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Adjuvant ipilimumab versus placebo after complete resection of stage III melanoma: long-term follow-up results of the European Organisation for Research and Treatment of Cancer 18071 double-blind phase 3 randomised trial

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Abstract

Background: Since 2015, adjuvant therapy with ipilimumab is an approved treatment for stage III melanoma based on a significantly prolonged recurrence-free survival (RFS). At a median follow-up of 5.3 years, RFS, distant metastasis-free survival (DMFS) and overall survival (OS) were each significantly prolonged in the ipilimumab group compared with the placebo group, despite a 53.3% (ipilimumab) versus 4.6% (placebo) treatment discontinuation rate due to adverse events. We present now long-term follow-up results of this European Organisation for Research and Treatment of Cancer 18071 trial.

Patients, methods and results: A total of 99 sites randomised 951 patients with stage III cutaneous melanoma (excluding lymph node metastasis ≤ 1 mm or in-transit metastasis) with adequate resection of lymph nodes to receive intravenous infusions of ipilimumab 10 mg/kg or placebo, every 3 weeks for 4 doses, then every 3 months for up to 3 years. The RFS, DMFS and OS, as reported by the local investigators, were assessed by the intention-to-treat analysis. Among 431 patients randomised at 63 sites and who were still alive at the analysis reported in 2016, recent follow-up information could be obtained for 264 patients. The median OS follow-up was 6.9 years. The RFS (hazard ratio [HR] 0.75, 95% confidence interval 0.63-0.88; $P < 0.001$), DMFS (HR 0.76, 0.64-0.90; $P = 0.002$) and OS (HR 0.73, 0.60-0.89; $P = 0.002$) benefit observed in the ipilimumab group was durable with an 8.7% absolute difference at 7 years for OS. The benefit was consistent across subgroups.

Conclusions: Adjuvant therapy with ipilimumab prolongs RFS, DMFS and OS significantly. The benefit is sustained long term and consistent across subgroups.

Keywords: Adjuvant therapy; Ipilimumab; Long-term results; Melanoma; Phase III trial; Stage III.

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