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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 PRESENTATION OF PRECLINICAL DATA ON A MULTI-SPECIFIC ANTIBODY-BASED THERAPEUTIC CANDIDATE CS2006/NM21-1480 AT THE AMERICAN ASSOCIATION FOR CANCER RESEARCH (AACR) ANNUAL MEETING 2022

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the preclinical data of multi-specific antibody CS2006/NM21-1480 has been presented at the American Association for Cancer Research (AACR) Annual Meeting 2022.

Key Highlights

- Results from pharmacokinetic/pharmacodynamic modeling demonstrated that binding affinity optimization of CS2006/NM21-1480 allowed optimal PD-L1 blockade and 4-1BB stimulation concomitantly, at a broad dose range and thereby facilitating dose-finding in the clinic.

- CS2006/NM21-1480 was efficacious as monotherapy in both hot and cold tumor models; combination with a CD3-T cell engager resulted in enhanced anti-tumor activity, with increased CD8-positive T memory cells within the tumor.

- These data provide translational support for the ongoing clinical development of CS2006/NM21-1480 as a potential best-in-class, next-generation immune-oncology agent.

Summary of the Presentation

- Session: PO.IM02.09 - Therapeutic Antibodies 1

- Date: April 12, 2022, 9:00 AM - 12:30 PM ET

- Format: E-posters

- Title: 2870/13-Dose selection investigations and combination strategies of NM21-1480, a PD-L1/4-1BB/HSA tri-specific MATCH3 therapeutic clinical candidate

- Presenter: Dr. Dan Snell

CS2006/NM21-1480 is a monovalent, tri-specific antibody-based molecule targeting PD-L1, 4-1BB, and human serum albumin ("**HSA**"). CS2006/NM21-1480 represents a leading class of broadly acting next-generation anti-PD-1/PD-L1 cancer immunotherapies and a new backbone molecule for tumor-specific combination therapies. CS2006/NM21-1480 is designed to bind to the immune co-stimulatory receptor 4-1BB and conditionally activate T cells only when engaging and blocking 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.

Compared to other PD-L1/4-1BB bispecific antibody candidates, CS2006/NM21-1480's unique monovalent structure and ultra-high-affinity PD-L1-binding are designed to tap the synergistic potential of tumor-localized modulation of PD-L1 and 4-1BB, to provide broader and more sustained treatment response and at the same time and to avoid systemic toxicities. Furthermore, half-life extension via the HSA-binding is designed to enable 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, "the preclinical data of CS2006/NM21-1480 are encouraging and further demonstrate its potential to become the best-in-class anti-4-1BB agonist and next-generation immune checkpoint inhibitor. The bell-shape dose-response curve associated with this class of agents presents a unique challenge with dose-selection in the clinic. However, this concern seems to be alleviated by the fine affinity balance engineered in CS2006/NM21-1480 which allows optimal PD-L1 blockade and 4-1BB activation at the same time. The first-in-human dose escalation study is ongoing in the United States, and patient enrollment has commenced in Taiwan, China. In addition, the investigational new drug application has been approved by the National Medical Products Administration of China and the clinical trial is underway. Moving forward, we will step up our efforts to drive research and development of CS2006/NM21-1480, and other pipeline assets to provide high-quality treatments for a wider range of cancer patients as soon as possible."

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), 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 seven NDA approvals for four drugs. Multiple late-stage drug candidates are now under pivotal clinical trials or registration. 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, April 13, 2022

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. Kenneth Walton Hitchner III, 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.