EUA 000104

GRANTING LETTER-
REVISED FACT SHEET

AstraZeneca Pharmaceuticals LP
Attention: Stacey Cromer Berman, PhD
Senior Regulatory Affairs Director and Team Lead
One MedImmune Way
Gaithersburg, MD 20878

Dear Dr. Cromer Berman:

Please refer to your Emergency Use Authorization (EUA) authorizing EVUSHELD™ (tixagevimab co-packaged with cilgavimab) under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3) for emergency use as pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and:

- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or

- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

We refer to your submissions dated December 16 and December 20 2022, to EUA 000104 wherein you submitted revisions to the authorized Fact Sheet for Healthcare Providers to support updated EVUSHELD neutralization activity data against certain SARS-CoV-2 viral variants.

We have completed our review and concur with the revisions to the Fact Sheet for Healthcare Providers which consist of the following:

Full Fact Sheet for Healthcare Providers

- Updates to Section 12.4 (Microbiology) to add neutralization data of cilgavimab, tixagevimab, and tixagevimab and cilgavimab in combination against virus-like particles pseudotyped with the spike glycoproteins of BA.5.2.6, BN.1, BF.11, and XBB variants.

Text was added to Section 12.4 indicating that substitutions at spike protein positions R346 or K444 and F486 are associated with resistance to EVUSHELD.

By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the Letter of Authorization for EUA 000104, dated October 27, 2022[1], authorizing the emergency use of EVUSHELD for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kg) as stated above.

Sincerely,

--/S/--

Wendy Carter, DO
Deputy Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Fact Sheet for Healthcare Providers

[1] FDA's Letter of Authorization for EVUSHELD was initially issued on December 08, 2021. The letter was subsequently re-issued on December 10, 2021, December 20, 2021, February 24, 2022, May 17, 2022, October 27, 2022, and December 08, 2022.