[redacted]

Basel, 6th September 2024

Subject: Withdrawal of Type II Variation EMEA/H/C/004143/II/0081 for Tecentriq (atezolizumab)

[redacted]

We would like to inform you that, at this point of time, Roche Registration GmbH has taken the decision to withdraw the Type II variation application to extend the use of Tecentriq (atezolizumab) in combination with bevacizumab for the adjuvant treatment of adult patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation.

This withdrawal is based on IMbrave050 updated study results that are not sufficient to support an extension of indication for the use of Tecentriq in combination with bevacizumab in the proposed indication stated above.

The withdrawal of this application only impacted studies using the doublet combination of Tecentriq and bevacizumab for the adjuvant treatment of HCC and appropriate measures have been taken. The IMbrave050 study results have no impact on all other ongoing clinical trials with atezolizumab as monotherapy or in combination with bevacizumab or 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.

We agree for this letter to be published on the EMA website.

Yours sincerely,

On behalf of the Marketing Authorization Holder, Roche Registration GmbH