December 13, 2024

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 111

Dear Ms. Riddle Camp:

This letter is in response to the request from Eli Lilly and Company (Lilly), received on December 5, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for bebtelovimab. The EUA for bebtelovimab was issued initially on February 11, 2022. Lilly has informed the FDA that all lots of bebtelovimab manufactured, labeled and distributed for use under EUA 111 have expired and that Lilly does not intend to offer this product in the United States anymore. FDA understands that Lilly will issue a communication to notify healthcare providers that have received bebtelovimab under the EUA of this revocation with instructions for product destruction or return 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 bebtelovimab, because FDA understands that Lilly no longer intends to offer bebtelovimab in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because Lilly has requested that FDA revoke the EUA for bebtelovimab, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 111 for bebtelovimab pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, bebtelovimab 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, bebtelovimab 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 bebtelovimab.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2024.12.13 10:50:06 -05'00'

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