MULTIPLE SCLEROSIS

Daclizumab HYP shows efficacy in patients with relapsing–remitting MS

The results of the SELECT trial, recently published in *The Lancet*, indicate that the humanized monoclonal antibody daclizumab reduces disease activity in relapsing–remitting multiple sclerosis (RRMS). Daclizumab blocks the α subunit of the IL-2 receptor, and its therapeutic effects in MS have been attributed to expansion of CD56^{bright} natural killer cells, which kill activated T cells.

The multicentre study, conducted by Ralf Gold and colleagues, recruited a total of 621 patients with RRMS, who were randomly assigned to receive placebo ($n = 204$), daclizumab high-yield process (HYP) 150 mg ($n = 208$) or daclizumab HYP 300 mg ($n = 209$) subcutaneously every 4 weeks for 52 weeks. 186 patients in the placebo group, 189 in the 150 mg dose group and 192 in the 300 mg dose group completed the treatment course.

At week 52, the annualized relapse rate was significantly lower in the daclizumab-treated patients than in those treated with

placebo. 65% of patients in the placebo group, compared with 81% and 80% in the daclizumab HYP 150 mg and 300 mg groups, respectively, remained relapse-free throughout the trial period.

Daclizumab HYP also produced improvements in imaging and clinical parameters. Patients who received the antibody exhibited less new lesion activity on MRI than did those who received placebo. In addition, the daclizumab-treated patients showed reduced progression of disability, which was not invariably linked to effects on relapse rates.

Serious adverse events, including infections, hepatic dysfunction and rash, occurred in 7% and 9% of the daclizumab 150 mg and 300 mg groups, respectively, compared with 6% of the placebo group. One patient in the 150 mg dose group died from complications of a psoas abscess.

“The SELECT study aimed at getting novel information on the active dosage of monotherapy with daclizumab,” says Gold.

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“Not only the high relapse rate reduction, but also the reduction in disability progression, opens new avenues to which type of MS may be the best responder.” DECIDE, a phase III trial of daclizumab HYP versus IFN- β , is in progress, and the results are expected in 2014.

Heather Wood

Original article Gold, R. *et al.* Daclizumab high-yield process in relapsing–remitting multiple sclerosis (SELECT): a randomised, double-blind, placebo-controlled trial. *Lancet* doi:10.1016/S0140-6736(12)62190-4

Further reading Bielekova, B. *et al.* Regulatory CD56^{bright} natural killer cells mediate immunomodulatory effects of IL-2R α -targeted therapy (daclizumab) in multiple sclerosis. *Proc. Natl. Acad. Sci. USA* **103**, 5941–5946 (2006)