Adagene to Announce Updated Data from Phase 1b/2 Study of Muzastotug in Combination with KEYTRUDA® (pembrolizumab) in Colorectal Cancer at ASCO Gastrointestinal Cancers Symposium

January 21, 2025

SAN DIEGO and SUZHOU, China, Jan. 21, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. (“Adagene”) (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced it will share updated clinical data from ADG126 in microsatellite stable colorectal cancer (MSS CRC) at the ASCO Gastrointestinal (GI) Cancers Symposium in San Francisco, CA on Saturday, January 25, 2025.

This Phase 1b/2, open-label, multicenter dose escalation and expansion combination study of ADG126 in combination with Merck’s (known as MSD outside of the US and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab; 200 mg, Q3W) in MSS CRC previously demonstrated efficacy at the 10 mg/kg Q3W dose.

New data will include initial results from the 20 mg/kg loading dose followed by 10 mg/kg Q3W in combination with pembrolizumab.

ASCO-GI Poster Presentation Details

Title: Update of phase 1b/2 study of muzastotug (ADG126, an anti-CTLA-4 SAFEbody) in combination with pembrolizumab in advanced/metastatic MSS CRC

Date: Saturday, January 25

Time: 7:00 a.m. – 7:55 a.m. Pacific Time

Onsite Location: Moscone West, San Francisco

Abstract Number: 193

Poster Board: H5

Following the presentation, the poster will also be available on the Publications page of the Company’s website.

Virtual KOL Event to Discuss Anti-CTLA-4 SAFEbody® ADG126 in Advanced/Metastatic Microsatellite-Stable (MSS) Colorectal Cancer (CRC) on January 25, 2025

Company will host a virtual key opinion leader (KOL) event on Saturday, January 25, 2025 at 1:00 PM ET, featuring Aurélien Marabelle, MD, PhD (Université Paris-Saclay), Daneng Li, MD (City of Hope), and Marwan Fakih, MD (City of Hope), who will join company management to discuss the unmet need and current treatment landscape for patients with advanced/metastatic microsatellite-stable (MSS) colorectal cancer (CRC) and why CTLA-4 targeting is essential for achieving durable responses in this cold tumor type. To register, click here.

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 globally unmet patient needs. The company has forged strategic collaborations with reputable global partners that leverage its SAFEbody® precision masking technology in multiple approaches at the vanguard of science.

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. The company’s 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 tumor microenvironment, this allows for tumor-specific targeting of antibodies in tumor microenvironment, while minimizing on-target off-tumor toxicity in healthy tissues.

Adagene’s lead clinical program, ADG126 (muzastotug), is a masked, anti-CTLA-4 SAFEbody that targets a unique epitope of CTLA-4 in regulatory T cells (Tregs) in the tumor microenvironment. ADG126 is currently in phase 1b/2 clinical studies in combination with anti-PD-1 therapy, particularly focused on Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC). Validated by ongoing clinical research, the SAFEbody platform can be applied to a wide variety of antibody-based therapeutic modalities, including Fc empowered antibodies, antibody-drug conjugates, and bi/multispecific T-cell engagers.

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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding certain clinical results of ADG126, 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.

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Source: Adagene Inc.