Swiss Summary of the Risk Management Plan (RMP) for Maribavir (LIVTENCITY®)

Version 1.0, 18-Aug-2023
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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 LIVTENCITY 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 LIVTENCITY in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of LIVTENCITY.

Summary of risk management plan for LIVTENCITY (Maribavir)

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

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

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

I. The medicine and what it is used for

LIVTENCITY is indicated for the treatment of cytomegalovirus (CMV) infection and/or disease that is refractory (with or without resistance) to one or more prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adult patients who have undergone a haematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT).

Further information about the evaluation of LIVTENCITY's benefits can be found in LIVTENCITY'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/livtencity

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

Important risks of LIVTENCITY, together with measures to minimise such risks and the proposed studies for learning more about LIVTENCITY'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 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 LIVTENCITY is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of LIVTENCITY are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 LIVTENCITY. 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	• Increased risk of serious adverse reactions due to an increase in immunosuppressant drug level
Missing information	• Use in patients with end stage renal disease (ESRD) including peritoneal dialysis or haemodialysis

II.B Summary of important risks and missing information

Important Potential Risk: Increased risk of serious adverse reactions due to an increase in immunosuppressant drug level	
Evidence for linking the risk to the medicine	Clinical Study Reports.
Risk factors and risk groups	It is likely that this phenomenon is dose dependent, and patients on the highest doses of maribavir are at highest risk for drug interactions when maribavir is administered concomitantly with the immunosuppressant drug.
Risk minimization measures	**Routine risk minimisation measures:** SmPC Section 4.4, Section 4.5, Section 4.8 and PL Section 2. The prescribers are informed of the potential for increased immunosuppressant drug levels (tacrolimus, sirolimus, everolimus, cyclosporine) while on maribavir therapy. The prescribers are advised to frequently monitor these immunosuppressant drug levels throughout LIVTENCITY treatment, especially following initiation and after discontinuation of LIVTENCITY and adjust the immunosuppressant dose, as required. **Additional risk minimisation measures:** None.
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None.

Missing Information: Use in patients with end stage renal disease (ESRD) including peritoneal dialysis or haemodialysis	
Risk minimization measures	**Routine risk minimisation measures:** SmPC Section 4.2.

Missing Information: Use in patients with end stage renal disease (ESRD) including peritoneal dialysis or haemodialysis	
	Additional risk minimisation measures: None.
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None.

II.C. Post-authorisation development plan

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

Not applicable.

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

Not applicable.