Invivyd Doses First Participants in Phase 1 Trial of VYD222, a Novel Monoclonal Antibody Candidate for COVID-19

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A clinical trial generating safety, pharmacokinetics, and dosing data with the goal of providing information to allow for rapid advancement into a pivotal Phase 3 trial

WALTHAM, Mass., March 30, 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 dosing of the first participants in a Phase 1 healthy volunteer trial of VYD222, a novel monoclonal antibody (mAb) candidate for COVID-19.

The Phase 1 randomized, blinded, placebo-controlled, dose-ranging trial will evaluate the safety, pharmacokinetics, and tolerability of VYD222 (NCT05791318). The dose-ranging trial will evaluate three different doses, each administered in an IV infusion. All dose levels are designed to provide durability in the face of viral evolution and flexibility at the time of regulatory submission. This Phase 1 trial is being conducted in Australia.

The company expects preliminary data readouts from the Phase 1 trial in the second quarter and anticipates additional clinical readouts from the VYD222 program throughout the remainder of 2023.

“We are excited to initiate a first in human clinical trial of VYD222,” said Dave Hering, chief executive officer of Invivyd. “With previously authorized mAbs losing activity against currently circulating SARS-CoV-2 variants, there is a global, urgent unmet need for new therapeutic options for vulnerable populations, including individuals who have a reduced immune response to vaccination. By leveraging our expertise in virology, predictive modeling and antibody engineering, VYD222 is the next of multiple candidate mAbs we aim to advance from our pipeline with the goal of keeping pace with viral evolution and protecting the most vulnerable.”

About VYD222
VYD222 is a novel monoclonal antibody (mAb) candidate being developed for COVID-19 to address the urgent need for new therapeutic options for vulnerable populations, including immunocompromised people. Globally, there are millions of immunocompromised people, with an estimated 8 million in the U.S. alone, who may not adequately respond to COVID-19 vaccination, increasing their risk for severe outcomes from COVID-19. As of March 2023, there are no monoclonal antibodies authorized or approved in the U.S. for the prevention or treatment of COVID-19.

VYD222 has demonstrated *in vitro* neutralizing activity against currently circulating variants of concern, including XBB.1.5. 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 company believes the adintrevimab clinical data have the potential to support accelerated development of VYD222.

About Invivyd
(Nasdaq: IVVD)
Invivyd, Inc., is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect yvulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. Invivyd’s technolog works at the intersection of 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, our ongoing research and clinical development plans and the timing thereof, including with respect to the clinical development of VYD222; our goal for the Phase 1 trial of VYD222 to provide information to allow for rapid advancement into a pivotal Phase 3 trial; the timing of anticipated data readouts in 2023 from the VYD222 program; our plans to evaluate three different doses in our Phase 1 trial of VYD222; our design of the Phase 1 trial to include VYD222 dose levels intended to provide durability in the face of viral evolution and to provide flexibility at the time of regulatory submission; the potential for the adintrevimab clinical data to support accelerated development of VYD222; 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

immunocompromised 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 plans to advance VYD222 and multiple other candidate mAbs with the goal of keeping pace with viral evolution and protecting the most vulnerable; the potential for VYD222 or other product candidates to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; our plans 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 trial design and 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, 2022 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.

Contacts

Media Contact:
Kate Burdick, Evoke Canale
860-462-1569
kate.burdick@evokegroup.com

Investor Contact:
Chris Brinzey, ICR Westwicke
339-970-2843
chris.brinzey@westwicke.com