New Publication Demonstrates Variant-Agnostic Correlate of Protection from COVID-19 for Invivyd Monoclonal Antibody, Useful for Understanding of and Confidence in COVID-19 Antibodies

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- *"A Statistical Immune Correlates of Protection Model for Predicting Efficacy from Neutralizing Antibody Titers to Establish Immunobridging of Monoclonal Antibodies for Prevention of COVID-19" was published in Infectious Diseases and Therapy*
- *This peer-reviewed analysis describes the relationship between anti-COVID monoclonal antibody (mAb) levels in patient serum and demonstrated clinical protection from multiple Omicron-virus variants in a modern, COVID-endemic, seropositive population, adding to prior work demonstrating similar relationships from the pandemic era*
- *Model-derived estimates align with observed infection outcomes and external analyses including work with prior Invivyd and other COVID mAbs, supporting model validity and variant-agnostic protection from COVID across multiple Invivyd antibodies*
- *Analysis highlights the predictability of clinical efficacy from drugging stable epitopes, irrespective of SARS-CoV-2 virus variation outside drug epitope, and predicts meaningful protection at low overall monoclonal antibody levels*

NEW HAVEN, Conn., Feb. 24, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced a peer-reviewed publication by Invivyd that uses data from the recent CANOPY pivotal clinical trial of Invivyd's monoclonal antibody pemivibart to predict clinical protection levels from COVID purely from laboratory-determined serum monoclonal antibody activity levels, irrespective of virus variation. This newly published analysis builds on similar, earlier peer-reviewed analyses[1] demonstrating similar findings from pre-Omicron virus variants with a prior Invivyd antibody. Together these findings support a correlate of protection for Invivyd's COVID-directed monoclonal antibodies, a critical relationship for understanding antibody-mediated protection from COVID, and a potentially useful tool to support clinical decision making, COVID antibody regulation, and overall stewardship of public health.

"Our perspective at Invivyd from the beginning of the COVID pandemic through today is clear: we believe that once the safety of an Invivyd COVID monoclonal antibody that targets a stable epitope on the virus has been established, one can reliably estimate its ability to prevent COVID disease directly from its laboratory-assessed antiviral activity," said Robert Allen, Ph.D., Chief Scientific Officer at Invivyd. "This predictable phenomenon has been demonstrated to be consistent across an extraordinary swath of virus evolution and variation across all our work in COVID clinical trials, as well as earlier work from other companies and colleagues. As we continue to develop this field, our hope is that healthcare professionals, policymakers, and regulators will recognize the demonstrated consistent responsiveness of SARS-CoV-2 to our highly active monoclonal antibodies, irrespective of virus variation, which may enhance the development and use of new monoclonal antibody options for patients in need, if approved."

Michael Mina, M.D., Ph.D., former Harvard infectious disease epidemiologist, immunologist, and physician commented, "Peer-reviewed data like these are critical to advancing infectious disease prevention and control. This new work supports that Invivyd's COVID monoclonal antibodies can provide clinically meaningful protection that can be estimated directly from straightforward laboratory measurements, saving crucial time and resources, and improving human health. Importantly, the findings demonstrate robust protection even at relatively low antibody levels, a result that is both plausible and expected because it is consistent with normal human immune physiology, where antibodies confer benefit in proportion to their concentration and antiviral activity."

"By carefully quantifying this relationship between protection and their monoclonal antibody levels in the post-Omicron era, the study shows that clinical benefit can be assessed from easy to obtain laboratory data," continued Dr. Mina. "This could have important implications, including the potential to accelerate regulatory pathways without animal models or cumbersome trials, and to expand durable COVID-19 protection strategies beyond the current reliance on repeated annual vaccine boosting, which for various reasons has shown markedly declining uptake alongside declining durability of protection. New tools like accessible, durable, variant-agnostic, and highly effective monoclonals would be a welcomed addition to the arsenal against COVID-19 and other viruses, like RSV and measles."

The CANOPY Phase 3 clinical trial provided a contemporary opportunity to assess the clinical protection of Invivyd's monoclonal antibody pemivibart in reducing symptomatic COVID, and allowed the construction of a formal, statistically derived correlate of protection curve that depicts reassuring effects of variable antibody activity on protection from symptomatic disease. The curve is drawn by observing clinical protection across a large range of different COVID virus variants and across a substantial range of different serum monoclonal antibody concentrations. The range of variants reflects ordinary virus evolution in America across the year of CANOPY conduct, with associated different pemivibart potency values for each major variant. The serum concentration range follows from the pharmacokinetics of pemivibart and resulting high concentrations immediately post infusion, followed by low

serum concentrations during the open-label drug run-off period.

In contrast to vaccine-based correlate of protection analyses that require performance of a biological analysis to identify which immune response to vaccination constitutes a potential serum correlate, antibody prophylaxis via the pharmaceutical monoclonal antibody leaves no ambiguity on the source and mechanism of protection because the monoclonal antibody is the only active biological agent dosed. In contrast to vaccine mechanisms of action, monoclonal antibodies are designed to supplement normal immune function and are directly responsible for mediating clinical protection. COVID monoclonal antibody-mediated clinical protection has been assessed and observed using consistent clinical criteria across a wide range of virus variants.

The now peer-reviewed and published correlate of protection model, therefore, provides a mechanism for healthcare professionals, policymakers, and regulators to quantify and understand the basic physiologic and biologically predictable relationship between monoclonal antibodies and estimated clinical protection for related monoclonal antibodies derived from the same platform without requiring clinical assessment of every individual COVID variant.

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 the treatment of COVID-19, Long COVID, or COVID-19 Post-Vaccination Syndrome, or for 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 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 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.

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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 potential of laboratory-determined serum monoclonal antibody (mAb) activity levels to predict clinical protection levels from COVID, irrespective of virus variation; expectations about the predictability of clinical efficacy from drugging stable epitopes, irrespective of SARS-CoV-2 virus variation outside drug epitope; the potential of the published correlate of protection analysis as a useful tool to support clinical decision making, COVID antibody regulation, and overall stewardship of public health; the possibility that healthcare professionals, policymakers, and regulators may use the published correlate of protection model as a mechanism to quantify and understand the basic physiologic and biologically predictable relationship between mAbs and estimated clinical protection; the potential of the published analysis to accelerate regulatory pathways without animal models or cumbersome trials, and to expand durable COVID-19 protection strategies beyond the current reliance on repeated annual vaccine boosting; the potential for meaningful clinical protection from COVID at low overall mAb levels; 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 predictability of clinical success of the company’s product candidates based on neutralizing activity in nonclinical studies; whether healthcare professionals, policymakers, and regulators utilize the published correlate of protection model as a mechanism to quantify and understand the basic physiologic and biologically predictable relationship between mAbs and estimated clinical protection; 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; 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 and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that pemivibart targets remains 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; whether Invivyd’s mAbs provide robust protection from COVID-19 at low overall antibody levels irrespective of future virus variation; whether healthcare professionals, policymakers, and regulators recognize the demonstrated consistent responsiveness of SARS-CoV-2 to Invivyd’s highly active mAbs irrespective of virus variation and whether this enhances the development and use of new mAb options for patients in need, if approved; 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; changes in the regulatory environment; the outcome of the company’s engagement with regulators; macroeconomic and political uncertainties; 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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[1] Schmidt P, et al. 2023. Antibody-mediated protection against symptomatic COVID-19 can be achieved at low serum neutralizing titers. Science Translational Medicine. 15(688)