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CStone Pharmaceuticals

基石藥業

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2616)

INSIDE INFORMATION ANNOUNCEMENT

CSTONE ANNOUNCES THE FIRST-IN-CLASS REGISTRATIONAL STUDY OF SUGEMALIMAB MET ITS PRIMARY ENDPOINT IN STAGE III NSCLC AND PLANS TO SUBMIT A NEW DRUG APPLICATION

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

CStone Pharmaceuticals (the “**Company**” or “**CStone**”) is pleased to announce that that a registration study (GEMSTONE-301 study) of the anti-PD-L1 monoclonal antibody sugemalimab in patients with stage III non-small cell lung cancer (“**NSCLC**”) met its primary endpoint at a planned interim analysis reviewed by the independent Data Monitoring Committee (“**iDMC**”). The findings showed that sugemalimab as a consolidation therapy brought statistically significant and clinically meaningful improvement in the Blinded independent central review (“**BICR**”) assessed progression-free survival (“**PFS**”) in patients with locally advanced/unresectable NSCLC without disease progression after concurrent or sequential chemoradiotherapy. Investigator assessed PFS showed consistent results as those of the primary endpoint. Sugemalimab was well-tolerated with no new safety signals. Subgroup analyses demonstrated that sugemalimab was associated with clinical benefit regardless of whether patients received concurrent or sequential chemoradiotherapy prior to sugemalimab.

Key Highlights

- Sugemalimab becomes the world’s first anti-PD-1/PD-L1 monoclonal antibody to successfully improve PFS in patients with stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy
- Sugemalimab is also the world’s first anti-PD-1/PD-L1 monoclonal antibody covering both locally advanced/unresectable (stage III) and metastatic (stage IV) NSCLC patients
- CStone plans to submit a New Drug Application (“**NDA**”) to the National Medical Products Administration

(“NMPA”) of China for sugemalimab in stage III NSCLC and will work closely with EQRx on regulatory discussions for new drug applications for the two indications of stage III and stage IV NSCLC in multiple countries including the U.S. Food and Drug Administration (“FDA”)

Professor Yi-long Wu of Guangdong Provincial People’s Hospital, the Leading Principal Investigator on the GEMSTONE-301 study, said, “Lung cancer is the leading cause of cancer-related mortality globally. There are currently few effective therapies for patients with stage III NSCLC whose disease did not progress after sequential chemoradiotherapy. The successful results from the study indicated that sugemalimab will meet the urgent treatment needs of these patients.”

Dr. Frank Jiang, Chairman and CEO of CStone, said, “We are excited that sugemalimab becomes the first anti-PD-1/PD-L1 monoclonal antibody in the world to cover both stage III and stage IV NSCLC patients. The continued success of sugemalimab in lung cancer demonstrates CStone’s leading research and development capabilities in the field of immuno-oncology. We are working closely with Pfizer and EQRx, our commercial partners for sugemalimab, on the next steps in our joint efforts to deliver this best-in-class drug to patients worldwide.”

Dr. Jason Yang, Chief Medical Officer of CStone, said, “Currently, there has not been an approved PD-1 or PD-L1 monoclonal antibody for treating patients in stage III NSCLC who have not developed disease progression after sequential chemoradiotherapy. The GEMSTONE-301 is the first-in-class clinical study design that enrolled patients with either concurrent or sequential chemoradiotherapy to better reflect real-world clinical practice and cover a broader population. CStone is committed to providing treatment options for unmet medical needs. The GEMSTONE-301 study will advance and facilitate the use of multidisciplinary treatment (“MDT”) approaches in China to improve the quality of the diagnosis and treatment of stage III NSCLC. We will continue to explore the potential of sugemalimab in registration studies for patients with hematologic malignancies and advanced gastric and esophageal cancers.”

CStone plans to submit an NDA to the NMPA for sugemalimab in stage III NSCLC and will work with EQRx to hold regulatory discussions on the indications of stage III and stage IV NSCLC with regulators in multiple countries, including the FDA. Specific study data will be presented at an upcoming academic conference.

CStone formed a strategic collaboration agreement with Pfizer that includes the development and commercialization of sugemalimab in mainland China and a framework to bring additional oncology assets to the Greater China market. CStone subsequently formed a strategic collaboration agreement with EQRx, under which EQRx licensed the exclusive rights to two key late-stage immuno-oncology assets, sugemalimab and CS1003 (anti-PD-1 antibody), for the global development and commercialization outside of the Greater China market. Please refer to the Company’s announcements dated September 30, 2020 and October 27, 2020, respectively for more details.

About NSCLC

In recent years, China has had rising lung cancer incidence. According to the latest estimates on the global burden of cancer released by International Agency for Research on Cancer (“IARC”), in 2020, an estimated 0.82 million new lung cancer cases and 0.71 million new lung cancer deaths occurred in China. Among all Chinese cancer patients, lung cancer is the leading cause of cancer-related deaths. NSCLC is the most common type of lung cancer.

There are currently limited treatment options for patients with locally advanced/unresectable (stage III) NSCLC. In China, sequential chemoradiotherapy is widely used, while concurrent chemoradiotherapy is with limited use. But both are with unsatisfactory efficacy.

About Sugemalimab (anti-PD-L1 antibody)

Sugemalimab is an investigational anti-PD-L1 monoclonal antibody discovered by CStone. Authorized by the U.S.-based Ligand Corporation, sugemalimab is developed by the OmniRat[®] transgenic animal platform, which

can generate fully human antibodies in one step. As a fully human, full-length anti-PD-L1 monoclonal antibody, sugemalimab mirrors the natural G-type immunoglobulin 4 (“**IgG4**”) human antibody, which reduces the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

Currently, sugemalimab is being investigated in a number of ongoing clinical trials, including one Phase II registration studies for lymphoma (CS1001-201) and four Phase III registrational studies on stage III NSCLC, stage IV NSCLC, gastric cancer, and esophageal cancer, respectively.

CS1001-201 is a single-arm, multicenter, Phase II pivotal study designed to evaluate the efficacy and safety of sugemalimab as monotherapy for the treatment of adult patients with relapsed or refractory extranodal natural killer/T-cell lymphoma (“**R/R ENKTL**”). Based on the encouraging preliminary efficacy results, sugemalimab was granted Orphan Drug Designation (“**ODD**”) for the treatment of T-cell lymphoma and Breakthrough Therapy Designation (“**BTD**”) for the treatment of R/R ENKTL by the FDA. It has also been granted Breakthrough Therapy Designation by the National Medical Products Administration of China. The proposed indication is R/R ENKTL.

About GEMSTONE-301 Study

GEMSTONE-301 study is a multicenter, randomized, double-blind Phase III clinical trial (clinicaltrials.gov registration number: NCT03728556; drug clinical trial registration number: CTR20181429), designed to evaluate the efficacy and safety of sugemalimab as consolidation therapy in patients with locally advanced/unresectable stage III NSCLC without disease progression after concurrent or sequential chemoradiotherapy. The trial’s primary endpoint was PFS as assessed by BICR according to RECIST v1.1; the secondary endpoints included overall survival, PFS as assessed by investigators and safety profile.

About GEMSTONE-302 Study

GEMSTONE-302 (clinicaltrials.gov registration number: NCT03789604; drug clinical trial registration number: CTR20181452) is a randomized, double-blind, Phase III study of anti-PD-L1 monoclonal antibody sugemalimab plus chemotherapy as first-line treatment for stage IV squamous or NSCLC to evaluate the efficacy and safety of sugemalimab combined with chemotherapy vs. placebo combined with chemotherapy in first-line treatment naïve patients with stage IV NSCLC. The primary endpoint of the study was investigator-assessed PFS. Secondary endpoints included overall survival, BICR-assessed PFS and safety.

In August 2020, GEMSTONE-302 study met its primary endpoint of significantly PFS and reducing the risk of disease progression or death by 50% with sugemalimab in combination with chemotherapy compared to placebo in combination with chemotherapy, as assessed by iDMC at the planned interim analysis. Subgroup analysis showed clinical benefit in patients with squamous versus non-squamous NSCLC, and in patients with PD-L1 expression $\geq 1\%$ versus PD-L1 expression $< 1\%$. Sugemalimab in combination with chemotherapy was well tolerated, no new safety signals were identified. Specific study data were presented in a Proffered Paper Oral Presentation (Late-Breaking Abstract) at ESMO Asia 2020. In November 2020, the NMPA of China accepted the New Drug Application for sugemalimab combined with chemotherapy for the first-line treatment of advanced squamous and non-squamous NSCLC patients.

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.

About CStone

CStone is a biopharmaceutical company focused on researching, developing and commercializing innovative immunology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research, and commercialization. The company has built an oncology-focused pipeline of

14 drug candidates with a strategic emphasis on immuno-oncology combination therapies. Currently, CStone has received three drug approvals in Greater China, including two in Mainland China and one in Taiwan. CStone's vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide.

For more information about CStone, please visit: www.cstonepharma.com.

About Pfizer

At Pfizer, Pfizer apply science and their global resources to bring therapies to people that extend and significantly improve their lives. Pfizer strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of their time. Consistent with Pfizer's responsibility as one of the world's premier innovative biopharmaceutical companies, Pfizer collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, Pfizer have worked to make a difference for all who rely on Pfizer.

For more information about Pfizer, please visit: www.Pfizer.com.

ABOUT EQRx

EQRx is committed to catalyzing a market-based solution to one of society's biggest healthcare challenges by developing important new medicines and offering them at lower prices. Through strategic partnerships with stakeholders from across the healthcare system and cutting-edge science and technology, EQRx aims to provide high-quality, patent-protected medicines more efficiently and cost-effectively than ever before. EQRx is a purpose-built disruptor at scale, remaking medicine to bend the cost curve in drug pricing.

For more information about EQRx, please visit: www.eqr.com.

By order of the Board
CStone Pharmaceuticals
Dr. Frank Ningjun Jiang
Chairman

Suzhou, People's Republic of China, May 28, 2021

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Frank Ningjun Jiang as Chairman and Executive Director, Dr. Wei Li, Mr. Qun Zhao, Mr. Yanling Cao, Mr. Xianghong Lin and Dr. Lian Yong Chen as non-executive Directors, and Dr. Paul Herbert Chew, Mr. Ting Yuk Anthony Wu and Mr. Hongbin Sun as independent non-executive Directors.