Invivyd Publishes Model for Evaluating Biomarker Correlates of Protection for Monoclonal Antibodies Against Symptomatic COVID-19

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- ***Research published online today in peer-reviewed journal Science Translational Medicine***
- ***Analysis of data from a Phase 2/3 COVID-19 prevention study (EVADE) of adintrevimab suggests clinically meaningful protection can be achieved at low neutralizing antibody titers***
- ***Work builds on vaccine studies demonstrating neutralizing antibody titers as correlates of protection against disease and could inform evolution of regulatory framework for therapeutic antibodies***

WALTHAM, Mass., March 22, 2023 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a clinical-stage biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced the publication of research in the peer-reviewed journal *Science Translational Medicine* describing a model for evaluating biomarker correlates of protection for monoclonal antibodies (mAb) against symptomatic COVID-19. The research concluded that neutralizing antibodies are mechanistic in providing protection against symptomatic disease and identified serum neutralizing antibody titers as a correlate of protection. These findings have potential to support accelerated development and innovative regulatory frameworks for mAbs for prevention of COVID-19.

Invivyd chief medical officer, Pete Schmidt, M.D., M.Sc, was lead author of the manuscript titled, “Antibody-mediated protection against symptomatic COVID-19 can be achieved at low serum neutralizing titers,” which was published online today.

“The dramatic difference in neutralizing activity conferred by adintrevimab against the Delta and Omicron variants observed in the Phase 2/3 prevention study provided a unique opportunity to determine a threshold of serum virus neutralization associated with potential protection against symptomatic COVID-19,” said Dr. Schmidt. “We are proud to make such an important contribution to the collective understanding of SARS-CoV-2 immunity. Establishing correlates of protection for monoclonal antibodies has proven challenging due to the confounding presence of preexisting humoral or cellular immunity, induced by vaccination or natural infection. We believe that our scientific contributions could help inform the development of a new regulatory framework to support accelerated development of mAbs that keep pace with viral evolution.”

The publication provides details of a model incorporating pharmacokinetic and clinical data from adintrevimab and previously published data from other mAbs and vaccines. The model suggests that clinically meaningful protection from symptomatic disease could be achieved with monoclonal antibody titers as low as 1:30 (90% confidence interval, 1:24-1:40). Like vaccine studies, mAb data modeling suggests that protection increases with increased neutralization titers with no absolute threshold for protection.

Dr. Schmidt continued, “Our research positions Invivyd to meet the challenge of rapidly developing next-generation antibodies that provide broad and durable protection against current and future variants of concern. We look forward to continuing to provide our scientific findings to regulators as they explore potential pathways to expedite availability of new products for prevention and treatment of COVID-19.”

Invivyd scientists presented related data at a joint FDA-EMA workshop on SARS-CoV-2 mAbs in December.

Supported by the research included in the *Science Translational Medicine* manuscript, the company continues to plan to advance VYD222 into the clinic in the first quarter of this year. VYD222 was engineered from adintrevimab, Invivyd’s investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19. The adintrevimab clinical data package has the potential to support accelerated development of VYD222. Once aligned with regulatory authorities, pivotal studies are planned to swiftly follow Phase 1.

About Invivyd
(Nasdaq: IVVD)
Invivyd, Inc., is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people ffrom the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. Invivyd’s technology works at the intersection o evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. The company is generating a robust pipeline of product candidates which could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications. 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,” “intends,” “potential,” “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, the ability for Invivyd, other companies or combination of companies and industry representatives to influence regulators to change or adopt new development pathways or timelines; the ability for Invivyd, other companies or combination of companies and industry representatives to influence regulators to change or adopt new development pathways or timelines; the ability of Invivyd to accelerate development timelines for the unmet need for treatment of COVID-19; the interest or acceptance by regulatory authorities of regulatory and clinical strategies to support potentially expedited development of novel monoclonal antibody therapies; the potential for success and or expedited discovery, development, or commercialization of antibody therapies for COVID-19; the continued unmet need for prevention and treatment of COVID-19 particularly for immuno compromised and other vulnerable populations; the viability and acceptability of new regulatory strategy, policy or approach to drug development and the potential of the same to maintain pace with changing COVID-19 variants; the future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; our ongoing research and clinical development plans and the

timing thereof; our plans to advance VYD222 other early stage candidates as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent, the potential for VYD222 or other product candidates to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; the potential for the clinical data package resulting from clinical trials of adintrevimab to support accelerated VYD222 monotherapy development; our plans to advance VYD222 into the clinic; our expectations that we will be able to achieve regulatory alignment and advance pivotal studies with VYD222; our plans, technology and resources to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and seasonal influenza, in the U.S. and globally; and other statements that are not historical fact.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the ability to gain alignment with the applicable regulatory authorities on the clinical development pathway for VYD222 and the timing thereof; the ability for Invivyd and/or other companies, scientists, clinicians or industry representatives to impact the strategy, policy or approach to drug development drafted or applied by regulatory authorities, including the FDA and EMA; the impact of any such change on the speed or success of development and commercialization of antibodies for the prevention and/or treatment of COVID-19; the ability of the company to generate and utilize tools to discover and develop antibodies to treat current and potential future variants; the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of VYD222 or other pipeline candidates or combination of candidates based on neutralizing activity in pre-clinical studies; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process, including the outcome of our discussions with regulatory authorities concerning our clinical trials; whether VYD222, or any other pipeline candidate or combination of candidates is able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use authorization submission; whether research and development efforts will improve efficacy of adintrevimab against predominant variants or identify additional monoclonal antibodies or combination of antibodies for the prevention and treatment of COVID-19 and other infectious diseases; whether research and development efforts will identify and result in safe and effective therapeutic or preventative options for other infectious diseases in the U.S. or globally and whether we have adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause our 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 our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, each filed with the Securities and Exchange Commission (the “SEC”), and in our other filings with the SEC, and in Invivyd’s future reports to be filed with the SEC and available at www.sec.gov. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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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