

INVIVYD INC.

Invivyd Announces Inclusion of PEMGARDA® (pemivibart) in National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for B-Cell Lymphomas

May 23, 2025

WALTHAM, Mass., May 23, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), today announced that PEMGARDA® (pemivibart), its investigational monoclonal antibody, has been added to the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for B-Cell Lymphomas. NCCN joins the Infectious Disease Society of America (IDSA) that updated its COVID-19 guidelines in August 2024 to recommend the use of PEMGARDA (pemivibart) for pre-exposure prophylaxis (PrEP) in moderately to severely immunocompromised adults and adolescents (aged 12 or older) at risk for progression to severe COVID-19 when predominant regional variants are susceptible to pemivibart.

This inclusion in the NCCN Guidelines recognizes PEMGARDA as a potential option for PrEP against COVID-19 in patients with B-cell malignancies. Immunocompromised patients may not mount an adequate immune response to vaccination.

"Managing B-cell lymphoma is inherently challenging for patients, and the added risk of severe COVID-19 further complicates their care," said George Yagmour, MD. "The inclusion of PEMGARDA in the NCCN Guidelines is an important development, providing clinicians with a valuable tool to guide treatment decisions. It helps protect vulnerable patients from COVID-19, allowing them to stay out of the hospital, continue their cancer care, and focus on their recovery."

"We are honored that NCCN has acknowledged the role of PEMGARDA in helping protect one of the most vulnerable patient populations - those with compromised immune systems due to B-cell lymphomas - especially in light of ongoing COVID-19 threats," said Tim Lee, Chief Commercial Officer at Invivyd. "This recognition reflects the growing confidence in the therapeutic potential of PEMGARDA, and reinforces our commitment to immunocompromised patients including those facing difficult to treat lymphomas, particularly as COVID-19 remains a year-round threat, with another surge expected this summer."

The NCCN's recommendation is based on the unmet need in patients with B-cell lymphomas, many of whom experience reduced vaccine efficacy and are at elevated risk for COVID-19-related complications. PEMGARDA is a monoclonal antibody engineered to retain activity against circulating SARS-CoV-2 variants and is currently authorized under Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for PrEP of COVID-19 in certain patients with moderate-to-severe immune compromise.

The updated NCCN Guidelines are now available on the NCCN website and serve as an important resource for oncology providers making evidence-based treatment decisions. They reflect growing clinical and real-world evidence supporting the use of passive immunization to complement vaccination strategies in high-risk oncology populations.

NCCN is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to defining and advancing quality, effective, equitable, and accessible cancer care and prevention so all people can live better lives.

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 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 PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents who have moderate-to-severe immune compromise; PEMGARDA as a potential option for PrEP against COVID-19 in patients with B-cell malignancies; the future of the COVID-19 landscape; the company’s commitment to immunocompromised patients; the potential of PEMGARDA to retain activity against circulating SARS-CoV-2 variants; 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: 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; the success of the company’s in-house sales force, and the company’s ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; 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; the timing, progress and results of the company’s discovery, preclinical and clinical development activities; 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; 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; 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 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; the company’s reliance on third parties; clinical trial site activation or enrollment rates; 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