and Company, EMD Merck Serono, Genentech/Roche, Gilead Sciences, Inc., GSK, Novartis, RPharm, Sanofi Genzyme
DOI: 10.1136/annrheumdis-2020-eular.2059

SAT0152 EFFICACY OF BARICITINIB IN PATIENTS WITH MODERATE-TO-SEVERE RHEUMATOID ARTHRITIS WITH 3 YEARS OF TREATMENT: RESULTS FROM A LONG-TERM STUDY

J. S. Smolen[1], L. Xie[2], B. Jia[2], P. C. Taylor[3], G. R. Burmester[4], Y. Tanaka[5], A. Elias[2], A. Cardoso[2], R. Ortmann[2], C. Walls[2], M. Dougados[6]. *[1]Medical University of Vienna, Division of Rheumatology, Vienna, Austria*; *[2]Eli Lilly and Company, Indianapolis, United States of America*; *[3]University of Oxford, Oxford, United Kingdom*; *[4]Charité - University Medicine Berlin, Berlin, Germany*; *[5]University of Occupational and Environmental Health, Japan, Kitakyushu, Japan*; *[6]Hospital Cochin Paris, Paris, France*

Background: Baricitinib (Bari) is an oral, selective and reversible Janus kinase 1 and 2 inhibitor approved for the treatment of adults with active RA. In addition to long-term safety which has been disclosed previously with data up to 7 years [1], an important clinical consideration is whether treatment efficacy can be maintained over the long term.
Objectives: To evaluate the long-term efficacy of once-daily Bari 4 mg in patients with active rheumatoid arthritis (RA) who were either naïve to or who had inadequate response (IR) to methotrexate (MTX)
Methods: Post hoc analyses of data from two phase 3 studies, RA-BEGIN (MTX-naïve) and RA-BEAM (MTX-IR) for 52 weeks, and one long-term extension (LTE) study (RA-BEYOND) for an additional 96 weeks were conducted (148 weeks in total). At week 52, MTX-naïve patients initially treated with MTX monotherapy, Bari 4 mg monotherapy, or Bari 4 mg +MTX in RA-BEGIN were switched to open-label Bari 4 mg monotherapy for treatment in the LTE. Similarly, at week 52, MTX-IR patients initially treated with Bari 4 mg [+ background MTX noted as (+MTX) for RA-BEAM] or adalimumab (ADA) (+MTX) in RA-BEAM were switched to open-label Bari 4 mg (+MTX) for treatment in the LTE. Patients who received placebo (+MTX) were switched to open-label Bari 4 mg (+MTX) at week 24. The analyses of efficacy (SDAI) and physical function (HAQ-DI) were conducted on all patients who were randomized into the RA-BEGIN and RA-BEAM studies and had received ≥1 dose of study drug after randomization (mITT population). The proportion of patients who reached low disease activity (LDA), as measured by SDAI ≤11, was evaluated along with change from baseline in HAQ-DI. The non-responder imputation (NRI) method was used for the categorical analysis.
Results: By week 24 in RA-BEGIN (N=584), 62% of patients treated with Bari 4 mg monotherapy or Bari 4 mg +MTX achieved SDAI LDA in comparison to 40% of pts in the MTX monotherapy group; response rates seen at week 24 in the Bari treatment groups were maintained through week 148 (Fig 1A). Similarly, by week 24 in RA-BEAM (N=1,305), 52% of patients treated with Bari 4 mg (+MTX) and 50% of patients treated with ADA (+MTX) achieved a SDAI LDA in comparison to 26% of patients from the PBO (+MTX) group. The response rate seen at week 24 with Bari 4 mg and ADA were maintained through week 148, even after patients switched from ADA to Bari 4 mg at week 52 (Fig 1B). Similar improvement and maintenance patterns in physical function measured by HAQ-DI were demonstrated. The overall discontinuation rate across treatment groups from RA-BEGIN (19.5%) and RA-BEAM (14.2%) have been published. In the LTE, the discontinuation rate from Bari treatment was 13.7% for patients originating from RA-BEGIN (1.1% due to lack of efficacy, 6.4% due to safety) and 12.6% for patients originating from RA-BEAM (1.8% due to lack of efficacy, 5.9% due to safety).

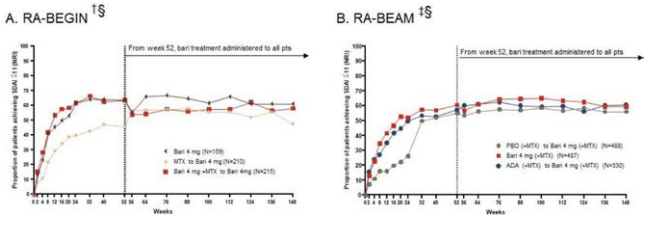

Figure 1. Proportion of patients achieving SDAI ≤11 in the NRI analysis†In RA-BEGIN, rescue to Bari 4 mg + MTX was offered at week 24.‡In RA-BEAM, rescue to Bari 4 mg (+ MTX) was offered at week 16. At week 24, all PBO + MTX patients were switched to Bari 4 mg + MTX.§Upon entering RA-BEYOND at week 52, MTX and ADA patients were switched to Bari 4 mg.

Conclusion: Long-term treatment with Bari 4 mg demonstrated the maintenance of clinically-relevant outcomes for up to 3 years. Low discontinuation rates during the LTE indicated that Bari 4 mg treatment was well-tolerated.

References:
[1] Genovese et al. *Annals of the Rheumatic Diseases*. 2019;78:308-309.
Disclosure of Interests: : Josef S. Smolen Grant/research support from: AbbVie, AstraZeneca, Celgene, Celltrion, Chugai, Eli Lilly, Gilead, ILTOO, Janssen, Novartis-Sandoz, Pfizer Inc, Samsung, Sanofi, Consultant of: AbbVie, AstraZeneca, Celgene, Celltrion, Chugai, Eli Lilly, Gilead, ILTOO, Janssen, Novartis-Sandoz, Pfizer Inc, Samsung, Sanofi, Li Xie Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Bochao Jia Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Peter C. Taylor Grant/research support from: Celgene, Eli Lilly and Company, Galapagos, and Gilead, Consultant of: AbbVie, Biogen, Eli Lilly and Company, Fresenius, Galapagos, Gilead, GlaxoSmithKline, Janssen, Nordic Pharma, Pfizer Roche, and UCB, Gerd Rüdiger Burmester Consultant of: AbbVie Inc, Eli Lilly, Gilead, Janssen, Merck, Roche, Pfizer, and UCB Pharma, Speakers bureau: AbbVie Inc, Eli Lilly, Gilead, Janssen, Merck, Roche, Pfizer, and UCB Pharma, Yoshiya Tanaka Grant/research support from: Asahi-kasei, Astellas, Mitsubishi-Tanabe, Chugai, Takeda, Sanofi, Bristol-Myers, UCB, Daiichi-Sankyo, Eisai, Pfizer, and Ono, Consultant of: Abbvie, Astellas, Bristol-Myers Squibb, Eli Lilly, Pfizer, Speakers bureau: Daiichi-Sankyo, Astellas, Chugai, Eli Lilly, Pfizer, AbbVie, YL Biologics, Bristol-Myers, Takeda, Mitsubishi-Tanabe, Novartis, Eisai, Janssen, Sanofi, UCB, and Teijin, Ayesha Elias Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Anabela Cardoso Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Robert Ortmann Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Chad Walls Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Maxime Dougados Grant/research support from: AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma, Consultant of: AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma, Speakers bureau: AbbVie, Eli Lilly, Merck, Novartis, Pfizer and UCB Pharma
DOI: 10.1136/annrheumdis-2020-eular.2398

SAT0153 GENDER DOES NOT INFLUENCE CLINICAL RESPONSE TO JAK INHIBITORS IN RHEUMATOID ARTHRITIS: AN ITALIAN MULTICENTRE ANALYSIS

F. R. Spinelli[1], M. S. Chimenti[2], M. Vadacca[3], C. Iannuccelli[1], P. Conigliaro[2], S. L. Bosello[4], F. Ceccarelli[1], C. Garufi[1], G. Raffone[2], P. Di Noi[3], D. Bruno[5], A. Afeltra[3], R. Perricone[2], F. Conti[6], E. Gremese[4,5]on behalf of FRS, MSC, PC, MV, CI, SLB and EG on behalf of ReDO - Reumatologhe Donne - association of italian female rheumatologists.. *[1]Sapienza Università di Roma, Rheumatology Unit, 00161, Italy*; *[2]University of Rome Tor Vergata, Rheumatology, Allergology and Clinical Immunology, Rome, Italy*; *[3]Campus Biomedico University of Rome, Rheumatology, Allergology and Clinical Immunology, Rome, Italy*; *[4]Fondazione Policlinico Universitario A. Gemelli IRCCS, Rheumatology Division, Rome, Italy*; *[5]Università Cattolica del Sacro Cuore, Rheumatology Division, Rome, Italy*; *[6]Sapienza Università di Roma, Rheumatology Unit, Rome, Italy*

Background: Gender medicine aims at describing how diseases differ between men and women in terms of epidemiology, clinical feature, therapeutic approach, treatment response and prognosis, psychological and social impact. Rheumatoid Arthritis (RA) affects women 2-3 times more than men. Female gender seems to be independently associated to a more refractory disease and a worst response to conventional synthetic Disease Modifying Anti-Rheumatic Drugs (csDMARDs) and biological DMARDs. Male patients achieve remission more often than females probably due to the higher number of tender joints reported by the latter.
Objectives: In the light of the effect of Janus kinases inhibitors (JAKi) on pain, the objective of the study was to investigate whether gender might affect the achievement of remission or low disease activity in RA patients treated with baricitinib and tofacitinib.
Methods: We performed a multicentric, prospective study on consecutive patients starting one of the two available JAKi: baricitinib and tofacitinib. Demographic and clinical data were recorded in a dedicate database and included: gender, age, disease duration, serological status (Rheumatoid Factor – RF; anti-citrullinated peptide antibodies, ACPA) number of previous csDMARDs and bDMARDs, number of tender joints (TJ) and swollen joints (SJ), C reactive protein (CRP); patient global assessment (PGA) and pain were recorded on a 0-100 mm visual-analogue scale (VAS). Disease activity score (DAS) 28 was calculated at baseline and at two follow-up visits (after 3-4 months and after 6-8 months). Data were expressed as mean±standard deviation or median (interquartile range) according to variables' distribution. Continuous variables were compared by Mann Whitney test while dichotomous ones by Chi-squared test; p value < 0.05 were considered statistically significant.
Results: We enrolled 182 RA patients (149 F:33 M) with similar age (F 58±12 vs M 60±10) and disease duration (F 143±101 vs M 147±105 months). Females and males were previously treated with the same number of csDMARDs [2(2)] but female have previously received numerically more bDMARDs [2(3) vs 1(2)]. At the 3 timepoints females and males showed similar number of TJ, SJ, similar values of CRP, PGA and pain. We did not observe any difference in percentage