REFERENCE:

- [1] Gerdes S, Thaci D, Griffiths CEM, Arenberger P, Poetzel J, Wuerth G, et al. Multiple switches between GP2015, an etanercept biosimilar, with originator product do not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis: 30-week results from the phase 3, confirmatory EQUALITY study. *Journal of the European Academy of Dermatology and Venereology*: JEADV 2017.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.2769

THU0223

IMPACT OF TREATMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS AND DEPRESSIVE SYMPTOMS IN THE MONARCH PHASE 3 TRIAL OF SARILUMAB

V. Strand¹, O. Hagino², S. Guillonnet³, S. Boklage⁴, M. Reaney⁵, J. Sadeh², N. Narcisse⁶, E. Mangan⁴, T. Kimura⁴. ¹Stanford University, Palo Alto; ²Sanofi, Bridgewater, USA; ³Sanofi, Chilly-Mazarin, France; ⁴Regeneron Pharmaceuticals, Inc., Tarrytown, USA; ⁵Sanofi, Guildford, UK; ⁶AXIAL, Boulogne-Billancourt, France

Background: In the MONARCH Phase 3 randomised controlled trial (RCT) [NCT02332590], sarilumab subcutaneous (SC) 200 mg every 2 weeks (q2w) improved clinical outcomes and multiple aspects of health status/health-related quality of life (HRQoL), as measured by the Medical Outcomes Survey Short Form (SF-36) questionnaire, to levels greater than adalimumab SC 40 mg q2w. Both treatments were administered as monotherapy in patients with active rheumatoid arthritis (RA) who had discontinued treatment with methotrexate. Depression/mood disorder is a common co-morbidity in people with RA.

Objectives: To explore whether observed differences in health status/HRQoL following treatment with sarilumab compared with adalimumab are also seen in the subgroup of patients in the MONARCH trial with probable depressive symptoms.

Methods: Post-hoc statistical analyses were performed. Patients were categorised as having probable major depressive disorder¹ (PMDD; SF-36 mental health (MH) domain score ≤ 56) or probable depressed mood and anhedonia² (PDMA; score ≤ 10 on both items of the MH domain: "Have You Felt Downhearted and Depressed" and "Have You Felt So down in the Dumps that nothing could cheer you up"). Least squares mean (LSM) differences in changes from baseline (CFB) in SF-36 domains at Week 24 were calculated for sarilumab PMDD/PDMA versus adalimumab PMDD/PDMA. Sensitivity analysis included adjustment for Disease Activity Score 28 C-reactive protein (DAS28-CRP) at baseline.

Results: Of the 369 patients from MONARCH, 250 (67.78%) were categorised with PMDD (mean age 52 years, 85% female) and 194 (52.6%) with PDMA (mean age 52 years, 87% female). Disease duration, DAS-28 CRP, tender and swollen joint counts (table 1) and SF-36 domain scores (figure 1) were similar between sarilumab and adalimumab within the PMDD and PDMA subpopulations at baseline. LSM differences in CFB in SF-36 domains were greater for sarilumab versus adalimumab at Week 24 in physical functioning (PF), bodily pain (BP), vitality (VT) and social functioning (SF) domains in both the PMDD and PDMA subgroups, and role-physical (RP) in the PMDD subgroup (nominal $p < 0.05$) (figure 1). Sensitivity analysis showed similar results.

Abstract THU0223 – Table 1

Table Baseline characteristics in MONARCH patients with PMDD or PDMA	PMDD: SF-36 MH domain score ≤ 56 (N=250)		PDMA: ≤10 on both items of SF-36 MH domain (N=194)	
	Sarilumab 200mg q2w (n=128)	Adalimumab 40mg q2w (n=132)	Sarilumab 200mg q2w (n=98)	Adalimumab 40mg q2w (n=96)
Duration of RA since diagnosis, years, mean (SD)	8.29 (8.13)	7.03 (8.53)	7.92 (7.30)	7.46 (8.49)
DAS28-CRP, mean (SD)	6.13 (0.85)	6.18 (0.88)	6.17 (0.96)	6.18 (0.83)
Tender joint count (0-68), mean (SD)	29.03 (14.05)	28.36 (14.21)	28.98 (14.34)	28.69 (14.46)
Swollen joint count (0-66), mean (SD)	19.20 (11.67)	18.69 (10.74)	19.68 (11.78)	19.53 (11.09)

Conclusions: Among patients with RA and probable depressive symptoms, sarilumab SC 200 mg q2w monotherapy was more effective than adalimumab SC 40 mg q2w monotherapy in demonstrating clinically meaningful improvements in some domains of health status/HRQoL. This may be a function of the different

target of sarilumab (soluble IL-6 receptor [sIL-6R]) and associated improvements in disease activity versus adalimumab (tumour necrosis factor [TNF α]).

REFERENCES:

- [1] Matcham, et al. *BMC Musculoskeletal Disorders* 2016;17:224.
[2] Sun Y, et al. *EULAR Congress* 2017; June 14–17 2017; Madrid, Spain.

Acknowledgements: Research sponsored by Sanofi and Regeneron Pharmaceuticals, Inc.

Disclosure of Interest: V. Strand Consultant for: AbbVie, Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Celltrion, Corrona, Crescendo Bioscience, Eli Lilly, Genentech/Roche, GlaxoSmithKline, Horizon, Janssen, Merck, Novartis, Pfizer, Regeneron Pharmaceuticals, Samsung, Sandoz, Sanofi and UCB, O. Hagino Shareholder of: Sanofi, Employee of: Sanofi, S. Guillonnet Shareholder of: Sanofi, Employee of: Sanofi, S. Boklage Shareholder of: Regeneron Pharmaceuticals, Inc., Employee of: Regeneron Pharmaceuticals, Inc., M. Reaney Shareholder of: Sanofi, Employee of: Sanofi, J. Sadeh Shareholder of: Sanofi, Employee of: Sanofi, N. Narcisse Consultant for: Sanofi, E. Mangan Shareholder of: Regeneron Pharmaceuticals, Inc., Employee of: Regeneron Pharmaceuticals, Inc., T. Kimura Shareholder of: Regeneron Pharmaceuticals, Inc., Employee of: Regeneron Pharmaceuticals, Inc.

DOI: 10.1136/annrheumdis-2018-eular.3714

THU0224

RENACER STUDY: EFFICACY AND SAFETY ASSESSMENT OF CZP THERAPY IN THE TREATMENT OF 501 PATIENTS WITH RHEUMATOID ARTHRITIS(RA) AMONG SPANISH POPULATION IN CLINICAL PRACTICE

V. Torrente-Segarra¹, M. Fernandez², R. Expósito³, N.P. Garrido⁴, A. Sanchez-Andrade⁵, J.R. Lamua⁶, A. Olivé⁷, J.V. Tovar⁸, on behalf of On behalf of RENACER Study Group. ¹Rheumatology, Hospital General Hospitalet-Moisès Broggi, Hospitalet Llobregat; ²Rheumatology, Hospital Universitario de Guadalajara, Guadalajara; ³Rheumatology, Hospital Comarcal de Laredo, Laredo; ⁴Rheumatology, Hospital Universitario Virgen del Rocío, Sevilla; ⁵Rheumatology, Complejo Hospital Universitario Lucas Augusti, Lugo; ⁶Hospital Universitario del Henares, Alcalá de Henares; ⁷Hospital Germans Trias i Pujol, Badalona; ⁸Hospital General Universitario de Elche, Elche, Spain

Background: Certolizumab PEGol (CZP) differs from other anti-TNFs in that it is monovalent and it lacks the Fc region found in monoclonal antibodies. CZP is also PEGylated. Its efficacy in patients with rheumatoid arthritis (RA) has been evaluated in previous clinical trials.

Objectives: The purpose of the current study is to assess effectiveness, safety and survival rate in patients with RA after 12 months of treatment and also within specific subgroups, in clinical practice settings.

Methods: Observational longitudinal prospective study of RA patients from 40 sites in Spain. Variables (baseline, 3- and 12 month assessment): socio-demographics, smoking status, previous synthetic DMARD (sDMARD) and biological DMARD (bDMARD) use; TJC, SJC, ESR, CRP, DAS28. Response variables EULAR Moderate/Good Response and DAS28 remission and Safety were assessed. Descriptive, comparative and Logistic regression analyses were performed. Kaplan-Meier survival curve was performed.

Results: A total of 501 patients were included: 78.6% women, mean age 53.6 year (± 13.2 SD) and 77% were aged < 65 year Mean disease duration 7.5 year (± 7.3 SD) and 27.7% having early RA. Baseline features are shown in table 1. Mean number of prior sDMARD 1.5 (± 1.1 SD). Mean number of prior bDMARD was 0.8 (± 1.2 SD). Mean duration of exposure to CZP was 9.8 months (± 3.4 SD); Concomitant steroids intake 12.6%, sDMARD 24.2% and sDMARD plus steroids 54.9%; Smoking status: 69.8% never smoked, 12.9% former smoker and 17.3% current smoker.

Baseline predictors of response: lower prior number sDMARD; low number prior bDMARD; higher CRP, ESR, TJC, SJC and DAS28 ($p < 0.05$) scores.

Patients < 65 year had shown better DAS28 Remission rates as well as those who had previously received < 2 sDMARDs, those who were "bionative" at CZP initiation and those who used CZP in combination.

CZP survival rates are shown in Figures 1 and 2.

Adverse effects from treatment were reported in 65 patients (13%), mostly mild.

Conclusions: CZP showed benefit in active RA patients, with clear improvement in all clinical parameters, mostly in < 65 yo patients and those who had received low number of previous sDMARD and bDMARD. Survival rate at 12 month assessment was high, demonstrating a reasonable safety profile.

REFERENCE:

- [1] Torrente-Segarra V, et al; (RENACER StudyGroup). RENACER study: Assessment of 12-month efficacy and safety of 168 certolizumab PEGol rheumatoidarthritis-treated patients from a Spanish multicenter national database. *Mod Rheumatol* 2015 Nov 7:1–6.

Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2018-eular.1186

THU0225 THE PROGRESSION OF LUNG INVOLVEMENT IN RHEUMATOID ARTHRITIS PATIENTS RECEIVING BIOLOGICAL THERAPIES

Y. Yalçinkaya¹, M. Can¹, S. Karakurt², N. Coşkun³, E. Albayrak⁴, H. Mursaloglu⁴, A. Topcu⁵, M. Demir⁵, E. Dalkılıç³, N. Inanc¹. ¹Department of Internal Medicine, Division of Rheumatology; ²Department of Pulmonary Medicine, Marmara University, School of Medicine, Istanbul; ³Department of Internal Medicine, Division of Rheumatology, Uludağ University, Bursa; ⁴Marmara University, School of Medicine, Istanbul, Turkey; ⁵Department of Internal Medicine, Marmara University, School of Medicine, Istanbul, Turkey

Background: Lung involvement is one of the extra-articular manifestations that is shown to be related to morbidity and mortality in Rheumatoid arthritis (RA).

Objectives: We evaluated the progression of lung involvement in RA patients receiving biological treatment.

Methods: Eighty RA patients fulfilling ACR/EULAR classification criteria (2010) receiving biologics who had high-resolution computerised tomography (HRCT) of chest within 6 months of respiratory symptoms (cough/dyspnea) and/or any pathology in chest radiography were included. Warrick score, evaluating alveolitis and fibrosis, was calculated in RA patients by using HRCT of chest.

Results: The demographics and clinical findings were summarised in table 1. In 29 RA patients with interstitial findings in HRCT of chest; 7 (24%) were regressed and 1 (4%) was progressed with biologic drugs. Findings of alveolitis and fibrosis were completely regressed in 2, only alveolitis component was completely regressed in 3 and partially in 2 patients. The patient who progressed had new findings of alveolitis (table 2). Twenty-one patients in whom Warrick scores did not change, 5 received rituximab (RTX) and 10 received TNF inhibitors (TNF-inh). The mean Warrick scores was improved after biologics (11,3±9 (3–30) vs 10,3±9 (0–30), p=0,035). The improvement in alveolitis scores was significant (2,1±1,6 vs 1,5±1,6, p=0,031) while fibrosis scores were not (9,2±7,7 vs 8,8±8). Initial and control Warrick scores were higher in RTX receivers (16±9 vs 9,2±8, p=0034 and 14,8±10,1 vs 8,4±8,1), but the improvement after biologics was not different.

Abstract THU0225 – Table 1. Demographics in Rheumatoid Arthritis Patients

	n=80
Age(year)	53±12
Gender(F/M)	61/19
Disease duration(year)	12±9
Smoking(%)	26%
RF(+)	64 (80%)
AntiCCP(+)	50 (63%)
DAS28-ESR-after biologics	3,3 ±1,1

Scores	Initial Warrick-Alveolitis	Initial Warrick-Fibrosis	Initial Warrick-Total	Control Warrick-Alveolitis	Control Warrick-Fibrosis	Control Warrick-Total	Current Therapy
Case 1	3	8	11	0	0	0	RTX+MTX,seropositive
Case 2	3	5	8	0	0	0	TNFi+MTX,seropositive
Case 3	3	8	11	2	8	10	RTX,seropositive
Case 4	4	17	21	3	17	20	RTX,seropositive
Case 5	3	0	3	0	0	0	TNFi+MTX,seropositive
Case 6	3	0	3	0	0	0	TNFi+MTX,seronegative
Case 7	3	4	7	0	4	4	TNFi+MTX,seronegative
Case 8	0	3	3	2	3	5	RTX+MTX,seropositive

Abstract THU0225 – Table 2. Progression of Warrick Scores in Cases After Biologics

Conclusions: This study revealed an improvement in alveolitis after biologic drugs in RA patients. Fibrosis was not found to be effected by therapy. Lung lesions were improved in both RTX and TNF-inh groups.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.5823

THU0226 SERIAL INTERFERON-GAMMA RELEASE ASSAYS IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH BIOLOGIC AGENTS

Y.J. Huang, Y.F. Fang, Y.F. Chen, P.H. Tsai, C.F. Kuo, K.H. Yu, S.F. Luo. Division of Rheumatology, Allergy and Immunology, Chang Gung Memorial Hospital and Chang Gung University, Taoyuan, Taiwan, Province of China

Background: It is increasing attention about the risk of latent tuberculosis infection (LTBI) reactivation during the treatment of biologic agents for patients with rheumatoid arthritis. Taiwan rheumatology association recommend performing at least annual interferon-gamma release assays (IGARs) testing during biologic treatment course because of the moderate prevalence of tuberculosis in Taiwan. [1] Although several studies have reported the risk of active tuberculosis infection in patients with rheumatoid arthritis (RA), the long-term serial IGARs testing in patients with RA is limited.

Objectives: The aims of this study is to use serial interferon-gamma release assays(IGRAs) as a screening tool in patients with rheumatoid arthritis treated with different biologic agents in Taiwan.

Methods: We retrospectively collected 189 patients with rheumatoid arthritis receiving biologic agents between 2013 to 2017 in Chang Gung Memorial hospital in Taiwan. All RA patients underwent semi-annual IGRA test during biologic agents treatment.

Results: The seroconversion rate of IGAR in patients with rheumatoid arthritis after biologic treatment is 6.9%. The median seroconversion period is 19 months. Out of the 13 patients with seroconversion, 8 (61.5%) patients were treated with TNF block and 5 (38.5%) patients were treated with non-TNF blocker. All the patients with seroconversion evaluate the possible active TB infection and 69.2% (9/13) received chemoprophylactic therapy by isoniazid. There is no active tuberculosis infection during serial IGAR tests. The risk factor included high baseline TBAG-nil/nil (OR 3.44, CI 6.64–1.78), leflunomide(OR 11.51, CI 61.34–2.16).

Abstract THU0226 – Table 1

	Total (n=189)	Seroconversion (n=13)	Non-seroconversion (n=176)	p-value
Female	162(14.3%)	10(76.9%)	152(86.4%)	0.348
Age (Mean± standard deviation)	54.7±12.2	60.0±13.6	54.3±12.1	0.104
Disease duration (Mean± standard deviation)	4.9±1.4	4.6±1.4	4.9±1.4	0.591
Prednisolone Mean dose (mg/day)	132/189(69.8%) 8.8±9.5	9/13(69.2%) 8.3±3.5	123/176(69.88%) 8.8±9.8	0.873
Methotrexate	146(77.2%)	9(69.2%)	137(77.8%)	0.475
Sulfasalazine	99(52.4%)	9(69.2%)	90(51.1%)	0.207
Leflunomide	24(12.7%)	5(38.5%)	19(10.8%)	0.015*
Hydroxychloroquine	104(55%)	11(84.6%)	93(52.8%)	0.026*
TNF blocker	143(75.7%)	8(61.5%)	135(76.7%)	0.219
Non-TNF blocker	46(24.3%)	5(38.5%)	41(23.3%)	0.219
TB AG-nil	0.02±0.12	0.14±0.12	0.01±0.12	<0.001*
Mitogen-nil	6.66±5.2	8.16±4.84	6.52±5.23	0.278
DAS28	6.06±1.09	6.42±0.91	6.03±1.1	0.261
Characteristics	OR(95%CI)		p value	
Age	1.02 (1.09, 0.95)		0.474	
Disease duration	1.31 (2.36, 0.72)		0.366	
TB AG-nil/nil	3.44 (6.64, 1.78)		<0.001*	
Leflunomide	11.51 (61.34, 2.16)		0.004*	
Hydroxychloroquine	6.49 (43.88, 0.96)		0.055	

Conclusions: Our study revealed patients with rheumatoid arthritis receiving long-term biologic therapy had a low rate IGAR seroconversion rate (6.9%). Patients with background Leflunomide had higher odds ratio of seroconversion. However, the clinical importance of IGAR seroconversion remain controversial and further long-term large scale investigation is needed.

REFERENCE:

- [1] Chen Y-H. 2015 TRA revised recommendations for screening and management of tuberculosis infection in patients before and after anti-tumor necrosis factor-alpha biological treatment. 2015;29:1–8.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.1456