European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Basel, 8 January 2021

Subject: Withdrawal of Type II Variation EMEA/H/C/004143/II/0042 for Tecentriq (atezolizumab), 1200mg, solution for infusion

Dear Dr Enzmann,

I would like to inform you that, at this point of time, Roche Registration GmbH has taken the decision to withdraw the application for a new indication for Tecentriq (atezolizumab) in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic urothelial carcinoma.

This withdrawal is based on the reason that the CHMP considers that the IMvigor130 study data provided do not allow the committee to conclude on a positive benefit risk balance for the use of Tecentriq in the proposed indication stated above.

The study will continue as per protocol to the next analysis for overall survival.

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

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Roche Registration GmbH 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.

Yours sincerely,

On behalf of the Marketing Authorisation Holder, Roche Registration GmbH