Adagene Announces First Patient Dosed with Novel, Proprietary Combination of Anti-CD137 Agonist, ADG106, and Anti-CTLA-4 Monoclonal Antibody, ADG116

January 27, 2022

SAN DIEGO and SUZHOU, China, Jan. 27, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced the first patient has been dosed in a combination cohort of its anti-CD137 agonist, ADG106, with its anti-CTLA-4 monoclonal antibody (mAb), ADG116, in patients with advanced/metastatic solid tumors. The dose escalation cohort will evaluate the safety and tolerability of this novel, proprietary combination in patients with advanced/metastatic solid tumors.

"Existing cancer therapies that target CD137 and CTLA-4 are associated with safety concerns, creating a significant unmet need and high threshold for agents that are both safe and potent. With ADG106 and ADG116, we now have two promising agents to test the therapeutic potential of these two potent pathways together to safely inhibit tumor growth," said Anthony W. Tolcher, M.D., FRCPC, FACP, co-founder of NEXT Oncology™ and study investigator. "While the oncology community has long known of the compelling preclinical rationale for this intriguing combination, safety has been a barrier to further exploration. Given the encouraging individual safety profiles of both ADG 106 and ADG116 in patients so far, we finally have the rare and exciting opportunity to be the first to move this combination into clinic and improve patient care."

The combination is part of an open-label, global phase 1b/2 clinical trial (ADG116-1003) at multiple sites in the U.S. and Asia Pacific (APAC). The combination part begins with dose-escalation, followed by dose expansion once a recommended dose is established.

"Published research in preclinical models underscores the potential synergistic effect of combining these two potent pathways. We are proud to pioneer exploration of this novel combination, which also demonstrates the translational power of our NEObody™ platform — targeting unique epitopes with novel mechanisms of action by species cross reactive antibodies that can move directly from preclinical syngeneic mouse models to clinical studies," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "This innovative clinical research will establish the safety and potential complementary effects of ADG106 and ADG116 against two challenging but orthogonal pathways for T-cell priming by anti-CTLA-4 and proliferation by anti-CD137, respectively, building on the promising preclinical and clinical data on safety and preliminary efficacy from our global trials. This pursuit aligns with our goal to transform the development paradigm of antibody-based immunotherapies for global cancer care."

As single agents, both ADG106 and ADG116 have demonstrated robust safety profiles and early signals of efficacy. In monotherapy trials in 98 patients, ADG106 was well tolerated at doses of 3 mg/kg and 5 mg/kg and at 300mg and 400mg flat doses, with limited liver toxicity or hematologic abnormalities observed. Results showed evidence of efficacy and a potential biomarker associated with tumor shrinkage was identified.

In monotherapy evaluation, ADG116 demonstrated a strong safety profile at doses up to 10 mg/kg, and showed early signals of efficacy, including in treatment-resistant "cold" and "warm" tumors such as ovarian and pancreatic cancers. ADG116 has achieved the recommended dosing range as a single agent and for evaluation in combination therapy.

About ADG116
ADG116 is a fully human ligand-blocking anti-CTLA-4 mAb generated using Adagene's proprietary NEObody technology and being developed for the treatment of advanced/metastatic solid tumors. ADG116 is designed to enhance efficacy by potent Treg depletion in the tumor microenvironment (TME) and to maintain its physiological function by soft ligand blocking thereby addressing safety concerns associated with existing CTLA-4 therapeutics.

About ADG106
ADG106, is a fully human ligand-blocking, agonistic anti-CD137 IgG4 mAb generated using Adagene's proprietary NEObody technology and being developed for the treatment of advanced solid tumors and non-Hodgkin's lymphoma. CD137 stimulates the immune system to attack cancer cells and is a key driver for long-lasting T-cell proliferation and survival. Clinical trials of ADG106 as monotherapy have been conducted in the U.S. and China, and combination trials are underway with multiple anti-PD-1 therapies.

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.

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.

Internal Contact:
Ami Knoefler
Adagene
650-739-9952
ir@adagene.com

External Contact:
Bruce Mackle
LifeSci Advisors
646-889-1200
bmackle@lifesciadvisors.com

Source: Adagene, Inc.