Adagio Therapeutics Provides Update on Timing of Adintrevimab EUA Request

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WALTHAM, Mass., April 14, 2022 (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, recently announced positive preliminary clinical results from its Phase 2/3 clinical trials of adintrevimab (ADG20) and is providing an update on the anticipated timing for its Emergency Use Authorization (EUA) request for adintrevimab for the prevention and treatment of COVID-19. The Omicron BA.2 variant, which has shown reduced *in vitro* susceptibility to monoclonal antibodies, has recently emerged as the current predominant variant of SARS-CoV-2 in the U.S. Adintrevimab, which has demonstrated broadly neutralizing activity *in vitro* against SARS-CoV-2 variants of concern including Alpha, Beta, Delta, Delta Plus, Gamma and Omicron BA.1, has markedly reduced neutralization activity *in vitro* against the Omicron BA.2 variant. Based on feedback from the U.S. Food and Drug Administration (FDA) regarding adintrevimab's lack of neutralizing activity against the BA.2 variant, Adagio is pausing the submission of an EUA request. Adagio intends to continue engaging with the FDA and monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the U.S. to determine the optimal timing for its planned EUA request.

Adagio is committed to advancing adintrevimab as a potential future therapeutic option in anticipation of the emergence of new variants. The company is also conducting an ongoing Phase 1 trial evaluating pharmacokinetics and safety of higher doses of adintrevimab in healthy volunteers and is continuing its antibody research efforts, including efforts to modify adintrevimab to improve binding to the Omicron BA.1 and BA.2 subvariants. Adagio is on-track to have more than one million doses of adintrevimab secured in 2022, in preparation of its potential utility as a prophylaxis and treatment option for COVID-19 in the future.

Adintrevimab Preliminary Clinical Data
Preliminary clinical results from the Phase 2/3 clinical trial of adintrevimab for the prevention (EVADE) and treatment (STAMP) of COVID-19 showed that in the pre-Omicron population, adintrevimab administered as a single 300mg intramuscular dose met the primary endpoints with statistical significance across all three indications: 1) pre-exposure prophylaxis (PrEP), 2) post-exposure prophylaxis (PEP), and 3) treatment. Preliminary data from EVADE showed that adintrevimab reduced the risk of symptomatic COVID-19 by 71% compared to placebo in the PrEP cohort and by 75% compared to placebo in PEP cohort. Preliminary data from STAMP showed that adintrevimab reduced the risk of hospitalization or death by 66% compared to placebo in the primary efficacy analysis population, and by 77% compared to placebo in patients who received treatment within three days of symptom onset. In addition, in a pre-specified exploratory analysis of the PrEP cohort following the emergence of the Omicron (BA.1) variant, a clinically meaningful reduction in cases of symptomatic COVID-19 was observed with adintrevimab, as compared to placebo. Across both trials, administration of adintrevimab was well-tolerated and had a similar safety profile to that of placebo.

Adintrevimab *In Vitro* Data
In vitro data from externally conducted assays shows that adintrevimab has demonstrated *in vitro* neutralizing activity against SARS-CoV-2 variants of concern including Alpha, Beta, Delta, Delta Plus, Gamma and the BA.1 lineage of the Omicron variant. However, published data show that in *in vitro* assays, ADG20 has markedly reduced neutralization activity against the BA.2 lineage of the Omicron variant.

About Adintrevimab
Adintrevimab (ADG20), Adagio's lead product candidate, is designed to be a potent, broadly neutralizing antibody for both the prevention and treatment of COVID-19, including disease caused by most variants, as either a single or combination agent. Adintrevimab is being assessed in two separate Phase 2/3 clinical trials: the EVADE trial for the prevention of COVID-19 in both the post-exposure and pre-exposure settings, and the STAMP trial for the treatment of COVID-19. Preliminary data from these trials demonstrated that in the pre-Omicron population, adintrevimab met the primary endpoints across all three indications, demonstrating statistically significant and clinically meaningful efficacy. Across each of the trials, intramuscular (IM) administration of adintrevimab at the 300mg dose had a similar safety profile to that of placebo. Adintrevimab is also being evaluated in a Phase 1 study to evaluate safety and pharmacokinetics at higher doses, and as of an interim data cut, no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions were reported across all dose levels evaluated. Adintrevimab is an investigational monoclonal antibody that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established.

About Adagio Therapeutics
Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious diseases. The company is developing its lead product candidate, adintrevimab, for the prevention and treatment of COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. Beyond COVID-19, Adagio is leveraging robust antibody discovery and development capabilities that have enabled expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza.
Adintrevimab is an investigational monoclonal antibody that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established. For more information, please visit www.adagiotx.com.

Cautionary Note Regarding 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," "could", "expects," "intends," "potential", "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, our plans and strategies related to our EUA submission for adintrevimab; our plans to advance adintrevimab as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent; our ongoing research and development plans, including our efforts to modify adintrevimab to improve binding to the Omicron BA.1 and BA.2 subvariants; our expectations that we are on-track to have more than one million doses of adintrevimab secured in 2022; our plans to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza; and other statements that are not historical fact. 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: the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of adintrevimab based on neutralizing activity in pre-clinical studies; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and the uncertainties and timing of the regulatory approval process, including the outcome of our discussions with regulatory authorities concerning our Phase 2/3 clinical trials, whether adintrevimab is able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S., whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use application submission. Other factors that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (the “SEC”), and in our other filings with the SEC, and in Adagio’s future reports to be filed with the SEC. 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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