Bristol-Myers Squibb Pharma EEIG

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Dr. Tomas Salmonson
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

13 December 2017

Dear Dr. Salmonson,

Subject: Withdrawal of Type II variation EMEA/H/C/03985/II/0030 for nivolumab (OPDIVO)

I would like to inform you that, at this point of time, Bristol-Myers Squibb Pharma EEIG (BMS) has taken the decision to withdraw the application for a new indication for OPDIVO (nivolumab) for the treatment of adults with mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) metastatic colorectal cancer after prior fluoropyrimidine based therapy.

This withdrawal is based on the CHMP considerations that, despite the promising data shown for nivolumab in the target indication, uncertainties in the context of the non-comparative design of the pivotal study and the limited number of patients do not allow the Committee to conclude on a positive benefit-risk balance at the present time.

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

We remain fully committed to the development of nivolumab in dMMR or MSI-H colorectal cancer 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.

[redacted]

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