Invivyd Announces the FDA Has Cleared Its IND Application for VYD222, a Monoclonal Antibody Candidate for Prevention of COVID-19, and Provides Phase 1 VYD222 Clinical Trial Update

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- ***On track for initial readouts in Q2 2023 from ongoing Phase 1 VYD222 clinical trial being conducted in Australia, with cohort 1 dosing complete***
- ***Discussions are underway with the FDA and global regulators regarding the company's proposed VYD222 pivotal clinical trial design***

WALTHAM, Mass., April 25, 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 that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for VYD222, a monoclonal antibody (mAb) candidate. Invivyd is developing VYD222 for the prevention of COVID-19 in vulnerable populations, such as immunocompromised people. As previously announced, VYD222 is currently being evaluated in an ongoing Phase 1 healthy volunteer clinical trial being conducted in Australia.

"We are pleased that the FDA has cleared our IND for VYD222 and we are excited by the progress we've made in our ongoing Phase 1 VYD222 clinical trial," said Dave Hering, chief executive officer of Invivyd. "We have completed dosing of the first cohort and have moved to the second dosing cohort, with initial readouts from the Phase 1 clinical trial on track for the second quarter. The swift progress of our Phase 1 VYD222 clinical trial, along with the FDA's recent clearance of the VYD222 IND, are important steps in our plan to rapidly advance a stream of mAb candidates designed to keep pace with SARS-CoV-2 viral evolution."

"For the millions of immunocompromised people around the world who may not generate adequate protection from SARS-CoV-2 vaccines, there is an urgent need for new therapeutics that provide the rapid, passive immunity that results from the direct delivery of mAbs," said Pete Schmidt, M.D., M.Sc., chief medical officer of Invivyd. "With the previously authorized anti-SARS-CoV-2 mAbs losing activity against current variants of concern, we look forward to continuing to work with the FDA and global regulators to advance VYD222 and our platform-based approach to development."

In March 2023, Invivyd announced the election of VYD222 for clinical development and subsequently announced dosing of the first participants in a Phase 1 VYD222 clinical trial. The ongoing Phase 1 trial is a randomized, blinded, placebo-controlled, dose-ranging trial that will evaluate the safety, pharmacokinetics, tolerability, and serum virus neutralizing activity of VYD222 in healthy adult volunteers (NCT05791318). The dose-ranging trial will evaluate three different doses, each administered as a single IV push. All doses are designed to provide durability in the face of viral evolution and flexibility at the time of regulatory submission.

About VYD222

VYD222 is a novel monoclonal antibody (mAb) candidate in development for the prevention of COVID-19 in vulnerable populations, such as 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 April 2023, there are no monoclonal antibodies authorized or approved in the U.S. for the prevention 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

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with ySARS-CoV-2. Invivyd's technology works at the intersection of evolutionary virology, predictive modeling, and antibod 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; the timing of anticipated data readouts from the VYD222 program; our plans to evaluate three different doses in our Phase 1 trial of VYD222, which dose levels are designed to provide durability in the face of viral evolution and flexibility at the time of regulatory submission; the potential for the adintrevimab clinical data to support accelerated development of VYD222; our plan to rapidly advance a stream of mAb candidates designed to keep pace with SARS-CoV-2 viral evolution; our intention to continue to working with the FDA and global regulators to advance VYD222 and our platform-based approach to development; our ability to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats; the potential for VYD222 and other product candidates to be high-quality, long-lasting antibodies with a high barrier to viral escape; our plans to generate a robust pipeline of product candidates which could be used in prevention or treatment of serious viral threats, starting with COVID-19 and expanding into influenza and other high-need indications; 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 timing and progress of our discovery, preclinical and clinical development activities; the ability of the company to generate and utilize tools to discover and develop a pipeline of antibodies to treat current and potential future SARS-CoV-2 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 product 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 and platform-based approach to development; whether VYD222 or any other product candidate or combination of candidates is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variant(s); whether VYD222 or other product candidates will be high-quality, long-lasting antibodies with a high barrier to viral escape; 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 our research and development efforts will identify and result in safe and effective therapeutic options for infectious diseases other than COVID-19; 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.

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