Invivyd Reports Preliminary Third Quarter 2024 Results, Withdraws Prior Financial Guidance, and Targets Near-Term Profitability

October 29, 2024

- *Preliminary Q3 2024 PEMGARDA™ (pemivibart) net product revenue of $9.3 million; Invivyd ended Q3 2024 with approximately $107 million in cash and cash equivalents*
- *Expects to finish 2024 with $65 million or more in cash and cash equivalents*
- *Withdraws formal revenue guidance due to recent growth headwind from U.S. FDA's late-Q3 2024 warning on potential for substantially reduced activity of pemivibart through the PEMGARDA Fact Sheet and other media based on contested, third-party, non-peer-reviewed, non-reproducible, virologic activity data from a non-pemivibart antibody*
- *Targets near-term (1H 2025) profitability with existing cash and cash equivalents, anticipated growth of net product revenue, and various operational efficiency improvements*
- *Further update to be provided on Q3 2024 earnings call*

WALTHAM, Mass., Oct. 29, 2024 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today reported preliminary third quarter (Q3) 2024 financial results and an update to prior financial guidance.

Invivyd previously guided to $150-200 million in PEMGARDA™ (pemivibart) net product revenue in 2024 and expected to finish the year with $75 million or more in cash and cash equivalents. This previous guidance did not contemplate the impact on product growth at the most critical moment in Invivyd's financial year arising from the U.S. Food and Drug Administration (FDA) updating the PEMGARDA Fact Sheet for Healthcare Providers (HCPs) (Fact Sheet) in late-Q3 2024 to include a link to contested, third-party, non-peer-reviewed, non-reproducible, virologic activity data from a non-pemivibart antibody and convey that, based on such data, PEMGARDA may have substantially reduced susceptibility to the currently circulating SARS-CoV-2 variants (i.e., KP.3.1.1). Invivyd previously communicated this unfortunate and unnecessary action that created doubt regarding the antiviral activity of PEMGARDA against current circulating variants. This resulted in confusion in the HCP and vulnerable population communities and an uncertainty regarding the pursuit of additional options for protection against COVID-19 for certain immunocompromised people.

Though not at previously anticipated rates, PEMGARDA net product revenue grew through the third quarter and continues to grow. Now with a corrected PEMGARDA Fact Sheet removing the aforementioned data reference and including authentic pemivibart data reflecting ongoing neutralization activity against currently circulating variants tested in line with prior variants represented in the CANOPY Phase 3 clinical trial, Invivyd expects ongoing commercial optimization to drive growth.

Based on currently available information, the company is announcing preliminary Q3 2024 PEMGARDA net product revenue of $9.3 million. The company estimates that Invivyd ended Q3 2024 with approximately $107 million in cash and equivalents, and, with anticipated growth of net product revenue and various operational efficiencies underway, believes existing cash and cash equivalents will be sufficient to fund operations through profitability. These estimates are preliminary and are subject to change upon completion of the company's financial closing procedures for Q3 2024, and finalization of the unaudited interim condensed consolidated financial statements.

"At the Infectious Disease (ID) Week meeting in mid-October, we were thrilled to engage with healthcare professionals in an effort to alleviate any remaining confusion regarding the antiviral activity of PEMGARDA, and to share the positive, CANOPY clinical trial data and the safety data included in the Fact Sheet," said Tim Lee, Chief Commercial Officer of Invivyd. "Today's announcement of a new exploratory analysis from the CANOPY Phase 3 clinical trial showing that PEMGARDA provided substantial protection from symptomatic COVID-19 versus placebo in immunocompetent participants through month twelve, absent additional dosing and with minimal drug concentration, only amplifies our confidence about re-accelerating our product growth in COVID-19 pre-exposure prophylaxis (PreP) in the appropriate immunocompromised population. It also reflects our potential to deliver meaningful protection to certain immunocompromised adults and adolescents who may not mount a strong enough immune response to vaccines alone. This population must not be forgotten."

"We continue to feel confident about the demand for PEMGARDA and our ability to return to strong product growth despite the unnecessary headwinds inflicted by the Agency," said Marc Elia, Chairman of the Invivyd Board of Directors. "While we are engaged in discussions with key leaders at the FDA, it is clear that we must also focus on what matters most: the vulnerable populations who deserve more protection against this devastating virus, especially as we enter the winter season where many individuals hope to gather with friends and family. Our confidence in the ultimate commercial potential of PEMGARDA is unchanged."

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.

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. 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 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. 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.

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," "preliminary," "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 preliminary third quarter 2024 results; the company's expectation regarding its cash and cash equivalents balance at the end of 2024; the company's aim for near-term profitability, expectations regarding the commercialization of PEMGARDA, and plans for operational efficiency improvements; the company's belief that its existing cash and cash equivalents, and anticipated growth of net product revenue and various operational efficiencies, will be sufficient to fund operations through profitability; the company's expectations regarding its interactions with the FDA; the company's ongoing research and clinical development activities, as well as future potential research and clinical development efforts; the company's expectations regarding potential PEMGARDA product growth in the appropriate immunocompromised population, and the company's potential to deliver meaningful protection to certain immunocompromised adults and adolescents who may not mount a strong enough immune response to vaccines alone; the company's belief in the ultimate commercial potential of PEMGARDA; 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 devotion 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; the company's business strategies and objectives; 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 or future sales and revenue generated by PEMGARDA; uncertainties regarding the potential advantages from the company's planned operational efficiency improvements; the timing, progress and results of the company's discovery, preclinical and clinical development activities; 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; 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; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; 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 pemivibart 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; 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 company's ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of the company's product candidates; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; changes in the regulatory environment; changes in expected or existing competition; the complexities of manufacturing mAb therapies; 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; any change in the preliminary estimates of the company's third quarter 2024 results upon completion of the company's financial closing procedures, and finalization of the unaudited interim condensed consolidated financial statements; 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 June 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.

Contacts:
Media Relations
(781) 208-1747
media@invivyd.com

Investor Relations
(781) 208-1747
investors@invivyd.com