SUBCUTANEOUS TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS: A HIGH NUMBER OF PATIENTS ACHIEVE DOPPLER REMISSION AFTER 24 WEEKS


Background: Clinical remission in rheumatoid arthritis (RA) is evaluated by Composite Disease Activity Scores (CDAS) including DAS28 and CDAI. Ultrasound (US) is more sensitive than clinical examination for detection of synovitis and vasculitis, and Doppler is more sensitive than clinical examination for detection of synovitis.[1] US remission. CDAS and EULAR/ACR Boolean remission were defined as remission, and Doppler sum scores of 0 to 3 were presently explored as definitions.

Methods: A regional multi-country (Denmark, Finland, Norway, Sweden) open-label, single-arm study (part of TOZURA®), enrolled pts with inadequate response to csDMARDs. Pts received TCZ-SC 162 mg qw for 24 weeks as monotherapy or in combination with a csDMARD. Stable oral NSAIDs and corticosteroids (CS) were calculated. C. tenderness and swollen joints, laboratory tests, safety assessments as well as US examination (36 joints and 4 tendons, scored according to the Nordic US atlas) were performed at baseline, 4, 12 and 24 weeks. US reliability between centres was assessed prior to the study. There is no consensus on definitions of Doppler remission, and Doppler sum scores of 0 to 3 were presently explored as definitions.

Results: 133 pts were included, and 110 pts were followed with US assessments (83% female, mean (SD) age 55.6 (12.1) years and RA duration 8.7 (9.5) years, 81% anti-CCP positive and 62% with erosive disease). All clinical, laboratory and US variables decreased significantly, already after 4 weeks (p<0.001) (Table 1). Table 2 illustrates the high percentages of patients reaching remission, especially for DAS28/ESR and Doppler. Fourteen serious AE were reported in 12 pts and 15 AEs led to permanent withdrawal of treatment.

Disclosures of Interest: None declared

A POOLED ANALYSIS OF THREE TNF-A INHIBITOR BIOSIMILAR STUDIES IN PATIENTS WITH RHEUMATOID ARTHRITIS COMPARING RADIOGRAPHIC PROGRESSION BY DISEASE ACTIVITY STATES

J.S. Smolen1, M. Weinblatt2, P. Emery3, E. Keystone4, M. Genovese5, G. Myung6, E. Hong7, I. Baek8, S. Lee9, J. Ghi10, Medical University of Vienna, Vienna, Austria, Brigham and Women’s Hospital, Boston, USA; Leeds Institute of Rheumatic and Musculoskeletal Disease, Leeds, UK; Mount Sinai Hospital, Toronto, Canada; Stanford University Medical Center, Stanford, USA; Samsung Bioplus Co., Ltd., Incheon, Korea, Republic of Ireland

Background: SB4, SB2, and SSB are biosimilars of the reference etanercept (ETN), infliximab (IFN), and adalimumab (ADA), respectively. Radiographic progression using the modified Total Sharp Score (mTSS) at week 0 and final week (week 52 for etanercept and adalimumab and week 54 for infliximab) was measured in phase III randomised, double-blind studies comparing efficacy and safety of biosimilar to its reference product.

Methods: Patients with radiographic data from each phase III study were pooled and grouped based on their disease activity state (remission, low disease activity [LDA], moderate disease activity [MDA], and high disease activity [HDA]) at week 24 or 30 in terms of DAS28. The mean change in mTSS and the proportion of radiographic non-progressors of high disease activity groups (LDA, MDA, and HDA) were compared between remission scores summarised descriptively and odds ratios (OR) were compared using 95% confidence interval (CI) obtained from logistic model with baseline DAS28.

Results: This open label study showed TCZ-SC to significantly reduce inflammation assessed by both CDAS and Doppler US. A high number of pts (53%–79%) obtained Doppler remission at 24 weeks using the different definitions. The safety profile was similar to what has previously been reported.

Disclosures of Interest: None declared

References: