Invivyd Announces Initiation of DECLARATION Clinical Trial, a Phase 3 Placebo-Controlled Pivotal Study of VYD2311, a Vaccine-Alternative Antibody to Prevent COVID

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- *DECLARATION is a Phase 3, randomized, placebo-controlled clinical trial to evaluate the safety and efficacy of VYD2311 in the prevention of COVID versus placebo, at three months, from a single intramuscular (IM) dose, with protection beyond three months anticipated*
- *A second arm will evaluate monthly IM doses versus placebo to demonstrate the safety and efficacy of more frequent dosing to support individual choice should at-risk persons seek periodic extra protection from COVID*
- *Primary endpoint is the reduction of PCR-confirmed symptomatic COVID incidence versus placebo; total expected enrollment of 1770 people across all three arms*
- *DECLARATION is part of the Company's REVOLUTION clinical program aimed at establishing monoclonal antibody prophylaxis for prevention of COVID; top-line data are expected mid-2026*

NEW HAVEN, Conn., Dec. 23, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced initiation of the DECLARATION trial evaluating VYD2311, an investigational vaccine-alternative monoclonal antibody candidate for the prevention of COVID. DECLARATION is the company's Biologics License Application (BLA)-enabling, Phase 3 randomized, triple-blind, placebo-controlled clinical trial to evaluate VYD2311 efficacy and safety in prevention of symptomatic COVID in a broad population of participants including adults and adolescents.

The DECLARATION study will evaluate prevention of symptomatic COVID at three months, with either a single dose or monthly doses of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. A single IM dose of VYD2311 is expected to confer strong protection from COVID across the three-month measured dosing interval and beyond, with further clinical demonstration of long-term protection possible post-approval. By including a monthly dosing arm, the DECLARATION trial could also provide safety and efficacy data that support a VYD2311 indication and administration paradigm that enables individual choice and flexibility for extra periodic protection from COVID if desired, as opposed to a single centrally defined or mandated protection regimen. If approved, access to baseline and periodic extra protection via VYD2311 could, for example, support long interval protection such as annual or semi-annual dosing, as well as provide a mechanism for increased protection through additional doses for at-risk populations seeking extra protection or for individuals facing periods of enhanced risk of COVID. In the Phase 1/2 study, IM administered VYD2311, at 4 times the planned dose in DECLARATION, was well tolerated, with all adverse events (AEs) considered mild to moderate in severity with no serious or severe AEs reported. All AEs, including headache and injection site pain, were deemed unrelated to study drug,

"Initiating the clinical trial by the end of the year, as we committed to doing less than two months ago, marks a significant milestone as we move swiftly to bring Americans a potential vaccine-alternative choice for protection from COVID," said Marc Elia, Chairman of Invivyd's Board of Directors. "Enrollment in the DECLARATION study is expected during one of the peak seasons for COVID infections. Based on CDC data from the last two years, COVID infections peaked in January, and again in the summer. With COVID attack rates projected to follow historical trends or perhaps a bit later in the winter, we are looking forward to recruiting and executing the study."

Invivyd has produced commercial launch quantities of VYD2311 and, over the past four months, has secured significant capital to support the DECLARATION pivotal study and commercial preparedness for the potential launch of VYD2311, if approved.

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 DECLARATION

DECLARATION 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 monthly doses 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, and the potential duration of protection of single IM dose of VYD2311; the company’s goal to provide more Americans with a potential vaccine-alternative choice for protection from COVID; expectations regarding the COVID landscape, attack rates, and infection peaks; 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 the DECLARATION clinical trial, and finalization and initiation of other aspects of the REVOLUTION clinical program, such as the LIBERTY clinical trial, subject to final alignment with the U.S. FDA; 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 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; 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; 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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