Adagene Announces First Patients Dosed in Global Phase 1 Clinical Trial of ADG126, Lead SAFEbody™ Program

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SAFEbody technology enables precision masking of antibodies for enhanced safety

SAN FRANCISCO and SUZHOU, China, March 16, 2021 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biopharmaceutical company committed to transforming the discovery and development of novel antibody-based immunotherapies, today announced the first patients have been dosed in its global Phase 1 clinical trial of ADG126 for the treatment of various advanced solid tumors. ADG126 is a fully-human, antagonistic monoclonal antibody (mAb) targeting a novel epitope of CTLA-4 and is Adagene's lead SAFEbody™ product candidate.

"Dosing the first patients in our Phase 1 clinical trial of ADG126 is an exciting milestone for the development of our SAFEbody technology platform," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "SAFEbody technology is designed to mask antibody binding sites, which will be activated specifically within the tumor microenvironment (TME), to provide favorable safety and efficacy with significantly enhanced therapeutic windows. Our most advanced SAFEbody candidate, ADG126 targets a conserved epitope of CTLA-4 with broad species cross-reactivity for potent Treg depletion via strong antibody-dependent cellular cytotoxicity (ADCC) in TME versus peripheral tissue. Our preclinical studies provide proof-of-concept for the potential of ADG126 in leveraging our SAFEbody platform to overcome standing issues associated with existing anti-CTLA-4 therapies by limiting on-target off-tumor toxicities in normal tissues."

"Existing cancer therapies that target CTLA-4 are associated with safety concerns, creating an unmet need for new anti-CTLA-4 therapies that are both safe and potent," said Anthony W. Tolcher, M.D., FRCPC, FACP, medical oncologist, co-founder of NEXT Oncology ™, Adagene advisor and study investigator. "ADG126 demonstrated an impressive safety margin while maintaining its potent antitumor efficacy in pre-clinical studies, and I look forward to its evaluation in patients with advanced solid tumors."

The global Phase 1 open-label, dose-escalation clinical trial is investigating the tolerability and anti-tumor activity of ADG126 in patients with advanced/metastatic tumors in multiple clinical sites in Australia. Adagene has also received approval from the FDA to initiate the Phase 1 clinical trial of ADG126 in the United States. The dose escalation trial will test five doses at 0.1, 0.3, 1.0, 3.0 and 10 mg/kg, with dose-limiting toxicities (DLT) evaluation for 3 weeks. Additional information about this clinical trial is available at ClinicalTrials.gov using the identifier: NCT04645069.

About ADG126
ADG126 is a fully human antagonistic mAb targeting a novel epitope of CTLA-4 and has been shown to specifically deplete regulatory T-cells in tumors. ADG126 is Adagene's lead SAFEbody™ product candidate. The SAFEbody technology, developed using Adagene's AI-powered platform, enables binding of an antibody to a specific target only after conditional activation of the antibody in target tissues.

In preclinical studies, ADG126 was well tolerated in cynomolgus monkeys in a four-week repeat-dose GLP toxicology study at doses up to 200 mg/kg, and demonstrated an encouraging antitumor response in multiple immune-competent mouse tumor models in a dose-dependent manner both as a single agent and in combination with anti-PD1 and other therapies.

Unlike anti-PD1/PD-L1 check point inhibitors, anti-CTLA-4 is known for its dose-dependent clinical response in single and combination therapies, which is severely limited by the narrow therapeutic window available to current anti-CTLA-4 therapies. The large safety margin shown by ADG126 GLP toxicology studies of up to 200 mg/kg in targeting CTLA-4 will make it possible to dose patients for their optimal clinical benefits in single and combination 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 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.

Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding data from the ADG126 preclinical studies and Phase I clinical trial, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of ADG126. 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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