Casirivimab-Imdevimab Serious Adverse Event Reporting

1. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events* potentially related to casirivimab-imdevimab treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "REGEN-COV use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report.
    - Submit adverse event reports to FDA MedWatch using one of the following methods:
        - Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
        - Complete and submit a postage-paid Form FDA 3500 (https://www.fda.gov/media/76299/download) and return by:
            - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
            - Fax (1-800-FDA-0178), or
        - Call1-800-FDA-1088 to request a reporting form
        - Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" a statement "REGEN-COV use for COVID-19 under Emergency Use Authorization (EUA)."

    *Serious Adverse Events are defined as:
    - death;
    - a life-threatening adverse event;
    - inpatient hospitalization or prolongation of existing hospitalization;
    - a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - a congenital anomaly/birth defect;
    - a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

2. The prescribing health care provider and/or the provider's designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of casirivimab-imdevimab.

3. OTHER REPORTING REQUIREMENTS
    - In addition, please provide a copy of all FDA MedWatch forms to:
      Regeneron Pharmaceuticals, Inc
      Fax: 1-888-876-2736
      E-mail: medical.information@regeneron.com
      Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events.

Source: REGEN-COV™ (casirivimab with imdevimab) Fact Sheet for Healthcare Providers. Available from: https://www.fda.gov/media/145611/download