EUA 105

EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS

Pfizer, Inc.
Attention: Karen Baker
Director, Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Baker:

Please refer to your Emergency Use Authorization (EUA) for PAXLOVID for the following uses:

- Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death

We refer to the Agency's communications dated March 1, 11, and 15, 2022 and your response submissions dated March 7, 15, and 16, 2022 wherein we discussed the following changes:

- Addition of Velkury as an FDA-approved available alternative therapy to PAXLOVID to the Fact Sheets for Health Care Providers and Patients
- Updates to section 12.4 of the Fact Sheet for Healthcare Providers:
    - to include new data on the antiviral activity of nirmatrelvir against an expanded panel of SARS-CoV-2 variants
    - to add an additional Mpro amino acid substitution that emerged in a nirmatrelvir cell culture resistance selection study using MHV
    - to expand the listing of nirmatrelvir treatment-emergent Mpro and Mpro cleavage site amino acid substitutions detected in samples from clinical trial EPIC-HR

We have completed our review and agree with the proposed changes.

The updated Fact Sheet for Health Care Providers and Recipients are attached to this correspondence for your reference.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the December 22, 2021, letter authorizing the emergency use of PAXLOVID for the following uses:

- Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and 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