Invivyd Aligns with U.S. FDA on Rapid Pathway to Full Approval (BLA) of Vaccine Alternative Monoclonal Antibody VYD2311 to Protect American Adults and Adolescents from COVID-19

August 14, 2025

- *Alignment follows Type C meeting for VYD2311 as previously disclosed*
- *BLA pathway for VYD2311 to be supported by a single, Phase 2/3 randomized, double-blind, placebo-controlled trial with a primary endpoint of reduction in symptomatic COVID-19, resembling CANOPY Cohort B*
- *Company's target product profile is low-dose, intramuscular, scalable, low-cost, long-lasting, protective option for target populations, including adults and adolescents (12 years+; 40kg+) and, subject to FDA alignment, pediatrics (aged 0 to 12 years)*
- *Anticipate compact trial (12-week primary endpoint analysis) evaluating prevention of COVID-19 largely among ordinary Americans, enabling rapid enrollment*
- *Planned head-to-head safety evaluation with COVID-19 vaccine, pending regulatory alignment*
- *Quantities of VYD2311 potential commercial launch product available*

WALTHAM, Mass., Aug. 14, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced it has received and is aligned with advice from the U.S. Food and Drug Administration (FDA) on a compact and, therefore, rapid pathway to potential Biologics License Application (BLA) approval for Invivyd's novel monoclonal antibody (mAb) candidate VYD2311, for the prevention of COVID-19. As part of a recent Type C meeting, FDA advised that a single, Phase 2/3 randomized, double-blind, placebo-controlled trial evaluating mAb efficacy from a relatively modest number of RT-PCR -confirmed symptomatic COVID-19 disease events could support a BLA submission for VYD2311 for the prevention of COVID-19 in a broad population of Americans (12 years of age and older, weighing at least 40kg), including immunocompromised people, subject to agreement on safety database size and pending full protocol review.

"We believe monoclonal antibodies such as VYD2311 can serve as a powerful alternative to vaccines for COVID-19 prevention, and represent an important potential paradigm shift to move American medicine beyond the real and perceived limitations of COVID-19 vaccines. Amidst declining public trust in vaccines, we want to offer Americans a new, non-vaccine choice," said Marc Elia, Chairman of Invivyd's Board of Directors. "COVID-19 monoclonal antibody medicines work alongside natural human immunity without needing to activate the immune system, and, if we can make them widely available, we believe mAbs represent the natural next step beyond vaccination to keep people safe and well, if approved, in the face of pervasive COVID-19."

FDA advice and background statements to Invivyd cited observations on Invivyd's efficient execution of its Phase 3 randomized clinical trial of pemivibart for the prevention of COVID-19 (CANOPY), the antiviral durability of pemivibart, and the strong protection demonstrated by pemivibart among ordinary Americans in CANOPY Cohort B, while recognizing that Invivyd antibodies stem from a common molecular lineage. Multiple such Invivyd antibodies have undergone successful randomized, placebo-controlled clinical trials, including efficacy assessment in contemporary Americans. In agreement with FDA advice, Invivyd plans to study two doses of VYD2311 to assess any differences in resulting levels of protection or differences in safety, with a goal to unlock further choice for Americans in need of COVID-19 protection.

"We are grateful for the FDA's clear and constructive feedback, which provides a well-defined path forward for our COVID-19 development program. We believe the FDA's feedback underscores the shared urgency to advance innovative solutions for prevention of COVID-19," said Rachael Gerlach, Ph.D., Vice President, Regulatory Affairs at Invivyd. "Combined with Invivyd's unique discovery platform, this alignment is a critical step in bringing forward a potentially important, medically attractive and patient-friendly alternative to COVID vaccination, providing protective monoclonal antibodies, if approved, to any American who wishes protection, whether immune compromised, at high risk for severe disease, or just interested in not getting sick."

The FDA provided advice for pursuit of a traditional BLA pathway for the prevention of COVID-19 caused by SARS-CoV-2 in adults and adolescents weighing at least 40 kg, recommending a Phase 2/3 randomized, double-blind, placebo-controlled trial with a primary endpoint of RT-PCR-confirmed symptomatic COVID-19, with a timepoint for measuring the primary endpoint coinciding with the expected duration of protection, anticipated as 12 weeks (3 months), and the potential for selection of an additional, longer duration timepoint, which Invivyd anticipates as 24 weeks (6 months).

Invivyd's analysis of CANOPY clinical trial data and Cox Proportional Hazards modeling, combined with biophysical properties of VYD2311, suggest likely robust, long-term protection from symptomatic COVID-19 due to high potency and observed long half-life of ~76 days, following a relatively low dose of VYD2311 via intramuscular route of administration. Invivyd's most recent analysis aligns well with multiple similar analyses spanning the majority of SARS-CoV-2 virus variation since emerging as a global human disease in 2020, lending confidence to dose selection and anticipated clinical benefit. In addition, as COVID-19 monoclonal antibodies represent additional immune support and do not require engagement of the human immune system with associated

inflammation symptoms (reactogenicity), Invivyd anticipates, pending regulatory alignment, a clinical trial cohort exploring randomized, active-controlled safety and tolerability of VYD2311 compared to vaccination.

“Our completed first-in-human study of VYD2311 demonstrated high SARS-CoV-2 antiviral titers and an attractive safety profile at very high doses, well beyond doses we contemplate going forward with in development. We look forward to opening a U.S. IND and moving as quickly as possible to finalize a pivotal clinical trial design with the FDA,” said Mark Wingertzahn, Ph.D., Senior Vice President, Clinical Development at Invivyd, “If successful, we have the potential to change practice and provide consumers and central health authorities with an attractive alternative to COVID-19 vaccination. We anticipate sharing our plans as soon as possible once we finalize them with FDA.”

Invivyd has quantities of VYD2311 clinical supply and potential commercial launch product available.

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 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, 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 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, plans related to the company’s research and development activities; expectations regarding the biophysical properties, clinical trial design and enrollment, regulatory pathway, target product profile and target populations for VYD2311; 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 expected advantages of mAbs such as VYD2311 as an alternative to COVID-19 vaccines, and Invivyd’s goal to provide Americans with choice; the company’s regulatory plans and the timing thereof, including expectations related to Invivyd’s engagement with regulators; anticipated future announcements about the VYD2311 program, and the timing thereof; the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain immunocompromised persons; 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, including finalization of a pivotal clinical trial design for VYD2311 and initiation thereof; uncertainties related to agreement with FDA on the safety database size for the pivotal clinical trial of VYD2311 and full protocol review; clinical trial site activation or enrollment rates; 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; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that VYD2311 and pemivibart 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; changes in the regulatory environment; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways; the company’s ability to generate the clinical data needed to support a potential BLA submission for VYD2311; 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 ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; changes in expected or existing competition; the company’s reliance on third parties; complexities of manufacturing mAb therapies, and availability of quantities of commercial launch product in the future, if authorized or approved; 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 as 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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