Invivyd Announces Preprints Conveying CANOPY Phase 3 Clinical Trial Data Including Long-Term Protection Versus Recent JN.1 Sublineages at Low Residual Titers, and Describing a Novel Approach for Predicting Monoclonal Antibody Activity Were Uploaded to MedRxiv and BioRxiv, Respectively

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- CANOPY manuscript preprint includes six-month off-drug follow-up period that highlighted strong protection by pemivibart versus placebo in the immunocompetent Cohort B during KP.3 and KP.3.1.1 dominant wave
- CANOPY exploratory clinical efficacy data, to date, reconfirm a high level of risk reduction from developing symptomatic COVID-19 in immunocompetent participants
- Preprint describes Invivyd scientists' novel method for predicting the activity of a monoclonal antibody in the face of variant evolution; method predicts continued neutralization activity for pemivibart against SARS-CoV-2 variant XEC, with formal assay assessment pending

WALTHAM, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced that a manuscript preprint conveying data from the CANOPY Phase 3 clinical trial of pemivibart, a half-life extended investigational monoclonal antibody (mAb) for the pre-exposure prophylaxis (PrEP) of COVID-19, including long-term protection shown versus recent JN.1 sublineages at low residual titers, was uploaded to MedRxiv, and a preprint describing a novel approach for predicting mAb activity was uploaded to BioRxiv.

CANOPY clinical trial data supported the emergency use authorization (EUA) of PEMGARDA™ (pemivibart) by the U.S. Food and Drug Administration (FDA) for PrEP of COVID-19 in certain moderate-to-severe immunocompromised patients via an immunobridging pathway. To date, the CANOPY clinical trial has been conducted over a period of substantial transmission of COVID-19 disease in the U.S., yielding important exploratory clinical efficacy data from Cohort B, a placebo-controlled cohort of immunocompetent individuals at risk of contracting symptomatic COVID-19 disease from regular unmasked face-to-face interactions with others in indoor settings. The safety profile for pemivibart remains consistent with the PEMGARDA Fact Sheet for Healthcare Providers. The manuscript preprint conveying pivotal safety, immunobridging, and exploratory clinical efficacy results from the CANOPY clinical trial will be submitted to a major scientific journal shortly.

Previous disclosures from Invivyd have underlined the strong protection shown in the CANOPY clinical trial from symptomatic disease conferred by PEMGARDA over multiple waves and lineages of SARS-CoV-2, including 6-month data from a JN.1 dominant wave during active dosing (84% relative risk reduction in symptomatic disease versus placebo), and long-term follow-up from months 7-12 after cessation of drug (64% relative risk reduction in symptomatic disease versus placebo) during a KP.3 and KP.3.1.1 wave. [see link here].

Publication of the CANOPY clinical trial long-term follow-up, exploratory clinical efficacy data showing continued protection against KP.3 and KP.3.1.1 are particularly critical as they indicate that 1) strong protection was available from pemivibart over a 12-month period, supporting Invivyd's route toward enhanced and more scalable product forms, and 2) strong protection was conferred during the off-drug interval in the trial with low, residual titer levels.

Additionally, a preprint describing a novel methodology for assessing and predicting the structure-neutralization relationships between authorized or approved antibodies and novel viral variants to add speed and confidence to overall assessments of antibody activity has been uploaded to BioRxiv. Specifically, a preprint from Invivyd scientists Powers, et al. describes the use of a large panel of close molecular relatives to pemivibart to interrogate neutralization behavior across the panel against emerging variants of interest. This molecular panel approach adds confidence to the gold-standard pseudovirus assessment of authentic pemivibart at Labcorp-Monogram Biosciences by interrogating a large group of similarly structured variants of pemivibart with overlapping assessed binding sites that collectively portray a probabilistic cloud of likely pemivibart neutralization activity against variants of interest. This panel approach previously predicted ongoing neutralization activity for pemivibart against KP.3.1.1. The same method predicts continued neutralization activity for pemivibart against XEC, with formal assay assessment pending.

"Academic labs continue to make claims about 'pemivibart' activity that do not reflect the data outputs for PEMGARDA (pemivibart) when Invivyd's industrial-grade processes with authentic pemivibart are utilized. Given the variability of virology assessments and the critical need to assess outputs through the lens of biological plausibility, at Invivyd we have developed a systematic mechanism to parse the structural basis of individual neutralization results prospectively using a multi-antibody panel approach. Such an approach adds confidence and context to our understanding of the neutralization data we ultimately submit to FDA for their continued evaluation of the risk-benefit profile of PEMGARDA and inclusion in the PEMGARDA Fact Sheet, as

reflected in the most recent update," commented Dr. Robert Allen, Ph.D., Chief Scientific Officer at Invivyd and an author of the preprint. "Beyond these methods, we are also gratified with the recent CANOPY long-term controlled exploratory clinical data that put to rest any open questions on the activity of PEMGARDA against major variants circulating during the CANOPY trial, including KP.3 and KP.3.1.1."

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.

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, KP.3, KP.3.1.1 and LB.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 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 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 ongoing CANOPY Phase 3 clinical trial is 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 are 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 includes 365-day data. The CANOPY clinical trial enrolled participants in two cohorts: Cohort A is a single-arm, open-label trial in adults who have moderate-to-severe immune compromise including complex underlying medical conditions. Cohort B is a randomized, placebo-controlled cohort that enrolled adults without moderate-to-severe immune compromise who are at risk of acquiring COVID-19 due to regular unmasked face-to-face interactions in indoor settings.

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,” “preliminary,” “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; the company’s expectation that the manuscript preprint conveying CANOPY clinical trial data will be submitted to a major scientific journal shortly; the potential clinical benefit of PEMGARDA at low, residual titer levels; Invivyd’s potential route toward enhanced and more scalable product forms; the expected utility and benefits of Invivyd’s molecular panel approach method for predicting mAb activity in the face of variant evolution; expectations regarding the neutralization activity of pemivibart against SARS-CoV-2 variants, including XEC; 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 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; the company’s plans for an innovative series of antibody candidates; 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 and methods used to predict activity against SARS-CoV-2 variants; formal assay assessment results in comparison to predictions made using Invivyd’s molecular panel approach with respect to neutralization activity of pemivibart; whether 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 revised or revoked by the FDA; 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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