Adagio Therapeutics Announces Expansion of Patient Population in Global Phase 2/3 Clinical Trial of ADG20 for the Prevention of COVID-19

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Independent Data Monitoring Committee Supports Expansion to Adolescents and Pregnant and Nursing Women Based on Safety and Tolerability Data from Phase 2 Lead-In

WALTHAM, Mass., Sept. 10, 2021 (GLOBE NEWSWIRE) -- Adagio Therapeutics, Inc., a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential, today announced that the independent data monitoring committee (IDMC) for the EVADE Phase 2/3 trial of ADG20 for the prevention of COVID-19 has provided a recommendation to expand Phase 3 trial enrollment to include adolescents and pregnant or nursing women, as well as to decrease the protocol-specified, post injection monitoring time. The IDMC's assessments are based on their review of unblinded safety and tolerability data from 200 participants enrolled in the Phase 2 lead-in portion of the trial. Adagio remains blinded to the data and plans to implement the IDMC recommendations for the Phase 3 portion of the trial. EVADE is being conducted globally, including in regions where there is a high prevalence of SARS-CoV-2 variants of concern, to evaluate the ability of a single, intramuscular dose of ADG20 to prevent COVID-19 in both pre- and post-exposure settings.

"Given the urgent need for additional treatment and preventative options for COVID-19, particularly in vulnerable populations, we are pleased that an independent assessment of the safety data from the lead-in portion of EVADE supported inclusion of adolescents and pregnant or nursing women in the next phase of the study," said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. "Based on the potent and broad activity of ADG20 in non-clinical studies, as well as its extended half-life and ease of administration, we believe this antibody has the potential to become a preferred prophylactic option for COVID-19, particularly for vulnerable groups such as children and the immunocompromised, for whom there are currently limited or no available options."

The EVADE trial is a global, multi-center, double-blind, placebo-controlled clinical trial evaluating ADG20 in two independent cohorts. The first cohort (post-exposure prophylaxis) is designed to assess the safety and efficacy of ADG20 compared to placebo for the prevention of COVID-19 after exposure to an individual with laboratory confirmed SARS-CoV-2 infection. The second cohort (pre-exposure prophylaxis) is designed to assess the efficacy and safety of ADG20 compared to placebo in individuals who are at increased risk for SARS-CoV-2 infection due to occupational, housing or recreational situations, and in individuals who are at increased risk of poor vaccine response, including individuals with compromised immune systems or other co-morbidities. The primary efficacy endpoint in both cohorts is the prevention of laboratory confirmed, symptomatic COVID-19. For more information on the EVADE trial, please visit https://clinicaltrials.gov/ct2/show/NCT04859517.

The clinical development program for ADG20 includes two additional trials: the ongoing Phase 1 clinical trial of ADG20 in healthy volunteers and the ongoing STAMP trial evaluating ADG20 as a treatment for high-risk individuals with mild or moderate COVID-19 (see clinicaltrials.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 formulated at high concentrations, enabling intramuscular administration, 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 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 through the completion of clinical trials and, if approved by regulatory authorities, through initial commercial launch. For more information, please visit www.adagiotx.com.

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