Adagene Announces FDA Clearance of IND for Phase 1b/2 Trial of Anti-CTLA-4 Monoclonal Antibody ADG116 in Combination Therapy with Anti-PD-1 Antibody Pembrolizumab

November 29, 2021

- ADG116-P001 trial being initiated at multiple sites with dosing to begin early 2022 -

SAN DIEGO and SUZHOU, China, Nov. 29, 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 that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application to proceed with a Phase 1b/2 clinical trial of its anti-CTLA-4 monoclonal antibody (mAb), ADG116, in combination with the anti-PD-1 antibody, pembrolizumab. The global trial (ADG116-P001 / KEYNOTE-C97) will evaluate patients with advanced/metastatic solid tumors at multiple sites in the U.S. and Asia Pacific (APAC).

ADG116 utilizes Adagene’s proprietary NEObody™ platform technology and is designed to target a unique conserved epitope of CTLA-4 with enhanced efficacy by potent Treg depletion in the tumor microenvironment (TME). ADG116 is designed with a soft ligand blocking to address safety concerns associated with existing CTLA-4 therapeutics.

“The FDA clearance of this trial represents a significant milestone for our anti-CTLA-4 program as we advance our evaluation of ADG116 in combination with anti-PD-1 therapy,” said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. “By applying NEObody technology, ADG116 can overcome existing safety limitations of anti-CTLA-4 therapies to achieve improved clinical benefit. Our exploration of ADG116 with pembrolizumab aims to unleash the dual CTLA-4/PD-1 blockade and realize the full potential of this combination therapy approach as a cornerstone of cancer treatment – balancing safety and efficacy.”

The ADG116-P001 trial is expected to dose the first patient in early 2022, and is designed to evaluate the safety and tolerability, determine the maximum tolerated dose, and assess preliminary efficacy of the combination of ADG116 and pembrolizumab.

Additionally, the ongoing ADG116-1003 trial is on track to expand with two combination cohorts investigating safety and preliminary efficacy of ADG116 with either toripalimab or ADG106 in patients with advanced/metastatic solid tumors.

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 programsAdagene 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 the potential implications of clinical data for patients, and Adagene’s advancement of, and anticipated clinical 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.