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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 EWOPHARMA ENTER INTO STRATEGIC PARTNERSHIP FOR SUGEMALIMAB IN CENTRAL EASTERN EUROPE AND SWITZERLAND

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that today CStone has entered into a strategic commercial collaboration with the European pharmaceutical company Ewopharma. Under the licensing and commercialization agreement, Ewopharma will gain the commercial rights for sugemalimab in Switzerland and 18 Central Eastern European countries (CEE). This includes EU member countries Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia, as well as non-EU countries Albania, Bosnia & Herzegovina, Kosovo, North Macedonia, Moldova, Montenegro, and Serbia.

Key Highlights

- The partnership will maximize the market potential and value of sugemalimab (anti-PD-L1 monoclonal antibody) in Central Eastern Europe and Switzerland.
- CStone will receive up to USD51.3 million consisting of an upfront payment and additional consideration payable upon the achievement of certain regulatory and sales milestones.
- CStone will book international revenue via the sales of drug supply to Ewopharma.
- The European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) are reviewing the marketing authorization application (MAA) for sugemalimab in combination with chemotherapy as the first-line treatment of metastatic non-small cell lung cancer (NSCLC).

Under the terms of the licensing and commercialization agreement, CStone will receive up to USD51.3 million consisting of an upfront payment and additional consideration payable upon the achievement of certain regulatory and sales milestones. In addition, CStone will book revenue from sales of drug supply to Ewopharma and its affiliates. Ewopharma will be in charge of pricing, reimbursement, sales &

marketing, and distribution, whilst CStone will be responsible for product supply and provide necessary training and support for the brand.

Dr. Jianxin Yang, CEO, President of R&D and Executive Director at CStone, said, "As a potentially bestin-class anti-PD-L1 monoclonal antibody, sugemalimab has demonstrated remarkable efficacy in multiple clinical trials and has already been approved in China for five indications, covering stage III and IV NSCLC, gastric cancer, esophageal squamous carcinoma, and extranodal NK/T-cell lymphoma. In European markets, we look forward to receiving MAA approval from the European Medicines Agency in the near future. We believe sugemalimab has a broad application prospect in Europe and global markets. Ewopharma is a reliable pharmaceutical marketing partner with abundant experience and extensive channels in CEE markets. The collaboration will undoubtedly help us to maximize the clinical and commercial value of sugemalimab and to benefit more patients in Europe. We look forward to taking a firm step toward the international commercialization of sugemalimab with Ewopharma."

Alain Staub, CEO and Chairman of the Board of Ewopharma comments: "We are delighted to enter into this strategic partnership with CStone. Sugemalimab is an innovative treatment further expanding our oncology franchise and allows us to make an important contribution to health equity in our region. According to Globocan 2022, lung cancer is the third most common cancer in Europe and the leading cause of cancer-related deaths, accounting for one-fifth of all cancer deaths. Sugemalimab will improve the treatment landscape for patients with advanced non-small cell lung cancer. We are very happy to bring hope and optimism to patients and healthcare professionals alike."

Sugemalimab, an anti-PD-L1 monoclonal antibody developed by CStone, has been granted approvals in China for all five indications that entered late-stage clinical trials, including stage III and IV NSCLC, extranodal NK/T-cell lymphoma, esophageal squamous carcinoma, and gastric cancer. The EMA and the UK MHRA are reviewing the MAA for sugemalimab in combination with chemotherapy as the first-line treatment of metastatic NSCLC.

The clinical data of sugemalimab have been presented at various international academic conferences and published in top-tier journals such as The Lancet Oncology, Nature Medicine, Nature Cancer, and Journal of Clinical Oncology. CStone is also in discussions with regulatory authorities including the EMA, the UK MHRA, and the US Food and Drug Administration (FDA) concerning other indications for sugemalimab and actively expanding partnerships for development and commercialization in other regions worldwide.

This announcement is made by the Company on a voluntary basis. The entering into of the licensing and commercialization agreement is of a revenue nature in the ordinary and usual course of business of the Group and does not constitute a notifiable transaction under Chapter 14 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited.

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 worldwide, the company has made significant strides since its inception. To date, the company has successfully launched 4 innovative drugs and secured approvals for 14 New Drug Applications (NDAs) covering 9 indications. The company's pipeline is balanced by 12 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 researches to clinical development, drug manufacturing, business development, and commercialization.

For more information about CStone, please visit: <u>www.cstonepharma.com</u>.

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About Ewopharma

Ewopharma AG, headquartered in Schaffhausen, Switzerland, covers all aspects of market access and medical marketing of pharmaceuticals and consumer health products in Switzerland and Central Eastern Europe. The company has enjoyed an excellent reputation as a compliant, reliable, and innovative partner for over 60 years. Ewopharma AG has commercialization agreements with many leading healthcare companies including Eisai and Biogen.

For more information about Ewopharma, please visit: <u>www.ewopharma.com</u>

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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, May 27, 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.