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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 LONG-TERM SURVIVAL DATA FOR CEJEMLY®(SUGEMALIMAB) IN COMBINATION WITH PLATINUM-BASED CHEMOTHERAPY AS FIRST-LINE TREATMENT OF STAGE IV NSCLC AT ESMO 2024

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce the presentation of long-term treatment and survival data for sugemalimab (brand name: Cejemly®) in combination with platinum-based chemotherapy from the GEMSTONE-302 study at the 2024 European Society for Medical Oncology (ESMO) Annual Meeting.

Key Highlights

- Sugemalimab remains as the first and only anti-PD-L1 monoclonal antibody to present long-term survival benefits when combined with platinum-based chemotherapy as a first-line treatment for both squamous and non-squamous non-small cell lung cancer (NSCLC).
- Four-year follow-up data continue to demonstrate significant benefit in progression-free survival (PFS) and overall survival (OS) for sugemalimab in combination with platinum-based chemotherapy compared to placebo in combination with platinum-based chemotherapy. The four-year survival rates were 32.1% and 17.3%, respectively.
- Sustained and consistent benefits are observed across different histological subtypes and PD-L1 expression levels.
- Patients who received at least two years of sugemalimab treatment achieved durable response and impressive four-year OS rates, underscoring the survival advantages of long-term sugemalimab therapy.
- In patients with baseline brain metastases, sugemalimab in combination with platinum-based chemotherapy continues to extend both PFS and OS compared to placebo in combination with platinum-based chemotherapy, with median OS of 26.0 months and 9.0 months, respectively.

GEMSTONE-302 study is a multicenter, randomized, double-blind phase III trial evaluating the efficacy

and safety of sugemalimab in combination with platinum-based chemotherapy as a first-line treatment for patients with stage IV NSCLC compared to placebo in combination with platinum-based chemotherapy. The primary endpoint was investigator-assessed PFS. Key secondary endpoints included OS, PFS assessed by blinded independent central review (BICR), PFS in patients with PD-L1 expression ≥1% as assessed by investigators, objective response rate (ORR), duration of response (DoR), and safety.

Dr. Jason Yang, CEO, President of R&D and Executive Director at CStone, said, "Following the recent European Commission's approval based on the predefined PFS and OS analyses in the GEMSTONE-302 study, the four-year follow-up data presented at ESMO further confirmed the significant long-term benefit of sugemalimab combined with platinum-based chemotherapy as a first-line treatment of Stage IV NSCLC. These data demonstrate sugemalimab's potential to significantly improve patient outcomes on a global scale. We plan to continue expanding patient access to this important treatment globally, and dedicating to address unmet medical needs."

Professor Caicun Zhou from East Hospital, Tongji University, the Principal Investigator of the GEMSTONE-302 study, commented, "The primary goal of the first-line treatment for advanced lung cancer is to maximally improve a patient's long-term survival benefit. The results of the GEMSTONE-302 study have confirmed the long-term clinical benefits of sugemalimab combined with platinum-based chemotherapy in first-line treatment of Stage IV NSCLC, with the extension of patient survival and the quality-of-life improvement. Sugemalimab combination treatment also significantly extended the PFS and OS of patients with brain metastases, highlighting the benefit of sugemalimab regimen to patients with high-risk NSCLC. We expect this regimen will become one of the preferred immunotherapy options for NSCLC."

Detailed data from the GEMSTONE-302 study presented at the ESMO are as follows:

- As of the data cutoff on May 15, 2023, 479 patients were randomized to receive either sugemalimab in combination with platinum-based chemotherapy (320 patients) or placebo in combination with platinum-based chemotherapy (159 patients). Median follow-up durations were 43.5 and 43.0 months, respectively.
- In the intent-to-treat (ITT) population, median OS was 25.2 months in the sugemalimab group compared to 16.9 months in the placebo group, hazard ratio (HR) 0.68 (95% CI, 0.54-0.85), with four-year OS rates of 32.1% and 17.3%, respectively.
- Median PFS in the ITT population was 9.0 months in the sugemalimab group compared to 4.9 months in the placebo group (HR=0.49 [95% CI, 0.39-0.60]).
- Sugemalimab in combination with platinum-based chemotherapy demonstrated sustained PFS and OS across different histological subtypes and PD-L1 expression levels.Among the 58 patients who received sugemalimab for over two years, the median DoR was not reached, and the four-year OS rate was 92.6%.
- For patients with baseline brain metastases, sugemalimab extended PFS (HR=0.31 [95% CI, 0.17-0.58]) and OS (mOS: 26.0 vs 9.0 months respectively, HR=0.44 [95% CI, 0.24-0.81]) with a four-year survival rate of 36.4%.
- The safety profile of sugemalimab in combination with chemotherapy remained consistent with previously reported results

	ITT N=479	TPS≥1% n=291	TPS<1% n=188	TPS 1-49% n=140	TPS≥50% n=151	sq-NSCLC n=192	nsq-NSCLC n=287
OS HR (95% CI)	0.68 (0.54, 0.85)	0.63 (0.47, 0.85)	0.75 (0.53, 1.08)	0.68 (0.45, 1.04)	0.58 (0.38, 0.89)	0.61 (0.43, 0.87)	0.72 (0.53, 0.98)
4-y OS rate, %[a]	32.1 vs 17.3	37.7 vs 17.4	23.2 vs 16.6	29.3 vs NE	45.3 vs 20.1	27.6 vs 11.7	35.5 vs 20.2
PFS HR (95% CI)[b]	0.49 (0.39, 0.60)	0.46 (0.35, 0.60)	0.58 (0.42, 0.80)	0.52 (0.36, 0.75)	0.41 (0.28, 0.60)	0.37 (0.26, 0.51)	0.57 (0.44, 0.75)
4-y PFS rate, %[a]	12.4 vs NE	16.6 vs NE	NE vs NE	12.7 vs NE	18.8 vs NE	15.3 vs NE	11.9 vs NE

HR, Hazard Ratio; ITT, intention-to-treat; NE, not estimable; NSCLC, non-small cell lung cancer; nsq, non-squamous; OS, overall survival; PFS, progression-free survival; sq, squamous; TPS, tumour proportion score. Data are for suge + chemo vs placebo + chemo.
[a]Kaplan-Meier estimate. [b]Per RECIST v1.1 by investigator.

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 unique 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 potentially best-in-class 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 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 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 as a 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 United Kingdom has accepted the marketing authorization application for sugemalimab in combination with platinum-based chemotherapy as a first-line treatment for metastatic NSCLC with no sensitizing EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations. The application is currently under review.

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 15 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 (BRAND NAME: Cejemly®) 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, September 16, 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.