



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# New treatment for advanced melanoma

## Opdivo offers treatment option for patients with poor prognosis

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Opdivo (nivolumab). Opdivo is recommended to be used on its own (monotherapy) for the treatment of adult patients with advanced (unresectable or metastatic) melanoma.

Melanoma is the most aggressive type of skin cancer and the leading cause of death from skin disease. The main risk factor for developing melanoma is ultraviolet (UV) light and intermittent exposure to the sun. If melanoma is detected early, it can often be removed by surgery (resected) and has a very good prognosis. However, patients with advanced melanoma have a poor prognosis. It is estimated that five years after the first diagnosis of advanced metastatic melanoma only 10 to 30% of patients will still be alive.

For decades, chemotherapy was the standard treatment for patients with advanced melanoma, but it did not improve survival. In the last three years, the authorisation of targeted treatments, including monoclonal antibodies, BRAF V600 and MEK inhibitors, have significantly changed the therapeutic landscape.

The active substance in Opdivo (nivolumab) is a monoclonal antibody. Nivolumab attaches to and blocks a receptor called 'programmed death-1' (PD-1). By blocking the usual receptor interactions, Opdivo leads to activation of the immune system to kill melanoma cells. Opdivo is the first cancer treatment selectively targeting PD-1 recommended for approval in the European Union (EU).

Opdivo's recommendation is based on two main studies in patients with advanced malignant melanoma. The first study randomly assigned 418 patients who had not received previous treatment for their melanoma, to receive either Opdivo or standard chemotherapy (dacarbazine). After 12 months, the survival rate of patients treated with Opdivo was much higher than the rate of patients who received dacarbazine (73% compared with 42%). The second study randomised 405 patients who had received previous treatment for their melanoma to receive Opdivo or chemotherapy (either dacarbazine or carboplatin and paclitaxel) and found that a greater proportion of patients responded to Opdivo compared with chemotherapy (31.7% compared with 10.6%). A follow-up plan to monitor the safety and efficacy of Opdivo was agreed by the Committee for Medicinal Products for Human Use (CHMP).



The applicant received scientific advice on quality and clinical aspects of the application from the CHMP.

The opinion adopted by the CHMP at its April 2015 meeting is an intermediary step on Opdivo's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisation. Once a marketing authorisation has been granted, a decision about price and reimbursement will take place at the level of each Member State considering the potential role/use of this medicine in the context of the national health system of that country.

### **Notes**

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1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Opdivo is Bristol-Myers Squibb Pharma EEIG.
3. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

### **Contact our press officer**

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