Imfinzi®

50 mg/ml, Concentrate for solution for infusion

Summary of the Risk Management Plan (RMP) for Imfinzi® (durvalumab)

Document Version: 5.0

Document Date: 13 January 2025

Based on EU RMP version 12.1, 20 June 2024 (Data lock point 15 January 2024)

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 Imfinzi® 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 Imfinzi® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.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 Imfinzi®.

1. THE MEDICINE AND WHAT IT IS USED FOR

IMFINZI is authorised

- As monotherapy for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adult patients whose disease has not progressed following platinum-based chemoradiation therapy (CRT).
- In combination with etoposide and either carboplatin or cisplatin for the first line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- In combination with gemcitabine and cisplatin for the first line treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- In combination with platinum-based chemotherapy as neoadjuvant treatment, followed by as monotherapy after surgery, for the treatment of adult patients with resectable (tumours ≥ 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
- As monotherapy for the treatment of adult patients with inoperable limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

IMFINZI contains durvalumab as the active substance and is administered as an intravenous infusion.

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

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

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and product information addressed to patients and healthcare professionals
- Important advice on the medicine's packaging
- The authorised pack size — the amount of medicine in a pack is chosen 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report

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 IMFINZI 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 IMFINZI. 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).

There are no safety concerns for IMFINZI.

2.2 Summary of important risks

There are no safety concerns for IMFINZI.

3. POST-AUTHORISATION DEVELOPMENT PLAN

3.1 Studies that are conditions of the marketing authorisation

The following study is a condition of the marketing authorisation:

- **Study D9311C00001 (DUO-E) - A study to assess the efficacy and safety of IMFINZI in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance IMFINZI with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer**
    - *Purpose of the study*: To investigate the efficacy of IMFINZI in combination with standard-of-care platinum-based chemotherapy (carboplatin and paclitaxel) followed by IMFINZI with or without olaparib, compared to standard-of-care platinum-based chemotherapy, by the assessment of progression-free survival in

patients with newly diagnosed advanced or recurrent endometrial cancer.

3.2 Other studies in post-authorisation development plan

There are no studies required for IMFINZI.