Merck Sharp & Dohme (Europe), Inc
Siège d'exploitation: 5, Clos du Lynx 1200 Bruxelles
Exploitatiezetel: Lynx Binnenhof 5, 1200 Brussels

MERCK SHARP & DOHME

Amsterdam, 10th December 2019

SUBJECT: Withdrawal of Type II variation EMEA/H/C/03820/II/0072 for KEYTRUDA (pembrolizumab)

Dear Dr Enzmann,

I would like to inform you that Merck Sharp & Dohme ("MSD"), the MAH for KEYTRUDA (pembrolizumab), has made the decision to withdraw its Type II variation application to extend the use of KEYTRUDA as monotherapy for the treatment of recurrent locally advanced or metastatic oesophageal cancer in adults whose tumours express PD-L1 with CPS ≥10 and who have received prior systemic therapy.

This withdrawal is based on the Phase 3 Study KEYNOTE-181 results that were deemed not sufficient to support an extension of indication at this time.

MSD reserves the right to make further submissions at a future date in this or other therapeutic indications.

This withdrawal does not have any impact on ongoing clinical trials with pembrolizumab as monotherapy or in combination with other agents.

MSD would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and 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.