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

A. Kavanaugh1, E. Lubrano2, T. Muram3, C. Y. Lin4, S. Liu Leage5, F. Van den Bossche6, L. E. Kristensen1, 1University of California, San Diego, United States of America; 2University of the Studi di 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.

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, ≥3/6 tender and ≥3/6 swollen joints, ≥5% psoriasis body surface area (BSA) involvement, no prior treatment with bDMARDs, and prior inadequate response to ≥1 conventional synthetic DMARD (cDMARD), were randomized 1:1 to open-label IXE or ADA (label dosing according to presence/absence of moderate-to-severe psoriasis [baseline BSA≥10%, PASI≥12, and static Physician’s Global Assessment≥3] in Study 11F-1MC-RHFC (NCT03151551). In this analysis, max ACRx was defined as the max ACRx response a patient can achieve where ACRx derivation follows the typical ACR response criteria: ≥50% improvement in tender joint count (TJC) and swollen joint count (SJC) and ≥30% improvement in ≥3 of the 5 remaining components, Health Assessment Questionnaire-Disability Index total score (HAQ-DI), C-reactive protein (CRP), Patient Global Assessment (PtGA), Physician Global Assessment (PhyGA), and patient assessment of joint pain (patJP).

Results: Missing data were imputed using the last observation carried forward (LOCF) method. 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 (PtGA), 10.2 (CRP), and 61.0 (patJP). Mean PASI total score was 7.8. Figures 1 and 2 show the maximum ACRx 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 PASI<50 (76.6% vs. 57.5% at week 24 and 83.0% vs. 59.6% at Week 52). Evaluation of patient-level data compared to adalimumab-treated patients achieved ≥PASI 90 (76.6% vs. 57.5% at Week 52; 83.0% vs. 59.6% at Week 52). Evaluation of patient-level data compared to adalimumab-treated patients achieved ≥PASI 90 (76.6% vs. 57.5% at Week 52; 83.0% vs. 59.6% at Week 52).

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 improvement.

References: