Invivyd Announces Completion of Enrollment in Upsized DECLARATION Clinical Trial, a Phase 3 Pivotal Study of VYD2311, an Investigational Antibody to Prevent COVID

June 1, 2026

- *DECLARATION is a Phase 3, randomized, placebo-controlled clinical trial to evaluate the safety and efficacy of VYD2311 in the prevention of symptomatic COVID-19 versus placebo, at three months, from a single intramuscular (IM) dose, with protection beyond three months anticipated*
- *A second arm is evaluating monthly IM doses of VYD2311 versus placebo to demonstrate the safety and efficacy of more frequent dosing to support individual choice should at-risk people seek periodic extra protection from COVID*
- *Invivyd previously conducted a pre-specified sample size re-estimation analysis designed to add statistical power robustness given future COVID event rate variability; upsizing was triggered and added ~500 additional subjects*
- *Rapid enrollment of upsized cohort leaves top-line results on track for approximately late Q3 2026*

NEW HAVEN, Conn., June 01, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced the completion of enrollment in the DECLARATION trial evaluating VYD2311, an investigational monoclonal antibody candidate for the prevention of symptomatic COVID-19. DECLARATION is the company's Biologics License Application (BLA)-enabling, Phase 3 randomized, 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. Top-line results continue to be expected in approximately late Q3 2026.

"We are pleased that recruitment into the DECLARATION study has remained rapid, which we see as indicative of the appeal of monoclonal antibody technology to protect people from COVID," said Marc Elia, Chairman of Invivyd's Board of Directors. "We are looking forward to additional, expected event accumulation in our study over the summer, which generally involves a COVID wave in the U.S., and then, with data in hand, moving VYD2311 forward as quickly as possible to vulnerable populations in concert with the U.S. FDA."

As previously announced, the DECLARATION study is evaluating prevention of symptomatic COVID-19 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.

DECLARATION included a prospectively designed, algorithmic sample size re-estimation pooled, blinded analysis aimed at adding COVID-19 clinical events and associated study statistical power. The re-estimation algorithm was designed conservatively given the variability of COVID-19 attack rates in the community. Based on the sample-size re-estimation analysis, upsizing was triggered and included approximately 500 additional subjects. The upsizing, combined with initial event accumulation, provides additional projected statistical support for VYD2311 efficacy assessment.

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 approximately 2,400 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,” “future,” and “target” 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, enrollment, event accumulation and progress, regulatory pathway, product profile, indication, patient populations, and administration paradigm for VYD2311, including the company’s REVOLUTION clinical program and the timing of results related thereto; the potential of VYD2311 as a novel mAb candidate for the prevention of COVID-19, and the potential duration of protection of single IM dose of VYD2311; the company’s plans to move VYD2311 forward as quickly as possible to vulnerable populations in concert with the U.S. FDA; expectations regarding the COVID landscape, attack rates, and infection surges; 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 with respect to the REVOLUTION clinical program; uncertainties regarding clinical trial event accumulation 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 U.S. FDA for a mAb in the company’s pipeline will remain in effect and whether such EUA is revised or revoked by the U.S. FDA; the ability to maintain a continued acceptable safety, tolerability, and efficacy profile of any product candidate following regulatory authorization or approval; the risk that a lack of awareness of mAb therapies and regulatory scrutiny of mAb therapies to prevent or treat COVID-19 or other infectious diseases may adversely impact the development or commercial success of the company’s product candidates; changes in expected or existing competition; the company’s reliance on third parties; complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; 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, 2025, as 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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