P.IIIb OL&RCT/Certolizumab/CD

Certolizumab Pegol in Patients With Moderate to Severe CD and Secondary Failure to Infliximab

Patients with LOR to IFX received OL certolizumab pegol induction and were randomised to receive double-blind maintenance treatment with certolizumab pegol 400 mg either q4w or q2w through w24, with a final evaluation at w26.

Primary end point: Response at w6 defined as a decrease in the CDAI score of at least 100 points from baseline.

Results:

- At w6, 62.0% achieved response and 39.3% remission.
- A total of 329 patients were randomized and received maintenance therapy.
- At w26, 39.9% and 36.6% in the q4w and q2w groups were in clinical response, respectively (p 0.55). Corresponding remission rates at w26 were 29.2% and 30.4%, (p 0.81).

Conclusions:

Response to OL induction therapy with certolizumab pegol was achieved by 62% of patients with moderate to severely CD and secondary failure to infliximab.

Among these patients, certolizumab pegol 400 mg every 4 weeks showed similar efficacy to every-2-weeks dosing for maintenance of response and remission.

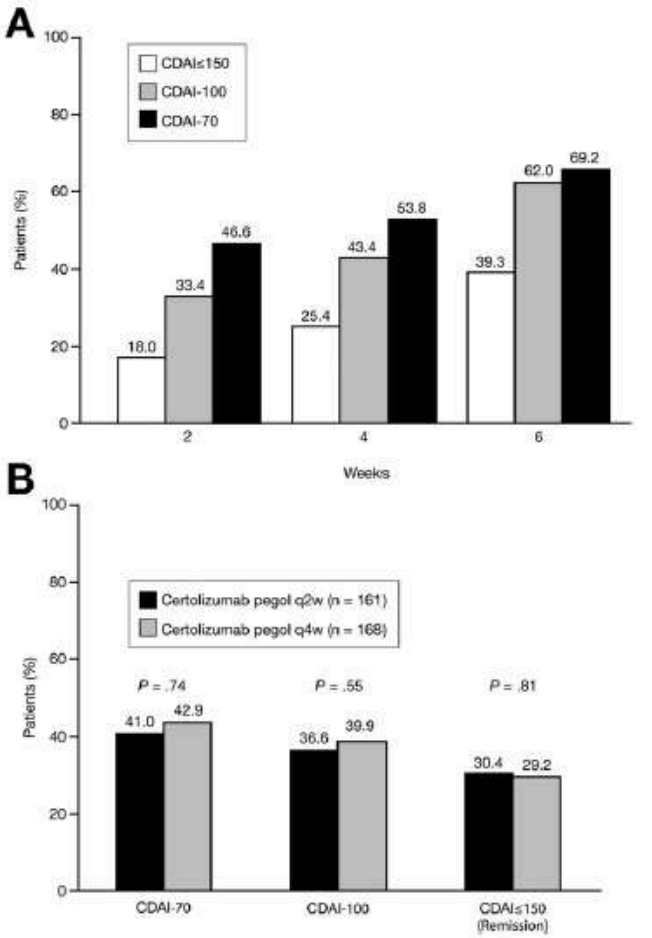

Figure 1. Response and remission rates (*A*) over the open-label induction phase (n = 539) and (*B*) at week 26 (n = 329).

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