Invivyd and SPEAR Study Group Announce Plan for Phase 2 Study of VYD2311 for Treatment of Long COVID and COVID Vaccine-Injured Individuals to Commence Mid-2026

January 20, 2026

- Phase 2 clinical trial will evaluate the safety, translational biology, and exploratory clinical efficacy of VYD2311 in people with Long COVID or COVID vaccine injury
- Participants to include people with Long COVID who demonstrate evidence of chronic infection or antigen persistence in a variety of tissues, and COVID vaccine-injured people including those who have demonstrated persistence of vaccine-delivered spike protein
- Design includes multiple highly active antibody doses administered over the long term to assess the safety and potential clinical benefit of VYD2311 treatment, versus placebo
- Millions of individuals continue to live with persistent and debilitating symptoms of Long COVID, underscoring the significant unmet need for development of effective treatment options

NEW HAVEN, Conn., Jan. 20, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) and the SPEAR Study Group today announced the plan to initiate a Phase 2 clinical trial evaluating monoclonal antibody VYD2311 in individuals with Long COVID or COVID vaccine injury.

“More and more data, including detailed sampling of multiple human tissues, indicate protracted infection and/or prolonged presence of spike protein antigen in people living with Long COVID. Spike protein has also been found in the blood of some people who report a chronic debilitating condition after COVID vaccination,” noted David Putrino, Ph.D., the Nash Family Director of the Cohen Center for Recovery from Complex Chronic Illness at Mount Sinai and Founding Member of the SPEAR Study Group. “We formed the SPEAR Study Group with Invivyd leadership specifically to provide what we believe would be the most important and valuable next step in understanding both the biology of and potential relief from Long COVID, a disease that impairs millions of American lives and which is growing with near-constant, unchecked virus circulation in America.”

“The SPEAR Study Group and Invivyd have longstanding interest in clinical disease that can follow COVID infection and COVID vaccination,” noted Amy Proal, Ph.D., CEO of PolyBio Research Foundation and founding member of the SPEAR Study Group. “Chronic exposure to SARS-CoV-2 spike protein in any form may be driving ongoing morbidity in America, and we believe the monoclonal antibodies discovered and developed by Invivyd may provide an extremely promising route to stopping and perhaps reversing some of that damage. We as a group are thrilled to take this next step with Invivyd.”

The Phase 2 clinical trial is expected to be initiated by mid-2026 and to include the following features:

- Multiple high doses of highly active monoclonal antibody VYD2311, an investigational antibody that has demonstrated in vitro antiviral activity across all clinically recorded variants of SARS-CoV-2 tested since the original Wuhan strain, across many months of therapy
- Double-blind, placebo control
- Inclusion criteria designed to enroll people with demonstrated persistent infection or antigenemia, to the extent technologically possible
- Clinical efficacy evaluations including functional performance tests and Patient-Reported Outcomes assessment (PROs) consistent across prior studies of Long COVID and other infection-associated chronic conditions and illnesses

“Not long after launching PEMGARDA® (pemivibart) for the prevention of COVID in certain immunocompromised people, we became aware of increasing, independent case reports of Long COVID treatment successes, as we previously noted,” said Marc Elia, Chairman of Invivyd’s Board of Directors. “These reports echo earlier work with other monoclonal antibodies and, along with continuously emerging reports and observations of chronic infection, give us confidence to explore this potential therapeutic signal in a prospective, placebo-controlled study, especially given the strong and broad antiviral activity we have observed with VYD2311. With the SPEAR Study Group, we believe we have the partnership of the leading minds in Long COVID and COVID vaccine injury, and we are looking forward to expanding our work radically for the benefit of people suffering from Long COVID, if we generate a meaningful signal of therapeutic benefit.”

Further details on the planned Phase 2 Long COVID trial of VYD2311 are expected to be made available in coming months, including details on www.clinicaltrials.gov when possible.

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 PEMGARDA

PEMGARDA® (pemivibart) is a half-life extended investigational monoclonal antibody (mAb). PEMGARDA was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1, XEC, LP.8.1 and XFG. PEMGARDA targets the SARS-CoV-2 spike protein receptor binding domain (RBD), thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for intravenous use is an investigational mAb that has not been approved, but has been authorized for emergency use by the U.S. FDA under an EUA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

PEMGARDA is not authorized for use for the treatment of COVID-19, Long COVID, or COVID-19 Post-Vaccination Syndrome, or for post-exposure prophylaxis of COVID-19. Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccinations, should receive COVID-19 vaccination. In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation. For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

To support the EUA for PEMGARDA, an immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum virus neutralizing titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Further, the variability associated with cell-based EC50 value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior clinical trials, impact the ability to precisely estimate protective titer ranges. Additionally, certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

About SPEAR Study Group
Invivyd and leading researchers formed the SPEAR (Spike Protein Elimination and Recovery) Study Group to assess the effects of monoclonal antibody (mAb) therapy for Long COVID and COVID-19 Post-Vaccination Syndrome.

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,” “intends,” “potential,” “predicts,” “plans,” “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 planned Phase 2 clinical trial to evaluate VYD2311 for treatment of Long COVID and COVID vaccine injury, including anticipated timing and study design features; beliefs about the COVID-19 landscape and significant unmet need for development of effective treatment options for Long COVID; beliefs about consequences of chronic exposure to SARS-CoV-2 spike protein and the potential of Invivyd mAbs to stop or reverse some of that damage; the potential of Invivyd to expand its work for the benefit of people suffering from Long COVID; 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 planned Phase 2 Long COVID clinical trial of VYD2311, 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, 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; whether mAb therapy is able to offer a therapeutic approach to Long COVID; 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 PEMGARDA 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 September 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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