IMPORTANT PRESCRIBING INFORMATION

Subject: Preventing Medication Errors with Casirivimab and Imdevimab

Dear Healthcare Provider:

This notice is to make you aware of the correct route of administration of casirivimab and imdevimab. Although they are packaged separately, casirivimab and imdevimab must be administered together after dilution by single intravenous (IV) infusion only.

Casirivimab and imdevimab are authorized¹ for emergency use for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19 and/or hospitalization. Healthcare Providers should administer casirivimab and imdevimab per the full Fact Sheet for Healthcare Providers available at www.REGENCOV2.com.

Casirivimab and Imdevimab Are Authorized ONLY for Intravenous Infusion after Dilution.

You may receive cartons and vials of casirivimab and imdevimab that are labeled “for intravenous infusion or subcutaneous injection.” However, casirivimab and imdevimab MUST be administered by INTRAVENOUS (IV) INFUSION ONLY under this emergency use authorization. Healthcare providers should review the enclosed Fact Sheet for instructions on dosing, preparation and administration of casirivimab and imdevimab by intravenous infusion.

Casirivimab and imdevimab must be administered together although they are packaged separately.

There are three versions of casirivimab and imdevimab packaging, which are reproduced in the enclosure. Please note:

- Some cartons and vials of casirivimab and imdevimab may be instead labeled REGN10933 and REGN10987, respectively.
- Casirivimab and imdevimab may each be supplied as two different strengths: 1332 mg/11.1 mL single-dose vials and 300 mg/2.5 mL single-dose vials.
- One 11.1 mL vial of one antibody and four 2.5 mL vials of the other antibody can be used to create one treatment course.

¹ Casirivimab and imdevimab are not approved, but The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products casirivimab and imdevimab to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization only for the duration of the declaration.
Regardless of the packaging, the 2 components, casirivimab and imdevimab, must be administered together as a single intravenous infusion. The route of administration authorized under the EUA is by intravenous infusion only after dilution.

**Healthcare Provider Action**

Healthcare providers should consider the following strategies in order to mitigate the risk of a possible medication error:

- Store casirivimab and imdevimab together in inventory.
- Create alerts in the electronic health record (EHR) systems for healthcare providers that casirivimab and imdevimab must be used together.
- Ensure that EHR systems always use casirivimab and imdevimab and only include an option for single IV infusion of casirivimab and imdevimab after dilution.

**Reporting Adverse Events and Medication Errors**

Healthcare providers should direct questions about casirivimab and imdevimab packaging or use to the Regeneron Medical Information Department at 1-844-734-6643 or to medical.information@regeneron.com.

Under the Emergency Use Authorization, adverse events must be reported within 7 calendar days from the onset of the event. MedWatch adverse event reports can be submitted to FDA online at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form https://www.accessdata.fda.gov/scripts/medwatch/index.cfm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

Healthcare providers must report all serious adverse events and medication errors when utilizing casirivimab and imdevimab to Regeneron at medical.information@regeneron.com.

The EUA Fact Sheet for Healthcare Providers is included with this notice, available at www.REGENCOV2.com, or available by scanning the QR Code below:

Johnathan Lancaster, MD
Vice President, Global Medical Affairs
Variations of the packaging and labeling of casirivimab and imdevimab

1a: casirivimab (also referred to as REGN10933) – 1332 mg/11.1 mL (120 mg/mL solution)

1b: imdevimab (also referred to as REGN10987) – 1332 mg/11.1 mL (120 mg/mL solution)
2a: casirivimab (also referred to as REGN10933) – 300 mg/2.5 mL (120 mg/mL solution)

Carton
Ref No. XXXXXXX
Lot XXXXXXXXXXX
REGN10933
300 mg/2.5 mL (120 mg/mL)
MUST ADMINISTER WITH REGN10987

Vial

Subject Number
Investigator
Date Dispensed

Contains:
1 vial Solution of intravenous infusion or subcutaneous injection.
Administer in accordance with protocol instructions.
Store refrigerated at 2°C–8°C (36°F–46°F) in the original carton to protect from light.
Keep Out of Reach of Children. For Clinical Trial Use Only.
Caution: New Drug - Limited by Federal (or United States) law to investigational use.
Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 USA
Tel: +1 914-847-7000

The top panel of this illustration has been rotated for readability.

2b: imdevimab (also referred to as REGN10987) – 300 mg/2.5 mL (120 mg/mL solution)

Carton
Ref No. XXXXXXX
Lot XXXXXXXXXXX
REGN10987
300 mg/2.5 mL (120 mg/mL)
MUST ADMINISTER WITH REGN10933

Vial

Subject Number
Investigator
Date Dispensed

Contains:
1 vial Solution of intravenous infusion or subcutaneous injection.
Administer in accordance with protocol instructions.
Store refrigerated at 2°C–8°C (36°F–46°F) in the original carton to protect from light.
Keep Out of Reach of Children. For Clinical Trial Use Only.
Caution: New Drug - Limited by Federal (or United States) law to investigational use.
Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 USA
Tel: +1 914-847-7000

The top panel of this illustration has been rotated for readability.
3a: casirivimab (also referred to as REGN10933) – 300 mg/2.5 mL (120 mg/mL solution)

3b: casirivimab (also referred to as REGN10933) – 1332 mg/11.1 mL (120 mg/mL solution)
3c: imdevimab (also referred to as REGN10987) – 300 mg/2.5 mL (120 mg/mL solution)

3d: imdevimab (also referred to as REGN10987) – 1332 mg/11.1 mL (120 mg/mL solution)