VYLOY™ (ZOLBETUXIMAB)

Public Risk Management Plan (RMP) Summary

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 Vyloy 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 Vyloy in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Astellas Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Vyloy.

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PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

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Summary of risk management plan for zolbetuximab

This is a summary of the risk management plan (RMP) for zolbetuximab. The RMP details important risks of zolbetuximab, and how these risks can be minimized.

Zolbetuximab's summary of product characteristics (SmPC) and its Patient Information Leaflet (PIL) give essential information to healthcare professionals and patients on how zolbetuximab should be used.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Zolbetuximab in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are CLDN18.2 positive. It contains genetically engineered, highly purified chimeric (mouse/human IgG1) antibody as the active substance and it is given by intravenous infusion over a minimum of 2 hours every 3 weeks at starting dose of 800 mg/m^2 administered on day 1 of the first cycle, followed by a subsequent dose of 600 mg/m^2 every 3 weeks or 400 mg/m^2 every 2 weeks.

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

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

Important risks of zolbetuximab, together with measures to minimize such risks and the proposed studies for learning more about zolbetuximab'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 EU-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 a prescription) can help to minimize its risks.

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

II.A List of important risks and missing information

Important risks of zolbetuximab are risks that need special risk management activities to further investigate or minimize 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 zolbetuximab. 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).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Not Applicable

II.C Postauthorization development plan

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

There are no studies that are conditions of the marketing authorization or specific obligation of zolbetuximab.

II.C.2 Other studies in postauthorization development plan

There are no studies required for zolbetuximab.