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ASIA EDITION

Adagene announces acceptance of IND in China for ADG-106

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It has also announced the dosing of its first patient in its Phase I trial in United States.

Adagene, an innovative antibody engineering and discovery company based in Suzhou, China as well as San Francisco, California has announced the dosing of its first patient in its Phase I trial in American for its lead product ADG-106, a fully human agonistic monoclonal antibody (mAb) targeting a novel epitope of CD137. Adagene is also announcing a record speed of review and acceptance of their IND in China for ADG-106. Adagene will investigate the safety and efficacy of ADG-106 therapy as a single agent across a range of solid tumor and non-Hodgkin lymphoma patients in the Phase I clinical study.

CD137 or 4-1BB, a member of the tumor necrosis factor (TNF) receptor superfamily is a promising immune-oncology target. Ligation of CD137 induces a co-stimulatory signal on activated CD8+ T cells and natural killer (NK) cells, resulting in proliferation, increased pro-inflammatory cytokine secretion, and cytolytic function. 4?1BB co-stimulation is the clinically validated pathway for the optimal T cell activation and its anti-tumor response as highlighted by the successful approval of the 4?1BB-containing CART therapy by the US FDA.

"The initiation of a Phase I clinical study of ADG-106 is a pivotal milestone for Adagene and our novel approach to improving cancer care," said Peter Luo, CEO of Adagene. "Also, we are honored to receive the IND approval from the NMPA (National Medical Products Administration) in an expedited time. We believe it shows their commitment to support drugs with novel biology and mechanism of action. The preclinical evidence shows we are targeting a novel epitope and the antibody behaves very differently compared with the other two monoclonal antibodies previously in the clinic."

"I have worked on this target previously and believe 4-1BB agonists have tremendous therapeutic potential in immunotherapy by targeting the costimulatory pathway," said Anthony W. Tolcher, M.D., FRCPC, Founder, CEO and Director of Clinical Research at NEXT Oncology (San Antonio, Texas) and an investigator on the trial. "Our team is eager to evaluate ADG-106 because it has shown both excellent safety and efficacy in numerous native preclinical models, and we look forward to assessing the clinical benefit of ADG-106 via its novel mechanism of action that would potentially expand the opportunity for patients to benefit from a novel IO target in both single and combinational therapy."