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DEPRESSIVE SYMPTOMS IN PATIENTS WITH RHEUMATOID ARTHRITIS IN SARILUMAB TARGET AND MOBILITY TRIALS AND IMPACT OF TREATMENT

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Background: In patients with clinical depression, elevated interleukin-6 (IL-6) levels have been associated with higher symptom severity and greater resistance to standard antidepressant treatments. Depression and IL-6 elevation are highly prevalent in patients with rheumatoid arthritis (RA), and their co-occurrence may have an impact on health-related quality of life (HRQoL). Sarilumab is a human immunoglobulin G1 anti IL-6 receptor α (anti-IL-6R α) monoclonal antibody for treatment of moderately-to-severely active RA.

Objectives: To explore the effect of sarilumab on HRQoL in patients with moderate-to-severely active RA with co-existing symptoms of depression.

Methods: Post-hoc statistical analyses were performed on the Medical Outcomes Study Short Form 36 (SF-36) in 2 randomized controlled trials, MOBILITY (NCT01061736) and TARGET (NCT01709578), of sarilumab subcutaneous 150 mg or 200 mg every 2 weeks vs placebo, each combined with conventional synthetic disease modifying anti-rheumatic drugs. Patients were classified at baseline for 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"). Analyses of least squares mean differences in changes from baseline in SF-36 domain scores for sarilumab versus placebo in the PMDD and PDMA subgroups were performed at Weeks 4, 12 and 24 for TARGET and Weeks 24 and 52 for MOBILITY. Sensitivity analysis adjusted for baseline Disease Activity Score 28 C-reactive protein (DAS28-CRP).

Results: Of the 546 patients from TARGET and 1197 from MOBILITY, 59.5% and 60.2% were classified as PMDD respectively, and 50.4% and 51.6% as PDMA. In both RCTs disease duration and baseline DAS-28 CRP, tender and swollen joint count (table 1) and SF-36 domain scores (figure 1) were similar between sarilumab and placebo within the PMDD and PDMA subpopulations. TARGET: MH scores for PMDD and PDMA subgroups were nominally higher ($p < 0.05$) for sarilumab 200 mg versus placebo at all assessments. Both subgroups also scored nominally higher ($p < 0.05$) in the domains of physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT) and social functioning (SF) but not role-emotional (RE) in the PMDD subgroup at Week 24 (figure 1). MOBILITY: all scores except PF and RE were nominally higher ($p < 0.05$) for sarilumab 200 mg versus placebo for Weeks 24 (figure 1). Sensitivity analysis provided similar results. Exploratory results also suggested reduced prevalence of depressive symptoms over the course of the trial.

Figure 1. PMDD: SF-36 MH domain score ≤ 56 ; PDMA: ≤ 10 on both items of SF-36 MH domain

Conclusions: In patients with RA and depressive symptoms, sarilumab provided clinically meaningful improvements in most domains of health status/HRQoL compared with placebo, which may be a function of targeting the IL-6R α and subsequent reduction in disease activity.

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SAT0208

HOW GOOD ELDERLY RHEUMATOID ARTHRITIS PATIENTS RESPOND AT FIRST YEAR OF TREATMENT WITH CERTOLIZUMAB PEGOL?

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Background: In rheumatoid arthritis (RA), the efficacy and safety of Certolizumab pegol (CZP) is well established, as reported in randomized clinical trials (RCT)¹ and some registries². Only the 30% of RA patients are within the age range of 65 years or older. However, they are usually excluded from the RCT. Aging is associated with declining immune cell function and age-related comorbidities^{3,4}.

Objectives: The aim of this study was to determine the effectiveness and safety of CZP in elderly patients in a real world setting at 12 months follow-up.

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. Low Disease Activity as DAS28 remission or mild DAS28. Descriptive, comparative and Logistic regression analyses were performed comparing < 65 vs. ≥ 65 yr population. Kaplan-Meier survival curve was performed.

Results: A total of 501 RA patients were included, 23% were aged ≥ 65 yr (mean age 70.8 (± 4.5 SD)yr). Sociodemographics and baseline features are shown in table 1.

Table 1.

	< 65	≥ 65	P
Women	77.7%	80.7%	NS
Disease evolution (yr)	6.7 (± 6.5 SD)	10.4 (± 9.1 SD)	< 0.001
- ≤ 2 yr	-30.5%	-18.3%	-0.012
Smoking status:			0.024
Current	19.9%	9.1%	
Ex-smoker never	13.6%	11.1%	
Bio-naïve	66.5%	79.8%	NS
	56%	53.1%	
		*previous Abatacept use was higher in ≥ 65 yr ($p = 0.017$)	

Efficacy variables are shown in table 2.

Variable	< 65 years	≥ 65 years	p value
DAS28 Remission (yes)	43%	31.3%	0.026
DAS28 Low Disease Activity	57.5%	47.3%	NS
DAS28 > 1.2 score reduction	55.4%	60.7%	NS
EULAR Response	67.7%	75%	NS
CZP Retention rate	74.6%	67.5%	NS
Adverse Events	11.3%	19.3%	0.026