CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(**Stock Code: 2616**)

VOLUNTARY ANNOUNCEMENT
CSTONE RECEIVED IND APPROVAL BY THE NMPA OF CHINA FOR CS2006/NM21-1480, A PD-L1/4-1BB/HSA MULTI-SPECIFIC ANTIBODY-BASED MOLECULE, MARKING FURTHER EXPANSION OF ITS PIPELINE 2.0

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the investigational new drug ("**IND**") application of multi-specific antibody CS2006/NM21-1480 has been approved by the National Medical Products Administration ("**NMPA**") of China. CS2006/NM21-1480 represents a leading class of next-generation anti-PD-1/PD-L1 cancer immunotherapies and a new backbone molecule for combinations.

CS2006/NM21-1480 is a monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin ("**HSA**"). CS2006/NM21-1480 is designed to bind to the immune co-stimulation receptor 4-1BB and conditionally activate T cells only when engaging the checkpoint receptor ligand PD-L1 on the surface of tumor cells, potentially preventing the liver toxicities observed with previous anti-4-1BB agonistic antibodies. As a potential best-in-class drug, CS2006/NM21-1480 could be used as monotherapy or in combination with multiple treatments. The upcoming clinical study is designed to evaluate the safety, pharmacokinetics, and anti-tumor efficacy of CS2006/NM21-1480 in Chinese patients with various advanced solid tumors.

Compared to other PD-L1/4-1BB bispecific antibody candidates, CS2006/NM21-1480's unique monovalent structure and ultra-high-affinity PD-L1-binding is designed to fully exploit the synergistic potential of tumor-localized modulation of PD-L1 and 4-1BB, to provide broader and more sustained treatment response and at the meantime, to avoid systemic toxicities. Furthermore, half-life extension via the HSA-binding motif enables convenient dosing schedules for patients. CS2006/NM21-1480 is anticipated to be effective against tumors with a wide range of PD-L1 expression levels and may overcome primary and/or acquired resistance to anti-PD-1/PD-L1 therapies.

Dr. Archie Tse, Chief Scientific Officer of CStone, said, "We are very glad that the IND application of CS2006/NM21-1480 in China has been approved by the NMPA of China. With the clinical trial starting soon, it marks a significant milestone in CStone's Pipeline 2.0 strategy which focused on assets with first-in-class or best-in-class potential. Since April 2020, the first-in-human study of CS2006/NM21-1480 has been well underway in the United States. Moving forward, we will step up our efforts to drive the research and development of CS2006/NM21-1480, and other pipeline assets to provide potentially more effective treatments for Chinese and global patients."

CS2006/NM21-1480 was discovered and engineered by Numab Therapeutics ("**Numab**"), CStone's partner, using its proprietary λcap™ technology and MATCH™ platform. CStone and Numab signed an exclusive regional licensing agreement for the development and commercialization of the drug candidate. Pursuant to the terms of the licensing agreement, CStone will fund the research and development of CS2006/NM21-1480 up to completion of an initial Phase Ib clinical trial. In exchange, CStone obtains exclusive rights from Numab to develop and commercialize CS2006/NM21-1480 in Greater China (including Mainland China, Hong Kong, Macau and Taiwan, China), South Korea and Singapore. Numab retains all CS2006/NM21-1480 rights for the rest of the world. Upon completion of CStone's funding period, no further financial obligations will be owed by either party.

About CStone

CStone is a biopharmaceutical company focused on researching, developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in Mainland 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 of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received three drug approvals in Greater China, including two in Mainland China and one in Taiwan, China. CStone's vision is to become globally recognized as a world-renowned 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, the People's Republic of China, September 15, 2021

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. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive directors.