

Invivyd Inc.

NDC	DRUG PROD DESC	INTRODUCED TO MARKET DATE
81960-0031-03	Pemgarda Intravenous Solution 500 MG/4ML Package Size 4ML Package Quantity 9	4/15/2024

WAC AT INTRODUCTION	MARKETING PRICING PLAN
\$ 5,775.00	To the best of Invivyd Inc.'s knowledge and in good faith understanding of 18 V.S.A § 4367, Invivyd does not believe its marketing or pricing plans used in the launch of PEMGARDA are in the public domain and, therefore, declines to provide further information in accordance with 18 V.S.A § 4637(d).

**MARKETING PRICING
NONPUBLIC**

Yes

ESTIMATED PATIENTS

No information regarding the volume of patients who may be prescribed PEMGARDA is in the public domain or publicly available.

The total addressable market in the U.S. for PEMGARDA is limited to the population that falls within the product's authorized use, specifically certain adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Of the various groups with moderate-to-severe immune compromise, we believe that there are approximately 485,000 people in the highest risk group, such as solid organ transplant recipients and those with certain hematological/lymphatic cancers, including stem cell transplant recipients.

BREAKTHROUGH THERAPY INDICATOR

On March 22, 2024, pursuant to § 564(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §360bbb-3), the Company received emergency use authorization (“EUA”) from the U.S. Food and Drug Administration for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

PRIORITY REVIEW INDICATOR	ACQUISITION DATE	ACQUISITION PRICE
N/A	N/A	N/A

ACQUISITION PRICE NONPUBLIC	ACQUISITION PRICE COMMENT	GENERAL COMMENTS
N/A	N/A	N/A