The most commonly occurring adverse reactions in controlled trials of Crohn's disease treated with certolizumab pegol were: pain at the injection site, headache, fatigue, and upper respiratory tract infection. Infections were the most common serious adverse reactions in controlled trials of certolizumab pegol treated patients with Crohn's disease and included upper respiratory tract infections, cellulitis, and bronchitis. Adverse reactions associated with serious infections included sepsis, pyelonephritis, urinary tract infection, and peritonitis.

Other adverse reactions observed in clinical studies included abdominal pain, diarrhea, and nausea. Serious adverse events occurred in 4.1% of patients treated with certolizumab pegol compared to 1.9% of placebo-treated patients. The proportion of patients with adverse events was similar between certolizumab pegol treated patients and placebo-treated patients. The most commonly reported adverse reactions leading to discontinuation of treatment were: injection site reaction (2.8%), upper respiratory tract infection (1.9%), and abdominal pain (1.8%).

In clinical trials of certolizumab pegol, more cases of malignancies have been observed among patients taking TNF inhibitors compared to placebo. Cases of lymphoma were observed among patients treated with certolizumab pegol. In a controlled clinical trial of 1,514 patients with Crohn's disease treated with certolizumab pegol, 17 patients were diagnosed with lymphoma (1.1%) compared to 5 patients (0.3%) in placebo-treated patients. Among the 17 patients with lymphoma, 12 were on long-term treatment with certolizumab pegol for up to 7 years. Among the 5 patients with lymphoma in the placebo group, 4 were on long-term treatment with placebo for up to 6 years. These findings suggest a potential increased risk of lymphoma among patients treated with certolizumab pegol for long-term periods.

In clinical studies of certolizumab pegol, cases of malignancies have been observed among patients taking TNF inhibitors compared to placebo. Cases of lymphoma have been observed among patients treated with certolizumab pegol. In a controlled clinical trial of 1,514 patients with Crohn's disease treated with certolizumab pegol, 17 patients were diagnosed with lymphoma (1.1%) compared to 5 patients (0.3%) in placebo-treated patients. Among the 17 patients with lymphoma, 12 were on long-term treatment with certolizumab pegol for up to 7 years. Among the 5 patients with lymphoma in the placebo group, 4 were on long-term treatment with placebo for up to 6 years. These findings suggest a potential increased risk of lymphoma among patients treated with certolizumab pegol for long-term periods.

In patients treated with certolizumab pegol, serious infections were observed at an incidence rate of 1.8% in controlled trials. Serious infections included sepsis, pneumonia, and cellulitis. These infections were similar to those observed in placebo-treated patients. However, the incidence of serious infections was higher in patients treated with certolizumab pegol compared to placebo. The most commonly reported serious infections were: cellulitis, bronchitis, and sinusitis. These infections were similar to those observed in placebo-treated patients.

Infections were the most common serious adverse reactions in controlled trials of certolizumab pegol treated patients with Crohn's disease and included upper respiratory tract infections, cellulitis, and bronchitis. Adverse reactions associated with serious infections included sepsis, pyelonephritis, urinary tract infection, and peritonitis. The most commonly reported serious infections were: cellulitis, bronchitis, and sinusitis. These infections were similar to those observed in placebo-treated patients.

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Study CD1 was a randomized placebo-controlled study in 662 patients with active Crohn's disease. 6% of patients had a baseline CDAI of 150 points.

In Study RA-I, inhibition of progression of structural damage was assessed in 294 patients with rheumatoid arthritis (RA) and 165 patients with Crohn's disease. The mean (SD) change from baseline in Erosion Score (ES) and Joint Space Narrowing (JSN) score, at Week 52, compared to baseline. CIMZIA inhibited the progression of structural damage compared to placebo plus MTX after 12 months of treatment as shown in Table 4.

\[ E_{before} - E_{after} = 0.4 \]

The percent of patients achieving ACR20 responses by visit for Study RA-I is shown in Figure 1. Among the 294 patients treated with CIMZIA in Study RA-I, 14% were ACR20 responders at Week 24.

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