



Adagene Establishes Collaboration for Clinical Trial of ADG106 in Combination with Nivolumab in Patients with Non-Small Cell Lung Cancer in Singapore

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- Phase 1b/2 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 -

- ADG106 now being evaluated in combinations with three leading anti-PD-1 therapies -

SAN DIEGO and SUZHOU, China and SINGAPORE, Oct. 27, 2021 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), the National University Cancer Institute, Singapore (NCIS) at the National University Hospital in Singapore, National Cancer Centre Singapore (NCCS), and the Singapore Translational Cancer Consortium (STCC), today announced the initiation of a phase 1b/2 clinical trial of the anti-CD137 agonist antibody, ADG106, in combination with the anti-PD-1 antibody, Nivolumab.

The trial will be led by Professor Goh Boon Cher, Senior Consultant, Department of Haematology-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 centres in Singapore for scaled up capacity, efficiency and expertise in conducting cancer clinical trials.

ADG106 is being developed by Adagene for the treatment of advanced solid tumours and non-Hodgkin's lymphoma. The phase 1b/2 trial will evaluate this novel combination in advanced non-small cell lung cancer (NSCLC) patients who have progressed on prior therapies.

Professor Goh commented, "NSCLC is the most prevalent type of lung cancer, which is the leading cause of cancer-related deaths worldwide. Despite recent progress, most patients will progress after receiving the newest generation of immunotherapy and immune checkpoint treatments. ADG106 has been shown to enhance the activity of T-cells based on pre-clinical data, including evidence of synergistic effect with anti-PD-1 agents in a refractory NSCLC tumour model. We look forward to evaluating the combination of ADG106 with Nivolumab and exploring the potential of this promising therapy in a patient population with unmet needs."

"Pre-clinical studies evaluating the use of ADG106 with anti-PD-1 antibodies have shown promising results and we believe that this novel combination therapy can potentially address resistance to immune checkpoint inhibitors in metastatic NSCLC," said Associate Professor Tan. "Through this study, we plan to utilise a series of cutting-edge translational approaches to understand mediators of response and resistance to checkpoint inhibitors."

"We are excited to support this trial evaluating ADG106 in combination with Nivolumab, another leading anti-PD-1 therapy to be combined in clinical trials with ADG106 as a potential best-in-class treatment targeting CD137," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene.

"Building on the evidence of clinical efficacy demonstrated in our monotherapy trials, this trial will further explore the potential additive effect between ADG106 and anti-PD-1 agents. We are also delighted to partner with esteemed oncology research organisations that are leading cutting-edge care for patients in the region, as well as Bristol-Myers Squibb, a pioneer in research on anti-PD-1 therapy and anti-CD137 agonist antibodies."

The phase 1b/2 open label trial is designed to evaluate safety, tolerability, and anti-tumour 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, including immune cell profiling in response to treatment.

The trial will involve work under the Lung Cancer programme that is supported by the RIE2020 Open Fund - Large Collaborative Grant (OF-LCG) programme, administered by the Singapore Ministry of Health's National Medical Research Council (NMRC) and supported by the National Research Foundation Singapore, where Associate Professor Tan is the Corresponding Principal Investigator. OF-LCG is composed of a multi-disciplinary team of clinician-scientists, clinicians, researchers, molecular biologists and computational biologists across various research institutes in Singapore.

"This collaboration continues STCC's goals to synergise cancer research capabilities across Singapore in a concerted approach, and promotes institutional-industry partnerships. We look forward to further collaborations with global biotech companies on innovations in screening, treatment and care for cancer patients," said Professor Chng Wee Joo, Executive Director of STCC and Director of NCIS.

About Non-Small Cell Lung Cancer

There are two major types of lung cancers: small cell lung cancer and non-small cell lung cancer (NSCLC). About 85 percent to 90 percent of lung cancers are non-small cell lung cancers. The major differences between these two types of lung cancers are the size and shape of the cancer cell, forms of treatment and the speed at which the cancer spreads.

NSCLC is the leading cause of cancer-related deaths worldwide, accounting for approximately 18 per cent of all cancer deaths. 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 percent¹. Metastatic disease is the primary cause of death from NSCLC.

Until recently, chemotherapy has been the only available therapy for metastatic disease. However, much effort has been made to understand the molecular underpinning of NSCLC, and in non-squamous NSCLC, molecular drivers have been uncovered to direct the specific treatment of this subgroup of patients.

About ADG106

ADG106, is a fully human ligand-blocking, agonistic anti-CD137 IgG4 mAb being developed for the treatment of advanced solid tumours 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 in the U.S. and Asia Pacific (APAC).

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-tumour 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 programmes. 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>.

About National University Cancer Institute, Singapore (NCIS)

NCIS offers a broad spectrum of cancer care and management covering both paediatric and adult cancers, with expertise in prevention, screening, diagnosis, treatment, rehabilitation and palliative care. The Institute's strength lies in the multi-disciplinary approach taken to develop a comprehensive and personalised plan for each cancer patient and his or her family. Our award-winning clinician-scientists and clinician-investigators conduct translational research and clinical trials, providing patients with access to evidence-based cancer diagnostics, technology and therapies.

For more information about NCIS, please visit <http://www.ncis.com.sg>.

About Singapore Translational Cancer Consortium

STCC aims to strengthen the overall impact of cancer research and translation in Singapore by bringing together key basic, clinical and translational teams on joint platforms to actively establish and implement collaborative cancer programmes. STCC strives to establish Singapore as a global leader for oncology in research translation and its applications to health and economic value creation.

STCC is a business unit under the Consortium for Clinical Research and Innovation, Singapore (CRIS), a subsidiary of Ministry of Health Holdings (MOHH), and is anchored by the cancer research programmes and commercialisation platforms of STCC's research partners (NCCS, NCIS, National University of Singapore [NUS] Cancer Science Institute [CSI] and Agency for Science, Technology and Research [A*STAR]).

STCC is supported with funding from the National Research Foundation, Singapore and administered by the Singapore Ministry of Health.

For more information, please visit www.stcc.sg.

About the National Cancer Centre Singapore

The National Cancer Centre Singapore (NCCS) is a leading national and regional tertiary cancer centre with specialists who are experts in treating cancer. NCCS attends to the majority of cancer cases in Singapore's public healthcare sector. In addition to offering holistic and multidisciplinary oncology care, our clinicians and scientists collaborate with local and international partners to conduct robust, cutting-edge clinical and translational research. To achieve the vision of being a global leading cancer centre, NCCS offers world class care and shares its depth of experience and expertise by training local and overseas medical professionals.

To meet growing needs, the new NCCS building will be completed in 2022 with increased capacity and expanded facilities dedicated to cancer care, rehabilitation, research and education. To give patients the best treatment outcomes, NCCS will offer access to advanced and innovative treatment such as proton therapy at the new Goh Cheng Liang Proton Therapy Centre.

For more information, please visit: www.nccs.com.sg

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.

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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

The logo for Adagene, featuring the word "ADAGENE" in a bold, teal, sans-serif font.

Source: Adagene, Inc.