



Adagene Announces Investigator Initiated Phase 2 Trial for Neoadjuvant Muzastotug (ADG126) in Colorectal Cancer

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- Trial to begin enrolling in April; expected primary completion in mid-2027 -

- Primary study endpoint of rate of major pathological response -

SAN DIEGO and SUZHOU, China, Feb. 27, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced an investigator initiated (IIT) Phase 2 neoadjuvant trial of ADG126 for patients with stage II or stage III colorectal cancer.

The new study (NCT06846268), led by primary investigator Dr. Yong Wei Peng, Senior Consultant at the Department of Haematology-Oncology, National University Cancer Institute, Singapore, is expected to begin patient enrollment in April 2025. Patients will receive high doses of ADG126 in combination with KEYTRUDA® prior to surgery. The trial's primary endpoint is the rate of Major Pathologic Response (MPR), defined as ≤10% residual viable tumor in the surgical specimen, and will be evaluated in up to 20 patients. Secondary endpoints include complete pathological response, disease-free survival, and safety/tolerability. Additionally, the study will explore the pharmacodynamic effects of neoadjuvant ADG126 and pembrolizumab on the tumor microenvironment's immune profile, as well as the pharmacokinetic profile of ADG126 in tumor tissues, to further elucidate the compound's unique mechanism of action and enhanced therapeutic index.

"The foundation for this neoadjuvant study is supported by the compelling combination efficacy and safety profile of ADG126 with pembrolizumab in late-stage MSS CRC patients," said Peter Luo, Chairman, CEO, and President of R&D at Adagene. "We believe that advancing immunotherapy into the curative neoadjuvant setting holds significant promise. By combining CTLA-4-mediated T regulatory cell depletion with anti-PD-1's ability to reinvigorate exhausted T cells, this approach restores anti-tumor immunity, offering patients a head start and the potential for long-term clinical benefits."

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 in tumor microenvironment, 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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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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