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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
LATEST UPDATE ON GLOBAL MULTICENTER PHASE III STUDY OF
NOFAZINLIMAB IN HEPATOCELLULAR CARCINOMA

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) today announce the update on the CS1003-305 study.

CS1003-305 study is a global, multicenter, randomized, double-blind Phase III registrational trial conducted across 74 sites worldwide. The study evaluates the efficacy and safety of the anti-PD-1 monoclonal antibody nofazinlimab (CS1003) in combination with lenvatinib versus placebo in combination with lenvatinib as first-line treatment for patients with unresectable or metastatic hepatocellular carcinoma (HCC). The primary endpoint was overall survival (OS). Key secondary endpoints included progression-free survival (PFS) and objective response rate (ORR) as assessed by Blinded Independent Central Review (BICR).

Final analysis demonstrated a clinical compelling trend in OS for the nofazinlimab-lenvatinib combination compared to placebo-lenvatinib, indicating meaningful patient benefit despite not reaching statistical significance. In addition, clinically meaningful improvements in PFS and ORR were achieved, with outcomes numerically competitive against established therapeutic benchmarks. Nofazinlimab demonstrated a manageable safety profile, consistent with prior research findings and marketed PD-(L)1 antibodies, and no new safety signals were observed. The Company will engage with regulatory authorities to explore the registration pathway for this combination therapy.

About nofazinlimab

Nofazinlimab is a humanized recombinant IgG4 monoclonal antibody targeting human programmed cell death protein 1 (“PD-1”) being developed in solid tumors. Nofazinlimab shows comparable high binding affinities to the PD-1 of humans, cynomolgus monkey, and mouse, and can block the interaction of PD-1 with its ligands PD-L1 and PD-L2.

The U.S. FDA has granted nofazinlimab Orphan Drug Designation (“ODD”) in July 2020 for the treatment

of patients with HCC.

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 16 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 NOFAZINLIMAB 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, July 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 and Ms. Yip Betty Ho as independent non-executive directors.