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Swiss Summary of the Risk Management Plan (RMP) for IMDYLLTRA® (TARLATAMAB)
Version: 1.0

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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 minimize them.

The RMP summary of IMDYLLTRA® 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 IMDYLLTRA® 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 IMDYLLTRA®.

Summary of Risk Management Plan for IMDYLLTRA® (tarlatamab)

This is a summary of the risk management plan (RMP) for tarlatamab. The RMP details important risks of IMDYLLTRA, how these risks can be minimized, and how more information will be obtained about IMDYLLTRA's risks and uncertainties (missing information).

IMDYLLTRA's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how IMDYLLTRA should be used.

This summary of the RMP for IMDYLLTRA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of IMDYLLTRA's RMP.

I. The Medicine and What it is Used for

IMDYLLTRA is authorized as monotherapy for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC), who require systemic therapy following disease progression on or after first-line treatment with platinum-based chemotherapy (see SmPC for the full indication). It contains tarlatamab as the active substance and it is given intravenously.

Further information about the evaluation of IMDYLLTRA's benefits can be found in IMDYLLTRA's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/imdylltra#overview

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

Important risks of IMDYLLTRA, together with measures to minimize such risks and the proposed studies for learning more about IMDYLLTRA'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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions 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.

II.A. List of Important Risks and Missing Information

Important risks of IMDYLLTRA are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. 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 IMDYLLTRA. 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).

List of important risks and missing information	
Important identified risks	• Cytokine Release Syndrome (CRS) • Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)
Important potential risks	• None
Missing information	• Long-term Safety Data

II.B. Summary of Important Risks

Important identified risk: Cytokine Release Syndrome (CRS)	
Evidence for linking the risk to the medicine	This risk was identified based on the data from tarlatamab clinical studies.
Risk factors and risk groups	In the tarlatamab monotherapy studies, the greatest risk of developing cytokine release syndrome was predominantly in cycle 1 (day 1 and day 8) of tarlatamab treatment.
Risk minimization measures	Routine risk minimization measures: • SmPC Section 4.2 where the following recommendations are provided: – IMDYLLTRA treatment should be initiated under the direction of and supervised by physicians experienced in the use of cancer therapy. – Patients should be premedicated with IV dexamethasone 8 mg (or equivalent) within 1 hour prior to the first 2 doses (day 1 and day 8) and 1 liter of IV sodium chloride 9 mg/mL (0.9%) solution for injection should be administered immediately after completion of IMDYLLTRA infusion (day 1 and day 8). – Step-dosing with the recommended dosing schedule of IMDYLLTRA (initial dose of 1 mg on day 1, followed by 10 mg on days 8 and 15, and every 2 weeks thereafter). – Patients should be monitored from the start of the infusion for 6 to 8 hours on day 1 and day 8. Additional monitoring and monitoring on subsequent infusions is at the discretion of the physician. On day 1 and day 8, patients should be instructed to remain within proximity of an appropriate healthcare facility for 24 hours starting from each IMDYLLTRA infusion, accompanied by a caregiver. – Patients and caregivers should be informed on the signs and symptoms of CRS prior to discharge. – Guidelines for grading, dosage modifications, and management of CRS.

Important identified risk: Cytokine Release Syndrome (CRS) (continued)	
Risk minimization measures (continued)	Routine risk minimization measures (continued) • SmPC Section 4.4 where the following recommendations are provided: – IMDYLLTRA should be administered in a healthcare facility equipped to monitor and manage CRS. It should be ensured that patients are euvolemic prior to initiating the infusions – Patients should be closely monitored for signs and symptoms of CRS during the initiation of IMDYLLTRA treatment and should be managed according to the recommendations in the SmPC Section 4.2. – Patients and caregivers should be advised of the potential for CRS onset after discharge and instructed to seek immediate medical attention if any signs or symptoms occur. – To mitigate the risk of CRS, it is important to initiate IMDYLLTRA at the recommended starting dose. • SmPC Section 4.8 • PL Section 2 • PL Section 3 • PL Section 4 • Restricted medical prescription Additional risk minimization measures: • Patient Card

Important identified risk: Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)	
Evidence for linking the risk to the medicine	This risk was identified based on the data from tarlatamab clinical studies.
Risk factors and risk groups	Patients with pre-existing neurologic and medical comorbidities, high disease burden, increased intensity of lymphodepleting therapy and cytopenias, and severe cytokine release syndrome with high levels of inflammatory cytokines may be at higher risk of developing neurologic events.
Risk minimization measures	Routine risk minimization measures • SmPC Section 4.2 where the following recommendations are provided: – Patients should be monitored from the start of the infusion and for 6 to 8 hours on day 1 and day 8. Additional monitoring and monitoring on subsequent infusions is at the discretion of the healthcare provider. On day 1 and day 8, patients should be instructed to remain within proximity of an appropriate healthcare facility for 24 hours starting from each IMDYLLTRA infusion, accompanied by a caregiver. – Patients and caregivers should be informed on the signs and symptoms of ICANS prior to discharge. – Guidelines for grading, dosage modifications, and management of ICANS. • SmPC Section 4.4 where the following recommendation is provided: – Patients should be closely monitored for signs and symptoms of ICANS during IMDYLLTRA treatment. • SmPC Section 4.7 where the following recommendation is provided: – In the event of any neurological symptoms, patients should be advised to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, until they resolve. • SmPC Section 4.8 • PL Section 2 • PL Section 3 • PL Section 4 • Restricted medical prescription Additional risk minimization measures: • Patient Card
Missing information: Long-term Safety Data	
Risk minimization measures	Routine risk minimization measures: • Restricted medical prescription Additional risk minimization measures: • None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: • Integrated Safety Analysis

II.C. Postauthorization Development Plan

II.C.1. Studies Which Are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of IMDYLLTRA.

II.C.2. Other Studies in Postauthorization Development Plan

Study Short Name	Purpose of the Study
Integrated Safety Analysis[a] Category 3	To evaluate the long-term safety of tarlatamab for 3 years, Safety concerns addressed: • Long-term safety data

[a] List of clinical studies from which available safety data will be drawn for the integrated safety analysis is included in Annex 3 of the EU RMP.