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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 NMPA APPROVAL OF IND FOR THE PHASE II CLINICAL TRIALS OF CS2009 (PD-1/VEGF/CTLA-4 TRI-SPECIFIC ANTIBODY) COMBINATION THERAPIES, FURTHER EXPLORING ITS THERAPEUTIC POTENTIAL

This announcement is made by CStone Pharmaceuticals (the "**Company**," together with its subsidiaries, collectively referred to as the "**Group**" or "**CStone**") on a voluntary basis for the purpose of keeping the shareholders of the Company and potential investors abreast of the latest business development of the Group.

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CStone today announced that the Investigational New Drug (IND) application for the Phase II clinical trials of CS2009 (PD-1/VEGF/CTLA-4 tri-specific antibody) combination therapies for advanced solid tumors has been approved by the China National Medical Products Administration (NMPA).

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated, "The promising preliminary data from the Phase I study of CS2009 has given us great confidence, supporting our efforts to accelerate its Phase II development. Based on this, the Phase II clinical trial for CS2009 features a multi-cohort, parallel expansion design, comprising 15 monotherapy and combination therapy cohorts across 9 solid tumor indications, including non-small cell lung cancer (NSCLC) and hepatocellular carcinoma (HCC). The Phase II study is currently actively enrolling patients in Australia. The approval of the IND in China will further accelerate the clinical development progress, allowing us to explore and validate the broad therapeutic potential of CS2009."

About CS2009 (PD-1/VEGF/CTLA-4 Tri-specific Antibody)

CS2009, an innovative tri-specific antibody designed and developed by CStone, combines three clinically validated targets: PD-1, VEGFA, and CTLA-4, and exerts multidimensional anti-tumor effects through

synergistic actions. Specifically, anti-PD-1 activity reverses T cell exhaustion, anti-CTLA-4 activity promotes T cell activation and proliferation, while anti-VEGFA activity blocks tumor angiogenesis and improves the tumor micro-environment (TME). In the TME, anti-PD-1 and anti-CTLA-4 activities are significantly enhanced by crosslinking with VEGFA. Meanwhile, CS2009 preferentially blocks PD-1 and CTLA-4 on double-positive tumor-infiltrating T cells while minimizing interference with CTLA-4 regulation in peripheral T cells.

CStone has disclosed the preliminary Phase I data of CS2009 at the 2025 European Society for Medical Oncology (ESMO) Annual Congress.

The ongoing global, multicenter Phase II clinical trial of CS2009 features a multi-cohort, parallel expansion design to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics (PK/PD), and efficacy of CS2009 as monotherapy and combination regimens. The study comprises 15 monotherapy and combination therapy cohorts across 9 solid tumor indications, including NSCLC, HCC, colorectal cancer (CRC), platinum-resistant ovarian cancer (PROC), triple-negative breast cancer (TNBC), extensive-stage small cell lung cancer (ES-SCLC), cervical cancer (CC), gastric or gastroesophageal junction cancer (GC/GEJC), and esophageal squamous cell carcinoma (ESCC). Patient enrollment is actively ongoing in Australia and will soon commence in China, with subsequent expansion planned for the United States.

About CStone

CStone (HKEX: 2616), established in late 2015, is an innovation-driven biopharmaceutical company focused on the research and development of therapies for oncology, autoimmune/inflammation, and other key disease areas. 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 16 new drug applications 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 Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: THE COMPANY CANNOT GUARANTEE THAT WE MAY BE ABLE TO ULTIMATELY DEVELOP AND MARKET CS2009 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, November 4, 2025

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 and Mr. Edward Hu as non-executive directors, and Mr. Ting Yuk Anthony Wu, Mr. Kenneth Howard Jarrett and Ms. Fang Xie as independent non-executive directors.