Retsevmo

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 IA /	B.II.d.2 Change in test procedure for the	18/11/2025	N/A		

[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/0000312896	finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted				
Renewal - 1 year / EMA/R/0000286890	- Renewal - Renewal of conditional marketing authorisation	16/10/2025	12/12/2025	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 Retsevmo, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. Section 5.1 of the SmPC have been revised to reflect the updated efficacy data available from LIBRETTO-001 study with data cut-off of 14 February 2025.
Variation type IA / EMA/VR/0000278785	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	08/09/2025	N/A		
Variation type II / EMA/VR/0000247142	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of	10/04/2025	12/12/2025	SmPC	Section 5.3 Long-term studies to assess the carcinogenic potential of selpercatinib have not been performed.In a 2-year carcinogenicity study of selpercatinib in rats, vaginal tumours were observed in some females at plasma exposure levels similar to levels observed in adult patients treated with the dose of 160 mg twice daily. No pre-neoplastic

	Regulation 1901/2006 - C.I.3.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted Update of section 5.3 of the SmPC in order to update information on carcinogenesis based on results from a non-clinical 2-year carcinogenicity study of selpercatinib in rats. The RMP version 14.2 has also been submitted.				changes were observed in the reproductive tract of female rats. The clinical relevance of these findings is unknown. Selpercatinib was not carcinogenic in male rats in this study. Selpercatinib was not carcinogenic in male and female mice in a 6-month study.
PSUR / EMA/PSUR/0000248503	- -		N/A		Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing selpercatinib remains unchanged and therefore recommends the maintenance of the marketing authorisation.