duration, mo	70.0 (78.78)	79.0 (81.62)
BASDAI score	5.58 (1.80)	5.79 (1.94)
ASDAS-CRP score	3.38 (1.16)	3.38 (1.28)
nocturnal pain	4.2 (2.42)	5.1 (2.29)
spinal pain	4.4 (2.41)	5.3 (2.40)

* mean (standard deviation) BASDAI=Bath Ankylosing Spondylitis Disease Activity Index, ASDAS-CRP=Ankylosing Spondylitis Disease Activity Score with C-reactive protein

Table 2. Changes in BASDAI and ASDAS-CRP vs baseline

	BASDAI		ASDAS-CRP	
	NTK (N=54)	PBO (N=50)	NTK (N=54)	PBO (N=50)
Wk 4	-2.45 (1.94)	-0.51 (1.26)	-1.44 (1.06)	-0.19 (0.60)
Wk 8	-2.77 (2.22)	-0.38 (1.55)	-1.53 (1.07)	-0.21 (0.74)
Wk 16	-2.77 (1.83)	-0.17 (1.67)	-1.52 (0.98)	-0.10 (0.97)
Wk 24	-2.83 (2.15)	-0.19 (1.70)	-1.57 (1.06)	-0.11 (0.95)

mean (standard deviation)

Figure 1. Mean change in BASDAI, ASDAS-CRP, spinal pain, and nocturnal pain at Wk 24

Conclusion: About 50% of subjects, randomized to PATERA study, had IBP at baseline. NTK leads to rapid and sustained improvement in axial disease in patients with active PsA.

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PREVALENCE OF OBESITY AND ITS LINK TO PSORIATIC ARTHRITIS (PSA) ACTIVITY AND RESPONSE TO THERAPY: DATA FROM THE RUSSIAN PSA REGISTRY (RU-PSART)

Y. Korsakova^{1,2}, E. Loginova³, E. Gubar³, E. Vasilenko⁴, A. Vasilenko⁵, N. Kuznetsova⁶, I. Patrikeeva⁷, T. Korotaeva⁸, E. Nasonov⁸ on behalf of RU-PSART Study Group. ¹Nasonova Research Institute of Rheumatology, Department of Spondyloarthritis and Psoriatic Arthritis, Moscow, Russian Federation; ²V.A. Nasonova Research Institute of Rheumatology, Department of Spondyloarthritis and Psoriatic Arthritis, Moscow, Russian Federation; ³V.A. Nasonova Research Institute of Rheumatology, Department of Spondyloarthritis and Psoriatic Arthritis, Moscow, Russian Federation; ⁴Clinical Rheumatological Hospital No 25, St. Petersburg, Russian Federation; ⁵Novgorod Regional Clinical Hospital, Novgorod, Russian Federation; ⁶Municipal Autonomous Institution "City Clinical Hospital No. 40, Ekaterinburg, Russian Federation; ⁷Tyumen Regional Clinical Hospital No 1, Tyumen, Russian Federation; ⁸V.A. Nasonova Research Institute of Rheumatology, Moscow, Russian Federation

Background: Obesity is a common comorbidity of psoriasis and PsA. It is connected to low-grade inflammation and it has a negative impact on the response to therapies. Although a high prevalence of obesity has been shown in a whole number of epidemiology and observational studies, its relationship to PsA activity has been less investigated. In the RU-PSART registry data was collected from 43 rheumatology centers of the Russian Federation

Objectives: to evaluate the prevalence of obesity and its association to PsA activity as well as its impact on therapy response in real clinical practice

Methods: 614 (M/F=331(54%)/283(46%)) PsA pts fulfilling the CASPAR criteria were included from the RU-PSART cohort. Mean age 45.2±0.52 yrs, PsA duration 5.7±0.27 yrs, PsO duration 15.71±0.56 yrs, DAPSA 28.79±0.75. At baseline (BL) and 6 mo/12 mo of observation PsA activity was evaluated by Tender Joint Count (TJC68), Swollen Joint Count (SJC66); PGA, physician global assessment by Visual Analog Scale (VAS); PtGA VAS; PtPain VAS; DAPSA and body mass index (BMI, kg/m²) were calculated. Pts were treated with conventional/target synthetic disease-modifying antirheumatic drugs csDMARDs (55%)/tsDMARDs (5%), biological DMARDs (23%), NSAID (17%) according to physician's decision. At BL/6/12 mo all pts were categorized according to DAPSA as high activity (DAPSA>28) and Moderate (Mo≤28)/Low Activity (LA≤14)/Remission DAPSA (REM≤4). All pts were divided into three groups according to BMI (kg/m²): normal<25, overweight >25-30, obese>30. M±m, %, multivariate analysis of variance (MANOVA), ANOVA, OR 95% (CI) were performed. All p<0.05, were considered to indicate statistical significance

Results: The baseline BMI was 27.7±0.23 kg/m² with the following BMI categories: normal - 212 pts (34.6%), overweight - 214 pts (34.8%) and obese - 187 (30.45%). In all pts DAPSA significantly improved to 16.11±0.82/14.71±1.17 at 6/12 mo accordingly. At BL and 6/12 mo of therapy DAPSA was significantly higher in the obese pts compared to the normal and the overweight pts despite of improvements seen in all groups (table 1). By the last visit significant differences were found in DAPSA depending on BMI at BL (ANOVA, p<0.031). BMI>30 at BL was associated with lower probability of DAPSA improvement from high activity to Mo/LA/REM state compared to normal BMI pts and the overweight pts: OR 2.484 (95% CI 1.135-5.439) and OR 2.346 (95% CI 1.07-5.143) accordingly (Fig 1)

Table 1. Dynamics of DAPSA from BL to 6/12 mo depending on BMI categories.

BMI (kg/m ²)	DAPSA BL	DAPSA 6 mo	DAPSA 12 mo
<25	27.20 ± 1.15	13.84 ± 1.01	13.33 ± 1.53
25-30	26.93 ± 1.17	14.48 ± 1.43	13.83 ± 2.36
>30	32.86 ± 1.57	21.19 ± 1.84	18.92 ± 2.54

Fig. 1. OR analysis of relationship between BMI at BL and treatment response.