December 13, 2024

GlaxoSmithKline LLC
Attention: Danielle Lumbatis, MBA, RAC
Associate Director, Global Regulatory Affairs
Specialty Therapeutic Group
1250 S. Collegeville Rd.
Collegeville, PA 19426

Re: Revocation of EUA 100

Dear Ms. Lumbatis:

This letter is in response to the request from GlaxoSmithKline LLC (GSK), received on November 22, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for sotrovimab. The EUA for sotrovimab was issued initially on May 26, 2021. GSK has informed the FDA that all lots of sotrovimab manufactured, labeled and distributed for use under EUA 100 have expired and that GSK does not intend to offer this product in the United States anymore. FDA understands that GSK will issue a communication to notify healthcare providers that have received sotrovimab 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 sotrovimab, because FDA understands that GSK no longer intends to offer sotrovimab in the United States under the EUA; because all product manufactured, labeled and distributed pursuant to the EUA has expired; and because GSK has requested that FDA revoke the EUA for sotrovimab, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 100 for sotrovimab pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, sotrovimab 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 GSK's request, sotrovimab 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 sotrovimab.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2024.12.13 10:45:42 -05'00'

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