SAT0182

TOCILIZUMAB S.C. – IMPROVEMENT OF THE DEPRESSIVENESS, FATIGUE AND PAIN IN RA THERAPY

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Background: The non-interventional ARATA study (NCT02251860) observes the clinical effectiveness and safety of subcutaneous Tocilizumab [TCZ] s.c. treatment under routine conditions over a 2-year period.

Objectives: In this interim analysis, the treatment with TCZ s.c., in particular with respect to patient-reported outcomes regarding depression, fatigue and pain, was evaluated.

Methods: TCZ-naïve patients (Pts) (≥18 years) with RA, who receive TCZ s.c. treatment, could be included in the study since 2014. Demographic and disease-specific characteristics, the progression of the disease under treatment, concomitant medications, adverse events (AE) and patient questionnaires were documented.

Results: This interim analysis (reporting date 01-FEB-2017) included 912 Pts. 75% of the Pts were female, the average age at baseline (BL) was 57 years, the median disease duration was 8 years. 319 Pts (35%) were pretreated exclusively with sDMARD and 585 Pts (64%) were also pretreated with bDMARD. For the readjustment, TCZ s.c. was applied for 69% without sDMARD, 31% in combination with MTX and for 66% with glucocorticoids.

In the course of the study, 65% of the Pts achieved a DAS28-BSG remission. Furthermore, the functional restrictions in day-to-day life (HAQ-DI D from BL: -0.3) improved. No new safety signals were observed.

By means of the Beck Depression Inventory (BDI-II) score (Englbrecht et al., Arthritis Care Res 2017; 69:58–66), validated for RA, the depressive symptoms could be documented. At baseline, 186 Pts (50%) showed no, 70 (19%) minor, 67 (18%) moderate and 47 (13%) severe depression. Under the treatment with TCZ, the depressive symptoms improved (compare figure 1).

The patients reported a significant improvement of the pain (VAS: average change from BL to week 52 by -21 points and to week 104 by -24 points) as well as the fatigue (VAS: average change from BL to week 52 by -11 points and 104 by -12 points).

Conclusions: In the ARATA study, TCZ s.c. demonstrated an effective and persistent reduction in the disease activity of the treated RA patients. The patients confirmed improved physical functionality as well as less fatigue and pain. Depression plays an important role in RA, as the results of BDI-II highlight, whereby the depressive symptoms also improved distinctively under treatment with TCZ s.c.

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SAT0183

SWITCHING FROM ADALIMUMAB TO SARILUMAB IS ASSOCIATED WITH COMPARABLE EFFICACY BUT LOWER FUNCTIONAL IMPROVEMENT VERSUS CONTINUOUS SARILUMAB MONOTHERAPY THROUGH 48-WEEK OPEN-LABEL EXTENSION (OLE) OF THE PHASE 3 MONARCH TRIAL

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Background: Sarilumab is a human mAb blocking IL-6Rα. In Phase 3 MONARCH (NCT02332590), sarilumab (200 mg subcutaneously [SC] every 2 wks [q2w] for 24 wks) was superior to adalimumab monotherapy (40 mg SC q2w) in reducing disease activity and improving physical function in RA patients (pts) with an inadequate response or intolerance to methotrexate.

Objectives: To assess whether pts who achieved clinical response on sarilumab during MONARCH sustained this response in the OLE and to evaluate efficacy and safety of switching from adalimumab to sarilumab vs continuous sarilumab treatment.

Methods: Pts completing the double-blind phase of MONARCH were eligible for the ongoing OLE, in which all pts receive sarilumab (200 mg SC q2w) for a maximum duration of 276 wks. Disease activity, physical function, and safety were assessed regularly.

Results: 320/369 Pts enrolled in MONARCH entered the OLE; pts either switched from adalimumab to sarilumab (n=155) or continued on sarilumab (n=165). At OLE entry (Wk 24 of the double-blind phase), the mean Δ from baseline DAS28-ESR was -2.28 in the switch group vs -3.36 in the continuation group, and by Wk 48 was -4.06 vs -4.18, respectively. By Wk 48 of the OLE, the proportion of pts in the switch and continuation groups who achieved DAS28-ESR≤3.2 was 61.3% vs 61.2%, DAS28-ESR<2.6 was 43.9% vs 49.7%, and DAS28-CRP<2.6 was 52.9% vs 52.1%, respectively. From OLE entry to Wk 48, mean HAQ-DI improved in the switch group from 1.21 to 0.91, but did not reach the level of improvements in the continuation group (1.01 to 0.84). See table 1 for ACR responses. After 166 vs 182 cumulative patient-years exposure in the switch vs continuation groups, treatment-emergent adverse events (TEAEs) were observed in 76.1% vs 70.9%, serious TEAEs in 11.0% vs 3.6%, and infections in 41.9% vs 35.8%, respectively, with 2 deaths in the switch group (malignancy; cerebrovascular accident) and 1 death (subarachnoid hemorrhage) in the continuation group. No GI related AEs (ulcerations, perforations or diverticulitis) were observed in either group.

ACR responses & mean HAQ-DI in the OLE of MONARCH (OLE ITT Popn)

	Wk 0 OLE		Wk 48 OLE	
	Switch group: Adalimumab 40 mg q2w → Sarilumab 200 mg q2w (N=155)	Continuation group: Sarilumab 200 mg q2w (N=165)	Switch group: Adalimumab 40 mg q2w → Sarilumab 200 mg q2w (N=155)	Continuation group: Sarilumab 200 mg q2w (N=165)
ACR20/50/ 70, % responders	68.4/35.5/14.2	79.4/50.9/26.1	77.4/59.4/38.1	81.2/63.0/41.8
HAQ-DI, mean	1.21	1.01	0.91	0.84

Figure 1 Mean V from baseline in DAS28-ESR (OLE population; as observed). **Conclusions:** Switching from adalimumab (40 mg q2w) to sarilumab monotherapy (200 mg q2w) improved the signs and symptoms of RA to a similar level as continuous sarilumab treatment, and was associated with a lower HAQ-DI score, which may have resulted in numerical differences in ACR responses between the two groups.

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the analysis. Treatment response was evaluated as achievement of "BASDAI50" or "ASDAS Clinically important improvement (CII)" at the 3-months' and 6 months' visits. Clinical and demographic parameters were compared between current/never and current/previous smoker groups. Demographic and descriptive data are presented by medians/interquartile ranges (IQRs). Groups were compared by non-parametric tests (χ^2 , Kruskal Wallis and Mann Whitney tests). Kaplan Meier plots, Cox and logistic regression analyses were calculated for treatment adherence and treatment response.

Results: Among 561 AS patients included in the study, 506 (90%) had known smoking status (37% current, 35% never, 17% previous smokers). The median follow-up time was 1.9 years (IQR 0.85–3.5) and disease duration was 3.1 years (0.6–7.7). At baseline, current smokers were younger (34, IQR 29–41) compared with never (38, IQR 30–46 $p=0.007$) and previous smokers (42, IQR 34–49 $p<0.001$). Current smokers had male predominance ($n=148$, 43.9%; $n=85$, 25.2%); lower erythrocyte sedimentation rate (28 mm/h (13–42); 34 mm/h, (20–49) and higher change in BASMI (40, IQR 10–57.5; 10, IQR 4–30) compared with never smokers (all $p<0.005$). HLA status, body mass index, CRP, baseline disease indexes (BASDAI, BASFI, BASMI, HAQ, ASDAS) and treatment response was not found to be different between current and never smoker patients in our population (table 1). In multivariate analysis, male (OR:1.98; 95% CI (1.39–2.82), $p<0.01$), HLA positive (OR:1.54; 95%CI (1.08–2.18), $p=0.016$) and active DMARD user (OR:1.84; (95%CI 1.12–3.01) $p=0.015$) patients had better treatment response and treatment adherence (HR:1.93; 95% CI (1.36–2.73); HR:1.60; 95% CI (1.13–2.27); HR:1.80; 95% CI (1.10–2.95) all $p<0.005$) but smoking status were not significant ($p>0.05$).

	Smoking status			p ^a	p ^b	Smoking status	p ^a	p ^b	Smoking status
	Current	Never	Previous			Current			Current
Number, n (%)	209 (37)	199 (35)	98 (17)			55 (10)			55 (10)
Age, median (IQR), years	34 (29–41)	38 (30–46)	42 (34–49)	0.007	<0.001	38 (29–46)			38 (29–46)
Disease duration, median (IQR), years	3.5 (1.5–5.5)	3.5 (1.5–5.5)	3.5 (1.5–5.5)	0.13	0.48	3.5 (1.5–5.5)			3.5 (1.5–5.5)
Women, n (%)	61 (29)	114 (58)	22 (22)	<0.001	0.37	27 (50)			27 (50)
Men, n (%)	148 (71)	85 (42)	76 (78)			28 (50)			28 (50)
HLA positive, n (%)	84 (40)	77 (39)	54 (55)	0.23	0.4	12 (22)			12 (22)
Body Mass Index, kg/m ² , median (IQR)	25.0 (23.4–26.4)	25.0 (23.4–26.4)	25.0 (23.4–26.4)	0.19	0.84	25.4 (23.4–26.4)			25.4 (23.4–26.4)
TNF drug type, n (%)	209 (37)	199 (35)	98 (17)	0.4	0.37	55 (10)			55 (10)
Adalimumab	49 (24)	54 (27)	17 (17)			21 (38)			21 (38)
Etanercept	60 (29)	45 (23)	17 (17)			13 (24)			13 (24)
Infliximab	48 (23)	39 (20)	35 (35)			11 (20)			11 (20)
Goldimab	38 (18)	42 (21)	14 (14)			7 (13)			7 (13)
Control group	14 (7)	19 (10)	1 (1)			3 (5)			3 (5)
Methotrexate use, n (%)	12 (6)	7 (4)	7 (7)	0.28	0.87	5 (9)			5 (9)
DMARD use, n (%)	12 (6)	22 (11)	13 (13)	0.05	0.08	10 (18)			10 (18)
Methotrexate	6 (3)	9 (5)	3 (3)			0 (0)			0 (0)
Sulfasalazine	5 (2)	1 (0)	4 (4)			0 (0)			0 (0)
Hydroxychloroquine	1 (0)	1 (0)	1 (1)			0 (0)			0 (0)
Azathioprine	0 (0)	1 (0)	2 (2)			0 (0)			0 (0)

Conclusions: In this study of TNFi-treated AS patients in clinical practice, smoking was not found to be associated with disease activity, treatment response and treatment adherence.

Disclosure of Interest: None declared

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SAT0184

THE EFFECT OF SMOKING ON RESPONSE TO TUMOR NECROSIS FACTOR-ALPHA INHIBITOR TREATMENT IN ANKYLOSING SPONDYLITIS PATIENTS: RESULTS FROM THE TURKBIO REGISTRY

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Background: Although there is good evidence that smoking has a dose-dependent impact on structural damage progression in ankylosing spondylitis (AS) the evidence is poor for its impact on disease activity, physical mobility, life quality and treatment response.

Objectives: We aimed to investigate the impact of smoking on disease activity, treatment adherence and treatment response in Turkish patients with AS treated with their first tumor necrosis factor-alpha inhibitor (TNFi) therapy in a real-life cohort.

Methods: 561 patients fulfilling the modified New York criteria for AS and treated with their first TNFi therapy since 2011 from 8 centers in Turkey were included in

SAT0185

CERTOLIZUMAB PEGOL SERUM LEVELS ≥ 20 MG/L ARE ASSOCIATED WITH IMPROVEMENT IN DAS28 IN RHEUMATOID ARTHRITIS PATIENTS. DATA FROM THE NOR-DMARD STUDY

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Background: Measurement of serum drug levels can help clinicians tailor treatment with TNF-inhibitors. An association between certolizumab pegol (CP) serum levels and treatment response in rheumatoid arthritis (RA) patients (pts) has previously been demonstrated in a prospective observational study (1). These results need to be confirmed in other studies, with particular focus on finding an optimal therapeutic serum level for CP.

Objectives: To examine the association between serum CP drug levels and treatment response in RA pts and to identify a therapeutic target level.

Methods: Patients with a clinical diagnosis of RA starting standard treatment with CP included in the NOR-DMARD registry with biobank sample at 3 months follow-up, were included in the present analyses. Serum drug levels (non-trough) were analysed with an in-house immunofluorometric assay automated on the AutoDELTA immunoassay platform. We studied association between serum CP level and Δ DAS28 and EULAR good/moderate response at 3 months by multivariable linear and logistic regression analyses, respectively, adjusting for age, sex and prior bDMARD (Y/N).

Results: In 91 included patients, median serum drug level at 3 months follow up was 34.7 mg/L (17.6–44.6). Response data were available in 81/91 patients. Serum CP level ≥ 20 mg/L was associated with greater improvement in DAS28 at