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,

tight-control approach could produce remission (defined as DAS28 <2.6).

Immediately following the clinical diagnosis of RA, patients were started on an initial dose of MTX 15 mg/week after diagnosis. If remission was not achieved at Week 8, the dose was increased to 25 mg/week. In the absence of remission at Week 12, sulfasalazine (2 grams/day) was added and, if indicated, increased to 3 grams/day at Week 20. If remission still was not achieved at Week 24, adalimumab (40 mg every 2 weeks) was added. Thereafter, therapy was adjusted every 3 months, including the use of other TNF-blockers, based on DAS28 score. Patients were permitted to use NSAIDs and prednisolone ≤10 mg/day. Intra-articular corticosteroid injections also were allowed. T-test and Pearson chi-square were used to compare baseline patient characteristics between the hospitals, and Kaplan-Meier survival curves were used to estimate the time (95% CI, weeks) to first remission and to first low disease activity (DAS28 ≤3.2).

As of January 2008, 190 patients were enrolled in the study. Dr. Kuper presented results for the first 169 patients with DAS28 at inclusion >3.2. Baseline patient characteristics are shown in Table 1.

Table 1. Baseline Patient Characteristics.

Age (years ± SD)	57.3 ± 13.7
Women, %	63.9
Duration of signs and symptoms (median, 25-27th percentile)	14 (8-25)
Rheumatoid factor positive, %	52.7
Anti-CCP positive, %	57.3
ESR (mm/h ± SD)	33.2 ± 20.5
CRP (mg/L ± SD)	23.5 ± 26.4
DAS28 (0-10 score ± SD)	5.1 ± 1.1
HAQ-SDI (0-3 score ± SD)	1.3 ± 0.6

Remission was achieved in 52.1% (38/73) at Week 36. Low disease activity was achieved by 53.3% of patients by Week 20 (Table 2). Remission was sustained in 61.5% of patients 3 months after first remission and in 53.2% of patients 6 months after first remission.

"Our results show that remission is indeed achievable in as many as half of clinical practice patients who follow this schedule, which could indicate that remission is a realistic treatment goal of daily clinical practice," concluded Dr. Kuper.

Table 2. Remission and Low Disease Activity at Follow-up (%).

	DAS28 <2.6	DAS28 ≤3.2
Week 8 n=148	15.5	23.6
Week 12 n=108	22.2	36.1
Week 20 n=75	30.7	53.3
Week 24 n=85	38.8	58.8
Week 36 n=73	52.1	74.0
Week 48-52 n=51	51.0	72.5