Summary of risk management plan for IMFINZI™ (durvalumab)

This is a summary of the Risk Management Plan (RMP) for IMFINZI (durvalumab). The RMP details important risks of IMFINZI, how these risks can be minimised, and how more information will be obtained about IMFINZI's risks and uncertainties (missing information).

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

This summary of the RMP for IMFINZI 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 IMFINZI's RMP.

I. 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 adults whose tumours express programmed cell death ligand 1 (PD-L1) on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy.
- In combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer.
- In combination with gemcitabine and cisplatin for the first-line treatment of adults with unresectable or metastatic biliary tract cancer.
- In combination with tremelimumab and platinum-based chemotherapy for the first-line treatment of adults with metastatic NSCLC with no sensitising epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) positive mutations.
- In combination with tremelimumab for the first-line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC).

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

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

II. 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*.

II.A 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.

II.B Summary of Important Risks

There are no safety concerns for IMFINZI.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation for IMFINZI.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for IMFINZI.