REGENERON

IMPORTANT PRODUCT INFORMATION

Subject: REGEN-COV Emergency Use Authorization Voluntary Revocation

Dear Healthcare Provider:

Given the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to REGEN-COV® (casirivimab and imdevimab), REGEN-COV is not currently authorized in any U.S. region. This notice is to make you aware that the emergency use authorization (EUA) for REGEN-COV is no longer in effect. Regeneron voluntarily requested that FDA revoke the EUA as both Regeneron and the FDA agree it is not medically appropriate, at this time, to use REGEN-COV for the treatment of mild to moderate COVID-19 or as post-exposure prophylaxis for COVID-19 in the United States.

All formulations and presentations of casirivimab and imdevimab or REGEN-COV distributed under the EUA have expired.

HEALTHCARE PROVIDER ACTION:

Patients who have received REGEN-COV should be reminded to seek timely medical attention if they experience symptoms of COVID-19.

Given that all of the distributed REGEN-COV vials are expired, any unused REGEN-COV should be disposed on site following your institution's established protocols for destruction of materials.

Reporting Adverse Events and Medical Errors

All medication errors and serious adverse events considered potentially related to REGEN-COV must be reported within 7 calendar days from the onset of the event. Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program 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 (MedWatch, 5600 Fishers Lane, Rockville, MD 208529787, or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form.

Please provide a copy of all FDA MedWatch forms to Regeneron via fax (1-888-876-2736) or email (medical.information@regeneron.com).

Healthcare providers should direct questions about REGEN-COV to the Regeneron Medical Information Department at 1-844-734-6643 or to medical.information@regeneron.com.

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