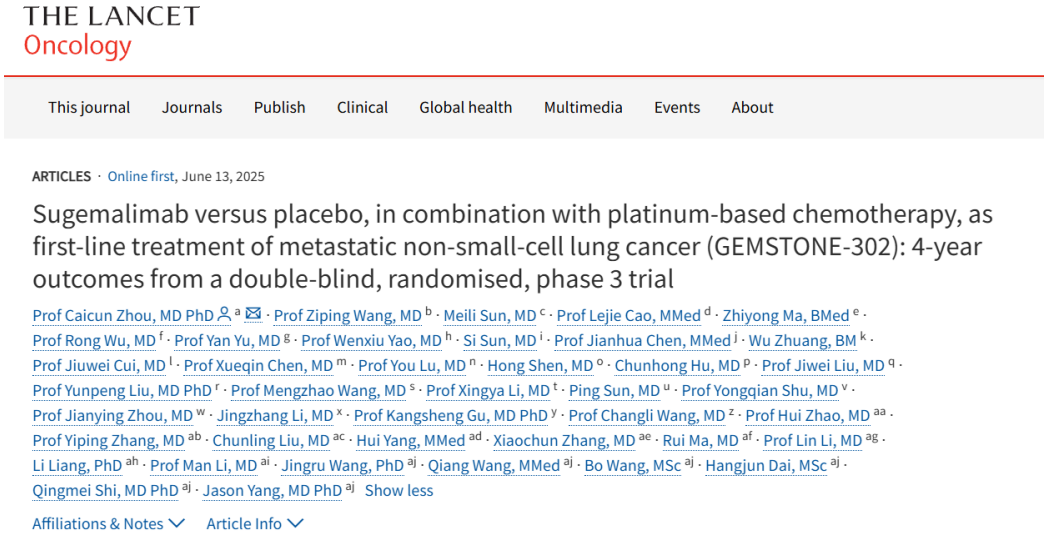
CStone Pharmaceuticals
基石藥業
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2616)

VOLUNTARY ANNOUNCEMENT
LONG-TERM SURVIVAL DATA OF GEMSTONE-302 TRIAL ON SUGEMALIMAB PUBLISHED IN THE LANCET ONCOLOGY

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the publication of long-term survival data from its Phase III GEMSTONE-302 trial in The Lancet Oncology, a globally renowned medical journal. The study evaluates sugemalimab combined with platinum-based chemotherapy as a first-line treatment for both squamous and non-squamous, non-oncogene-addicted metastatic non-small cell lung cancer (NSCLC). This marks the trial's third publication in top-tier journals, following earlier reports of final progression-free survival (PFS) analysis in The Lancet Oncology (2022) and interim overall survival (OS) results in Nature Cancer (2023). The latest results reinforce sugemalimab's clinical value and its established role as a standard first-line therapy for advanced NSCLC in China and Europe.


THE LANCET
Oncology

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ARTICLES · Online first, June 13, 2025

Sugemalimab versus placebo, in combination with platinum-based chemotherapy, as first-line treatment of metastatic non-small-cell lung cancer (GEMSTONE-302): 4-year outcomes from a double-blind, randomised, phase 3 trial

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**Screenshot from the official website of The Lancet Oncology*

GEMSTONE-302 is a multicenter, randomized, double-blind Phase III clinical trial comparing the efficacy and safety of sugemalimab combined with platinum-based chemotherapy against placebo plus chemotherapy in treatment-naïve Stage IV NSCLC. The primary endpoint was investigator-assessed PFS, and key secondary endpoints included OS, blinded independent central review (BICR)-assessed PFS, investigator-assessed PFS in PD-L1 expression ⩾1% subgroups, objective response rate (ORR), duration of response (DoR), and safety. Supported by robust clinical evidence from this study, sugemalimab has been approved in China, the EU, and the UK as a first-line treatment for metastatic NSCLC and also recommended in the ESMO guideline for both squamous and non-squamous, non-oncogene-addicted metastatic NSCLC.

GEMSTONE-302: key data highlights from The Lancet Oncology publication

- **Study Population**: As of May 15, 2023, 479 patients were randomized to receive either sugemalimab plus platinum-based chemotherapy (n=320) or placebo plus chemotherapy (n=159), with median follow-up durations of 43.5 and 43.0 months, respectively.

- **OS**: In the intent-to-treat (ITT) population, the sugemalimab group demonstrated a median OS of 25.2 months versus 16.9 months in the placebo group (HR = 0.68, 95% CI: 0.54–0.85), with 4-year OS rates of 32.1% versus 17.3%. Among patients receiving sugemalimab for >2 years (n=58), the 4-year OS rate reached 92.6%.

- **PFS**: Median PFS in the ITT population was 9.0 months with sugemalimab versus 4.9 months with placebo (HR=0.49, 95% CI: 0.39–0.60).

- **Subgroup Analyses**: Consistent PFS and OS benefits were observed across all tumor histologies or PD-L1 expression levels. In patients with baseline brain metastases, sugemalimab achieved a median OS of 26.0 months (vs. 9.0 months for placebo; HR=0.44, 95% CI: 0.24–0.81) and a 4-year survival rate of 36.4%.

- **Safety**: Grade 3–4 treatment-related adverse events (TRAEs) occurred in 56% of sugemalimab-treated patients versus 57% in the control arm, with no new safety signals identified during extended follow-up.

Dr. Jason Yang, CEO, President of R&D, and Executive Director of CStone, stated: "The triple publication of GEMSTONE-302 data in premier journals demonstrates global scientific recognition of sugemalimab's validated clinical profile. These results not only establish the regimen's durable survival advantage but also solidify its evidence-based position in the treatment algorithms for metastatic NSCLC in China and Europe. Through commercialization partnerships, we are expanding sugemalimab's global access in alignment with regulatory approvals across major markets, aiming to fulfill our vision of benefiting patients worldwide by pioneering innovative therapies."

Professor Caicun Zhou from Shanghai East Hospital (Tongji University), Principal Investigator of GEMSTONE-302, commented: "This Lancet Oncology publication reaffirms the established clinical value of sugemalimab-chemotherapy as a first-line regimen for advanced NSCLC. The regimen elevated the 4-year survival rate to 32.1%—nearly doubling the historical benchmark of 17.3% with chemotherapy alone—delivering significant long-term clinical benefits. Notably, in high-risk populations such as patients with baseline brain metastases, the combination provides clinically actionable outcomes. Its consistent efficacy across diverse patient populations and manageable safety profile will further inform the clinical practice in first-line treatment of NSCLC."

About Sugemalimab

The anti-PD-L1 monoclonal antibody sugemalimab was developed by CStone using OmniRat® transgenic

animal platform, 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.

The European Commission (EC) and the Medicines and Healthcare products Regulatory Agency (MHRA) have approved sugemalimab 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 tumor aberrations. In March 2025, a Type II variation application has been submitted to the European Medicines Agency (EMA) for sugemalimab. The application seeks approval for the treatment of patients with unresectable stage III NSCLC who have not progressed following concurrent or sequential platinum-based chemoradiotherapy.

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

- In combination with chemotherapy as 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 first-line treatment of patients with unresectable locally advanced, recurrent or metastatic ESCC; and
- In combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment for unresectable locally advanced or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression (CPS ≥5).

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 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, June 19, 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.