Lumykras

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IAIN/0006	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	22/11/2022	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).

II/0004	Update of section 4.5 of the SmPC based on the results of Study 2020042, a phase 1 clinical drug interaction study undertaken to assess the effect of concomitant sotorasib administration on the systemic exposure of breast cancer resistance protein (BCRP) transporter substrates. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/09/2022		SmPC and PL	Further to the results of study 20200426, it is concluded that Lumykras is a weak BCRP inhibitor. Co-administration of Lumykras with a BCRP substrate led to an increase in the plasma concentrations of the BCRP substrate, which may increase the effect of the substrate. Co-administration of Lumykras with rosuvastatin (a BCRP substrate) increased the rosuvastatin Cmax by 70% and AUC by 34%. When Lumykras is co-administered with a BCRP substrate, including but not limited to lapatinib, methotrexate, mitoxantrone, rosuvastatin and topotecan, patients should be monitored for adverse reactions of the BCRP substrate and reduce the BCRP substrate dose in accordance with its current summary of product characteristics. For more information, please refer to the Summary of Product Characteristics.
II/0003	Update of section 4.2 of the SmPC based on results from the enteral feeding tube in vitro study (RPT-574024), undertaken to assess the feasibility of administration of sotorasib 120 mg film-coated tablets through an enteral feeding tube. The Package Leaflet was updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/09/2022		SmPC and PL	The SmPC section 4.2 has been updated as follows: In patients who have difficulty swallowing solids and if administration through a nasogastric (NG) tube or percutaneous endoscopic gastrostomy (PEG) tube is required, patients should disperse the 120 mg tablets. The dispersed suspension and rinse should be administered as per the NG or PEG tube manufacturer's instructions with appropriate water flushes within 2 hours of preparation, stored at room temperature. The PL has been updated accordingly
IA/0001	B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation	16/03/2022	n/a		