Invivyd Announces Additional Positive Initial Data from Ongoing Phase 1 Clinical Trial of VYD222, a Monoclonal Antibody Candidate in Development for the Prevention of Symptomatic COVID-19 in Immunocompromised People

July 17, 2023

- *Continued favorable safety and tolerability profile for all dose levels tested*
- *Serum samples from all dose levels tested showed robust neutralization activity against Omicron XBB.1.5, one of the dominant SARS-CoV-2 variants circulating globally*
- *Ongoing analysis of serum neutralizing activity and pharmacokinetic data expected to support rapid anticipated transition to pivotal clinical trial*

WALTHAM, Mass., July 17, 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 additional positive initial data from its ongoing Phase 1 healthy volunteer clinical trial of its lead investigational monoclonal antibody (mAb) candidate, VYD222. VYD222 is a broadly neutralizing, half-life extended mAb candidate in development for the prevention of symptomatic COVID-19 in vulnerable populations, such as immunocompromised people.

The Phase 1 clinical trial of VYD222 enrolled 30 healthy volunteers across three different dosing cohorts. In each cohort, participants were randomized 8:2 to VYD222 or placebo. The initial Phase 1 data showed that a single administration of VYD222 was generally well-tolerated at all three dose levels tested with no serious adverse events (SAEs) reported to date. At the middle VYD222 dose tested (2500 mg), geometric mean serum neutralizing titers were 9647.0 (95% CI: 6115.4, 15218.0) against Omicron XBB.1.5 at Day 7, with a geometric mean 92.82-fold rise (95% CI: 21.2, 406.6) from baseline to Day 7. At the highest VYD222 dose tested (4500 mg), geometric mean serum neutralizing titers were 16864.7 (95% CI: 12825.5, 22176.1) against Omicron XBB.1.5 at Day 7, with a geometric mean 120.97-fold rise (95% CI: 31.4, 466.2) from baseline to Day 7. The higher VYD222 dose levels tested in the Phase 1 clinical trial are designed to provide additional protection from potential loss of neutralization activity as SARS-CoV-2 evolves over time. The results announced today add to the positive initial Phase 1 data reported in June 2023, which showed that the lowest VYD222 dose tested (1500 mg) resulted in geometric mean serum neutralizing titers of 3245.1 (95% CI: 1882.5, 5594.0) against Omicron XBB.1.5 at Day 7, with a geometric mean 38.87-fold rise (95% CI: 10.3, 146.8) from baseline to Day 7.

Analysis of the serum neutralizing activity from samples collected at different timepoints across all dose cohorts in the Phase 1 clinical trial is ongoing, as is detailed pharmacokinetic analysis and modeling. Invivyd intends to use these analyses, combined with published clinical outcome data from prior clinical trials of vaccines and mAbs for the prevention of symptomatic COVID-19, including data from its Phase 2/3 clinical trial of adintrevimab for the prevention of COVID-19 (EVADE), to further inform its VYD222 dosing strategy.

“We are pleased to see a favorable safety and tolerability profile as well as robust serum neutralizing titers against Omicron XBB.1.5 for all the VYD222 dose levels tested in our ongoing Phase 1 clinical trial,” said Dave Hering, chief executive officer of Invivyd. “We believe these high neutralizing titer values and fold increases at this early timepoint are extremely encouraging as they indicate the potential for VYD222 to protect longer between doses and to provide additional protection from potential loss of neutralization activity as SARS-CoV-2 evolves over time.”

Mr. Hering continued, “As a point of reference, we find it encouraging to observe that even our lowest VYD222 dose tested in our Phase 1 clinical trial resulted in higher titers against Omicron XBB.1.5 than the maximum titers against XBB.1.5 from investigational XBB-containing mRNA vaccines tested in humans that were shared at the FDA’s recent vaccines advisory committee meeting. Higher VYD222 doses tested in our Phase 1 clinical trial have resulted, as expected, in higher titer levels that were well above those reported mRNA COVID-19 vaccine titer levels. We believe these initial Phase 1 clinical trial results support the potential for VYD222 to provide safe, meaningful, durable protection for vulnerable populations, such as immunocompromised people who may not generate adequate protection from COVID-19 vaccines, and we look forward to advancing VYD222 as fast as possible in collaboration with global regulators, starting with the FDA.”

About the Phase 1 Clinical Trial of VYD222

The ongoing VYD222 Phase 1 clinical 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 of VYD222, 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. In May 2023, Invivyd finished dosing all 30 participants in the trial; follow up is ongoing.

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. As of July 2023, 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 previously circulating SARS-CoV-2 variants and current variants of concern, including Omicron sub-lineages up to and through 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 2/3 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 the Phase 2/3 Clinical Trial of Adintrevimab for the Prevention of COVID-19 (EVADE)

EVADE was a multi-center, double-blind, placebo-controlled, randomized Phase 2/3 clinical trial of adintrevimab for post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) of symptomatic COVID-19 in SARS-CoV-2 naïve, unvaccinated individuals (NCT04859517). Eighty-eight sites randomized 2,582 participants in 8 countries. Eligible participants were adults (≥18 years) and adolescents (12 to <18 years) whose circumstances placed them at risk of acquiring SARS-CoV-2 infection. The PrEP cohort included participants whose advanced age (≥55 years) or health status placed them at risk for developing severe COVID-19 or COVID-19 complications, such as participants with chronic cardiopulmonary disease, diabetes, obesity, or an immune compromised state. The efficacy portion of EVADE was conducted during the emergence and global spread of SARS-CoV-2 variants Delta and Omicron BA.1/BA.1.1. Due to the marked differences in adintrevimab potency against these two variants, the EVADE trial provided a unique opportunity to assess the relationship between serum neutralizing titers and clinical protection against symptomatic COVID-19 in the absence of pre-existing SARS-CoV-2 immunity. The company believes it can leverage these data, along with its manufacturing platform, to support the accelerated development of VYD222 and a stream of mAb candidates designed to keep pace with SARS-CoV-2 evolution and protect the vulnerable.

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 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.

References

U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) 182nd Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting on June 15, 2023: https://www.fda.gov/media/169539/download

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 future of the COVID-19 landscape; the company's ongoing research and clinical development plans and the timing thereof, including with respect to the clinical development of VYD222; the company's plans to utilize data from the Phase 1 VYD222 clinical trial to support the rapid anticipated transition to a pivotal clinical trial; the company's belief that initial data from the Phase 1 VYD222 clinical trial indicate the potential for VYD222 to protect longer between doses and to provide additional protection from potential loss of neutralization activity as SARS-CoV-2 evolves over time; the potential for VYD222 to provide safe, meaningful, durable protection for vulnerable populations, such as immunocompromised people; the company's plans to advance VYD222 as fast as possible in collaboration with global regulators, starting with the FDA; the company's belief that it can leverage adintrevimab data, along with its manufacturing platform, to support the accelerated development of VYD222 and a stream of mAb candidates designed to keep pace with SARS-CoV-2 evolution; the company's beliefs about its competitive position; estimates regarding the size of the company's target patient populations and the potential market opportunity for its product candidates; the company's 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 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 ability to gain complete alignment with the applicable regulatory authorities on the clinical trial design and development pathway for VYD222, including the use of an immunobridging pathway in the U.S., and the timing thereof; whether the company is able to leverage adintrevimab data, along with its manufacturing platform, to support the accelerated development of VYD222 or other mAb candidates; the timing and progress of the company's discovery, preclinical and clinical development activities, including the company's ability to rapidly initiate a VYD222 pivotal clinical; 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 the company's business and those of its collaborators, the company's clinical trials and its 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 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; 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 the company's discussions with regulatory authorities concerning its 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 variants, particularly in the face of viral evolution; whether VYD222 or other product candidates will be high-quality, long-lasting antibodies with the potential to resist viral escape; whether the company is able to successfully submit an emergency use authorization (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 (the "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. 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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