PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ERLOTINIB (TARCEVA)

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

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

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Tarceva is authorized for first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations, for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy and also in patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. In patients with tumors without EGFR activating mutations, erlotinib is indicated when other treatment options are not considered suitable. Tarceva is also authorized in combination with gemcitabine 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 by oral administration.

Further information about the evaluation of Tarceva's benefits can be found in Tarceva's EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERISE THE RISKS

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

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

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, 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 Tarceva are risks that need special risk management activities to further investigate or minimize 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 Tarceva. 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 Tarceva.

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

There are no studies required for Tarceva.