Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Basel, 23 June 2021

Subject: Withdrawal of Type II Variation EMEA/H/C/004143/II/0052 for Tecentriq (atezolizumab), 840mg, 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, in combination with nab-paclitaxel and anthracycline-based chemotherapy, for the neoadjuvant treatment of adult patients with locally advanced or early Triple-Negative Breast Cancer.

This withdrawal is based on the reason that the CHMP considers that the IMpassion031 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.

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

Roche is committed to further advance the standard of care for patients with early TNBC and reserves 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.

[redacted]

Yours sincerely,

On behalf of the Marketing Authorisation Holder, Roche Registration GmbH