Invivyd Announces Continued Neutralizing Activity of PEMGARDA™ (pemivibart) Against Currently Dominant SARS-CoV-2 Variant LP.8.1

March 5, 2025

- *New in vitro neutralization data show continued, consistent neutralizing activity of PEMGARDA™ (pemivibart) against LP.8.1*
- *Centers for Disease Control reports LP.8.1, XEC and KP.3.1.1 together constitute the majority of current national SARS-CoV-2 variants; current dominant variants are all susceptible to PEMGARDA*
- *Pemivibart antiviral activity remains within the range of expected assay variability since Omicron BA.2; affirms structural biology within Invivyd's unique technology and reflects consistently stable epitope for pemivibart*
- *VYD2311 also demonstrates stable epitope and clinically meaningful in vitro neutralization against LP.8.1*
- *Data provided to U.S. FDA, with update to PEMGARDA Fact Sheet for Healthcare Providers anticipated*

WALTHAM, Mass., March 05, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced positive, continued, clinically meaningful in vitro neutralization data for PEMGARDA™ (pemivibart) against the currently dominant LP.8.1 variant of SARS-CoV-2. Notably, and consistent with all dominant variants for the past three years, LP.8.1 did not generate any meaningful change to the neutralization activity of pemivibart or VYD2311, the company's next generation COVID-19 monoclonal antibody (mAb) candidate, as the epitope these mAbs target remains structurally intact. PEMGARDA (pemivibart) is authorized in the U.S. for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients.

Invivyd has demonstrated positive PEMGARDA neutralization activity against KP.3.1.1, XEC, and LP.8.1, estimated to be the three most dominant variants currently circulating in the U.S. according to the latest Centers for Disease Control (CDC) COVID Data Tracker update. Further, the company estimates that every clinical variant reported in the CDC COVID Data Tracker since the Omicron BA.2 lineage has been susceptible to pemivibart even if untested due to the consistent structural integrity of the pemivibart epitope. Therefore, Invivyd does not anticipate any meaningful change to pemivibart neutralization activity, aside from expected normal quantitative variation in assay output, for the foreseeable future if the epitope pemivibart targets remains structurally intact, as it has since Omicron BA.2.

"Pemivibart neutralization activity has been remarkably stable in the face of constant SARS-CoV-2 evolution. Scientifically, the ongoing in vitro neutralization activity as reported for pemivibart is a demonstration of our foundational hypothesis: that virus variants with the structural properties required for fitness and broad infectivity among humans will also likely be susceptible to pemivibart due to our intended accommodation of ACE2 binding and immune evasion in our molecular design and selection criteria," commented Robert Allen, Ph.D., Chief Scientific Officer of Invivyd. "Invivyd's focus on high resistance barrier molecules and our unique ability to design monoclonal antibodies with evolution in mind has continued with VYD2311. We look forward to improving the properties of Invivyd's medicines as we aim to scale them to larger populations rapidly."

"Vulnerable patient populations such as cancer patients, those who have had an organ transplant, those with an immunodeficiency, and individuals on immunosuppressive therapies are at risk of the short-term and long-term systemic damage COVID-19 continues to pose today," commented Timothy Lee, Chief Commercial Officer of Invivyd. "Vaccination for these patients, despite serial boosts, has offered modest, short-term, and waning protection; per data provided by the Advisory Committee on Immunization Practices (ACIP), vaccine efficacy is reduced for this population to nearly 0% after four to six months. Further, data presented by ACIP showed that immunocompromised people with COVID-19 are two times more likely to be in the Intensive Care Unit (ICU), at three times greater risk to require invasive mechanical ventilation, and four times more likely to die in the hospital than the general population. Invivyd's proprietary integrated technology platform has continued to allow us to assess, monitor, develop, and adapt to create best in class antibodies to serve these vulnerable patient populations."

Data showing continued in vitro neutralizing activity of PEMGARDA™ (pemivibart) against LP.8.1 have been provided to the FDA, with an update to the PEMGARDA Fact Sheet for Healthcare Providers anticipated.

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,” “hypothesizes,” “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, 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 major SARS-CoV-2 variants; anticipated update to the PEMGARDA Fact Sheet for Healthcare Providers; the company’s expectations regarding the neutralization activity of pemivibart

for the foreseeable future; the company's beliefs about the stability of the epitope targeted by pemivibart and VYD2311; the company's hypothesis that SARS-CoV-2 variants with the structural properties required for fitness and broad infectivity among humans will also likely be susceptible to pemivibart; the likely risks of COVID-19 for certain vulnerable patient populations; the potential of Invivyd's proprietary integrated technology platform to assess, monitor, develop, and adapt to create best in class antibodies to serve vulnerable patient populations; the potential of PEMGARDA as a mAb for PrEP of COVID-19 in certain adults and adolescents who have moderate-to-severe immune compromise; the potential of the company to improve on the properties of its medicines as it aims to scale them to larger populations rapidly; the potential of VYD2311 as a novel mAb candidate and the potential VYD2311 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: the timing and progress 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; 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 SARS-CoV-2 variants with the structural properties required for fitness and broad infectivity among humans are also susceptible to pemivibart; 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 maintain and expand 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 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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