



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

Basel, 4 July 2023

Subject: Withdrawal of Type II Variation **EMA/H/C/002799/II/0052** for Gazyvaro

Dear Dr Enzmann,

I would like to inform you that, at this point in time, Roche Registration GmbH has taken the decision to withdraw the application for a new indication for Gazyvaro as a pre-treatment (Gpt) to reduce the risk of cytokine release syndrome (CRS) induced by glofitamab.

This withdrawal is based on the reason that the CHMP considers that the submitted data, provided in support of this Type II variation, do not allow the Committee to conclude on a positive benefit/risk balance for the proposed indication.

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

Roche is committed to further advance the standard of care for patients 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.

Yours sincerely,

