Invivyd Announces Dosing of First Participant in CANOPY Phase 3 Pivotal Clinical Trial Investigating VYD222 for the Prevention of Symptomatic COVID-19

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Initial primary endpoint data anticipated in late 2023 or early Q1 2024

WALTHAM, Mass., Sept. 11, 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 first participant has been dosed in the CANOPY Phase 3 pivotal clinical trial of VYD222, a broadly neutralizing, half-life extended monoclonal antibody, for the prevention of symptomatic COVID-19. This clinical trial is designed to rapidly generate the clinical data needed to support a potential emergency use authorization (EUA) submission for VYD222. CANOPY is expected to enroll approximately 750 participants in two cohorts (A and B) including 300 individuals who are significantly immunocompromised.

“The initiation of the CANOPY pivotal clinical trial marks a major milestone for Invivyd, and it is a significant step in our journey to rapidly advance VYD222 toward a potential EUA submission,” said Dave Hering, Chief Executive Officer of Invivyd. “Thanks to the hard work and dedication of our teams, Invivyd is at the forefront of advancing new therapeutics to address circulating viral threats. With our proprietary database of potentially eligible individuals and a Day 28 primary efficacy endpoint in the immunocompromised cohort, we expect CANOPY to enroll quickly, and we remain on track to have initial primary endpoint data around year end.”

Commenting on the milestone, Pete Schmidt, M.D., M.Sc., Chief Medical Officer at Invivyd added, “In recent months we have seen both the number of COVID-19 cases and disease related hospitalizations increase at an alarming rate in vulnerable populations. It is clear COVID-19 is going to remain a major global health concern for the foreseeable future, and this increase comes at a time when immunocompromised individuals have limited options for the prevention of symptomatic COVID-19. It is this urgent public health need that drives us to advance important new therapeutics like VYD222 as quickly as possible.”

About CANOPY

The CANOPY pivotal clinical trial is a Phase 3 clinical trial designed to evaluate protection against symptomatic COVID-19 after receiving VYD222. The safety, tolerability, pharmacokinetic profile, and immunogenicity of VYD222 will also be evaluated. The clinical trial is expected to enroll approximately 750 participants in two cohorts (A and B) running in parallel across multiple trial sites in the U.S. Cohort A is expected to enroll approximately 300 participants who are significantly immunocompromised. For this cohort, the company will use serum neutralizing titers against relevant SARS-CoV-2 variants at Day 28 as the primary efficacy endpoint. The primary efficacy analysis will use an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical data from the company’s previous Phase 2/3 clinical trial of adintrevimab for the prevention of symptomatic COVID-19, in which serum neutralizing titers correlated with observed clinical efficacy. All Cohort A participants will receive VYD222 administered via intravenous (IV) infusion.

Cohort B will enroll approximately 450 participants at risk of exposure to SARS-CoV-2. The primary endpoint is safety and tolerability. Cohort B participants will be randomized 2:1 to receive VYD222 or placebo administered via IV infusion.

Invivyd is evaluating the 4500 mg dose of VYD222 in the CANOPY trial. The company expects to have initial primary endpoint data by late 2023 or early Q1 2024.

About VYD222

VYD222 is a broadly neutralizing, half-life extended monoclonal antibody (mAb) candidate in development for the prevention of symptomatic COVID-19 in vulnerable populations, such as immunocompromised people. Globally, there are millions of immunocompromised people, with an estimated 8-18 million in the U.S. alone, who may not adequately respond to COVID-19 vaccination, increasing their risk for severe outcomes from COVID-19. Currently, there are no monoclonal antibodies authorized or approved in the U.S. for the prevention of symptomatic COVID-19. VYD222 was designed for broad activity and has demonstrated *in vitro* neutralizing activity against various pre-Omicron and Omicron variants, such as XBB.1.5 and XBB.1.5.10, an Omicron variant that has the same mutations in the spike protein as EG.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 2/3 clinical trials for both the prevention and treatment of COVID-19.

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 SARS-CoV-2. Invivyd’s technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with the potential to resist 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 company’s ongoing research and clinical development plans and the timing thereof, including with respect to VYD222; the company’s expectation for its CANOPY Phase 3 pivotal clinical trial to rapidly generate the clinical data needed to support a potential EUA submission for VYD222; the company’s expectations regarding enrollment in the CANOPY clinical trial and the timing of anticipated initial primary endpoint data; the CANOPY clinical trial design, including the company’s plans to use an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical adintrevimab data; the company’s ability to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2; the potential for the company’s product candidates to be high-quality, long-lasting antibodies with the potential to resist viral escape; the company’s plans to generate a robust pipeline of product candidates which, if authorized or approved, could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications; 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 and progress of the company’s discovery, preclinical and clinical development activities; the company’s ability to rapidly generate the clinical data needed from the CANOPY clinical trial to support a potential EUA submission for VYD222; clinical trial site activation or enrollment rates that are lower than expected; 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 preclinical studies; the risk that results of preclinical studies or clinical trials may not be predictive of future results in connection with current or future clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; whether VYD222 or any other product candidate is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variants, particularly in the face of viral evolution; whether the company’s product candidates will be high-quality, long-lasting antibodies that resist viral escape; whether the company is able to successfully submit an EUA in the future, and the outcome of any such EUA submission; whether the company’s research and development efforts will identify and result in safe and effective therapeutic options for infectious diseases other than COVID-19; 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, 2022 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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