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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

CSTONE ANNOUNCES PATENT PUBLICATION FOR FIRST-IN-CLASS ANTIBODY-DRUG CONJUGATE (ADC) CS5006

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce the patent (WO/2024/208354) for its internally developed antibody-drug conjugate (ADC) CS5006 was published on October 10, 2024.

CS5006 is a first-in-class ADC with a novel therapeutic target – integrin $\beta 4$ (ITGB4). ITGB4 is a transmembrane protein that pairs exclusively with integrin $\alpha 6$ (ITGA6) to form the heterodimer $\alpha 6\beta 4$, with laminin as its extracellular ligand. ITGB4 is recognized as a biomarker in various cancers, with its overexpression linked to tumor aggressiveness and poor prognosis. Utilizing our internally developed bioinformatics platform, combined with cutting-edge AI algorithms and a comprehensive analysis of published literature, we identified that ITGB4 is highly expressed in non-small cell lung cancer, colorectal cancer, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, etc., making it a promising candidate for targeted therapy.

During the development of CS5006, CStone combined the candidate monoclonal antibody with clinically validated linkers and cytotoxic payloads, including GGFG-DXd and VC-MMAE, to create model ADC molecules for proof-of-concept studies. *In vitro* studies showed that both CS5006-GGFG-DXd and CS5006-VC-MMAE ADCs efficiently released cytotoxins upon internalization in tumor cells, rapidly inducing cell death. *In vivo* data further confirmed the potent anti-tumor activity and favorable tolerability of these two ADCs, providing robust support for the next phase of clinical development. CS5006, with an internally developed proprietary linker, is approaching completion of its preclinical candidate (PCC) selection, with an Investigational New Drug (IND) application expected in 2025.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, said, “The publication of the CS5006 patent highlights our innovations in the ADC field and underscores CStone’s end-to-end capabilities from research to commercialization. We are hopeful of the clinical potential of CS5006 and other innovative ADCs in our pipeline, and look forward to bringing groundbreaking therapies to cancer patients worldwide.”

Additionally, CStone is actively advancing the development of next-generation linkers with proprietary intellectual property to enhance the hydrophilicity and tumor selectivity of widely used linkers such as the GGFG tetrapeptide and VA/C dipeptide linkers. These new linkers aim to maximize ADC safety and efficacy, increase compatibility with diverse targets and antibodies, and support multiple upcoming ADC projects in CStone's pipeline 2.0, including CS5005 targeting SSTR2, CS5006 targeting ITGB4, and CS5007 dual-targeting EGFR&HER3.

About CStone

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of anti-cancer therapies. Dedicated to addressing patients' unmet medical needs in China and globally, the Company has made significant strides since its inception. To date, the Company has successfully launched 4 innovative drugs and secured approvals for 15 new drug applications (NDAs) covering 9 indications. The Company's pipeline is balanced by 16 promising candidates, featuring potentially first-in-class or best-in-class antibody-drug conjugates (ADCs), multispecific antibodies, immunotherapies and precision medicines. CStone also prides itself on a management team with comprehensive experiences and capabilities that span the entire drug development spectrum, from preclinical and translational research to clinical development, drug manufacturing, business development, and commercialization.

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

Cautionary Statement required by Rule 18A.05 of the Listing Rules: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS5006 SUCCESSFULLY. Shareholders of the Company and potential investors are advised to exercise due care when dealing in the shares of the Company.

Forward Looking Statement

There is no assurance that any forward-looking statements regarding the business development of the Group in this announcement or any of the matters set out herein are attainable, will actually occur or will be realized or are complete or accurate. The financial and other data relating to the Group as disclosed in this announcement has also not been audited or reviewed by its auditors. Shareholders and/or potential investors of the Company are advised to exercise caution when dealing in the securities of the Company and not to place any excessive reliance on the information disclosed herein. Any shareholder or potential investor who is in doubt is advised to seek advice from professional advisors.

By Order of the Board
CStone Pharmaceuticals
Dr. Wei Li
Chairman

Suzhou, the People's Republic of China, October 21, 2024

As at the date of this announcement, the board of directors of the Company comprises Dr. Wei Li as Chairman and non-executive director, Dr. Jianxin Yang as executive director, Mr. Kenneth Walton Hitchner III, 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.