Adagene Announces Updated Data from Phase 1b/2 Study of Muzastotug (ADG126) in Combination with KEYTRUDA® (pembrolizumab) in Colorectal Cancer at the American Society of Clinical Oncology (ASCO) Annual Meeting

May 22, 2025

CTLA-4 inhibitor ADG126 can be dosed at 20 mg/kg Q6W in combination with pembrolizumab with <20% Grade 3 adverse events

In combination with pembrolizumab, ADG126 showed a 29% confirmed overall response rate (ORR) in microsatellite stable colorectal cancer

All six responders in the 20 mg/kg cohorts remain on treatment, with four patients on study for over forty weeks

Median overall survival (OS) for the 10 mg/kg cohorts was 19.4 months, with a median follow-up of 17.8 months and only 1 out of 41 patients was censored due to early withdrawal within the first 12 months

SAN DIEGO and SUZHOU, China, May 22, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. (“Adagene”) (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced updated data from its Phase 1b/2 study of ADG126 in advanced microsatellite stable colorectal cancer (MSS CRC) with no liver metastases at ASCO.

Dr. Marwan Fakih, Professor of Medical Oncology and Therapeutics Research at City of Hope added, “The 20 mg/kg Q6W dose has demonstrated a significant reduction in treatment-related toxicities - with fewer than 20% Grade 3 adverse events and no discontinuations - while maintaining a near 30% ORR, including in patients with peritoneal involvement. Notably, responders in the 20 mg/kg cohorts remain on treatment, supported by tumor assessments, CEA levels, and ctDNA biomarkers.” Dr. Fakih continued, “It is exciting to see the higher ORR and durable responses. There is also early separation shown on the Kaplan-Meier overall survival curves when compared to historical controls. These data are consistent with the more mature overall survival seen in the 10 mg/kg cohorts.”

"CTLA-4 has been studied for over a decade, with toxicity remaining the primary limiting factor in maximizing efficacy," said Peter Luo, Ph.D., CEO and President of R&D at Adagene. "We are pleased with our predictive PK/PD framework, which integrates molecular design features and mechanism of action with clinical and preclinical tumor/plasma PK data for cross-reactive ADG126 in combination with anti-PD-1 therapy. This framework guides dosing regimens for MSS CRC patients without liver metastases, optimizing ADG126’s therapeutic index to maximize efficacy while minimizing cumulative treatment-related toxicities for long-term clinical benefit. Our masking technology further reduces toxicity, allowing patients to remain on treatment longer for sustained benefit."

As of April 22, 2025, a total of 67 MSS CRC patients with no liver metastases including those with peritoneal involvement were treated with ADG126 at a dose of either 10 mg/kg or 20 mg/kg, in combination with KEYTRUDA® (pembrolizumab: 200 mg, Q3W), Merck & Co., Inc., Rahway, NJ, USA’s anti-PD-1 therapy. The 10 mg/kg dose was administered once every three weeks or once every six weeks. The 20 mg/kg dose was administered once as a loading dose, followed by 10 mg/kg every three weeks, or 20 mg/kg every six weeks.

In the dose expansion phase of the study, patients in the 10 mg/kg Q3W cohort demonstrated an ORR of 17% and patients in the 20 mg/kg cohorts demonstrated a confirmed ORR of 29%. Median duration of response (DoR) in the 10 mg/kg cohorts was 6.2 months, while the median DoR was not yet reached in the 20 mg/kg cohorts and all the responses are ongoing. Median overall survival (OS) for the 10 mg/kg cohorts was 19.4 months, comparing favorably with current standard of care treatments and historical benchmarks. Median OS for the 20 mg/kg cohorts has not yet been reached.

Both 20 mg/kg cohorts achieved equivalent ORRs at 29%, while adverse events were less severe and seen less frequently with Q6W dosing compared to a 20mg/kg loading dose followed by 10mg/kg Q3W.

As data continue to mature in the 20 mg/kg cohorts, the Company plans to discuss dosing regimen with regulatory bodies and obtain their endorsement for the next phase of clinical development.

ASCO Poster Details

- **Abstract Title:** Safety and Efficacy of ADG126 (an Anti-CTLA-4 Masking Antibody) in Combination with Pembrolizumab: Updated Results of Phase 1b/2 Study in Advanced MSS CRC
- **Date:** Saturday, May 31, 2025
- **Poster Viewing:** 9:00 AM-12:00 PM CDT
- **Onsite Location:** McCormick Place, Chicago, IL, Board #248
- **Abstract Number:** 3579

Poster will be made available on the Publications page of the company’s website here.

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 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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