

INVIVYD INC.

Invivyd Earns Fast Track Designation for VYD2311, a Vaccine-Alternative Antibody to Prevent COVID

December 23, 2025

NEW HAVEN, Conn., Dec. 23, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for VYD2311, an investigational vaccine-alternative monoclonal antibody candidate for the prevention of COVID.

Fast Track is a process that enables the FDA to expedite the development and review of new drugs that address a serious or life-threatening condition and fill an unmet medical need. If relevant criteria are met, programs with Fast Track designation can become eligible for priority review and rolling Biologics License Application (BLA) submission, which can reduce the timelines associated with regulatory action. VYD2311 was granted Fast Track designation by the FDA for the prevention of COVID in individuals with underlying risk factors for severe COVID.

“COVID is a critical ongoing endemic and chronic health challenge, and Americans need more options to prevent themselves from getting sick,” said Marc Elia, Chairman of Invivyd’s Board of Directors. “We are thrilled that the FDA recognizes the need to move quickly to prevent COVID as we move forward with our placebo-controlled, pivotal clinical trial DECLARATION.”

Invivyd previously announced initiation of DECLARATION, the company’s BLA-enabling clinical trial of VYD2311. Top-line data from the trial are expected mid-2026.

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.

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 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.

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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,” “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 benefits of Fast Track designation; expectations regarding the COVID landscape, and beliefs about the need for more options to prevent Americans from getting sick; 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; 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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