Bristol-Myers Squibb Pharma EEIG

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[redacted]
Chair of Committee for Medicinal
Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

20 July 2017

Dear Dr Salmonson,

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) in the treatment of hepatocellular carcinoma after prior sorafenib therapy in adults.

This withdrawal is based on the CHMP consideration 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 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 hepatocellular carcinoma 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.

Yours sincerely,

[redacted]