Invivyd Announces Multiple Next Generation COVID-19 Antibody Candidates and Selects Combination for Clinical Advancement Based on Positive in vitro Data Against Omicron Variants

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- *Integrated discovery platform is producing a stream of candidate antibodies demonstrating broad in vitro neutralization against past variants of concern (e.g., D614G, beta, delta) and Omicron sublineages BA.1, BA.2, BA.4, BA.5 and BA.2.75, as well as SARS-CoV-1*
- *Antibodies target highly conserved epitopes under low immune pressure*
- *NVD200, a novel combination of two monoclonal antibodies, expected to advance into clinical trials in Q1 2023*

WALTHAM, Mass., Sept. 12, 2022 (GLOBE NEWSWIRE) -- Invivyd, (Nasdaq: IVVD beginning September 13), formerly Adagio Therapeutics (Nasdaq: ADGI), a clinical-stage biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases, announced today that the Company has generated multiple next-generation candidate antibodies for the prevention and treatment of COVID-19, including two molecules designated for near-term clinical development in combination as NVD200. NVD200 is expected to enter the clinic in the first quarter of 2023.

The integrated Invivyd discovery platform generated dozens of potent and broadly neutralizing anti-SARS-CoV-2 monoclonal antibody candidates over the past two quarters. Now included in Invivyd's pipeline are multiple novel discovery-stage molecules that were produced using the company's deep expertise at the intersection of evolutionary virology, predictive modeling, and antibody engineering. These molecules are all designed to be high-functioning and long-lasting with a high barrier to viral escape. The company's antibody candidates are tuned to optimize across potency, breadth of neutralization, barrier to escape, and half-life. Such antibodies may be deployed prior to exposure to SARS-CoV-2 to prevent disease or, once sick, to treat disease.

"COVID-19 continues to impose a significant and unacceptable burden on humanity, which is why I am pleased that our integrated discovery platform has been so productive at identifying novel candidates with potential to transcend the limitations of the human immune response," said David Hering, CEO of Invivyd. "Our approach is designed to find unique molecules that target the validated SARS-CoV-2 spike protein at sites under limited immune pressure, which we expect to translate into a high barrier to viral escape. We are rapidly advancing NVD200, our novel combination candidate, toward the clinic with a Phase 1 clinical trial expected to start in the first quarter of next year. At the same time, we are diligently monitoring emerging variants to inform our development plans for the multiple additional discovery candidates in our pipeline, as well as innovating to provide a steady stream of new candidates to address the continuously evolving viral threat."

NVD200 is a combination of two monoclonal antibodies which demonstrated potent *in vitro* neutralizing activity against prior and current SARS-CoV-2 variants of concern, including Omicron BA.1, BA.2, BA.4, BA.5, and BA.2.75 sublineages, as well as the more antigenically divergent SARS-CoV-1. This antibody combination has been selected for neutralization potency, breadth of coverage, and non-dominant epitope recognition. The antibodies in the combination target non-overlapping epitopes that are rarely targeted by endogenous neutralizing antibodies, which limits immune pressure on these sites and increases the probability of sustained utility in an evolving viral landscape. One of the antibodies in the combination is a re-engineered version of adintrevimab, the company's most advanced product candidate, which met all primary endpoints with statistical significance in a pre-Omicron setting in global Phase 3 clinical trials for the prevention and treatment of COVID-19.

"The multiple novel antibodies we have engineered further expand on our discovery work with adintrevimab and subsequent clinically meaningful results," said Laura Walker, Ph.D., co-founder and chief scientific officer of Invivyd. "Over the past two years, remarkable advances have been made in our understanding of the plasticity of the SARS-CoV-2 receptor binding domain, the co-evolution of the virus and the human antibody response, and the importance of neutralization in protection, allowing us to select and engineer lead molecules that we believe will have sustained utility. We have also created a continuous discovery process to stay ahead of viral variation, so any gaps in coverage may be rapidly filled."

Invivyd's platform includes continuous variant monitoring and extensive exploration of the vast universe of potential antibodies outside of the common human immune repertoire. The company has already identified hundreds of neutralizing monoclonal antibodies and selected them based on stringent selection criteria including potency, breadth of coverage across SARS-CoV-2 variants and other sarbecoviruses, immunorecessive epitope targeting, and specified developability criteria.

About Invivyd
(Nasdaq: IVVD)

Invivyd, formerly Adagio Therapeutics (Nasdaq: ADGI), is a biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases. The company is developing antibodies to transcend the limits of naturally occurring immunity and provide superior protection from viral diseases, beginning with COVID-19. 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 a high barrier to viral escape. The company is generating a robust pipeline of products for use in both prevention and treatment of disease. NVD200, Invivyd's first antibody combination product for COVID-19, is expected to enter the clinic in Q1 2023. Invivyd's most advanced pipeline candidate is adintrevimab, an investigational monoclonal antibody which has demonstrated clinically meaningful results in global Phase 3 clinical trials against multiple variants of concern for the prevention and treatment of COVID-19. Adintrevimab is not approved for use in any country. The safety and efficacy of adintrevimab have not been established. The company also has multiple discovery stage candidates for the prevention of seasonal influenza. Visit www.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 future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; our ongoing research and clinical development plans and the timing thereof; our plans to advance adintrevimab, NVD200, or other early stage candidates as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent, including our intention to initiate clinical development of NVD200 in the first quarter of 2023; the potential for adintrevimab and NVD200 to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; our plans, technology and resources 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 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 adintrevimab, NVD200, 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 adintrevimab, NVD200, 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, 2021 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, each 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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