Adagene Announces the Third Clinical Trial Collaboration with Merck to Advance Anti-CD137 Agonist, ADG106, in Combination Therapy with KEYTRUDA® (pembrolizumab)

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Collaboration to evaluate NEObody™ product candidate, ADG106, in combination with KEYTRUDA® for patients with advanced or metastatic solid and/or hematological malignancies

SAN FRANCISCO, Aug. 19, 2021 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biopharmaceutical company committed to transforming the discovery and development of novel antibody-based immunotherapies, today announced that it has entered into a third clinical trial collaboration and supply agreement with Merck (known as "MSD" outside the United States and Canada). The agreement includes an open-label, dose escalation and expansion clinical study of ADG106 in combination with Merck's anti-PD-1 KEYTRUDA® (pembrolizumab) in advanced or metastatic solid and/or hematological malignancies (ADG106-P2001/KEYNOTE-D12). This clinical study builds on the promising monotherapy and combination therapy data from a Phase I trial of ADG106. Engineered using Adagene's proprietary NEObody™ platform technology, ADG106 is a fully human, ligand-blocking, agonistic anti-CD137 immunoglobulin G4 (IgG4) monoclonal antibody (mAb).

"We are excited to continue our partnership with Merck in a third clinical collaboration that now combines our anti-CD137 agonist, ADG106, with KEYTRUDA," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "While PD-1 drugs have advanced the cancer treatment paradigm, there are still a substantial number of patients with advanced metastatic solid and hematological malignancies who either relapse or are unresponsive, highlighting the need for new approaches. ADG106 targets a unique and highly conserved epitope with a novel mechanism of action and broad species cross reactivity, which enables testing in immunocompetent hosts. In multiple syngeneic models, we have shown a strong additive effect between ADG106 and anti-PD-1/PD-L1 agents."

"We look forward to working closely with Merck and combining ADG106 with KEYTRUDA," said Steven Fischkoff, M.D., interim Chief Medical Officer of Adagene. "Together with our novel mechanism of action, extensive preclinical and strong clinical data generated to date, we believe ADG106 is an ideal candidate to combine with an anti-PD1 antibody to potentially create a new therapeutic option for cancer patients with unmet medical needs."

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

About ADG106
ADG106, is a fully human ligand-blocking, agonistic anti-CD137 IgG4 mAb being developed for the treatment of advanced solid tumors and non-Hodgkin's lymphoma. CD137 stimulates the immune system to attack cancer cells and is a key driver for long-lasting T cell proliferation and survival. In preclinical studies, we observed that ADG106 had robust antitumor activity and was well tolerated as a single agent and in combination with the existing standard-of-care and other immuno-oncology therapies. ADG106 activates CD137 in a native ligand-like fashion, blocks reverse CD137 ligand signaling, and induces potent cross-linking by Fc receptors. Because of this novel mechanism of action, ADG106 was observed to favorably balance CD137 agonism over CD137-induced liver toxicity, which we believe has potential to address the limitations of other existing anti-CD137 therapies.

ADG106 Phase I trials have been successfully completed with enrollment of nearly 100 patients with advanced solid tumors and non-Hodgkin's lymphoma in the United States and China. Based on the promising Phase I data, ADG106 is being evaluated in a Phase Ib/II combination study in advanced solid tumors and relapsed/refractory non-Hodgkin lymphoma.

About Adagene
Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biopharmaceutical 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 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.

Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding the therapeutic potential of ADG106 in combination with pembrolizumab to treat patients with advanced/metastatic solid and/or hematological malignancies, data from the ADG106 clinical trials, clinical development plans of ADG106, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of ADG106. 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 the potential failure of the combination of ADG106 and pembrolizumab to demonstrate safety and/or efficacy in the Phase 1 open-label, dose escalation and expansion studies; the clinical results for Adagene's 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.

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