11 October 2017

MSD
INVENTING FOR LIFE

[redacted]

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

SUBJECT: Withdrawal of Type II variation EMEA/H/C/03820/II/0027 for pembrolizumab (KEYTRUDA)

Dear Dr. Salmonson,

I would like to inform you that Merck Sharp & Dohme ("MSD") has made the decision to withdraw the application for a new indication for pembrolizumab (KEYTRUDA) in combination with chemotherapy for the first line treatment of patients with metastatic non squamous non-small cell lung cancer based on the results of the Phase 2 Study KEYNOTE-021.

This withdrawal is based on the CHMP consideration that uncertainties remain due to the limited number of patients in this randomized study, despite the robust clinically meaningful and statistically significant data shown for pembrolizumab in the targeted indication. MSD reserves the right to re-apply for the same indication at a future date.

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

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.

[redacted]