

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): March 28, 2024

Invivyd, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40703
(Commission
File Number)

85-1403134
(IRS Employer
Identification No.)

1601 Trapelo Road, Suite 178
Waltham, MA
(Address of Principal Executive Offices)

02451
(Zip Code)

Registrant's telephone number, including area code: (781) 819-0080

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	IVVD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On March 28, 2024, Invivyd, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2023, and recent business highlights. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 2.02.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any of the Company’s filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 28, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVIVYD, INC.

Date: March 28, 2024

By: /s/ Jill Andersen
Jill Andersen
Chief Legal Officer and Corporate Secretary

Invivyd Reports Full Year 2023 Financial Results and Recent Business Highlights

- *Received emergency use authorization for PEMGARDA™, a monoclonal antibody (mAb) authorized in the U.S. for pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise*
- *PEMGARDA product availability in the U.S. anticipated imminently*
- *PEMGARDA is the first authorized mAb from Invivyd's INVYMAB™ platform approach designed to address the challenge of rapid viral evolution*
- *Leveraged INVYMAB platform approach to design VYD2311, the company's next anticipated SARS-CoV-2 candidate*
- *Cash and cash equivalents of \$200.6 million as of December 31, 2023*
- *In February 2024, the Company sold shares totaling \$40.5 million in gross proceeds under its At-the-Market facility further strengthening its balance sheet ahead of PEMGARDA launch*

WALTHAM, Mass., March 28, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced financial results for the full year ended December 31, 2023 and recent business highlights.

“We made remarkable progress throughout 2023 and in recent months. Roughly one year ago we were initiating the Phase 1 clinical trial of VYD222, and today we are incredibly proud to have received emergency use authorization (EUA) of PEMGARDA for PrEP of COVID-19 in certain adults and adolescents (aged 12 or older weighing at least 40kg) in the U.S. with moderate-to-severe immune compromise who are unlikely to mount an adequate response to COVID-19 vaccination,” said Dave Hering, Chief Executive Officer of Invivyd. “PEMGARDA is the first PrEP mAb to receive an EUA using a rapid immunobridging trial design leveraging a biomarker as a surrogate of clinical efficacy and the first authorized mAb from our novel platform approach designed to rapidly and serially engineer durable mAbs targeting conserved viral epitopes. This exciting milestone is a testament to our team’s incredible dedication, skill, and ability to execute to plan.”

Mr. Hering continued, “With PEMGARDA now authorized and anticipated to be available for order in the U.S. imminently, we are laser-focused on executing our commercial launch plan and look forward to providing insights on key launch metrics as time progresses. With a relatively compact field sales organization, we believe that we can efficiently reach key healthcare practitioners and institutions who care for the highest risk moderately to severely immunocompromised adults and adolescents, with the opportunity to potentially expand our efforts and footprint over time within our authorized population.”

Recent Program Highlights

- **PEMGARDA received EUA from U.S. FDA:** On March 22, 2024, PEMGARDA (pemivibart) received EUA from the U.S. Food and Drug Administration (FDA) 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 response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2. The PEMGARDA EUA is based on the totality of scientific evidence available, including data from the company’s CANOPY clinical trial based on an immunobridging approach. The company expects to have PEMGARDA available for order in the U.S. imminently and is preparing for the full commercial launch of PEMGARDA, with the deployment of the contracted field sales force expected in the coming weeks.

- **Leveraged INVYMAB™ platform approach to design VYD2311, the company's next anticipated anti-SARS-CoV-2 mAb in a planned series of candidates:** In January 2024, Invivyd nominated VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, as a drug candidate. The company expects that VYD2311 will be the next candidate that it advances into clinical development. The company continues to engage with the FDA with the aim of establishing a streamlined development pathway that would allow the company to most efficiently leverage its INVYMAB platform approach to serially generate new or modified mAbs to keep pace with SARS-CoV-2 viral evolution.

Year End 2023 Financial Results

- **Cash Position:** Cash and cash equivalents were \$200.6 million as of December 31, 2023.
- **Cash Runway:** Based on current operating plans and excluding anticipated cash collections from PEMGARDA sales, Invivyd expects its existing total cash and cash equivalents will enable the company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2024.
- **Research & Development (R&D) Expenses (including In-Process Research & Development):** R&D expenses were \$163.6 million for the year ended December 31, 2023, compared to \$183.6 million for year ended December 31, 2022. This decrease is primarily attributable to a decrease in personnel-related costs in 2023 and to higher clinical trial costs in 2022 due to ongoing adintrevimab clinical trials, with no comparable costs during the same period in 2023 due to the wind-down of adintrevimab clinical trials, partially offset by an increase in commercial manufacturing costs of PEMGARDA and ongoing clinical trial costs associated with our CANOPY clinical trial in 2023.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were \$49.1 million for the year ended December 31, 2023, compared to \$47.0 million for the year ended December 31, 2022. This increase is primarily attributable to an increase in personnel-related costs and commercial costs, partially offset by a decrease in legal and corporate governance costs.
- **Net Loss and Net Loss Share:** Net loss was \$198.6 million for the year ended December 31, 2023, compared to \$241.3 million for the year ended December 31, 2022. Basic and diluted net loss per share was \$1.81 for the year ended December 31, 2023, compared to \$2.23 for the year ended December 31, 2022.

About PEMGARDA

PEMGARDA (pemivibart) is a half-life extended investigational monoclonal antibody (mAb). PEMGARDA was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in a global Phase 2/3 clinical trial for the prevention of COVID-19. PEMGARDA has demonstrated *in vitro* neutralizing activity in pseudotyped virus-like particle and authentic virus neutralization assays against major SARS-CoV-2 variants, including JN.1, the dominant variant in the U.S. currently according to estimates from the Centers for Disease Control and Prevention. PEMGARDA targets the SARS-CoV-2 spike protein receptor binding domain (RBD), thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for intravenous use is an investigational mAb that has not been approved, but has been authorized for emergency use by the U.S. FDA under an EUA 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. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2. PEMGARDA is not authorized for use for treatment of COVID-19 or post-exposure prophylaxis of COVID-19. Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse events (all grades, incidence $\geq 2\%$) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

To support the EUA for PEMGARDA, an immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum virus neutralizing titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Additionally, the variability associated with cell-based EC₅₀ value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior clinical trials, impact the ability to precisely estimate protective titer ranges.

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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is commercial-stage company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. The company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (mAbs) to keep pace with evolving viral threats. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for its first mAb in a planned series of innovative antibody candidates. Visit <https://invivyd.com/> to learn more.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipates,” “believes,” “could,” “expects,” “intends,” “potential,” “projects,” and “future” or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise; the company’s plans related to the commercialization of PEMGARDA, including its expectations regarding availability and supply of PEMGARDA, as well as the company’s plans to provide insights on key launch metrics as time progresses; the ability of the company’s INVYMAB platform approach to rapidly and serially engineer durable mAbs targeting conserved epitopes; the company’s ongoing research and clinical development efforts, and the timing thereof; the company’s expectation that PEMGARDA is the first mAb in a planned series of innovative antibody candidates and VYD2311 will be the next mAb candidate to enter clinical development; the company’s expectations to engage with the FDA with the aim of establishing a streamlined development pathway that would allow the company to most efficiently leverage its INVYMAB platform approach to serially generate new or modified mAbs to keep pace with SARS-CoV-2 viral evolution; the future of the COVID-19 landscape, particularly for vulnerable populations; the company’s expectations regarding the anticipated timeline of its cash runway; the company’s mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2; and other statements that are not historical fact. The company may not actually achieve the plans, intentions or expectations disclosed in the company’s forward-looking statements and you should not place undue reliance on the company’s forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause the company’s actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether the EUA is revoked or revised by the FDA; the company’s ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; the timing and progress of the company’s discovery, preclinical and clinical development activities; the outcome of the company’s engagement with the FDA on a potential streamlined development pathway; the uncertainties and timing of the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of the company’s product candidates; changes in the regulatory environment; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of PEMGARDA or any other product candidate following regulatory authorization or approval; the predictability of clinical success of the company’s product candidates based on neutralizing activity in preclinical studies; the risk that results of preclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; the company’s reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants; whether PEMGARDA or any other product candidate is able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; the complexities of manufacturing mAb therapies; the company’s dependence on third parties to manufacture, label, package, store and

distribute clinical and commercial supplies of its product candidates; whether the company is able to provide sufficient commercial supply of PEMGARDA to meet market demand; whether the company can obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; the company's ability to leverage its INVYTAB platform approach to rapidly and serially generate durable mAbs that keep pace with SARS-CoV-2 viral evolution or other viral threats; any litigation and other proceedings or government investigations relating to the company; the company's ability to continue as a going concern; and whether the company has adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause the company's actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (SEC), and in the company's other filings with the SEC, and in its future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

INVIVYD, INC.
CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 200,641	\$ 92,076
Marketable securities	—	279,915
Prepaid expenses and other current assets	24,240	4,926
Total current assets	224,881	376,917
Property and equipment, net	1,896	2,282
Operating lease right-of-use assets	2,229	3,777
Other non-current assets	175	191
Total assets	<u>\$ 229,181</u>	<u>\$ 383,167</u>
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,953	\$ 1,517
Accrued expenses	40,860	21,911
Operating lease liabilities, current	1,443	1,559
Other current liability	35	44
Total current liabilities	50,291	25,031
Operating lease liabilities, non-current	722	2,165
Other non-current liability	700	—
Early-exercise liability	—	1
Total liabilities	51,713	27,197
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock (undesignated), \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 1,000,000,000 shares authorized, 110,160,684 shares issued and outstanding at December 31, 2023; 109,044,046 shares issued and outstanding at December 31, 2022	11	11
Additional paid-in capital	909,539	889,657
Accumulated other comprehensive loss	(13)	(272)
Accumulated deficit	(732,069)	(533,426)
Total stockholders' equity	177,468	355,970
Total liabilities, preferred stock and stockholders' equity	<u>\$ 229,181</u>	<u>\$ 383,167</u>

INVIVYD, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development ⁽¹⁾	\$ 158,658	\$ 179,214
Acquired in-process research and development ⁽²⁾	4,975	4,400
Selling, general and administrative	49,125	47,044
Warrant expense ⁽³⁾	—	17,373
Total operating expenses	<u>212,758</u>	<u>248,031</u>
Loss from operations	<u>(212,758)</u>	<u>(248,031)</u>
Other income:		
Other income, net	14,115	6,714
Total other income, net	<u>14,115</u>	<u>6,714</u>
Net loss	<u>(198,643)</u>	<u>(241,317)</u>
Other comprehensive income (loss)		
Unrealized gain (loss) on available-for-sale securities, net of tax	259	(264)
Comprehensive loss	<u>\$ (198,384)</u>	<u>\$ (241,581)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.81)</u>	<u>\$ (2.23)</u>
Weighted-average common shares outstanding, basic and diluted	<u>109,526,053</u>	<u>108,268,289</u>

(1) Includes related-party amounts of \$8,418 and \$8,154 for the years ended December 31, 2023 and 2022, respectively.

(2) Includes related-party amounts of \$4,975 and \$4,400 for the years ended December 31, 2023 and 2022, respectively.

(3) Includes related-party amounts of \$0 and \$17,373 for the years ended December 31, 2023 and 2022, respectively.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

- **Anaphylaxis has been observed with PEMGARDA in 0.6% (4/623) of participants in a clinical trial.**
- **Anaphylaxis was reported during the first and second infusion of PEMGARDA.**
- **Anaphylaxis can be life-threatening.**
- **Prior to administering PEMGARDA, consider the potential benefit of COVID-19 prevention along with the risk of anaphylaxis.**
- **Administer PEMGARDA only in settings in which healthcare providers have immediate access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as necessary.**
- **Clinically monitor individuals during the infusion and for at least two hours after completion of the infusion.**
- **Discontinue PEMGARDA immediately if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

CONTRAINDICATIONS

PEMGARDA is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of PEMGARDA.

WARNINGS AND PRECAUTIONS

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with PEMGARDA. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals during the 60-minute infusion and for at least two hours after completion of the infusion.

Risk of Cross-Hypersensitivity With COVID-19 Vaccines

PEMGARDA contains polysorbate 80, which is in some COVID-19 vaccines and is structurally similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. For individuals with a history of severe hypersensitivity reaction to a COVID-19 vaccine, consider consultation with an allergist-immunologist prior to PEMGARDA administration.

Risk for COVID-19 Due to SARS-CoV-2 Viral Variants Not Neutralized by PEMGARDA

Certain SARS-CoV-2 viral variants may emerge that are not neutralized by monoclonal antibodies such as PEMGARDA. PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. Inform individuals of the increased risk, compared to other variants, for COVID-19 due to emergent SARS-CoV-2 viral variants not neutralized by PEMGARDA. If signs or symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.

ADVERSE REACTIONS

The most common adverse events (all grades, incidence $\geq 2\%$) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Lactation

There are no available data on the presence of PEMGARDA in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PEMGARDA and any potential adverse effects on the breastfed infant from PEMGARDA.

Pediatric Use

PEMGARDA is not authorized for use in pediatrics less than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PEMGARDA has not been established in pediatrics.

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved product PEMGARDA for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual 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.

LIMITATIONS OF AUTHORIZED USE

- PEMGARDA is not authorized for use:
 - For treatment of COVID-19, or
 - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

PEMGARDA may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under State law to prescribe drugs.

PEMGARDA has been authorized by FDA for the emergency use described above.

PEMGARDA is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

PEMGARDA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PEMGARDA under Section 564(b)(1) of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

See full **Fact Sheet for Healthcare Providers, Including Boxed Warning** and **Fact Sheet for Patients, Parents, and Caregivers** for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. The **FDA Letter of Authorization** is also available for reference.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to PEMGARDA within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below). The FDA requires that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, sex, weight, ethnicity, and race).
- A statement "PEMGARDA use for the pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization (EUA)" under the "**Describe Event, Problem, or Product Use/Medication Error**" heading.
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes).
- Patient's preexisting medical conditions and use of concomitant products.
- Information about the product (e.g., dosage, route of administration, NDC #).

Submit serious adverse event and medication error reports using FDA Form 3500 to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Complete and submit a postage-paid FDA Form 3500 (<https://www.fda.gov/media/76299/download>) and return by:
 - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
 - Fax to 1-800-FDA (332)-0178, or
- Call 1-800-FDA (332)-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to:

Invivyd, Inc.
Email: pv@invivyd.com
Or call Invivyd, Inc. at 1-800-890-3385 to report serious adverse events.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about serious adverse events and medication errors following receipt of PEMGARDA.

* Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions

-
- A congenital anomaly/birth defect
 - Other important medical events, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

You may report side effects related to Invivyd, Inc. products by sending an email to medinfo@invivyd.com.

Contacts:

Scott Young
(781) 208-1747
syoung@invivyd.com

Gabriella Linville-Engler
(781) 208-0160
gengler@invivyd.com