BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

CStone Pharmaceuticals announces dosing in Ph III trial for treating adenocarcinoma

16 April 2019 | News

CS1001 has completed a Phase I dose-escalation study in China, in which CS1001 showed good tolerance and produced sustained clinical benefit during the Phase Ia stage of the study.

CStone Pharmaceuticals has announced that the first patient has been successfully enrolled and dosed in Phase III clinical trial assessing CS1001, China's first fully human, full-length anti-PD-L1 antibody, in combination with chemotherapy for the treatment of gastric adenocarcinoma (GC) or gastroesophageal junction (GEJ) adenocarcinoma. The multi-center, placebo-controlled clinical trial GEMSTONE-303 will evaluate efficacy and safety of CS1001 plus oxaliplatin and capecitabine (XELOX) chemotherapy as first-line treatment in patients with unresectable, locally advanced, or metastatic gastric adenocarcinoma or GEJ adenocarcinoma.

According to data from the Chinese National Cancer Center, gastric cancer is the second most common cause of cancer-related death after lung cancer. In 2015, gastric cancer accounted for approximately 679,100 new cancer cases inChina, and approximately 498,000 patients died from the disease. Gastric adenocarcinoma comprises in excess of 90% of malignant neoplasms of the stomach, while the incidence of GEJ has been rising in recent years. Currently, chemotherapy is still the primary treatment option for both gastric adenocarcinoma and GEJ, while the only available biologic drug therapy for the indication is restricted to HER2-positive cases, which make up only 12% to 13% of total patient numbers.

"We are pleased to get this Phase III clinical study underway with the first patient enrolled and dosed," Dr.Frank Jiang, Chairman, and CEO of CStone commented. "For the past few decades, gastric cancer incidence rate and mortality rate have decreased in most areas of the world. However, in China, the number of cases of gastric cancer keeps increasing and both gastric adenocarcinoma and GEJ still represent major healthcare problems with serious unmet medical needs. We hope CS1001 can prove successful in this registration study and provide an important new treatment option for Chinese patients."

Dr. Jason Yang, CStone's Chief Medical Officer, commented: "Around 40%-60% of patients with gastric adenocarcinoma are

diagnosed at the advanced stage, for which treatment options are limited. Current clinical studies have shown that anti-PD-1/PD-L1 drugs, when paired with chemotherapy, are highly efficacious in multiple cancer types including gastric cancer. We expect that CS1001 in combination with oxaliplatin and capecitabine will generate significantly better efficacy than chemotherapy alone in patients with gastric cancer."

CS1001 is an investigational monoclonal antibody directed against PD-L1 being developed by CStone. Authorized by the U.S.-based Ligand Corporation, CS1001 is developed by the OMT transgenic animal platform, which can generate fully human antibodies in one step. As a fully human, full-length anti-PD-L1 monoclonal antibody, CS1001 mirrors natural G-type immune globulin 4 (IgG4) human antibody, which can reduce the risk of immunogenicity and potential toxicities in patients, potentially representing a unique advantage over similar drugs.

CS1001 has completed a Phase I dose-escalation study in China, in which CS1001 showed good tolerance and produced sustained clinical benefit during the Phase Ia stage of the study. In addition, two pivotal Phase II studies and three Phase III studies have been initiated in China.

CStone Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicine to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline with a strategic emphasis on immune-oncology combination therapies. Currently, 4 late-stage candidates are at or near pivotal trials. With an experienced team, a rich pipeline, a robust clinical development-driven business model, and substantial funding, CStone's vision is to become globally recognized as a leading Chinese biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.