Results From the Long-Term Extension of the AIM Trial

The results from the 2-year AIM (ABA in Inadequate responders to MTX) trial indicated that RA patients refractory to treatment with MTX, demonstrate significant reduction in radiographic progression after treatment with Abatacept (Aba) [*Ann Rheum Dis* 2005;64(Suppl III):56].

In a 2 year follow-up study, Aba (~10 mg/kg) slowed progression of structural damage when compared with placebo, as determined from radiographs of hands and feet. Paired radiographs were independently scored for erosion score (ES), joint-space narrowing (JSN) score, and total score (TS) using the Genant-modified Sharp scoring method [*Am J Med* 1983;75(6A):35-47].

After 2 years of treatment with Aba, signs of radiographic progression were minimal. Using a linear mixed model analysis to compare the slope of radiographic progression, 2 years of treatment with Aba was found to be significantly better than 1 year of placebo followed by 1 year of Aba (ES $p<0.001$; JSN $p<0.05$; TS $p<0.01$). Radiographic progression in the Aba group slowed more after 2 years of treatment than after 1 year. The slopes from year 1 to year 2 were: ES-0.6 vs 0.3; JSN- 0.4 vs 0.4; TS- 1.0 vs 0.7. Results of this study indicate that after 2 years of treatment, Aba significantly slowed radiographic progression in RA patients with an inadequate response to MTX. The effect seen after 2 years of treatment was significantly better than that seen after 1 year.

The Reflex Study: Prevention of Joint Structural Damage at 1 Year with Rituximab in Rheumatoid Arthritis Patients with an Inadequate Response to One or More TNF Inhibitors

Previous reports of 6-month data with rituximab (RTX) indicated that this selective CD20+ B cell targeted therapy can inhibit the radiographic progression of joint structural damage in RA patients with long-standing resistance to one or more TNF inhibitors (Cohen et al, *Arthritis Rheum* in press). This study extends those findings to report results at week 56 regarding the efficacy of RTX plus MTX versus MTX alone on joint structural damage in RA patients with inadequate response to one or more TNF inhibitors.

The mean change in the total Genant-modified Sharp score in the placebo group was 2.31 compared with 1.0 in the RTX group ($p = 0.0043$). Significant differences were also seen in ES and JSN changes. The proportion of patients with no change in ES was significantly ($p = 0.045$) higher in the RTX + MTX group (61%) versus the placebo + MTX group (52%).

	Placebo + MTX (n=184)	RTX + MTX (n=272)
Mean change in total Sharp/Genant score (SD)	2.31 (5.28)	1.00 (2.76) p=0.0043
Mean change in erosion score (SD)	1.32 (3.16)	0.59 (1.85) p=0.0106
Mean change in JSN (SD)	0.99 (2.57)	0.41 (1.33) p=0.0007
% of pts with no change in erosion score	52	61 p=0.0445

This is the first study to show that in RA patients refractory to 1 or more TNF inhibitors, treatment with RTX can prevent radiographically documented joint structural damage, which reinforces previous data that supports the use of RTX as an effective, innovative treatment for RA.