December 14, 2023

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Senior Director, GRA-NA
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Re: Revocation of EUA 094

Dear Jennifer Riddle Camp:

This letter is in response to the request from Eli Lilly and Company (Lilly), received on October 23, 2023[1], that the U.S. Food and Drug Administration (FDA or Agency) revoke the EUA for bamlanivimab and etesevimab administered together. The EUA for bamlanivimab and etesevimab administered together was issued initially on February 9, 2021. Lilly has informed FDA that all lots of bamlanivimab and etesevimab manufactured and labeled for use under EUA 094 have expired and that Lilly does not intend to offer this product in the United States anymore. FDA understands that Lilly will promptly notify healthcare facilities and providers that have received bamlanivimab and etesevimab administered together under the EUA to also stop using product that remains in distribution with instructions for product return.

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). FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization based on the reasons set forth in Lilly's request for revocation to the Agency.

Accordingly, FDA hereby revokes EUA 094 for bamlanivimab and etesevimab administered together pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, bamlanivimab and etesevimab administered together 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 Lilly's request, bamlanivimab and etesevimab administered together 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 bamlanivimab and etesevimab.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.12.14 13:47:55 -05'00'

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