## PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

### Summary of risk management plan for Gefitinib Mylan

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

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

This summary of the RMP for Gefitinib Mylan 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 European Public Assessment Report (EPAR).

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

### I. The medicine and what it is used for

Gefitinib Mylan is authorised for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK. It contains gefitinib as the active substance and it is given by oral route of administration.

Further information about the evaluation of Gefitinib Mylan benefits can be found in Gefitinib Mylan EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Gefitinib Mylan, together with measures to minimise such risks and the proposed studies for learning more about Gefitinib Mylan 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 public (e.g. with or without prescription) can help to minimises its risks.

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

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Gefitinib Mylan is not yet available, it is listed under 'missing information' below.

In the case of Gefitinib Mylan, the routine measures described above are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

**II.A List of important risks and missing information**

Important risks of Gefitinib Mylan are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely taken by patients. 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 Gefitinib Mylan. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.);

*Table 1 Part VI: Summary of safety concerns*

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | • Interstitial lung disease<br>• Hepatitis<br>• Gastrointestinal perforation<br>• Drug-drug interactions: interactions with inducers and inhibitors of CYP3A4 isoenzyme; interactions mediated by CYP2D6 isoenzyme; interactions with medicines that cause significant sustained elevations of gastric pH. |

| **List of important risks and missing information** | |
|---|---|
| Important potential risks | • Haemorrhage events (including Gastrointestinal haemorrhage and tumour haemorrhage)<br>• Cerebrovascular events<br>• Drug interactions: interactions with oral anticoagulants |
| Missing information | • Use in pregnant or lactating woman<br>• Use in patients with severe renal impairment |

## II.B Summary of important risks

The safety information in the proposed Product Information for procedure EMEA/H/C/004826 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 Gefitinib Mylan.

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

There are no studies required for Gefitinib Mylan.