Adagio Therapeutics Announces Dosing of First Patient in Phase 1 Trial of ADG20, its Lead Monoclonal Antibody Candidate for the Treatment and Prevention of COVID-19

-ADG20 is uniquely engineered to maximize potency, duration of effect, and ease of use in the community setting, and has shown outstanding manufacturability to meet global demand-

-ADG20 binds to a highly conserved region of the spike protein not targeted by other antibodies, enabling potent neutralization to all known SARS-CoV-2 variants and several pre-emergent coronavirus threats-

Waltham, MA – February 16, 2020- Adagio Therapeutics, Inc., a biotechnology company developing best-in-class antibodies to broadly neutralize coronaviruses, today announced the initiation of a Phase 1 clinical trial evaluating its lead monoclonal antibody product candidate, ADG20. The Phase 1 trial will be conducted in the United States and will evaluate the safety, tolerability and pharmacokinetics of ADG20, including serum SARS-CoV-2 neutralizing antibody levels, in healthy participants. Once adequate safety data are evaluated, Adagio plans to advance ADG20 into global pivotal trials for the treatment and prevention of COVID-19, including in countries with high rates of resistant variants.

“We are in the unique position of having a monoclonal antibody that binds to and protects against common circulating SARS-CoV-2 variants as well as SARS-related viruses with pandemic potential. This broadly neutralizing activity was intentionally designed into ADG20, as we anticipated the continued emergence of resistance mutations, and we took deliberate steps to engineer ADG20 to maximize its potential to avoid viral escape. This design feature also enables ADG20 to target and neutralize coronaviruses that may emerge in the future,” said Tillman Gerngross, Chief Executive Officer of Adagio. “We’re very proud of the impressive work the team at Adagio has done, rapidly moving from lead identification and manufacturing into clinical trials within eight months.”

“This Phase 1 study is the first step in the clinical development of ADG20, our broadly-neutralizing antibody for coronavirus threats, and we expect it to provide key information regarding safety, pharmacokinetics and serum SARS-CoV-2 neutralizing antibody levels,” said Lynn Connolly, Chief Medical Officer of Adagio. “We plan to evaluate intramuscular administration of ADG20, which could be a critical differentiator for patients and providers,

allowing for administration in the community setting for both prevention and treatment of COVID-19. We will be evaluating ADG20 across multiple clinical settings on a global basis from pre- and post-exposure prophylaxis to treatment. We are currently focused on outpatient populations, including an emphasis on addressing unmet needs in vulnerable groups such as the immune compromised and children."

In this Phase 1, randomized, double-blind, single ascending-dose study, healthy adult participants will either receive an intramuscular or intravenous dose of ADG20 or placebo. The primary endpoint of the study is safety and tolerability, while secondary endpoints include evaluations of pharmacokinetics and immunogenicity. The study will also explore the serum neutralizing activity of ADG20 ex vivo against SARS-CoV-2.

In closing, Gerngross notes, "We believe ADG20 is poised to address the endemic nature of SARS-CoV-2 as well as the pandemic potential of future coronaviruses. We are excited to initiate clinical trials and potentially commercialize a differentiated antibody whose combined attributes address key limitations of other antibody programs and have the potential to address the significant unmet need that remains in the treatment and prevention of COVID-19."

About Adagio Therapeutics

Adagio is developing best-in-class antibodies that can broadly neutralize SARS-CoV-2, SARS-CoV-1 and additional pre-emergent coronaviruses. Our candidates are 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, tolerability, and affordability. Our portfolio of SARS-CoV-2 antibodies includes multiple, non-competing antibodies with distinct binding epitopes. Pre-clinical data show that our lead antibody ADG20 matches or exceeds the potency and coverage of other clinical SARS-CoV-2 antibody programs. We plan to advance ADG20 aggressively through global clinical trials for both the prevention and treatment of symptomatic COVID-19 and anticipate data from both prevention and treatment clinical trials in 2021. 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: www.adagiotx.com

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