The forward-looking statements made in this announcement relate only to the events or information as of the date on which the statements are made in this announcement. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this announcement completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this announcement, statements of, or references to, our intentions or those of any of our directors and/or our Company are made as of the date of this announcement. Any of these intentions may alter in light of future development.

CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT

U.S. ORPHAN DRUG DESIGNATION FOR THE ANTI-PD1 ANTIBODY CS1003

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the United State ("**U.S.**") Food and Drug Administration ("**FDA**") has granted an orphan drug designation ("**ODD**") to the Company's drug candidate CS1003, an anti-programmed cell death protein 1 ("**PD-1**") antibody, for the treatment of patients with hepatocellular carcinoma ("**HCC**").

Provided for by the Orphan Drug Act, an ODD is an incentive created by the FDA to promote the development of innovative drugs for the treatment of rare diseases and conditions. New drugs with ODD have the opportunity to gain seven years of market exclusivity, along with a series of benefits provided by the FDA, including tax credits, deduction of or exemption from prescription drug user fees, research and development funding support, protocol assistance, and accelerated approval.

CS1003 is a humanized recombinant IgG4 monoclonal antibody targeting human PD-1, which is being developed by CStone for immunotherapy of various tumors. Compared to most of the monoclonal antibodies that bind human and monkey PD-1 that have been approved or are currently under clinical development, CS1003 not only can be cross-reactive to both human and murine PD-1, but also shows a unique competitive advantage in the efficacy test of homologous mouse tumor models. Currently, the phase I clinical trials of CS1003 are being conducted in Australia, New Zealand and China. In addition, a global multi-center, phase III clinical study to evaluate the efficacy and safety of CS1003 in combination with lenvatinib as first-line treatment for patients with advanced HCC, has started patient enrollment.

Dr. Frank Ningjun Jiang, chairman of the board of directors and the chief executive officer of CStone, said, "HCC is a highly aggressive disease, and China has a large population living with HCC. The lack of effective treatments has led to overall poor prognosis for patients. CS1003 is one of the core drug candidates of CStone's immune-oncology pipeline, and a number of clinical studies have been conducted to evaluate the combination therapy of CS1003 with other drugs. The ODD granted by the U.S. FDA will be a blessing for HCC patients who are in need of effective treatment."

Mr. Sanhu Wang, senior vice president of government and regulatory affairs of CStone, further commented, "CS1003 is an anti-PD-1 monoclonal antibody independently developed by CStone. Compared to other anti-PD-1 antibodies that have been launched or are currently under development, CS1003 has obvious differentiated advantages. The orphan drug status granted by the U.S. FDA is an important development in CS1003's global strategic layout. We will continue to work on exploring the efficacy and safety of combination therapy in complex cancers such as HCC to address the unmet clinical needs of patients."

About CS1003

PD-1 is an inhibitory receptor that is preferentially expressed in T cells. Under normal physiological conditions, PD-1 will bind to programmed death ligand 1 ("**PD-L1**") or ligand 2 ("**PD-L2**"), leading to reduced activity of T cells and the production of cytokines, which in turn protects the body from attacks by its own immune system. However, studies have found high level of PD-L1 expression on the surface of many solid tumor and some hematological malignant tumor cells in human. Tumor cells can successfully escape the identification and attack of the body's immune system through the binding of PD-L1 with PD-1 on T cells. Anti-cancer drugs such as PD-1 or PD-L1 immune checkpoint inhibitors can block the tumor immune escape mechanism and restore the anti-cancer function by the patients' immune system.

CS1003 is a humanized recombinant IgG4 monoclonal antibody targeting human PD-1, which is being developed for immunotherapy of various tumors. Compared to most of the anti-PD-1 monoclonal antibodies that bind to human and monkey PD-1 and have either been approved or are being investigated in clinical trials, CS1003 can bind to both human and murine PD-1, and has shown unique competitive advantages in synergistic mouse models for drug efficacy testing.

About CStone

CStone is a biopharmaceutical company focused on developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established at the end of 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 of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, five late-stage candidates are at 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.

For more information about CStone, please visit: www.cstonepharma.com.

By order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, People's Republic of China, July 24, 2020

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and executive Director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Guobin Zhang and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.