SAT0182

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

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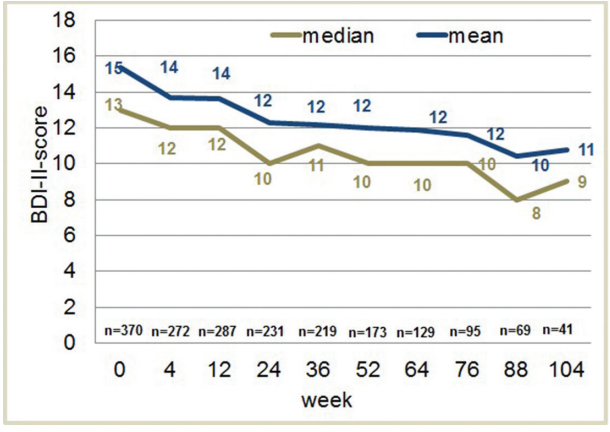
Background: The non-interventional ARATA study (NCT02251860) observes the clinical effectiveness and safety of subcutaneous Tocilizumab [TCZ] s.c. treatment under routine conditions over a 2-year period.
Objectives: In this interim analysis, the treatment with TCZ s.c., in particular with respect to patient-reported outcomes regarding depression, fatigue and pain, was evaluated.
Methods: TCZ-naive 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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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 △ 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