Adagio Therapeutics Announces New Data Highlighting the Potential of ADG20 for Treatment and Prevention of COVID-19

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ADG20 Continues to be Well Tolerated in Healthy Volunteers with Prolonged Half-Life and Serum Virus Neutralization Activity Observed out to Six Months in Ongoing Phase 1 Study

Data from Quantitative Systems Pharmacology/Whole-Body Physiologically Based Pharmacokinetic Modeling Support Evaluation of 300 mg Intramuscular Dose of ADG20 Given as a Single Intramuscular Injection in Ongoing Phase 2/3 Studies

Data to be Presented During IDWeek 2021 and 19th Annual Discovery on Target Conference

WALTHAM, Mass., Sept. 29, 2021 (GLOBE NEWSWIRE) -- Adagio Therapeutics, Inc., (Nasdaq: ADGI) a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential, today announced new data from the company's COVID-19 antibody program. Updated, six-month data from its ongoing Phase 1 study of ADG20 in healthy participants and data validating the selection of the 300 mg intramuscular (IM) dose given as a single injection that is being evaluated in the company's ongoing global Phase 2/3 treatment (STAMP) and prevention (EVADE) clinical trials will be presented during four poster sessions at the Infectious Disease Society of America's IDWeek 2021, being held from Sept. 29 – Oct. 3, 2021. In addition, Adagio's chief scientific officer, Laura Walker, Ph.D., will present a subset of the ADG20 Phase 1 data as well as background on the identification and optimization of this differentiated antibody clinical candidate in an oral presentation at the 19th Annual Discovery on Target Conference on Sept. 30, 2021.

"The continued strength of the safety and pharmacokinetic data from our Phase 1 study is encouraging and further underscores the potential impact an antibody like ADG20 – which was designed to be potent, broadly neutralizing and delivered as a single IM injection – could have on people with or at risk of COVID-19," said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. "These Phase 1 data combined with our dose selection strategy, which relied on our innovative modeling approach, have allowed us to initiate and advance our pivotal trials of ADG20 in the treatment and prevention of COVID-19. We anticipate these data will support an Emergency Use Authorization (EUA) application in the first quarter of 2022, which could enable us to bring an important treatment option to patients."

Phase 1 Trial Update

Adagio is evaluating ADG20 in a Phase 1 randomized, double-blind, placebo-controlled single ascending-dose study to assess safety and tolerability, pharmacokinetics (PK), immunogenicity, and serum virus neutralizing activity of ADG20 *ex vivo* against SARS-CoV-2. Data from a six-month evaluation timepoint confirmed the extended half-life of ADG20, which approached 100 days based on data from the 300 mg IM dose that was given as a single injection. In addition, 50% serum virus neutralization titers at six months after a 300 mg IM dose of ADG20 were similar to observed peak titers with the mRNA-1273 vaccine and exceeded those achieved with the AZD1222 vaccine series. Importantly, ADG20 was well tolerated with no study drug-related adverse events (AEs), serious AEs, or injection-site or hypersensitivity reactions reported through a minimum of three months follow-up across all cohorts. Participants will continue to be followed through 12 months to assess safety and tolerability, PK, immunogenicity and serum virus neutralizing activity.

Phase 1 Poster Information: (633) Preliminary Results from a Phase 1 Single Ascending-Dose Study Assessing Safety, Serum Viral Neutralizing Antibody Titers (sVNA), and Pharmacokinetic (PK) Profile of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Treatment and Prevention of Coronavirus Disease (COVID-19)

Dose Selection Strategy

To support dose selection for Adagio's global Phase 2/3 STAMP and EVADE clinical trials, the company modified an existing quantitative systems pharmacology whole-body physiologically-based pharmacokinetic (QSP/PBPK) model to better characterize the PK of extended half-life monoclonal antibodies in serum and key sites of viral replication in the respiratory tract. Adagio's model adequately *a priori* predicted the observed ADG20 serum PK in non-human primates (NHPs) and humans. The model was further optimized based on data from Adagio's Phase 1 clinical trial and then applied for dose selection for STAMP and EVADE.

For the STAMP treatment trial, data compiled to date suggest that the 300 mg IM regimen has a projected ability to rapidly achieve and maintain target concentrations at key tissue sites of viral replication, including the ability to attain near complete (> 90%) and durable (> 28-day) SARS-CoV-2 receptor occupancy across a range of baseline viral loads. Further, for the EVADE prevention trial, data compiled to date suggest the 300 mg IM regimen has a projected ability to rapidly exceed target serum concentrations in the majority of simulated patients and to maintain potentially effective concentrations for up to 12 months.

Dose Selection Poster Information

- (1086) A Whole-Body Quantitative System Pharmacology Physiologically-Based Pharmacokinetic (QSP/PBPK) Model that a priori Predicts Intramuscular (IM) Pharmacokinetics of ADG20: an Extended Half-life Monoclonal Antibody Being Developed for the Treatment and Prevention of Coronavirus Disease (COVID-19)
- (1089) Use of a Whole-Body Quantitative System Pharmacology Physiologically-Based Pharmacokinetic (QSP/PBPK) Model to Support Dose Selection of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Prevention of Coronavirus Disease (COVID-19)

- (1088) A Whole-Body Quantitative System Pharmacology Physiologically-Based Pharmacokinetic (QSP/PBPK) Model to Support Dose Selection of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Treatment of Coronavirus Disease (COVID-19)

The STAMP and EVADE clinical trials are currently ongoing and enrolling patients globally. For more information, please visit clincialtrials.gov.

About ADG20
ADG20, a monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is being developed for the prevention and treatment of COVID-19, the disease caused by SARS-CoV-2. ADG20 was designed and engineered to possess high potency and broad neutralization against SARS-CoV-2 and additional clade 1 sarbecoviruses, by targeting a highly conserved epitope in the receptor binding domain. ADG20 displays potent neutralizing activity against the original SARS-CoV-2 strain as well as all known variants of concern. ADG20 has the potential to impact viral replication and subsequent disease through multiple mechanisms of action, including direct blocking of viral entry into the host cell (neutralization) and elimination of infected host cells through Fc-mediated innate immune effector activity. ADG20 is administered by a single intramuscular injection, and was engineered to have a long half-life, with a goal of providing both rapid and durable protection. Adagio is advancing ADG20 through multiple clinical trials on a global basis.

About Adagio Therapeutics
Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. The company's portfolio of antibodies has been optimized using Adimab's industry-leading antibody engineering capabilities and is designed to provide patients and clinicians with a powerful combination of potency, breadth, durable protection (via half-life extension), manufacturability and affordability. Adagio's portfolio of SARS-CoV-2 antibodies includes multiple, non-competing broadly neutralizing antibodies with distinct binding epitopes, led by ADG20. Adagio has secured manufacturing capacity for the production of ADG20 with third-party contract manufacturers to support the completion of clinical trials and initial commercial launch. For more information, please visit www.adagiotx.com.

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," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the timing, progress and results of our preclinical studies and clinical trials of ADG20, including the timing of our planned EUA application, initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; our ability to obtain and maintain regulatory approvals for, our product candidates; our ability to identify patients with the diseases treated by our product candidates and to enroll these patients in our clinical trials; our manufacturing capabilities and strategy; and our ability to successfully commercialize our product candidates. 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, those risks described under the heading "Risk Factors" in Adagio's prospectus filed with the Securities and Exchange Commission ("SEC") on August 6, 2021 and in Adagio's future reports to be filed with the SEC, including Adagio's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. 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 Adagio undertakes no duty to update such information except as required under applicable law.

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