Invivyd Announces U.S. IND Clearance and Alignment with U.S. FDA on Pivotal Clinical Program for VYD2311, a Vaccine-Alternative Antibody to Prevent COVID

October 6, 2025

- *The DECLARATION (safety and efficacy vs. placebo) and LIBERTY (exploratory safety head-to-head and combination with mRNA-based COVID vaccination) clinical trials are expected to begin around year-end 2025; top-line data anticipated mid-2026*
- *DECLARATION is a Phase 3, randomized, placebo-controlled clinical trial to evaluate prevention of COVID, at three months, from a single intramuscular (IM) dose of VYD2311, with longer-term protection anticipated. A second VYD2311 arm will evaluate monthly IM doses to demonstrate the safety and efficacy of more frequent dosing to support individual choice should at-risk persons wish periodic extra protection. Total expected enrollment of ~2,000 people*
- *LIBERTY is a randomized, active-controlled safety and tolerability clinical trial of VYD2311 versus mRNA-based COVID vaccine with a co-administration arm exploring VYD2311 / vaccine combination; final alignment with the FDA on combination design with vaccination expected shortly. Total expected enrollment of ~300 people*
- *DECLARATION and LIBERTY clinical trials to be funded by Invivyd's recent capital raise; commercial launch quantities of VYD2311 are at-the-ready*
- *Details on DECLARATION and LIBERTY clinical trials, and further areas of potential post-approval research in Invivyd's broader REVOLUTION program, will be shared in a public investor event later this month*

NEW HAVEN, Conn., Oct. 06, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application and provided feedback to advance the company's REVOLUTION clinical program, Invivyd's development program for VYD2311, a vaccine alternative monoclonal antibody candidate for the prevention of COVID.

The DECLARATION clinical trial is the company's Biologics License Application (BLA)-enabling, Phase 3 pivotal clinical trial evaluating VYD2311 safety and prevention of COVID versus placebo. The LIBERTY clinical trial will assess the safety and tolerability of VYD2311 in a head-to-head clinical trial against mRNA-based COVID vaccine, as well as evaluate co-administration of VYD2311 with vaccination, subject to final alignment with the FDA. Together, these two clinical trials are designed to provide robust, medical practice-changing information to regulators, populations at risk for COVID, and policy makers seeking high-quality, safe, non-vaccine protection from COVID. Invivyd intends to initiate these clinical trials as soon as practicable, with the goal of year-end 2025 trial start and top-line data mid-2026. Additional studies in the REVOLUTION program may be contemplated for conduct post-approval of VYD2311, if a BLA is granted by the FDA, to further elaborate the profile of antibody prevention of COVID.

The DECLARATION Phase 3 clinical trial 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.

The LIBERTY clinical trial is anticipated to demonstrate the meaningful safety and tolerability advantage expected for antibody-based prophylaxis versus mRNA-based vaccine-induced inflammatory mechanisms, and to provide safety and immunologic data regarding any interaction between the mRNA-based vaccine and VYD2311 for people who may receive both, if approved. Invivyd expects that its broader REVOLUTION clinical program may also include pediatric and other post-approval Phase 4 studies designed to establish VYD2311 and potential future Invivyd antibodies as the preferred option for protection from COVID over mRNA-based vaccination going forward.

"We are moving as fast as possible to bring Americans a new choice in protection from COVID," said Marc Elia, Chairman of Invivyd's Board of Directors. "We have designed the DECLARATION and LIBERTY clinical trials towards providing Americans with a convenient, safe, high-quality protective option to avoid COVID harm and burden without repeated use of inflammatory COVID vaccines. These trials and the broader REVOLUTION program will aim to generate clinical data that support a new approach to COVID prevention: one that enables at-risk Americans to exercise their individual freedom of choice to select the timing and quantity of safe, high-quality protection both annually and during periods of heightened risk such as medical vulnerability or major

COVID waves, as well as during life's important moments, such as family gatherings, holidays, and travel. COVID antibody medicines build on the science of natural, human immunity that begins at birth with maternal antibody transfer, and could serve as a critical, first-line option for protection for millions of Americans."

Invivyd has produced commercial launch quantities of VYD2311 and has secured capital to support clinical trial execution through pivotal data readouts.

More details about the REVOLUTION clinical program for VYD2311, including the scientific basis for trial design, dose selection, endpoints, populations, and potential commercial implications will be shared in a public investor event later this month.

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 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 potential administration paradigm for VYD2311; expectations regarding FDA alignment; 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 company's goal to provide Americans with choice in protection from COVID; the potential of VYD2311 to be a medical practice-changing option, and the potential of antibodies to be a preferred option for protection from COVID over mRNA-based vaccination; the company's plan to share details about the REVOLUTION clinical program in a public investor event, and the timing thereof; 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 finalization of the DECLARATION clinical trial design for VYD2311 and initiation thereof, 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 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; 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 June 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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