Adagene Announces Completion of Enrollment in Randomized Dose Optimization Phase 2 Trial of Muzastotug in Combination with KEYTRUDA® (pembrolizumab) in Microsatellite Stable Colorectal Cancer

November 9, 2026

- Enrollment of 60 patients complete; initial results expected in 1H 2027 to inform dose regimen for the Phase 3 trial
- Adagene continues to own worldwide commercial rights to muzastotug

SAN DIEGO and SUZHOU, China, Nov. 09, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel antibody-based therapies, today announced completion of enrollment in its randomized Phase 2 dose-optimization trial of muzastotug (ADG126), a masked, anti-CTLA-4 SAFEbody®, in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with late-line microsatellite stable colorectal cancer (MSS CRC) without liver metastases.

"Completing enrollment in this randomized trial is an important step toward identifying the dose regimen of muzastotug for the Phase 3 registration trial," said Peter Luo, Ph.D., Chairman and President of R&D at Adagene. "We acknowledge Sanofi's additional equity investment associated with this trial, which supports continued development of muzastotug in solid tumors, including MSS CRC, where dose-limiting challenges have restricted the use of anti-CTLA-4 therapies. As we look ahead to initial results in the first half of 2027, we hope new data will validate muzastotug's broad applicability and combinability, further enhanced by its induction and maintenance dosing regimens. This could position muzastotug as a transformative next-generation backbone for combination therapies across multiple indications, in both early- and late-line treatment settings. It could also unlock value in indications where legacy CTLA-4/PD-1 based combinations are already FDA-approved, as well as in historically refractory tumors like MSS CRC."

About the Phase 2 Trial
The randomized Phase 2 trial (NCT05405595) was incorporated into the existing protocol for the Phase 1b/2 study following a 2025 meeting with the U.S. Food and Drug Administration (FDA). The primary endpoint of the Phase 2 trial is overall response rate (ORR), and secondary endpoints include duration of response (DOR), progression-free survival (PFS), and overall survival (OS).

The study enrolled 60 patients, randomized 1:1 into one of two treatment arms evaluating different dose regimens of muzastotug in combination with pembrolizumab. Both arms use induction to rapidly establish activated muzastotug exposure in tumors, followed by maintenance to sustain exposure and potentially improve ORR and OS:

- **Arm A:** Muzastotug 10 mg/kg every three weeks (Q3W) for four doses, followed by 10 mg/kg every six weeks (Q6W) maintenance
- **Arm B:** Muzastotug 20 mg/kg Q6W for two doses, followed by 15 mg/kg Q6W maintenance

As previously announced in July 2025, the following elements of the Phase 3 trial design were also confirmed following a meeting with the FDA:

- ***Patient Population:*** Trials will enroll late-line patients with MSS CRC without liver metastases, including those with peritoneal metastasis/involvement.
- ***Phase 3 Trial Design:*** The FDA agreed with Adagene's proposed standard-of-care (SOC) control arm for the Phase 3 clinical trial and confirmed that a muzastotug monotherapy arm was not required.
- ***Phase 3 Endpoints:*** The primary endpoint of the Phase 3 trial will be OS. Secondary endpoints will include PFS, DOR and ORR.

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, while minimizing on-target off-tumor toxicity in healthy tissues.

Adagene's lead clinical program, muzastotug (ADG126), is a masked, anti-CTLA-4 SAFEbody with FDA Fast Track designation that targets a unique epitope of CTLA-4 in regulatory T cells (Tregs) in the tumor microenvironment. Muzastotug is currently in Phase 1b/2 and Phase 2 clinical studies in combination with anti-PD-1 therapy, particularly focused on microsatellite stable (MSS) metastatic 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/multi-specific T-cell engagers.

For more information, please visit: https://investor.adagene.com/
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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, 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.

Investor Contacts:
Raymond Tam
Raymond_tam@adagene.com

Corey Davis
LifeSci Advisors
cdavis@lifesciadvisors.com

Media Contact:
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

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