December 13, 2024

Regeneron Pharmaceuticals, Inc.
Attention: Danise Subramanian, PhD
Senior Director, Regulatory Affairs
777 Old Saw Mill River Road
Tarrytown, NY 15091-6707

**Re: Revocation of EUA 091**

Dear Dr. Subramanian:

This letter is in response to the request from Regeneron Pharmaceuticals, Inc. (Regeneron), received on November 25, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for REGEN-COV (casirivimab and imdevimab administered together). The EUA for REGEN-COV was issued initially on November 21, 2020. Regeneron has informed the FDA that all lots of REGEN-COV manufactured, labeled and distributed for use under EUA 091 have expired and that Regeneron does not intend to offer this product in the United States anymore. FDA understands that Regeneron will issue a communication to notify healthcare providers that have received REGEN-COV under the EUA of this revocation with instructions for product destruction for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with REGEN-COV, because FDA understands that Regeneron no longer intends to offer REGEN-COV in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because Regeneron has requested that FDA revoke the EUA for REGEN-COV, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 091 for REGEN-COV pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, REGEN-COV is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of Regeneron's request, REGEN-COV was not authorized for use in any region of the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to REGEN-COV.

Sincerely,

Patrizia A. Cavazzoni -S

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Date: 2024.12.13 10:42:22 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration