Invivyd Reports First Quarter 2024 Financial Results and Recent Business Highlights

May 9, 2024

- *Launched PEMGARDA™ in the U.S. for COVID-19 pre-exposure prophylaxis (PrEP) in certain adults and adolescents with moderate-to-severe immune compromise*
- *Reported interim exploratory COVID-19 clinical event data from CANOPY Phase 3 clinical trial of VYD222*
- *Received product-specific reimbursement codes covering PEMGARDA from the U.S. Centers for Medicare & Medicaid Services (CMS), covering approximately half of target population*
- *Announced plans to pursue rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain immunocompromised people, based on U.S. FDA feedback*
- *Continued to advance VYD2311, the company's next monoclonal antibody candidate engineered with the company's state-of-the-art technologies for variant monitoring, predictive modeling and antibody engineering*
- *Ended Q1 2024 with cash and cash equivalents of $189.4 million*
- *Company expects to end 2024 with at least $75 million in cash and cash equivalents, based on anticipated 2024 net product revenue of $150-$200 million and recent resource realignment*
- *Management to host conference call today at 4:30pm ET*

WALTHAM, Mass., May 09, 2024 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced financial results for the quarter ended March 31, 2024, and recent business highlights.

"The recent months have been incredibly productive for Invivyd. Moving into the commercial phase is a critical step for the company and we are executing on the PEMGARDA launch with maximum focus across the company," said Marc Elia, Chairman of the Invivyd Board of Directors. "In addition, we look forward to sharing on today's quarterly update call more of the scientific underpinnings of our plans going forward, including detail on the innovative engine we believe can deliver meaningful product-level advancements with associated medical and economic value creation."

Recent Business Highlights

- **Launched PEMGARDA, the company's first monoclonal antibody (mAb) in a planned series of innovative antibodies, in the U.S.:** On March 22, 2024, PEMGARDA (pemivibart) received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise. At the beginning of April, Invivyd announced that PEMGARDA is available for purchase in the U.S. through a network of authorized specialty distributors. At the end of April, Invivyd's market access and sales, as well as medical affairs, teams were fully operational across the U.S. The company will begin reporting PEMGARDA net product revenue with its second quarter 2024 financial results.

- **Received product-specific reimbursement codes covering PEMGARDA from the U.S. Centers for Medicare & Medicaid (CMS):** In April 2024, Invivyd announced that CMS has granted a Healthcare Common Procedure Coding System (HCPCS) Q code (Q0224) covering product reimbursement and a product specific M code (M0224) covering the administration of PEMGARDA. The company estimates that CMS provides coverage for nearly half of the moderately to severely immunocompromised people at highest risk for severe COVID-19 that the company is initially targeting.

- **Reported interim exploratory COVID-19 clinical event data from CANOPY Phase 3 clinical trial of VYD222:** In March 2024, Invivyd announced interim exploratory data from the ongoing CANOPY Phase 3 clinical trial that reflect and add further to the initial potential signal of clinical protection from symptomatic COVID-19 shared in December 2023. While not part of the primary immunobridging endpoint of the CANOPY clinical trial, the interim exploratory data may be hypothesis generating for future discovery and development work.

Recent Pipeline Highlights

- **Announced plans to pursue rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain**

immunocompromised people, based on U.S. FDA feedback: In May 2024, Invivyd announced that it anticipates imminently submitting an EUA application to the FDA for pemivibart for the treatment of mild to moderate symptomatic COVID-19 in certain immunocompromised people utilizing a rapid immunobridging pathway. This immunobridging pathway leverages a similar approach Invivyd used to achieve its current EUA for PEMGARDA for COVID-19 PrEP in certain immunocompromised people and was aligned in principle with the FDA.

- **Continued to advance VYD2311, the company's next anticipated mAb candidate:** In March 2024, Invivyd announced that it expects that VYD2311 will be the next anti-SARS-CoV-2 mAb candidate that it advances into clinical development. VYD2311 is optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1. The design of VYD2311 leverages Invivyd's state-of-the-art technologies for variant surveillance, predictive modeling, and antibody engineering.

First Quarter 2024 Financial Results:

- **Cash Position:** Cash and cash equivalents were $189.4 million as of March 31, 2024.

- **Projected 2024 Year-End Cash Position:** Based on current operating plans, Invivyd expects to end 2024 with at least $75 million in cash and cash equivalents, based on anticipated 2024 net product revenue of $150 million to $200 million and recent resource realignment. Invivyd is maintaining its existing guidance, although the previously issued guidance was based on PEMGARDA being authorized for PrEP of COVID-19 in certain immunocompromised people and did not contemplate any potential sales for COVID-19 treatment, if authorized, or inventory build that may be required to deliver medicine timely to patients in need.

- **Research & Development (R&D) Expenses (including In-Process R&D):** R&D expenses were $31.2 million for the quarter ended March 31, 2024, compared to $28.0 million for the comparable period of 2023. This increase is primarily attributable to an increase in commercial manufacturing costs of PEMGARDA and an increase in clinical trial costs related to the ongoing monitoring of our CANOPY Phase 3 clinical trial.

- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $14.9 million for the quarter ended March 31, 2024, compared to $11.0 million for the comparable period of 2023. This increase is primarily attributable to an increase in personnel-related costs and commercial costs driven by the preparation for launch of PEMGARDA.

- **Net Loss and Net Loss per Share:** Net loss was $43.5 million for the quarter ended March 31, 2024, compared to $35.3 million for the comparable period in 2023. Basic and diluted net loss per share was $0.38 for the quarter ended March 31, 2024, compared to $0.32 for the comparable period in 2023.

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 a global Phase 2/3 clinical trial for the prevention and treatment 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. 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 ≥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. 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. 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 a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, 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 address 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, PEMGARDA as a mAb for COVID-19 PrEP in certain adults and adolescents with moderate-to-severe immune compromise; the company's plans and expectations related to the commercialization of PEMGARDA; the company's intention to pursue a rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain immunocompromised people; the company's anticipated submission of a COVID-19 treatment EUA request to the FDA for pemivibart, and the timing thereof; the company's research and clinical development efforts, and the timing thereof; the potential of VYD222 for clinical protection from symptomatic COVID-19 based on interim exploratory data from the CANOPY Phase 3 clinical trial; 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 advance into clinical development; the future of the COVID-19 landscape; the company's belief that its innovative engine can deliver meaningful product-level advancements with associated medical and economic value creation; the company's anticipated 2024 net product revenue and projected 2024 year-end cash position; the company's commitment to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; the design of the company's INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; 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 for COVID-19 PrEP in certain adults and adolescents with moderate-to-severe immune compromise will remain in effect and whether such EUA is revoked or revised by the FDA; the company's ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; the company's ability to effectively utilize an immunobridging pathway to potential EUA for pemivibart for COVID-19 treatment in certain immunocompromised people; whether the company is able to successfully submit a COVID-19 treatment EUA request to the FDA, and the timing, scope and outcome of any such EUA request; uncertainties related to the regulatory authorization or approval process; changes in the regulatory environment; the timing and progress of the company's discovery, preclinical and clinical development activities; 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 deliver meaningful product-level advancements with associated medical and economic value creation; the company's ability to leverage its INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; any litigation and other proceedings or government investigations relating to the company; the company's ability to continue as a going concern; the company's ability to optimize operating expenses; 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 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 189,388	$ 200,641
Inventory	109	—
Prepaid expenses and other current assets	20,386	24,240
Total current assets	209,883	224,881
Property and equipment, net	1,901	1,896
Operating lease right-of-use assets	1,827	2,229
Other non-current assets	1,857	175
Total assets	$ 215,468	$ 229,181
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,168	$ 7,953
Accrued expenses	34,003	40,860
Operating lease liabilities, current	1,134	1,443
Other current liability	40	35
Total current liabilities	36,345	50,291
Operating lease liabilities, non-current	625	722
Other non-current liability	—	700
Total liabilities	36,970	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 March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,221,230 shares issued and outstanding at March 31, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	954,063	909,539
Accumulated other comprehensive loss	(12)	(13)
Accumulated deficit	(775,565)	(732,069)
Total stockholders' equity	178,498	177,468
Total liabilities, preferred stock and stockholders' equity	$ 215,468	$ 229,181

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

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Operating expenses:		
Research and development[1]	$ 31,160	$ 27,201
Acquired in-process research and development[2]	—	825
Selling, general and administrative	14,929	11,045
Total operating expenses	46,089	39,071
Loss from operations	(46,089)	(39,071)
Other income:		
Other income, net	2,593	3,750
Total other income, net	2,593	3,750
Net loss	(43,496)	(35,321)
Other comprehensive income (loss)		
Unrealized gain on available-for-sale securities, net of tax	1	157
Comprehensive loss	$ (43,495)	$ (35,164)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.32)
Weighted-average common shares outstanding, basic and diluted	115,618,209	108,785,519

(1) Includes related-party amounts of $1,135 and $2,960 for the three months ended March 31, 2024 and 2023, respectively.
(2) Includes related-party amounts of $0 and $375 for the three months ended March 31, 2024 and 2023, respectively.