

# A Phase 3 Multi-National, Multi-Centre, Double-Blind Placebo-Controlled Parallel Group, 26 Week Study to Assess the Maintenance of Clinical Response to Certolizumab Pegol in the Treatment of Patients With Active Crohn's Disease who Have Responded to Open Induction Therapy With Certolizumab Pegol

## Short title: *Certolizumab Pegol for the Treatment of Crohn's Disease in Adults*

<b>Background</b>	<ul style="list-style-type: none"><li>• Crohn's disease is a chronic inflammatory disorder that affects the intestines. The main symptoms include loose stools (sometimes seen more at night), fever, weight loss, stomach pain and blood loss through the rectum.<sup>1</sup> Crohn's disease is categorised as either mild-to-moderate active disease or moderate-to-severe active disease.<sup>1</sup> In patients with Crohn's disease, C-reactive protein levels (markers for disease severity through inflammation) may be increased.<sup>2</sup></li></ul>
<b>Purpose of the study</b>	<ul style="list-style-type: none"><li>• To determine if the improvement of symptoms of Crohn's disease seen during the first 6 weeks of treatment with certolizumab pegol (Cimzia<sup>®</sup>), a tumour necrosis factor inhibitor, is maintained over the next 20 weeks.</li><li>• To determine if certolizumab pegol is well tolerated by these patients.</li></ul>
<b>Study participants</b>	<ul style="list-style-type: none"><li>• The study included 668 adult male and female patients aged 18-69 years who had active moderate-to-severe Crohn's disease for at least 3 months.</li></ul>
<b>Study design and research methodology</b>	<ul style="list-style-type: none"><li>• The study was conducted in 147 centres across Australia, Canada, Denmark, Germany, Hungary, Ireland, Israel, Lithuania, New Zealand, Norway, Spain, Poland, Serbia, Singapore, South Africa, Ukraine and the United States between February 2004 and May 2005. Patients participated in the study for a maximum of 7 months.</li><li>• The 668 patients included in the study received an initial dose of certolizumab pegol as an injection under the skin at weeks 0, 2 and 4 (initial phase).</li><li>• Out of the 668 patients, 428 patients showed improvement of symptoms during the initial 6 weeks. These 428 patients were randomly divided into 2 groups (maintenance phase) and were given either certolizumab pegol or placebo as an injection under the skin once every 4 weeks until week 24.<ul style="list-style-type: none"><li>○ They were further divided within each group based on their C-reactive protein levels: C-reactive protein levels of at least 10 mg per litre and C-reactive protein levels below 10 mg per litre.</li></ul></li><li>• Patients were followed for improvement in symptoms (clinical response) at 26 weeks and improvement in their overall health condition.</li><li>• Remission rates were calculated for all the patients. Remission rate is defined as having a Crohn's disease activity index (a tool that measures Crohn's disease symptoms) score of 150 or less.</li><li>• Side effects were also studied.</li></ul>
<b>Key findings</b>	<ul style="list-style-type: none"><li>• Among patients with C-reactive protein levels of at least 10 mg per litre at baseline, more patients treated with certolizumab pegol showed clinical response compared with patients treated with placebo.</li><li>• Irrespective of C-reactive protein levels, the rates of clinical response were larger in patients in the certolizumab pegol group compared with patients in the placebo group.</li><li>• Remission rates were higher in the certolizumab pegol group compared with the placebo group in patients with C-reactive protein levels of at least 10 mg per litre at baseline, as well as in all other patients.</li><li>• Patients with active moderate-to-severe Crohn's disease whose symptoms got better during the first 6 weeks of treatment with certolizumab pegol and who continued to receive the same medicine for the next 20 weeks showed continued improvement, compared with patients whose symptoms got better during the first 6 weeks of treatment with certolizumab pegol and were switched to placebo after the initial 6-week treatment period.</li><li>• Side effects were similar between the groups.</li><li>• The most common side effects reported in at least 5% of patients in either groups were headache, nasopharyngitis (viral infection of the upper respiratory system), cough, worsening of symptoms of Crohn's disease and pain at the site of injection.</li><li>• No follow-up trials are foreseen for this study.</li></ul>
<b>Peer-reviewed publication</b>	<p><a href="#">Schreiber S, Khaliq-Kareemi M, Lawrance IC, et al. Maintenance therapy with certolizumab pegol for Crohn's disease. <i>N Engl J Med.</i> 2007;357:239-250.</a></p>

**References:** 1. Lichtenstein GR, Hanauer SB, Sandborn WJ. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2009;104:465-483.  
2. Kiss LS, Papp M, Lovasz BD, et al. High-sensitivity C-reactive protein for identification of disease phenotype, active disease, and clinical relapses in Crohn's disease: a marker for patient classification? *Inflamm Bowel Dis.* 2012;18:1647-1654.

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