Bristol-Myers Squibb Pharma EEIG

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Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

30 January 2020

Dear Dr. Enzmann,

Subject: Withdrawal of Worksharing Type II variation EMEA/H/C/XXXX/WS/1372 for OPDIVO (nivolumab) and YERVOY (ipilimumab)

I would like to inform you that, at this point in time, Bristol-Myers Squibb Pharma EEIG (BMS) has taken the decision to withdraw the Worksharing Type II variation to extend the currently approved indications for OPDIVO and YERVOY to include first-line treatment of adult patients with metastatic Non-Small Cell Lung Carcinoma (NSCLC), based on data from Part 1 of study CA209227.

This withdrawal is based on the CHMP consideration that the data from study CA209227 Part 1, provided in support of this Type II variation, do not allow the Committee to conclude on a positive benefit-risk balance in the proposed indication.

This withdrawal does not have any impact on ongoing clinical trials with nivolumab and ipilimumab.

We remain fully committed to the development of nivolumab and ipilimumab in NSCLC and across other multiple tumour types and reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

BMS would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

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