



## Adagene Announces FDA Fast Track Designation for Muzastotug (ADG126)

December 16, 2025

*Designation underscores the potential of SAFEbody®-enabled anti-CTLA-4 therapy to address unmet need in MSS colorectal cancer*

SAN DIEGO and SUZHOU, China, Dec. 16, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced that the U.S. Food and Drug Administration (FDA) has designated muzastotug, in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), as a Fast Track product for adult patients with microsatellite stable metastatic colorectal cancer (MSS mCRC) without current or active liver metastases. Muzastotug is a next-generation masked anti-CTLA-4 SAFEbody® engineered to overcome CTLA-4-mediated Treg resistance in tumors with enhanced safety and efficacy, delivering a therapeutic index beyond the reach of existing CTLA-4 therapies.

The Fast Track Designation is supported by emerging clinical evidence demonstrating encouraging efficacy, deep and durable responses, and a favorable safety profile of muzastotug across a heavily pretreated patient population. Fast Track is designed to facilitate drug development and expedite the review of therapies intended to treat serious conditions with unmet medical need.

"Receiving Fast Track Designation marks an important milestone for Adagene and further validates the promise of our SAFEbody® technology to unlock CTLA-4 biology in a fundamentally safer and more effective way," said Peter Luo, Ph.D., Chief Executive Officer and President of R&D at Adagene. "We are deeply encouraged by the responses we are seeing with muzastotug in combination with pembrolizumab and believe this therapy has the potential to reshape the treatment paradigm by offering patients an opportunity for extended survival with an improved quality of life. We look forward to sharing updated topline Phase 1b/2 clinical data over the next few months as we continue advancing this program with urgency and purpose."

Muzastotug uses Adagene's proprietary masking technology to preferentially activate antibody binding within the tumor microenvironment, thereby reducing systemic toxicity while maintaining antitumor potency. Fast Track Designation enables more frequent FDA interactions and may allow for rolling review of future marketing applications as Adagene continues the ongoing randomized Phase 2 and prepares for the registration trial, planned to begin in 2027.

### Phase 2 Randomized Trial

Both the randomized Phase 2 and Phase 3 trial designs and endpoints were confirmed following a meeting with the US Food and Drug Administration (FDA):

- **Patient Population:** Future trials will enroll late-line patients with MSS CRC without liver metastases, including those with peritoneal metastasis/involvement.
- **Dose and Regimen:** Phase 2 dose optimization cohort will randomize patients to either 10 mg/kg or 20 mg/kg of muzastotug in combination with pembrolizumab, using an induction-maintenance regimen, without cycle limitations of muzastotug.
- **Phase 2 Trial Design:** Up to 30 patients will be enrolled in each arm of the Phase 2 study, without a requirement for a muzastotug monotherapy arm.
- **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 also not required.
- **Phase 2 Endpoints:** The primary endpoint of the Phase 2 trial will be overall response rate (ORR). Secondary endpoints include duration of response (DOR), progression-free survival (PFS), and overall survival (OS).
- **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, 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 and Phase 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>.

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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.

**Investor Contacts:**

Raymond Tam

[raymond\\_tam@adagene.com](mailto:raymond_tam@adagene.com)

Corey Davis

LifeSci Advisors

[cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)

**Media Contact:**

Lindsay Rocco

Elixir Health PR

862-596-1304

[lrocco@elixirhealthpr.com](mailto:lrocco@elixirhealthpr.com)

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