

INVIVYD INC.

Invivyd and the SPEAR Study Group Announce Initiation of “FLINTLOCK” Phase 2 Study of VYD2311, a Monoclonal Antibody for the Potential Treatment of Long COVID or Post-Vaccination Syndrome

October 14, 2026

- *FLINTLOCK Phase 2 clinical trial will evaluate the safety, tolerability, pharmacokinetics, and clinical efficacy of high-dose monoclonal antibody VYD2311 in adults aged 18-65 years with Long COVID or Post-Vaccination Syndrome, also known as COVID vaccine injury*
- *Design includes VYD2311 administered in three doses to assess the safety and potential clinical benefit of VYD2311 treatment versus placebo over 90 days*
- *VYD2311 has demonstrated high in vitro antiviral potency across all SARS-CoV-2 variants tested from original Wuhan through contemporary Omicron variants*
- *FLINTLOCK is part of Invivyd's broader REVOLUTION clinical program for VYD2311, including DECLARATION and LIBERTY*
- *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., Oct. 14, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) and the SPEAR Study Group today announced the initiation of FLINTLOCK, a Phase 2 clinical trial evaluating the safety, tolerability, pharmacokinetics, and clinical efficacy of high-dose monoclonal antibody VYD2311 in individuals with Long COVID or Post-Vaccination Syndrome (PVS), also known as COVID vaccine injury.

“Long COVID continues to be a significant challenge for millions of Americans. It is a disease state characterized by persistent and debilitating symptoms impacting multiple systems across the human body, including immune dysfunction, cardiovascular issues, respiratory challenges, nervous system dysfunction, pain, and other health issues that can impact a person's day-to-day life,” noted David Putrino, Ph.D., 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 are excited to take the next step in advancing this potential therapeutic option for patients living with Long COVID or Post-Vaccination Syndrome, a diagnosis which has received very little attention.”

The Phase 2 FLINTLOCK clinical trial includes the following study features:

- Randomized, double-blind, placebo-controlled, proof-of-concept study
- Tests Invivyd's monoclonal antibody VYD2311, an investigational monoclonal antibody that has been demonstrated to be pharmaceutically active against all SARS-CoV-2 variants tested to date from current variants back to original Wuhan variants
- High-dose initial intravenous (IV) infusion of VYD2311 followed by monthly intramuscular (IM) injections at days 30 and 60 with total dose targeted at 10x the prophylactic dose of VYD2311 assessed in DECLARATION and LIBERTY, while still below doses already assessed with a positive initial safety profile in VYD2311 first-in-human testing ([LINK](#))
- Inclusion criteria designed to enroll adults aged 18-65 years with confirmed Long COVID or PVS; criteria include having at least 2 persistent symptoms after a COVID-19 infection or following COVID-19 vaccine injury
- Clinical efficacy evaluations include functional performance tests consistent across prior studies of Long COVID and other infection-associated chronic conditions and illnesses, through Day 90
- Assessment of the safety and tolerability of VYD2311 based on the incidence, severity, causality, and outcome of treatment emergent adverse events (TEAEs) and hypersensitivity reactions through Day 90, as well as evaluation of the pharmacokinetics of VYD2311 by measuring serum concentrations through Day 90
- Initial data expected in mid-2027.

“Both Long COVID and COVID PVS may share the inflammatory presence of persistent SARS-CoV-2 spike protein in the underlying disease processes, and so we are bringing to bear our pharmacology that is specifically directed against the SARS-CoV-2 spike protein target in large quantities,” said Marc Elia, Chairman and CEO of Invivyd. “Previous Long COVID antiviral therapeutic efforts have been limited by use of short course therapies that may not adequately inhibit viral replication, or by the use of monoclonal antibody candidates that lacked activity against many known and circulating clinical variants. However, given anecdotal independent case reports of highly active monoclonal antibodies generating clinical improvements in Long COVID patients, including with our current monoclonal antibody medicine PEMGARDA® (pemivibart), we are looking forward to advancing

FLINTLOCK and potentially bringing forward a therapeutic option for the benefit of people suffering from Long COVID.”

Further details on the FLINTLOCK Phase 2 Long COVID trial of VYD2311 will be posted near-term to www.clinicaltrials.gov.

PEMGARDA® (pemivibart) is not authorized or approved for the treatment of Long COVID or PVS.

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 FLINTLOCK

FLINTLOCK is a Phase 2, randomized, double-blind, placebo-controlled, proof-of-concept study is being conducted to investigate the safety, tolerability, pharmacokinetics, clinical activity, immunogenicity, and SARS-CoV-2 neutralizing antibody response of VYD2311. VYD2311 will be administered first as a loading dose via intravenous infusion on Day 1 followed by additional intramuscular injections on Day 30 and Day 60 in adults aged 18-65 years with a confirmed diagnosis of Long COVID or Post-Vaccination Syndrome (PVS), with two or more symptoms, with or without SARS-CoV-2 spike antigen that are present ≥6 months after having a COVID-19 infection or vaccination. Total enrollment of the trial is approximately 130 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 injection, compared to placebo. Total enrollment of the trial is approximately 2,400 participants.

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 was approximately 210 participants.

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. 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.

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 authorization revoked sooner. On June 30, 2026, the U.S. Department of Health and Human Services (HHS) announced notice of the termination of the declaration, effective June 29, 2027.

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,” “future,” “intends,” “plans,” “potential,” “predicts,” “projects,” 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 FLINTLOCK Phase 2 clinical trial and the broader REVOLUTION clinical program; the potential of mAbs as a therapeutic option for patients living with 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 purpose and goals of the SPEAR Study Group; 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 the FLINTLOCK Phase 2 clinical trial and the broader REVOLUTION clinical program; 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 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; whether mAb therapy is able to offer a therapeutic approach for Long COVID or PVS; 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 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.

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