Invivyd Reports Fourth Quarter and Full-Year 2024 Financial Results and Provides Recent Business Highlights

March 20, 2025

- *Achieved Q4 2024 PEMGARDA™ (pemivibart) net product revenue of $13.8 million, representing 48% growth over Q3 2024 net product revenue of $9.3 million; full-year 2024 net product revenue totaled $25.4 million*
- *2024 year-end cash and cash equivalents of $69.3 million*
- *Continues to target near-term (by end of 1H 2025) profitability with existing cash and cash equivalents, anticipated growth of net product revenue, and continued reduction of manufacturing expenses*
- *Company announced in vitro neutralization data show continued, consistent neutralizing activity of PEMGARDA against LP.8.1, KP.3.1.1, and XEC, comprising the majority of SARS-CoV-2 variants currently circulating in the U.S, reinforcing the durability of PEMGARDA's neutralizing activity shown amid viral evolution*
- *Company announced positive Phase 1 clinical data for next-generation program VYD2311, evaluating multiple routes of administration and dose levels for a single dose, including intramuscular injection, for both safety and pharmacokinetics; in vitro neutralization potency of VYD2311 assessed across contemporary SARS-CoV-2 variants tested showed an average 17-fold greater neutralization potency than pemivibart*

WALTHAM, Mass., March 20, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced financial results for the fourth quarter and full year ended December 31, 2024, and recent business highlights.

"We are pleased with the significant PEMGARDA™ revenue growth of 48% in the fourth quarter, reflecting increased provider awareness and adoption," said Bill Duke, Chief Financial Officer of Invivyd. "We look forward to raising further awareness of PEMGARDA in the healthcare community and working to achieve near-term profitability. In parallel, we are advancing VYD2311, our next generation monoclonal antibody that has demonstrated highly promising Phase 1 clinical data and has the potential to offer an improved route of administration to protect vulnerable patient populations from COVID-19."

"With our impressive fourth quarter growth as our catalyst, we began 2025 with a newly transitioned, in-house sales force," said Tim Lee, Chief Commercial Officer. "Vulnerable patient populations such as cancer patients, those undergoing or living with an organ transplant, and those who are on immunosuppressive therapies are at risk of the short-term and long-term systemic damage of COVID-19. With hospitalizations and deaths from COVID-19 greater than influenza and RSV combined, it's imperative to keep COVID-19 at the forefront of the minds of vulnerable patients and their healthcare providers – including hematologists, transplant physicians, infectious disease clinicians, rheumatologists and primary care doctors."

Recent Business Highlights

- **PEMGARDA Neutralization Data Updates**
  - Continued, neutralization activity of PEMGARDA shown against currently dominant SARS-CoV-2 variants LP.8.1, KP.3.1.1 and XEC, comprising the majority of SARS-CoV-2 variants currently circulating in the U.S. This aligns with Invivyd's broader clinical and virology data, which have consistently demonstrated structural stability of the targeted epitope of PEMGARDA and prolonged neutralizing activity against contemporary variants.
  - LP.8.1 in vitro neutralization data provided to the U.S. Food and Drug Administration (FDA)
- **Regulatory Developments**
  - In February 2025, the FDA declined Invivyd's request to expand the existing emergency use authorization of PEMGARDA to include treatment of mild-to-moderate COVID-19 for immunocompromised patients who have no alternative therapeutic options. Invivyd has submitted a response requesting that the FDA reconsider and looks forward to meeting to discuss next steps.
- **Partnership & Awareness Campaigns**
  - The company announced collaboration with renowned professional football coach Jim Harbaugh to elevate awareness of the ongoing impact of COVID-19 and options available to vulnerable populations.
- **Manufacturing & Supply**
  - VYD2311 commercial manufacturing has been substantially completed.
  - Minimal manufacturing expenses expected in 2025, contributing to ongoing cost reductions.

Recent Pipeline Highlights

- Positive Phase 1 clinical data announced in February 2025 for VYD2311, a next-generation monoclonal antibody for COVID-19
    - Phase 1 clinical data, combined with antiviral assessment and COVID-19 antiviral correlate of protection data, including Invivyd's Phase 3 CANOPY clinical trial data for pemivibart, support a potentially attractive clinical profile for VYD2311.
    - VYD2311 pooled, blinded adverse events were mild or moderate and thus far deemed unrelated to study drug or largely related to injection site reaction or infusion reactions.
- In February 2025, the company announced that in vitro neutralization potency of VYD2311 assessed across contemporary SARS-CoV-2 variants tested showed an average 17-fold greater neutralization potency than pemivibart.
    - VYD2311 has also demonstrated stable epitope and clinically meaningful in vitro neutralization against LP.8.1 providing further validation of the company’s integrated technology platform’s potential to produce monoclonal antibodies with broad and durable viral protection along with improved drug properties.

Fourth Quarter and Full-Year 2024 Financial Results

- **Revenue:** Reported full year 2024 net product revenue of PEMGARDA of $25.4 million. Reported $13.8 million of net product revenue of PEMGARDA in Q4 2024, marking a 48% increase when compared to $9.3 million in Q3 2024.
- **Cash Position:** Cash and cash equivalents were $69.3 million as of December 31, 2024.
- **Research & Development (R&D) Expenses:** R&D expenses were $137.3 million for the year ended December 31, 2024, compared to $163.6 million (inclusive of in-process R&D) for the comparable period in 2023. This decrease is primarily attributable to lower personnel costs and commercial manufacturing costs of PEMGARDA, partially offset by commercial manufacturing costs of VYD2311 in 2024.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $63.4 million for the year ended December 31, 2024, compared to $49.1 million for the comparable period in 2023. This increase is primarily attributable to an increase in personnel costs and costs associated with commercialization of PEMGARDA.
- **Net Loss and Net Loss per Share:** Net loss was $169.9 million for the year ended December 31, 2024, compared to $198.6 million for the comparable period in 2023. Basic and diluted net loss per share was $1.43 for the year ended December 31, 2024, compared to $1.81 for the comparable period in 2023.

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 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 net product revenue growth and continued reduction of manufacturing expenses; the future of the COVID-19 landscape and potential impact of COVID-19 on certain patients; the company's plans to raise further awareness of PEMGARDA in the healthcare community; 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 and VYD2311 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 company's expectations regarding engagement with the FDA; the potential of VYD2311 as a novel mAb candidate that may be able to deliver clinically meaningful titer levels through more patient-friendly means; the company's devotion to delivering protection from serious viral infectious diseases, 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: 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 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, 2023 and the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, each 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)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 69,349	$ 200,641
Accounts receivable	10,906	—
Prepaid expenses and other current assets	20,426	24,240
Total current assets	100,681	224,881
Inventory, net	25,907	—
Property and equipment, net	1,508	1,896
Operating lease right-of-use assets	1,385	2,229
Other non-current assets	34	175
Total assets	$ 129,515	$ 229,181
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,448	$ 7,953
Accrued expenses[1]	50,197	40,860
Operating lease liabilities, current	1,304	1,443
Other current liability	27	35
Total current liabilities	61,976	50,291
Operating lease liabilities, non-current	—	722
Other non-current liability[2]	—	700
Total liabilities	61,976	51,713
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, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,835,162 shares issued and outstanding at December 31, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	969,526	909,539
Accumulated other comprehensive loss	(5)	(13)
Accumulated deficit	(901,994)	(732,069)
Total stockholders' equity	67,539	177,468

Total liabilities, preferred stock and stockholders' equity	$ 129,515	$ 229,181

(1) Includes related-party amounts of $1,274 and $0 for the years ended December 31, 2024 and 2023, respectively.
(2) Includes related-party amounts of $0 and $700 for the years ended December 31, 2024 and 2023, respectively.

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

	Year Ended December 31, 2024	Year Ended December 31, 2023
Revenue:		
Product revenue, net	$ 25,384	$ —
Total revenue	25,384	—
Operating costs and expenses:		
Cost of product revenue[1]	1,618	—
Research and development [2]	137,254	158,658
Acquired in-process research and development [3]	—	4,975
Selling, general and administrative	63,388	49,125
Total operating costs and expenses	202,260	212,758
Loss from operations	(176,876)	(212,758)
Other income:		
Other income, net	6,951	14,115
Total other income, net	6,951	14,115
Net loss	(169,925)	(198,643)
Other comprehensive income (loss)		
Unrealized gain on available-for-sale securities, net of tax	8	259
Comprehensive loss	$ (169,917)	$ (198,384)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.43)	$ (1.81)
Weighted-average common shares outstanding, basic and diluted	118,555,073	109,526,053

(1) Includes related-party amounts of $1,027 and $0 for the years ended December 31, 2024 and 2023, respectively.
(2) Includes related-party amounts of $4,546 and $8,418 for the years ended December 31, 2024 and 2023, respectively.
(3) Includes related-party amounts of $0 and $4,975 for the years ended December 31, 2024 and 2023, respectively.