Adagene Announces FDA Clearance to Proceed with Phase 1b/2 Trial of Anti-CTLA-4 ADG126 SAFEbody® in Combination Therapy With Anti-PD-1 Antibody Pembrolizumab

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– ADG126-P001 trial being initiated at multiple sites in U.S. and Asia Pacific –

– First SAFEbody candidate to advance into combination clinical trial, building on strong single-agent clinical profile –

SAN DIEGO and SUZHOU, China, March 16, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced FDA clearance to proceed with a Phase 1b/2 clinical trial of its anti-CTLA-4 monoclonal antibody (mAb), ADG126, in combination with the anti-PD-1 antibody pembrolizumab. The global trial (ADG126-P001 / KEYNOTE-C98) will evaluate patients with advanced/metastatic solid tumors at multiple sites in the U.S. and Asia Pacific (APAC).

ADG126 SAFEbody is designed for conditional activation in the tumor microenvironment (TME), as well as to enhance the efficacy profile by potent Treg depletion and to maintain its physiological function by soft ligand blocking in order to expand the therapeutic index and further address safety concerns with existing CTLA-4 therapies.

"The FDA clearance of this trial represents a major step forward in our wholly-owned CTLA-4 program. It builds on a strong safety profile for ADG126 SAFEbody and its parental antibody ADG116, respectively, as a single agent and the ability to achieve doses that may unlock the full potential of CTLA-4 as a proven target for strong ADCC-mediated Treg depletion in the TME. Our goal is to establish the CTLA-4 pathway as the cornerstone of cancer treatment in both single-agent and combination regimens," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "We are excited to initiate our clinical trial evaluating combination therapy with ADG126, which leverages SAFEbody precision masking technology to address toxicity limitations. This multi-regional trial of ADG126 with pembrolizumab also reflects our commitment to bringing highly differentiated therapies to cancer patients globally."

SAFEbody technology is designed to address safety and tolerability challenges associated with many antibody therapeutics by using precision masking technology to shield the binding domain of the biologic therapy. Through activation in the TME, this allows for tumor-specific targeting of antibodies, while minimizing on-target off-tumor toxicity in healthy tissues.

The ADG126-P001 trial is expected to dose the first patients soon. The trial is designed to evaluate safety and tolerability, and to determine the recommended Phase 2 dose for ADG126 in combination with pembrolizumab. The trial will begin with dose-escalation (ADG126 at 6 mg/kg) followed by dose expansion at the recommended dose for early efficacy evaluation. A combination cohort of ADG126 with the anti-PD-1 therapy, toripalimab is also being initiated in Australia.

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 potential impact of combination trial of ADG126 and Anti-PD-1 antibody pembrolizumab, 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.

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