Adagene Announces First Patient Dosed in Phase 1 Study of ADG138, a Novel HER2xCD3 Double-Masked Bispecific T-Cell Engager

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First-in-human study will enroll patients with HER2-positive advanced solid tumors

ADG138 design includes proprietary IgG1-based heterodimeric format and SAFEbody® double masking to support prolonged circulation and tumor-selective accumulation and activation

SAN DIEGO, Nov. 19, 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 the first patient has been dosed in a first-in-human Phase 1 study of ADG138, a double-masked HER2×CD3 bispecific T-cell engager built on an IgG1-based format and Adagene’s proprietary SAFEbody® precision masking technology.

“Dosing the first patient with ADG138 is an important step in moving our double-masked T-cell engager from preclinical research into the clinic,” said Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene. “Our preclinical data showed that masking both the HER2 and CD3 binding sites preserved ADG138’s antitumor activity, including in Enhertu (DS-8201)-resistant models, while reducing cytokine release and widening the therapeutic window compared with an unmasked T-cell engager.

“Clinical experience with muzastotug, our masked anti-CTLA-4 SAFEbody in IgG1 format, now includes more than 250 patients dosed with high, repeated dosing, and continuous treatment beyond two years in some patients. Together with ADG138’s robust preclinical findings, this reinforces our confidence in extending SAFEbody technology to T-cell engagers. We look forward to evaluating ADG138’s safety and preliminary efficacy in heavily pretreated patients who have progressed after multiple lines of therapies, including standard-of-care and investigational HER2-directed antibody-drug conjugates.”

The open-label Phase 1 study is designed to evaluate the safety and preliminary efficacy of ADG138 in patients with HER2-positive advanced solid tumors and determine the recommended Phase 2 dose. Dose escalation will begin with a starting dose of 2 mg of ADG138, and subsequent doses will be guided by emerging clinical data.

About ADG138

ADG138 is a double-masked HER2×CD3 bispecific T cell engager designed using Adagene’s proprietary IgG-based heterodimeric format and 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.

In preclinical models, the double-masked ADG138 has achieved approximately 220-fold and greater than 1,000-fold reductions in binding to HER2 and CD3, respectively, compared to its unmasked form. Upon activation in the tumor microenvironment, ADG138 enables highly efficient T cell-mediated tumor cell killing, driving tumor regression in both HER2-high and HER2-low tumor models, including a model refractory and/or resistant to the Enhertu (DS-8201). ADG138 has also shown 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 ADG138's potential therapeutic benefits, the intended effects of its dual-masking design, the objectives of its Phase 1 study and starting-dose strategy, and Adagene's 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, 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.

Investor Contacts

Raymond Tam
Raymond_tam@adagene.com

Corey Davis
LifeSci Advisors
cdavis@lifesciadvisors.com

Media Contact

Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

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