Adagene Announces Clinical Collaboration with Incyte to Evaluate Muzastotug (ADG126) in Combination with Incyte's TGFßR2xPD-1 Bispecific Antibody (INCA33890) in Patients with Microsatellite Stable Colorectal Cancer (MSS CRC)

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Phase 1 study of INCA33890 and muzastotug expected to begin in 2026 in 3L MSS CRC patients with and without liver metastases

Study will be sponsored and conducted by Incyte; Adagene to provide clinical supply of muzastotug

Collaboration provides additional validation of muzastotug as a potential backbone therapy for next-generation immuno-oncology combinations

SAN DIEGO and SUZHOU, China, April 02, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced a clinical collaboration with Incyte (Nasdaq:INCY), to evaluate the combination of muzastotug (ADG126) and INCA33890, a TGFβR2 × PD-1 bispecific antibody, in patients with microsatellite stable colorectal cancer (MSS CRC) with or without liver metastases.

Muzastotug in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) has demonstrated encouraging overall response rates and durable responses in a Phase 1b/2 trial in 3L MSS CRC patients. As a monotherapy, INCA33890 has demonstrated promising clinical efficacy and safety in immune checkpoint sensitive and insensitive cancers, including MSS CRC with and without liver metastases. Incyte has recently initiated a Phase 3 study (NCT07284849) evaluating bevacizumab and FOLFOX (standard of care chemotherapy) with or without INCA33890 in 700 first-line MSS CRC patients.

"This strategic collaboration marks the second instance in which Adagene's SAFEbody® technology is being paired with a leading PD-1–based bispecific, further reinforcing muzastotug's potential as a backbone immunotherapy with a wider therapeutic index for next-generation immuno-oncology combinations," said Peter Luo, Ph.D., CEO and President of R&D at Adagene. "We look forward to the clinical insights this study may provide to support our belief that muzastotug has the potential to both improve overall response rate and extend survival, meaningfully enhancing the clinical benefit for patients."

"This collaboration allows us to explore a novel combination approach for patients with microsatellite stable colorectal cancer, a disease that remains resistant to current immunotherapies," said Pablo J. Cagnoni, M.D., President, Head of Research & Development at Incyte. "By evaluating INCA33890 in combination with muzastotug, we aim to better understand whether complementary mechanisms may help enhance anti-tumor immune responses particularly for patients with liver metastases, who have an especially poor prognosis and limited treatment options."

Muzastotug, a masked anti-CTLA-4 SAFEbody® with FDA Fast Track designation, is currently being evaluated in multiple ongoing studies, including:

- A Phase 1b/2 clinical trial in combination with pembrolizumab in MSS CRC patients without liver metastases.
- A randomized Phase 2 study in MSS CRC patients without liver metastases designed to determine the optimal dose to advance into a Phase 3 registration trial.
- A Phase 1b/2 dose escalation and expansion study of muzastotug in combination with Sanofi's SAR445877 (PD-1 x IL-15 fusion protein) in adults with advanced solid tumors.

Under terms of the agreement, Incyte will sponsor and conduct the study and Adagene will provide clinical trial supply of muzastotug. The planned dose escalation portion of the study will evaluate safety and tolerability, followed by an efficacy expansion cohort in patients with chemotherapy-refractory MSS CRC patients with and without liver metastases. MSS CRC is well-known to be largely non-responsive to anti-PD-1 / PD-L1 therapy. INCA33890 monotherapy has demonstrated promising initial clinical efficacy and safety in immune checkpoint sensitive/insensitive tumors, including MSS CRC with and without liver metastases.

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 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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SAFEbody® is a registered trademark in the United States, China, Australia, Japan, Singapore, and the European Union.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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