Ipilimumab as adjuvant therapy improves overall survival in high risk stage III melanoma

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Ipilimumab as adjuvant therapy significantly improves overall survival in patients with high risk stage III melanoma, according to the EORTC 18071 phase III trial results presented for the first time today at the ESMO 2016 Congress in Copenhagen.

"Ipilimumab is an immune checkpoint inhibitor that blocks cytotoxic T-lymphocyte antigen-4 (CTLA-4)," said lead author Professor Alexander Eggermont, director general, Institut Gustave Roussy, Villejuif, France. "It was approved in 2011 for first-line treatment of advanced melanoma in the US and Europe. The next question was its utility in the adjuvant setting."

The EORTC 18071 phase III trial evaluated ipilimumab as adjuvant therapy for patients with high risk stage III melanoma. During 2008 to 2011, 951 patients were randomised to ipilimumab or placebo. Interferon was not used as the comparator because in Europe it is not routinely used nor accepted as a standard of care.

As reported in 2015, the study met its primary endpoint after a median follow up of 2.3 years, with ipilimumab significantly improving recurrence-free survival.2 The drug was subsequently approved by the US Food and Drug Administration as adjuvant therapy for stage III melanoma.

Now, at 5.3 years median follow up, the impact on overall survival is reported and represents a 28% reduction of the relative risk of death (hazard ratio 0.72, p=0.001). There was consistency across all endpoints with hazard ratios of 0.76 for recurrence-free survival and distant metastases-free survival (p