Adagene and City of Hope Open Clinical Trial to Test New Therapy for Patients with Hard-to-Treat Colorectal Cancer

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Study designed by medical oncologist to accelerate lifesaving care to patients

SAN DIEGO and LOS ANGELES, Nov. 17, 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, and City of Hope, one of the largest and most advanced cancer research and treatment organizations in the United States, today announced the launch of an innovative Phase 1 clinical trial to explore a new combination therapy for patients battling metastatic colorectal cancer, particularly for those whose disease has resisted standard treatments.

“Colorectal cancer is the second deadliest cancer in the U.S., and current treatments don’t work for everyone. We urgently need to find new options, especially for the advanced stages of this challenging disease,” said principal investigator Marwan G. Fakih, M.D., a City of Hope professor in the Department of Medical Oncology & Therapeutics Research and deputy director of City of Hope Comprehensive Cancer Center.

This year alone, an estimated 159,000 Americans will be diagnosed with colorectal cancer, and the disease will claim about 55,230 lives, according to the American Cancer Society.

City of Hope's trial will enroll up to 36 patients to evaluate two experimental drugs, ivonescimab and muzastotug (ADG126)*, in the treatment of advanced microsatellite stable colorectal cancer. Ivonescimab activates the immune system's T cells to attack cancer cells as it cuts off the blood supply to tumors, while ADG126 enhances the immune system’s ability to recognize and destroy cancer. The two drugs are expected to result in synergistic antitumor activity.

“Based on insights gleaned from past studies, we expect this powerful drug combination will result in more potent activation of the immune system within tumors, leading to potential tumor regression or death,” Dr. Fakih said. “Our mission is to speed lifesaving care to patients by crafting a more effective therapy that enhances quality of life and boosts survival rates.”

Physician-led innovation to reshape patient care

Investigator-initiated trials like this one are clinical studies designed by doctors or scientists rather than an industry sponsor. Fueled by researchers’ scientific curiosity, medical insight and dedication to patient-centered care, these trials provide independent, real-world data that can ignite therapeutic advances and shift clinical guidelines.

Dr. Fakih and his colleagues will initially evaluate the combination of ivonescimab and ADG126 in patients who progressed on prior systemic therapy and will determine the most optimal dosing combination based on safety and efficacy. Once the optimal dose is identified, they plan to move this combination earlier on in the treatment of metastatic colorectal cancer. Specifically, they will explore combining this immunotherapy combination with 5-FU, the backbone of chemotherapy treatments in colorectal cancer. Subsequently, they will add an additional chemotherapy drug, irinotecan, which is commonly used in the first-line and second-line treatment of metastatic colorectal cancer.

“We hope that the combination of immunotherapy with ivonescimab and ADG126 will work hand in hand with chemotherapy to improve further tumor shrinkage in advanced colorectal cancer,” Dr. Fakih said. “The combination of ivonescimab, ADG126 and 5-FU has the potential to serve as a more effective maintenance therapy in metastatic colorectal cancer, deepening and maintaining responses to therapy. The combination of ivonescimab, ADG126, 5-FU and irinotecan has the potential to serve as a first-line treatment in metastatic colorectal cancer and improve further on the chances of remission, regression and duration of disease control.”

Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene, added, “This is the third clinical program to combine muzastotug or ADG126 with a next generation PD-1 bispecific with the goal of driving additional survival benefit for patients. This trial further validates and broadens the potential use of ADG126 as a foundational combination backbone to potentially drive more clinically meaningful survival benefits for patients”.

“ADG126 is designed to activate preferentially in the tumor microenvironment, enabling CTLA-4 blockade while limiting on-target, off-tumor activity in healthy tissues. By combining this approach with complementary immune, angiogenic and cytotoxic mechanisms, the study will assess the safety and preliminary antitumor activity of these regimens. We value City of Hope’s leadership and clinical expertise in colorectal cancer.”

Fighting a high risk of recurrence

Some 85% of colorectal cancer cases are classified as microsatellite stable (MSS), which has a higher risk of returning after treatment. Despite numerous clinical studies, no new therapies have outperformed existing treatments in halting growth.

Recent findings, however, have suggested promising new directions, including:

- Integrating ivonescimab and chemotherapy significantly improved results in a small trial of 22 people, with 82% of the patients responding positively.
- Blending two treatments — one targeting a protein called PD-1 and another targeting blood vessel growth (VEGFR) — helped patients whose colorectal cancer had not spread to the liver.

- Ivonescimab targets both PD-1 and VEGF, potentially enhancing effectiveness while reducing side effects. When paired with drugs that block PD-1, ADG126 boosted the immune system's ability to combat cancer.

Building off these discoveries, Dr. Fakih and his team developed the current trial to investigate how combining ivonescimab and ADG126 affects patients with advanced colorectal cancer.

In integrating the approach with traditional chemotherapy, his work aims to pinpoint the safest dosage for new drug combinations and determine how long they combat cancer growth.

"The clock is ticking; we can't afford to lose more patients to this devastating disease," Dr. Fakih said. "Our study is a crucial step forward in finding better approaches for fighting advanced colorectal cancer."

** Dr. Fakih is a paid consultant to Adagene, the owner of ADG126.*

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 that targets a unique epitope of CTLA-4 on regulatory T cells (Tregs) in the tumor microenvironment. Muzastotug is currently being evaluated in Phase 1b/2 and Phase 2 clinical studies in combination with anti-PD-1 therapy, particularly in microsatellite stable (MSS) metastatic colorectal cancer (CRC). The FDA has granted Fast Track designation to muzastotug in combination with pembrolizumab for adult patients with MSS metastatic CRC without current or active liver metastases. 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 bispecific and multispecific T-cell engagers.

For more information, please visit: https://investor.adagene.com.
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About City of Hope
City of Hope's mission is to make hope a reality for all touched by cancer and diabetes. Founded in 1913, City of Hope has grown into one of the largest and most advanced cancer research and treatment organizations in the United States, and one of the leading research centers for diabetes and other life-threatening illnesses. City of Hope research has been the basis for numerous breakthrough cancer medicines, as well as human synthetic insulin and monoclonal antibodies. With an independent, National Cancer Institute-designated comprehensive cancer center that is ranked among the nation's top cancer centers by U.S. News & World Report at its core, City of Hope's uniquely integrated model spans cancer care, research and development, academics and training, and a broad philanthropy program that powers its work. City of Hope's growing national system includes its Los Angeles campus, Orange County, California, campus, a network of clinical care locations across Southern California and cancer treatment centers and outpatient facilities in the Atlanta, Chicago and Phoenix areas. City of Hope's affiliated group of organizations includes Translational Genomics Research Institute and AccessHope™. For more information about City of Hope, follow us on Facebook, X, YouTube, Instagram and LinkedIn.

Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding the initiation, timing, conduct and completion of the investigator-initiated Phase 1 study of muzastotug in combination with ivonescimab, with or without chemotherapy; the potential safety, tolerability, pharmacokinetic profile and antitumor activity of the investigational regimens; the identification of recommended Phase 2 doses; and Adagene's advancement of, and anticipated 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 relevant regulatory authorities regarding 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 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 those risks more fully discussed in the "Risk Factors" section of 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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