AstraZeneca

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European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
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Date: 15 December 2021

Subject: Withdrawal Letter – BRILIQUE (ticagrelor), Procedure EMEA/H/C/001241/II/0049

Type II variation application to update the product information with a new indication for Brilique based on the THALES study (D5134C00003).

Dear Dr Enzmann,

I am writing to notify you that, AstraZeneca has decided to withdraw the type II variation C.1.6.a). for the addition of a new therapeutic indication based on the THALES study in the application procedure EMEA/H/C/001241/II/0049.

The withdrawal of the new indication application is based on the CHMP requirement that AstraZeneca provide further detailed analysis to justify 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.

AstraZeneca agrees that this letter may be published on EMA website.

Yours sincerely,

[redacted]