Adagene Announces NMPA Clearance of Investigational New Drug Application for ADG138, a Novel HER2xCD3 Double-Masked Bispecific T-Cell Engager

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Phase 1 study with ADG138 for patients with advanced solid tumors is expected to begin in China in the fourth quarter of 2026

ADG138 is a double-masked T-cell engager, applying Adagene's proprietary SAFEbody® precision masking technology on both HER2 and CD3 binding sites to enable tumor-selective therapy with low systemic toxicity

Preclinical data demonstrated robust tumor regression in tumor models refractory and/or resistant to Enhertu, along with strong synergy in combination with anti-CTLA-4, anti-PD-1 or anti-CD137 antibodies

SAN DIEGO and SUZHOU, China, Sept. 22, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel antibody-based therapies, today announced that China's National Medical Products Administration (NMPA) has approved the company's investigational new drug (IND) application for ADG138, a double-masked HER2×CD3 bispecific T cell engager built on Adagene's proprietary SAFEbody® precision masking technology. Adagene expects to initiate a first-in-human Phase 1 study of ADG138 for the treatment of advanced solid tumors in the fourth quarter of 2026.

"The NMPA's rapid approval of our IND application for ADG138 speaks to the strength of the preclinical package and allows us to bring a differentiated, double-masked T-cell engager into the clinic for patients with HER2-expressing solid tumors," said Peter Luo, Ph.D., Chairman and President of R&D at Adagene. "In preclinical studies, ADG138 achieved potent, T-cell mediated anti-tumor activity in Enhertu (DS-8201) resistant tumor models while retaining a substantial reduction in cytokine release and a wider therapeutic window relative to an unmasked T-cell engager. We look forward to advancing ADG138 into first-in-human studies and building on the safety and efficacy profile we believe our SAFEbody platform can bring to T-cell engagers in solid tumors."

A Phase 1, first-in-human, open-label clinical study is designed to evaluate the safety and preliminary efficacy of ADG138 in patients with advanced solid tumors as well as to determine the recommended dose for Phase 2.

About ADG138

ADG138 is a double-masked HER2×CD3 bispecific T cell engager designed using Adagene's SAFEbody® precision masking technology, which covalently links masking peptides to both the HER2- and CD3-binding arms of the molecule. In its inactivated state, ADG138 is designed to minimally bind HER2-expressing cancer cells and T cells; the molecule becomes activated within the tumor microenvironment and engages T cells to selectively kill HER2-expressing tumor cells while limiting off-target toxicity.

Preclinical data presented at the American Association for Cancer Research (AACR) Annual Meeting in 2022 showed that double-masked ADG138 achieved approximately 220-fold and greater than 1,000-fold reductions in binding to HER2 and CD3, respectively, yet translating to high efficiency in T cell-mediated tumor cell killing and T cell activation. ADG138 drove regression in both HER2-high and HER2-low tumor models, including a model refractory and/or resistant to the Enhertu (DS-8201), and showed synergistic anti-tumor activity in combination with anti-CTLA-4, anti-PD-1, or anti-CD137 antibodies. In addition, ADG138 was tolerated at doses over 300-fold higher than an unmasked T-cell engager, with markedly reduced cytokine release and a favorable pharmacokinetic profile, including a longer apparent half-life and higher systemic exposure than the parental molecule.

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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Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding certain clinical results of ADG138, 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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