Adagio Therapeutics Announces ADG20 (adintrevimab) is the First Monoclonal Antibody to Meet Primary Endpoints with Statistical Significance Across Pre- and Post-exposure Prophylaxis and Treatment for COVID-19 and Plans to Seek U.S. Emergency Use Authorization

March 30, 2022

Risk of symptomatic COVID-19 was reduced by 71% compared to placebo in pre-exposure prophylaxis and 75% compared to placebo in post-exposure prophylaxis

Risk of hospitalization or death in participants with mild to moderate COVID-19 was reduced by 66% compared to placebo in the primary efficacy analysis population and by 77% compared to placebo in participants who received treatment within three days of symptom onset

Full year and fourth quarter 2021 financial results reported; $591 million in cash and investments expected to be sufficient to fund operations into second half of 2024

WALTHAM, Mass., March 30, 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, reported that the primary endpoints were met with statistical significance for all three indications in the company's ongoing global Phase 2/3 clinical trials evaluating its investigational drug adintrevimab (ADG20) as a pre-and-post-exposure prophylaxis (EVADE) and treatment (STAMP) for COVID-19. EVADE and STAMP were primarily conducted during a time when pre-Omicron SARS-CoV-2 variants were dominant. Following the emergence of the Omicron variant, in a pre-specified exploratory analysis in a subset of the pre-exposure cohort, a clinically meaningful reduction in cases of symptomatic COVID-19 was observed with adintrevimab compared to placebo. Across both trials, a single intramuscular (IM) administration of adintrevimab at the 300mg dose had a similar safety profile to that of placebo. Based on these data, Adagio plans to engage with the U.S. Food and Drug Administration (FDA) and to submit an Emergency Use Authorization (EUA) application in the second quarter of 2022 for adintrevimab for both the prevention and treatment of COVID-19.

In addition, Adagio provided an update on its ongoing Phase 1 study evaluating adintrevimab at higher doses and on research activities related to adintrevimab re-engineering and the identification of new antibodies to potentially address COVID-19 and other viruses.

"COVID-19 continues to pose significant challenges globally as waning immunity combined with the emergence of resistant variants has led to ongoing waves of disease. We believe that a suite of options – spanning prophylaxis and treatment – is needed to effectively address this virus as it continues to evolve, and these data give us confidence in the potential role adintrevimab can play in physicians' arsenals," said David Hering, MBA, interim chief executive officer and chief operating officer of Adagio. "Based on the data from both EVADE and STAMP, including the impacts observed in preliminary analyses from participants enrolled after the emergence of the Omicron variant, our team is initiating discussions with the FDA and preparing an EUA submission for adintrevimab. With more than one million doses of adintrevimab secured for 2022 and a solid financial position expected to take us into the second half of 2024, we are optimistic about the road ahead and the impact adintrevimab could have for the many people around the globe, particularly those at high risk with co-morbidities, who continue to need options."

Michael Ison, M.D., M.S., professor of Medicine in the Division of Infectious Diseases and of Surgery in the Division of Organ Transplantation, Northwestern University Feinberg School of Medicine, added, "the compelling data generated on adintrevimab in both of Adagio's clinical trials represent an important step toward further addressing the continuation of the COVID-19 pandemic. I am particularly encouraged by the consistent treatment effect observed across all three clinical settings and patient subpopulations, and the favorable safety profile, with just a single dose and convenient IM delivery for all patients. The risk-reduction in the post-exposure prophylaxis setting regardless of serostatus translates to real-world use when clinicians might not know the vaccination or prior infection status of their patients. In the STAMP trial, adintrevimab showed prevention of hospitalization and death in the face of the 'highest-risk' variant (Delta) to-date."

EVADE Preliminary Data
EVADE is a global, multi-center, double-blind, placebo-controlled Phase 2/3 clinical trial evaluating adintrevimab at the 300mg IM dose in two independent cohorts for the prevention of COVID-19. The study includes a pre-exposure prophylaxis (PrEP) cohort and a post-exposure prophylaxis (PEP) cohort. The study population is comprised of adults and adolescents at risk of SARS-CoV-2 infection due to reported recent exposure or whose circumstances placed them at increased risk of acquiring SARS-CoV-2 infection and developing symptomatic COVID-19.

In the primary efficacy analysis of the PrEP cohort, adintrevimab was associated with a lower incidence of symptomatic COVID-19 compared with placebo through month three or the emergence of Omicron, whichever was earlier (12/730, 1.6% vs. 40/703, 5.7%, respectively). The standardized risk difference was -4.0% (95% CI –6.0, -2.1; p <0.0001), demonstrating a 71% relative risk reduction in favor of adintrevimab through three months. There were five (0.7%) COVID-19 related hospitalizations in the placebo group compared to none in the adintrevimab group. In a pre-specified exploratory analysis of the PrEP cohort, which included 402 participants (196 and 206 in the adintrevimab and placebo groups, respectively) following the emergence of Omicron (BA.1), a clinically meaningful reduction in cases of symptomatic COVID-19 was observed with adintrevimab, as compared to placebo. Adintrevimab was associated with a relative risk reduction of 59% and 47% with a median follow-up duration of 56 and 77 days, respectively (nominal p <0.05).

In the primary efficacy analysis in the PEP cohort, adintrevimab met statistical significance and was associated with a lower incidence of symptomatic COVID-19 through day 28 compared with placebo (3/173, 1.7% vs. 12/175, 6.9%, respectively). The standardized risk difference was -4.9% (95% CI: -8.8, -1.0; p=0.0135), demonstrating a 75% relative risk reduction in favor of adintrevimab through 28 days. There were two (1.1%) COVID-19 related hospitalizations in the placebo group compared to none in the adintrevimab group.

In the EVADE cohorts across 1,239 adintrevimab-treated participants with a median range of follow up of 140 days for the PrEP cohort and 126 days

for the PEP cohort as of the March 2, 2022, data cut off, the safety profile was similar to that of placebo. The incidence of adverse events (AEs), including serious adverse events (SAEs), was similar between adintrevimab and placebo groups. No study drug related SAEs, including deaths, were reported. The most frequently reported AEs were injection-site reactions, the majority of which were mild or moderate in severity and occurred with similar frequency in both groups.

STAMP Preliminary Data
STAMP is a global, multi-center, double-blind, placebo-controlled Phase 2/3 clinical trial evaluating adintrevimab at the 300mg IM dose in patients with mild to moderate COVID-19 who are at high risk for disease progression. Adintrevimab was associated with a statistically significant lower incidence of COVID-19 related hospitalization or all cause death through day 29 compared with placebo (8/169, 4.7% vs. 23/167, 13.8%), with a standardized risk difference of -8.6% (95% CI: -14.65, -2.57; p=0.0052), demonstrating a 66% relative risk reduction in favor of adintrevimab. There was one death (0.6%) in the adintrevimab group, compared with six deaths (3.6%) in the placebo group through day 29. In patients treated within three days of symptom onset (adintrevimab n=91, placebo n=85), adintrevimab reduced the risk of COVID-19 hospitalization or death from any cause by 77% compared to placebo. STAMP enrolled 63 participants (29 in the adintrevimab group and 34 in the placebo group) with COVID-19 infection with the Omicron SARS-CoV-2 variant. There were two events of COVID-19 related hospitalization and no deaths through day 29 among the patients with the Omicron variant, and both events of hospitalization occurred in the placebo group.

In STAMP, across 192 adintrevimab-treated participants with a median follow up of 73 days in the adintrevimab group as of the February 2, 2022, data cut off, the incidence of AEs, including SAEs, was lower in the adintrevimab group. No study drug related SAEs, including deaths, were reported. The most frequently reported AEs were injection-site reactions, all of which were mild or moderate in severity and occurred with similar frequency in both groups.

“On behalf of the entire Adagio team, I’d like to thank the numerous investigators, clinical teams and, most importantly, the patients, families and caregivers for their participation in our clinical trials. We are encouraged by the data and look forward to submitting an EUA and discussing these results with the FDA and other regulatory authorities. Further, we are continuing our research efforts to improve adintrevimab activity against Omicron and identify antibodies targeting novel domains, which will provide potential additional product candidates to take into clinical development. Collectively, these efforts showcase the ability of our platform and expertise to discover, design and engineer novel antibodies, and execute global clinical trials, to potentially address infectious diseases,” said Ellie Hershberger, Pharm.D., chief development officer of Adagio.

Additional Development and Research Updates
Adagio continues to leverage its platform and expertise by conducting numerous efforts to address COVID-19, other coronaviruses, influenza and other infectious diseases, including:

- Advancing a Phase 1 trial in healthy volunteers to evaluate pharmacokinetics and safety of additional higher doses of adintrevimab to supplement the data generated to date, which has evaluated doses up to 600mg IM. Preliminary safety data through two weeks post-dosing suggest a favorable safety profile at the 1200mg dose administered with IM injection or intravenously (IV).
- Ongoing efforts to modify adintrevimab to improve binding to the Omicron subvariants (BA.1 and BA.2) in order to enhance neutralization potency while retaining the broad neutralization observed *in vitro* against other SARS-CoV-2 variants of concern. Re-engineered variants of ADG20 show over 100-fold improvement in binding and up to 40-fold enhanced neutralizing activity against the Omicron BA.1 variant while maintaining activity against all other variants of concern tested to date.
- Ongoing discovery efforts to assess additional monoclonal antibodies from the company’s proprietary library of previously isolated SARS-CoV-2 antibodies for neutralization breadth and potency, which could be developed as a standalone treatment or combination therapy. Novel antibodies isolated from Omicron breakthrough infection donors have displayed *in vitro* activity against the 2003 SARS virus and all SARS-CoV-2 variants of concern tested to date, including the BA.1 and BA.2 variants.
- Continuing discovery efforts to identify novel, broadly neutralizing antibodies that target epitopes both within and outside the receptor binding domain of SARS-CoV-2 and pan betacoronavirus neutralizing antibodies.

Full Year and Fourth Quarter 2021 Financial Results

- **Cash Position and Financial Guidance:** Cash, cash equivalents and marketable securities were $591.4 million as of December 31, 2021. Based on current operating plans, Adagio expects its existing cash, cash equivalents and marketable securities will enable the company to fund its operating expenses and capital expenditure requirements into the second half of 2024.
- **R&D Expenses:** Research and development (R&D) expenses, including in-process research and development expenses, were $68.4 million for the quarter ended December 31, 2021, and $190.4 million for the year ended December 31, 2021.
- **SG&A Expenses:** Selling, general and administrative (SG&A) expenses were $14.7 million for the quarter ended December 31, 2021, and $36.5 million for the year ended December 31, 2021.
- **Net Loss:** Net loss was $83.0 million, or $0.77 basic and diluted net loss per share, for the quarter ended December 31, 2021, and $226.8 million, or $5.32 basic and diluted net loss per share, for the year ended December 31, 2021.

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.

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, the timing, progress and results of our preclinical studies and clinical trials of adintrevimab, the review and analysis of data from our ongoing trials and the timing thereof, the initiation, modification and completion of studies or trials and related preparatory work, and our research and development programs; our plans related to engaging with regulatory authorities, including the timing of any regulatory submissions or applications; our pursuit of other strategies to broaden our portfolio of SARS-CoV-2 mAbs to address other SARS-CoV-2 variants of concern, including the Delta and Omicron variants; our discovery efforts to identify novel broadly neutralizing antibodies that target distinct epitopes both within and outside the receptor binding domain of SARS-CoV-2 and other beta coronaviruses; our expected cash runway; 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 and the result of any 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 Adagio's Form 10-Q for the quarter ended September 30, 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.

Contacts
Media Contact:
Dan Budwick, 1AB
dan@1abmedia.com

Investor Contact:
Monique Allaire, THRUST Strategic Communications
monique@thrustsc.com

ADAGIO THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 542,224	$ 114,988
Marketable securities	49,194	—
Prepaid expenses and other current assets	25,293	2,394
Total current assets	616,711	117,382
Property and equipment, net	83	—
Other non-current assets	3,297	—
Total assets	$ 620,091	$ 117,382
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,783	$ 8,153
Accrued expenses	56,277	4,919

Total current liabilities	62,060	13,072
Early-exercise liability	6	11
Other non-current liabilities	6	—
Total liabilities	62,072	13,083
Commitments and contingencies		
Convertible preferred stock (Series A, B and C), $0.0001 par value; no shares authorized, issued and outstanding at December 31, 2021; 12,647,934 shares authorized, issued and outstanding at December 31, 2020; aggregate liquidation preference of $0 and $169,900 at December 31, 2021 and December 31, 2020, respectively	—	169,548
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at December 31 2021; no shares authorized, issued and outstanding at December 31, 2020	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021; 150,000,000 shares authorized, 28,193,240 shares issued and 5,593,240 shares outstanding as of December 31, 2020	11	1
Treasury stock, at cost; 468,751 shares and 22,600,000 shares at December 31, 2021 and December 31, 2020, respectively	—	(85)
Additional paid-in capital	850,125	154
Accumulated other comprehensive loss	(8)	—
Accumulated deficit	(292,109)	(65,319)
Total stockholders' equity (deficit)	558,019	(65,249)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 620,091	$ 117,382

ADAGIO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Operating expenses:		
Research and development[1]	$ 182,891	$ 21,992
Acquired in-process research and development[2]	7,500	40,125
Selling, general and administrative	36,517	3,210
Total operating expenses	226,908	65,327
Loss from operations	(226,908)	(65,327)
Other income (expense):		
Other income (expense), net	118	8
Total other income (expense), net	118	8
Net loss	(226,790)	(65,319)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities, net of tax	(8)	—
Comprehensive loss	$ (226,798)	$ (65,319)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.32)	$ (18.10)
Weighted-average common shares outstanding, basic and diluted	42,621,265	3,608,491

(1) Includes related-party amounts of $4,150 for the year ended December 31, 2021 and $595 for the period from June 3, 2020 (inception) to December 31, 2020.
(2) Includes related-party amounts of $7,500 for the year ended December 31, 2021 and $39,915 for the period from June 3, 2020 (inception) to December 31, 2020.