VITRAKVI

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 IB /	This was an application for a group of	04/08/2025		SmPC	

[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/0000286907	variations. B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted				
Variation type IA / EMA/VR/0000279777	B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.b Downscaling down to 10-fold - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.b Downscaling down to 10-fold - Accepted	27/06/2025	N/A		
Renewal - 1 year / EMA/R/0000257511	- Renewal - Renewal of conditional marketing authorisation	22/05/2025	18/07/2025	SmPC and Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for VITRAKVI, subject to the Specific Obligations and Conditions as laid

					down in Annex II to the opinion. Sections 4.8 and 5.1 of the SmPC are updated to reflect the new safety and efficacy data from SOB1. Section 5.2 of the SmPC was updated to include updated information in special population, including paediatric patients, the absence of clinically meaningful difference in larotrectinib exposure in patients > 65 years compared to those in younger patients, and absence of race on systemic exposure based on population pharmacokinetic analysis. RMP version 3.1 was approved.
Variation type IA / EMA/VR/0000248755	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	19/02/2025	N/A		
PSUR / EMA/PSUR/0000257875	- -				Maintenance