



Date: 03 November 2022

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

Subject: Withdrawal of Type II variation EMEA/H/C/005413/II/0002/G for Gavreto, (Pralsetinib), 100 mg hard capsule.

Dear Dr Enzmann,

I would like to inform you that Roche Registration GmbH has taken the decision to withdraw the application to extend the use of Gavreto in RET-mutant medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancer (TC) in the second line setting.

This withdrawal is based on the following reason: a change in the Company's strategy. This is unrelated to product quality, efficacy or safety.

The withdrawal of this application has no impact on ongoing clinical trials. Further, this withdrawal does not impact the use of Gavreto in its approved indication (RET fusion-positive advanced non-small cell lung cancer).

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

Roche would like to sincerely thank the (Co-) Rapporteurs and EMA 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

A large black rectangular redaction box covering the signature area of the letter.