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 dated and submitted on September 9, 2022, proposing the following changes to the Fact Sheet for Health Care Providers (HCPs):

- Revisions to subsection 12.4, Microbiology, based on new pseudotyped virus-like particle data, highlighting that bebtelovimab retains activity to Omicron subvariant BA.4 [+R346T] (BA.4.6)

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

The updated Fact Sheet for Health Care Providers is attached to this correspondence for your reference with September 16, 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 February 11, 2022, 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