VANFLYTA

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
II/0002	To update section 4.5 and 5.2 of the SmPC in order to add information on interaction with Breast cancer resistant protein (BCRP) substrates based on results from study GE-2161 – Inhibitory Effects of Quizartinib on the Transport Activity of BCRP (REC). In addition, the MAH is taking this opportunity to introduce editorial changes to the PI.	23/05/2024		SmPC	SmPC new text: In vitro data indicate that quizartinib is an inhibitor of Breast cancer resistance protein (BCRP). The clinical relevance is currently not known. Caution should be used when quizartinib is co-administered with medicinal products that are substrates of BCRP. Quizartinib inhibits BCRP with an estimated in vitro IC50 of 0.813 µM. As no clinical data is available, it cannot be

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				excluded that quizartinib could inhibit this transporter at the recommended doses.