Adagio Therapeutics Provides Update for ADG20 COVID-19 Antibody Program and Reports Third Quarter 2021 Financial Results

November 15, 2021

FDA Feedback Supports Planned Emergency Use Authorization (EUA) Submission for ADG20 for Prevention of COVID-19; Interim Clinical Data Package from EVADE Prevention Trial to Support EUA Submission Expected in Second Quarter 2022

Enrollment Progressing in ADG20 STAMP Trial for Treatment of COVID-19; Planned Interim Efficacy Analysis Expected in Second Quarter 2022 to Support Potential EUA Submission

WALTHAM, Mass., Nov. 15, 2021 (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 with pandemic potential, today provided an update on its lead COVID-19 antibody program, ADG20, and reported third quarter 2021 financial results. ADG20 is an investigational monoclonal antibody product candidate designed to provide broad and potent neutralizing activity against SARS-CoV-2, including variants of concern, for the prevention and treatment of COVID-19.

“ADG20 continues to be the only monoclonal antibody in late-stage development that has the potential to offer a unique combination of potency, breadth of neutralization across known SARS-CoV-2 variants of concern as well as additional SARS-like viruses with pandemic potential, and durable protection against COVID-19 for up to one year. Further, our single injection delivery avoids the inconveniences associated with IV administration or multiple injections,” said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. “The world continues to face a host of challenges in fully addressing the COVID-19 crisis. Alternatives or supplements to vaccines for the prevention of COVID-19 are needed for immunocompromised individuals and those who remain hesitant to receive a vaccine or to vaccinate their children. Certain patient populations may not be ideal candidates for emerging oral treatment options due to adherence concerns, comorbidities or possible drug interactions. Based on its combined attributes, ADG20 has the potential to be a differentiated alternative for the prevention and treatment of COVID-19 that may address the needs of these populations, and our commitment to its advancement is unwavering.”

“We’ve made significant progress over the course of 2021, and 2022 is set to be a landmark year for Adagio as we prepare for potential EUA submissions for ADG20 for the prevention and treatment of COVID-19,” said Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio. “We recently received clear feedback from the FDA on a strategy to submit an EUA for ADG20 for the prevention of COVID-19, and have initiated efforts to expand our clinical program to additional patient subsets, including immunocompromised individuals and children. Our commercial-readiness efforts are well underway and with a strong balance sheet, we are ready to move quickly to enable access to individuals in need of COVID-19 prevention and treatment options, if authorization and/or approval is granted.”

ADG20 COVID-19 Program Updates

Prevention

Adagio continues to enroll adult and adolescent participants in its ongoing, global Phase 3 EVADE clinical trial evaluating ADG20 as a prevention for COVID-19 in both the pre-exposure and recent exposure settings.

- Adagio has received feedback from the U.S. Food and Drug Administration (FDA) on a data package needed and a pathway for an EUA submission for the pre-exposure prevention of COVID-19
- Adagio anticipates that the data package to support an EUA for ADG20 will be available in the second quarter of 2022 followed by expected submission to the FDA in the third quarter of 2022
- Adagio plans to add a new cohort in EVADE to evaluate ADG20 as a preventative option in immunocompromised individuals, with enrollment expected to begin in the first quarter of 2022
- Adagio also plans to initiate a trial evaluating ADG20 as a vaccine supplement
- Following discussion with the FDA, Adagio has aligned on a plan to evaluate ADG20 as a preventative option in the pediatric population, with a trial in individuals between two and 11 years of age expected to be initiated by mid-year 2022

Treatment

Adagio continues to enroll patients in its ongoing, global Phase 2/3 STAMP clinical trial evaluating ADG20 as a treatment for COVID-19.

- Adagio is planning to modify the trial design in order to expand the at-risk patient population eligible for enrollment in STAMP
- Based on current enrollment, Adagio anticipates reaching the Phase 2 independent data monitoring committee evaluation in the first quarter of 2022 and the interim efficacy analysis in the second quarter of 2022 to potentially support a subsequent EUA submission

Recent ADG20 Data Presentations at ISIRV-WHO and IDWeek2021

- New *in vitro* data demonstrated retained neutralizing activity of ADG20 against a diverse panel of circulating SARS-CoV-2 variants, including the newly emerged Lambda, Mu and Delta plus variants. Notably, findings showed that ADG20

demonstrated potent neutralizing activity against all SARS-CoV-2 variants of concern tested, including those with reduced susceptibility to mAb products currently available under EUA or in late-stage development.

- Data from a six-month evaluation in Adagio's Phase 1 healthy volunteer trial of ADG20 confirmed the extended half-life of ADG20, which approached 100 days based on data from the 300 mg intramuscular dose that was given as a single injection. In addition, an exploratory analysis showed that 50% serum virus neutralization titers at six months after a 300 mg intramuscular dose of ADG20 were similar to observed peak titers with the mRNA-1273 vaccine and exceeded those achieved with the AZD1222 vaccine series. ADG20 was well-tolerated with no study drug-related adverse events (AEs), serious AEs, or injection-site or hypersensitivity reactions reported through a minimum of three months follow-up across all cohorts.
- To support dose selection for Adagio's global Phase 2/3 STAMP and EVADE clinical trials, the company modified an existing quantitative systems pharmacology whole-body physiologically-based pharmacokinetic (QSP/PBPK) model to better characterize the PK of extended half-life mAbs in serum and key sites of viral replication in the respiratory tract. Adagio's model adequately *a priori* predicted the observed ADG20 serum PK in non-human primates (NHPs) and humans. The model was further optimized based on data from Adagio's Phase 1 clinical trial and then applied for dose selection for STAMP and EVADE, ultimately informing selection of the 300 mg intramuscular dose for the trials.

Intellectual Property

On October 29, 2021, the United States Patent and Trademark Office mailed a notice of allowance to the company for a patent application that will provide patent protection for ADG20 in the U.S.

Third Quarter 2021 Financial Results

- As of September 30, 2021, Adagio had cash, cash equivalents and marketable securities of $666.3 million, which are expected to support the company's current operating plans into 2023.
- Research & development expenses including in-process research and development for the third quarter of 2021 were $49.4 million.
- Selling, general & administrative expenses for the third quarter of 2021 were $11.1 million.
- Net loss for the third quarter was $60.4 million, or $0.98 per share.

About ADG20
ADG20, an investigational monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is advancing through global clinical trials 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 activity against SARS-CoV-2 and additional clade 1 sarbecoviruses by targeting a highly conserved epitope in the receptor binding domain. ADG20 was further engineered to provide an extended half-life for durable protection. ADG20 has demonstrated potent neutralizing activity against the original SARS-CoV-2 virus, all known SARS-CoV-2 variants of concern and additional SARS-like viruses in preclinical studies. ADG20 is administered in clinical trials by a single intramuscular injection. To date, ADG20 has been well-tolerated in a Phase 1 trial with no safety signals identified through a minimum of three months follow-up across all cohorts. ADG20 has not been approved for use in any country, and safety and efficacy have not yet been established.

About Adagio Therapeutics
Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential, including COVID-19 and influenza. The company's portfolio of antibodies has been optimized using Adimab's industry-leading antibody engineering capabilities and is designed to provide patients and clinicians with the potential for a powerful 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 to support the completion of clinical trials and initial commercial launch, ensuring the potential for broad accessibility to people around the world. 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," "expects," "intends," "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 ADG20, including the timing of our planned EUA submissions, initiation, modification and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; our ability to obtain and maintain regulatory approvals for, our product candidates; our ability to identify patients, including in specific populations, with the diseases treated by our product candidates and to enroll these patients in our clinical trials; our expectations regarding the scope of any approved indication for ADG20; and the benefits of our product candidates to patients; our manufacturing capabilities and strategy; and our ability to successfully commercialize our product candidates. 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, clinical trials and financial position, unexpected safety or efficacy data observed during preclinical studies or clinical trials, 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. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and in Adagio's future reports to be filed with the SEC, including Adagio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. 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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ADAGIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 478,269	$ 114,988
Marketable securities	188,053	—
Prepaid expenses and other current assets	13,833	2,394
Total current assets	680,155	117,382
Other non-current assets	6,115	—
Total assets	$ 686,270	$ 117,382
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 17,564	$ 8,153
Accrued expenses	35,485	4,919
Total current liabilities	53,049	13,072
Early-exercise liability	8	11
Total liabilities	53,057	13,083
Commitments and contingencies		
Convertible preferred stock (Series A, B and C) $0.0001 par value; no shares authorized, issued and outstanding at September 30, 2021; 12,647,934 shares authorized, issued and outstanding at December 31, 2020; aggregate liquidation preference of $0 and $169,900 at September 30, 2021 and December 31, 2020, respectively	—	169,548
Stockholders' equity (deficit):		
Preferred stock:		
Undesignated preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2021; no shares authorized at December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized at September 30, 2021; 150,000,000 shares authorized at December 31, 2020; 111,251,660 shares issued and outstanding at September 30, 2021; 28,193,240 shares issued and 5,593,240 shares outstanding at December 31, 2020	5	1
Treasury stock, at cost; no shares and 22,600,000 shares at September 30, 2021 and December 31, 2020, respectively	—	(85)
Additional paid-in capital	842,272	154
Accumulated other comprehensive income	3	—
Accumulated deficit	(209,067)	(65,319)
Total stockholders' equity (deficit)	633,213	(65,249)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 686,270	$ 117,382

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

	Three Months Ended September 30,	Three Months Ended September 30,	Nine Months Ended September 30,	Period from June 3, 2020 (Inception) to September 30,

	2021	2020	2021	2020
Operating expenses:				
Research and development[1]	$ 45,366	$ 7,251	$ 114,465	$ 7,299
Acquired in-process research and development[2]	4,000	39,915	7,500	39,915
Selling, general and administrative	11,052	842	21,853	892
Total operating expenses	60,418	48,008	143,818	48,106
Loss from operations	(60,418)	(48,008)	(143,818)	(48,106)
Other income (expense):				
Interest income	48	—	80	—
Other expense	(5)	—	(10)	—
Total other income (expense), net	43	—	70	—
Net loss	(60,375)	(48,008)	(143,748)	(48,106)
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities, net of tax	3	—	3	—
Comprehensive loss	$ (60,372)	$ (48,008)	$ (143,745)	$ (48,106)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.98)	$ (25.98)	$ (7.06)	$ (7.55)
Weighted-average common shares outstanding, basic and diluted	61,297,086	1,847,826	20,346,771	6,375,000

(1) Includes related-party amounts of $1,826 and $2,261 for the three and nine months ended September 30, 2021, respectively, and $291 for both the three months ended September 30, 2020 and for the period from June 3, 2020 (inception) to September 30, 2020.
(2) Includes related-party amounts of $4,000 and $7,500 for the three and nine months ended September 30, 2021, respectively, and $39,915 for both the three months ended September 30, 2020 and for the period from June 3, 2020 (inception) to September 30, 2020.