Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Aushad Bhaban, Mohakhali, Dhaka-1212
www.dgda.gov.bd

Memo No: DA/15-5/96(214)/ 17060 Date: 05-09-2021

To
The Managing Director
M/S Roche Bangladesh Limited,
Monem Business District, Level-5,
111 Bir Uttam C.R.Dutta Road (Sonargaon Road), Dhaka-1205.

Subject: Emergency use Authorization of Casirivimab and Imdevimab 120 mg/mL

As per the response to your request by the letter Dated: 28/07/2021, Directives of Section-4.2 (Kha) of Drug Policy-2016 and Notification no. 45.00.0000.182.99.017.08-110, Dated: 13 May, 2020 of Health Service Division, MOHFW, Directorate General of Drug Administration (DGDA) issues an Emergency use Authorization (EUA) of Casirivimab and Imdevimab 120 mg/mL for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-Cov-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death. (Reference: As per U.S Food and Drug Administration).

Product:
Generic Name: Casirivimab and Imdevimab 120 mg/mL concentrate for solution for infusion.
Pack size:

- One multidose vial contains 1332mg/11.1 mL of Casirivimab (120 mg/mL),
  One multidose vial contains 1332mg/11.1 mL of Imdevimab (120 mg/mL).
  (2 multidose vials of 20 mL)
- One vial contains 300mg/2.5 mL of Casirivimab (120 mg/mL),
  One vial contains 300mg/2.5 mL of Imdevimab (120 mg/mL).
  (2 vials of 6 mL)

Routes of Administration: Casirivimab and Imdevimab 120 mg/mL may be administered by intravenous infusion or subcutaneous injection. **(For treatment, intravenous infusion is strongly recommended. subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment).**
Strength: Casirivimab and Imdevimab 120 mg/mL.
Treatment Dosage:

- The authorized dosage is 600 mg of casirivimab and 600 mg of imdevimab administered together as a single intravenous infusion or by subcutaneous injection as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of symptom onset.

Storage: Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the individual original carton to protect from light. Do NOT freeze, shake, or expose to direct light.
Manufacturing site: Genentech Inc, 4625 NE Brookwood, Hillsboro, USA.
Marketing Authorization Holder: F. Hoffmann-La Roche Limited, Grenzacherstrasse 124, 4070 Basel, Switzerland.
Local Agent (for Bangladesh): Radiant Business Consortium Limited. Address: Lubdhok, 3rd Floor, 474 P, Road No 3, Sector 12, Uttara, Dhaka 1230, Bangladesh.

Conditions on Emergency use Authorization of Casirivimab and Imdevimab 120 mg/mL:

1. This medicine will only be used by healthcare providers for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-Cov-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death. **The product is not recommended for post exposure prophylaxis purpose.**

Criteria for identifying high risk individuals-

- Older age (for example, age ≥65 years of age)
- Obesity or being overweight (for example, BMI >25 kg/m2, or if age 12-17, have BMI ≥85th percentile for their age and gender based on CDC growth charts.
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)

2. This medicine may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.
3. **Limitations of Authorized Use: Casirivimab and Imdevimab 120 mg/mL is not authorized for use in the following patient populations:**
   - Adults or pediatric patients who are hospitalized due to COVID-19, or
   - Adults or pediatric patients who require oxygen therapy due to COVID19, or
   - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19, in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.
4. **Contraindications:** Casirivimab and Imdevimab 120 mg/mL is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to Casirivimab and Imdevimab 120 mg/mL.
5. Radiant Business Consortium Limited will ensure that Casirivimab and Imdevimab 120 mg/ml will be distributed with approved package insert/Patient Information Leaflet(PIL) and authorized labeling by DGDA, will be made available to health care facilities/or healthcare providers as per this Emergency Use Authorization.
6. **These drugs only be collected from the depot of the local agent of the MA holder upon submitting prescription from a specialist medical doctor and be administered under the supervision of a physician. The local agent has to submit to DGDA statistics of sale together with prescriptions of each month.**
7. Radiant Business Consortium Limited will ensure the appropriate storage is maintained.
8. Radiant Business Consortium Limited will ensure that the terms of this EUA are made available to all relevant stakeholders (Bangladesh Government Agencies; Authorized distributors, Healthcare facilities, Healthcare providers).
9. Radiant Business Consortium Limited will report to DGDA serious adverse events and all medication errors associated with the use of the authorized Casirivimab and Imdevimab 120 mg/mL.
10. Radiant Business Consortium Limited will report to DGDA within three working days of receipt of any information concerning any batch of authorized Casirivimab and Imdevimab 120 mg/mL (whether the batch is distributed or not), as follows: (1) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to (2) information concerning any bacteriological or microscopic contamination, or any significant chemical, physical, or other change in deterioration in the drug product, or any failure of one or more batches of the drug product to meet the established specifications. Radiant Business Consortium Limited will include in its notification to DGDA whether the batch, or batches, in question will be recalled.

11. Through a process of inventory control, Radiant Business Consortium Limited will maintain records regarding distribution of the authorized Casirivimab and Imdevimab 120 mg/mL (i.e. batch numbers, Quantity, Receiving site, receipt date).
12. Radiant Business Consortium Limited will make available to DGDA upon request any records maintained in connection with this EUA.
13. Radiant Business Consortium Limited will not implement any changes to the description of the authorized product, manufacturing process, facilities and equipment and elements of the associated control strategy that assure process performance and quality of the authorized product without notification to and concurrence by DGDA.
14. **The MA holder (Roche BD. Ltd.) and the local agent has to follow strictly the condition of EUA especially in case of medical promotion of the product.**
15. This Emergency Use Authorization (EUA) will be valid up to the COVID-19 Pandemic Situation.

Major General Md Mahbubur Rahman
Director General 05 SEP 2021
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