



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

New treatment for advanced form of kidney cancer

Treatment of renal cell carcinoma to be added to Opdivo's approved uses

The European Medicines Agency (EMA) has recommended extending the use of Opdivo (nivolumab) to include the treatment of adult patients with advanced renal cell carcinoma (a type of kidney cancer) who have received prior therapy.

Opdivo was first authorised in the European Union (EU) in June 2015 for the treatment of advanced melanoma (a type of skin cancer) and already had its use extended (in October 2015) to treatment of the advanced stages of a type of lung cancer, squamous non-small cell lung cancer (NSCLC).

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 against cancer cells.

Renal cell carcinoma is the most common form of kidney cancer in adults. Advanced renal cell carcinoma includes both metastatic disease and locally advanced renal cell carcinoma that cannot be resected (removed by surgery). Patients with advanced renal cell carcinoma have a poor long-term prognosis therefore new medicines are urgently needed for patients.

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on the results of a randomised phase 3 study evaluating Opdivo versus another type of kidney cancer treatment called everolimus. 821 patients with locally advanced or metastatic renal cell carcinoma whose disease worsened during or after treatment with anti-angiogenic therapy were included in the study.

The median survival time after starting treatment in patients taking Opdivo was 25 months compared to just under 20 months in patients treated with everolimus.

In addition, about 22% of patients taking Opdivo saw a complete or partial shrinkage of their tumors compared to 4% of those taking everolimus; on average the effect lasted around 12 months for both groups.

The most common side effects of Opdivo reported during the clinical trial were similar to those observed in the already approved indications of Opdivo. These include fatigue, nausea, rash, diarrhoea and decreased appetite.



Another extension of indication was also approved by the CHMP this month, recommending use of Opdivo as a single agent (monotherapy) in locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC).

The opinions adopted by the CHMP at its February 2016 meeting are an intermediary step on Opdivo's path to patient access. The CHMP opinions will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisations. Once the extensions of indications have 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

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

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