INVIVYD INC.

Invivyd Announces Positive DECLARATION Trial Data for Monoclonal Antibody VYD2311, and Ushers in a New Era for Immunization

November 23, 2026

- *VYD2311 (ibramvibart) achieved high, durable antiviral activity predictive of 70-90% protection from symptomatic COVID-19 infection for both single- and multi-dose intramuscular arms*
- *Highly attractive safety and tolerability profile observed for single- and multi-dose VYD2311 arms, supporting broad population use*
- *Positive dialogue with U.S. FDA and HHS leadership has resulted in progress toward regulatory consistency between Invivyd monoclonal antibodies and related vaccines (e.g., COVID-19). Based on FDA feedback, upon planned VYD2311 BLA submission, Invivyd anticipates review for accelerated approval either by, or with input from, CBER*
- *Invivyd anticipates submitting a BLA based on DECLARATION and LIBERTY data to FDA in Q1 2027*
- *Investor call to be held at 8:30 am EST on November 23, 2026*

NEW HAVEN, Conn., Nov. 23, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced all interim analysis primary and secondary endpoints were met in the DECLARATION Phase 3 trial of VYD2311 (ibramvibart). VYD2311, administered via intramuscular injection (IM), demonstrated high and durable antiviral activity, consistent with Invivyd's target 70-90% protection from RT-PCR confirmed symptomatic COVID-19, versus placebo. VYD2311 demonstrated an overall highly attractive safety and tolerability profile in both single- and multi-dose arms. Invivyd intends to submit a Biologics License Application (BLA) seeking accelerated approval of VYD2311 for the prevention of symptomatic COVID-19 based on the positive interim analysis of the Phase 3 DECLARATION trial and the supportive data from the Phase 3 LIBERTY trial comparing VYD2311 and an mRNA-based COVID-19 vaccine.

The interim DECLARATION analysis, designed to support accelerated approval, includes placebo-controlled safety, neutralizing antibody titers, and predicted clinical benefit of VYD2311 from 2,359 subjects randomized 1:1:1 to receive a single 250mg IM dose of VYD2311, monthly 250mg IM doses of VYD2311, or volume-matched IM saline placebo. Clinical COVID-19 events from the trial remain fully blinded to support traditional approval as Invivyd continues to gather further events.

"Today marks the dawn of a new era in our 300-year history of human immunization. Today's data point to a possible healthier future for millions of Americans facing the threat of COVID-19. People have long sought new options for protection against COVID infection, and we intend to make VYD2311 available soon," said Marc Elia, Chairman and Chief Executive Officer of Invivyd. "Our mission continues: to make products that give people the immune protection they cannot create on their own. More, our technological and regulatory progress makes us enthusiastic to rapidly advance multiple novel monoclonal antibodies that can complement vaccines and treat infection, including mAbs for RSV, measles, mumps, rubella, Lyme, and others as our discovery advances. Americans need high-quality solutions to important medical problems without the requirement for inflammation or exposure to a pathogen."

"Invivyd is making possible what has been elusive for years: giving people true protection from symptomatic COVID infection without experiencing inflammation and the safety and tolerability challenges of COVID-19 vaccines," said Robert Redfield, M.D., former director of the Centers for Disease Control and Prevention. "The unmet need in America today is to stop COVID infection and all of its downstream problems with a simple, safe, scalable medical solution. Invivyd's work with monoclonal antibodies, starting with adintrevimab, and then pemivibart, and now including VYD2311, has the potential to quickly become standard of care and stop COVID in its tracks."

In the DECLARATION interim analysis, VYD2311 generated mean antiviral titers consistent with expected clinical protection of 70-90% over the 90-day trial period for both dose arms. By contrast, COVID-19 vaccines are estimated by manufacturers to confer only a 30-35% reduction in medically attended COVID-19 for 90 days, falling to 15-20% thereafter (Slide 77 linked here). Invivyd expects single dose VYD2311 to protect from symptomatic COVID, medically attended or not, for approximately one year, without requiring inflammation, exposure to spike protein or liposomal mRNA. Multiple VYD2311 doses would confer higher protection against symptomatic COVID for longer, subject to an individual's choice.

Safety data for both single- and multi-dose arms was in-line with saline placebo, consistent with the intramuscular delivery of a high-quality antiviral monoclonal antibody.

Invivyd believes data from DECLARATION and also from the LIBERTY study, in which VYD2311 demonstrated superior safety and

tolerability compared to an mRNA-based COVID-19 vaccine, combined with data from previous Invivyd randomized, placebo-controlled trials EVADE (adintrevimab) and CANOPY (pemivibart), compare highly favorably to the evidentiary basis used to approve updated COVID-19 vaccines.

Invivyd has been in ongoing discussions with American regulatory and health policy leadership at the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) and believes the discussion has achieved understanding of the need for regulatory pathways for monoclonal antibody prophylaxis equitable to vaccine prophylaxis. Upon Invivyd's VYD2311 BLA submission for accelerated approval, Invivyd anticipates FDA to begin formalizing regulatory processes consistent with this goal in order to enable more rapid innovation on behalf of Americans. Invivyd currently expects that BLA review of VYD2311, and future Invivyd prophylactic monoclonal antibodies, will be conducted either by, or with input from, CBER.

Conference Call & Webcast
Listeners can register for the webcast via this link. Analysts wishing to participate in the question-and-answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 LIBERTY

LIBERTY is a Phase 3, randomized, double-blind clinical trial 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 was approximately 210 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," "future," "intends," "plans," "potential," "predicts," "projects," 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, expectations about the company's research and development activities, including the scope, timing, and results thereof; the potential of VYD2311 as a novel mAb candidate, including expectations about the protection from symptomatic COVID-19 infection versus placebo and the potential duration of protection, based on VYD2311 antiviral titer data from the DECLARATION interim analysis; expectations about the company's clinical trial designs, regulatory pathway and submissions, product profile, indication, patient populations, and administration paradigm for VYD2311; the company's beliefs, based on DECLARATION and LIBERTY data, regarding the safety and tolerability of VYD2311; the company's plans to submit a BLA to the FDA seeking accelerated approval of VYD2311, and the timing thereof; the potential role of CBER with respect to VYD2311, as well as future Invivyd prophylactic mAbs; expectations about the public health landscape, potential role mAbs can play in infectious disease, and a possible new era for immunization; the potential to create a new standard of care; the potential of Invivyd to rapidly advance multiple novel mAbs that can complement vaccines and treat infection; the company's strategies and objectives; the company's

future prospects; 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 outcome of the company's engagement with regulators, including American regulatory and health policy leadership; potential changes in the regulatory environment; uncertainties related to the regulatory approval process, and available development and regulatory pathways, including eligibility for any expedited regulatory review and approval approaches; the company's ability to finalize its planned BLA submission seeking accelerated approval of VYD2311, and uncertainties regarding the FDA's acceptance and review, as well as the outcome, of any such BLA submission, including the scope of prescribing information and indication of VYD2311, if approved; uncertainties regarding the involvement of CBER with respect to the company's planned VYD2311 BLA submission; the ability of the DECLARATION clinical trial to continue to generate data to support conversion of any accelerated approval of VYD2311 to traditional approval; uncertainties regarding clinical trial enrollment, event accumulation rates, and statistical powering; 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 and 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; 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 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, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, each 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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