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 use:

- 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 your submissions dated August 24, 2022, September 19, 2022, and September 22, 2022, and the Division's communications dated September 15, 2022 and September 21, 2022, proposing the following changes to the Fact Sheet for Health Care Providers (HCP) and the Fact Sheet for Patients, Parents, Caregivers:

HCP:

- Minor editorial changes to update table numbers
- Updates to section 5.2, Warnings and Precautions, to include anaphylaxis reported with PAXLOVID use
- Updates to section 6.2, Post-Authorization Experience, to include anaphylaxis reported with PAXLOVID use
- Updates to section 12.4, Microbiology, with information on the activity of nirmatrelvir against SARS-CoV-2 Omicron sub-variants in cell culture
- Updates to section 12.4, Microbiology, with information on the activity of nirmatrelvir and ritonavir in SARS-CoV-2-infected mice
- Updates to section 12.4, Microbiology, with information on antiviral resistance in cell culture and biochemical assays and addition of Table 8: SARS-CoV-2 M^{pro} Amino Acid Substitutions Selected by Nirmatrelvir in Cell Culture
- Updates to section 12.4, Microbiology, with information on antiviral resistance in clinical trials

- Updates to section 12.4, Microbiology, with information on cross-resistance between nirmatrelvir and anti-SARS-CoV-2 monoclonal antibodies, molnupiravir, and remdesivir
- Minor updates to section 14.1, Clinical Studies, for clarity
- Updates to section 17, Patient Counseling Information, to include anaphylaxis reported with PAXLOVID use

Fact Sheet for Patients, Parents, Caregivers:

- Addition of severe allergic reactions (known as 'anaphylaxis') as a Possible Side Effect of PAXLOVID

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

The updated Fact Sheet for Health Care Providers and the updated Fact Sheet for Patients, Parents, Caregivers are enclosed.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the August 5, 2022 letter[1] 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, Parents, Caregivers

[1] The Letter of Authorization for Paxlovid was initially issued on December 22, 2021 and subsequently re-issued on March 17, 2022, April 14, 2022, July 6, 2022 and August 5, 2022.