

## **CStone and Bayer to evaluate PD-L1 monoclonal antibody CS1001 in combination with regorafenib**

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**Combination therapy of PD-1/PD-L1 antibodies with multi-kinase inhibitors that target VEGFR can induce significant synergistic anti-tumour effects, demonstrating CS1001 immuno-oncology potential in patients suffering from gastric cancer and serious malignancies**



CStone Pharmaceuticals, on 9 June 2019, announced its global clinical collaboration with China focus with Bayer HealthCare LLC to evaluate the safety, tolerability, pharmacokinetics (PK) and antitumor activity of its PD-L1 monoclonal antibody CS1001 in combination with Bayer's regorafenib, an oral multi-kinase inhibitor (targeting VEGFR, FGFR, CSF1R, etc.), as a treatment for multiple cancers including gastric cancer, in Suzhou, China. This is the first global proof of concept study carried out as a collaboration between the two companies. CStone will be the study sponsor and Bayer will provide regorafenib throughout the clinical trial program.

Professor Lin Shen, Vice President at the Peking University Cancer Hospital, commented: "At present, patients with advanced gastric cancer lack safe and effective therapies. Preclinical and clinical evidence suggests that the combination of PD-1/PD-L1 antibodies with multi-kinase inhibitors that target VEGFR can induce significant synergistic anti-tumour effects. We hope this combination of therapy can provide a new treatment option for patients suffering from gastric cancer and other serious malignancies."

CS1001 is one of CStone's backbone immuno-oncology pipeline candidates, having demonstrated that it is well-tolerated and has promising anti-tumour activities across a variety of tumour types in clinical studies. Currently, CS1001 is being evaluated in 7 clinical trials, including 5 pivotal trials. Regorafenib is approved in over 90 countries for the treatment of metastatic colorectal cancer (mCRC) and metastatic gastrointestinal stromal tumours (GIST) and in more than 80 countries for the second-line treatment of advanced hepatocellular (HCC).

Dr Frank Jiang, CStone Chairman and CEO, commented: "We are very pleased that Bayer has chosen CStone as its partner and recognizes CS1001's potential. We hope, by complementing our two companies' pipelines via this combination therapy, that we can develop better cancer treatments for patients. In addition, this collaboration will be a big step forward for CStone's global strategy when we generate positive data."

Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division said: "Combining multi-kinase inhibitors, such as regorafenib, with checkpoint inhibitors is a rising trend in cancer therapy in order to find new solutions for the many treatment gaps that still remain for patients. We look forward to collaborating with

CStone, an innovative biopharmaceutical company, and exploring regorafenib's potential."