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CStone initiates CS1001 trial to treat ESCC in China

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The GEMSTONE-304 trial is a multicenter clinical study designed to evaluate the efficacy and safety of CS1001 in combination with 5-fluorouracil plus cisplatin (FP) doublet chemotherapy

CStone Pharmaceuticals has announced that the first patient has been dosed in the Phase III GEMSTONE-304 study of the Company's anti-PD-L1 antibody CS1001 in combination therapy as first-line treatment in patients with advanced esophageal squamous cell carcinoma (ESCC). The GEMSTONE-304 trial is a multicenter clinical study designed to evaluate the efficacy and safety of CS1001 in combination with 5-fluorouracil plus cisplatin (FP) doublet chemotherapy in the first-line treatment of unresectable locally advanced, relapsed, or metastatic ESCC.

According to the GLOBOCAN data released in 2018, there are approximately 307,000 new incidences of esophageal cancer and 283,000 cases of esophageal cancer-related deaths in China annually. The incidence and mortality rates of esophageal cancer are ranked 5th and 4th respectively among all tumor types nationwide. Epidemiological data indicate that 90% of all esophageal cancer cases in China are ESCC, and around 70% of ESCC cases were locally advanced or metastatic at the time of diagnosis. The platinum-based doublet chemotherapy is the current standard of care first-line treatment for patients with advanced ESCC, but it has limited efficacy. Existing data on this first-line treatment for advanced ESCC suggest an objective response rate (ORR) of 35%, a median progression-free survival (PFS) of less than six months, and a median overall survival (OS) of less than one year. There are no alternative treatments for ESCC patients who have failed the first-line treatment.

CS1001 is an investigational anti-PD-L1 antibody developed by CStone. Results released at the 2019 Chinese Society of Clinical Oncology (CSCO) Annual Meeting have shown that, as of July 1, 2019, the Phase Ib trial of CS1001 in combination with the FP chemotherapy regimen in first-line treatment of ESCC achieved an ORR of 77.8% with durable response as well as good overall safety and tolerability.

"Esophageal cancer is one of the tumor types that are particularly prevalent in China, with over 50% of the world's new esophageal cancer cases and related deaths occurring in the country. Furthermore, the lack of more effective treatments for this patient population has long represented an urgent unmet clinical need," said Dr. Frank Jiang, Chairman and CEO of CStone. "I am glad that we have dosed the first patient in the GEMSTONE-304 trial. I hope CS1001 will continue to demonstrate its clinical promise in its development programs, and soon be proven as a new treatment option for ESCC

patients in China."

"Early symptoms of esophageal cancer are relatively silent; as a result, esophageal cancer patients are commonly diagnosed at advanced stages for which there are very limited treatment options. Furthermore, no immunotherapy has been approved for the first-line treatment of ESCC. Recent results from the Phase Ib trial of CS1001 have already demonstrated promising preliminary antitumor efficacy in advanced ESCC. We will continue accelerate this Phase III trial with our best effort. Should this clinical program lead to successful outcomes, it will be a major breakthrough for advanced ESCC patients who are in urgent need of effective therapies," noted Dr. Jason Yang, Chief Medical Officer of CStone.