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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 FIRST PATIENT ENROLLMENT IN GLOBAL PHASE II TRIAL OF CS2009 (PD-1/VEGF/CTLA-4 TRISPECIFIC ANTIBODY) IN AUSTRALIA

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 first patient has been enrolled in Australia in the global multicenter Phase II clinical trial of core asset CS2009 (PD-1/VEGF/CTLA-4 trispecific antibody). The trial enrollment is currently ongoing in Australia and China, with subsequent expansion planned for the United States.

Phase I Dose-Escalation Study Demonstrates Promising Profile

In the Phase I dose-escalation study (6 cohorts, 1-45mg/kg, escalation and backfilling), CS2009 showed:

1. Favorable Safety: No dose-limiting toxicities (DLT) observed across all evaluated doses; well-tolerated in dozens of patients.

2. Pharmacokinetics/pharmacodynamics (PK/PD) Characteristics Consistent with Expectations:
   - Every-three-week (Q3W) dosing supported by linear pharmacokinetics with no accumulation.
   - Saturated receptor occupancy and robust T-cell activation/proliferation via PD-1/CTLA-4 blockade and potent and sustained VEGFA neutralization.

3. Broad & Deepening Antitumor Activity:
   - Notable anti-tumor activity was observed across all doses, and the activity continued to strengthen

with prolonged follow-up.

- Activity demonstrated in multiple tumor types, including cold tumors and PD-(L)1-refractory/resistant patients.
- Most patients remain on treatment.

Full Phase I clinical data of CS2009 will be presented at the European Society for Medical Oncology (ESMO) Congress in October 2025.

Global Phase II Trial Design Across Multiple Tumors

This global multicenter Phase II trial employs a multi-cohort parallel expansion design, encompassing 15 cohorts and multiple solid tumor indications. It will primarily evaluate the safety, tolerability, PK/PD profile, and efficacy of CS2009 as both monotherapy and in combination regimens. Specific study cohorts include:

1. Non-Small Cell Lung Cancer (NSCLC):
   - Monotherapy in treatment-naïve PD-L1 positive (tumor proportion score [TPS]$\geqslant$1%), actionable genomic alterations (AGA) negative patients.
   - Combination with chemotherapy for EGFR-mutant non-squamous patients after EGFR-TKI failure.
   - Combination with chemotherapy in first-line non-squamous AGA negative patients.
   - Combination with chemotherapy in first-line squamous AGA negative patients.
   - Combination with chemotherapy in second-line PD-(L)1 refractory/resistant patients.
2. Hepatocellular Carcinoma (HCC):
   - Monotherapy in unresectable advanced HCC after $\leqslant$2 prior systemic therapies.
3. Colorectal Cancer (CRC):
   - Combination with chemotherapy in first-line proficient mismatch repair/microsatellite stable (pMMR/MSS) patients.
4. Platinum-Resistant Ovarian Cancer (PROC):
   - Monotherapy after $\leqslant$2 lines post-platinum resistance.
   - Combination with chemotherapy after $\leqslant$2 prior therapies.
5. Triple-Negative Breast Cancer (TNBC):
   - Monotherapy after $\leqslant$2 prior therapies.
   - Combination with chemotherapy in first-line setting.
6. Extensive-Stage SCLC (ES-SCLC):
   - Combination with chemotherapy as first-line treatment.
7. Cervical Cancer (CC):
   - Combination with chemotherapy as first-line treatment.
8. Gastric/Gastroesophageal Junction Cancer (GC/GEJC):

- Combination with chemotherapy as first-line treatment.

9. Esophageal Squamous Cell Carcinoma (ESCC):

    - Combination with chemotherapy as first-line treatment.

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

CS2009 is a novel trispecific antibody targeting PD-1, VEGFA, and CTLA-4 to achieve multidimensional antitumor effects through synergistic mechanisms. It is independently developed by CStone from molecular inception, with the potential to be first- or best-in-class. Its differentiated molecular design combines these validated targets, preferentially invigorating exhausted tumor infiltrating lymphocytes (TILs) while demonstrating VEGF neutralization comparable to existing anti-VEGF antibodies. CS2009 covers a wide range of cancers, including but not limited to non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, gastric cancer, ovarian cancer, cervical cancer, breast cancer, colorectal cancer, esophageal cancer etc.

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, September 23, 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 and Ms. Yip Betty Ho as independent non-executive directors.