Invivyd Announces Publication of Landmark CANOPY Phase 3 PEMGARDA® (pemivibart) Clinical Trial; Results Underscore Strong Efficacy of Monoclonal Antibodies in Preventing COVID-19 in a Modern U.S. Population Against Relevant, Immune-Evasive SARS-CoV-2 Virus

May 27, 2025

- *CANOPY assessed pemivibart safety and tolerability, antiviral immunobridging, and exploratory efficacy against COVID-19, and is the only clinical trial of an authorized or approved COVID-19 monoclonal antibody or vaccine with placebo-controlled clinical efficacy data in a contemporary, seropositive U.S. population and facing modern, immune-evasive SARS-CoV-2 viruses*
- *Pemivibart demonstrated strong protection from symptomatic COVID-19 versus placebo during the 6-month on-drug period (84% relative risk reduction; nominal p <0.0001)*
- *Safety and tolerability profile of pemivibart over the 12-month clinical trial period in immunocompromised and immunocompetent persons as previously disclosed*
- *Pemivibart's ongoing, antiviral activity to date against evolving SARS-CoV-2 virus remains within the range of expected assay variability, affirming Invivyd's technology and pemivibart's unique binding to a highly conserved, stable epitope*

WALTHAM, Mass., May 27, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that results from its CANOPY Phase 3 clinical trial of pemivibart have been published online as an Advance Article in the peer-reviewed journal *Clinical Infectious Diseases (CID)*, available here. The publication, titled "Safety and Efficacy of Pemivibart, a Long-Acting Monoclonal Antibody, for Prevention of Symptomatic COVID-19: Interim Results From a Phase 3 Randomized Clinical Trial (CANOPY)" highlights attractive safety, substantial clinical antiviral activity, the immunobridge between calculated serum virus neutralizing antibody (sVNA) titers and pemivibart and historical clinical efficacy data, and nominally statistically significant and clinically meaningful efficacy of pemivibart versus placebo in a contemporary U.S. population facing, immune-evasive Omicron SARS-CoV-2 viruses.

The CANOPY Phase 3 clinical trial randomized 788 adult participants across 18 sites in two cohorts: A) immunocompromised and B) people at risk of contracting SARS-CoV-2 due to regular, unmasked face-to-face interactions in indoor settings, and met all primary and exploratory endpoints over a period of substantial transmission of COVID-19 in the U.S. from September 2023 until September 2024. The antiviral activity measured by calculated sVNA titers in CANOPY Cohort A immunocompromised persons supported the emergency use authorization (EUA) of PEMGARDA® (pemivibart) granted by the U.S. Food and Drug Administration (FDA) for pre-exposure prophylaxis (PreP) of COVID-19 in certain moderate-to-severe immunocompromised patients, while the exploratory, placebo-controlled, clinical efficacy results of CANOPY Cohort B provide additional support that PEMGARDA may be effective for PreP of COVID-19.

Pemivibart was generally well-tolerated, and most treatment-emergent adverse events in both CANOPY cohorts were classified as mild/moderate in severity. The most common study drug-related adverse events were infusion-related reactions (Cohort A: 11/306 [3.6%]; Cohort B: 7/317 [2.2%, pemivibart] and 0/160 [placebo]). Of 623 participants who received pemivibart, 4 (0.6%) experienced anaphylactic reactions (2 serious). The incidence of infusion related reactions (IRRs) and hypersensitivity reactions in CANOPY was consistent with the range (<0.1%-13%) observed in non-immunocompromised participants who received intravenous monoclonal antibodies in previous clinical trials for COVID-19 prophylaxis/treatment.

CANOPY is the first and only clinical trial of an authorized or approved COVID-19 monoclonal antibody or vaccine with a placebo-controlled, randomized cohort, conducted in a contemporary U.S. population of immunologically relevant individuals already seropositive, or immunologically experienced, at baseline from prior COVID-19 infection or vaccination, and who faced contemporary, Omicron-lineage immunologically-evasive virus. The randomized, placebo-controlled cohort in the CANOPY trial included ordinary Americans at risk of symptomatic SARS-CoV-2 from taking regular, unmasked, face-to-face meetings, and generated strong protection of an 84% relative risk reduction in the incidence of PCR-confirmed symptomatic COVID-19 disease compared to placebo, at six months.

"Most people, including clinicians and policy makers, are not aware that COVID-19 killed more Americans last year than breast cancer or car accidents," said Cameron R. Wolfe, MD, MPH, Professor of Medicine, Transplant Infectious Disease at Duke University. "There is still an unacceptable burden of severe sickness and hospitalization, not to mention Long COVID, all of which is borne disproportionately by immunocompromised persons. The full publication of the CANOPY Phase 3 clinical trial of pemivibart, including the clinical efficacy demonstrated by pemivibart in the exploratory Cohort B portion of the trial in a contemporary population and against contemporary virus, should make it very clear to clinicians that they can now attack the COVID-19 burden for immunocompromised patients directly through pre-exposure prophylaxis with a monoclonal antibody. I'm proud of the investigator team, grateful to CANOPY trial participants, and hopeful that the public health complex in the U.S. will take notice of these data and the role monoclonal antibodies should play with COVID-19 and other endemic viruses."

"We are proud to see our landmark study published in a leading peer-reviewed journal, and we remain impressed with the

clinically meaningful protection shown by pemivibart in exploratory efficacy analyses in a modern human population against relevant viruses," commented Marc Elia, Invivyd's Chairman of the Board. "This publication reaffirms our approach and supports our broader goal of educating the clinical community on the possibility of strong protection from COVID-19 through monoclonal antibodies, a more natural and equitable, additive form of immunity for modern humans who have already received multiple vaccines and boosts. As we innovate and work to bring newer, more scalable antibodies forward, we believe data from the CANOPY clinical trial substantiate the use of sVNA titers as a valid surrogate endpoint for COVID-19 prevention to expedite approval of novel Invivyd antibodies such as VYD2311. We expect to elaborate this possibility and the underlying data from CANOPY in a future forthcoming publication."

About CANOPY

The CANOPY Phase 3 clinical trial was designed to evaluate the safety and tolerability of pemivibart and to assess immunobridging from pemivibart to certain historical data from the company's previous Phase 2/3 clinical trial of adintrevimab (ADG20) for the prevention of symptomatic COVID-19 (EVADE). Additionally, there were pre-specified exploratory endpoints through three, six and twelve months to evaluate clinical efficacy of pemivibart compared to placebo in the prevention of RT-PCR-confirmed symptomatic COVID-19. The latest analysis from the Phase 3 CANOPY clinical trial included 365-day data. The CANOPY clinical trial enrolled participants in two cohorts: Cohort A was a single-arm, open-label trial in adults with moderate-to-severe immune compromise including complex underlying medical conditions. Cohort B was a randomized, placebo-controlled cohort that enrolled adults without moderate-to-severe immune compromise at risk of acquiring COVID-19 due to regular unmasked face-to-face interactions in indoor settings.

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," "intends," "potential," "predicts," "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 clinical development activities, as well as future potential research and clinical development efforts; beliefs about Invivyd's technology and expectations about pemivibart's unique binding to a highly conserved, stable epitope; the potential advantages and benefits of mAbs in a modern population against relevant, immune-evasive SARS-CoV-2 viruses; beliefs about the potential role that mAbs should play with COVID-19 and other endemic viruses; the potential use of sVNA titers as a valid surrogate endpoint for COVID-19 prevention to expedite approval of novel Invivyd antibodies such as VYD2311, and the company's plans to elaborate this possibility and the underlying data from CANOPY in a future forthcoming publication; 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 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; 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, 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 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; 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; the outcome of the company's engagement with regulators; changes in expected or existing competition; the complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; 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 the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

Contacts:

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

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