Invivyd and Collaborators Author New Manuscript Evaluating Early Tolerability of COVID Monoclonal Antibody and Comparing Results to COVID Vaccination

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- *Invivyd authors evaluated early side effects of prior low-dose investigational monoclonal antibody adintrevimab from the EVADE study, demonstrating minimal tolerability issues*
- *Results allow for comparison to contemporary COVID-19 mRNA and protein vaccine tolerability, as well as epidemiologic extrapolation of systemic symptom days experienced via each approach*
- *Upcoming LIBERTY trial head-to-head study comparing safety and tolerability between VYD2311 and mRNA vaccine will build on these results in a rigorous, prospective fashion*

NEW HAVEN, Conn., May 11, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that a preprint of original research regarding COVID monoclonal antibody and vaccine systemic reactogenicity is now available on MedRxiv and is titled “Safety first: should the high tolerability of intramuscular anti-spike COVID-19 monoclonal antibody change our expectations of vaccine safety?” Linked here.

On April 18, 2026, at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in Munich, Germany, Sanofi presented results from its COMPARE Phase 4 study, which characterized early systemic side effects of protein-based COVID-19 vaccine in comparison to mRNA-based COVID-19 vaccine. The results showed a statistically significant advantage in favor of protein-based vaccine in reactogenicity, defined as Grades 1/2/3 side effects occurring within seven days of vaccination, with protein vaccine resulting in a probability of experiencing at least one systemic reaction at 83.6% versus mRNA vaccine at 91.6%, with symptoms lasting 3.1 and 3.5 days, respectively.

Invivyd previously conducted the EVADE trial, a Phase 2/3 double-blind, randomized, placebo-controlled study of adintrevimab, a low-dose investigational monoclonal antibody for the prevention of COVID-19 that is the parent antibody to pemivibart and VYD2311. In new research announced today, safety and tolerability data from adintrevimab in EVADE were re-analyzed post-hoc to assess comparable systemic adverse events (AEs) within the same seven days post-dosing evaluated in COMPARE.

While limited by cross-trial comparison and methodologic differences, the data demonstrate a large gap in early tolerability between vaccine and monoclonal antibody COVID immunizations:

	COMPARE Trial			**EVADE Trial**	
COVID Immunization	**mRNA** vaccine	**Protein** vaccine		Monoclonal **Antibody**	**Placebo**
% Grades 1/2/3 systemic AEs in first 7 days	**91.6%**	**83.6%**		**2%**	**1%**

These results allow for epidemiologic extrapolation and calculation of the total symptom days immunization subjects would undergo under different combinations of immunization efficacy and COVID-19 community attack rate (Figure 1 of the new manuscript). Calculating total symptom days that include both vaccine symptomatic reactogenicity as well as the burden of symptomatic disease from breakthrough infection demonstrates the net symptomatic burden experienced by immunized subjects. Such analysis directly highlights the public health challenge of encouraging the public to stay well via vaccination by asking the public to feel sick via vaccination.

Dr. Michael Mina, Chief Medical Officer of Invivyd and senior author on the manuscript commented, “Our re-evaluation of the EVADE data for adintrevimab, a low-dose investigational monoclonal antibody highly similar to VYD2311, allows us to compare antibody versus vaccine immunization approaches on a metric that has contributed to meaningful reduction in COVID-19 vaccine utilization: the degree to which people feel sick after immunization. As we would expect from a monoclonal antibody that doesn’t engage the immune system, adintrevimab presents a minimal overall symptomatic burden and a de minimis difference from placebo. In this comparison, the difference between low-dose antibody and COVID vaccine is night and day. Further, the COMPARE study of two vaccine approaches highlights the challenge of trying to convince a population to protect itself from symptomatic COVID-19 when the protective vaccine itself gives most immunized subjects 3 to 3.5 days feeling of being sick, in return for apparent modest, short-term protection from being sick from COVID-19.”

“Vulnerable populations deserve next-generation tools to protect themselves from ubiquitous pathogens like SARS-CoV-2 with the least possible burden. Invivyd’s goal is to provide optimal protection for as many people as possible, and that starts with safety and tolerability. We are executing our pivotal program as rapidly as possible and hope that data, especially anticipated controlled data from our upcoming LIBERTY study, provide policy makers and regulators, and then, if approved, healthcare professionals and Americans, with the conviction to move forward into a new era of protection from COVID,” said Marc Elia, Chairman of Invivyd’s Board of Directors.

Invivyd anticipates near-term start of the LIBERTY study, which will evaluate mRNA vaccination and low-dose investigational monoclonal antibody candidate VYD2311 on systemic symptoms in a head-to-head single controlled study.

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.

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 about 210 participants.

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, beliefs regarding the potential advantages of monoclonal antibody immunization versus vaccine immunization; predictions based on epidemiologic extrapolation of systemic symptom days experienced post-dosing between vaccine and monoclonal antibody approaches to COVID immunization; the potential of next-generation tools to offer protection from pathogens like SARS-CoV-2 with the least possible burden, and the company’s goal to provide optimal protection for as many people as possible; plans related to the company’s research and development activities; expectations regarding the company’s pivotal program, including the company’s clinical trial designs, and the expected timing and results thereof; the potential of VYD2311 as a novel mAb candidate that may be able to deliver clinically meaningful titer levels through more patient-friendly means; expectations regarding the COVID landscape; 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; clinical trial site activation, enrollment, and event accumulation rates; unexpected safety or efficacy data observed during preclinical studies or clinical trials; 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; how long the EUA granted by the U.S. FDA for pemivibart 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; changes in expected or existing competition; changes in the regulatory environment; the outcome of the company’s engagement with regulators; uncertainties related to the regulatory authorization or 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; 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 pemivibart and VYD2311 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; 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; the company's reliance on third parties; 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, 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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