Invivyd Announces Positive Initial Results from Ongoing CANOPY Phase 3 Pivotal Clinical Trial Investigating VYD222 for the Prevention of COVID-19

December 18, 2023

- *VYD222 produced high serum virus neutralizing antibody titer levels in immunocompromised participants*
- *Data supportive of an immunobridging approach to the EVADE study of adintrevimab*
- *Overall favorable safety and tolerability profile of VYD222 including no study drug-related serious adverse events (SAEs) to date*
- *VYD222 demonstrates continued in-vitro neutralization activity against major SARS-CoV-2 variants, including against HV.1, the currently dominant variant in the U.S.*

WALTHAM, Mass., Dec. 18, 2023 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced positive initial results from the ongoing CANOPY Phase 3 pivotal clinical trial of VYD222, a broadly neutralizing, half-life extended monoclonal antibody candidate, for the prevention of symptomatic COVID-19.

"We are pleased to share positive initial topline results from CANOPY which bolster our belief that VYD222 holds the potential to provide vulnerable people, particularly the immunocompromised (IC), with meaningful protection from COVID-19," said Dave Hering, Chief Executive Officer of Invivyd. "VYD222 produced high serum virus neutralizing antibody (sVNA) titer levels against XBB.1.5 in the IC cohort, essentially replicating the titer levels observed in our Phase 1 clinical trial of VYD222 in healthy volunteers. We are also encouraged by the potential early signal of strong clinical protection from symptomatic COVID-19 in the CANOPY clinical trial to date, which would be expected given the high VYD222 sVNA titer levels and dose selected. We look forward to continued engagement with the FDA on these promising results, and we intend to submit a request for Emergency Use Authorization (EUA) as soon as practicable."

Pete Schmidt, M.D., M.Sc., Chief Medical Officer at Invivyd added, "The CANOPY clinical trial utilizes an innovative immunobridging design in which pharmacokinetic (PK) data from participants and potency data (IC50 values) are used to calculate sVNA titer levels. As characterized in our *Science Translational Medicine* paper, we believe calculated sVNA titer levels can be bridged back to the titer levels and corresponding clinical efficacy observed in EVADE, our pivotal clinical trial of ADG20 for prevention of COVID-19. We are encouraged by the initial results from CANOPY that we believe are supportive of an immunobridging approach for VYD222. Calculating sVNA titers also allows us to efficiently determine the sVNA titer levels against new SARS-CoV-2 variants as they emerge using *in vitro* VYD222 potency data."

Dr. Schmidt continued, "There is a growing body of strong scientific evidence showing that higher sVNA titer levels correlate with higher protection from symptomatic COVID-19, and we believe VYD222 holds the potential to be an important preventative option for immunocompromised populations. We extend our deepest gratitude to all our CANOPY trial participants, study teams, and Invivyd team members who have enabled this important clinical research and look forward to presenting additional findings from the CANOPY clinical trial next year."

Results showed that the safety and tolerability profile of VYD222 remains favorable with no study drug related serious adverse events reported to date. Adverse events attributed to VYD222 were Grade 1 or 2 (mild or moderate) in severity.

The company also today reported that *in vitro* pseudovirus testing shows VYD222 has potency against various SARS-CoV-2 variants currently circulating, such as HV.1, BA.2.86, XBB.1.5.10/EG.5, and HK.3. Importantly, VYD222 continues to show neutralizing activity against variants with the F456L mutation that is found in the majority of variants in the U.S. currently.

About CANOPY
The CANOPY pivotal clinical trial is an ongoing 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. In November 2023, Invivyd announced the completion of enrollment in the CANOPY clinical trial, with approximately 750 participants enrolled in two cohorts (A and B) across multiple trial sites in the U.S. Cohort A enrolled approximately 300 participants who are significantly immunocompromised. For this cohort, the primary endpoints include safety and tolerability and serum neutralizing titers against relevant SARS-CoV-2 variants at Day 28, which will be calculated based on the pharmacokinetic concentration of VYD222 from the immunocompromised participants and the IC50 value for VYD222 against relevant SARS-CoV-2 variants. The primary efficacy analysis uses 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 (ADG20) for the prevention of symptomatic COVID-19 (EVADE), in which serum neutralizing titers correlated with observed clinical efficacy. All Cohort A participants received VYD222 administered via intravenous (IV) infusion.

Cohort B enrolled approximately 450 participants at risk of exposure to SARS-CoV-2. Participants were randomized 2:1 to receive VYD222 or placebo administered via IV infusion. The primary endpoints include safety and tolerability and the proportion of

participants with RT-PCR-confirmed symptomatic COVID-19 through 6 months.

Invivyd is evaluating the 4500 mg dose of VYD222 in the CANOPY clinical trial.

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 more than 9 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 in pseudovirus assays against various pre-Omicron and Omicron variants, such as HV.1, BA.2.86, XBB.1.5.10/EG.5, and HK.3. 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. The company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. Leveraging its INVYMAB platform approach, 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 regulatory plans and the timing thereof, including the company's plans for continued engagement with the U.S. FDA and intention to submit a request for EUA as soon as practicable; the potential of VYD222 for strong clinical protection from symptomatic COVID-19 based on early signals observed in the CANOPY trial to date; the company's belief that the initial results from CANOPY are supportive of an immunobridging approach for the development of VYD222, including that calculated sVNA titer levels from CANOPY can be bridged back to the titer levels and corresponding clinical efficacy observed in EVADE; the ability of the company to determine the sVNA titer levels against new SARS-CoV-2 variants as they emerge using *in vitro* VYD222 potency data; the company's belief that VYD222 holds the potential to be an important preventative option for immunocompromised populations, including providing meaningful protection against COVID-19; the company's plans to present additional findings from the CANOPY clinical trial next year; 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 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; the company's interactions with the U.S. FDA regarding the VYD222 and a potential EUA submission; the development and regulatory pathways for authorization or approval of VYD222 or other product candidates; 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; the company's reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its 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 and timing of any such EUA submission; the Company's ability to manufacture sufficient clinical and commercial quantities of VYD222; the complexities of manufacturing monoclonal antibody therapies and the company's reliance on contract manufacturers to do so; 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.

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