Adagene Announces First Patients with Advanced Non-Small Cell Lung Cancer Dosed in Phase 1b/2 Clinical Trial of ADG106 in Combination with Nivolumab in Singapore

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Clinical trial to be conducted at the National University Cancer Institute, Singapore and the National Cancer Centre Singapore, in Collaboration with the Singapore Translational Cancer Consortium

SAN DIEGO and SUZHOU, China, Jan. 13, 2022 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG) today announced that the first patients have been dosed in a phase 1b/2 clinical trial of the anti-CD137 agonist antibody, ADG106, in combination with the anti-PD-1 antibody, Nivolumab for patients with advanced non-small cell lung cancer (NSCLC) who have progressed on prior therapies.

The phase 1b/2 open label trial is designed to evaluate safety, tolerability, and anti-tumor activity of the combination in up to 53 patients with advanced NSCLC who have progressed after prior treatment. The trial will also include exploratory biomarker analyses of a novel predictive biomarker and immune cell profiling in response to the treatment.

"This clinical trial is a key step in development of ADG106, which is being evaluated in combination with multiple anti-PD-1 therapies for synergistic T-cell stimulation that was shown in both preclinical and clinical studies in comparison with anti-CD137 monotherapy. With the combination of these two independent, complementary pathways, ADG106 has the potential to overcome resistance to anti-PD-1 therapy, which remains a major limitation in the treatment of metastatic NSCLC," said Peter Luo, Ph.D., Co-Founder, Chief Executive Officer and Chairman of the Board of Adagene. "The trial also applies a convenient flat dosing regimen presenting long-term development opportunities for ADG106. We are excited about the potential of ADG106 combinations to improve patient lives for this important indication, where exploratory biomarkers related to ADG106 are involved."

The clinical trial is being led by Professor Goh Boon Cher, Senior Consultant, Department of Hematology-Oncology and Deputy Director (Research) at NCIS, and Associate Professor Daniel Tan, Head of the Division of Clinical Trials and Epidemiological Sciences and Senior Consultant, Division of Medical Oncology, NCCS. Both Professor Goh and Associate Professor Tan lead the STCC's Cancer Clinical Trials & Investigational Medicine Unit that brings together centers in Singapore for scaled up capacity, efficiency and expertise in conducting cancer clinical trials.

NSCLC is the leading cause of cancer-related deaths worldwide. Despite the proven use of low-dose CT scan as a screening tool for lung cancer, most patients still present with stage 3 or 4 disease and only about 20 percent are operable, with a five-year survival overall of about 10 percent[1]. Metastatic disease is the primary cause of death from NSCLC.

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. Clinical trials of ADG106 as monotherapy have been conducted in the U.S. and China. A trial in combination with toripalimab is underway in China, and one in combination with pembrolizumab is planned.

About Nivolumab
Nivolumab, marketed globally as Opdivo, is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response. By harnessing the body's own immune system to fight cancer, Nivolumab has become an important treatment option across multiple cancers, including advanced NSCLC.

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 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.

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Safe Harbor Statement
This press release contains forward-looking statements, including statements regarding the potential impact of combination trial of ADG106 and nivolumab, potential implications of clinical data for patients, clinical development programs and related clinical trial data, the potential benefits, safety and efficacy of our collaboration partners' products and investigational therapies, 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.

Reference: [1] Howlader N, Forjaz G, Mooradian MJ, et al. The Effect of Advances in Lung-Cancer Treatment on Population Mortality. New England Journal of Medicine 2020;383:640-9.

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