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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCED NMPA OF CHINA'S ACCEPTANCE OF IND APPLICATION FOR CS2006/NM21-1480, A PD-L1/4-1BB/HSA MULTI-SPECIFIC ANTIBODY-BASED MOLECULE, MARKING FURTHER EXPANSION OF ITS PIPELINE 2.0 STRATEGY

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce the investigational new drug (“**IND**”) application of CS2006/NM21-1480, a multi-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin (“**HAS**”), has been accepted by the Center for Drug Evaluation, National Medical Products Administration (“**NMPA**”) of China. It further deepened and expanded CStone’s pipeline 2.0 strategy. With a forward-looking perspective, CStone has developed an innovative Pipeline 2.0 strategy, secured the global rights to multiple innovative molecules with first-in-class and best-in-class potential assets in emerging therapeutic categories.

CS2006/NM21-1480 is a monovalent tri-specific antibody-based molecule targeting PD-L1, 4-1BB and HSA. Its unique molecular design and innovative mechanism of action help reduce toxicity and improve efficacy. As a potential best-in-class drug, CS2006/NM21-1480 is a new immuno-oncology therapy that could be potentially used in combination with multiple treatments.

Dr. Archie Tse, Chief Scientific Officer of CStone, said, “The acceptance of the IND application for CS2006/NM21-1480 marks a significant milestone in CStone’s Pipeline 2.0 strategy. In April, 2020, CS2006/NM21-1480 was approved for early clinical development in the U.S. and the study is now well underway. Moving forward, we will step up efforts to drive the development of CS2006/NM21-1480 and other high-quality new drugs to benefit cancer patients.”

CS2006/NM21-1480 is a monovalent, tri-specific antibody-based molecule (“**scMATCH3™**”) that simultaneously targets PD-L1, 4-1BB, and HSA. CS2006/NM21-1480 is designed to bind to 4-1BB and activate T cells only when engaging with PD-L1 on the surface of tumor cells, potentially preventing liver toxicities observed in clinical trials with agonistic monospecific and bivalent anti-4-1BB antibodies.

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 expected to lead to better safety and higher efficacy. Furthermore, half-life extension via the HSA-binding motif in CS2006/NM21-1480 enables lower-frequency 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. Therefore, CS2006/NM21-1480 represents a leading class of next-generation cancer immunotherapies and a new backbone molecule for combinations.

CS2006/NM21-1480 was discovered and engineered by Numab Therapeutics (“**Numab**”), CStone's partner, using its proprietary λ cap™ 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), 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 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. 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, People's Republic of China, July 7, 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 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.