



## **Adagio Therapeutics Announces ADG20 Phase 1 Data and Initiation of Global Phase 2/3 Clinical Trial of ADG20 for the Prevention of COVID-19**

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**Preliminary Data from Ongoing Phase 1 Trial in Healthy Volunteers Support ADG20 Safety and Pharmacokinetic Profile and SARS-CoV-2 Neutralizing Activity**

**Phase 2/3 EVADE Trial to Evaluate ADG20 for the Prevention of COVID-19 in Pre- and Post-Exposure Settings to be Conducted at Over 100 Sites Worldwide**

**Waltham, MA** – May 05, 2021 – Adagio Therapeutics, Inc., a biotechnology company developing highly differentiated antibodies to broadly neutralize coronaviruses, today announced that the first patient has been treated in the company's Phase 2/3 pivotal trial evaluating ADG20 for the prevention of COVID-19, known as the EVADE trial. Trial initiation is supported by positive preliminary data from the company's ongoing Phase 1 trial in healthy volunteers. EVADE will be conducted globally at more than 100 sites, including in regions where there is a high prevalence of SARS-CoV-2 variants of concern, and will evaluate the ability of a single, intramuscular dose of ADG20 to prevent COVID-19 in both pre- and post-exposure settings.

The initiation of the EVADE trial is supported by blinded data from Adagio's ongoing first-in-human, randomized, placebo-controlled Phase 1 clinical trial. The Phase 1 trial was designed to evaluate the safety, tolerability, pharmacokinetics and serum SARS-CoV-2 neutralizing antibody levels of various ADG20 dose regimens. Preliminary data demonstrate that a single intramuscular injection of ADG20 is well tolerated at doses up to 600 mg, and the initial pharmacokinetic profile support a prolonged serum half-life, which has the potential to afford up to 12 months of protection against COVID-19. In addition, initial ADG20 serum virus neutralizing activity against authentic SARS-CoV-2 is similar to peak serum neutralizing antibody titers reported for mRNA COVID-19 vaccine recipients.

"We are pleased with the strength of our initial clinical data and with the initiation of the EVADE trial to assess the efficacy of ADG20 in two key settings for the prevention of symptomatic COVID-19," said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. "Based on its potent and broad activity and extended duration of effect in preclinical models, we believe that ADG20 has the potential to provide both rapid protection in the face of a known, recent exposure to an individual with SARS-CoV-2 infection as well as durable protection over several months, including for individuals who are unlikely to have a sufficiently protective immune response to vaccines. We appreciate the enthusiasm expressed by our investigators and their support in advancing this differentiated antibody therapy."

"COVID-19 continues to be a significant health crisis, and with the recurring emergence of new variants across the globe, we believe a broadly neutralizing therapy that could be given for both treatment and prevention will be necessary," said Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio.

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. After evaluation of data from the first 200 adult participants in the Phase 2 portion of the trial, enrollment may be opened to adolescents and pregnant women in Phase 3. 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 [clinicaltrials.gov](https://clinicaltrials.gov).

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](https://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 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](https://www.adagiotx.com).

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