Adagene Provides Business Update and 2026 Objectives

January 23, 2026

Data update from the ongoing Phase 1b/2 study of muzastotug + pembrolizumab in 3L+ MSS CRC patients remains on track for Q1 2026

Unaudited cash and cash equivalents of $74.5 million as of December 31, 2025 anticipated to provide sufficient runway into late 2027

SAN DIEGO and SUZHOU, China, Jan. 23, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. (“Adagene”) (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced year-end unaudited cash and cash equivalents of $74.5 million and provided a business update.

2025 Key Accomplishments:

- **Phase 1b/2 trial results with muzastotug in MSS CRC at ASCO:** Shared updated data from 10 mg/kg and 20 mg/kg cohorts at ASCO 2025, demonstrating a favorable safety profile at 10-20x times higher dosing than first generation CTLA-4 inhibitors. Encouraging overall response rates and durable responses suggest potential for long-term survival benefit.
- **FDA Fast Track designation for muzastotug** in combination with Merck’s (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), for adult patients with microsatellite stable metastatic colorectal cancer (MSS CRC) without current or active liver metastases.
- **Regulatory alignment** with FDA End-of-Phase 1 meeting, clarifying dose selection, trial design, patient population and endpoints for Phase 2 and Phase 3 with muzastotug.
- **Initiated** randomized Phase 2 dose-optimization study with muzastotug; first patient dosed in October 2025.
- **Strategic Partnerships and Collaborations:**
  - **Sanofi:** Secured a strategic investment of up to $25 million to support muzastotug’s randomized Phase 2 study. Separately, Adagene will supply Sanofi with muzastotug to evaluate the safety, efficacy, pharmacokinetics and biomarker data in combination with other anticancer therapies in over 100 patients in a Phase 1/2 clinical trial in advanced solid tumors. Sanofi also exercised its option for a third SAFEbody® discovery program.
  - **Third Arc Bio:** Partnered to develop two masked CD3 T cell engagers, expanding SAFEbody® into next-generation T cell therapies.
  - **Exelixis:** Advanced a third masked ADC against a solid tumor target, building on the 2021 collaboration.
  - **ConjugateBio:** Collaborated on bispecific ADCs using Adagene-derived antibody, further demonstrating scalable platform potential.

As of December 31, 2025, the Company had unaudited cash and cash equivalents of $74.5 million, which is anticipated to provide sufficient runway until late 2027. Such amount of cash and cash equivalents is preliminary, unaudited and subject to finalization. This financial information should not be viewed as a substitute for the audited financial statements prepared in accordance with US GAAP and is not incorporated into any Adagene's filings with the U.S. Securities and Exchange Commission.

2026 Objectives:

- Q1 2026: Data update from the ongoing Phase 1b/2 study of muzastotug + pembrolizumab in 3L+ MSS CRC, including 41 patients in the 10 mg/kg cohorts and 26 patients in the 20 mg/kg cohorts.
- Complete enrollment of the ongoing randomized Phase 2 dose-optimization study with muzastotug, which is being conducted in alignment with FDA Project Optimus, and designed to allow dose regimen selection for Phase 3.
- Provide preliminary clinical data, including pathological responses, to inform future development from investigator-initiated Phase 2 trial for neoadjuvant muzastotug + pembrolizumab in colorectal cancer.
- Provide initial clinical data from a new cohort of patients in the ongoing Phase 1b/2 study of muzastotug + pembrolizumab in combination with standard of care (fruquintinib) in MSS CRC patients.
- Share results of the clinical trial collaboration with Roche, which evaluates muzastotug in triplet combination with atezolizumab and bevacizumab in first-line treatment of locally advanced or metastatic hepatocellular carcinoma (HCC; liver cancer).
- Establish additional collaboration/licensing agreements.

Peter Luo, Ph.D., CEO and President of R&D at Adagene said, “Our strategy for muzastotug is grounded in Nobel Prize-recognized advances in regulatory T cell biology, which have fundamentally reshaped our understanding of immune suppression in cancer. We have translated these foundational insights into a clinical action plan for intratumoral T reg modulation that integrates mechanistic innovation with emerging clinical evidence and regulatory momentum. In 2026, we hope new data will demonstrate muzastotug’s broad applicability, positioning it as a potentially transformative next-generation backbone therapy that can be used in combination across multiple indications.”

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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