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

VOLUNTARY ANNOUNCEMENT
CHMP OF THE EUROPEAN MEDICINE AGENCY RECOMMENDS APPROVAL OF CEJEMLY® (SUGEMALIMAB, ANTI-PD-L1) AS FIRST-LINE TREATMENT FOR NSCLC

CStone Pharmaceuticals (the "**Company**" or "**CStone**") is pleased to announce that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of sugemalimab in combination with chemotherapy as a first-line treatment for metastatic non-small cell lung cancer (NSCLC), which is one of the largest cancer indications and a leading cause of cancer death in the world. Sugemalimab is expected to become the first anti-PD-L1 monoclonal antibody (mAb) to be approved in Europe for both first-line squamous and non-squamous NSCLC, regardless of PD-L1 expression, also making CStone the very first biopharmaceutical company in China to potentially launch a domestic anti-PD-L1 mAb in international markets.

Product details

Name of medicine	Cejemly
Active substance	Sugemalimab
International non-proprietary name (INN) or common name	sugemalimab
Therapeutic area (MeSH)	Carcinoma, Non-Small-Cell Lung
Anatomical therapeutic chemical (ATC) code	L01FF11
EMA product number	EMEA/H/C/006088
Marketing authorisation applicant	SFL Pharmaceuticals Deutschland GmbH
Opinion adopted	30/05/2024
Opinion status	Positive

** CStone has designated SFL as the applicant for sugemalimab marketing authorization application (MAA) in Europe.*

Key Highlights

- CHMP's recommendation is based on the results of a Phase 3 clinical trial (GEMSTONE-302) demonstrating significant progression-free survival (PFS) and overall survival (OS) benefits of sugemalimab in combination with chemotherapy as a first-line treatment for non-small cell lung cancer (NSCLC).
- Sugemalimab is expected to become the first anti-PD-L1 monoclonal antibody (mAb) in the world to be approved in Europe for both first-line squamous and non-squamous NSCLC, regardless of PD-L1 expression, potentially also the first domestic anti-PD-L1 mAb to be marketed in internaltional regions.
- In addition to the recent strategic commercial collaboration with Ewopharma in 18 Central Eastern Europe countries and Switzerland, multiple potential partners in other countries or regions are in deep conversations with CStone for sugemalimab.

Dr. Jason Yang, CEO, President of R&D and Executive Director at CStone, said, "The positive opinion from EMA CHMP normally indicates an upcoming approval for market authorization by the European Commission, marking a significant milestone not only for sugemalimab but also for CStone and the entire pharmaceutical industry in China. The CHMP recommendation brings us closer to delivering this innovative treatment to European patients with lung cancer, and it also highlights a major milestone in CStone's global strategy. Stage IV NSCLC is the first of several other indications where sugemalimab has been shown to bring significant benefits and we are planning to file for registration in these other important indications including stage III NSCLC, gastric cancer, esophageal cancer, etc. In addition, we have been actively engaging in substantive discussions with numerous other potential partners in various countries or regions to follow our recently announced strategic commercial collaboration with Ewopharma in 18 Central Eastern Europe countries and Switzerland. We are confident and eagerly anticipate collaborating to swiftly propel sugemalimab into wider global markets and benefiting more patients across multiple indications. I would also like to thank the CStone team for their hard work and persistence over the years to achieve this important milestone."

CHMP's positive opinion is primarily based on the results of GEMSTONE-302, a multi-center, randomized, double-blind, Phase 3 clinical trial. Sugemalimab in combination with chemotherapy significantly improved PFS and OS compared to placebo in combination with chemotherapy in previously untreated stage IV NSCLC patients. The clinical trial results have been published in The Lancet Oncology and Nature Cancer and reported in oral sessions at various international academic conferences.

Sugemalimab is an anti-PD-L1 monoclonal antibody developed by CStone, which has been approved in China for five indications, including stage III and IV NSCLC, extranodal NK/T-cell lymphoma, esophageal squamous cell carcinoma, and gastric cancer. Additionally, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) is currently reviewing the marketing authorization application (MAA) for sugemalimab combined with chemotherapy as a first-line treatment for metastatic NSCLC. The Company is also in communications with regulatory authorities such as the EMA, MHRA, and U.S. Food and Drug Administration (FDA) regarding additional indications for sugemalimab and is actively seeking development and commercialization partnerships in other countries and regions worldwide.

About Lung Cancer

In 2020, lung cancer was the third most diagnosed cancer in Europe and the leading cause of cancer-related mortality, accounting for one fifth of cancer deaths. Approximately 50% to 70% of lung cancer

cases in Europe are diagnosed in Stage IV. Globally, it is estimated that NSCLC accounts for approximately 85% of all lung cancers.

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, 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 (trade name: Cejemly®) 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 (Combined Positive Score [CPS] ≥5).

In addition to the EMA, the UK MHRA has also accepted the MAA for sugemalimab in combination with chemotherapy as first-line treatment for metastatic NSCLC. 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 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: 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 3, 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.