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_IN /	E.4 Change in the name and/or address of	05/02/2026	10/02/2026	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/0000315499	the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.a) The change in the name and/or address concerns the marketing authorisation holder - Accepted			Labelling and PL	
PSUR / EMA/PSUR/0000288253	In view of available data on Stevens-Johnson syndrome (SJS) from the literature, including a close temporal relationship in 1 case from literature , and a diagnosis based on clinical picture together with histopathological findings, the PRAC Rapporteur considers a causal relationship between selpercatinib and Stevens-Johnson syndrome is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing selpercatinib should be amended accordingly	11/12/2025	10/02/2026	SmPC and PL	Variation
Variation type IA / EMA/VR/0000312896	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	18/11/2025			

Renewal - 1 year / EMA/R/0000286890	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			
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 Regulation 1901/2006 - C.I.3.b Implementation of change(s) which require	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 changes were observed in the reproductive tract of female rats. The clinical relevance of these findings

	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.				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					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.