FRI0067 TREATMENT WITH ANAKINRA REDUCES THE RATE OF JOINT DESTRUCTION AND SHOWS ACCELERATED BENEFIT IN THE SECOND 6 MONTHS OF TREATMENT FOR PATIENTS WITH RHEUMATOID ARTHRITIS

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Background

Objectives Evaluate the effect of anakinra treatment on joint destruction in 1) patients completing a previous 6 months of anakinra treatment, and 2) patients completing 24 weeks of placebo.

Methods 472 Patients with RA entered a 24 week, randomised clinical trial and received placebo or anakinra 30, 75 or 150 mg daily. On completing this phase, patients receiving placebo were re-randomised to one of the treatment groups and patients receiving anakinra continued treatment for a further 24 week extension study. Radiographs, obtained at 0, 24 and 48 weeks, were evaluated for joint damage using a modified Sharp method (Genant AJR '00).

Results For those patients who rolled over to treatment with anakinra after 6 months of placebo, all three anakinra dose groups showed significant reduction in the rate of joint destruction. Patients who received the same dose of anakinra for the entire 12 months showed an accelerated benefit by slowing radiographic progression in the second 6 months (75 and 150 mg).

Abstract FRI0067 Table 1

	30 mg	75 mg	150 mg	All
Change on placebo	2.55	2.01	5.79	3.43
0-6 mo				
Change on anakinra	1.10	0.88	1.99	1.31
6-12 mo				
Difference placebo -> anakinra	-1.46 (n = 19) p = 0.008	-1.13 (n = 20) p = 0.010	-3.81 (n = 19) p = 0.002	-2.11 (n = 58) p < 0.001
Change on anakinra	1.74	1.95	1.78	1.82
0-6 mo				
Change on anakinra	1.61	0.95	0.85	1.18
6-12 mo				
Difference anakinra -> anakinra	-0.13 (n = 68) p = 0.282	-1.00 (n = 61) p = 0.006	-0.93 (n = 49) p = 0.008	-0.65 (n = 178) p < 0.001

p values are results of Wilcoxon signed rank test.

Conclusion In a 24 week study of RA, anakinra significantly reduced the rate of progressive joint damage. When treatment was maintained for a further 24 weeks, the rate of progressive joint damage was significantly slower compared to the first 24 week period.

FRI0068 102-WK CLINICAL AND RADIOLOGIC RESULTS FROM THE ATTRACT TRIAL: A 2 YEAR, RANDOMISED, CONTROLLED, PHASE 3 TRIAL OF INFlixIMAB (REMICADE®) IN PTS WITH ACTIVE RA DESPITE MTX

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Background The ATTRACT trial studied the long term efficacy and tolerability of infliximab in 428 pts with active RA despite MTX (median dose of 15 mg/wk).

Objectives

Methods While continuing MTX, pts were randomly assigned to one of five therapeutic arms in which infliximab at 3 or 10 mg/kg or placebo infusions were given at 0, 2, and 6 wks and every 4 or 8 wks thereafter. Clinical benefit was assessed by maintenance of at least an ACR20 level of response. Using the van der Heijde modified Sharp system assessing bone erosions and joint space narrowing, the total radiologic score (TRS) was calculated for each patient at 0, 30, 54, and 102 wks. Adverse events were tabulated.

Results Infliximab in combination with MTX is well tolerated and results in a sustained clinical benefit at all doses and frequencies over 2 years. Additionally, radiologic progression was essentially arrested in all infliximab plus MTX treatment arms as compared to the MTX control group. All infliximab dose regimens were comparable in clinical and radiologic benefit.

Abstract FRI0068 Table 1

	Placebo	3 mg/kg q 8 wks	3 mg/kg q 4 wks	10 mg/kg q 8 wks	10 mg/kg q 4 wks	Total Infliximab	p-value
ACR20	16	41	40	48	42	43	<0.001
Change in HAQ Mean	0.3	0.4	0.5	0.5	0.4	0.5	<0.001
Change in HAQ Median	0.1	0.3	0.3	0.4	0.3	0.4	<0.001
Change in TRS Mean	12.6	1.0	1.0	1.1	-0.4	0.7	<0.001
Change in TRS Median	4.3	0.4	0.5	1.0	0.0	0.5	<0.001
% pts >= 1 serious AE	33%	33%	23%	29%	32%	29%	0.603

No unexpected adverse events, nor an increase in any previously observed side effect were reported.

Conclusion Infliximab in combination with MTX is well tolerated and results in a sustained clinical benefit at all doses and frequencies over 2 years. Additionally, radiologic progression was essentially arrested in all infliximab plus MTX treatment arms as compared to the MTX control group. All infliximab dose regimens were comparable in clinical and radiologic benefit.