Invivyd Presented Joint Industry Rationale on Potential Expedited Development Pathways for Monoclonal Antibodies at FDA-EMA Workshop

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WALTHAM, Mass., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a clinical-stage biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases, was invited to participate in an FDA-EMA workshop on SARS-CoV-2 monoclonal antibodies held on December 15, 2022. Invivyd's chief scientific officer, Laura Walker, Ph.D., alongside Eli Lilly and Company and Regeneron Pharmaceuticals, Inc., presented a joint industry approach for anti-spike monoclonal antibody development to keep pace with SARS-CoV-2 variants. The meeting featured presentations by scientists, clinicians, regulators, and industry representatives to discuss alternative strategies to support the expedited availability of novel monoclonal antibody therapies including those based on development stage products that have reported positive safety and efficacy data in clinical trials.

The industry presentation highlighted the significant unmet medical need for therapeutic options to prevent and treat COVID-19 along with scientifically sound, data driven policy change recommendations to shorten development timelines and keep pace with the rapid evolution of variants.

“There is a sound scientific basis for relying on evidence from first generation mAbs and vaccines to support development of new mAbs through the use of standardized neutralization assays to determine correlation of neutralization titers and protection against the development of symptomatic SARS-CoV-2 infection,” said Laura Walker, Ph.D. “We are very pleased that both the FDA and EMA dedicated time listening to industry & academic experts on potential pathways to expedite the availability of new products that retain activity against circulating strains,” added Dr. Walker.

About Invivyd
(Nasdaq: IVVD)
Invivyd, Inc., 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 candidate for the prevention and treatment of COVID-19, includes a re-engineered version of adintrevimab, an investigational monoclonal antibody which demonstrated clinically meaningful results against multiple variants of concern in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19, prior to the emergence of Omicron. 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 ability for Invivyd, other companies or combination of companies and industry representatives to influence regulators to change or adopt new development pathways or timelines; the interest or acceptance by regulatory authorities of regulatory and clinical strategies to support potentially expedited development of novel monoclonal antibody therapies; the potential for success and or expedited discovery, development, or commercialization of antibody therapies for COVID-19; the continued unmet need for prevention and treatment of COVID-19; the viability and acceptability of new regulatory strategy, policy or approach to drug development and the potential of the same to maintain pace with changing COVID-19 variants; 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 ability for Invivyd and/or other companies, scientists, clinicians or industry representatives to impact the strategy, policy or approach to drug development drafted or applied by regulatory authorities, including the FDA and EMA; the impact of any such change on the speed or success of development and commercialization of antibodies for the prevention and/or treatment of COVID-19; the ability of the company to generate and utilize tools to discover and develop antibodies to treat current and potential future 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 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 September 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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