SUMMARY OF RISK MANAGEMENT PLAN FOR ONBEVZI

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

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

This summary of the RMP for Onbevzi 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 Onbevzi RMP.

I. The medicine and what it is used for

Onbevzi is proposed for metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer (NSCLC), advanced and/or metastatic renal cell cancer, advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, and persistent, recurrent, or metastatic carcinoma of the cervix (see EU SmPC for the full indication).

It contains bevacizumab as the active substance and it is given as 25 mg/ml concentrate for solution for infusion.

Further information about the evaluation of Onbevzi’s benefits can be found in Onbevzi’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/onbevzi

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

Important risks of Onbevzi, together with measures to minimise such risks and the proposed studies for learning more about Onbevzi'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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR (periodic safety update report) assessment - 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 Onbevzi is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Onbevzi 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 Onbevzi. 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

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

II.C Post-authorisation development plan

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

There are no studies that are conditions of the marketing authorisation or specific obligations of Onbevzi.

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

There are no studies required for Onbevzi.