# Part VI: Summary of the risk management plan

Summary of risk management plan for Ganciclovir Oresund Pharma

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

Ganciclovir Oresund Pharma's summary of product characteristics (SmPC) and its leaflet provide essential information to healthcare professionals and patients on how Ganciclovir Oresund Pharma should be used.

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

Ganciclovir Oresund Pharma is authorized in adults and adolescents from 12 years of age for the treatment of Cytomegalovirus (CMV) disease in immunocompromised patients and prevention of CMV disease in patients with drug-induced immunosuppression (for example following organ transplantation or cancer chemotherapy). (see SmPC for the full indication). The product contains Ganciclovir as the active substance and its pharmaceutical form is powder for concentrate for solution for infusion (powder for concentrate).

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

Important risks of Ganciclovir Oresund Pharma, together with measures to minimise such risks and the proposed studies for learning more about Ganciclovir Oresund Pharma's risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC addressed to 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 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 assessment so that immediate action can be taken, as necessary. These measures constitute *routine pharmacovigilance activities.*

If information that may affect the safe use of Ganciclovir Oresund Pharma is not yet available, it is listed under 'missing information' below.

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

Important risks of Ganciclovir Oresund Pharma 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 Ganciclovir Oresund Pharma. 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 product, as applicable).

There were no safety concerns applicable for this EU RMP on the requirement to present only important identified or potential risks and missing information linked to further PV 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 being conditions of the marketing authorisation or specific obligation of Ganciclovir Oresund Pharma.

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

There are no studies required for Ganciclovir Oresund Pharma.