Adagene Announces Publication at ASCO of Interim Monotherapy Dose Escalation Data Showing Compelling Safety Profile of Anti-CTLA-4 SAFEbody® ADG126, with Repeat Dosing Across Dose Levels

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- First clinical data demonstrating potential of SAFEbody technology platform to create best-in-class therapeutics -

- Additional data from ongoing ADG126 clinical program to be presented in second half of 2022, including safety in combination with anti-PD-1 therapies -

SAN DIEGO and SUZHOU, China, May 26, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced the publication of data showing the potential best-in-class safety profile of its anti-CTLA-4 monoclonal antibody (mAb), ADG126. Interim results from the Phase 1 dose escalation portion of an ongoing Phase 1b/2 trial of ADG126 are published in an abstract on the American Society of Clinical Oncology (ASCO) meeting website in conjunction with the 2022 Annual Meeting taking place in Chicago from June 3-7, 2022.

Key data in the abstract, titled "Phase 1 study of ADG126, a novel masked anti-CTLA-4 SAFEbody, that combines tumor-localized activation with strong Treg depletion and soft ligand blocking in patients with advanced solid tumors," include the following:

- In this dose escalation of 16 patients with advanced metastatic solid tumors, approximately one third received three or more lines of prior therapies, and approximately one third had progressed from immuno-oncology (IO) therapy. ADG126 was administered to this heavily pretreated patient population intravenously as monotherapy once every three weeks at doses up to 10 mg/kg.
- No dose-limiting toxicities or treatment-related SAEs were observed and only Grade 1 treatment related adverse events (TRAEs) were reported with repeat dosing across all dose levels; fatigue (19%) and pruritis (13%) were most common.
- Plasma pharmacokinetics (PK) were approximately linear and the activated ADG126 accumulated steadily during repeat dosing across different dose levels. As the first clinical data validating the SAFEbody precision masking technology, the approximately 1.7-fold increase in half-life of total ADG126 is reflective of prolonged exposures of activated ADG126 in the tumor microenvironment (TME).
- In an early indication of antitumor activity, two heavily pretreated patients with cold tumors (one ovarian and one uveal melanoma) showed durable reductions in target lesions (over 20%) and increased CD8+ T cells post-dosing. After the seventh cycle of ADG126 treatment at 1 mg/kg the ovarian cancer patient also showed a 77% reduction in CA-125 levels, an established biomarker of clinical benefit for ovarian patients. This activity is likely due to the accumulation of activated ADG126 in the TME upon repeat dosing at 1 mg/kg. The uveal melanoma patient was resistant/refractory to prior IO-IO combination therapy, having progressed on the combination of nivolumab and ipilimumab.
- At the data cut-off of February 15, 2022, stable disease was seen in 5/16 patients, including the ovarian cancer and uveal melanoma patients. Dose escalation in this trial continues at 20 mg/kg and dose expansion has started at 10 mg/kg.

Commenting on the findings, Dr. Gary Richardson, OAM, MBBS, FRACP, Group Director at Cabrini Health Research, Neil Beauglehall Endowed Chair, Medical Oncology Research, and Professor of Medicine at Monash University, Australia, said, "With the emerging clinical data evaluating this novel immunotherapy candidate ADG126, a masked anti-CTLA-4 SAFEbody, we have the opportunity to detangle safety from efficacy, and deeply understand the benefits of Treg depletion while we optimize anti-CTLA-4 therapy as a cornerstone of future therapy. Another exciting and surprising aspect of these interim findings is that we see early signals of efficacy in certain 'cold' tumors with SAFEbody ADG126, which further builds on prior clinical evidence with its parental antibody ADG116, targeting a unique epitope of CTLA-4 to enable not only a safer but potentially better therapy than the options we have available today."

ADG126 SAFEbody applies precision-masking technology to the parental anti-CTLA-4 antibody, ADG116, for conditional activation in the TME to expand the therapeutic index and further address safety concerns with existing CTLA-4 therapies. Binding to the same unique epitope as ADG116, the masked 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 these monotherapy dose escalation results, we look forward to releasing further data in coming months to confirm if the strong safety profile of ADG126 is preserved in combination with anti-PD-1 therapy, consistent with our preclinical observations," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene.

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: https://investor.adagene.com. Follow Adagene on WeChat, LinkedIn and Twitter.

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Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding certain clinical results of ADG126, the potential implications of clinical results of the product candidate, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of Adagene pipeline 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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