ADAGENE

Adagene Reports Full Year 2021 Financial Results and Provides Corporate Update

March 31, 2022

- 2022 clinical data readouts on track to show potential best-in-class safety profile for anti-CTLA-4 programs (ADG116, ADG126) with PD-1 for proven and new indications, thereby enabling greater efficacy through higher and more frequent dosing -

- Advanced three wholly-owned clinical programs both in single agent and combination trials -

- Advanced five IND-enabling programs, including two on track for IND or equivalent filing in 2022 -

- Established Sanofi technology licensing collaboration with potential value over US\$2.5 billion, endorsing both SAFEbody[®] platform and pipeline, while advancing collaboration with Exelixis -

- Strong cash position and efficient operations support expected milestones -

SAN DIEGO and SUZHOU, China, March 31, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today reported financial results for the full-year ended December 31, 2021, and provided corporate updates.

"We are committed to delivering on our promise to transform cancer immunotherapy, concentrating on overcoming the known safety issues linked to promising yet challenging targets," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "On the clinical front, we are focused on revitalizing anti-CTLA-4 as a safe and efficacious backbone therapy, which remains a huge market opportunity and the only checkpoint inhibitor approved as both monotherapy and combination therapy with anti-PD-1. We are developing potential best-in-class molecules to unleash the full potential of this target for strong Treg depletion in the tumor microenvironment (TME) and superior safety profiles."

Dr. Luo continued, "We are also leveraging our SAFEbody technology to overcome challenges of bispecific T-cell engagers (TCEs), particularly for solid tumors, and to address safety issues of widely expressed targets like CD47. We have made wonderful progress to de-risk our clinical pipeline, grow our transformative preclinical assets, and validate our AI-powered, scalable antibody technology platform with global partnerships. With a solid cash position, we are well-positioned to achieve our expected milestones while continuing to enhance value of our pipeline."

PIPELINE GROWTH & HIGHLIGHTS

During 2021, Adagene advanced its wholly-owned, differentiated pipeline of antibody-based therapeutics, including three clinical programs in single and combination phase 1b/2 trials, five programs in IND-enabling studies and over 50 more across stages of discovery.

Clinical candidates include multiple modalities of antibody therapeutics against established targets such as CTLA-4 with ADG116 (NEObody[™]) and ADG126 (SAFEbody), challenging targets such as CD137 with ADG106 (NEObody) and ADG206 (the masked anti-CD137 POWERbody[™]), and targets with known safety issues such as CD47 with ADG153 (SAFEbody). The company's expanding preclinical portfolio further applies the company's AI-powered technology platform to create transformative antibody-based therapeutics across targets with different MOAs.

A summary of pipeline progress and recent corporate highlights is below:

ADG116: This NEObody program, targeting a unique epitope of CTLA-4, is being evaluated in patients with advanced/metastatic solid tumors. ADG116 is designed to provide an enhanced efficacy profile by potent Treg depletion in the TME and to maintain its physiological function by soft ligand blocking to address safety concerns associated with existing CTLA-4 therapeutics.

- Advanced the global phase 1b/2 trial evaluating ADG116 as monotherapy (ADG116-1003) in dose escalation and dose
 expansion in targeted tumors.
- Presented clinical data at ESMO-IO 2021 in December from the dose-escalation part of the ADG116 monotherapy trial. Results showed strong safety profile and early signals of efficacy profile in a heavily pre-treated patient population with advanced metastatic diseases, including dose-dependent T-cell activation and tumor suppression in treatment-resistant "cold" and "warm" tumors such as pancreatic, ovarian and renal cell cancers.
 - ADG116 monotherapy was well-tolerated up to 10 mg/kg with primarily Grade 1 and limited Grade 2 treatmentrelated adverse events (TRAEs) observed in 25 patients (data cut off was October 15, 2021); a single rash (Grade 3) and dose limiting toxicity event (Grade 4 hyperglycemia) occurred in a patient with renal cell carcinoma who relapsed on nivolumab. This safety profile compared favorably to the benchmark antibody in a comparable dose range.
 - Dose escalation at 10 mg/kg is now complete and dose expansion is ongoing at 10 mg/kg in this monotherapy trial (ADG116-1003). No DLTs have occurred for additional patients at the ongoing 10 mg/kg dose level.
- Initiated dose escalation in phase 1 trial in China evaluating ADG116 as monotherapy (ADG116-1002) in patients with advanced/metastatic solid tumors.
- Initiated dose escalation of ADG116 in combination with either anti-PD-1 (toripalimab) or anti-CD137 (ADG106) therapy in patients with advanced/metastatic solid tumors.
- Initiated the global phase 1b/2 trial (ADG116-P001 / KEYNOTE-C97) following FDA clearance to evaluate ADG116 in combination with anti-PD-1 antibody, pembrolizumab in patients with advanced/metastatic solid tumors at multiple sites in

the U.S. and Asia Pacific.

ADG126: This SAFEbody program applies precision masking technology to ADG116 for conditional activation in the TME to expand the therapeutic index and to further address safety concerns with existing CTLA-4 therapies. ADG126 is designed to provide enhanced safety and efficacy profiles due to the combination of the potent Treg depletion in the TME and soft ligand blocking.

- Following completion of dose escalation up to 10 mg/kg, initiated monotherapy dose expansion of an ongoing global phase 1b/2 clinical trial evaluating the safety profile and tolerability of ADG126 in patients with advanced/metastatic solid tumors (ADG126-1001).
 - In dose escalation cohorts, ADG126 was well tolerated with no dose-limiting toxicities up to 10 mg/kg even in patients who received more than four cycles. Following evaluation of data by a Safety Review Committee (SRC), dose expansion was approved at 10 mg/kg and initiated in both "warm" and "cold" tumor types.
 - o Patients have received multiple cycles with continuous dosing, and favorable pharmacokinetic and pharmacodynamic activity compared to ADG116 has been observed. ADG126 has consistently shown a potential best-in-class profile, which is supported by preclinical evaluation, including GLP toxicology data, and enabled by the broad species cross-reactivity of ADG126.
 - The ADG126 clinical results have been submitted for presentation at the 2022 ASCO Annual Meeting.
- Initiated a global phase 1b/2 trial (ADG126-P001 / KEYNOTE-C98) following FDA clearance to evaluate ADG126 in combination with pembrolizumab in patients with advanced/metastatic solid tumors at multiple sites in the U.S. and Asia Pacific.
- ADG106: This NEObody program is a fully human ligand-blocking, agonistic anti-CD137 IgG4 monoclonal antibody (mAb) that is being evaluated in patients with advanced solid tumors and/or non-Hodgkin's lymphoma.
 - Initiated dose escalation for the phase 1b/2 clinical trial in Singapore (ADG106-T6001) evaluating ADG106 in combination with the anti-PD-1 antibody, nivolumab, for patients with advanced non-small cell lung cancer (NSCLC) who have progressed after prior treatment. The investigator-initiated trial is being conducted at the National University Cancer Institute, Singapore and the National Cancer Centre Singapore, in collaboration with the Singapore Translational Cancer Consortium.
 - As noted above, initiated a dose escalation cohort in the global phase 1b/2 trial (ADG116-1003) evaluating ADG106 in combination with ADG116.
 - Advanced the phase 1b/2 trial (ADG106-1008) in China evaluating safety and preliminary efficacy profiles of ADG106 in combination with toripalimab, an approved anti-PD-1.
 - In December 2021, presented data at ESMO-IO 2021 on the biomarker kinetics for ADG106 as a monotherapy or combined with toripalimab. The combination of ADG106 with toripalimab resulted in a 2-fold synergistic effect for immune activation compared to ADG106 monotherapy, even amongst patients who failed prior anti-PD-1 and CTLA-4 therapies.

Preclinical Discovery Programs: The company continues to expand its preclinical pipeline by applying its three-body technology platforms - NEObody, SAFEbody and POWERbody - across modalities. New POWERbody candidates are designed to unleash the efficacy of a therapeutic through Fc-engineering, drug conjugation, or T-cell engagement, while securing safety by precision masking with SAFEbody technology. Thus, POWERbody candidates incorporate SAFEbody precision masking technology.

- In November 2021, unveiled preclinical data at the 63rd ASH Annual Meeting & Exposition on two highly differentiated programs for transformative therapies for novel or validated targets: anti-CD47 (ADG153) and CD20xCD3 (ADG152).
 - o ADG153, an anti-CD47 SAFEbody in IgG1 format, introduces IgG1-mediated effects for potent tumor killing with a compelling safety profile, minimal red blood cell (RBC)-related and antigen sink liabilities, and 8-fold prolonged half-life in comparison with benchmark clinical antibodies in the IgG4 subclass. By integrating efficacy and safety profiles, as well as prolonged pharmacokinetics into one single modality, anti-CD47 ADG153 IgG1 SAFEbody or ADG153 has a potential best-in-class profile.
 - o ADG152, is a CD20xCD3 POWERbody integrating the company's proprietary bispecific TCE platform with its precision masking technology. In preclinical mouse xenograft tumor models, ADG152 has demonstrated strong and sustained anti-tumor activity; in comparison with a benchmarked antibody in clinical development, improved safety with cytokine release control even at a 100-fold higher dose than the benchmarked antibody analog and 2- to 3-fold prolonged half-life than the benchmarked antibody analog in exploratory preclinical monkey studies.
- Announced presentation of four posters at the American Association for Cancer Research (AACR) Annual Meeting 2022. At AACR, presentations will show the potential best-in-class profiles for three differentiated preclinical product candidates in IND-enabling studies: ADG138, ADG206 and ADG153, which all three apply the SAFEbody precision masking technology. The fourth presentation introduces a new capability for the company's proprietary bispecific TCEs with CD28.
 - ADG138 is a novel HER2×CD3 POWERbody integrating a bispecific TCE with precision masking technology to control CRS and on-target off-tumor toxicity for single agent and combination therapies in HER2-expressing solid tumors.
 - o ADG206, is an Fc-engineered anti-CD137 agonistic POWERbody with tailor-made efficacy and safety profiles by

strong crosslinking and tumor selective activation for single agent and combinational cancer immunotherapy.

- The proprietary tumor-targeted CD28 bispecific POWERbody platform is designed for safe and synergistic T cell-mediated immunotherapy candidate.
- Additional data will be presented supporting the advancement of the anti-CD47 antibody ADG153 into clinical development for both hematologic and solid tumor indications.
- During 2022, Adagene plans to submit an IND or equivalent for two POWERbody product candidates: ADG206 and ADG153.

Collaborations:

- Established an exclusive technology licensing agreement with Sanofi in March 2022 to generate novel masked monoclonal and bispecific candidate antibodies, with a potential transaction value of US\$2.5 billion. Under the terms of the agreement, Adagene will be responsible for early-stage research activities to develop masked versions of Sanofi provided candidate antibodies, using Adagene's SAFEbody technology. Sanofi will be solely responsible for later stage research and all clinical, product development and commercialization activities. The collaboration includes an upfront payment of US\$17.5 million for the initial two programs (US\$8.75 million per program), an option fee for two additional programs, potential milestone payments of up to US\$2.5 billion (US\$625 million per program), and tiered royalties.
- Achieved a US\$3 million milestone in December 2021 for the successful nomination of lead SAFEbody candidates in a technology licensing agreement with Exelixis, established in February 2021 to develop SAFEbody novel masked antibody-drug conjugate candidates. Terms of the agreement included an upfront payment of US\$11 million for 2 programs (US\$5.5 million per program), potential milestone payments of up to US\$780 million (US\$390 million per program), and tiered royalties.
- Finalized clinical trial collaboration and supply agreements with Merck to evaluate pembrolizumab in combination therapy with all three wholly-owned clinical candidates.
- Advanced global partnerships and collaboration with Sanjin and Dragon Boat Biopharmaceutical for two antibodies out-licensed in Greater China, including an anti-PD-L1 (ADG104) in phase 2 development, and a novel anti-CSF-1R (ADG125/BC006) in phase 1.

Corporate Updates:

- In light of the Holding Foreign Companies Accountable Act (HFCAA), Adagene is proactively evaluating additional business processes and control changes to meet the requirements of the HFCAA and intends to leverage its flexible, global infrastructure and its focus on developing highly differentiated therapeutics for patients worldwide.
- Liu Yuwen was appointed as an independent board member and member of the Audit Committee, to support the company's corporate development. Liu Yuwen is a leading advocate for the biotechnology, biopharmaceutical and medical technology industries, with over 20 years as an entrepreneur, advisor and investor.
- The company has expanded and strengthened its leadership team with recent hires across strategy, clinical, regulatory, communications and CMC functions.

EXPECTED 2022 MILESTONES & OUTLOOK

Adagene has previously provided its outlook for 2022, including planned advancement of both its clinical product candidates and preclinical portfolio. The company recently achieved its goal to complete a major collaboration following the Sanofi licensing agreement, and it continues to work towards strategic development collaborations for its pipeline. Additional milestones and expected progress during 2022 include:

- Demonstrate single-agent activity for anti-CTLA-4 programs (ADG116, ADG126) in heavily pretreated patients with "warm" and "cold" tumors.
- Demonstrate potential best-in-class safety and preliminary efficacy profiles for anti-CTLA-4 programs with anti-PD-1 therapy.
- Evaluate the profile for novel combinations of wholly owned anti-CD137 (ADG106) with either anti-CTLA-4 or anti-PD-1 therapy.
- Submit filings to advance at least two candidates to clinic, and expand programs into IND-enabling phase.
- Continue efficient discovery operations, with more than 50 projects underway.

FULL-YEAR 2021 FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents:

Cash and cash equivalents were US\$174.4 million as of December 31, 2021, compared to US\$75.2 million as of December 31, 2020. The increase was mainly due to net proceeds of US\$145.9 million from the company's Initial Public Offering in February 2021. Further, the year-end 2021 cash balance does not include the US\$3 million milestone payment from Exelixis received in January 2022, or the expected US\$17.5 million upfront payment from Sanofi for the recently announced technology licensing collaboration.

Net Revenue:

Net revenue in 2021 was US\$10.2 million compared to US\$0.7 million in 2020. The increase was due to recognition of US\$8.5 million from the collaboration and technology license agreement with Exelixis and a payment of US\$1.2 million from Dragon Boat Biopharmaceuticals, a subsidiary of

Sanjin, related to the companies' collaboration to develop antibody-based therapies. Due to the Exelixis collaboration, contract liabilities were US\$5.5 million as of December 31, 2021, compared to US\$0.7 million as of December 31, 2020.

Research and Development (R&D) Expenses:

R&D expenses were US\$68.1 million for the year ended December 31, 2021, compared to US\$33.5 million for the same period in 2020. The increase in R&D was primarily due to an increase in personnel, including non-cash share-based compensation of US\$13.6 million, and greater preclinical testing, clinical activities and CMC activities (provided by related parties and third parties) associated with the company's three clinical candidates and five preclinical programs in the IND-enabling phase.

General and Administrative (G&A) Expenses:

G&A expenses were US\$14.4 million for the year ended December 31, 2021, compared to US\$10.3 million for the same period in 2020. The increase was primarily due to an increase in personnel, professional fees and office-related expenses.

Net Loss:

The Company reported a net loss of US\$73.2 million and US\$42.4 million for the full year ended December 31, 2021, and 2020, or (US\$1.46) and (US\$2.67) per ordinary share on diluted basis, respectively. The 2021 net loss was higher largely due to increases in clinical, operating and CMC activities.

Non-GAAP Net Loss:

Non-GAAP net loss, which is defined as net loss attributable to ordinary shareholders for the period after excluding (i) share-based compensation expenses and (ii) accretion of convertible redeemable preferred shares to redemption value. The Non-GAAP net loss was US\$54.5 million for the year ended December 31, 2021, compared to US\$32.3 million for the same period in 2020. 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 (i) share-based compensation expenses, and (ii) accretion of convertible redeemable preferred shares to redemption value. 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/period.

About Adagene

Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biopharmaceutical 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 unmet patient needs. 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. Adagene has forged strategic collaborations with reputable global partners that leverage its technology in multiple approaches at the vanguard of science.

For more information, please visit: <u>https://investor.adagene.com</u>.

Follow Adagene on WeChat, LinkedIn and Twitter.

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

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding 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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FINANCIAL TABLES FOLLOW

Consolidated Balance Sheets

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Total current liabilities16,145,76829,821,914Long-term borrowings2,965,5632,991,829Deferred tax liabilities-44,163Other non-current liabilities91,95594,107TOTAL LIABILITIES19,203,28632,952,013Commitments and contingenciesLIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT (CONTINUED)-Mezzanine equity:Series A-1 convertible redeemable preferred shares5,473,957-Series A-2 convertible redeemable preferred shares27,999,995-Series C-1 convertible redeemable preferred shares18,975,456-Series C-2 convertible redeemable preferred shares18,999,999-Series C-3 convertible redeemable preferred shares50,000,000-Series C-3 convertible redeemable preferred shares50,000,000-	Current portion of long-term borrowings	1,183,926	1,376,319
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Deferred tax liabilities	Long-term borrowings		
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Accumulated other comprehensive income (loss) (350,981) (93,981)	•		336.099.931
	Accumulated deficit	(105,655,324)	(178,833,259)

Total shareholders' equity (deficit)	(89,389,956)	156,558,713
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY (DEFICIT)	84,262,737	189,510,726

Consolidated Statements of Comprehensive Loss

	For the Year Ended December 31, 2020 (audited)	For the Year Ended December 31, 2021 (unaudited)
	US\$	US\$
Revenues		
Licensing and collaboration revenue	700,913	10,175,258
Expenses		
Research and development expenses	(33,538,035)	(68,099,385)
Third parties	(23,645,740)	(55,020,367)
Related parties	(9,892,295)	(13,079,018)
Administrative expenses	(10,314,536)	(14,439,962)
Loss from operations	(43,151,658)	(72,364,089)
Interest income	629,288	76,166
Interest expense	(202,165)	(363,762)
Other income, net	971,949	1,778,822
Foreign exchange gain (loss), net	(644,693)	(603,459)
Loss before income tax	(42,397,279)	(71,476,322)
Income tax expense		(1,701,613)
Net loss attributable to Adagene Inc.'s shareholders	(42,397,279)	(73,177,935)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	(6,087)	257,000
Total comprehensive loss attributable to Adagene Inc.'s shareholders	(42,403,366)	(72,920,935)
Net loss attributable to Adagene Inc.'s shareholders	(42,397,279)	(73,177,935)
Accretion of convertible redeemable preferred shares to redemption value	(248,113)	(28,553)
Net loss attributable to ordinary shareholders	(42,645,392)	(73,206,488)
Weighted average number of ordinary shares used in per share calculation:		, , , ,
-Basic	15,950,698	50,032,009
—Diluted	15,950,698	50,032,009
Net loss per ordinary share		
-Basic	(2.67)	(1.46)
—Diluted	(2.67)	(1.46)
	()	

Reconciliation of GAAP and Non-GAAP Results

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2021
	US\$	US\$
GAAP net loss attributable to ordinary shareholders	(42,645,392)	(73,206,488)
Add back:		
Share-based compensation expenses	10,129,541	18,679,658
Accretion of convertible redeemable preferred shares to redemption value	248,113	28,553
Non-GAAP net loss	(32,267,738)	(54,498,277)
Weighted average number of ordinary shares used in per share calculation:		
—Basic	15,950,698	50,032,009
—Diluted	15,950,698	50,032,009
Non-GAAP net loss per ordinary share		
—Basic	(2.02)	(1.09)
—Diluted	(2.02)	(1.09)



Source: Adagene Inc.