FDA approves Adjuvant Yervoy in melanoma based on results of EORTC trial 18071

November 13 2015, by John Bean

Based on the results of EORTC trial 18071, the FDA expanded the approval of Yervoy (ipilimumab) in melanoma to include adjuvant treatment of patients with stage 3 melanoma at high risk of recurrence following complete resection.

EORTC Headquarters handled project management, data management, and analysis for this successful registration trial.

Results of this EORTC trial appeared earlier this year in *The Lancet Oncology* and showed 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.

Ipilimumab had already been approved as a treatment for patients with advanced melanoma. The 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.

This marked 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.

More information: Alexander M M Eggermont et al. Adjuvant

ipilimumab versus placebo after complete resection of high-risk stage III melanoma (EORTC 18071): a randomised, double-blind, phase 3 trial, *The Lancet Oncology* (2015). DOI: 10.1016/S1470-2045(15)70122-1