Verzenios

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 /		10/04/2026			

[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/0000325390	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.12 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies, including be to be d. bioequivalence studies, to the competent authority - Accepted Submission of the population pharmacokinetic study report based on studies I3Y-MC-JPCS and J1S-MC-JP04, listed as study 4 (Modelling and simulation study to evaluate the use of the product in the proposed paediatric indication in children from 1 year to less than 18 years of age (and adults) with Ewing's sarcoma) in the PIP, in order to complete the PIP (P/0037/2024).				
Variation type II / EMA/VR/0000307389	Outcome: C.I HUMAN AND VETERINARY MEDICINAL 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	29/01/2026	12/03/2026	SmPC, Annex II and PL	Section 5.1 Pharmacodynamic properties of the SmPC […] Clinical efficacy and safety Early breast cancer Randomised Phase 3 Study monarchE: Verzenios in combination with endocrine therapy […] A total of 5 637 patients were randomised in a 1:1 ratio to receive 2 years of Verzenios 150 mg twice daily plus physician's choice of standard endocrine therapy, or standard endocrine therapy alone. Randomization was stratified by prior chemotherapy, menopausal status, and region. Men were stratified as postmenopausal. Patients had

	Update of section 5.1 of the SmPC in order to update efficacy information based on final OS data from study monarchE (I3Y-MC-JPCF) listed as a PAES in the Annex II; this is a randomized, open-label, phase 3 study of abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone in patients with high risk, node positive, early stage, hormone receptor positive, human epidermal receptor 2 negative, breast cancer. The Annex II and Package Leaflet are updated accordingly. The RMP version 2.1 has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes and to update the list of local representatives in the Package Leaflet.				completed definitive locoregional therapy (with or without neoadjuvant or adjuvant chemotherapy). Patients must have recovered from the acute side effects of any prior chemotherapy or radiotherapy. A washout period of 21 days after chemotherapy and 14 days after radiotherapy prior to randomization was required. Patients were allowed to receive up to 12 weeks of adjuvant endocrine therapy prior to randomisation following the last non-endocrine therapy (surgery, chemotherapy or radiation). […] The primary objective of the study was met at the pre planned interim analysis (16 Mar 2020 cut off). A statistically significant improvement in IDFS was observed in patients who received Verzenios plus endocrine therapy versus endocrine therapy alone in the ITT population. At the time of the subsequent final overall survival (OS) analysis (15 July 2025 cut-off) a statistically significant improvement in OS was also observed in patients who received Verzenios plus endocrine therapy versus endocrine therapy alone in the ITT population. The approval was granted for the large subpopulation, Cohort 1. At the final OS analysis all patients in Cohort 1 were off the 2 year study treatment period and the median duration of follow up was 76 months (6.3 years). For more information, please refer to the Summary of Product Characteristics.
Variation type IA_IN / EMA/VR/0000315519		27/01/2026	12/03/2026	SmPC, Labelling and PL	

	Outcome: A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted				
Variation type II / EMA/VR/0000282650	Outcome: C.I HUMAN AND VETERINARY MEDICINAL 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 section 5.1 of the SmPC based on the final results from study J1S-MC-JP04, a PIP study and submitted in accordance with Article 46 of Regulation (EC) No 1901/2006; study J1S-MC-JP04is a randomized, open-label, phase 2 study evaluating abemaciclib in combination with irinotecan and temozolomide in participants with relapsed or refractory Ewing's sarcoma.	18/09/2025	12/03/2026	SmPC	SmPC 5.1 Pharmacodynamic properties Paediatric population The European Medicines Agency has waived the obligation to submit the results of studies with Verzenios in all subsets of the paediatric population in breast cancer (see section 4.2 for information on paediatric use). The efficacy and safety of Verzenios in combination with irinotecan and temozolomide was evaluated in Study J1S-MC-JP04, a multicentre, randomised, open-label, phase 2 study in participants with relapsed or refractory Ewing sarcoma. The primary endpoint was progression-free survival (PFS) assessed by a blinded independent review committee. 46 participants, 3 to 35 years of age, were randomised to receive Verzenios plus irinotecan and temozolomide or irinotecan and temozolomide in a 2:1 ratio. 58.7 % of patients (27 patients) were < 18 years of age. 45 participants were treated in 21-day cycles until disease progression or having met other discontinuation criteria. No difference in PFS was observed with the addition of Verzenios. The median PFS was 2.8 months in patients treated with Verzenios in combination irinotecan and temozolomide and 2.9 months in patients treated with irinotecan and temozolomide (HR 0.64 [95% CI: 0.28, 1.45]). For more information, please refer to the Summary of

					Product Characteristics.
Variation type IA / EMA/VR/0000295409	Outcome: A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	08/09/2025			
Variation type IB / EMA/VR/0000248638	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z (IB) - To update ANNEX IID to amend the due of the monarchE study from	07/03/2025	12/03/2026	Annex II	

	June 2025 to June 2026.				