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CStone's PD-1 inhibitor CS1003 gets clinical trial approval in China

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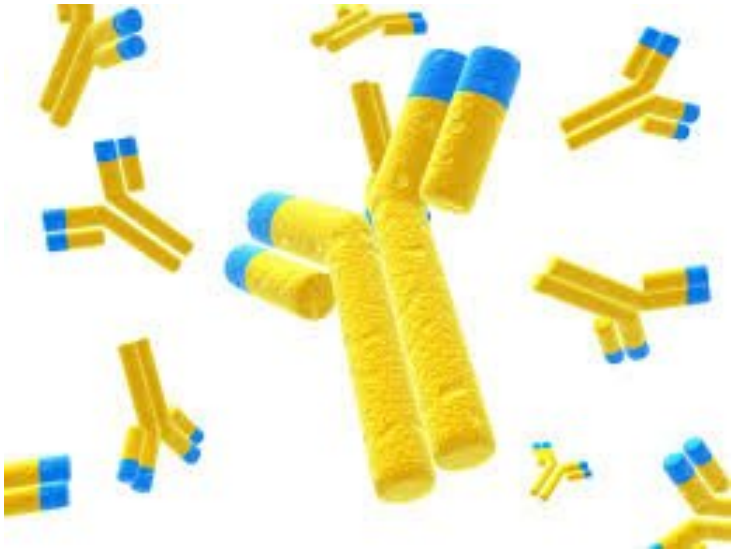

CStone Pharmaceuticals Co. LTD devoted to developing next-generation innovative drugs, announced that the China National Drug Administration (CNDA) has approved the first clinical trial application (CTA) in China for CS1003, a self-developed and wholly-owned anti-programmed death-1 (PD-1) monoclonal antibody (mAb).

CS1003's CTA filing was entered into the new process by the CNDA and approved after less than four months of review by the Center for Drug Evaluation. CStone will initiate a multi-center Phase I clinical trial to assess the safety, tolerability and preliminary anti-tumor activity of CS1003 in Chinese patients with advanced cancers.

"We are pleased to begin the development of CS1003 in China, which follows a first-in-human dose escalation trial initiated in Australia in May this year," said Dr. Frank Jiang, Chief Executive Officer at CStone. "The start of clinical evaluation for CS1003 in China is an important step in the development path for this molecule, which is a key component of CStone's immunotherapy strategy and will form the backbone of combination therapies. Alongside the programmed death-ligand 1 (PD-L1) mAb CS1001, CS1003 is the second CStone pipeline candidate to be tested in Chinese patients."

"PD-1 and PD-L1 immunotherapies have demonstrated significant clinical benefits for patients with various cancers, and we look forward to assessing the safety and efficacy of this high-quality PD-1 candidate in Chinese cancer patients," commented Dr. Jason Yang, Chief Medical Officer at CStone.