EUA 111

EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Associate Director-Global Regulatory Affairs-North America
Lilly Corporate Center Drop Code 2543
Indianapolis, IN 46285

Dear Ms. Riddle Camp:

Please refer to your Emergency Use Authorization (EUA) for bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients who are at high-risk for progression to severe COVID-19, including hospitalization or death.

We refer to your communication submitted on October 31, 2022, the Division's responses dated November 2, 2022, and your submission dated November 3, 2022, proposing the following changes to the Fact Sheet for Health Care Providers (HCPs) and the Fact Sheet for Patients, Parents and Caregivers:

Fact Sheet for HCPs:

- Revisions to subsection 12.4, Microbiology based on new pseudotyped virus-like particle data, highlighting that bebtelovimab showed a large reduction in susceptibility to Omicron BA.5 [+N444T, N460K] (BQ.1), and Omicron BA.5 [+R346T, N444T, N460K] (BQ.1.1) variants. Pseudotyped virus-like particle data are also included showing no change in susceptibility of bebtelovimab to Omicron BA.2 [BA.2.75+R346T+F486S] (BA.2.75.2). Authentic SARS-CoV-2 neutralization data are also included for Omicron BA.5, BA.4.6 and BA.2.75 showing no change in susceptibility for bebtelovimab.

Fact Sheet for Patients, Parents and Caregivers:

- To remove an erroneous inclusion of an email address for reporting adverse events.

We have reviewed your submissions and agree with your proposed changes.

The updated Fact Sheets for Health Care Providers and for Patients, Parents and Caregivers are attached to this correspondence for your reference with November 4, 2022, as the new revised date.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the October 22, 2022[1], letter authorizing the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients who are at high-risk for progression to severe COVID-19, including hospitalization or death.

Sincerely,

--/S/--

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- EUA Fact Sheets
  - Fact Sheet for Health Care Providers
  - Fact Sheet for Patients, Parents and Caregivers

[1] The EUA for bebtelovimab was issued initially on February 11, 2022 and was subsequently reissued on August 5, 2022 and October 24, 2022.