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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT

CSTONE AND STEINCARES ENTER INTO STRATEGIC PARTNERSHIP TO MARKET SUGEMALIMAB IN LATIN AMERICA

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce a strategic commercialization partnership with SteinCares, a leading pharmaceutical company with more than 40 years of experience and a strong presence in Latin America (LATAM). Under the license and commercialization agreement, SteinCares will gain the commercialization rights for sugemalimab in 10 LATAM countries, including Brazil, Argentina, Mexico, Chile, Colombia, Costa Rica, Panama, Peru, Guatemala and Ecuador.

Key Highlight

- CStone will receive upfront, regulatory and commercial milestone payments, and book revenue from SteinCares via the supply of sugemalimab in 10 LATAM countries.
- This marks CStone's third major global commercialization partnership for sugemalimab, with additional commercialization deals in Western Europe, Southeast Asia, Canada, etc. anticipated soon. CStone has received marketing authorization for sugemalimab in the EU, EEA countries (Iceland, Liechtenstein, and Norway), and the UK, while actively advancing regulatory submissions for additional indications.

In this collaboration, SteinCares will be responsible for the regulatory affairs and commercialization activities of sugemalimab in the above-mentioned 10 LATAM countries. CStone will supply sugemalimab and will receive upfront, regulatory and commercial milestone payments as well as revenue from the supply of sugemalimab to SteinCares.

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, commented, “Following our successful market entries in Central and Eastern Europe, Switzerland, as well as the Middle East and Africa, we are excited to announce another key milestone in the global expansion of sugemalimab. As the first anti-PD-L1 monoclonal antibody approved in both the EU and UK for first-line, all-comer, Stage IV non-small cell lung cancer (NSCLC), sugemalimab is well-positioned for success in Latin America. SteinCares’s extensive distribution network and deep marketing expertise across LATAM will significantly enhance

sugemalimab's sales channels. We are also actively discussing with international partners in Western Europe, Southeast Asia, and Canada, while advancing regulatory submissions for additional indications of sugemalimab. We are confident that these efforts will further unlock the therapeutic and commercial potential of sugemalimab, and we anticipate more collaborations with overseas partners, to benefit more patients worldwide.”

Mitchell Wasserstein, CEO of SteinCares, added: “This agreement with CStone represents a significant step forward in our mission to create healthcare opportunities for patients in LATAM. At SteinCares, we are committed to providing more Latin Americans with greater access to safe, innovative, and affordable therapies. With our extensive experience and established sales network across the region, we are confident in our ability to successfully commercialize sugemalimab in LATAM and make a meaningful impact on patients' health and well-being.”

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was developed by CStone using OmniRat[®] transgenic animal platform licensed from Ligand Pharmaceuticals in the United States, which allows creation of fully human antibodies in one step. Sugemalimab is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may reduce the risk of immunogenicity and toxicity for patients, a unique advantage over similar drugs. Sugemalimab's differentiated molecular design enables a dual mechanism of action that not only blocks PD-1/PD-L1 interaction, but also induces antibody dependent cellular phagocytosis (ADCP) by cross-linking PD-L1 expressing tumor cells with tumor associated macrophages (TAMs) without harming Effector T-cells. This differentiation has resulted in a competitive efficacy/safety across a variety of tumor types.

The National Medical Products Administration (NMPA) of China has approved sugemalimab for five indications:

- In combination with chemotherapy as a first-line treatment of patients with metastatic squamous and non-squamous NSCLC;
- For the treatment of patients with unresectable stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy;
- For the treatment of patients with relapsed or refractory extranodal NK/T-cell lymphoma;
- In combination with fluorouracil and platinum-based chemotherapy as a first-line treatment of patients with unresectable locally advanced, recurrent or metastatic ESCC; and
- In combination with fluoropyrimidine- and platinum-containing chemotherapy as a first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression (Combined Positive Score [CPS] ≥ 5).

The European Commission (EC) has approved sugemalimab (brand name: Cejemly[®]) in combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations.

The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK has approved the marketing authorization application for sugemalimab in combination with platinum-based chemotherapy for first-line treatment of metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations.

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 17 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.

About SteinCares

SteinCares is a leader in commercializing and distributing specialty healthcare products in Latin America, including innovative pharmaceuticals, biosimilars, plasma-derived therapies and complex generics. With more than 40 years of progressive healthcare experience and operations in over 30 countries in Latin America and the Caribbean, SteinCares serves as a bridge between global pharmaceutical companies and the region's healthcare providers. The company is deeply committed to creating healthcare opportunities that positively impact the lives of patients and their families in Latin America, with a vision of increasing access to innovative and cost-effective healthcare for patients in the region.

For more information about SteinCares, please visit: www.steincare.com or follow the company on [LinkedIn](#).

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 SUGEMALIMAB 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, January 27, 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, Mr. Xianghong Lin and Mr. Edward Hu as non-executive directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu, Mr. Hongbin Sun and Ms. Yip Betty Ho as independent non-executive directors.