EUA 000122

EMERGENCY USE AUTHORIZATION
EXTENSION OF SHELF LIFE

Invivyd, Inc.
Attention: Rachel Gerlach, Ph.D.
Vice President, Regulatory Affairs
1601 Trapelo Road, Suite 178
Waltham, MA 02451

Dear Dr. Gerlach:

Please refer to your Emergency Use Authorization (EUA) for Pemgarda (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 completed our review of the data and information provided in the quality amendment (eCTD 0170) submitted to IND 165736 on May 30, 2025, and concur with the extension of the shelf life for the 16 drug product lots (specified in Table 1 below) from 30 to 36 months. The expiry of these lots was previously extended from 24 to 30 months.

Table 1: Extended expiry of 36 months for Pemgarda (pemivibart) Authorized under EUA 000122

Finished Good Lot Number	Source Drug Product Lot Number	Labeled Expiry Date (with 24-Month Expiry)	Extended Expiry Date (with 36-Month Expiry)
2053018	20230502	April 2025	April 2026
2053020	20230502	April 2025	April 2026
2053022	20230502	April 2025	April 2026
2066667	20230502	April 2025	April 2026
2066670	20230503	April 2025	April 2026
2066671	20230804	July 2025	July 2026
2098979	20230804	July 2025	July 2026

2068066	20230805	July 2025	July 2026
2068071	20240101	December 2025	December 2026
2069568	20240203	January 2026	January 2027
2070221	20240304	February 2026	February 2027
2072055	20240305	February 2026	February 2027
2120203	20240305	February 2026	February 2027
2072056	20240306	February 2026	February 2027
2072227	20240307	February 2026	February 2027
2072228	20240308	February 2026	February 2027

By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the August 26, 2024, letter authorizing the emergency use of Pemgarda for pre-exposure prophylaxis of COVID-19 in certain individuals.

If you have any questions, contact Andrew Shiber, Senior Regulatory Business Process Manager, at Andrew.Shiber@fda.hhs.gov or (301) 796 - 4798.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director
Division of Product Quality Assessment XIII
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

FDA initially issued the Letter of Authorization for pemivibart 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/

PATRICK J LYNCH
07/21/2025 03:26:41 PM