Adjuvant Ipilimumab effects survival after high risk lymph node and melanoma resection

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Results of an EORTC trial appearing in *The Lancet Oncology* show that adjuvant Ipilimumab significantly improves recurrence-free survival in patients with completely resected stage III melanoma at high risk of disease recurrence, but that this treatment was also associated with a high rate of immune-related adverse events.

Prof Alexander M M Eggermont of the Gustave Roussy Cancer Campus

and lead author of this study says, "Ipilimumab has already been approved as a treatment for patients with advanced melanoma. Our intention with this study was to assess Ipilimumab as an adjuvant treatment for patients with completely resected stage III melanoma at high risk of recurrence. In my experience, this marks both the first clinical trial of an approved drug with an effect on survival in advanced melanoma in the adjuvant setting, and, in this same setting, the first to study an immune checkpoint inhibitor in the adjuvant setting. Our results show that Ipilimumab is active in the adjuvant setting, but the side-effects are considerable."

Between 2008 and 2011, the double-blind, phase III EORTC trial 18071 accrued 951 patients who were randomly assigned to receive either Ipilimumab (475 patients) or placebo (476 patients). All patients were included in the intention-to-treat analyses. At a median follow-up of 2.74 years, the median recurrence-free survival was 26.1 months (95% confidence interval (CI) 19.3 - 39.3) in the Ipilimumab group and 17.1 months (95% CI 13.4 - 21.6) in the placebo group (hazard ratio 0.75; 95% CI 0.64 - 0.90; p = 0.0013). The 3-year recurrence-free survival rate was 46.5% (95% CI 41.5 - 51.3) in the Ipilimumab group and 34.8% (30.1 - 39.5) in the placebo group.

Despite these significant recurrence-free survival results, the trial also found important side-effects, in particular the following grade 3 - 4 immune-related adverse events were reported: gastrointestinal, 75 events (16%) in the Ipilimumab group and four (

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