Adagene Presents Interim Results Reinforcing Best-in-Class Profile of Masked anti-CTLA-4 SAFEbody® ADG126 (muzastotug) in Combination with Pembrolizumab in Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC)

January 16, 2024

- Data from first tranche of MSS CRC patients treated with ADG126 10 mg/kg every three weeks (Q3W) in dose expansion showed clinical benefit including confirmed responses at higher, more frequent and repeat doses of the anti-CTLA-4 therapy -

- Preliminary survival analysis of ADG126 10 mg/kg dosing regimens in patients without liver and peritoneal metastases indicates best-in-class median progression-free survival (PFS) of seven months -

- Data from additional patients at 10 mg/kg Q3W dosing regimen expected throughout 2024 -

SAN DIEGO and SUZHOU, China, Jan. 16, 2024 (GLOBE NEWSWIRE) -- Adagene Inc. (“Adagene”) (Nasdaq: ADAG), a company transforming the discovery and development of novel antibody-based therapies, today announced data from its presentation at the American Society of Clinical Oncology (ASCO) 2024 Gastrointestinal (GI) Cancers Symposium, taking place January 18-20 in San Francisco.

“The expanded therapeutic index for the masked ADG126 allows us to dose with a higher and more frequent effective dose of anti-CTLA-4 therapy than today’s options,” said Daneng Li, MD and Associate Professor Department of Medical Oncology & Therapeutics Research at the City of Hope Comprehensive Cancer Center. “These promising data support further evaluation of this potential best-in-class anti-CTLA-4 antibody, ADG126, in combination with pembrolizumab for MSS CRC patients, including battling new liver lesions in those patients initially without detectable liver metastasis. We also see a tremendous opportunity to help patients in other tumor types where there is a significant need for safe and potent anti-CTLA-4 therapy.”

Key highlights from the poster (November 30, 2023 data cutoff) include:

- Results from dose escalation and dose expansion cohorts of ADG126 in combination with Merck & Co., Inc., Rahway, NJ, USA’s anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) (200 mg/Q3W) demonstrated a best-in-class safety profile for ADG126 at doses from 6 mg/kg to 10 mg/kg in heavily pre-treated advanced/metastatic patients (N=46):
  - Limited dose-dependent toxicities were observed.
  - Grade 3 TRAEs occurred in 5/46 patients (10.8%), with no Grade 4 or 5 TRAEs and a discontinuation rate of 6.5% (3/46).
- In dose escalation across tumor types, two partial confirmed responses (PRs) were observed among the three patients treated with ADG126 10 mg/kg Q3W, which triggered expansion cohorts at this dosing regimen. One of the patients had PD-1 refractory cervical cancer and the other had endometrial cancer. Both confirmed PRs are sustained after more than 55 weeks (over 14 cycles) of treatment.
- In dose expansion of patients with MSS CRC, 12 evaluable patients without liver metastases were treated at the active, potent dose of 10 mg/kg Q3W:
  - Two confirmed PRs were observed in nine of these patients without peritoneal and liver metastases, resulting in an overall response rate of 22% in this subset.
  - An additional seven of these nine patients experienced stable disease (SD) for an overall disease control rate 100% (2 PRs and 7 SD).
  - Observation of these clinical activities triggered further expansion into Stage 2 of the Simon’s 2-stage design for this dose level, which is currently ongoing with data anticipated throughout 2024.
- In a preliminary PFS analysis of those MSS CRC patients free of liver and peritoneal metastasis, a median PFS of seven months was observed in those treated with ADG126 10 mg/kg at two dosing frequencies pooled together [every three weeks (n=9) and every six weeks (n=6)]. The durable clinical activity of ADG126 in combination with pembrolizumab will continue to be evaluated as a larger cohort of subjects becomes evaluable at the 10 mg/kg Q3W dose level.

Commenting on the results, Heinz Josef-Lenz, MD, FACP, Associate Director for Clinical Research and Co-leader of the Translational Science Program at the USC Norris Comprehensive Cancer Center (NCCC) said, “I believe that CTLA-4 is an essential part of an effective immunotherapy for MSS CRC, yet physicians have been limited by the safety challenges from first generation options. The clinical profile of ADG126 in combination with pembrolizumab presents a great opportunity for MSS CRC patients that otherwise have limited immunotherapy options available.”

ASCO-GI Poster Presentation Details

Title: *Results of a phase 1b/2 study of ADG126 (a masked anti-CTLA-4 SAFEbody) in combo with pembrolizumab (Pembro) in patients (Pts) with metastatic microsatellite-stable (MSS) colorectal cancer (CRC)*

- Date: Saturday, January 20
- Time: 6:30 a.m. – 7:55 a.m. Pacific Time
- Onsite Location: Moscone West

- Abstract Number: 127
- Poster Board: H12

Consistent with the ASCO-GI embargo policy, the data are being released today in conjunction with the abstract publication.

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

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.

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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