Invivyd Aligns with the U.S. FDA on LIBERTY, a Phase 3 Trial to Evaluate the Safety of VYD2311 Antibody Versus mRNA COVID Vaccine, and to Characterize the Safety and Immunology of Antibody and Vaccine Co-Administration

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- *LIBERTY is part of the Company's broader REVOLUTION clinical program designed to elaborate the profile of monoclonal antibody-mediated prophylaxis from COVID-19 and the potential medical benefits to vulnerable Americans*
- *The LIBERTY clinical trial will evaluate comparative safety and immunology of VYD2311 versus mRNA COVID vaccine, as well as explore the safety and immunology of co-administered VYD2311 and mRNA COVID vaccine*
- *FDA, providing feedback jointly from CDER and CBER, requested specific monitoring of adverse events of special interest (AESIs) relevant to mRNA COVID vaccines, citing the known risk of myocarditis/pericarditis in the young adult population following mRNA COVID vaccination; no similar requests have been made for other Invivyd clinical trials without an mRNA COVID vaccine arm*

NEW HAVEN, Conn., Feb. 03, 2026 (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 the LIBERTY Phase 3 clinical trial, which will assess the safety and immunologic profile of VYD2311, the company's vaccine- alternative monoclonal antibody investigational candidate for the prevention of COVID-19, versus commercially available mRNA COVID vaccines. The trial will also explore the safety and immunologic profile of VYD2311 and mRNA COVID vaccine administered simultaneously.

"Invivyd is aligning with the FDA to explore the safety and immunology of our medicines carefully and prospectively under well-controlled conditions. This work, including our anticipated LIBERTY trial, stands in stark contrast to the rapid, short-term work to characterize mRNA COVID vaccine safety and efficacy, as was required at the height of the COVID pandemic," said Marc Elia, Chairman of Invivyd's Board of Directors. "The LIBERTY trial is intended to build on the placebo-controlled DECLARATION trial of VYD2311, and is designed to provide an exploratory look at the potential improvement in safety and tolerability associated with monoclonal antibody-mediated prophylaxis compared to mRNA-based vaccine control."

The Centers for Disease Control and Prevention surveyed Americans who had not received a COVID booster during the 2023-2024 season, and the main reason, among others, identified was concern about serious or unknown side effects. Citing known risk of myocarditis/pericarditis in young adult Americans who take the mRNA COVID vaccine, the FDA requested Invivyd specifically monitor for these adverse events of special interest in this LIBERTY trial, which includes mRNA vaccination. No such request has been conveyed for DECLARATION or other Invivyd monoclonal antibody clinical trials without an mRNA COVID vaccine arm. Further, myocarditis and pericarditis have not been observed in any Invivyd clinical trial, nor have myocarditis and pericarditis been observed in postmarketing Adverse Event reports for pemivibart.

"We are grateful for the FDA's clear and constructive feedback to our LIBERTY trial design, which we believe underscores the shared urgency to study the safety of potential COVID prevention options," said Rachael Gerlach, Ph.D., Senior Vice President, Regulatory Affairs at Invivyd. "As part of our REVOLUTION clinical program, we believe we can provide Americans with useful, contemporary information about safety and side effects for potential COVID prevention options."

Invivyd previously announced initiation of DECLARATION (NCT07298434), the company's Biologics License Application (BLA)-enabling clinical trial of VYD2311. DECLARATION is a Phase 3, randomized, triple-blind, placebo-controlled trial to evaluate VYD2311 safety and efficacy in prevention of symptomatic COVID in a broad population of participants including adults and adolescents both with and without underlying risk factors for progression to severe COVID-19, at three months. Participants will receive either a single dose or a monthly dose of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is expected to be 1770 participants. Top-line data from the trial are expected mid-2026.

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 LIBERTY

LIBERTY is a Phase 3, randomized, double-blind study to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of VYD2311, an mRNA COVID vaccine, and co-administered VYD2311 with an mRNA COVID vaccine. Total enrollment of the trial is expected to be about 210 participants.

About DECLARATION

DECLARATION (NCT07298434) is a Phase 3, randomized, triple-blind, placebo-controlled trial to evaluate VYD2311 efficacy and safety in prevention of symptomatic COVID in a broad population of participants including adults and adolescents both with and without risk factors for progression to severe COVID-19, at three months. Participants will receive either a single dose or a monthly dose of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is expected to be 1770 participants.

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,” “plans,” “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, and the timing and potential results thereof; expectations regarding the company’s clinical trial designs and enrollment, regulatory pathway, product profile, indication and administration paradigm 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 potential improvement in safety and tolerability associated with monoclonal antibody-mediated prophylaxis compared to mRNA-based vaccine; expectations regarding the COVID landscape, and the potential of Invivyd to provide Americans with useful, contemporary information about safety and side effects for potential COVID prevention options; 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 advancement of REVOLUTION clinical program; 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 epitopes that VYD2311 and pemivibart target remain 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; the outcome of the company’s engagement with regulators; uncertainties related to the regulatory approval process, and available development and regulatory pathways; the company’s ability to generate the data needed to support a potential BLA submission for VYD2311; whether the company is able to realize the potential benefits of Fast Track designation for VYD2311; how long the EUA granted by the FDA for a mAb in the company’s pipeline 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; 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 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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