AZ Swiss Marketing Company

Imjudo®

20 mg/ml, Concentrate for solution for infusion

Summary of the Risk Management Plan (RMP) for Imjudo® (Tremelimumab)

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AstraZeneca	**AZ Swiss Marketing Company**

Disclaimer:

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 Imjudo® 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 Imjudo® in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. AstraZeneca AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Imjudo®.

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

IMJUDO's Summary of Information for Healthcare Professionals gives essential information to healthcare professionals on how IMJUDO should be used.

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

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

1. THE MEDICINE AND WHAT IT IS USED FOR

IMJUDO is authorised in the following indication:

- IMJUDO in combination with durvalumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC), who have not received prior systemic therapy (see “Clinical efficacy”).

It contains tremelimumab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of IMJUDO’s benefits can be found in IMJUDO’s SwissPAR, including in its plain-language summary, available on the Swissmedic website.

2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of IMJUDO, together with measures to minimise such risks and the proposed studies for learning more about IMJUDO’s risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the Information for Healthcare Providers addressed to healthcare professionals
- Important advice on the medicine’s packaging
- The authorised 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 patient (eg, with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of IMJUDO, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute routine *pharmacovigilance activities*.

2.1 List of important risks and missing information

Important risks of IMJUDO are risks that need special risk management activities to further investigate or minimise 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 IMJUDO. 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).

Table 1 List of Important Risks and Missing Information

Important identified risks	• Immune-mediated adverse reactions
Important potential risks	• Cerebrovascular accident (CVA)
Missing Information	None

2.2 Summary of important risks

A summary of the important identified risk of immune-mediated adverse reactions is provided in Table 2 and a summary of the important potential risk of cerebrovascular accident is provided in Table 3.

Table 2 Important Identified Risk: Immune-mediated Adverse Reactions

Evidence for linking the risk to the medicine	The development of immune-mediated adverse reactions is consistent with the anti-CTLA-4 drug class. In IMJUDO clinical trials, double check-point inhibition with IMJUDO plus durvalumab (a PD-L1 inhibitor) exhibited a higher overall toxicity in relation to immune-mediated adverse reactions in the target patient population versus durvalumab alone.
Risk factors and risk groups	Risk factors specific for immune-mediated adverse reactions associated with CTLA-4 inhibition are unknown. It is conceivable that any pre-existing immune conditions in any organ system could be risk factors for IMJUDO immune-mediated adverse reactions.

Table 2 Important Identified Risk: Immune-mediated Adverse Reactions

Risk minimisation measures	**Routine risk minimisation measures:** • Information for Healthcare Professionals, Sections “Undesirable Effects” and “Dosage / Administration” • Prescription-only medicine **Additional risk minimisation measures:** • Patient card

Table 3 Important Potential Risk: Cerebrovascular Accident (CVA)

Evidence for linking the risk to the medicine	CVA was added at the request of Swissmedic.
Risk factors and risk groups	No specific risks factors have been identified for patients treated with tremelimumab in combination durvalumab. However, the combination with tremelimumab, durvalumab and standard of care platinum-based chemotherapy could be a risk factor for CVA.
Risk minimisation measures	**Routine risk minimisation measures:** • Information for Healthcare Professionals, Sections “Warning and Precautions” • Prescription-only medicine

3. POST-AUTHORISATION DEVELOPMENT PLAN

3.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of IMJUDO.

3.2 Other studies in post-authorisation development plan

There are no studies required for IMJUDO.