Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 November 2021

ROCHE (PHILIPPINES), INC.
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Bonifacio Global City
Taguig City, Metro Manila

Amended Emergency Use Authorization (EUA) for Casirivimab + Imdevimab

This refers to your request for amendment of the Emergency Use Authorization (EUA) for Casirivimab + Imdevimab (COVID-19 Drug Casirivimab + Imdevimab) dated 01 October 2021 to delete the brand name "Ronapreve" and extend shelf life of the drug product to twenty-four (24) months.

After due consideration, the Food and Drug Administration (FDA) hereby revises the EUA granted to the COVID-19 Drug Casirivimab + Imdevimab.

The foregoing revisions are made pursuant to the discretionary power of the FDA under Section 6 of Executive Order (EO) No. 121, entitled *"Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefor, and for Other Purposes,"* to revisit any issued EUA as may be appropriate to protect the general public health and safety.

The details of the COVID-19 Drug Casirivimab + Imdevimab are as follows:

Product Name:	Casirivimab + Imdevimab
Dosage Strength and Form:	120 mg/mL Concentrate for Solution for Infusion
Pharmacologic category:	Drug
Storage:	Store in a refrigerator at 2° C – 8° C in the original carton to protect from light. Do not freeze. Do not shake.
Shelf Life:	24 months
Packaging:	1 box contains 1 vial of Casirivimab and 1 vial Imdemivab Casirivimab: 6 mL clear Type 1 borosilicate vial with 20mm D77-1 butyl rubber, flouroresinalaminated, latex free (liquid type) and 20 mm dark blue flip-off seal: Aluminum with Clear lacquered finish 20 mL clear Type 1 borosilicate vial with 20mm D77-1 butyl rubber, flouroresinalaminated, latex

	free (liquid type) and 20 mm dark grey flip-off seal: Aluminum with Clear lacquered finish Imdemivab: 6 mL clear Type 1 borosilicate vial with 20mm D77-1 butyl rubber, flouroresinalaminated, latex free (liquid type) and 20 mm green flip-off seal: Aluminum with Clear lacquered finish 20 mL clear Type 1 borosilicate vial with 20mm D77-1 butyl rubber, flouroresinalaminated, latex free (liquid type) and 20 mm green white flip-off seal: Aluminum with Clear lacquered finish
Manufacturer:	F. Hoffman- La Roche Ltd.- 4303 Kaiseraugst Switzerland
Indication:	For treatment of confirmed mild to moderate COVID-19 in patients aged 12 years and older and weighing at least 40 kg that do not require supplemental oxygen for COVID-19 and who are at high risk of progressing to severe COVID-19

After careful consideration of the application, with all its supporting documents and a review of local experts, the FDA has been satisfied that all the conditions for the issuance of an EUA exist as provided under Executive Order (EO) No. 121, s. 2020 entitled *"Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization for COVID-19 Drugs and Vaccines, Prescribing Conditions Therefor, and for Other Purposes,"* particularly:

1. Based on the totality of evidence available to date, including data from adequate and well- known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose, or treat COVID-19;
2. The known and potential benefits of the drug or vaccine, when used to diagnose, prevent or treat COVID-19, outweigh the known and potential risks of the drug or vaccine as of date; and
3. There is currently no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

In issuing this EUA, recognition and reliance have been accorded to the WHO Living Guideline: Therapeutics and COVID-19, and emergency use authorizations given by mature and established National Regulatory Authorities (NRAs) such as the United States of America and the European Union, respectively. Under Section 5 of EO No. 121, the Director General of the FDA has been granted power to implement reliance and recognition processes, and accept regulatory decisions of recognized and established regulatory authorities.

This EUA is not a marketing authorization or a Certificate of Product Registration (CPR). Hence, this EUA cannot be used as an authorization to market the drug commercially.

While the evaluation process was facilitated, strict conditions on the authorization granted in this Letter shall be imposed as follows:

I. Scope

The scope of the EUA shall be limited as follows:

A. Roche (Philippines) Inc. shall supply the COVID-19 Drug Casirivimab + Imdevimab only to the Department of Health (DOH) or the National Task Force Against COVID-19 (NTF) consistent with the terms and conditions of this EUA.

   The DOH or the NTF is authorized to procure or purchase COVID-19 Drug Casirivimab + Imdevimab in line with the COVID-19 management and prevention program.

B. The COVID-19 Drug Casirivimab + Imdevimab shall be delivered to healthcare facilities and administered only by healthcare providers, and used only for COVID-19 according to the approved indication stated herein.

   Healthcare facility, and healthcare provider, including physicians and nurses, as used in this EUA refer to those designated by the DOH or the NTF to receive and administer the COVID-19 Drug Casirivimab + Imdevimab, in accordance with the COVID-19 management and prevention program.

II. Posology and Method of Administration

COVID-19 Drug Casirivimab + Imdevimab should be supplied as a clear to slightly opalescent and colorless to pale yellow solution with a pH of 6.0 for infusion (120mg/ml concentrate).

This should be administered together (Casirivimab 600mg and Imdevimab 600mg) as a single intravenous infusion for the treatment of confirmed mild to moderate COVID-19 in patients aged 12 years and older and weighing at least 40 kg that do not require supplemental oxygen for COVID-19 and who are at high risk of progressing to severe COVID-19.

III. Storage and Supply Chain Management

In the absence of agreement with the DOH or NTF, Roche (Philippines) Inc. shall ensure that appropriate storage, transport, distribution, handling and supply chain is maintained until the product is delivered to healthcare facilities and administered by healthcare providers consistent with the terms of this letter, and ensure that a contingency plan is in place.

IV. Pharmacovigilance

Roche (Philippines) Inc. shall have a comprehensive pharmacovigilance system for the COVID-19 Drug Casirivimab + Imdevimab following system or protocol for a registered drug and biologic product as stated in the FDA Circular No. 2020-003. Submission of serious and non-serious adverse reaction reports is mandatory.

Roche (Philippines) shall ensure compliance with the Risk Management Plan (RMP) along with the Philippine-specific Annex. Additional pharmacovigilance activities such as interventional and non-interventional studies (ongoing or new studies, or additional activities) shall be implemented as stated in the RMP. The RMP must be updated whenever there is a significant change which may affect the benefit-risk profile of the drug or when an important milestone is reached.

Roche (Philippines) shall submit monthly summary safety reports as planned and discussed in the RMP.

V. Responsibility of Healthcare Facilities and Healthcare Providers

Under FDA Circular No. 2020-036 or the *Guidelines for the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19,* the pharmacovigilance obligations and post-authorization commitments imposed in the Letter shall be shared to the fullest extent possible and applicable by the national procurer and health program implementors. Healthcare facilities and healthcare providers shall have the following responsibilities.

A. Healthcare facilities shall:

1. Receive the COVID-19 Drug Casirivimab + Imdevimab in sites identified by DOH, and ensure appropriate storage and supply chain management is maintained in said facilities, in the absence of an agreement with Roche (Philippines) Inc.;
2. Ensure administration of the COVID-19 Drug Casirivimab + Imdevimab is consistent with the terms of this Letter, latest product information and the COVID-19 management and treatment program; and
3. Ensure that healthcare providers of the COVID-19 Drug Casirivimab + Imdevimab are aware of this Letter of Authorization and the terms herein and any subsequent amendments thereof, instructed about the means which they are to obtain and administer the COVID-19 Drug Casirivimab + Imdevimab, and provided with approved fact sheets.

B. On the other hand, healthcare providers shall:

1. Administer the COVID-19 Drug Casirivimab + Imdevimab, in accordance with this EUA, and participate and comply with the terms and training required by the DOH for the COVID-19 management and treatment program;
2. Provide fact sheets to the recipients and caregivers, and provide necessary information for receiving their second dose;
3. Obtain written informed consent from the recipient of the COVID-19 Drug Casirivimab + Imdevimab prior to administration;
4. Report any Adverse Drug Reaction (ADR) on the use of the COVID-19 Drug Casirivimab + Imdevimab;
5. Monitor and comply with drug management requirements (e.g. obtaining, tracking and handling drug) of the DOH; and

6. Ensure that records associated with this EUA are maintained until notified by FDA. Such records shall be made available to DOH and FDA for inspection upon request.

Notwithstanding the foregoing, Roche (Philippines) Inc. has the ultimate responsibility for monitoring the safety and quality of the COVID-19 Drug Casirivimab + Imdevimab.

VI. Validity

Unless otherwise revoked, this EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of a marketing authorization/Certificate of Product Registration.

In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, this EUA shall have a provisional validity for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

This EUA is subject to revocation, suspension or cancellation due to violations of pharmacovigilance obligations and post authorization commitments, as well as any violation of the EO No. 121, and RA 3720 as amended by RA No. 9711, FDA Circular No. 2020-036, and other rules and regulations issued thereunder.

For strict compliance.