



Bristol-Myers Squibb Pharma EEIG

Official address:
Uxbridge Business Park, Sanderson Road
Uxbridge, Middlesex UB8 1DH
United Kingdom

Registered in England and Wales
No. GE000087

Dr Tomas Salmonson
Chair of Committee for Medicinal
Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

27 June 2018

Dear Dr Salmonson,

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 application for a new indication for OPDIVO (nivolumab) in the treatment of advanced or recurrent gastric or gastroesophageal junction cancer 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 extrapolation of data from an Asian population to the European population 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 gastric 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.