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Date: 05 March 2021

**Subject: Withdrawal Letter - Brilique (ticagrelor) Procedure EMEA/H/C/001241/II/0047/G**

**Type II variation (C.1.6a) application to update the product information with a new indication for Brilique based on the THEMIS study (D513BC00001).**

Dear Dr Enzmann,

I would like to inform you that, at this point in time, AstraZeneca has taken the decision to withdraw the type II variation C.1.6.a. for the addition of a new therapeutic indication based on the THEMIS study in the application procedure EMEA/H/C/001241/II/47/G.

The withdrawal of the new indication application is based on the CHMP requirement for further justification and data on the use of Brilique in the targeted population.

AstraZeneca reserves the right to make further submissions to CHMP at a future date for the proposed indication or other associated therapeutic indications.

This withdrawal does not have any impact on any ongoing clinical trials.

AstraZeneca 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 EMA website.

Yours sincerely,