Certolizumab Pegol for Active Crohn’s Disease

Dear Editor:

We read with interest the findings and conclusions of Sandborn et al regarding the efficacy of certolizumab pegol as induction therapy for patients with active Crohn’s disease who are naïve to biological agents. However, we were greatly concerned that no data were provided regarding the smoking status of the patients. It is well-documented that current smokers with Crohn’s disease have a poorer prognosis with increased disease severity and a significantly higher risk of surgical resection. Smoking is also an independent predictor of biologic treatment failure in Crohn’s disease.

The primary end point of this multicenter, randomized, double-blind, placebo-controlled trial was clinical remission at week 6. This was achieved in 32% of patients in the certolizumab pegol group, compared with 25% in the placebo group. These results did not reach statistical significance. We are concerned that the results were adversely influenced by smoking in the treatment group or by more ex-smokers in the placebo group. We would be interested to know whether further analysis of the results on the basis of smoking status would alter the interpretation of the data.

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Conflicts of interest
The authors disclose no conflicts.


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We feel that the overall placebo clinical remission rate of 25% might reflect the relatively high proportion of patients with a baseline C-reactive protein concentration <4 mg/L and that patient selection for clinical trials should emphasize the treatment of patients who have objective evidence of inflammation in addition to symptoms of active disease. It is clear that we need to learn more about how anti-TNF therapies, active inflammation, and factors such as smoking status interact to influence clinical outcome.

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2. Kiss LS, Szamosi T, Molnar T, et al. Early clinical remission and normalisation of CRP are the strongest predictors of efficacy,

Conflicts of interest
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