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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

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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: Score ≤ 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]).

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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

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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.

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