GlaxoSmithKline AG

Swiss Summary of the Risk Management Plan (RMP)
for

XEVUDY
(Sotrovimab)

RMP Summary: Version 1, February 2022
EU RMP: Version 1.0, 10. December 2021

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 minimize them.

The RMP summary of Xevudy 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 Xevudy in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Xevudy.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Xevudy (Sotrovimab)

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

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

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

I. The medicine and what it is used for

Xevudy is authorized for the treatment of patients with coronavirus disease 2019 (COVID-19) who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID-19 (see SmPC for the full indication). It contains sotrovimab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of Xevudy's benefits can be found in Xevudy'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/xevudy

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

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

II.A List of important risks and missing information

Important risks of Xevudy 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 Xevudy. 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	
Missing information	Use in pregnancy Use in children ≥12 to <18 years old

II.B Summary of important risks

Missing Information: Use in pregnancy	
Risk minimisation measures	**Routine risk minimisation measures:** The SmPC includes appropriate information in Section 4.6, Fertility, Pregnancy and Lactation, and Section 5.3 Preclinical Safety Data Equivalent wording is included in the patient leaflet Section 2 **Additional risk minimisation measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** *Short study name:* COVID-19 International Drug Pregnancy Registry (COVID-PR) *See section* II.C *of this summary for an overview of the post-authorisation development plan.*

Missing Information: Use in children ≥12 to <18 years old	
Risk minimisation measures	**Routine risk minimisation measures:** The SmPC includes appropriate information in Section 4.2, Posology and method of Administration, Section 5.1, Pharmacodynamic properties, and Section 5.2, Pharmacokinetic properties.

	Equivalent wording is included in the patient leaflet Section 2 **Additional risk minimisation measures:** None
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** *Short study name:* Planned open-label COMET-PACE study to evaluate pharmacokinetics, pharmacodynamics and safety following single dose of sotrovimab in paediatric patients with mild to moderate COVID-19 at high risk of progression. *See section* II.C *of this summary for an overview of the post-authorisation development plan.*

II.C Post-authorisation development plan

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

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

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

Study Short Name:

COVID-19 International Drug Pregnancy Registry (COVID-PR)

Purpose of the Study:

The overall objective of the COVID-19 International Multi-Drug Pregnancy Registry (COVID-PR) is to evaluate obstetric, neonatal, and infant outcomes among women who required at least one in-hospital or ambulatory medication for mild to severe COVID-19 at any time during pregnancy. Sotrovimab exposure in pregnancy will be one of the medications monitored in the COVID-PR.

Study Short Name:

Planned COMET-PACE study to evaluate pharmacokinetics, pharmacodynamics and safety following single dose of sotrovimab in paediatric patients with mild to moderate COVID-19 at high risk of progression

Purpose of the Study:

There is an urgent medical need for treatments of coronavirus disease 2019 (COVID-19). While children are more likely than adults to have asymptomatic or mild infection, those that are young or have a history of obesity, gastrointestinal conditions, heart disease since birth,

genetic or metabolic conditions, neurologic disease, diabetes mellitus, asthma or chronic lung disease, immunosuppression, Sickle Cell Disease, or baseline medical complexity are more likely to be hospitalised with severe disease or die.

In the sotrovimab clinical development program to date patents <18 years of age were excluded. Therefore, there is a need to evaluate sotrovimab in children (age <18).

In this planned study the main objectives are:

- to assess pharmacokinetics and pharmacodynamics of sotrovimab
- to evaluate safety and tolerability of sotrovimab