Ronapreve® (Casirivimab/Imdevimab) Injektions-/Infusionslösung, 120 mg/ml Zul.-Nr. 68329

Public Risk Management Plan (RMP) Summary

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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 “Ronapreve” 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 “Ronepreve” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Roche Pharma (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Ronepreve”.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR RONAPREVE® (CASIRIVIMAB & IMDEVIMAB)

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

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

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

I. THE MEDICINE AND WHAT IT IS USED FOR

RONAPREVE is a combination of casirivimab and imdevimab authorized for the treatment and prevention of COVID-19 in adults and in adolescents aged 12 years and older weighing at least 40 kg (see prescribing information for the full indication). It contains casirivimab and imdevimab as the active substances, and it is given by intravenous (IV) or subcutaneous (SC) route.

Further information about the evaluation of Ronapreve's benefits can be found in Ronapreve's EPAR, including in its plain-language summary, available on the EMA Website, under the medicine's Webpage.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Ronapreve, together with measures to minimize such risks and the proposed studies for learning more about Ronapreve's risks, are outlined below.

Measures to minimize 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 authorized pack size - the amount of medicine in a pack is chosen so as 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, including periodic safety update report (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 casirivimab and imdevimab is not yet available, it is listed under "missing Information" below.

II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of Ronapreve are risks that need special risk-management activities to further investigate or minimize 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 Ronapreve. 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 about 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	*Use in pregnancy*

II.B SUMMARY OF IMPORTANT RISKS

Use in pregnancy

Risk minimization measures	*Routine risk minimization measures:* *EU SmPC Section 4.6 : Fertility, pregnancy and lactation* *EU SmPC Section 5.3: Preclinical safety data* *PL Section 2* *Other risk minimization measures beyond the Product Information:* *Medicine's legal status:* *The combination of casirivimab and imdevimab is a prescription only medicine* *Additional risk minimization measures:* *None*
Additional pharmacovigilance activities	*Additional pharmacovigilance activities:* *COVID-PR (COVid-19 International Drug Pregnancy Registry)* *See Section II.C of this summary for an overview of the postauthorization development plan.*

EU SmPC = EU Summary of product characteristics; PL= Package Leaflet

II.C POST-AUTHORIZATION DEVELOPMENT PLAN

II.C.1 Studies That Are Conditions of the Marketing Authorization

There are no studies that are conditions of the marketing authorization or specific obligation Ronapreve.

II.C.2 Other Studies in Post-Authorization Development Plan

Study short name: COVID-19 International Drug Pregnancy Registry (COVID-PR)

Purpose of the study: to estimate the effect specific newly developed medications indicated for mild to severe COVID-19 have on the risk of obstetric, neonatal, and infant outcomes compared to the effects of repurposed treatments for COVID-19.