Adagene Presents Interim Monotherapy Data at ESMO 2022 Showing Compelling Safety, Anti-Tumor Activity and Pharmacokinetics of Masked, Anti-CTLA-4 SAFEbody® ADG126 in Patients with Advanced Tumors

September 10, 2022

- Best-in-class profile demonstrated with repeat dosing across dose levels -

- Antitumor activity observed in cold tumors with steady accumulation of activated ADG126 -

- On track in 2022 to report results of ADG126 dose escalation in combination with anti-PD-1 therapy, establishing dose regimen for phase 2a dose expansion cohorts -

SAN DIEGO and SUZHOU, China, Sept. 10, 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 best-in-class potential of ADG126, a masked, anti-CTLA-4 SAFEbody®. Interim results from the Phase 1 portion of an ongoing Phase 1b/2 trial of ADG126 are being presented at the European Society for Medical Oncology (ESMO) Congress 2022 in Paris, September 9 – 13, 2022.

The poster, titled "Phase 1 Results Demonstrate Highly Differentiated Safety and PK Profile of ADG126, a Masked anti-CTLA-4 SAFEbody® in Patients with Advanced Solid Tumors," reviewed data from the first-in-human, open label, phase 1 dose-escalation and dose expansion trial. The poster reports data on 26 patients with advanced metastatic solid tumors, the majority (58%) of whom received three or more lines of prior therapies and nearly half (42%) of whom progressed from prior immuno-oncology (IO) therapy.

Key findings include:

- ***Safety:*** ADG126 monotherapy showed an unprecedented clinical safety profile at dosing levels up to 20 mg/kg when administered to this heavily pretreated patient population once every three weeks. ADG126 was well tolerated, with no dose-limiting toxicities or treatment-related Grade 3 or higher adverse events observed. The most frequent treatment related adverse events (TRAEs) (≥10%) were fatigue (12%), pruritis (12%), rash (12%) and diarrhea (12%). Dose escalation is completed at 20 mg/kg and dose expansion is ongoing at 10 mg/kg.

- ***Antitumor Activity in Cold Tumors***: With 18 cycles of treatment at 1 mg/kg, an ovarian cancer patient experienced significant, continued reduction of an established ovarian cancer biomarker, CA125, dropping 90% to within the normal range for full clinical benefit. As of cycle 16, the patient experienced a 22% decrease in target lesions. Previously, this patient had surgery and five prior lines of systemic therapies. At the data cut-off of August 17, 2022, the disease control rate was 39% (9/23 evaluable patients).

- ***Pharmacokinetics:*** ADG126 plasma pharmacokinetics (PK) were approximately linear and activated ADG126 accumulated steadily during repeat dosing across different dose levels. This suggests prolonged exposures of activated ADG126 in the tumor microenvironment (TME), with cleaved ADG126 on average accumulating ≥3-fold during repeat dosing, resulting from an approximately 1.5-fold longer half-life of total ADG126 compared with its parental antibody.

"ADG126 continues to demonstrate a remarkable safety profile, highly differentiated from both the currently approved anti-CTLA-4 therapy and others in development, as well as antitumor activity in heavily pre-treated patients with cold tumors," said 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, "An intriguing case study of our poster is the experience of a patient with ovarian cancer, whose tumor reduced by 22 percent accompanied by normalization of an established clinical biomarker, CA125, dropping by tenfold after more than one year of treatment with ADG126 administered every three weeks at only 1 mg/kg. These data clearly demonstrate the monotherapy activity of this novel antibody, ADG126, supporting its ongoing evaluation as both monotherapy and in combination with anti-PD-1 agents."

Trials evaluating the combination of ADG126 and anti-PD-1 therapies are ongoing in patients with advanced, metastatic tumors in the US, China and Asia Pacific (APAC), evaluating optimized doses of ADG126 in targeted tumors.

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 partial ligand blocking by the activated ADG126, which is accumulated steadily for the prolonged tumor killing effect in TME.

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 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.

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 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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Source: Adagene Inc.