INVIVYD INC.

Invivyd Announces Positive Topline Results from LIBERTY Phase 3 Study Demonstrating VYD2311 Safety and Tolerability Superior to mRNA-based COVID-19 Vaccine; Announces Regulatory Submission Plans for VYD2311

September 29, 2026

- *VYD2311 met all primary and secondary endpoints comparing VYD2311 to an mRNA-based COVID-19 vaccine, demonstrating VYD2311 safety and tolerability that is clinically and statistically superior to the safety and tolerability of an mRNA-based COVID-19 vaccine*
- *VYD2311 combined with an mRNA-based COVID-19 vaccine demonstrated no interference with vaccine-induced neutralizing titers, and instead added substantially to vaccine-induced neutralizing titers*
- *VYD2311 observed profile in LIBERTY indicates high measured neutralizing antiviral titers supporting the target profile for VYD2311 under study in the DECLARATION pivotal clinical study*
- *Invivyd plans for DECLARATION and LIBERTY clinical studies to be the basis of a planned Biologics License Application (BLA) submission for VYD2311 to the U.S. Food and Drug Administration via Accelerated Approval Program following a recent Type C meeting; DECLARATION topline data on safety and immunogenicity to support the submission are now expected in October; DECLARATION clinical efficacy data will be planned to be unblinded post-Accelerated Approval, if granted, subject to clinical event accrual*
- *Investor call to be held at 8:30 am ET on September 29, 2026*

NEW HAVEN, Conn., Sept. 29, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced positive, clinically meaningful, and statistically significant topline data from the LIBERTY Phase 3, randomized, double-blind, active controlled study evaluating the safety and tolerability of (1) VYD2311, Invivyd's investigational COVID-directed monoclonal antibody candidate, (2) mRNA-based COVID-19 vaccine COMIRNATY® (mRNA-based COVID-19 vaccine, COVID-19 mRNA vaccine, or COVID vaccine), and (3) VYD2311 co-administered with mRNA-based COVID-19 vaccine. The study also evaluated the potential for immunologic interference between VYD2311 and mRNA-based COVID-19 vaccine. LIBERTY is a companion study to DECLARATION, the ongoing placebo-controlled pivotal study of VYD2311 for pre-exposure prophylaxis of symptomatic COVID-19.

LIBERTY's co-primary endpoints evaluated the proportion of subjects experiencing a treatment-emergent adverse event (TEAE), injection site reaction (ISR), or hypersensitivity reaction over the first 6 days following dosing, and the proportion of subjects experiencing a systemic adverse event (AE) solicited via an e-diary over the first 6 days following dosing. The key secondary endpoint evaluated the proportion of subjects experiencing a TEAE, ISR, or hypersensitivity reaction over the full 56 days of the study following dosing.

"We are thrilled to report on this landmark study. LIBERTY has generated the first Phase 3, randomized, blinded, controlled data we are aware of in history that compare different mechanisms for achieving immunization in vulnerable humans: the specific, highly potent investigational monoclonal antibody VYD2311, and an approved mRNA-based COVID-19 vaccine currently in wide clinical use. The observed profile of VYD2311 in LIBERTY and measured in vitro potency data of VYD2311 against circulating variants leave us confident and looking forward to the placebo-controlled safety and immunogenicity data we expect shortly in the DECLARATION study," said Marc Elia, Chairman and CEO of Invivyd. "We want to move as quickly as possible to the regulatory filings required to bring Americans a new choice in protection from COVID."

LIBERTY recruited 210 healthy adults (18-49 years) and randomized subjects 1:1:1 to receive a single intramuscular dose of either 250mg VYD2311, COMIRNATY® (COVID-19 vaccine, mRNA), or the combination of VYD2311 and mRNA-based COVID-19 vaccine. Both single dose arms were blinded with a concomitant placebo injection such that every subject in LIBERTY received two injections irrespective of treatment arm. All subjects were dosed using intramuscular needles consistent with COVID-19 vaccination, and, for blinding purposes, placebo injections were volume-matched to either VYD2311 (2mL) or COVID-19 vaccine (0.5mL). The 250mg VYD2311 dose studied in LIBERTY is the same dose under evaluation in the DECLARATION study in single and multiple-dose arms.

Clinical Data

Primary and key secondary endpoint data from LIBERTY along with accompanying statistical analysis results are provided below:

Co-Primary Endpoint 1: Short Term (6 Days) Overall Safety and Tolerability

Percent of subjects experiencing any TEAE, ISR, or hypersensitivity for 6 days post-administration				
Treatment Arm	***%***	***Comparator***	***%***	***Significance***
VYD2311	**56.5%**	**COVID-19 mRNA vaccine**	**91.4%**	**P <0.0001**
Combination VYD2311 + COVID-19 mRNA vaccine	78.9%	COVID-19 mRNA vaccine	91.4%	P = 0.057
COVID-19 mRNA vaccine	91.4%	N/A		

Co-Primary Endpoint 2: Short Term (6 Days) Systemic AEs *Percent of subjects experiencing systemic AEs solicited via e-diary for 6 days post-administration*				
Treatment Arm	***%***	***Comparator***	***%***	***Significance***
VYD2311	**44.1%**	**COVID-19 mRNA vaccine**	**68.1%**	**P = 0.008**
Combination VYD2311 + COVID-19 mRNA vaccine	50.0%	COVID-19 mRNA vaccine	68.1%	P = 0.023
COVID-19 mRNA vaccine	68.1%	N/A		

Key Secondary Endpoint: Long Term (56 Days) Overall Safety and Tolerability *Percent of subjects experiencing any TEAE, ISR, or hypersensitivity for 56 days post-administration*				
Treatment Arm	***%***	***Comparator***	***%***	***Significance***
VYD2311	**60.9%**	**COVID-19 mRNA vaccine**	**91.4%**	**P <0.0001**
Combination VYD2311 + COVID-19 mRNA vaccine	83.1%	COVID-19 mRNA vaccine	91.4%	P = 0.21
COVID-19 mRNA vaccine	91.4%	N/A		

LIBERTY data demonstrate the favorable safety and tolerability of VYD2311 across both early and late follow-up time periods compared to COVID-19 mRNA vaccine. Of note, no AEs related to VYD2311 were higher than Grade 2, and no hypersensitivity or anaphylaxis was observed with VYD2311 or in any arm of the LIBERTY study.

Vaccine-induced neutralizing antiviral titers were analyzed to identify any immunologic interference between VYD2311 and COVID-19 mRNA vaccine. The data demonstrate that VYD2311 added to the COVID-19 mRNA vaccine increased the neutralizing titers from COVID-19 mRNA vaccine alone by approximately 2.5x over the 56-day study. To identify the vaccine's role within the combination neutralizing titers, Invivyd removed VYD2311 from the combination samples. Neutralizing titers from these VYD2311-depleted samples are essentially identical to the neutralizing titers observed in the monotherapy mRNA-based COVID-19 vaccine arm, confirming lack of immunologic interference.

VYD2311 observed pharmacokinetics, while pending definitive demonstration in the DECLARATION study, demonstrated results in LIBERTY consistent with Invivyd's expectations. These data, combined with VYD2311 in vitro potency data against circulating variants, allow Invivyd to estimate neutralizing antiviral titers consistent with Invivyd's target profile of VYD2311 under evaluation in DECLARATION.

The VYD2311 and COVID-19 mRNA vaccine combination arm data and comparative analyses suggest that dosing VYD2311 concomitant with COVID-19 mRNA vaccine may improve the safety and tolerability of COVID-19 mRNA vaccine while also adding substantially to neutralizing antiviral titers from the combination. This finding provides an area of potential future clinical study for Invivyd within COVID and other disease areas, consistent with Invivyd's broad early-stage antiviral monoclonal antibody pipeline.

VYD2311 Regulatory Submission Plans

Invivyd has been in constructive ongoing dialogue with the U.S. Food and Drug Administration (FDA) regarding regulatory pathways for VYD2311, including a recent Type C meeting in September and other discussions with FDA leadership. As a result of those discussions, Invivyd intends to submit a BLA under the Accelerated Approval Program pending results from the ongoing DECLARATION pivotal study.

Invivyd, therefore, plans to unblind and report the placebo-controlled safety and neutralizing antiviral titers of VYD2311 in the DECLARATION study, while keeping blinded clinical events collected to date. If the data are supportive, Invivyd intends to pursue Accelerated Approval based on DECLARATION and LIBERTY data, along with reference to prior Invivyd monoclonal antibody data. Invivyd then plans to continue accumulating PCR-positive symptomatic COVID-19 pooled, blinded events in a post-approval confirmatory randomized cohort to enhance statistical powering of target efficacy (70%-90% relative risk reduction in PCR+ symptomatic COVID-19 versus placebo). Invivyd believes that as an evidence base, data from LIBERTY, and the upcoming safety and neutralizing titers DECLARATION data on VYD2311, if positive, combined with data from previous Invivyd randomized, placebo-controlled trials EVADE (adintrevimab) and CANOPY (pemivibart) compare favorably to the evidentiary basis routinely used to approve updated COVID vaccines, which also change compositionally to a similar extent as Invivyd monoclonal antibodies.

"The LIBERTY data provide us with high confidence in the profile of VYD2311. With placebo-controlled safety and neutralizing

antiviral titer data for VYD2311 still pending from the DECLARATION study, this formal comparison of VYD2311 to standard of care COVID-19 mRNA vaccine provides an important window into VYD2311's clinical profile," commented Michael Mina, M.D., Ph.D., Chief Medical Officer and Chief Epidemiologist of Invivyd. "Today's LIBERTY data alone, even before DECLARATION data, provide more robust contemporary human clinical information than the data associated with recently approved updated COVID-19 vaccines, leaving us enthusiastic about moving forward toward BLA submission and rapidly serving vulnerable populations, if approved. With regard to the combination of VYD2311 and COVID-19 vaccine, we are intrigued and gratified that the combination may enhance vaccination by reducing unwelcome vaccine-related adverse events, while simultaneously adding the substantial virus neutralizing activity of a highly active monoclonal antibody. This finding suggests potentially broader, as yet unexplored, complementarity between Invivyd monoclonal antibodies and vaccines against COVID-19 and perhaps other pathogens."

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 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 is approximately 210 participants.

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, including with respect to the DECLARATION pivotal clinical trial; expectations regarding the company's anticipated regulatory pathway, product profile, indication, patient populations, and administration paradigm for VYD2311, including the company's plans to submit a BLA for VYD2311 to the FDA via Accelerated Approval Program; expectations regarding the public health landscape, potential advantages of mAbs, and potential complementarity between vaccines and Invivyd mAbs; potential future areas of clinical study for Invivyd; 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 expectations about the clinical profile of VYD2311; 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, including implementation of any necessary protocol amendments; uncertainties regarding clinical trial event accumulation rates and statistical powering; 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; 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 its planned BLA submission for VYD2311, and uncertainties regarding the FDA's acceptance and review of any such BLA submission; 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 June 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.

Contacts:

Media Relations
(781) 208-0160
media@invivyd.com

Investor Relations
(781) 208-1747
investors@invivyd.com