Adagio Therapeutics Initiates Global Clinical Trial of ADG20 as a Treatment for COVID-19

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Phase 1/2/3 STAMP Trial to be Conducted Globally, Including in Countries with High Rates of SARS-CoV-2 Variants Resistant to Other Monoclonal Antibody Products

Potential for Early Access to Therapy by End of 2021

Data Published by University of Oxford Highlight that ADG20 Neutralizes All SARS-CoV-2 Variants of Concern with Comparable or Higher Potency than Other Antibodies in Development

Waltham, MA – April 13, 2021- -- Adagio Therapeutics, Inc., a biotechnology company developing best-in-class antibodies to broadly neutralize coronaviruses, today announced the initiation of recruitment in its Phase 1/2/3 clinical trial to evaluate ADG20 as a treatment for high-risk individuals with mild or moderate COVID-19. Known as the STAMP trial, this pivotal study will be conducted globally, including in regions with a high prevalence of SARS-CoV-2 variants of concern. The goal of the trial is to evaluate the ability of a single dose of ADG20 to prevent COVID-19 related hospitalizations and death. The company anticipates reporting initial results, with the potential for early patient access to treatment based on these data, by the end of 2021.

“We are thrilled to initiate this important trial, which we expect will establish the safety and efficacy of ADG20 for the treatment of mild to moderate COVID-19, including cases due to variants resistant to other antibody products,” said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. “With its potential to address resistant variants and ability to be easily administered as a low dose, affordable, intramuscular injection in the outpatient setting, ADG20 is uniquely poised to address the current need for effective, safe and convenient outpatient therapy for individuals at high risk of disease progression. The initiation of the STAMP trial marks a critical step towards this goal, and we look forward to working closely with our sites and investigators to complete this trial.”

“ADG20 is the only antibody in development that possesses potent activity against SARS and all currently circulating SARS-CoV-2 variants of concern, including those resistant to other clinicalstage antibodies,” said Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio. “Based on data that continue to emerge including the data published by the Screaton lab at the University of Oxford, we believe ADG20 has the potential to offer unsurpassed treatment and prevention not only of COVID-19 and its variants of concern but also future coronaviruses.”

The STAMP trial is a global, multi-center, double-blind, placebo-controlled clinical trial evaluating ADG20 in patients with mild to moderate COVID-19 who are at high risk for disease progression. The study will be conducted across up to 100 sites worldwide and consists of two parts. Phase 1 will assess the safety and tolerability of a single dose of ADG20 in 30 ambulatory patients with COVID-19. Following this initial evaluation of safety, the seamless Phase 2/3 portion of the study will be initiated with the goal of preventing progression of disease, as assessed by the proportion of patients with COVID-19 related hospitalization or death within 29 days of study drug administration. The trial is strategically designed to enable the rapid advancement of ADG20 to proof-of-concept data, which if positive, are intended to support an Emergency Use Authorization submission by the end of 2021. For more information on the STAMP trial, please visit clinicaltrials.gov.

The clinical development program for ADG20 includes two additional trials. A Phase 1 clinical trial of ADG20 in healthy volunteers is currently underway, evaluating the safety, tolerability, pharmacokinetics and serum SARS-CoV-2 neutralizing antibody levels of various ADG20 doses, with initial data anticipated in the second quarter of 2021. Adagio also plans to initiate a Phase 2/3 trial (EVADE) in the prevention of COVID-19 in the second quarter of 2021.

University of Oxford Data Findings

In work recently published in Cell, researchers at the University of Oxford examined monoclonal antibody neutralization of authentic SARS-CoV-2 isolates, including Victoria (a strain similar to the original Wuhan strain) and newly emergent SARS-CoV-2 variants of concern, P.1 (originated in Brazil), B.1.351 (originated in South Africa) and B.1.1.7 (originated in the UK). Compared with other antibodies in development, preclinical data generated demonstrate that ADG20, as well as ADG10 and ADG30, show comparable or higher potency against all three variants of concern, including those resistant to other clinical stage antibodies. Separately, Adagio has also demonstrated that ADG20 shows no loss of binding activity against the recently emerged Southern California variant, CAL.20C, which contains the L452R mutation.

“The scale of the COVID-19 pandemic has led to significant levels of viral replication, increasing the chances that adaptive mutations will occur. ADG20 is distinguished from other antibodies targeting SARS-CoV-2 by virtue of its ability to effectively neutralize a broad range of clade I sarbecoviruses, including all SARS-CoV-2 variants of concern,” said Laura Walker, Ph.D., co-founder and chief scientific officer of Adagio. “These data further validate the differentiated features of ADG20 and support our confidence in its ability to treat and prevent COVID-19, as well as disease due to future outbreaks of other coronaviruses with pandemic potential.”

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 for both prevention and treatment of COVID-19, and was engineered to have a long half-life, allowing for immediate and durable protection. Adagio is advancing ADG20 through multiple clinical trials on a global basis.

About Adagio Therapeutics

Adagio is developing best-in-class antibodies that can broadly neutralize SARS-CoV-2, SARSCoV and additional pre-emergent coronaviruses. The company's portfolio of antibodies has been optimized using Adimab's industry-leading antibody engineering capabilities and are designed to provide patients and clinicians with an unsurpassed 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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