Adagene Presents Two Posters at AACR 2026 with New Data Highlighting Muzastotug's Potential as a Backbone Combination Therapy for Multiple Tumor Types

April 17, 2026

Triple combination of muzastotug + atezolizumab + bevacizumab resulted in much higher overall response rates (ORR) compared to the atezolizumab + bevacizumab control arm (66.7% vs. 32.5%, respectively by Investigator per HCC-specific Modified RECIST v1.1) as 1L therapy in a Phase 1b/2 trial in locally advanced or metastatic and/or unresectable hepatocellular carcinoma (HCC) patients

Triple combination of muzastotug + pembrolizumab + fruquintinib exhibited a dose-dependent response (25% and 40% ORR for 10 mg/kg and 15 mg/kg, respectively) in a Phase 1b/2 trial in late-line microsatellite stable colorectal cancer (MSS CRC) patients

New data are further evidence that muzastotug's masking technology uncouples efficacy from typical anti-CTLA-4 toxicity; it reduces peripheral toxicity and allows high-dose anti-CTLA-4 therapy specifically within the tumor microenvironment (TME) to potentially improve efficacy of current immunotherapies in advanced HCC and MSS CRC patients

SAN DIEGO and SUZHOU, China, April 17, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today presented new data from two ongoing Phase 1b/2 studies of muzastotug in triple combination regimens at the American Association of Cancer Research (AACR) annual meeting 2026, held April 17-22 in San Diego. Results support muzastotug's mechanistic advantages over traditional anti-CTLA-4 therapies, and its continued development as a potential backbone therapy in combination regimens for difficult-to-treat cancers. FDA has previously 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.

"At AACR, Adagene shared new data from two triplet regimens supporting muzastotug's potential as a combination backbone for multiple tumor types," said Peter Luo, Ph.D., CEO and President of R&D at Adagene. "In HCC, adding muzastotug to the atezolizumab plus bevacizumab combo resulted in higher efficacy, with a safety profile consistent with historical studies of the doublet alone. In MSS CRC, adding muzastotug to pembrolizumab plus fruquintinib showed dose-dependent response rates, with no DLTs or Grade 4 or 5 treatment related adverse events. As muzastotug continues to generate more data in additional settings, we are increasingly convinced that its intentionally designed wider therapeutic index has potential to improve the efficacy of current immunotherapies without worsening the toxicity for patients with difficult to treat solid tumors."

Final copies of the two posters from AACR can be found on the Pipeline Publications section of the company's website.

AACR Poster Presentations

Abstract CT054

The MORPHEUS-Liver study (NCT04524871) is a Phase 1b/2 open-label randomized umbrella study designed to evaluate immunotherapy-based combinations as first line therapy in patients with locally advanced or metastatic hepatocellular carcinoma (HCC). As of July 11, 2025, six patients had been randomized to the triple combination of muzastotug (6 mg/kg Q6W), atezolizumab and bevacizumab and 40 patients had received atezolizumab and bevacizumab in the active control arm. Interim results from patients in the muzastotug arm (18.8 months median duration of follow-up) demonstrated a 66.7% overall response rate (ORR; 4/6) using HCC-specified modified RECIST v1.1 criteria[1]. ORR was 50.0% (3/6) using RECIST v1.1 criteria. The median progression free survival (mPFS) was 8.2 months (same for both RECIST criteria) and the median overall survival (mOS) was not yet reached at the data cut but was greater than 22 months.

These results compared favorably to the 40 patients in the active control arm (17.2 months median duration of follow-up) that demonstrated an ORR of 32.5% (13/40) using HCC-specified modified RECIST v1.1 criteria, mPFS of 5.5 months, and mOS of 17.5 months. Using RECIST v1.1 criteria, the ORR was 17.5% (7/40) and the mPFS was 4.3 months. The mOS in the doublet control arm was largely overlapping with that reported in the IMbrave150 Phase 3 study[2,3] (19.2 months), which served as the basis for approval of atezolizumab (Tecentriq®) for HCC in 2020[4].

The triplet regimen of muzastotug, atezolizumab and bevacizumab was well-tolerated with safety data comparable to the doublet active control arm of atezolizumab and bevacizumab. Grade 3 or greater TRAEs were 50% (3/6) in the muzastotug arm and 45% (18/40) in the active control arm, which supports the potential for continuous dosing with muzastotug. Muzastotug was safely administered continuously at 6 mg/kg Q6W in a triplet setting, which is twice the dose of ipilimumab in the currently approved HCC doublet regimen, (capped at 3 mg/kg Q3W for only 4 cycles)[5]. In addition, encouraging durability was observed with responses maintained beyond 84 weeks in some patients. Ongoing muzastotug plus atezolizumab treatment after bevacizumab discontinuation suggests potential flexibility to modify individual agents during safety-related interruptions while preserving durable clinical benefit.

Abstract CT083

A Phase 1b/2 single arm study (NCT05405595) is evaluating the triple combination of muzastotug, pembrolizumab and fruquintinib in patients with advanced and metastatic microsatellite stable (MSS) colorectal cancer (CRC). As of February 21, 2026, nine patients have been treated with the triple combination — four (4) patients at a dose of 10 mg/kg every 6 weeks (Q6W) of muzastotug and five (5) patients at a dose of 15 mg/kg Q6W of muzastotug. All patients were without liver metastases (NLM). Interim results demonstrated a 25% ORR (1/4) among patients in the 10 mg/kg arm (6.7 months median follow-up), and a 40% ORR (2/5) among patients in the 15 mg/kg arm (5.9 months median follow-up).

The triplet regimen was well-tolerated with no new safety signals relative to known CTLA-4, PD-1, and fruquintinib monotherapy and combination safety data. There were no dose-limiting toxicities, 25 – 60% Grade 3 TRAEs, and no Grade 4 or Grade 5 TRAEs. Given that fruquintinib is known to be active in MSS CRC patients with liver metastases, the triple combination may have therapeutic benefit beyond the NLM population being evaluated

in this study.

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

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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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[1] *BMJ Open. 2022 Jun 1;12(6):e052294. Unlike RECIST v1.1 which measures the longest diameter of the entire lesion (including necrotic areas), HCC-specified modified RECIST v1.1 evaluates the longest diameter of the viable (arterially enhanced) portion of the target lesion. It was developed to address the limitations of conventional RECIST v1.1, which may underestimate treatment efficacy due to persistent necrotic tumor size, and may better correlate to overall survival in HCC.*

[2] *N Engl J Med 2020;382:1894-1905*

[3] *J Clin Oncol **39**, 267(2021) Volume 39, Number 3_suppl*

[4] *May 29, 2020; FDA press release*

[5] *April 11, 2025; FDA press release*

Source: Adagene Inc.