Summary of Risk Management Plan for Regkirona™

Active substance:	Regdanvimab
Dosage strength:	60mg/ml
Pharmaceutical form:	Concentration for solution for infusion (sterile concentrate)
Version number of RMP summary	3.0
Name of Marketing Authorisation Holder:	iQone Healthcare Switzerland SA
Date:	21 January 2022
Reference RMP	EU RMP version 1.0 (November 2021)

Disclaimer:

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 Regkirona™ 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 Regkirona™ in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. iQone Healthcare Switzerland SA is fully responsible for the accuracy and correctness of the content of the published summary RMP of Regkirona™.

Part VI: Summary of the risk management plan

Summary of risk management plan for Regkirona

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

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

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

I. The medicine and what it is used for

Regkirona is authorised for treatment of confirmed coronavirus disease 2019 (COVID-19) in adults (see SmPC for the full indication). It contains regdanvimab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of Regkirona’s benefits can be found in Regkirona’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/regkirona

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

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

II.A List of important risks and missing information

Important risks of Regkirona 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 Regkirona. 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	Not applicable
Important potential risks	Not applicable
Missing information	Use during pregnancy Long-term safety data

II.B Summary of important risks

Missing information - Use during pregnancy	
Risk minimisation measures	Routine risk minimisation measures - SmPC section 4.6 - PL section 2 Legal status: Medicinal product subject to medical prescription Additional risk minimisation measures - None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: - CT-P59 4.1 - COVID-PR See section II.C of this summary for an overview of the post-authorisation development plan.

Missing information - Long-term safety data	
Risk minimisation measures	Routine risk minimisation measures - None Legal status: Medicinal product subject to medical prescription Additional risk minimisation measures - None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: - CT-P59 3.2 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 of Regkirona.

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

CT-P59 3.2: A Phase 2/3, Randomized, Parallel-group, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of CT-P59 in Combination with Standard of Care in Outpatients with Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) Infection

Purpose of the study: There are currently no approved monoclonal antibody therapy available to treat coronaviruses such as SARS-CoV-2 and there is an urgent public health need for rapid development of such interventions.

The study is initiated to evaluate efficacy and safety of CT-P59 in outpatients with mild to moderate symptoms of SARS-CoV-2 infection, not requiring supplemental oxygen therapy.

The safety concern addressed in this study is long-term safety data which is missing information. The data generated from this ongoing clinical study will allow more confident assessment of the safety profile of regdanvimab.

CT-P59 4.1: Post-Marketing Surveillance of REGKIRONA® 960 mg (Regdanvimab) (monoclonal antibody, gene recombination) to Evaluate Its Safety and Efficacy

Purpose of the study: The objectives of this post-marketing surveillance (PMS) are to evaluate the safety and efficacy of REGKIRONA® 960 mg (monoclonal antibody, gene recombination) in Korea under routine care.

The safety concern addressed in this study is use during pregnancy which is missing information. The data generated from this post-marketing surveillance will allow more confident assessment of the safety profile of regdanvimab.

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

Purpose of the study: Medicine developers, academic labs, and other organizations globally are developing medical products to treat COVID-19. Potential treatments include medications currently used or studied to treat other diseases ("repurposed" treatments), as well as medications newly identified or designed to treat COVID-19. Pregnant women will be treated with these medications which, for the most part, lack scientific evidence regarding safety for the mother and the developing offspring.

The objective of the COVID-19 International Drug Pregnancy Registry (COVID-PR) is to estimate the effect that medications indicated for mild to severe COVID-19 have on obstetric, neonatal, and infant outcomes.

The safety concern addressed in this study is use during pregnancy which is missing information. The data generated from this registry will allow more confident assessment of the safety profile of regdanvimab.