CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
CSTONE INITIATES NATIONWIDE COMMERCIAL SUPPLY OF LOCALLY MANUFACTURED PRALSETINIB CAPSULES

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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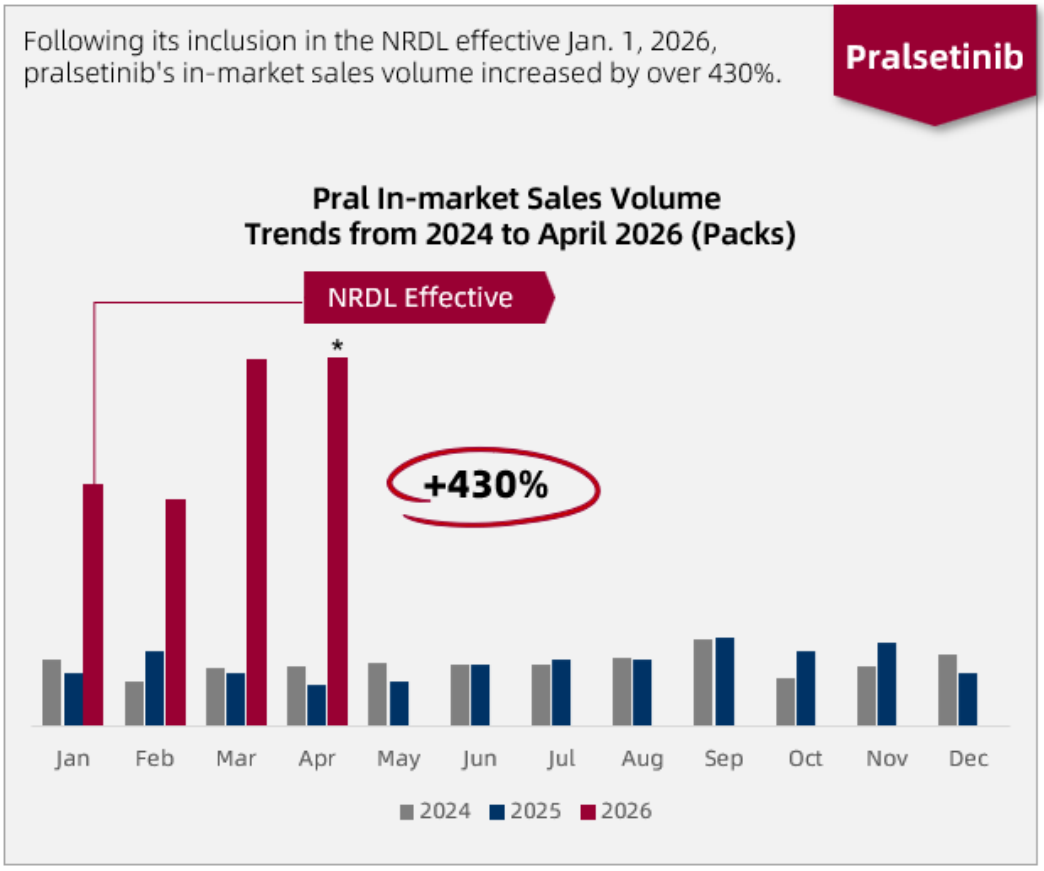
CStone today announced the successful production and release of its first batch of domestically manufactured pralsetinib capsules (100 mg). The shipment marks the official commencement of the drug's nationwide commercial distribution, signifying a major milestone in securing a localized supply chain for this innovative therapy.

First batch of locally-manufactured pralsetinib capsules products at the shipment site

Following the inclusion of pralsetinib capsules in China's National Reimbursement Drug List (NRDL) in late 2025—effective January 1, 2026—patient access has improved significantly. As of April 2026, in-market sales volume has surged by over 430% year-on-year. Capitalizing on this growth trajectory, CStone projects that full-year 2026 sales revenue for pralsetinib capsules will exceed RMB 300 million.

Pralsetinib capsules in-market sales volume increased by over 430%



** Estimate*

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated, "The seamless execution of this first domestic shipment reflects the rigor of our cross-functional teams in manufacturing, quality, regulatory, and supply chain. Through stringent technical transfers and process validation, we have ensured that our locally manufactured pralsetinib capsules is highly comparable to the imported version in both quality and efficacy, fully adhering to global standards. With a mature domestic supply chain now in place, we are well-positioned to meet the surging clinical demand driven by NRDL inclusion, while also optimizing our cost structure and enhancing margin resilience. Moving forward, CStone remains steadfast in our commitment to delivering high-quality, stable drug supply to patients across China."

About Pralsetinib Capsules

Pralsetinib capsules is a once-daily oral targeted therapy approved by the National Medical Products Administration (NMPA) of China for the first-line treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC, the treatment of adults with locally advanced or metastatic RET fusion-positive NSCLC previously treated with platinum-based chemotherapy; and RET fusion-positive thyroid cancer (TC). In addition, this medicine has been approved by the Department of Health of the Government of Hong Kong (HK DoH) for the treatment of patients with RET fusion-positive locally advanced or metastatic NSCLC and it has been approved by the Taiwan Food and Drug Administration (TFDA) for the treatment of adult patients with locally advanced or metastatic RET fusion-positive NSCLC and advanced or metastatic RET fusion-positive TC.

GAVRETO® 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; and
- 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).*

Pralsetinib capsules was discovered by CStone's partner, Blueprint Medicines (acquired by Sanofi in July 2025). CStone has an exclusive collaboration and license agreement with Blueprint Medicines for the development and commercialization of pralsetinib capsules 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 pralsetinib capsules in Mainland China.

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, 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 21 new drug applications covering 9 indications. The Company's pipeline is balanced by 16 promising candidates, featuring 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 PRALSETINIB CAPSULES 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 11, 2026

As at the date of this announcement, the Board 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. Kenneth Howard Jarrett, Ms. Fang Xie and Ms. Catherine Yen as independent non-executive directors.