Lytgobi

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary	
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	18/09/2025		SmPC and PL	Section 4.5	Interaction with other medicinal

[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).

EMA/VR/0000282565	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.4, 4.5 and 5.2 of the SmPC in order to revise the drug-drug interaction information based on the final results of study TAS-120-110. This is a Phase 1, open-label, fixed-sequence study to assess the effect of futibatinib on P-gp and BCRP and the effect of P-gp inhibition by quinidine on the pharmacokinetics of futibatinib in healthy adult subjects. The Package Leaflet is updated accordingly.				products and other forms of interaction […] P-gp inhibitors Co-administration of multiple doses of 200 mg quinidine, a P-gp inhibitor, increased futibatinib Cmax by 8% and AUCinf by 17% following a single oral dose of 20 mg futibatinib. Therefore, co-administration of P-gp inhibitors is not likely to have a clinically relevant effect on futibatinib exposure. Proton pump inhibitors Futibatinib geometric mean ratios for Cmax and AUC were 108% and 105%, respectively, when co-administered in healthy subjects with lansoprazole (a proton pump inhibitor) relative to futibatinib alone. Therefore, co-administration of proton pump inhibitors is not likely to have a clinically relevant effect on futibatinib exposure. Effects of futibatinib on other medicinal products Effect of futibatinib on CYP3A substrate Midazolam (a CYP3A sensitive substrate) geometric mean ratios for Cmax and AUC were 95% and 91%, respectively, when co-administered in healthy subjects with futibatinib relative to midazolam alone. Therefore, co-administration of futibatinib is not likely to have a clinically relevant effect on the exposure of CYP3A substrates. Effect of futibatinib on P-gp substrates Digoxin (a sensitive P-gp substrate) geometric mean ratios for Cmax and AUCinf were 95% and 100%, respectively, when co-administered in healthy subjects with futibatinib relative to digoxin alone. Therefore, co-administration of futibatinib is not likely to have a clinically relevant effect on the exposure of P-gp substrates. Effect of futibatinib on BCRP substrates Rosuvastatin (a sensitive BCRP substrate)

					geometric mean ratios for Cmax and AUCinf were 110% and 113%, respectively, when co-administered in healthy subjects with futibatinib relative to rosuvastatin alone. Therefore, co-administration of futibatinib is not likely to have a clinically relevant effect on the exposure of BCRP substrates. Section 5.2 Pharmacokinetic properties […] Effect of futibatinib on drug transporters In vitro studies indicated that futibatinib didn't inhibit OAT1, OAT3, OCT2, OATP1B1, OATP1B3, MATE1 or MATE2K at clinically relevant concentrations. Futibatinib is a substrate of P-gp and BCRP in vitro. Inhibition of BCRP is not expected to result in clinically relevant changes in the exposure of futibatinib. Inhibition of P-gp did not result in a clinically relevant effect on futibatinib exposure in vivo (see section 4.5). For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000291638	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	29/08/2025	N/A		
Variation type IA / EMA/VR/0000290192	This was an application for a group of variations.	06/08/2025	N/A		

	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				