



Adagene Announces Dosing of First Patient in Phase 1 Study of Muzastotug in Combination with Incyte's INCA33890 in Patients with Microsatellite Stable Colorectal Cancer

October 28, 2026

Phase 1 study to evaluate the combination of muzastotug, a masked anti-CTLA-4 SAFEbody, and INCA33890, Incyte's TGFβR2 × PD-1 bispecific antibody, in 3L MSS CRC patients with and without liver metastases

SAN DIEGO and SUZHOU, China, Oct. 28, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel antibody-based therapies, today announced the dosing of the first patient in a Phase 1 study evaluating the combination of muzastotug and INCA33890, Incyte's TGFβR2 × PD-1 bispecific antibody, in patients with microsatellite stable colorectal cancer (MSS CRC).

The Phase 1 study is an open-label dose escalation and expansion trial in third-line MSS CRC patients with and without liver metastases who have progressed on prior therapies. Per the terms of the study collaboration first announced in April 2026, Incyte is sponsoring and conducting the study and Adagene is providing clinical supply of muzastotug.

"Building on the clinical activity observed with muzastotug plus pembrolizumab, this study will evaluate whether adding muzastotug to Incyte's TGFβR2 × PD-1 bispecific can deepen and sustain antitumor responses in MSS colorectal cancer, including patients with liver metastases," said Peter Luo, Ph.D., Chairman and President of R&D at Adagene. "The combination brings together muzastotug's intended intratumoral Treg-depleting activity and INCA33890's inhibition of two pathways that suppress T-cell function. The study will assess whether these complementary mechanisms can broaden clinical benefit with an acceptable safety profile based on the optimized doses in combination with PD-1. The strength of muzastotug as a potential backbone therapy for multiple indications continues to be recognized through several collaborations with leading biopharmaceutical companies, reflecting its differentiated safety profile relative to legacy CTLA-4 therapies."

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>.

Follow Adagene on WeChat, LinkedIn and X.

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 Phase 1 study of muzastotug (ADG126) in combination with INCA33890, 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.

Investor Contacts:

Raymond Tam

Raymond_tam@adagene.com

Corey Davis

LifeSci Advisors

cdavis@lifesciadvors.com

Media Contact:

Michael Fitzhugh

LifeSci Communications

mfitzhugh@lifescicomms.com

ADAGENE