Invivyd at the Ready for Upcoming Respiratory Virus Season with PEMGARDA™ (pemivibart) to Help Protect Vulnerable Immunocompromised Persons from COVID-19

September 12, 2024

- *Centers for Disease Control and Prevention (CDC) reports death rate due to COVID-19 has continued to increase throughout 2024*
- *Immunocompromised patients at greatest risk for serious infections or even death due to COVID-19*
- *PEMGARDA™ available under Emergency Use Authorization (EUA) for certain immunocompromised adults and adolescents; recommended by Infectious Disease Society of Americas (IDSA) guidelines*
- *Covered by Medicare and Medicaid and has achieved rapid growth in commercial coverage across national and regional plans, including United Health Care, Aetna, Cigna, and Regional Blue Cross Blue Shield plans*
- *Continued neutralizing activity of PEMGARDA™ shown against dominant SARS-CoV-2 variants KP.3.1.1 and LB.1*

WALTHAM, Mass., Sept. 12, 2024 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced a business readiness update in response to a recent increase in COVID-19 cases nationwide.

According to the Centers for Disease Control and Prevention (CDC), as of early September, the rate of death due to COVID-19 has continued to increase throughout 2024. While the CDC recommends COVID-19 vaccination for a broad population, the U.S. Food and Drug Administration (FDA) has recognized there are vulnerable individuals at high-risk of infection and that require a preventative therapeutic alternative where vaccines may not provide adequate protection.

COVID-19 is a particular threat for immunocompromised adults and adolescents with moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments because they may not mount a strong enough immune response to vaccines due to their condition. The lack of immunity can leave this community of people vulnerable to serious infection or death.

Invivyd's PEMGARDA (pemivibart), an investigational monoclonal antibody (mAb) that has been granted Emergency Use Authorization (EUA) by the FDA for pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents (aged 12 or older weighing at least 40kg) in the U.S. with moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments who are unlikely to mount an adequate response to COVID-19 vaccination, is ready nation-wide to meet the demand for appropriate patients in need.

In August, the Infectious Disease Society of Americas (IDSA) updated their COVID-19 guidelines to recommend the use of PEMGARDA (pemivibart) for 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.

"COVID-19 remains an ever-present threat, and the ramifications of infection can be disastrous, especially for those who are immunocompromised. PEMGARDA is designed to add more protection as COVID-19 vaccines alone may be insufficient or not recommended for certain immunocompromised people, leaving the most vulnerable populations at risk," said Marc Elia, Chairman of the Invivyd Board of Directors.

Invivyd is prepared for the surge in COVID-19 with a robust supply of PEMGARDA, and the company is working to ensure access. PEMGARDA (pemivibart) is currently covered by Medicaid and Medicare, and Invivyd is in active, positive discussions with national payors to advocate for broad and equitable access to PEMGARDA for appropriate immunocompromised patients. While coverage decisions by insurers across payor segments can take time, Invivyd is focused on helping patients who are prescribed PEMGARDA to gain access as quickly as possible.

The company has launched the Invivyd Patient Savings Program (PSP), a financial assistance program for eligible commercially insured patients. The PSP may assist eligible patients by covering up to $250 per dose of PEMGARDA and up to $1,000 per year for deductible and costs related to PEMGARDA.

Patients prescribed PEMGARDA (pemivibart) can find an infusion center location by visiting pemgarda.com/hcp/infusion-center-locator/.

Additionally, earlier this month, Invivyd announced continued neutralizing activity of PEMGARDA against dominant SARS-COV-2 variants KP.3.1.1 and LB.1, and attractive neutralization potency of VYD2311, a next generation mAb candidate for COVID-19 with high in vitro neutralization potency shown against post-Omicron COVID-19 variants tested to date, and other potentially favorable biophysical properties. In addition, Invivyd recently announced dosing of the first participants in a first-in-human clinical trial for VYD2311.

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 a global Phase 2/3 clinical trial for the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.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 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 events (all grades, incidence ≥2%) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea. 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 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 therapeutic options for vulnerable populations, including immunocompromised people. Globally, there are millions of immunocompromised people, with an estimated 8 million in the U.S. alone, who may not adequately respond to COVID-19 vaccination, increasing their risk for severe outcomes from COVID-19.

VYD2311 was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19. The pharmacokinetic profile of VYD2311 may offer the ability to deliver clinically meaningful titer levels through more patient-friendly means such as an intramuscular route of administration.

About Invivyd
Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. The company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (mAbs) to address evolving viral threats. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for its first mAb in a planned series 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," "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, expectations

regarding the upcoming respiratory virus season and COVID-19 landscape; the potential threat and ramifications of COVID-19 for certain immunocompromised people; the company's beliefs regarding readiness with PEMGARDA for appropriate patients in need; the company's progress and plans related to the commercialization of PEMGARDA, including its preparedness for the surge in COVID-19 and efforts to ensure access; the company's ongoing research and clinical development activities, as well as future potential research and clinical development efforts; the continued *in vitro* neutralizing activity of PEMGARDA and VYD2311 against major SARS-CoV-2 variants; 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 potentially favorable biophysical properties of VYD2311 and the potential ability of VYD2311 to deliver clinically meaningful titer levels through more patient-friendly means such as an intramuscular route of administration; the company's devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; the design of the company's INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; 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 VYD2311, pemivibart or any other product candidate is 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 revoked or revised by the FDA; the company's ability to build and maintain 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 leverage its INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; any legal proceedings or investigations relating to the company; 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 June 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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