Invivyd Reports Second Quarter 2024 Financial Results and Recent Business Highlights

August 14, 2024

- *PEMGARDA™ launched commercially in Q2 2024 with $2.3 million of net product revenue*
- *Notable acceleration of commercial results in early Q3 2024, with the anticipated peak fall/winter respiratory virus season approaching*
- *New commercial leadership with Chief Commercial Officer, Tim Lee, an experienced biopharmaceutical leader with demonstrated commercial success*
- *Achieved Medicare and Medicaid coverage, rapid growth in commercial coverage across national and regional plans, and strong growth in infusion center utilization*
- *Submitted Emergency Use Authorization (EUA) amendment request to U.S. FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients*
- *Next generation molecule VYD2311 first-in-human clinical trial dosing scheduled to begin late August*
- *Ended Q2 2024 with cash and cash equivalents of $147.9 million*
- *Management to host conference call today at 8:30AM ET*

WALTHAM, Mass., Aug. 14, 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 June 30, 2024, and recent business highlights.

Shortly after the PEMGARDA Emergency Use Authorization (EUA) was issued by the U.S. Food and Drug Administration (FDA) for pre-exposure prophylaxis (PrEP) of COVID-19 in certain immunocompromised patients, Invivyd transitioned its commercial strategy to reflect the novel features of a newly commercial COVID-19 PrEP antibody marketplace. This commercial transition was designed to increase the company's capabilities and accelerate awareness and education about PEMGARDA across multiple stakeholders in the field including healthcare professionals (HCPs), academic and major community medical institutions, and high-volume infusion centers. Under new commercial leadership, the company has onboarded multiple, highly experienced biopharmaceutical commercial leaders with an eye toward activating the marketplace in the coming respiratory virus season.

"Against the backdrop of rising, persistent COVID-19 disease, we are pleased with our progress in the quarter establishing a robust infrastructure to support PEMGARDA demand, access and utilization. We believe our early revenues reflect just the beginning of a unique, fast growing, medically critical prophylactic category in infectious disease. As we enter the peak fall/winter respiratory virus season, we aim to substantially increase PEMGARDA awareness and activation among HCPs, institutions, and vulnerable populations. Our expectation is that our ongoing commercial work can build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules that may offer step changes in patient- and system-friendliness," said Marc Elia, Chairperson of the Invivyd Board of Directors.

In addition, Invivyd expects to initiate in late August dosing a first-in-human clinical trial for VYD2311, a next generation anti-RBD monoclonal antibody (mAb) with substantially increased measured in vitro potency to date and other potentially favorable biophysical properties. While Invivyd has secured more than 100,000 total doses of PEMGARDA, expected potency and associated potential improvements to dose may result in substantially greater commercial quantities of VYD2311 should the molecule achieve regulatory authorization.

"Over two months at Invivyd, my appreciation for the company's unique technology platform and ability for PEMGARDA to address the significant COVID-19 unmet need for certain immunocompromised people has grown tremendously," said Tim Lee, Chief Commercial Officer of Invivyd. "We are excited about the positive commercial momentum we've seen, doubling available infusion sites from the end of May to the end of June, and again doubling from the end of June to the end of last week. We are enthusiastic about our efforts to drive awareness of PEMGARDA in the HCP community, expand reach to additional infusion centers, and add new programs to support patients. The fall will be here in weeks and the team is ready for action."

Recent Business Highlights

- Reported PEMGARDA net product revenue of $2.3 million in the second quarter of 2024.
- Announced general alignment with the FDA on an immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19. This pathway, similar to the approach used to obtain EUA for PEMGARDA, provides for the establishment of a master, registrational clinical trial protocol that could obviate the need to submit a new protocol for the evaluation of each new mAb, streamlining the process required to evaluate new mAbs in compact clinical programs envisioned to include hundreds of participants (e.g., 300-600) exposed to a new mAb, with the specific number of exposures to be determined in consultation with the FDA.
- Expanded organizational expertise adding new Chief Commercial Officer and two new independent directors to the company's Board of Directors.
    - Timothy Lee joined in June 2024 as Invivyd's new Chief Commercial Officer. While at Amylyx, the commercial

organization generated $390 million in net product revenue in 14 months and was on track to be in the top five orphan drug launches. Tim also previously held key commercial leadership roles across a variety of life science companies including Biohaven Pharmaceuticals and Alexion Pharmaceuticals. Tim's appointment is intended to accelerate the addition of commercial capabilities associated with orphan medicines to the ongoing PEMGARDA commercial launch.
    - Srishti Gupta, M.D. joined the company's Board of Directors in May 2024 and is an experienced physician leader with over 20 years of experience in health and a global career spanning various sectors, including private, public, and non-profit.
    - Kevin F. McLaughlin joined the company's Board of Directors in May 2024 bringing with him more than 40 years of financial and operating management experience spanning the biotech, high-tech and education industries.
- Submitted EUA amendment request to FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients. The submission is based on immunobridging analyses of pemivibart versus comparator mAbs and safety data from the CANOPY Phase 3 clinical trial. The immunobridging pathway for COVID-19 treatment was previously aligned in principle with FDA, similar to the approach utilized for the EUA of PEMGARDA for PrEP of COVID-19 in certain immunocompromised patients granted in March 2024. If authorized, we anticipate PEMGARDA would be the only mAb available for both PrEP of moderate to severe COVID-19 and treatment of mild-to-moderate COVID-19 in certain immunocompromised patients.
- Invivyd was added to the Russell 2000® and Russell 3000® Indexes.

Recent Pipeline Highlights

- Announced antiviral activity of VYD222 (pemivibart) and VYD2311 against SARS-CoV-2 KP.1.1 FLiRT and KP.3 variants: Initial data demonstrated continued in vitro neutralization activity of VYD222 and VYD2311 in pseudovirus assays designed to represent the predominant emerging variants of SARS-CoV-2, including the KP.1.1 FLiRT and KP.3 variants. FLiRT variants are predicted to become the most dominant SARS-CoV-2 lineage nationally in the near term and accounted for over half of circulating SARS-CoV-2 variant sequences for the two-week period ending June 8, 2024, with KP.3 prevalence increasing per the Centers for Disease Control and Prevention.

Second Quarter 2024 Financial Results:

- Revenue: Reported $2.3 million of net product revenue following the launch of PEMGARDA in the second quarter of 2024.
- Cash Position: Cash and cash equivalents were $147.9 million as of June 30, 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 moderate to severe 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 $30.3 million for the quarter ended June 30, 2024, compared to $43.8 million for the comparable period of 2023. This decrease is primarily attributable to a decrease in commercial manufacturing costs of PEMGARDA and partially offset by an increase in VYD2311 manufacturing.
- Selling, General & Administrative (SG&A) Expenses: SG&A expenses were $21.1 million for the quarter ended June 30, 2024, compared to $10.1 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 launch of PEMGARDA.
- Net Loss and Net Loss per Share: Net loss was $47.2 million for the quarter ended June 30, 2024, compared to $50.2 million for the comparable period in 2023. Basic and diluted net loss per share was $0.40 for the quarter ended June 30, 2024, compared to $0.46 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 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 immunocompromised patients; the company's plans, strategies, goals and expectations related to the commercialization of PEMGARDA; the company's EUA amendment request to the FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients; the company's general alignment with the FDA on a immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19, including the company's beliefs regarding the potential benefits of utilizing such pathway; the company's research and clinical development efforts, and the timing thereof, including with respect to a first-in-human clinical trial for VYD2311; the company's expectation that PEMGARDA is the first mAb in a planned series of innovative antibody candidates; the company's aim to build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules; the future of the COVID-19 landscape, including the anticipated fall/winter respiratory virus season; 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 immunocompromised patients 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 outcome of the company's EUA amendment request for PEMGARDA for treatment of mild-to-moderate COVID-19 in certain immunocompromised patients, and the timing thereof; 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 any product candidate following regulatory authorization or approval; 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; the company's reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its clinical trials; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; 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 can obtain and maintain third-party coverage and

adequate reimbursement for PEMGARDA or any other product candidate; the company's ability to build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules; 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 legal proceedings or 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, 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 147,881	$ 200,641
Accounts receivable, net	2,888	—
Inventory, net	5,333	—
Prepaid expenses and other current assets	16,909	24,240
Total current assets	173,011	224,881
Property and equipment, net	1,772	1,896
Operating lease right-of-use assets	782	2,229
Other non-current assets	1,781	175
Total assets	$ 177,346	$ 229,181
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,499	$ 7,953
Accrued expenses	26,822	40,860
Deferred revenue	1,681	—
Operating lease liabilities, current	681	1,443
Other current liability	21	35
Total current liabilities	36,704	50,291
Operating lease liabilities, non-current	—	722
Other non-current liability	—	700
Total liabilities	36,704	51,713
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—

Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,442,635 shares issued and outstanding at June 30, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	963,454	909,539
Accumulated other comprehensive loss	(12)	(13)
Accumulated deficit	(822,812)	(732,069)
Total stockholders' equity	140,642	177,468
Total liabilities, preferred stock and stockholders' equity	$ 177,346	$ 229,181

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

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Revenue:				
Product revenue, net	$ 2,264	$ —	$ 2,264	$ —
Total revenue	2,264	—	2,264	—
Operating costs and expenses:				
Cost of product revenue	88	—	88	—
Research and development [1]	30,334	43,618	61,494	70,819
Acquired in-process research and development [2]	—	150	—	975
Selling, general and administrative	21,089	10,107	36,018	21,152
Total operating costs and expenses	51,511	53,875	97,600	92,946
Loss from operations	(49,247)	(53,875)	(95,336)	(92,946)
Other income:				
Other income, net	2,000	3,647	4,593	7,397
Total other income, net	2,000	3,647	4,593	7,397
Net loss	(47,247)	(50,228)	(90,743)	(85,549)
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities, net of tax	—	93	1	250
Comprehensive loss	$ (47,247)	$ (50,135)	$ (90,742)	$ (85,299)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.46)	$ (0.77)	$ (0.78)
Weighted-average common shares outstanding, basic and diluted	119,362,670	109,450,071	117,490,439	109,119,630

(1) Includes related-party amounts of $1,131 and $2,266 for the three and six months ended June 30, 2024, respectively, and $2,258 and $5,218 for the three and six months ended June 30, 2023, respectively.
(2) Includes no related-party amounts for both the three and six months ended June 30, 2024, and $0 and $375 for the three and six months ended June 30, 2023, respectively.