Adagene Reports Full Year 2024 Financial Results and Provides Corporate Update

March 24, 2025

Muzastotug Phase 2 dose expansion in MSS CRC with a 20 mg/kg loading dose regimen shows 33% overall response rate with four confirmed partial responses

SAFEbody technology utilized to create masked T cell engagers for potentially superior safety profile with enhanced therapeutic index

Cash balance of $85.2 million provides runway into late 2026

SAN DIEGO and SUZHOU, China, March 24, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel anti-body-based therapies, today reported financial results for the full year 2024 and provided corporate updates.

"The clinical data we generated in 2024 with ADG126 gives us great confidence in our ability to provide patients with colorectal cancer a tolerable, efficacious treatment option. These data also provide the basis for us to expand our study in microsatellite stable colorectal cancer (MSS CRC) to include earlier lines of therapy and patients with liver metastases, a patient subpopulation that has historically seen little to no benefit from checkpoint inhibitors," said Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene. "Regulatory T cells, a primary mechanism of resistance, can be overcome through higher and more frequent dosing of a conditionally active anti-CTLA-4 antibody. We continue to believe that anti-CTLA-4 therapy can transform immunotherapy in combination with anti-PD-1 and other therapies. Our SAFEbody masking capability enables the best therapeutic index among all CTLA-4 programs, showing the potential to unlock therapeutic value with a target previously limited by safety concerns."

Dr. Luo continued, "In addition to ADG126, we have also utilized our SAFEbody masking technology to create T cell engagers (TCEs) that can link T cells to any number of antigens presented on tumor cells. These masked TCEs can recruit the immune system for conditional cytotoxicity, shrinking tumors and prolonging patient survival. The combination of TCEs with ADG126, which depletes CTLA-4 mediated regulatory T cells, is expected to enhance the response to TCE therapy. We look forward to sharing more on our TCE programs going forward."

PIPELINE HIGHLIGHTS

ADG126 - Phase 1b/2 data:

- 20 mg/kg loading dose followed by 10 mg/kg Q3W in combination with pembrolizumab, Merck's (known as MSD outside of the US and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), cohort achieved an improved ORR of 33%.
    - All responders remain on treatment at a maintenance dose of 10 mg/kg Q3W or 10 mg/kg Q6W in combination with pembrolizumab
- Good tolerability with a manageable safety profile for ADG126 + pembrolizumab combo, with overall low discontinuation rate (6%) for the MSS CRC expansion cohort. No Grade 4/5 safety events were seen to date.
- Based on robust safety data of ADG126 at 20 mg/kg Q6W in combination with pembrolizumab, the efficacy of this dosing regimen is being evaluated in the cohort expansion stage of the Phase 1b/2 trial.
- Company also plans to evaluate a broader patient population, including patients with liver metastases, by combining with standard of care medicines, a combination that has been limited by safety concerns in the past.
- Investigator initiated Phase 2 trial of ADG126 in neoadjuvant colorectal cancer to begin enrolling patients in April at the National University Cancer Institute in Singapore

ADG138, a SAFEbody engineered T cell engager targeting HER2, has shown a wide therapeutic window and extended half-life for prolonged circulation in the tumor micro-environment in preclinical models. ADG138 is currently IND-ready.

ADG152, a SAFEbody engineered T cell engager targeting CD20, is designed to conditionally bind to CD20 on tumor cells and show negligible interaction with healthy cells, yielding a 100-fold reduction in cytokine release syndrome in preclinical models. ADG152 is currently in the IND-enabling phase.

The Company is pursuing strategic partnerships to advance the SAFEbody T cell engager programs.

ONGOING COLLABORATIONS

Exelixis: In June 2023, Adagene received a US$3.0 million milestone payment from Exelixis for the successful nomination of lead SAFEbody candidates for the second collaboration program under a technology licensing agreement to develop novel masked antibody-drug conjugate candidates. Including upfront and other milestone payments, we have received over US$18 million in total from Exelixis to date.

Sanofi: Adagene and Sanofi are collaborating to develop both bispecific and monoclonal SAFEbody antibody candidates, preparing preclinical candidates using Adagene's SAFEbody precision masking technology for future development and commercialization by Sanofi. The collaboration

announced in March 2022 included an upfront payment of US$17.5 million for the initial two programs, an option fee for two additional programs, potential milestone payments of up to US$2.5 billion, and tiered royalties.

Roche: Roche is sponsoring and conducting a phase 1b/2 multi-national trial to evaluate ADG126 in a triple combination with atezolizumab and bevacizumab in first-line hepatocellular carcinoma (HCC). To date, the combination has been well tolerated. Adagene retains global development and commercialization rights to ADG126.

2025 MILESTONES & CASH RUNWAY

Consistent with ongoing initiatives to prudently manage its cash balance, Adagene expects its current cash balance to fund activities into late 2026, with the following milestones expected in 2025:

- Provide longer-term time-to-event data from the existing Ph 1b/2 study of ADG126 + pembrolizumab in 3L+ MSS CRC
- Update 20 mg/kg loading dose cohort for durability of response (DOR and other time-to-event endpoints)
- Conduct EOP1 meeting with FDA by Q3 to obtain their endorsement on the proposed dose regimens, trial design and patient population
- Initiate evaluation of ADG126 + pembrolizumab in combination with standard of care in MSS CRC patients including those with liver metastases, beginning Q2
- Provide initial clinical data from investigator initiated Phase 2 trial for neoadjuvant ADG126 in colorectal cancer
- Establish additional collaboration/licensing agreements

CORPORATE UPDATES

JC Xu, M.D., Ph.D., Adagene's Chief Strategy Officer and Head of Regulatory Affairs, has recently transitioned from a full-time employee of Adagene to a consulting role. JC will continue to support the Company's development while serving as a consultant.

Ms. Yumeng Wang, a member of Adagene's Board of Directors and a Vice President at General Atlantic, will step down from the Board upon filing of the Company's 2024 Annual Report on form 20-F due to personal reason. Ms. Wang has served on Adagene's Board since 2023 and provided invaluable guidance as Adagene has developed ADG126 through first-in-human clinical trials.

Mervyn Turner, Ph.D., Independent Director of Adagene's Board of Directors, will complete his term as Independent Director concurrent with the filing of the Company's 2024 Annual Report on form 20-F, and transition to an advisory role. Mr. Turner has served on Adagene's Board of Directors since April of 2023 and will continue to provide strategic guidance to the Company in this advisory capacity.

FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents:
Cash and cash equivalents were US$85.2 million as of December 31, 2024, compared to US$109.9 million as of December 31, 2023. Total borrowings from commercial banks in China (denominated in RMB) decreased to US$18.2 million as of December 31, 2024 from US$21.9 million as of December 31, 2023. The associated loan proceeds were primarily used to support the company's R&D activities.

Net Revenue:
Net revenue was US$0.1 million for the year ended December 31, 2024, compared to US$18.1 million in 2023.

Research and Development (R&D) Expenses:
R&D expenses were US$28.8 million for the year ended December 31, 2024, compared to US$36.6 million in 2023. The decrease of approximately 21% in R&D expenses reflects clinical focus on and prioritization of the company's masked, anti-CTLA-4 SAFEbody ADG126.

Administrative Expenses:
Administrative expenses were US$7.3 million for the year ended December 31, 2024, compared to US$8.7 million in 2023. The decrease was due to both a reduction in personnel and in office-related expenses as a result of cost-control measures.

Other Operating Income, Net:
Other operating income, net was nil for the year ended December 31, 2024 compared to US$3.5 million in 2023. The amount of US$3.5 million included a one-time compensation payment from a contract manufacturer for a preclinical-related outsourcing arrangement.

Net Loss:
Net loss attributable to Adagene Inc.'s shareholders was US$33.4 million for the year ended December 31, 2024, compared to US$18.9 million in 2023.

Ordinary Shares Outstanding:
As of December 31, 2024, there were 58,886,944 ordinary shares issued and outstanding. Each American depository share, or ADS, represents one and one quarter (1.25) ordinary shares of the company.

Non-GAAP Net Loss:
Non-GAAP net loss, which is defined as net loss attributable to ordinary shareholders for the period after excluding share-based compensation expenses, was US$28.5 million for the year ended December 31, 2024, compared to US$11.7 million in 2023. Please refer to the section in this press release titled "Reconciliation of GAAP and Non-GAAP Results" for details.

Non-GAAP Financial Measures:

The company uses non-GAAP net loss and non-GAAP net loss per ordinary shares for the year, which are non-GAAP financial measures, in evaluating its operating results and for financial and operational decision-making purposes. The company believes that non-GAAP net loss and non-GAAP net loss per ordinary shares for the year help identify underlying trends in the company's business that could otherwise be distorted by the

effect of certain expenses that the company includes in its loss for the year. The company believes that non-GAAP net loss and non-GAAP net loss per ordinary shares for the year provide useful information about its results of operations, enhances the overall understanding of its past performance and future prospects and allows for greater visibility with respect to key metrics used by its management in its financial and operational decision-making.

Non-GAAP net loss and non-GAAP net loss per ordinary shares for the year should not be considered in isolation or construed as an alternative to operating profit, loss for the year or any other measure of performance or as an indicator of its operating performance. Investors are encouraged to review non-GAAP net loss and non-GAAP net loss per ordinary shares for the year and the reconciliation to their most directly comparable GAAP measures. Non-GAAP net loss and non-GAAP net loss per ordinary shares for the year here may not be comparable to similarly titled measures presented by other companies. Other companies may calculate similarly titled measures differently, limiting their usefulness as comparative measures to the company's data. The company encourages investors and others to review its financial information in its entirety and not rely on a single financial measure. Non-GAAP net loss and non-GAAP net loss per ordinary shares for the year represent net loss attributable to ordinary shareholders for the year excluding share-based compensation expenses. Share-based compensation expense is a non-cash expense arising from the grant of stock-based awards to employees. The company believes that the exclusion of share-based compensation expenses from the net loss in the "Reconciliation of GAAP and Non-GAAP Results" assists management and investors in making meaningful period-to-period comparisons in the company's operating performance or peer group comparisons because (i) the amount of share-based compensation expenses in any specific period may not directly correlate to the company's underlying performance, (ii) such expenses can vary significantly between periods as a result of the timing of grants of new stock-based awards, and (iii) other companies may use different forms of employee compensation or different valuation methodologies for their share-based compensation. Please see the "Reconciliation of GAAP and Non-GAAP Results" included in this press release for a full reconciliation of non-GAAP net loss and non-GAAP net loss per ordinary shares for the year to net loss attributable to ordinary shareholders for the year.

About Adagene

Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biotechnology company committed to transforming the discovery and development of novel antibody-based cancer immunotherapies. Adagene combines computational biology and artificial intelligence to design novel antibodies that address globally unmet patient needs. The company has forged strategic collaborations with reputable global partners that leverage its SAFEbody® precision masking technology in multiple approaches at the vanguard of science.

Powered by its proprietary Dynamic Precision Library (DPL) platform, composed of NEObody™, SAFEbody, and POWERbody™ technologies Adagene's highly differentiated pipeline features novel immunotherapy programs. The company's SAFEbody technology is designed to address safety and tolerability challenges associated with many antibody therapeutics by using precision masking technology to shield the binding domain of the biologic therapy. Through activation in the tumor microenvironment, this allows for tumor-specific targeting of antibodies in tumor microenvironment, while minimizing on-target off-tumor toxicity in healthy tissues.

Adagene's lead clinical program, ADG126 (muzastotug), is a masked, anti-CTLA-4 SAFEbody that targets a unique epitope of CTLA-4 in regulatory T cells (Tregs) in the tumor microenvironment. ADG126 is currently in phase 1b/2 clinical studies in combination with anti-PD-1 therapy, particularly focused on Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC). Validated by ongoing clinical research, the SAFEbody platform can be applied to a wide variety of antibody-based therapeutic modalities, including Fc empowered antibodies, antibody-drug conjugates, and bi/multispecific T-cell engagers.

For more information, please visit: https://investor.adagene.com.
Follow Adagene on WeChat, LinkedIn and Twitter.

SAFEbody® is a registered trademark in the United tates, China, Australia, Japan, Singapore, and the European Union.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding certain clinical results of ADG126, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated preclinical activities, clinical development, regulatory milestones, and commercialization of its product candidates. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Adagene's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Adagene's drug candidates; Adagene's ability to achieve commercial success for its drug candidates, if approved; Adagene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Adagene's reliance on third parties to conduct drug development, manufacturing and other services; Adagene's limited operating history and Adagene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Adagene's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Adagene's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in Adagene's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Adagene, and Adagene undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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Unaudited Consolidated Balance Sheets

	December 31, 2023	December 31, 2024
	US$	US$
ASSETS		
Current assets:		
Cash and cash equivalents	109,934,257	85,194,502
Amounts due from related parties	222,027	8,309
Prepayments and other current assets	3,287,445	2,575,194
Total current assets	**113,443,729**	**87,778,005**
Property, equipment and software, net	1,835,121	1,125,389
Operating lease right-of-use assets	365,103	283,645
Other non-current assets	84,885	81,386
TOTAL ASSETS	**115,728,838**	**89,268,425**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,093,752	4,241,773
Amounts due to related parties	16,714,326	13,187,966
Accruals and other current liabilities	3,001,508	2,816,038
Income tax payable	52,884	5,265
Short-term borrowings	4,235,673	4,868,956
Current portion of long-term borrowings	4,161,549	12,923,599
Current portion of operating lease liabilities	195,955	141,341
Total current liabilities	**31,455,647**	**38,184,938**
Long-term borrowings	13,540,034	417,339
Operating lease liabilities	173,660	142,304
TOTAL LIABILITIES	**45,169,341**	**38,744,581**
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares (par value of US$0.0001 per share; 640,000,000 shares authorized, and 55,145,839 shares issued and outstanding as of December 31, 2023; and 640,000,000 shares authorized, and 58,886,944 shares issued and outstanding as of December 31, 2024)	5,547	5,889
Treasury shares, at cost (1 share as of December 31, 2023 and nil as of December 31, 2024)	(4)	—
Additional paid-in capital	350,105,518	362,220,445
Accumulated other comprehensive loss	(1,800,088)	(526,903)
Accumulated deficit	(277,751,476)	(311,175,587)
Total shareholders' equity	**70,559,497**	**50,523,844**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**115,728,838**	**89,268,425**

Unaudited Consolidated Statements of Comprehensive Loss

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2024
	US$	US$
Revenues		
Licensing and collaboration revenue	18,111,491	103,204
Operating expenses and income		
Research and development expenses	(36,639,146)	(28,781,412)
Third parties	(33,978,642)	(26,837,889)
Related parties	(2,660,504)	(1,943,523)
Administrative expenses	(8,672,843)	(7,273,335)
Other operating income, net	3,480,632	—
Loss from operations	**(23,719,866)**	**(35,951,543)**
Interest and investment income	4,283,085	3,801,345
Interest expense	(1,107,820)	(851,874)
Other income, net	1,843,437	466,620
Foreign exchange gain (loss), net	1,446,202	(906,212)
Loss before income tax	**(17,254,962)**	**(33,441,664)**
Income tax benefit (expense)	(1,691,408)	17,553
Net loss attributable to Adagene Inc.'s shareholders	**(18,946,370)**	**(33,424,111)**

Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	(950,783)	1,273,185
Total comprehensive loss attributable to Adagene Inc.'s shareholders	**(19,897,153)**	**(32,150,926)**
Net loss attributable to Adagene Inc.'s shareholders	**(18,946,370)**	**(33,424,111)**
Net loss attributable to ordinary shareholders	**(18,946,370)**	**(33,424,111)**
Weighted average number of ordinary shares used in per share calculation:		
—Basic	54,737,530	56,287,903
—Diluted	54,737,530	56,287,903
Net loss per ordinary share		
—Basic	(0.35)	(0.59)
—Diluted	(0.35)	(0.59)

Reconciliation of GAAP and Non-GAAP Results

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2024
	US$	US$
GAAP net loss attributable to ordinary shareholders	**(18,946,370)**	**(33,424,111)**
Add back:		
Share-based compensation expenses	7,271,700	4,909,573
Non-GAAP net loss	**(11,674,670)**	**(28,514,538)**
Weighted average number of ordinary shares used in per share calculation:		
—Basic	54,737,530	56,287,903
—Diluted	54,737,530	56,287,903
Non-GAAP net loss per ordinary share		
—Basic	(0.21)	(0.51)
—Diluted	(0.21)	(0.51)

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Source: Adagene Inc.