Nature Reviews Clinical Oncology 8, 691 (2011); published online 8 November 2011; doi:10.1038/nrclinonc.2011.172

IMMUNOTHERAPY A FIRST FOR FIRST-LINE THERAPY IN NSCLC

Chemotherapy is the standard of care for patients with advanced-stage non-smallcell lung cancer (NSCLC), and it is widely agreed that therapy efficacy needs to be improved. A study led by Elisabeth Quoix has now shown that it is feasible to add immunotherapy to first-line chemotherapy in these patients, and that it might improve long-term outcomes.

The immunotherapy in question is TG4010, which consists of a suspension of a recombinant modified vaccinia virus (Ankara strain) that codes for the MUC1 tumor-associated antigen and for interleukin-2. TG4010 was previously shown to have efficacy in combination with cisplatin and vinorelbine in a phase II trial. The present study takes this further, comparing chemotherapy alone with chemotherapy plus TG4010 in patients with advanced-stage NSCLC.

In this phase IIB, open-label, controlled trial, 148 chemotherapy-naive patients with stage IIIB or IV NSCLC—who were recruited from 23 centers in Europe were randomly assigned to receive either chemotherapy alone (cisplatin and gemcitabine) or chemotherapy in combination with TG4010. The authors stated that previously, "no randomized clinical trial has assessed the addition of a therapeutic cancer vaccine to first-line chemotherapy in advanced NSCLC."

At 6 months, 43.2% of the patients receiving the combination therapy were progression free, compared with 35.1% of the chemotherapy-alone group. As Quoix states: "the main finding is that the end point we had chosen was met with a 6-month progression-free survival of more than 40% in the experimental arm." TG4010 in combination with chemotherapy was well tolerated, with no significant difference in grade 3 or 4 adverse events between the groups. Interestingly, the level of activated natural killer cells was identified as a possible predictive biomarker for TG4010 efficacy.

These data are very promising but must be followed up with a properly powered phase III clinical trial, which is planned, to assess the immunotherapy in combination with chemotherapy, and will perhaps open up new treatment options for patients.

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Original article Quoix, E. et al. Therapeutic vaccination with TG4010 and first-line chemotherapy in advanced non-small-cell lung cancer: a controlled phase 2B trial. *Lancet Oncol.* doi:10.1016/S1470-2045(11)70259-5