5 January 2016
EMA/6927/2016
EMEA/H/C/003840

Public statement

Nivolumab BMS

Withdrawal of the marketing authorisation in the European Union

On 30 November 2015, the European Commission withdrew the marketing authorisation for Nivolumab BMS (nivolumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Bristol-Myers Squibb Pharma EEIG, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Nivolumab BMS was granted marketing authorisation in the EU on 20 July 2015 for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults. The marketing authorisation was initially valid for a 5-year period.

Nivolumab BMS is identical to Opdivo, which is also authorised in the EU to treat squamous NSCLC as well as melanoma. The marketing authorisation holder has committed to ensure that patients who need treatment with Nivolumab BMS continue to receive it until complete exhaustion of stock. Patients with squamous NSCLC currently being treated with Nivolumab BMS will then be automatically switched to Opdivo.

The European Public Assessment Report (EPAR) for Nivolumab BMS will be updated accordingly to indicate that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact