

HAEMATOLOGICAL CANCER

PROLONGING PFS with ofatumumab in patients with CLL

For patients with chronic lymphocytic leukaemia (CLL) who are in remission, although many treatments improve progression-free survival (PFS), only stem-cell transplantation is potentially curative. Thus, for patients with CLL, prolonging PFS and overall survival are vital treatment goals. Now, the interim results of the PROLONG randomized, phase III trial, in which ofatumumab maintenance therapy was assessed in patients with relapsed CLL, have shown that achieving this goal is possible.

The monoclonal antibody ofatumumab, which targets CD20, was shown to have potent *in vivo* activity in preclinical studies. These data prompted the latest phase III trial, which was conducted in 130 centres in 24 countries. A total of 474 patients were enrolled into the trial and randomly assigned to receive either ofatumumab (300 mg followed by 1,000 mg 1 week later and then every 8 weeks for 1 year) or to observation. The primary end point of the trial was PFS, and secondary end points included overall

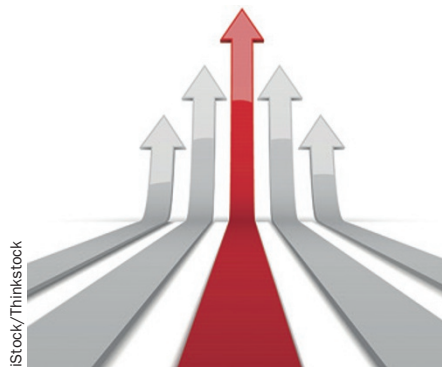
survival, time to next treatment, safety, and quality of life. The results of prespecified interim analysis after two-thirds of the planned events have now been reported.

At a median follow up of 19.1 months, the PFS was significantly longer in patients treated with ofatumumab than in patients randomly assigned to observation (29.4 months versus 15.2 months). No difference in overall survival between the two groups was reported; however, the absence of an effect on this end point is not unexpected in light of the relatively short

follow-up duration and the availability of effective salvage treatments at relapse.

A longer time to next treatment was noted for patients in partial or complete remission after treatment with ofatumumab, compared with observation (38 months versus 31 months). A greater number of adverse events of all grades and of grade 3 or higher were noted in the ofatumumab group, although this drug was well tolerated when given intravenously once every 8 weeks. No notable difference in quality of life between the two groups was observed. These trial data point to a new option for patients with relapsed CLL; future trials are needed to determine the optimum maintenance strategies for such patients.

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Original article van Oers, M. H. *et al.* Ofatumumab maintenance versus observation in relapsed chronic lymphocytic leukaemia (PROLONG): an open-label, multicentre, randomised phase 3 study. *Lancet Oncol.* doi:10.1016/S1470-2045(15)00143-6