Invivyd Announces First Participants Dosed in LIBERTY, a Phase 3 Clinical Trial to Evaluate the Safety and Tolerability of VYD2311 Antibody Versus mRNA COVID Vaccine and to Characterize the Safety and Immunology of Antibody and mRNA Vaccine Co-Administration

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- *LIBERTY clinical trial will evaluate the comparative safety and tolerability of VYD2311 versus mRNA COVID-19 vaccine, as well as explore the safety and immunology of co-administered VYD2311 and mRNA COVID-19 vaccine*
- *Depending on study recruitment rate, Invivyd expects to report topline data from LIBERTY in Q3 2026, to accompany anticipated data from the pivotal DECLARATION clinical trial*
- *Prior exploration of monoclonal antibody (mAb) interaction with vaccine published **here** suggests a minimal clinical consequence to a similar interaction today, but could provide data to aid in potential product labelling language, if approved. This earlier work demonstrated an expected, modest reduction in vaccine-induced neutralizing antibody titers from co-administration of mAb and vaccine, in seronegative populations, with T Cell and other vaccine-induced metrics minimally changed*
- *LIBERTY is part of Invivyd's broader REVOLUTION clinical program, including DECLARATION, designed to characterize the profile of mAb-mediated prophylaxis from COVID-19 and the potential medical benefits to vulnerable Americans*

NEW HAVEN, Conn., June 09, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that the first participants have been dosed in the LIBERTY Phase 3 clinical trial, a randomized, double-blind study that is evaluating the safety and tolerability and immunology of VYD2311 alone, an mRNA COVID-19 vaccine alone, and VYD2311 co-administered with a COVID-19 vaccine in healthy adults. VYD2311 is Invivyd's vaccine-alternative monoclonal antibody (mAb) investigational candidate for the prevention of COVID-19. Depending on study recruitment rate, Invivyd expects to report topline data from the LIBERTY trial in Q3 2026, to accompany anticipated data from the pivotal DECLARATION clinical trial.

"We are pleased to have dosed the first participants in LIBERTY, a trial we believe can better characterize the favorable tolerability profile of a mAb and highlight the benefits of our expected new standard of care in COVID-19 prevention if VYD2311 is approved," said Marc Elia, Chairman of Invivyd's Board of Directors. "In light of Sanofi's recent findings in the COMPARE study that greater than 80% of patients who received a COVID-19 vaccine experienced at least one systemic side effect, we are moving with urgency to provide Americans with a COVID prevention option that does not require the repeated inflammation of COVID-19 vaccination. CDC data have shown that concern about serious or unknown side effects have been leading reasons adults have elected not to receive a COVID-19 vaccine booster, which is why Invivyd is focused on developing a potential prevention option that is more tolerable."

LIBERTY is an innovative head-to-head clinical trial to evaluate the comparative safety and tolerability of a mAb and an mRNA COVID-19 vaccine. Prior data from Invivyd's EVADE study and Sanofi's COMPARE study provided exploratory evidence that mAbs may offer a more tolerable prevention profile than traditional vaccines.

LIBERTY is expected to enroll approximately 210 adult participants aged 18 to 49 years. Patients will be randomized 1:1:1 across three treatment arms:

1) An mRNA COVID-19 vaccine administered by intramuscular (IM) injection and placebo administered by IM injection
2) VYD2311 (250 mg) administered by IM injection and placebo administered by IM injection
3) VYD2311 (250 mg) administered by IM injection and an mRNA COVID-19 vaccine administered by IM injections

The primary endpoints of the trial are safety, based on treatment-emergent adverse events, injection site reactions, and hypersensitivity reactions through Day 6, and the number of participants reporting ≥1 systemic symptoms post-injection through Day 6, in participants administered VYD2311 alone, COVID-19 mRNA vaccine alone, or VYD2311 and a COVID-19 mRNA vaccine concurrently.

LIBERTY is part of Invivyd's broader REVOLUTION clinical program, which is designed to establish VYD2311 as the preferred option for protection from COVID over mRNA-based vaccination, if approved. Data from the LIBERTY clinical trial are expected to be included in anticipated VYD2311 regulatory filings.

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 study 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 expected to be 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; expectations regarding the company's clinical trial designs, enrollment, regulatory pathway, product profile, indication, patient populations, and administration paradigm for VYD2311, including the company's REVOLUTION clinical program and the timing of results thereof; the expectation for data from the LIBERTY clinical trial to be included in anticipated VYD2311 regulatory filings; the potential of VYD2311 as a novel mAb candidate for the prevention of COVID-19, and the expectation for a new standard of care in COVID-19 prevention if VYD2311 is approved; the potential for the REVOLUTION clinical program to establish VYD2311 as the preferred option for protection from COVID over mRNA-based vaccination going forward and to bring potential medical benefits to vulnerable Americans; the potential for mAbs to offer a more tolerable prevention profile than traditional vaccines; 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 enrollment and 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 Biologics License Application 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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