22 May 2015
EMA/CHMP/329429/2015
Press Office

Press release

New treatment option for patients with advanced lung cancer

Recommendation of Nivolumab BMS follows previous positive opinion for nivolumab to treat advanced melanoma

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Nivolumab BMS (nivolumab). Nivolumab BMS can be used to treat adult patients with a type of lung cancer called squamous non-small cell lung cancer (NSCLC), when the disease is advanced, and has already been treated with chemotherapy. It is the first immunotherapy medicine recommended for approval for squamous NSCLC in the European Union (EU).

In April 2015, EMA recommended for approval another nivolumab-containing medicine, Opdivo, for the treatment of patients with advanced (unresectable or metastatic) melanoma.

Lung cancer is among the most common cancers in the world. Approximately 85% of all lung cancers are NSCLCs, which are frequently further subdivided into non-squamous and squamous cell carcinoma. Most patients with NSCLC are found to have advanced disease at the time of diagnosis, and patients are generally treated with chemotherapy and/or radiation. These treatments, however, rarely cure the disease and the disease often reoccurs or progresses. Although more medicines have become available in recent years for NSCLC, these do not generally help people with squamous NSCLC. The treatment options for patients with squamous NSCLC whose disease reoccurs or progresses despite chemotherapy are limited.

The active substance in Nivolumab BMS, nivolumab, is a monoclonal antibody. Nivolumab attaches to and blocks a receptor called 'programmed death-1' (PD-1). By blocking the usual receptor interactions, Nivolumab BMS leads to activation of the immune system against cancer cells.

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on one main randomised trial in patients with advanced squamous NSCLC who had previously failed treatment with chemotherapy. This phase III study randomly assigned 272 patients to receive either nivolumab or docetaxel (a commonly used type of chemotherapy). The study found that nivolumab improved overall survival compared with docetaxel (median 9.2 months compared with 6.0 months). After 12 months, 42% of patients treated with nivolumab were still alive compared with 24% of patients treated with docetaxel. Nivolumab BMS' recommendation is also supported by data from an

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

uncontrolled study involving 117 patients with squamous NSCLC who had at least two previous chemotherapy treatments and who were then treated with nivolumab. A follow-up plan to monitor the safety and efficacy of Nivolumab BMS was agreed by the CHMP.

The company received scientific advice from the CHMP on quality, non-clinical and clinical aspects of the application. This is one of the Agency's main tools to facilitate and stimulate research and development within the EU.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Nivolumab BMS is Bristol-Myers Squibb Pharma EEIG.
3. Opdivo (nivolumab) was recommended for approval as monotherapy for the treatment of adult patients with advanced (unresectable or metastatic) melanoma by the CHMP in April 2015. The applicant was Bristol-Myers Squibb Pharma EEIG. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/04/news_detail_002314.jsp&mid=WC0b01ac058004d5c1
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu