Summary of risk management plan for Erlotinib STADA (Erlotinib)

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

Erlotinib STADA's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Erlotinib STADA should be used.

I. The medicine and what it is used for

Erlotinib STADA is authorised for the treatment of Non-Small Cell Lung Cancer (NSCLC):

- Erlotinib STADA is indicated for the first-line treatment of patients with locally advanced or metastatic non- small cell lung cancer (NSCLC) with EGFR activating mutations.
- Erlotinib STADA is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first- line chemotherapy.
- Erlotinib STADA is also indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

It is also authorised for the treatment of Pancreatic cancer:

- Erlotinib STADA in combination with gemcitabine is indicated for the treatment of patients with metastatic pancreatic cancer.

See SmPC for the full indication. It contains erlotinib as the active substance and it is given orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Erlotinib STADA, together with measures to minimise such risks and the proposed studies for learning more about Erlotinib STADA'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 package leaflet and SmPC 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 so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Erlotinib STADA are risks that need special risk management activities to further investigate or minimise 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 Erlotinib STADA. 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 (e.g. on the long-term use of the medicine);

There were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

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

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Erlotinib STADA.