Invivyd Reports Preliminary Fourth Quarter 2025 Revenue and Recent Business Highlights

January 8, 2026

- *Preliminary Q4 2025 PEMGARDA® (pemivibart) net product revenue of $17.2 million, representing 25% growth year-over-year and 31% growth quarter-over-quarter*
- *Preliminary ending 2025 cash and cash equivalents of $226.7 million after raising over $200 million from financing transactions in 2H 2025*
- *Announced initiation of DECLARATION Phase 3 pivotal clinical trial of vaccine-alternative antibody VYD2311 to prevent COVID, with top-line data expected mid-2026; Fast Track designation for VYD2311 granted by FDA in December 2025*
- *Potential best-in-class RSV antibody VBY329 nominated for preclinical development*
- *Preclinical measles mAb candidate selection targeted for 1H 2026 for treatment and prevention of measles*
- *Further updates to be provided in conjunction with Form 10-K filing and upcoming ordinary quarterly reporting*

NEW HAVEN, Conn., Jan. 08, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced preliminary fourth quarter (Q4) revenue and recent business highlights.

“We are pleased by strong top-line revenue growth of PEMGARDA® (pemivibart), which we believe is attributable to our commercial execution and the fundamental appeal of monoclonal antibody prophylaxis even in the face of declining COVID vaccination trends. We are actively preparing for the potential commercial launch of VYD2311, an accessible vaccine-alternative to prevent COVID, which, if approved, could represent a step-change from PEMGARDA, a specialty medicine for the immunocompromised,” noted Bill Duke, Chief Financial Officer of Invivyd. “With a strong balance sheet bolstered by our recent capital raises, we are well-positioned to support the DECLARATION pivotal clinical trial and VYD2311 commercial launch, if approved, and look forward to trial enrollment during the anticipated upcoming peak season of COVID infections.”

“2026 will be a critical year for Invivyd and vulnerable people seeking relief from the continued burden of COVID as we execute our pivotal program and attempt to institute a new standard of care for COVID prophylaxis,” commented Marc Elia, Chairman of the Invivyd Board of Directors. “The company is also rapidly expanding its pipeline of monoclonal antibodies that can treat critical infectious diseases or provide important alternatives and complements to vaccination for the most vulnerable Americans. We are looking forward to providing a host of updates in the coming year across all of our programs that we believe can drive substantial medical and shareholder value creation.”

Recent Business Highlights

- **Clinical & Regulatory Developments**
    - In December 2025, Invivyd announced the initiation of its DECLARATION clinical trial.
        - DECLARATION is a Phase 3, randomized, placebo-controlled clinical trial to evaluate the safety and efficacy of VYD2311 in the prevention of COVID versus placebo, at three months, from a single intramuscular (IM) dose, with protection beyond three months anticipated.
        - A second arm will evaluate monthly IM doses versus placebo to demonstrate the safety and efficacy of more frequent dosing to support individual choice should at-risk persons seek periodic extra protection from COVID.
        - The primary endpoint of DECLARATION is the reduction of PCR-confirmed symptomatic COVID incidence versus placebo; total expected enrollment of 1770 people across all three arms.
        - DECLARATION is part of Invivyd’s REVOLUTION clinical program aimed at establishing monoclonal antibody prophylaxis for prevention of COVID; top-line data are expected mid-2026.
        - In the Phase 1/2 study, IM administered VYD2311, at 4 times the planned dose in DECLARATION, was well tolerated, with all adverse events (AEs) considered mild to moderate in severity with no serious or severe AEs reported; all AEs, including headache and injection site pain, were deemed unrelated to study drug.
    - In December 2025, Invivyd announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for VYD2311.
        - Fast Track is a process that enables the FDA to expedite the development and review of new drugs that address a serious or life-threatening condition and fill an unmet medical need. If relevant criteria are met,

programs with Fast Track designation can become eligible for priority review and rolling Biologics License Application (BLA) submission, which can reduce the timelines associated with regulatory action.
- VYD2311 was granted Fast Track designation by the FDA for the prevention of COVID in individuals with underlying risk factors for severe COVID.

- **Pipeline Expansion**
    - In November 2025, Invivyd announced selection of a potential best-in-class Respiratory Syncytial Virus (RSV) antibody candidate VBY329.
        - VBY329 is designed for the prevention of RSV infections in newborns, infants, and children, and results from Invivyd's proprietary antibody discovery technology platform.
        - VBY329 meets Invivyd's target profile of higher potency and improved barrier to resistance compared to standard of care RSV medicines, as assessed *in vitro*:
            - Antiviral potency 1.5-fold greater on average than nirsevimab and 1.2-fold greater on average than clesrovimab against established authentic RSV strains representing circulating variants.
            - Resistance profile compared to nirsevimab reflects up to approximately 500-fold greater enhanced neutralization activity against RSV F protein variants resistant to nirsevimab in pseudovirus assays that reflect contemporary, circulating, nirsevimab-resistant variants associated with various RSV A & B strains.
            - Half-life extension technology and biophysical properties expected to confer equivalent or greater *in vivo* half-life compared to nirsevimab and clesrovimab, which, along with higher potency, may expand the protective window of VBY329 compared to standard of care.
        - Invivyd expects to advance VBY329 toward IND readiness in 2H 2026 for development in pediatric RSV prophylaxis, a blockbuster pharmaceutical market in 2024, expected to grow to $3-$4 billion in annual revenues globally by 2030.
        - Additional Invivyd discovery efforts focus on ultra-long half-life RSV antibodies with the aim of a candidate RSV vaccine-alternative for elderly and immunocompromised populations.
    - Invivyd has initiated discovery efforts to assess pipeline expansion beyond SARS-CoV-2 and RSV, and anticipates providing an update on selection of a preclinical measles mAb candidate in the first half of 2026.

- **Corporate and Financial Updates**
    - Based on currently available information, the company is announcing preliminary Q4 2025 PEMGARDA® (pemivibart) net product revenue of $17.2 million, representing a 25% increase over Q4 2024 net product revenue of $13.8 million and a 31% increase over Q3 2025 net product revenue of $13.1 million.
    - In the second half of 2025, Invivyd secured over $200 million of capital, resulting in a strong balance sheet with anticipated 2025 ending cash and cash equivalents of $226.7 million.
    - Total shares of common stock outstanding as of December 31, 2025 were 281,987,033, excluding pre-funded warrants totaling 27,342,442 which will be included in shares outstanding utilized to calculate earnings per share.
    - Invivyd's current cash and cash equivalents are anticipated to be sufficient to support the DECLARATION pivotal study, commercial preparedness for the potential launch of VYD2311, continued research and development related to its pipeline programs such as RSV and measles, continued advancement of the Spike Protein Elimination and Recovery (SPEAR) Study Group efforts related to assessing the effects of monoclonal antibody therapy for Long COVID and COVID-19 Post-Vaccination Syndrome, and for working capital and other general corporate purposes.

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, LP.8.1 and XFG. 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, treatment of Long COVID, 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 DECLARATION
DECLARATION is a Phase 3, randomized, triple-blind, placebo-controlled trial to evaluate VYD2311 efficacy and safety in prevention of symptomatic COVID in a broad population of participants including adults and adolescents both with and without risk factors for progression to severe COVID-19, at three months. Participants will receive either a single dose or a monthly dose of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is expected to be 1770 participants.

About VBY329
VBY329 is a novel, potential best-in-class monoclonal antibody (mAb) candidate being developed to prevent Respiratory Syncytial Virus (RSV) among neonates, infants, and children.

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 Statement Regarding Preliminary Financial Results
The preliminary financial results for the fourth quarter 2025 included in this press release are preliminary, unaudited and subject to completion. The preliminary financial data included in this press release has been prepared by, and is the responsibility of, the company's management. PricewaterhouseCoopers LLP, the company's independent registered public accounting firm, has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto. Such preliminary results are subject to the finalization of quarter- and year-end financial and accounting procedures, and actual results may vary from the preliminary results presented herein. The preliminary financial results represent management's estimates that

constitute forward-looking statements subject to certain risks and uncertainties.

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,” “plans,” “potential,” “predicts,” “projects,” “future” and “target” 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 fourth quarter financial results; plans related to the company’s research and development activities, and the timing and potential results thereof; expectations regarding the company’s clinical trial designs and enrollment, regulatory pathway, product profile, indication and administration paradigm for VYD2311, as well as preparations for the potential commercial launch of VYD2311, if approved; the potential benefits of Fast Track designation; expectations regarding the COVID landscape and peak season of COVID infections; the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain immunocompromised persons; 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; pipeline expansion beyond SARS-CoV-2, including potential targets such as RSV and measles, and expected announcements related thereto; the potential of VBY329 as a novel, potential best-in-class RSV mAb candidate; the company’s business strategies and objectives, and ability to execute on them; expectations about the market size and opportunity for the company’s product candidates; the company’s beliefs that it can drive substantial medical and shareholder value creation; the company’s future prospects; 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 any authorized or approved product; how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether such 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 any authorized or approved product; 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; whether or not any preclinical candidate identified by the company is determined to be suitable for clinical development; the timing, progress and results of the company’s discovery, preclinical and clinical development activities; clinical trial site activation or enrollment rates; unexpected safety or efficacy data observed during preclinical studies or clinical trials; 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 ability to generate the data needed to support a potential BLA submission for VYD2311; 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 epitopes that pemivibart and VYD2311 target remain structurally intact and 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; the company’s reliance on third parties; complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; any change in the preliminary estimates of the company’s Q4 2025 results upon completion of the company’s financial closing controls and procedures, and finalization of the 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, 2024 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, 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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