Invivyd Reports First Quarter 2025 Financial Results and Recent Business Highlights

May 15, 2025

- *PEMGARDA™ (pemivibart) net product revenue of $11.3 million reported for Q1 2025, influenced by planned transition (Jan/Feb) from a contracted to an internalized sales force*
- *PEMGARDA revenue re-acceleration observed in Q2 2025 to date*
- *Invivyd continues to target near-term profitability (1H 2025) with existing cash and cash equivalents, anticipated growth of net product revenue, and continued reduction of operating expenses*
- *Since Emergency Use Authorization (EUA) of PEMGARDA in March 2024, no documented cases of anaphylaxis reported, across thousands of post-authorization doses*
- *VYD2311 Phase 1 clinical trial data read-out anticipated later in Q2 2025*

WALTHAM, Mass., May 15, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced financial results for the quarter ended March 31, 2025, and provided recent business highlights.

“To drive long-term topline growth, we made a strategic decision to internalize our sales force at the beginning of 2025,” said Bill Duke, Chief Financial Officer of Invivyd. “Although this shift created a short-term headwind, we’re now seeing positive momentum with a return to growth and early signs of acceleration in Q2 2025. Backed by a strong cash position and potential to access up to $30 million in non-dilutive funding through our term loan facility, we remain focused on disciplined financial execution and continue to target profitability by the end of the first half of 2025.”

Recent Business Highlights

- **Commercial Execution**
  - PEMGARDA™ (pemivibart) uptake continues to grow among healthcare providers caring for immunocompromised patients, supported by Invivyd’s in-house sales force and expanded field presence across key specialties.
- **Ongoing Variant Coverage and Safety Profile of PEMGARDA**
  - In vitro neutralization data show sustained neutralizing activity of PEMGARDA against currently dominant SARS-CoV-2 variants, including LP.8.1 and XEC, consistent with expectations based on the observed stability of PEMGARDA target epitope and prior variant surveillance. LP.8.1 and XEC represent more than 75% of SARS-CoV-2 variants circulating in the U.S., according to the Centers for Disease Control.
  - PEMGARDA safety profile remains consistent with the Fact Sheet for Healthcare Providers; no additional documented cases of anaphylaxis reported since emergency use authorization (EUA) in March 2024.
- **Regulatory Developments**
  - In February 2025, the U.S. Food and Drug Administration (FDA) declined Invivyd’s request to expand the existing EUA of PEMGARDA to include treatment of mild-to-moderate COVID-19 for certain immunocompromised patients who have no alternative therapeutic options. The FDA declination letter provides reasoning that may provide a near-term pathway for VYD2311.
- **Pipeline Expansion**
  - Invivyd has initiated discovery efforts to assess pipeline expansion beyond SARS-CoV-2, including potential targets such as respiratory syncytial virus (RSV) and measles
    - These evaluations are focused on high-value unmet needs in which a best- in class or first-and-best in class antibody may offer an attractive alternative or complement to traditional vaccines, or a high-value treatment.
- **Corporate and Financial Updates**
  - In April 2025, Invivyd secured a $30 million non-dilutive term loan facility with Silicon Valley Bank, a division of First Citizens Bank, supporting balance sheet optionality and providing potential additional runway for commercial and pipeline execution if certain conditions and milestones are met.

Recent Pipeline Highlights

- VYD2311 Phase 1 clinical trial data read-out, including potency, half-life and full safety unblinding anticipated later in Q2 2025.

First Quarter 2025 Financial Results:

- **Revenue:** Reported Q1 2025 PEMGARDA net product revenue of $11.3 million, as compared to $13.8 million in Q4 2024.

There were no revenues reported during Q1 2024.

- **Cash Position:** Cash and cash equivalents were $48.1 million as of March 31, 2025.
- **Research & Development (R&D) Expenses (including In-Process R&D):** R&D expenses were $10.6 million for the quarter ended March 31, 2025, compared to $31.2 million for the comparable period of 2024. This decrease is primarily attributable to a decrease in commercial manufacturing costs of PEMGARDA, a decrease in clinical trial costs related to our CANOPY Phase 3 clinical trial and a decrease in personnel-related costs.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $16.8 million for the quarter ended March 31, 2025, compared to $14.9 million for the comparable period of 2024. This increase is primarily attributable to sales and marketing costs related to PEMGARDA.
- **Net Loss and Net Loss per Share:** Net loss was $16.3 million for the quarter ended March 31, 2025, compared to $43.5 million for the comparable period in 2024. Basic and diluted net loss per share was $0.14 for the quarter ended March 31, 2025, compared to $0.38 for the comparable period in 2024.

Conference Call & Webcast

Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 global Phase 2/3 clinical trials for the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1, XEC and LP.8.1. 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. 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 vaccinations, 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.

Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation. For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

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. Further, 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. Additionally, certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants.

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. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

About CANOPY

The CANOPY Phase 3 clinical trial was designed to evaluate the safety and tolerability of pemivibart and to assess immunobridging from pemivibart to certain historical data from the company's previous Phase 2/3 clinical trial of adintrevimab (ADG20) for the prevention of symptomatic COVID-19 (EVADE). Additionally, there were pre-specified exploratory endpoints through three, six and twelve months to evaluate clinical efficacy of pemivibart compared to placebo in the prevention of RT-PCR-

confirmed symptomatic COVID-19. The latest analysis from the Phase 3 CANOPY clinical trial included 365-day data. The CANOPY clinical trial enrolled participants in two cohorts: Cohort A was a single-arm, open-label trial in adults with moderate-to-severe immune compromise including complex underlying medical conditions. Cohort B was a randomized, placebo-controlled cohort that enrolled adults without moderate-to-severe immune compromise at risk of acquiring COVID-19 due to regular unmasked face-to-face interactions in indoor settings.

About VYD2311

VYD2311 is a novel monoclonal antibody (mAb) candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. The pharmacokinetic profile and antiviral potency of VYD2311 may offer the ability to deliver clinically meaningful titer levels through more patient-friendly means such as an intramuscular route of administration.

VYD2311 was engineered using Invivyd's proprietary integrated technology platform and is the product of serial molecular evolution designed to generate an antibody optimized for neutralizing contemporary virus lineages. VYD2311 leverages the same antibody backbone as pemivibart, Invivyd's investigational mAb granted emergency use authorization in the U.S. for the pre-exposure prophylaxis (PrEP) of symptomatic COVID-19 in certain immunocompromised patients, and adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. Invivyd deploys a proprietary integrated technology platform unique in the industry designed to assess, monitor, develop, and adapt to create best in class antibodies. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for a monoclonal antibody (mAb) in its pipeline 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," "estimates," "intends," "potential," "predicts," "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 company's goal of near-term profitability; the company's expectations regarding anticipated growth of net product revenue and continued reduction of operating expenses; expectations related to the company's term loan facility; the company's ongoing research and development activities, as well as future potential research and development efforts; the ongoing in vitro neutralizing activity of PEMGARDA against dominant SARS-CoV-2 variants; the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents who have moderate-to-severe immune compromise; the potential of VYD2311 as a novel mAb candidate that may be able to deliver clinically meaningful titer levels through more patient-friendly means, and potentially available regulatory pathways; the company's devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; potential pipeline expansion beyond SARS-CoV-2, including potential targets such as RSV and measles; 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: uncertainties regarding the company's expectations, projections and estimates regarding future costs and expenses, future revenue, capital requirements, and the availability of and the need for additional financing; whether the company's cash and cash equivalents are sufficient to support its operating plan for as long as anticipated; uncertainties regarding market acceptance, payor coverage and reimbursement, or future revenue generated by PEMGARDA; how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether the EUA is revised or revoked by the FDA; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; the success of the company's in-house sales force, and company's ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; changes in the regulatory environment; the outcome of the company's engagement with regulators; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways; the timing, progress and results of the company's discovery, preclinical and clinical development activities; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies; the risk that results of nonclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that pemivibart and VYD2311 targets remains structurally intact; whether the company's product candidates are able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; whether the company's integrated technology platform is able to produce mAbs with broad and durable viral protection along with improved drug properties; the company's reliance on third parties; clinical trial site activation or enrollment rates; the complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; the company's ability to realize the anticipated benefits of its term loan facility; 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, 2024, as 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.

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

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 48,078	$ 69,349
Accounts receivable	8,561	10,906
Prepaid expenses and other current assets	19,186	20,426
Total current assets	75,825	100,681
Inventory	25,419	25,907
Property and equipment, net	1,523	1,508
Operating lease right-of-use assets	953	1,385
Other non-current assets	24	34
Total assets	$ 103,744	$ 129,515
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,739	$ 10,448
Accrued expenses[(1)]	39,928	50,197
Operating lease liabilities	894	1,304
Other current liability	34	27
Total current liabilities	49,595	61,976
Total liabilities	49,595	61,976
Commitments and contingencies		
Stockholders' equity:		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,961,445 shares issued and outstanding at March 31, 2025; 119,835,162 shares issued and outstanding at December 31, 2024	12	12
Additional paid-in capital	972,433	969,526
Accumulated other comprehensive loss	(13)	(5)
Accumulated deficit	(918,283)	(901,994)
Total stockholders' equity	54,149	67,539
Total liabilities, preferred stock and stockholders' equity	$ 103,744	$ 129,515

(1) Includes related-party amounts of $456 and $1,274 as of March 31, 2025 and December 31, 2024, respectively.

INVIVYD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Revenue:		
Product revenue, net	$ 11,304	$ —
Total revenue	11,304	—
Operating costs and expenses:		
Cost of product revenue[1]	834	—
Research and development[2]	10,641	31,160
Selling, general and administrative	16,751	14,929
Total operating costs and expenses	28,226	46,089
Loss from operations	(16,922)	(46,089)
Other Income:		
Other Income, net	633	2,593
Total other income, net	633	2,593
Net Loss	(16,289)	(43,496)
Other comprehensive income (loss)		
Unrealized (loss) gain, net of tax	(8)	1
Comprehensive loss	$ (16,297)	(43,495)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.14)	$ (0.38)
Weighted-average common shares outstanding, basic and diluted	119,883,479	$ 115,618,209

(1) Includes related-party amounts of $452 for the three months ended March 31, 2025 and no related-party amounts for the three months ended March 31, 2024.
(2) Includes related-party amounts of $1,128 and $1,135 for the three months ended March 31, 2025 and 2024, respectively.