SPEAR Study Group to Present its Recommended Long COVID Antibody Study Design Featuring Invivyd's VYD2311 At RECOVER-TLC Workshop September 9-10, 2025

September 4, 2025

- *SPEAR proposal reflects current evidence on monoclonal antibodies in treatment for Long COVID and identifies VYD2311 as a promising next-generation candidate for the clinical study*
- *Recommendation is for a robust, comprehensive, translational study to evaluate the ability of VYD2311 to decrease circulating spike protein in eligible patients and to explore potential associated clinical benefits*
- *Study design contemplates maintaining high antiviral antibody titers over an extended period to maximally suppress underlying chronic infection that may drive Long COVID pathology*
- *Drs. Amy Proal and David Putrino to present on behalf of SPEAR Study Group*

WALTHAM, Mass., Sept. 04, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that the SPEAR Study Group has issued their consensus recommendation for a clinical study design to evaluate the effects of monoclonal antibody (mAb) therapy on Long COVID. The recommendation will be presented for consideration to RECOVER-TLC, an NIH initiative devoted to testing potential treatments for Long COVID.

Formed by leading investigators in the field, the SPEAR Study Group is focused on designing studies that explore the role of persistent viral reservoirs or circulating spike protein in driving Long COVID. The study group's proposed clinical study centers on anti-SARS-CoV-2 spike protein monoclonal antibodies designed to be broadly neutralizing, including VYD2311, as potential therapies for people suffering from Long COVID or Post-Vaccination Syndrome (PVS).

Drs. Amy Proal and David Putrino will present the proposed study design for the consideration of RECOVER-TLC at the Second Annual RECOVER-TLC Workshop being held September 9-10, 2025 in Bethesda, Maryland.

Key elements of the proposed clinical study include:

1) Deploying high levels of neutralizing monoclonal antibody over the long-term (months) that confer antiviral activity at or above levels associated with successful treatment of active COVID-19 infection
2) Randomized, placebo-controlled study with more than 100 patients per arm, powered to generate definitive, reliable evidence
3) Enrollment based on biomarkers indicating persistent spike antigen in serum and/or viral RNA in tissue
4) Measuring reduction in detectable spike antigen in serum and/or viral RNA as the critical translational endpoint
5) Exploring potential symptom improvement using standardized instruments to correlate potential modification of potential underlying chronic infection or presence of antigens to clinical benefit.

"Long COVID studies, including those testing antiviral therapies, have not explored at scale the critical, underlying biology of SARS-CoV-2 RNA or spike antigen persistence, and whether that persistence can be modulated via monoclonal antibodies – in particular modern, potent mAbs," said SPEAR member Dr. Michael Peluso. "At this point, the time is right and potential best-in-class mAb tools are available to try to advance our understanding of the biology of Long COVID. Using investigational mAbs like VYD2311 from Invivyd to answer these questions should be at the top of our agenda, and we are excited to propose this approach to RECOVER-TLC."

"Long COVID/Post-Vaccination Syndrome stole my ability to function in even the most ordinary parts of life, leaving me disabled and grieving the loss of who I was," said Melissa Walker, Long COVID sufferer. "The work that the SPEAR Study Group is doing gives me hope that there could be a therapy to help our patient community."

The RECOVER-TLC Second Annual Workshop will take place September 9-10, 2025 in Bethesda, Maryland. Dr. David Putrino will present the proposed clinical study design for funding consideration by RECOVER-TLC on September 10, 2025 at 9:25 a.m. ET. Dr. Amy Proal will discuss the overall antiviral landscape, the potential role of monoclonal antibody therapy, and implications for Long COVID research on September 10, 2025 at 1:00 p.m. ET.

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.

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," "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, expectations regarding the SPEAR Study Group and its anticipated focus and goals; expectations regarding the SPEAR Study Group's recommended Long COVID antibody study design, including anticipated key elements and objectives, and the potential of VYD2311 as a candidate for such clinical study; plans to present the study design for consideration at the RECOVER-TLC Second Annual Workshop for funding consideration; the potential of mAbs designed to be broadly neutralizing, including VYD2311, as therapies for people suffering from Long COVID or PVS; 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 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 SPEAR Study Group initiatives, including the potential Long COVID antibody study, as well as 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 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; whether mAb therapy is able to offer a therapeutic approach to Long COVID and PVS; the ability to gain alignment with the applicable regulatory authorities on clinical trial designs and regulatory pathways for COVID-19 mAbs, and the timing thereof; changes in the regulatory environment; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways; future clinical trial site activation or enrollment rates; how long the EUA granted by the FDA for pemivibart 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; 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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