PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

ZIRABEV (bevacizumab)

Marketing Authorization Number 67501

Concentrate for solution for infusion, 100 mg/4 ml and 400 mg/16 ml

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LIST OF ABBREVIATIONS

EMA	European Medicines Agency
EPAR	European Public Assessment Reports
PL	Package Leaflet
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics (Europe)

OVERVIEW

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

SUMMARY OF RISK MANAGEMENT PLAN FOR ZIRABEV (BEVACIZUMAB)

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

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

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

I. The Medicine and What It Is Used For

Zirabev has been developed as a biosimilar to Avastin (bevacizumab) and is authorised for the treatment of metastatic colorectal cancer, metastatic breast cancer, advanced, metastatic or recurrent non-small cell lung cancer, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube and primary peritoneal cancer, and cervical cancer (see SmPC for the full indication). It contains bevacizumab as the active substance and it is administered intravenously.

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

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Zirabev, together with measures to minimise such 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.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR 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 Zirabev 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 Zirabev. 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).

Table 1. List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B. Summary of Important Risks and Missing Information

Since there are no safety concerns identified in the summary of safety concerns, no summary of routine risk minimisation measures is applicable.

II.C. Post-Authorisation Development Plan

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