# Adagene Announces Progress and Expansion of Clinical Collaboration Program for Masked, Anti-CTLA-4 SAFEbody® ADG126 (muzastotug) in Combination with KEYTRUDA® (pembrolizumab) to Demonstrate Further Efficacy in Patients with Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC)

February 9, 2024

*- Interim data from additional MSS CRC patients dosed at 10 mg/kg every three weeks (Q3W) in combination with pembrolizumab anticipated in 2024 at a medical conference -*

*- Initiated evaluation of 20 mg/kg loading doses of ADG126 in combination with pembrolizumab to explore enhanced efficacy given superior therapeutic index of ADG126 -*

*- Received clearance from China's Center for Drug Evaluation (CDE) to evaluate ADG126 in combination with pembrolizumab -*

SAN DIEGO and SUZHOU, China, Feb. 09, 2024 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced progress and expansion of the clinical collaboration development program for its masked, anti-CTLA-4 SAFEbody, ADG126 in combination with Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab), in patients with metastatic microsatellite-stable (MSS) colorectal cancer (CRC).

"Following completion of enrollment of 12 additional patients at the end of last year, together with our ongoing expansion plans, we are on track to deliver data in 2024 that support the findings released at the recent ASCO-GI Symposium demonstrating the safety and efficacy profile of ADG126 in combination with pembrolizumab in MSS CRC," said Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene.

He continued, "To address the requirements for Project Optimus by FDA, we have initiated evaluation of ADG126 20 mg/kg loading doses in combination with pembrolizumab, which we believe can unlock even greater efficacy for MSS CRC in planned cohort expansion, while still maintaining a robust safety profile. Additionally, we are now cleared to evaluate ADG126 in combination with pembrolizumab in China, strengthening our efficacy evaluation with additional patients enrolled at unprecedented dosing regimens for anti-CTLA-4 therapy."

The updates, which increase the ongoing phase 2 dose expansion in MSS CRC to over 50 patients, include the following:

- The company announced it completed enrollment of 12 additional patients in the fourth quarter of 2023 in the ongoing phase 2 dose expansion cohort evaluating ADG126 10 mg/kg Q3W in combination with pembrolizumab in MSS CRC. These Part 2 results are expected to support data from Part 1 of the dose expansion in MSS CRC that was recently presented at the 2024 ASCO-GI Symposium.

- Given the safety profile of ADG126, Adagene has also initiated evaluation of 20 mg/kg loading doses in combination with pembrolizumab in patients with advanced/metastatic cancer. Following the ongoing safety evaluation, the company plans to study efficacy of the loading doses followed by a maintenance regimen of ADG126 10 mg/kg Q3W in combination with pembrolizumab. The company plans dose expansion with this regimen in patients with MSS CRC in the US and Asia Pacific.

- Adagene has also received clearance from the CDE in China to initiate clinical evaluation of ADG126 in combination with pembrolizumab. This enables the company to broaden its dose expansion cohorts for MSS CRC at selected dosing regimens, and potentially in other tumor types.

**2024 Milestones**

Data from the ongoing phase 1b/2 clinical trial of ADG126 in combination with pembrolizumab, including dose expansion cohorts, are anticipated throughout 2024:

- Follow up of Part 1 evaluable patients at 10 mg/kg Q3W (n=12) and 10 mg/kg Q6W (n=10)
- Data from Part 2 patients at 10 mg/kg Q3W (n=12)
- Evaluation of 20 mg/kg loading doses for Project Optimus requirements:
    - Safety data with repeat doses
    - Dose expansion in MSS CRC (n~10)
- Additional patients in China (n≥10)

**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 unmet patient needs. 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. Adagene has forged strategic

collaborations with reputable global partners that leverage its technology in multiple approaches at the vanguard of science.

For more information, please visit: https://investor.adagene.com. Follow Adagene on WeChat, LinkedIn and Twitter.

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.

**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.

Investor & Media Contact:
Ami Knoefler
Adagene
650-739-9952
ir@adagene.com

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