EUA 122

EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS

Invivyd, Inc.
Attention: Rachael Gerlach, PhD
Vice President, Regulatory Affairs
209 Church Street
New Haven, CT 06510

Dear Dr. Gerlach:

Please refer to your Emergency Use Authorization (EUA) for pemivibart for pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40kg):

- who are not currently infected with SARS-CoV-2 and who have not been known to be exposed to someone who is 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 are unlikely to mount an adequate response to COVID-19 vaccination,

issued on March 22, 2024, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We have reviewed your August 20, 2025 and September 1, 2025 submissions, and have updated the EUA Fact Sheet for Healthcare Providers to include updated information on PEMGARDA pseudotyped lentivirus virus-like particle (VLP) neutralization activity data against currently dominant SARS-CoV-2 variant XFG and recently circulating and low frequency variants LF.7.9 and NB.1.8.1 and to reflect your change in address. The updated Fact Sheet for Healthcare Providers is attached to this correspondence for your reference with September 2025, as the new revised date.

We have also updated the EUA Fact Sheet for Patients, Parents and Caregivers to reflect your change in address, and this is also attached 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 August 26, 2024[1], letter authorizing the emergency use of pemivibart for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

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

[1] The EUA for pemivibart was issued initially on March 22, 2024. The Letter of Authorization was subsequently reissued on April 3, 2024 and August 26, 2024.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WENDY W CARTER
09/12/2025 10:14:02 AM