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Swiss Summary of the Risk Management Plan (RMP) for Lumykras® (Sotorasib)

RMP Summary: Version 2, January 2023
EU RMP: Version 1.0, 15. November 2022

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Lumykras® is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Lumykras® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

AMGEN Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Lumykras®.

The medicine and what it is used for

Lumykras is authorized as monotherapy for the treatment of adult patients with previously treated Kirsten rat sarcoma viral oncogene homolog *(KRAS) G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)] (see SmPC for the full indication). It contains sotorasib as the active substance and it is given orally.

Further information about the evaluation of Lumykras's benefits can be found in Lumykras's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Lumykras, together with measures to minimize such risks and the proposed studies for learning more about Lumykras's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (eg, with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed including periodic safety update report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Lumykras is not yet available, it is listed under 'missing information' below.

List of Important Risks and Missing Information

Important risks of Lumykras are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Lumykras. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

Summary of safety concerns

List of important risks and missing information

Important Identified Risk	None
Important Potential Risk	None
Missing Information	None

Summary of Important risks

There are no important identified risks, important potential risks, or missing information for Lumykras®

Post-authorisation development plan

Studies which are a condition of the marketing authorisation

The following studies are conditions of the marketing authorization.

Study Short Name	Purpose of the Study
Study 20190009 A phase 3, multicenter, randomized, open-label, active-controlled study of AMG 510 versus docetaxel for the treatment of previously treated locally advanced and unresectable or metastatic NSCLC subjects with mutated KRAS p.G12C	Primary Objectives: • To compare the efficacy of AMG 510 versus docetaxel as assessed by progression-free survival (PFS) in previously treated subjects with KRAS p.G12C mutated non-small cell lung cancer (NSCLC) Key Secondary Objectives: • To compare the efficacy of AMG 510 versus docetaxel as assessed by: − Overall Survival (OS) − Objective response rate (ORR) • To compare patient reported outcomes (PRO) as assessed by: − European Organization for Research and Treatment of Cancer Quality-of-life Questionnaire Core 13 (EORTC QLQ-LC13) − European Organization for Research and Treatment of Cancer Quality-of-life Questionnaire Core 30 (EORTC QLQ-C30)

Other studies in Postauthorization Development Plan

Not applicable.

Summary of Changes to the Risk Management Plan Over Time

Version	Date of RMP Approval Date Procedure	Change
0.1	Date of RMP: 04 December 2020 Procedure: EMEA/H/C/005522/0000	Not applicable
0.2	Date of RMP: 25 June 2021 Submitted Within Procedure: EMEA/H/C/005522/0000	**Safety Concerns** No changes Pharmacovigilance Plan Updated the milestone date for Study 20200362 **Postauthorization Efficacy Plan** No change **Risk Minimization Measures** No change **Annexes** • Annex 2 (Tabulated Summary of Planned, Ongoing, and Completed Pharmacovigilance Study Program): Updated the milestone date for Study 20200362 • Annex 3 (Protocols for Proposed, Ongoing, and Completed Studies in the Pharmacovigilance Plan): Added the protocol for Study 20200362 • Annex 5 (Protocols for Proposed and Ongoing Studies in RMP Part IV): Added the updated protocol for Study 20190009 **Other changes** • Updated the relevance to human usage part of the key findings from nonclinical studies • Added a brief summary of the clinical trial program in relation to the clinical trial exposure data included in the RMP
0.3	Date of RMP: 28 September 2021 Approval Date: 11 November 2021 Submitted Within Procedure: EMEA/H/C/005522/0000	**Safety Concerns** No changes **Pharmacovigilance Plan** No changes **Postauthorization Efficacy Plan** Updated the milestone due date for Study 20190009 Clinical Study Report primary analysis **Risk Minimization Measures** Added reference to the Package Leaflet (PL) to Section V.1 (Routine Risk Minimization Measures) and Section V.3 (Summary of Risk Minimization Measures) for the safety concern of 'Use in patients with hepatic impairment'. **Annexes** No change
1.0	Date of RMP: 15 November 2022 Approval Date: To be determined Submitted Within Procedure:	**Safety Concerns** The following safety concern was removed as missing information: • Use in patients with hepatic impairment **Pharmacovigilance Plan** The following additional pharmacovigilance activity was removed as study was completed: • Study 20200362 **Postauthorization Efficacy Plan** No change

Version	Date of RMP Approval Date Procedure	Change
		<u>Risk Minimization Measures</u> The following additional risk minimization measure was removed as study was completed: • Study 20200362 **<u>Annexes</u>** • Annex 2: Removed Category 3 PASS Study 20200362 from the tabulated summary of planned and ongoing studies in the pharmacovigilance study program and added it to the tabulation of completed studies in the pharmacovigilance study program • Annex 5: Updated protocol amendment for Study 20190009 added

This summary was generated in January 2023