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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 FOR LOCALIZED MANUFACTURING OF GAVRETO® (PRALSETINIB) IN CHINA**

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. The Company is pleased to announce that the National Medical Products Administration (NMPA) of China has approved the manufacturing localization application for GAVRETO® (pralsetinib, 100mg). Commencing in 2026, supply for the Chinese market will transition gradually from imported to locally manufactured product.

Dr. Jason Yang, Chief Executive Officer (“**CEO**”), President of R&D, and Executive Director at CStone, stated, “The approval of GAVRETO®’s localized production marks another important milestone in CStone’s lifecycle management strategy, particularly in establishing robust manufacturing and quality management systems. This authorization enables end-to-end domestic production—from active pharmaceutical ingredient (API) to finished drug product (DP)—significantly enhancing supply chain flexibility and resilience. This transition ensures sustainable product access, better serves RET-positive patients, and strengthens GAVRETO®’s market position. We remain committed to collaborating with partners to improve treatment accessibility across China.”

#### **About GAVRETO® (pralsetinib)**

GAVRETO® is a once-daily oral targeted therapy approved by the NMPA of China for the treatment of adults with locally advanced or metastatic RET fusion-positive Non-Small Cell Lung Cancer (NSCLC), and for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant Medullary Thyroid Carcinoma (MTC) who requires systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who requires systemic therapy and radioactive iodine-refractory (if radioactive iodine treatment is appropriate).

GAVRETO® has been approved in Hong Kong, China for the treatment of adult patients with RET fusion-

positive metastatic NSCLC, and in Taiwan, China for the treatment of adult patients with locally advanced or metastatic RET fusion-positive NSCLC, advanced or metastatic RET-mutant MTC who require systemic therapy, and advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

GAVRETO<sup>®</sup> is approved by the U.S. Food and Drug Administration (FDA) for the treatment of:

- Adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). \*

*\*This indication is approved under accelerated approval based on Objective Response Rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).*

GAVRETO<sup>®</sup> was discovered by CStone's partner, Blueprint Medicines. CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of GAVRETO<sup>®</sup> in Greater China, which encompasses Mainland China, Hong Kong, Macau and Taiwan. In November 2023, CStone announced an exclusive agreement with Shanghai Allist Pharmaceuticals Co., Ltd. to commercialize GAVRETO<sup>®</sup> in Mainland China.

Blueprint Medicines and associated logos are trademarks of Blueprint Medicines Corporation. GAVRETO<sup>®</sup> and associated logos are trademarks of Blueprint Medicines Corporation outside of 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 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](http://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 GAVRETO<sup>®</sup> (PRALSETINIB) 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 10, 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.*