endpoint was ACR20 response; safety and secondary endpoints also were assessed.

Significantly more patients who received TCZ achieved improvement across all 3 ACR response criteria versus those who received placebo (Figure 1). DAS28 also was significantly improved in TCZ patients versus those who received placebo (Figure 2). TCZ was effective irrespective of the number of or the most recently failed anti-TNF treatments.

Both 8 mg/kg and 4 mg/kg doses of TCZ were generally well tolerated. The adverse event (AE) profile was consistent with data from other studies of tocilizumab and with the immunomodulatory properties of the drug. AEs were seen in 81%, 87%, and 84% and serious AEs in 11%, 7%, and 6% of the placebo, 4 mg/kg, and 8 mg/kg groups, respectively. Infections occurred in 41%, 47%, and 50% and serious infections in 3%, 2%, and 5% of the placebo, 4 mg/kg, and 8 mg/kg groups, respectively. There was no difference in safety or tolerability based on prior anti-TNF treatment.

Figure 1. Clinical Response at Week 24.

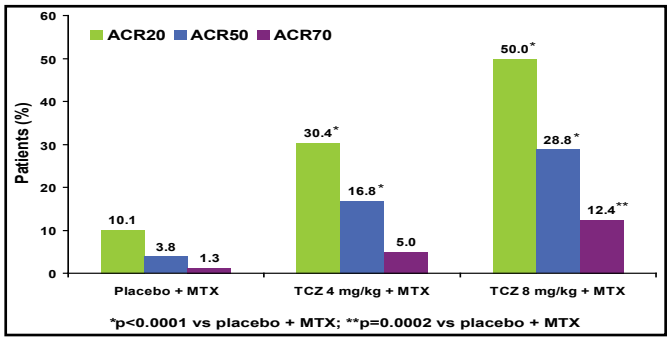
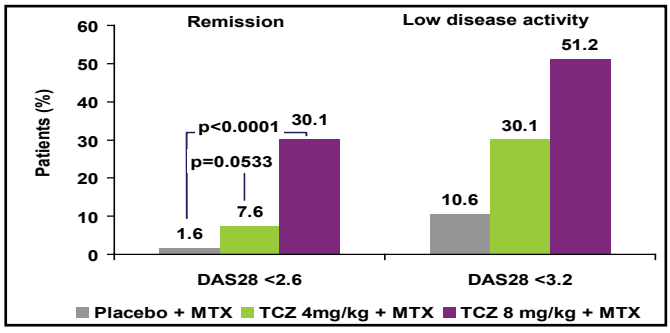


Figure 2. Remission and low disease activity (DAS28) at Week 24.



Combination therapy using TCZ plus MTX resulted in clinical improvements in efficacy and safety in this refractory population, irrespective of the number of, or most recently failed, anti-TNF treatments. The dose response favored the 8 mg/kg TCZ dose, and a low proportion of patients in this group experienced serious AEs or serious infections. Patients who are refractory to one or more courses of anti-TNF therapy have very limited options, so the findings of this trial may have significant impact on clinical management for a select group of patients who are "particularly responsive to IL-6 inhibition," Prof. Emery said.

Adalimumab Therapy is Effective and Well Tolerated in AS, RA, and PsA Patients with a History of Insufficient Response or Intolerance to Other Anti–TNF Therapies

G.R. Burmester, MD, PhD, Berlin University Hospital, Berlin, Germany, presented data from 3 open-label trials that examined the effectiveness of adalimumab treatment in patients with ankylosing spondylitis (AS), rheumatoid arthritis (RA), or psoriatic arthritis (PsA) who had a history of anti-TNF therapy.

The objective of this post hoc analysis of data from the RHAPSODY (NCT00478660; AS), ReAct (NCT00650026; RA), and STEREO (NCT00235885; PsA) trials was to investigate the effectiveness and safety of adalimumab treatment in patients who had received prior anti-TNF therapy with etanercept or infliximab but did not have a satisfactory response. Patients who had prior TNF experience could enroll in the original studies only if infliximab had been discontinued ≥2 months before baseline and/or if etanercept had been discontinued ≥3 weeks before baseline in RHAPSODY and STEREO or ≥2 months before entry in ReAct. Subjects in these studies received adalimumab 40 mg subcutaneously every other week in addition to their current antirheumatic treatment regimens for 12 weeks.

Patients who had failed prior anti-TNF therapy with etanercept and/or infliximab achieved a significant clinical response with adalimumab, which was similar to the response of patients who were naïve to anti-TNF therapy.

After 12 weeks of treatment with adalimumab, patients with AS who previously were treated with etanercept and/or infliximab had a mean reduction in the BASDAI of 2.6 versus 3.5 for patients who had no prior anti-TNF therapy. Patients with RA who had previously received treatment with etanercept and/or infliximab had a mean reduction of 1.9 in DAS28 score versus 2.2 in patients who were not previously treated with a TNF inhibitor. Baseline disease characteristics and effectiveness data are shown in Table 1.

Table 1. Effectiveness of Adalimumab by Indication, Prior Anti-TNF, and Reason for Discontinuation.

Ankylosing Spondylitis (RHAPSODY Study) n=1250						
	Baseline BASDAI [0-10]	Baseline BASFI	Week 12 ASAS 20	Week 12 ASAS 40	Week 12 Change in BASDAI	Week 12 Change in BASFI
No prior anti-TNF (n=924)	6.2	5.2	76%	59%	-3.5	-2.4
≥1 prior anti-TNF therapy (n=326)	6.5	5.7	54%	38%	-2.6	-1.6
No response n=84	6.9	6.1	41%	27%	-1.9	-0.9
Lost response n=136	6.7	5.8	61%	42%	-3.0	-1.9
Intolerance n=62	6.0	5.5	54%	37%	-2.6	-1.6
Rheumatoid Arthritis (ReAct Study) n=6610						
	Baseline DAS28	Baseline HAQ DI	Week 12 ACR20	Week 12 ACR50	Week 12 Change in DAS28	Week 12 Change in HAQ DI
No prior anti-TNF therapy n=5711	6.0	1.60	70%	41%	-2.2	-0.55
≥1 prior anti-TNF therapy n=899	6.3	1.85	60%	33%	-1.9	-0.48
No response n=195	6.5	2.01	51%	26%	-1.8	-0.42
Lost response n=327	6.2	1.84	66%	36%	-1.9	-0.50
Intolerance n=188	6.4	1.82	67%	39%	-2.2	-0.55
Psoriatic Arthritis (STEREO Study) n=442						
	Baseline DAS28	HAQ DI	Week 12 ACR20	Week 12 ACR50	Week 12 Change in DAS28	
No prior anti-TNF therapy n=376	4.9	1.22	75%	52%	-2.3	
Prior anti-TNF therapy n=66	5.1	1.39	67%	42%	-2.1	

Adalimumab was well tolerated by patients with and without a history of prior anti-TNF therapy. Although the rate of serious adverse events was lower in anti-TNF-naïve patients (Table 2), the investigators suggested that this may have been due to the somewhat greater disease activity and level of disability in patients with prior anti-TNF therapy.

Prof. Burmester commented, "An increasing number of patients with rheumatic diseases, such as ankylosing spondylitis, rheumatoid arthritis, or psoriatic arthritis, are experiencing an inadequate response to, or are intolerant of, treatment with existing anti-TNFs, including etanercept or infliximab. The results of our study show that adalimumab offers new hope for those who have tried but have not responded well to other treatment options for their diseases."

Table 2. Serious Adverse Events Through Week 12.

	Any SAE (%)	Serious Infection (%)	Serious Allergy (%)
Ankylosing spondylitis			
No prior anti-TNF therapy	2.6	0.3	0
Prior anti-TNF therapy	3.4	0.3	0
Rheumatoid arthritis			
No prior anti-TNF therapy	5.3	1.3	0.1
Prior anti-TNF therapy	9.6	2.0	0.6
Psoriatic arthritis			
No prior anti-TNF therapy	2.9	0	0.3
Prior anti-TNF therapy	3.0	1.5	0

Remission Can Be Achieved In 50% of Early Rheumatoid Arthritis Patients After 25 Weeks in Daily Clinical Practice

Randomized clinical trials have shown that remission in early rheumatoid arthritis (RA) is a realistic treatment goal, using combination therapy of conventional disease-modifying antirheumatic drugs (DMARDs) with high-dose prednisolone or TNF-α blockers. Methotrexate (MTX) monotherapy in very early RA and in undifferentiated arthritis also results in high remission rates. It is unknown, however, whether these results can be replicated in daily clinical practice.

Ina Kuper, MD, PhD, Medisch Spectrum Twente, Enschede, The Netherlands, presented the results of a prospective, descriptive clinical practice-based study (NCT00122382) that was conducted in a cohort of patients with recent onset RA who were DMARD-naïve. The objective of the study was to evaluate whether a step-up DMARD,